RESPONSIVENESS TO CHANGE OF THE MALAY-ECOHIS FOLLOWING TREATMENT OF EARLY CHILDHOOD CARIES UNDER GENERAL ANAESTHESIA

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ABSTRACT

Background: Oral health-related quality of life (OHRQoL) measures should be tested for their sensitivity and responsiveness to changes in OHRQoL if they are to be used as outcome measures in clinical interventions. **Objectives**: (a) To evaluate the sensitivity of the Malay version of Early Childhood Oral Health Impact Scale (Malay-ECOHIS) to dental treatment of early childhood caries (ECC) under General Anesthesia (GA) by: (i) assessing changes in the distribution of Malay-ECOHIS scores before and after treatment under GA, (ii) assessing the association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorized by the median and percentile score, (iii) assessing the correlation between Malay-ECOHIS change scores and the number of decayed teeth, and (iv) assessing the correlation between Malay-ECOHIS change scores and number of extracted teeth; (b) evaluate the responsiveness of the Malay-ECOHIS to dental treatment of ECC under GA by comparing whether the observed changes in Malay-ECOHIS scores and effect size (ES) took the form of a gradient across the global transition judgement; and (c) establish the Minimal Important Difference (MID) of the Malay-ECOHIS. **Methods**: A consecutive sample of parents of 158 preschool children (aged 6 and younger) with ECC attending five public hospitals in Selangor for dental treatment under GA was recruited over an 8-month period. Parents self-completed the Malay-ECOHIS prior to and 4 weeks following their child's dental treatment. In addition, parents answered a global health transition judgement concerning the change in their child's overall oral health condition compared to before treatment. Data were analyzed using independent and paired samples T-test, ANOVA, Pearson correlation, and standardised scores. **Results:** Overall, 138 children completed the study with response rate of 87.3%. The final sample comprised parents of 76 male (55.1%) and 62 female (44.9%) preschool children with mean age of 4.54 years (SD=1.01). The ECOHIS mean score after treatment was significantly lower compared to before treatment. This

significant reduction in mean score existed for total Malay-ECOHIS, Child Impact Section (CIS), Family Impact Section (FIS), and all the sub-domains, respectively ($P<0.001$). The magnitude of change (ES) of total Malay-ECOHIS following treatment was +1.0 and among domains ranged from +0.4 to +1.9. There was no significant association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorized by median or percentile score. However, there was a weak, positive correlation between number of decayed teeth (dt) and Malay-ECOHIS ($r=0.165$, $p=0.05$) and CIS change scores ($r=0.175$, $p<0.05$), respectively. No significant correlation was found between Malay-ECOHIS change scores and number of extracted teeth. Based on global health transition judgement, 62.3% of parents reported their child's oral condition "a little improved" while 37.7% reported "much improved" following treatment under GA with ECOHIS mean change score of 6.7 (ES=+1.1) and 9.6 (ES=+1.2), respectively. There was an observed gradient in the changes of Malay-ECOHIS scores and effect sizes in relation to global health transition judgement of oral change following treatment, supporting the responsiveness of the measure. The Malay-ECOHIS MID was found to be 7-point change with large ES of +1.0. **Conclusion**: The Malay-ECOHIS is empirically proven to be sensitive and responsiveness to dental treatment of ECC under GA.

ABSTRAK

Latar Belakang: Ukuran kualiti hidup yang berkaitan dengan kesihatan Oral (OHRQoL) perlu diuji untuk kepekaan dan responsif kepada perubahan dalam OHRQoL jika digunakan sebagai ukuran dalam pencegahan klinikal. **Objektif:** (a) Untuk menilai sensitiviti versi Melayu *Early Childood Caries Impact Scale* (Malay-ECOHIS) untuk rawatan karies awal kanak-kanak (ECC) di bawah General Anesthesia (GA) melalui: (i) menilai perubahan dalam taburan skor Malay-ECOHIS sebelum dan selepas rawatan di bawah GA, (ii) menilai hubungan di antara skor perubahan Malay-ECOHIS dan keterukan gigi reput (dt) yang dikategorikan oleh median dan skor persentil, (iii) menilai korelasi antara skor perubahan Malay- ECOHIS dan bilangan gigi reput, dan (iv) menilai korelasi antara skor perubahan Malay-ECOHIS dan bilangan gigi yang dicabut; (b) menilai responsif kepada perubahan Malay-ECOHIS untuk rawatan ECC di bawah GA dengan membandingkan sama ada perubahan yang diperhatikan dalam skor Malay-ECOHIS dan saiz kesan (ES) mengambil bentuk kecerunan *global transition judgement*; dan (c) menubuhkan *Minimal Important Difference* (MID) Malay-ECOHIS. **Kaedah:** Satu sampel berturut-turut yang terdiri daripada ibu bapa kepada 158 kanak-kanak pra-sekolah (berumur 6 tahun dan ke bawah) dengan ECC yang menghadiri lima hospital awam di Selangor untuk rawatan pergigian di bawah GA telah diambil untuk tempoh 8 bulan. Ibu bapa sendiri menyempurnakan Malay-ECOHIS sebelum dan 4 minggu selepas rawatan gigi anak mereka. Di samping itu, ibu bapa menjawab *global health transition judgement* mengenai perubahan kesihatan mulut secara keseluruhan anak mereka berbanding sebelum rawatan. Data dianalisis dengan menggunakan sampel bebas dan berpasangan ujian-t, ANOVA, korelasi Pearson, dan skor yang seragam. **Keputusan:** Secara keseluruhan, 138 kanak-kanak menamatkan pengajian dengan kadar respons sebanyak 87.3%. Sampel akhir terdiri daripada ibu bapa kepada 76 lelaki (55.1%) dan 62 perempuan (44.9%) kanak-kanak pra-sekolah dengan min umur 4.54 tahun (SD = 1.01).

Min skor ECOHIS selepas rawatan adalah jauh lebih rendah berbanding sebelum rawatan. Pengurangan ketara dalam skor min wujud dalam Malay-ECOHIS, *Child Impact Section* (CIS), *Family Impact Section* (FIS), dan semua sub-domain masing-masing (P <0.001). Magnitud perubahan (ES) rawatan bagi Malay-ECOHIS adalah 1.0 dan di antara domain antara 0.4-1.9. Tidak ada hubungan yang signifikan antara skor perubahan Malay-ECOHIS dan keterukan gigi reput (dt) yang dikategorikan oleh skor median atau persentil. Walau bagaimanapun, terdapat korelasi positif yang lemah antara bilangan gigi reput (dt) dan Malay-ECOHIS (r = 0.165, p = 0.05) dan skor perubahan CIS (r = 0.175, p <0.05), masing-masing. Tiada hubungan yang signifikan didapati antara skor perubahan Melayu-ECOHIS dan bilangan gigi diekstrak. Berdasarkan kepada *global health transition judgement*, 62.3% ibu bapa melaporkan keadaan oral anak mereka "yang lebih baik sedikit" manakala 37.7% melaporkan "lebih baik" selepas rawatan di bawah GA dengan perubahan skor min ECOHIS 6.7 (ES = +1.1) dan 9.6 (ES = +1.2), masing-masing. Terdapat kecerunan diperhatikan dalam perubahan skor Malay-ECOHIS dan ES dengan *global health transition judgement* selepas rawatan, dan ini menyokong responsif kepada perubahan. MID Malay-ECOHIS adalah 7-mata dengan ES besar iaitu 1.0. **Kesimpulan:** Malay-ECOHIS adalah terbukti secara empirikal peka dan responsif kepada perubahan bagi rawatan pergigian ECC di bawah GA.

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LIST OF SYMBOLS AND ABBREVIATIONS

ANOVA	:	One-Way Analysis of Variance
ASA	:	American Society of Anaesthesiology
Child-OIDP	:	Child-Oral Impact of Daily Performance
CIS	:	Child Impact Section
COHIP	:	Child Oral Health Impact Profile
COHQoL	:	Child Oral Health Quality of Life
COHRQoL	:	Child Oral Health-Related Quality of Life
CPQ_{11-14}	:	Child Perceptions Questionnaire for children aged 11 – 14 years
dft	:	decayed, filled teeth for deciduous teeth
dmft	:	decayed, missing, filled teeth for deciduous teeth
ECC	:	Early Childhood Caries
ECOHIS	:	Early Childhood Oral Health Impact Scale
ES	:	Effect Size
FIS	:	Family Impact Section
GA	:	General Anaesthesia
H_0	:	Null hypothesis
H_1	:	Alternative hypothesis
HRQoL	:	Health-Related Quality of Life
ICC	:	Intraclass Correlation Coefficient
ICF	:	International Classification of Functioning and Disability
ICF-CY	:	International Classification of Functioning and Disability for Child and Youth

ICIDH	:	International Classification of Impairment, Disability and Handicap
MID	:	Minimal Important Difference
NHMS III	:	National Health and Morbidity Survey III
NMRR	:	National Medical Research Register
OHRQoL	:	Oral Health-Related Quality of Life
OHD	:	Oral Health Division
OIDP	:	Oral Impact on Daily Performance
OT	:	Operation Theatre
QoL	:	Quality of Life
SD	:	Standard Deviation
SDI	:	Socio-Dental Indicator
SEM	:	Standard Error of Measurement
SIP	:	Sickness Impact Profile
SPSS	:	Statistical Package for the Social Science
SSHD	:	Selangor State Health Division
WHO	:	World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Quality of Life (QoL) is an individual's perception of their position in life in the context of culture and the value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept and in a complex way to do with what people perceive to be most important in their life (WHO, 1995). Quality of life is defined as "the degree to which a person enjoys the important possibilities of life" (Raphael et al., 1994). This suggests that quality of life is a complex multidimensional phenomenon that is not captured solely by questions about health.

Oral Health-Related Quality of Life (OHRQoL) characterizes a person's perception of how oral health influences an individual's quality of life and overall well-being (Slade and Spencer, 1994; Kressin et al., 2001; McGrath and Bedi, 2001; Allen, 2003; John et al., 2004). Kressin et.al (2001) defined OHRQoL as "a broad conception of health, encompassing the traditional definition of health, as well as individual's subjective impact of health on well- being and functioning in everyday life".

Information on the sensitivity and responsiveness of an index is important as increasingly QOL measures are being used in research studies. The definition of QOL as described by Bjornson and McLaughlin compromised two components; QOL should be assessed over broad domains, and also be a measure of well-being (Bjornson and McLaughlin, 2006). Reliability and validity are the two performance measures that are well established in psychometrics. To these performance measures, we can include 'sensitivity', which incorporates both between-subject and within-subject variability. Sensitivity and specificity are diagnostic and screening performances which most clinical investigators are familiar with. Sensitivity is defined as the probability of a diagnostic or

screening test detecting disease when disease is present, reflecting the test's ability to detect a true positive (Marcia and Donald, 2009). When used to judge scale performance, sensitivity can be particularly important for evaluating a scale's ability to detect treatment or intervention effects. When referring to longitudinal changes, it is often referred to as responsiveness of a scale score. Responsiveness is defined as the ability of a scale to change when the underlying construct changes, and as such, is really part of the scale's validity (Marcia and Donald, 2009). Table 1.1 summarizes these primary performance criteria.

Table 1.1: Scale performance properties, tests and criteria for evaluation (Marcia and Donald, 2009)

Scale performance property	Test of performance	Performance criteria
Reliability	**Test-retest reliability** Intra-class correlation coefficient should be high in the presence of significant between-individual variance, and the mean levels should not differ between assessments taken during steady state	Assesses the ability of the scale to remain stable during a period when external influencing factors are negligible (steady state)
	Internal consistency Within-item correlation should be relatively high as measured by an internal consistency statistic such as coefficient alpha	Assesses the degree to which items in the scale are measuring the same construct, or constructs related to the same phenomena
Validity	**Content** Items and response options are relevant and are comprehensive measures of the domain or concept. The scale's item should be from a randomly chosen subset of the universe of appropriate items	Easiest to determine when the domain is well defined. Much more difficult to establish when measuring attributes such as beliefs, attitudes or feelings because it is difficult to determine exactly what the range of potential items is and when a sample of items is representative

'Table 1.1, continued'

Scale performance property	Test of performance	Performance criteria
	Criterion-related Items or scale is required to have only an empirical association with some criterion or 'gold standard' (also called predictive validity)	Establishes the strength of the empirical relationship between two events which should be associated
	Construct Concerned with the theoretical relationship of the scale score to other variables	Assesses the extent to which a measure behaves the way that the construct it purports to measure should behave with regard to established measures of other constructs
Sensitivity	**Metric or scale** Has enough precision to accurately distinguish cross-sectionally between two levels on the scale known to be important to patients, often referred to as the minimum importance difference (MID)	Determines whether there are sufficient number and accurate 'ticks' on the scales ruler not to miss a difference which is considered important
	Responsiveness Has enough precision to accurately distinguish between two measures at different times longitudinally to estimate changes known to be important to patients – the minimum important change	Determines whether taking everything together in terms of reliability, validity and precision, that when a change occurs in the underlying construct that there is a corresponding change in the scale

1.2 Oral Health-Related Quality of Life Indicators

OHRQoL indicators have been developed and used to assess the impacts of oral health status on QoL. According to Slade et al., (1998), these measures vary in terms of content (ranging from 3 to 49 items) and aspects of oral health which they assess such as ranging from symptoms only to assessing physical, social and psychological functions.

It is important to assess the impact of mouth and teeth on QoL among young children as oral health status can affect their growth, weight, socializing, self-esteem and learning abilities. Moreover, oral and dental problems can also restrict normal activities of both the children and their parents/caregivers (Gift et al., 1992; WHO, 2003). Based on previous research, preschool children may suffer from a number of oral health problems such as teething pain (Moura-Leite et al., 2008), eruption disturbances (Macknin et al., 2000), early childhood caries (Feldens et al., 2010) and dental trauma (Jorge et al., 2009; Robson et al., 2009). These conditions may impact on the preschool children's daily activities and those of his/her sibling(s) and parents who live with the child (Gift et al., 1992). Furthermore, long term impacts can have wider repercussions on the child not only for the present but also in adulthood.

Preschool children are also unique. Up to the age of five, they have difficulty in understanding basic health concepts, are incapable of adequately expressing themselves and tend to give exaggerated responses (Rebok et al., 2001). Children's self-concept and health cognition is age dependent and results from continuous cognitive, emotional, social and language development (Li et al., 2008a). According to child development psychology, the age of six marks the beginning of abstract thinking and self-concept (Hetherington et al., 1999). Their ability to make evaluative judgements regarding their appearance, quality of friendships and other people's thoughts, emotions and behaviour gradually develops throughout middle childhood (six to ten years old) (Bee, 1998).

Due to the possible long duration of oral impacts, these issues have stimulated much interest in children's OHRQoL (McGrath et al., 2004b). To this date, different OHRQoL questionnaires for children of different ages have been developed and used in clinical studies (Jokovic et al., 2002; Jokovic et al., 2003b; Jokovic et al., 2004; Gherunpong et al., 2004; Foster Page et al., 2005; Broder et al., 2007; Pahel et al., 2007). For preschool

aged children, the Early Childhood Oral Health Impact Scale (ECOHIS) have been developed for used among preschool children and younger (Pahel et al., 2007). The ECOHIS was developed to assess the impact of oral health problems and related treatment experiences on the OHRQoL of preschool children aged 3-5 years old and their families. ECOHIS structurally composed of 13 items distributed between two subscales: the Child Impact Section (CIS) and Family Impact Section (FIS). The CIS has four domains: child symptom, child function, child psychology and child self-image and social interaction. The FIS has two domains: parental distress and family function. Total ECOHIS score ranges from 0-52 and uses a 5-point Likert scale. Higher score indicates a greater oral health impact and poorer OHRQoL and vice versa.

1.3 Problem Statement

Early childhood caries (ECC) is one frequently encountered oral disease among preschool children worldwide. In South East Asia countries including Malaysia, the prevalence of caries is still high, for example, caries prevalence of children aged 2-6 years old in northern Philippines were 52-92% (Carino et al., 2003).

Based on Malaysia's report on dental caries over a 10-year period from 1995 to 2005, although caries-free teeth among 5-year-old children had increased from 12.9% to 23.8%, the dft had decreased only slightly, i.e. from 5.8 to 5.5 (Khairiyah et al., 2013). Caries prevalence among 6-year-olds remained high, with only a small decline from 80.9% in 1997 to 74.5% in 2007 (Oral Health Division, 2007). In the most recent epidemiological study among 5 year-olds, it was reported that the caries prevalence was 76.2% with mean decayed, missing, and filled teeth (dmft) score of 5.6. About 55.8% of the 5-year-old children had 3 or more deciduous teeth affected by caries whilst 25.3% had dmft ≥10 (Ministry of Health Malaysia, 2005). These epidemiologic data in Malaysia indicates that

ECC among preschool children is of concern and continues to be a major challenge for oral health practitioners.

Furthermore, consequences of ECC include a higher risk of new carious lesions (Grindefjord et al., 1995; O'Sullivan and Tinanoff, 1996; Al-Shalan et al., 1997; Heller et al., 2000), hospitalizations and emergency room visits (Griffin et al., 2000; Ladrillo et al., 2006), increased treatment cost and time spent in treatment (Ramos-Gomez et al., 1995; Kanellis et al., 2000), higher risk for delayed physical growth and development (Acs et al., 1992; Ayhan et al., 1996), loss of school days and increased days with restricted activity (Gift et al., 1992; Hollister and Weintraub, 1993) and diminished ability to learn (Schechter, 2000; Blumenshine et al., 2008).

OHRQoL has also been shown to be significantly correlated with ECC. Children with ECC had significantly worse OHRQoL than caries-free children (Filstrup et al., 2003). In our local setting, the National Health Morbidity Survey III (NHMS III) showed that of 10.0% of the study population who reported dental pain/problem, preschoolers (5-6 years old) reported the highest prevalence (15.7%) followed by the 16-year-olds (13.6%) (Ministry of Health Malaysia, 2006).

The management of ECC is affected by the extent of the carious lesions and the compliance of the child and parent. In Malaysia, ECC is managed by (i) control of the carious process for example with fluoride application, (ii) stabilisation of carious lesions by temporization by sealing the carious cavity after caries removal, (iii) restorative treatment approach, taking into consideration the child's risk factors and age, (iv) extraction of poorly diagnosed tooth, and (v) dental treatment under general anaesthesia (GA) for non-compliant children (Oral Health Division, 2012). The ultimate goal of the treatment of ECC is to improve the quality of life of the children.

ECOHIS has been shown to be a valid and reliable measure to describe how oral health conditions and treatment affects children's quality of life. It is the only validated OHRQoL measure available for preschool children and has been translated and validated into other languages (Pahel et al., 2007; Li et al., 2008b; Lee et al., 2009; Jabarifar et al., 2010; Scarpelli et al., 2011; Noemí et al., 2012; Hashim et al., 2015). The Malay-ECOHIS has also been validated to be used in the Malaysian setting (Hashim et al., 2015). However, its responsiveness to change has not been established. In order for it to be useful as an outcome measure in clinical interventions, it must also be shown to be sensitive and responsive to the treatment effects (Slade, 1998).

In Malaysia, it is recommended that chairside non-compliant children with ECC be managed by providing comprehensive treatment under GA when treatment cannot be conducted by other means (Oral Health Division, 2012). This guideline offers an appropriate treatment model to evaluate ECOHIS' responsiveness to change in OHRQoL among preschool children (Li et al., 2008a; Klaassen et al., 2009; Lee et al., 2011; Pakdaman et al., 2014; Jankauskiene et al., 2014; Erkmen et al., 2014; Abanto et al., 2016).

By establishing the responsiveness to change of the Malay- ECOHIS, it can then be used as an outcome measure by oral health service personnel in Malaysia to evaluate impairments in OHRQoL following treatment or clinical interventions in clinical practice. It can also be used in oral health research related to preschool children's OHRQoL in Malaysia. Moreover, in the current budget constrained oral health financing system in Malaysia, the use of the measure can help to justify costly dental treatment under GA if OHRQoL can be shown to improve significantly following treatment. Future oral health services for targeted preschool could also be improved.

1.4 Aim of the study

The aim of this study was to evaluate the sensitivity and responsiveness of the Malay-ECOHIS to dental treatment of early childhood caries under general anaesthesia.

1.5 Specific objectives of the study

The objectives of the study were to:

a) Evaluate the sensitivity of the Malay-ECOHIS to dental treatment of ECC under GA by:

i. Assessing changes in the distribution of Malay-ECOHIS scores before and after dental treatment of ECC under GA,
ii. Assessing the association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by the median and percentile score,
iii. Assessing the correlation between Malay-ECOHIS change scores and the number of decayed teeth.
iv. Assessing the correlation between Malay-ECOHIS change scores and the number of extracted teeth.

b) Evaluate the responsiveness of the Malay-ECOHIS to dental treatment of ECC under GA by comparing the Malay-ECOHIS change scores with a global transition judgement.

c) Establish the Minimal Important Difference (MID) of the Malay-ECOHIS.

1.6 Hypothesis

1.6.1 Null Hypothesis (H_0)

1. There was no difference in total ECOHIS scores between pre- and post-treatment of ECC under GA.

2. There was no association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by the median and percentile score.
3. There was no significant correlation between Malay-ECOHIS change scores and the number of decayed teeth.
4. There was no significant correlation between Malay-ECOHIS change scores and the number of extracted teeth.
5. There was no observed gradient in the ECOHIS change scores as the global transition judgement changed.

1.6.2 Alternative Hypothesis (H_1)

1. There was a significant difference in total ECOHIS scores between pre- and post-treatment of ECC under GA.
2. There was an association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by the median and percentile score.
3. There was a significant correlation between Malay-ECOHIS change scores and the number of decayed teeth.
4. There was a significant correlation between Malay-ECOHIS change scores and the number of extracted teeth.
5. The ECOHIS change scores showed an observed gradient in the expected direction across the categories of the global transition judgement following dental treatment of ECC under GA.

CHAPTER 2: LITERATURE REVIEW

2.1 Literature Review Methodology

Literature review methodology outlines the search strategy and selection criteria adopted for this review, and provides descriptions of the types of studies reviewed.

2.1.1 Search strategy

Relevant research concerning testing responsiveness to change of the ECOHIS following treatment of ECC under GA was identified by searching the dental and social sciences databases for primary research material. A total of 9 research databases were searched for publications from 2000 through to the present (2017), with key articles obtained primarily from Dentistry & Oral Sciences Source @ EBSCOhost, MEDLINE, PubMed, and BioMed Central. A complete list of the databases searched is included in Appendix A.

The search terms remained broad in order to ensure that relevant studies were not missed. These included "ECOHIS", plus "oral health", plus "quality of life", plus "responsiveness to change", plus “general anesthesia”, plus “dental treatment” anywhere in the title or abstract. The search was limited to articles in English only. Studies were eligible for consideration in this review if: (a) the focus of the study was preschool children under 6 years of age; and (b) the studies were assessing changes in OHRQoL.

2.1.2 Selection criteria

The next step was a detailed assessment of the research papers. At this point, studies were excluded if the responsiveness to change in OHRQoL was insufficiently described, and therefore the study did not contribute towards important information for this review.

For the studies that testing responsiveness to change of the ECOHIS, the review included all peer reviewed longitudinal studies. Longitudinal studies were seen as particularly valuable resources as they facilitate the testing of the relationships between early events or characteristics and later outcomes, and enable the identification of developmental sequences and pathways, as well as the construction of theoretical models which can then be validated in future research. Cross-sectional studies which used large samples and methodologically sound research designs were also retained. Studies with methodological weaknesses arising from small convenience samples, few factors measured, or weak data analysis, were included only when they provided insights not available from more rigorous studies. For the review of intervention research, studies were retained if: (i) they employed "control" or "no-treatment" groups; (ii) participants were randomly assigned to treatment and non-treatment groups; and (iii) the studies included pre-intervention measures as well as post-intervention or follow-up measures.

2.1.3 Study Description

Previous studies have shown the ability of ECOHIS to describe OHRQoL levels in children with different oral health status (Pahel et al., 2007; Li et al., 2008b; Lee et al., 2009; Erkmen et al., 2014; Hashim et al., 2015). Although this ability is essential to measure preschool children's OHRQoL in surveys, evidence on the index's ability to demonstrate change in OHRQoL is lacking. There is a need for the index to be able to evaluate and demonstrate longitudinal changes in OHRQoL in individuals when change does occur, is predicted or desired, e.g. following clinical treatment/intervention. Furthermore, this ability in the index will allow it to be used as an outcome measure in evaluating treatment in oral health service (it must be sensitive and responsive to the treatment effects) (Slade, 1998; Lee et al., 2011). Dental treatment under GA is a

treatment option for cases of ECC among preschool children who are extremely difficult to manage by other means and as such offers an appropriate treatment model to evaluate ECOHIS' longitudinal validity and responsiveness to change (Li et al., 2008a; Klaassen et al., 2009)

2.1.4 Methodological considerations

Regarding the methodological foundations upon which the reviewed research rest, there are at least two key issues which must be kept in mind when considering the research outcomes. These are: (a) the testing responsiveness to change of ECOHIS variables; (b) the comparability of cross-cultural findings.

First, most research on preschool children has used parent or adolescent reports, collected via self-administered questionnaires. Several questionnaires have been developed to measure the impacts of oral health status on adults' quality of life. Some of them were then adapted for use on school-aged children (Yusuf et al., 2006; Easton et al., 2008). They are usually based on self-administered questionnaires or self-reported interviews, and are sometimes accompanied by questionnaires for parents/caregivers (Locker et al., 2002; Page et al., 2008; Tsakos et al., 2008). However, assessing oral health status of preschool children and its impact on quality of life, needs a special approach. Young children have specific oral health needs. Their memory may not be as reliable, and they may not be able to fully express themselves (Rebok et al., 2001; Filstrup et al., 2003). Evidence indicates that children younger than 8 years old are less likely to be able to recall details of past events that were important to their health more than 24 hours previously (Hetherington et al., 1999) and that the child's oral health problems affect not only his/her overall health, but also impact on family welfare, i.e. lost of workdays and time associated with the child's dental treatment (Gift et al., 1992).

Finally, this review aimed to summarize both the Malaysian and international literature. The international research was relied on quite heavily because of the limited number of Malaysian studies which published both preschool children and OHRQoL data.

Key issues to consider when comparing Malaysian and international research are: first, whether preschool children in Malaysia display similar patterns of oral health status when compared with preschool children internationally, and second, the comparability of Malaysian and international populations in terms of parental and cultural norms concerning oral health status among preschool children.

2.2 Oral Health Related Quality of Life (OHRQoL)

2.2.1 Concept

Although common oral diseases are not life threatening, their outcomes may influence the overall well-being of individuals and populations. As mentioned previously, OHRQoL characterizes a person's perception of how oral health influences an individual's life quality and overall well-being. This concept has received a lot of attention in the past two decades from sociologists, psychologists and the health professions, with different instruments being developed to measure OHRQoL.

Gregory et al. (2005) defined the term OHRQoL as "the cyclical and self-renewing interaction between the relevance and impact of oral health in everyday life." This is a complicated psychosocial interaction where variation and change emerge through OHRQoL as the recursive relationship between impact and relevance, the individual and the social structure.

Most of the OHRQoL instruments developed so far assess either the "effect" or the "impact" of oral health on life quality while others measure the "effect and "impact" together (MacEntee, 2005). The "effect" dimension examines the physical, psychological and social effects of oral health attributes, meanwhile the "impact" dimension examines the impact of oral health attributes on daily activities, chewing ability and talking to people. It also examines the impact of the effects on individuals' overall quality of life. This "effect" and "impact" domains of oral health are better assessed using OHRQoL measures rather than the traditional clinical disease.

2.2.2 Why such measures exist

The theoretical framework such as the conceptual (theoretical) model underlying the development of HRQoL and OHRQoL provides a basis for understanding the behaviour of the system being studied and allows hypotheses or prediction about how the instrument being tested should relate to other measures.

As emphasized by Locker (1988), the importance of the theoretical framework underpinned the OHRQoL in the conceptualization of disease and illness as well as theoretical assumptions in the measurement of OHRQoL**.** The developed OHRQoL measures shared many of the same theoretical assumption as HRQoL. For the most part they have shared the dominant biomedical paradigm and the underlying theories of illness (Coulter et al., 1994). These theories significantly influenced both the instruments and their methods of measurement.

Certain conceptual models and theories to illustrate the issues on the theoretical framework to measure health and oral health are discussed below.

a. Biomedical Model

Biomedicine is a concept dominant in Western Scientific Medicine since the 16th century. Health is seen as a property of biological beings. The main criticism of the medical model is that the model was reductionist and mechanistic in approach (Doyal and Doyal, 1984). Reductionist means the model looks at smaller parts of the body, thus neglecting the patient as a whole person.

A disease-based theoretical model drawn from biomedicine focused almost exclusively on the professional and objective instruments and employed quantitative methods of measurement (Coulter et al., 1994). In fact the biomedicine paradigm is no longer appropriate to be applied in health context. Coulter et al. (1994) highlighted the flaws of the model as follows:

(a) Unable to deal with lifestyle disease,

(b) Increasing number of illness cannot be classified by its taxonomy of disease, and

(c) Cannot account for social distribution of illnesses

The biomedical paradigm has become the dominant social model for understanding illness, disease and health apart from its influence on medicine. Traditional dentistry has adopted the medical model uncritically and it was reflected in the treatments and dental care needs of the patients.

b. Sick-role theory (Parsons, 1951)

Within the sick-role theory, illness is seen as a deviant behaviour that upsets productivity and thus must be contained by mechanisms of social control (Parsons, 1951). Parsons' concept of health as "the state of optimum capacity of an individual for the effective performance of the roles and tasks for which he has been socialised" relates not

to the individual but the society to which he belongs. If the level of illness in a society is too high, its productive capacity declines and its stability threatened.

Reisine (1981) applied Parson's sick-role theory to dental conditions and concluded that the impact of disease should be conceptualized in terms of disruptions in social performance. Locker (1988) commented that the sick-role theory did not provide an adequate conceptual basis for the development of oral health measurement. It missed out the full scope of changes consequent to oral condition and ignored the impacts of oral diseases at individual levels.

c. Sickness Impact Profile (Gilson et al., 1975)

Sickness Impact Profile (SIP) evolved from Parsons' theory. It is a generic psychometric instrument for measuring behavioural dysfunction related to ill-health and has a profound influence on the structural design of socio-dental indicators (SDIs) and OHRQoL. SIP contains structured questions about sickness-related dysfunction and social disruption to measure how respondents feel about the roles and tasks expected of them by society.

d. Biopsychosocial Model (George and Engel, 1980)

It is a holistic health model which takes into account the patient, the social context and the role of physician and health care. Contrary to the biomedical model, this model is not purely biological, non-reductionist and focuses on total patient. It proposes that diseases are influenced not only by the underlying pathology, but also by the individual's perception, personality and his stress levels. The HRQoL measures encompassing this model examine a combination of physical and psychologically impact.

However, this model still tends to be within the positivist conception of science which is the extreme form of positive science that claims science does more than describe the observations it makes (Coulter et al., 1994).

e. International Classification of Impairment, Disability and Handicap (WHO, 1980)

The International Classification of Impairment, Disability and Handicap (ICIDH) (WHO, 1980) recognizes impairment as an exteriorised loss of structure, or abnormality of function at the organ level, disability as a restriction of actions at the person level and handicap as a set of disadvantages within the individual's particular social context. Thus, three different levels are involved with, in most cases, impairment leading to disability and disability leading to handicap (Figure 2.1).

The concepts of impairment, functional limitation, disability and handicap have become pivotal to the development of SDI's and many OHRQoL measures are based on the ICIDH. Disability is seen as a dysfunctional burden on patients and society. Most SDIs take an overwhelmingly negative approach to oral impairment and disability but overlook the positive behaviours and beliefs along with the coping and adaptive strategies of many disabled people.

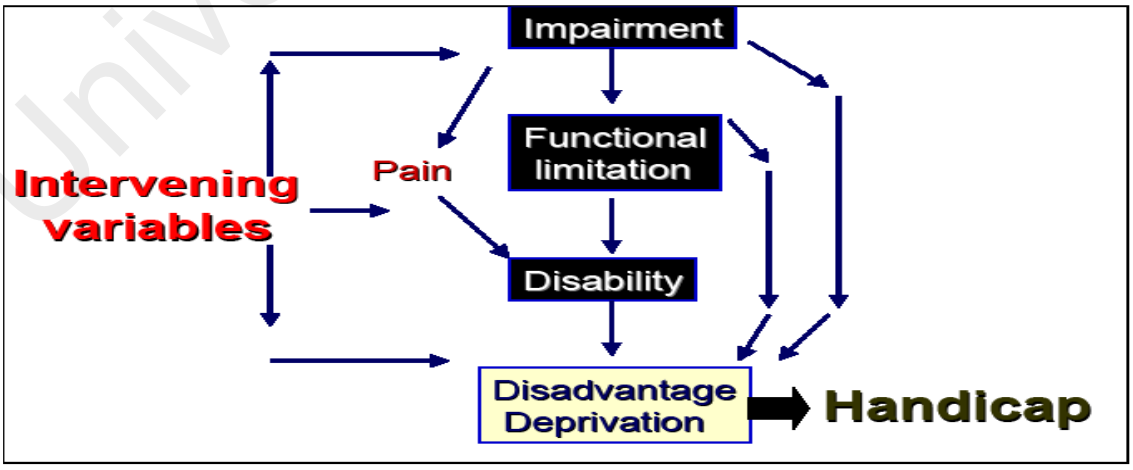

Figure 2.1: International Classification of Impairment, Disability and Handicap (WHO, 1980)

f. The conceptual model for measuring oral health status (Locker, 1988)

The conceptual framework for measuring oral health status described by Locker (1988) and shown in Figure 2.2 is based on the ICIDH framework (WHO, 1980). It attempts to capture all possible functional and psycho-social outcomes of oral disorders.

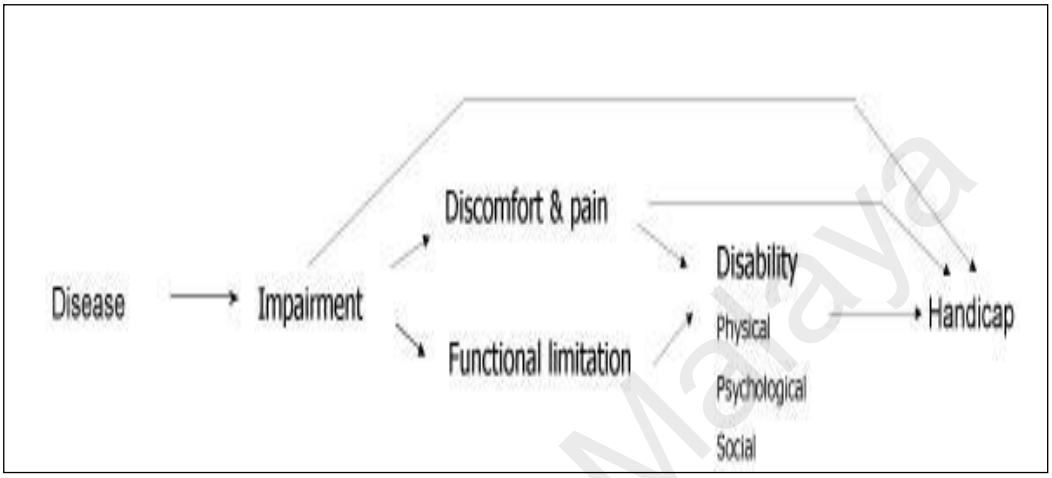

Figure 2.2: The conceptual model for measuring oral health status

The main definitions of this conceptual model are:

(a) Impairment is a loss or abnormality of mental, physical or biochemical function either present at birth or arising out of disease or injury such as edentulousness, loss of periodontal attachment or malocclusion. All pathology is associated with impairment, but not all impairments lead to functional limitations.

(b) Functional limitation is restriction in function customarily expected of the body or its encompassed organ or system, such as limitation of jaw mobility.

(c) Disability is any limitation in or lack of ability to carry out socially defined tasks and roles that individuals generally are expected to be able to do (Pope and Tarlov, 1991).

The model proposes that disease may cause impairment and limited function at the organ level. The individual may die or be disabled and may be disadvantaged in society and hence may be handicapped.

For example, people who lose teeth are impaired, i.e. have lost a body part. Consequences of tooth loss include disability, i.e. lack of ability to perform tasks of daily living such as speaking and eating, and handicap, e.g. minimizing social contact due to embarrassment with complete denture wearing.

The model is applicable to individual and society level and the relationship between impairment, disability and handicap is a dynamic continuum that is reversible. However, impairment does not necessarily result in disability or handicap. Although this model does not predict exact outcomes, it is able to give researchers and clinicians a framework for assessing need (Locker, 1988).

This model defines health not only as an absence of disease but also includes functional aspects, social and psychological well-being. It is able to distinguish health, disease, impairment, disability and handicap as separate but interlinked entities. The model addresses many of the limitations of normative need through clinical assessment. It has provided the context for the development of OHRQoL.

g. A conceptual model of patient outcomes (Wilson and Cleary, 1995)

Wilson's and Cleary's conceptual model (Figure 2.3) classifies oral health outcomes into five main levels; biological variables, symptom status, functioning, health perceptions, and overall quality of life/well-being. This model indicates that the relationships between biological variables and HRQoL outcomes are not direct but mediated by a variety of personal, social and environmental variables. Concepts

pertaining to characteristics of the individual (e.g. motivation and values) and characteristics of the environment (e.g. social support) were also included in this model.

Biologic factors are about the functioning of the cells and organs, the symptoms on the human being as a whole such as physical, emotional and psychological symptoms. This model implies that the presence of disease results in symptoms that affect a variety of health outcomes, such as physical and mental functioning, and perceived health status, which in turn affect overall quality of life.

Functional status is an important point of integration and relates to measuring the ability of the individual to perform particular tasks. That is influenced by social and economic support (environment) and personality and motivation (individual characteristic) of the individual.

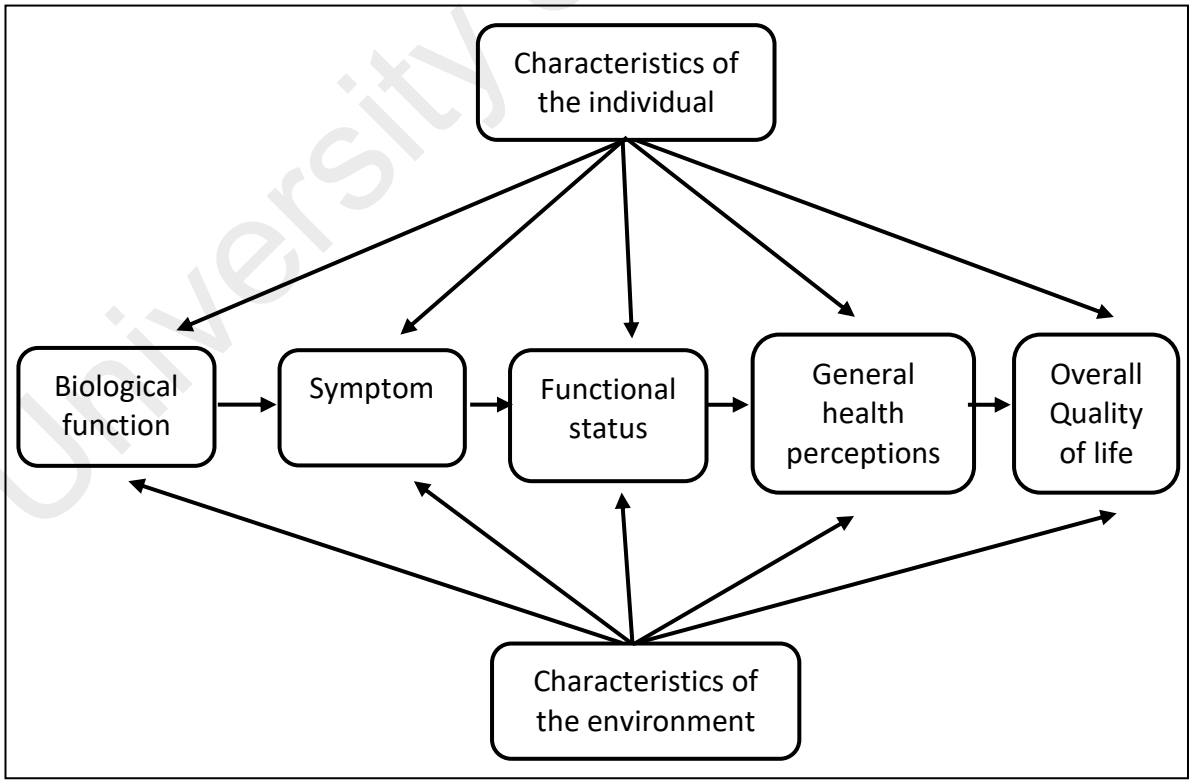

Figure 2.3: A conceptual model of patient outcomes (Wilson and Cleary, 1995)

h. Theoretical framework of consequences of oral impacts (Adulyanon and Sheiham, 1997)

It is the modification of the ICIDH framework (WHO, 1980) which led to the theoretical framework for the Oral Impact of Daily Performance (OIDP) Index. The main modification is that different levels of the concepts are established namely:

(a) Level 1: Oral status and oral impairments which most clinical indices attempt to measure

(b) Level 2: 'Intermediate impacts' which refer to the possible early negative impacts caused by oral health status, e.g. pain, discomfort, functional limitation or dissatisfaction with appearance. Any of these dimensions may lead to impacts on performance ability.

(c) Level 3: 'Ultimate impacts' which reflects the translation of the aforementioned dimensions into impacts on the ability to perform daily activities. This level covers the concepts of disability and handicap (Figure 2.4).

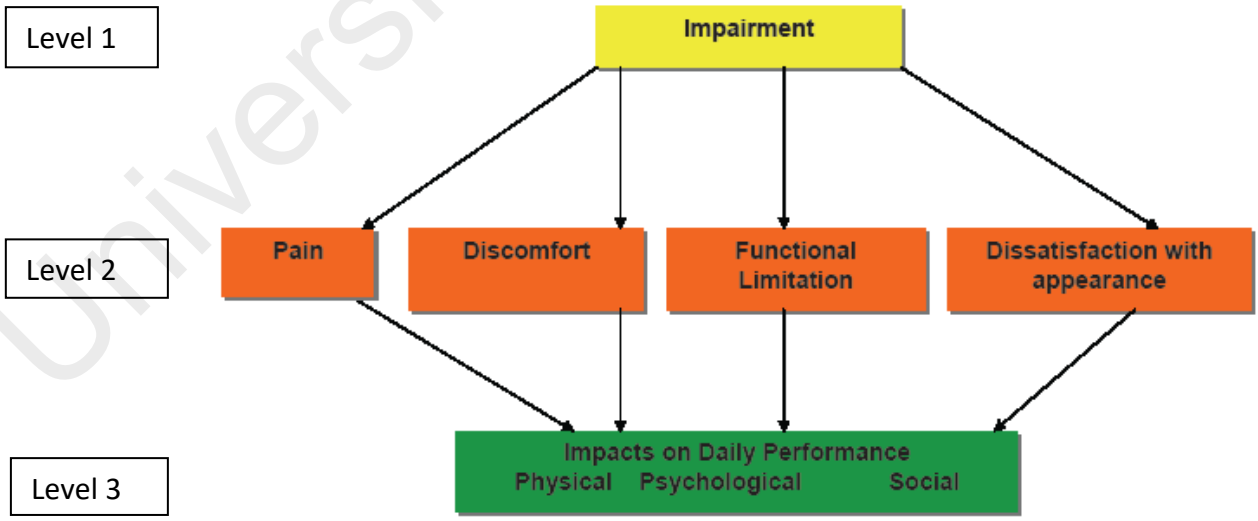

Figure 2.4: Theoretical framework of consequences of oral impacts (Adulyanon and Sheiham, 1997)

The OIDP index focuses on the 'ultimate impact' at the third level of measurement, thus assessing impacts on the ability to perform daily activities. It screens for the significant impacts and measure behavioral impacts in terms of performance (Sheiham and Tsakos, 2007). Thus the screened outcomes should be more useful in the context of policy planning.

i. International Classification of Functioning, Disability and Health (WHO, 2001)

ICF classification and ICIDH framework belong to the "family" of international classifications developed by the WHO for application to various aspects of health. The overall aim of ICF classification is to provide a unified and standard language and framework for the description of health and health-related states (WHO, 2001). It defines components of health and some health-related components of well-being.

ICF distinguishes between body functions (physiological or psychological, e.g. vision) and body structures (anatomical parts, e.g. the eye and related structures). Impairment in bodily structure or function is defined as involving an anomaly, defect, loss or other significant deviation from certain generally accepted population standards, which may fluctuate over time. Activity is defined as the execution of a task or action. The ICF lists 9 broad domains of functioning which can be affected by health status:

(a) Learning and applying knowledge

(b) General tasks and demand

(c) Communication

(d) Mobility

(e) Self-care

(f) Domestic life

(g) Interpersonal interaction and relationship

(h) Community, social and civic life.

The differences between the ICF classification and ICIDH framework are ICF has moved away from being a "consequences of disease" classification (1980 version) to become a "components of health" classification. "Components of health" identifies the constituents of health, whereas "consequences of disease" focuses on the impacts of diseases or other health conditions that may follow as a result.

The health domains and health-related domains of ICF.

These domains are described from the perspective of the body, the individual and society in two basic lists:

(a) Body Functions and Structures; and

(b) Activities and Participation.

ICF classification also lists environmental factors that interact with all these constructs. In this way, it enables the user to record useful profiles of individuals' functioning, disability and health in various domains. ICF classification provides a description of situations with regard to human functioning and its restrictions and serves as a framework to organize this information.

ICF classification organizes information into two parts. Part 1 deals with Functioning and Disability, while Part 2 covers Contextual Factors. Each part has two components:

(1) Components of Functioning and Disability

The Body component comprises two classifications, one for functions of body systems, and one for body structures.

The Activities and Participation component covers the complete range of domains denoting aspects of functioning from both an individual and a societal perspective.

(2) Components of Contextual Factors

Part 2 consists of (a) Environmental Factors, and (b) Personal Factors

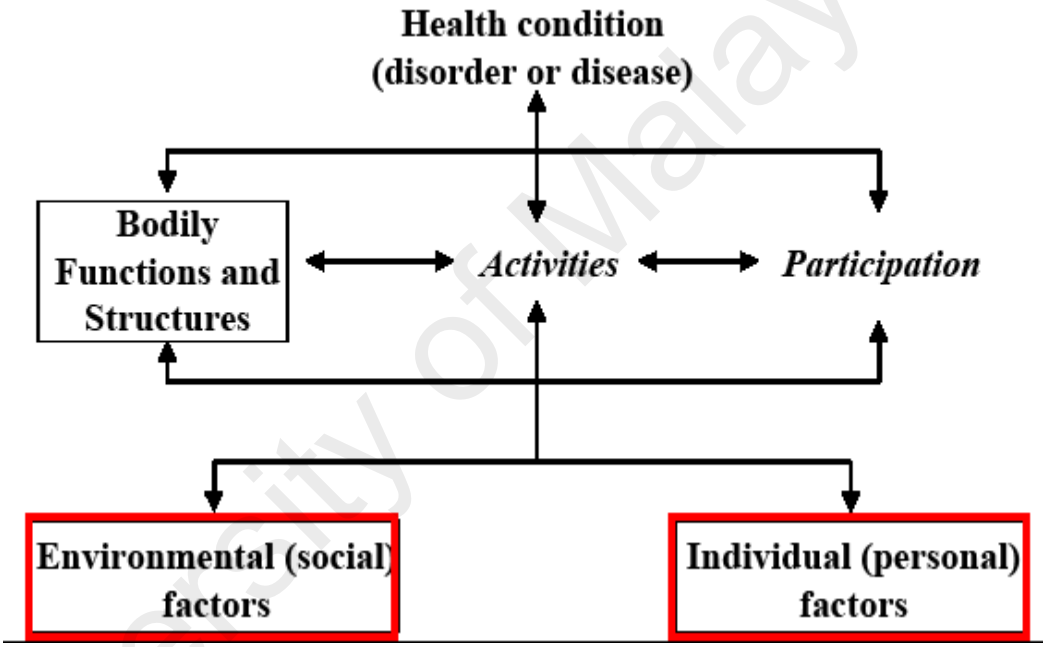

Figure 2.5: Interactions between components of the ICF (WHO, 2001)

Interaction between components of ICF

Functioning and disability are viewed as a complex interaction between the health condition of the individual and the contextual factors of the environment as well as personal factors (Figure 2.5). An individual's functioning in a specific domain is an interaction or complex relationship between the health conditions and contextual factors

such environmental and personal factors. There is a dynamic interaction among these entities.

Brondani and MacEntee (2007) suggested that the ICF provided a more encompassing conceptual framework to measure health-related beliefs and behaviours. They highlighted that the ICF:

(a) Dismisses the negative view of disability to the concept of existential or self-directed interpretation of health

(b) Attempts to promote health or minimise the negative consequences of impairment and disability, and

(c) Portrays disability and physical impairment as an integral part of the social, cultural and psychological context of people's lives.

In addition, MacEntee (2006) suggested that the language, definitions and theoretical model contained within the ICF may be useful for further development of OHRQoL. (Locker and Allen, 2007) added that the definitions and theoretical models of this model are wholly concerned with health and functioning. It does not refer to issues such as HRQoL or quality of life.

j. The International Classification of Functioning, Disability and Health for Children and Youth (WHO, 2007)

The International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) is a derived version of the ICF (WHO, 2001) designed to record characteristics of the developing child and the influence of environments surrounding the child. This derived version of the ICF can be used by providers, consumers and all those concerned with the health, education, and wellbeing of children and youth. It provides a

common and universal language for clinical, public health, and research applications to facilitate the documentation and measurement of health and disability in child and youth populations.

As a version for children and youth, the classification builds on the ICF conceptual framework and provides a common language and terminology for recording problems involving functions and structures of the body, activity limitations and participation restrictions manifested in infancy, childhood and adolescence and relevant environmental factors. The ICF-CY can assist clinicians, educators, researchers, administrators, policy makers and parents to document the characteristics of children and youth of importance for promoting their growth, health and development.

k. The Existential Model of Oral Health (MacEntee, 2006) and the Model of Oral Health (MacEntee, 2007)

Existentialism is a concept in humanistic psychology which emphasises that human's capability to shape his or her own life by exploring options for creating a meaningful existence. (MacEntee, 2006) developed the existential model of oral health in a form of concentric circles to illustrate the dynamic and broad components of the model. It incorporates the components of the ICF relating to coping, adaptation, and socio-cultural environment factors (Figure 2.6).

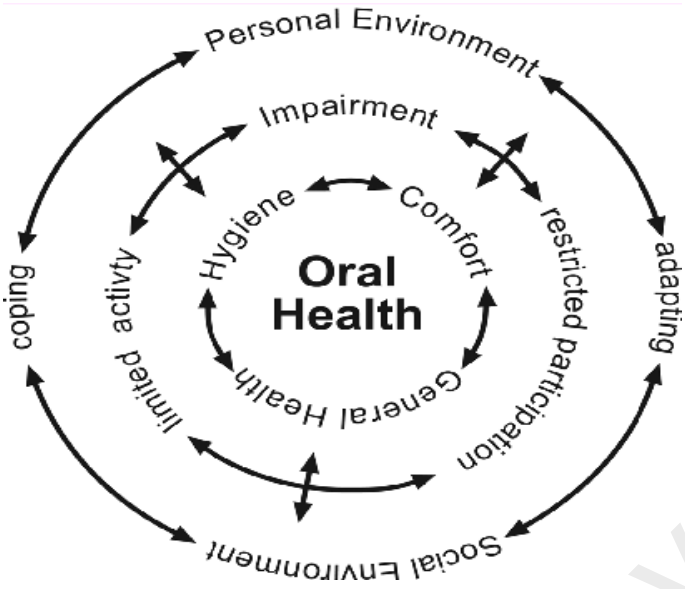

Figure 2.6: The existential model of oral health (MacEntee, 2006)

In the validation of this model by qualitative study in assessing oral health among elderly people, new components suggested by a focus groups such as finance and expectation were included (Brondani and MacEntee, 2007).

The result is a model of oral health composed of four major themes: comfort, general health, hygiene and diet (MacEntee, 2007). These themes affect people's lives both socially and personally will enhances our empirical basis in explaining oral health, evaluating treatment and developing psychometric instruments.

The model offers a conceptual framework for studies and possibly for questionnaires to explore how people adapt to, and cope with, oral ill health and impairment to maintain a positive perspective on life. More specifically, the model should help in the development of research methods that will explain the disability paradox of why tooth loss and other oral impairments are severely debilitating for some people and merely an indisposition for others (Davis, 1976).

2.2.3 Purpose of OHRQoL index

In the oral health context, the question of which measure or index to use has been the subject of intense research in recent years. At the present time, both generic and disease specific measures of health status are employed. Generic measures of health status have a number of important advantages. The psychometric properties of these measures are known, and comparisons can be made between populations with different problems using these scales. However, there is concern that generic health status measures are not sensitive to oral health outcomes (Allen et al., 2001a).

The common OHRQoL measure used in adults are Oral Health Impact Profile (OHIP), Oral Impacts on Daily Performance (OIDP) and Geriatric/General Oral Health Impact (GOHAI). While the use of health status measures to assess health-related quality of life is well established in many areas of medicine, their use in dentistry has not been widespread. Those measures are generic measures and their uses are as follows:

(a) Cross-sectional studies, presenting the profile of functional, psychological and social impacts of oral disorders,

(b) Studies assessing the relationship between clinical and OHRQoL domains,

(c) Intervention (Evaluation) studies assessing the effect of treatment, where quality of life is used as an outcome measure,

(d) Studies for the assessment of treatment need, further facilitating planning of health services.

As mentioned before, disease specific measures have an advantage over generic measures in that they are narrowly focus and thus potentially more responsive to small, but clinically important changes in health. They also contain statements and domains

which are only relevant to the clinical condition in question. This implies that the condition-specific measures are more appropriate for evaluation of clinical trials. An example of a condition-specific QoL measure is the Orthognathic Quality of Life Questionnaire (OQLQ) for young adults with dentofacial deformity (Cunningham et al., 2000).

A further approach suggested by Bowling is to use both an appropriate disease specific measure and a generic measure (Bowling, 1995). The rationale is to have a generic measure with core quality of life statements, and disease specific statements to improve responsiveness.

2.2.3.1 The use of OHRQoL measures in planning

Use of OHRQoL measures for planning oral health services has a number of implications (Sheiham et al., 1982).

1. It will encourage a shift in emphasis from mechanical to behavioural aspects of treatment.

2. It will support the development of health-oriented model of care in preference to the model that dominates current dental services.

3. It will promote the adoption of preventive behaviour by populations.

4. It will guarantee the higher effectiveness of treatment and a greater degree of long-term success.

5. It will facilitate a better division of labour in providing dental care and an improvement in the use of scarce resources.

2.2.4 Examples of OHRQoL measures

The OHRQOL measures currently available have limited theoretical foundation and scope of the measures, as shown in Table 2.1.

Table 2.1: The theoretical frameworks of SDIs and adults OHRQoL measures.

Adults OHRQoL measures	**Theoretical framework**	**Reference**
Oral Health Questionnaire	ICIDH	Locker (2001)
Oral Health Impact Profile	ICIDH	Slade (1997)
Liverpool Oral Rehabilitation Questionnaire	Unclear	Pace-Balzan et al. (2004)
Oral Health Related QoL-instrument	Multiple	Gadbury et al. (1999)
Dental Impact on Daily Living	SIP	Leao and Sheiham (1994)
Subjective Oral Health Status Indicators	Multiple	Locker (1994)
Dental Impact Profile	SIP	Strauss and Hunt (1993)
Oral Health QoL-UK	ICIDH2	McGrath and Bedi (2001)
Oral Health Quality of Life Inventory	SIP	Cornell et al. (1997)
Social Impacts of Dental Disease	SIP	Cushing et al. (1986)
Geriatric Oral Health Assessment Index	ICIDH and SIP	Atchison and Dolan (1990)
Oral Impacts on Daily Performances	Modified ICIDH	Adulyanon and Sheiham (1997)
DENTAL	Not specified	Bush et al. (1996)
Oral health related QoL Measure	ICIDH and SIP	Kressin (1997)
Self-rated Oral Health	ICIDH	Gilbert et al. (1998)

'Table 2.1, continued'

Adults OHRQoL measures	Theoretical framework	Reference
Rand Dental Questionnaire	SIP	Dolan and Gooch (1997)
Dental Health Status QoL Questionnaire	Generic QoL instrument	Kind et al. (1998)

2.3 Child Oral Health-Related Quality of Life (COHRQoL)

Untreated dental caries in primary dentition has been found to be the tenth most prevalent condition worldwide (Kassebaum et al., 2015), despite of its vigorous improvements in the prevention and treatment of dental caries over the past few decades. There is evidence that periodontal disease is prevalent among children in the form of plaque accumulation, gingival inflammation or calculus (Jenkins and Papapanou, 2001; Albandar and Tinoco, 2002). Many countries also reported an increase in the prevalent of malocclusion or in the demand for orthodontic treatment (Tickle et al., 1999). Previous studies also reported there were increasing trend in the form of dental trauma, defects of enamel and dental wear among children (Slayton et al., 2001; Jorge et al., 2009; Robson et al., 2009). These conditions may impact on the preschool children's daily activities.

Because of its significant impact, thus in recent years, there has been a growing interest in the psychosocial impact of oral health among children (McGrath et al., 2004a). A number of COHRQoL measures become available for use as presented in Table 2.2. McGrath et al. (2004a) had come out with recommendations for research and practice in assessing COHRQoL as listed below:

1. To define the age group of children in research between adults and children and between children (infants, children, adolescents)

2. It is important to evaluate the performance of general health measures in the setting of paediatric dentistry
3. It is imperative that the psychometric properties of such measures be empirically tested to verify their reliability, validity and suitability for the particular age group under study
4. A measure should contain the minimum number of items to capture the concept adequately and as to minimize the burden on the study participants and the costs of data collection

Table 2.2: Children's quality of life – adapted from Tesch et al. (2007)

Study	Country	Instrument	Age (years)	Instrument's composition	Outcomes
Pahel et al. (2007)	USA	ECOHIS	2-5	CIS (9 items) / FIS (4 items)	Functional, psychological and social conditions
Broder et al. (2007)	USA	COHIP	8-14	34 items	Oral symptoms, functional well-being, emotional, self-esteem and expectations
Foster Page et al. (2005)	New Zealand	CPQ_{11-14}	11-14	37 items	Oral symptoms, functional limitations, emotional and social well-being
Gherunpong et al. (2004)	Thailand	Child-OIDP	11-12	8 items	Daily activities related to the psycho-physical-social performance
Jokovic et al. (2002)	Canada	COHQOL	6-14	FIS (14 items)	Family activities, finances, conflicts in the family and emotions of parents

2.4 Parent-Proxy Report

The assessment of OHRQoL ideally attempts to encompass 'how well or poorly life works at a particular time' (Wallander et al., 2001) as a result of orofacial health. It requires a rating of an individual's subjective experience regarding well-being or disease. An individual considering treatment for an orofacial condition is often queried not only about the current experience but also post-treatment expectations for OHRQoL. When the individual who potentially needs treatment is a child, an obvious concern is: who should provide the opinion on the child's quality of life and treatment expectations? The child's opinion, it may be argued, is the most valuable opinion.

However, a child may be too young or too ill to give an impression of his or her well-being. If the child is able to provide a self-report, the information may be subject to a few qualifications. The dominance of short-term memory, strong influence of recent incidents, absence of a fully developed long-term perspective, language problems (interview) and reading ability (written questionnaire) may impact the reliability and validity of the results or responses (Vogels et al., 1998; Eiser and Morse, 2001c). For all these reasons, the usefulness of proxy reports has been investigated. Indeed, it is a 'standard practice' to examine how well the proxy rating mirrors the child's rating when assessing a new QoL instrument (Eiser and Morse, 2001b). Although it may seem that a caregiver should adequately estimate the well-being of his or her child, there is a good deal of evidence indicating that caregivers generally have low to modest agreement with the child's rating (Bates et al., 1998; Wilson-Genderson et al., 2007; Jozefiak et al., 2008).

Caregivers may over or under-estimate the importance of certain things like facial appearance, time away from school as well as symptomology and likely have biases and expectations that may influence the QoL rating (Eiser and Morse, 2001b). Further,

caregivers do not observe their school-aged children throughout the entire day (e.g., school interactions, tooth brushing). They have been found to report higher QoL as well as lower QoL (Theunissen et al., 1998; Annett et al., 2003; Ronen et al., 2003; Wilson-Genderson et al., 2007) than the rated child. Proxy reports have also been considered valuable because beyond being a possible substitute rating of QoL, they may enhance the understanding by providing 'a more comprehensive picture of the child across settings' (Achenbach et al., 1987). Thus, even if the rates of agreement among child-proxy reports are modest, such caregiver assessments could provide important additional information to guide treatment decisions. Teacher reports may also represent another proxy for the child (Broder et al., 2001).

While paediatric patient self-report should be considered the standard measuring perceived HRQoL, there may be circumstances when the child is too young, too cognitively impaired, too ill or fatigued to complete a HRQoL instrument, and parent-proxy report may be needed in such cases (Chang and Yeh, 2005; Hays et al., 2006). Further, a developmental framework is important when assessing paediatric QoL because children's cognitive abilities, attitudes and subjective experience of their own well-being change across development (Rebok et al., 2001; Spieth, 2001). Further, it is typically parents' perceptions of their children's HRQoL that influences healthcare utilization (Varni and Setoguchi, 1992; Janicke et al., 2001; Campo et al., 2002) Thus, HRQoL instruments should be selected that measure the perspectives of both the child and parent since these perspectives may be independently related to healthcare utilization, risk factors, and quality of care (Varni et al., 2005).

In a review of the relationship between child and parent QoL ratings, it was found that parent-child agreement can differ across domains investigated (i.e. higher agreement for physical aspects of health vs. emotional aspects (Eiser and Morse, 2001a; Cremeens et

al., 2006b). However, Eiser and Morse (2001a) showed domain and age differences in correlation consistency between child and parent ratings (i.e. higher agreement for younger age on physical health, compared to higher agreement on older age on psychosocial aspects of health). There was also reported evidence of higher agreement between parents and chronically sick children compared with parents and healthy children (Eiser and Morse, 2001a). Some researchers have found evidence that parents of sick children tend to underestimate their child's QoL compared with children's own ratings (Parsons et al., 1999). The reverse (i.e. overestimation) has been reported with parents of healthy children (Theunissen et al., 1998; Russell et al., 2006).

Agreement between child and parent proxy-ratings may also vary by the age of the child (Varni et al., 1998; Theunissen et al., 1998; Cremeens et al., 2006b). Studies found that parent-child agreement was related to child's age and their positive emotions ratings. The older children (10 – 11 years) with low positive emotions scores agreed less with their parents than younger children (8 – 9 years), and older children with high positive emotions scores agreed more with their parents (Theunissen et al., 1998). Similar conclusions reached with younger age predicting greater differences between parents and children with asthma and epilepsy (Annett et al., 2003; Ronen et al., 2003).

Further, in most child QoL research based on parent reports, the mother is usually the prime informant. Mothers who rated their own well-being as poor also rated their child's QoL as poor, suggesting that parents project their own feelings on to judgements about the child's functioning (Eiser et al., 2005). In addition, it was reported significant interaction effect of parental QoL and patients' self-reported QoL in predicting parental proxy reports of their children's QoL (Eiser et al., 2005).

Children have a unique perspective on their own health, and may be able to provide invaluable information to health care professionals, health planners, and health policy makers. Obtaining this information via children's self-reports seems increasingly possible (La Greca, 1990; Cremeens et al., 2006a). However, there are no existing instruments/tools to capture their expressions of health and well-being in a systematic manner (Landgraf and Abetz, 1996). This has very practical implications since neither parents nor clinicians are always able to adequately report on children's internal health experiences. Being able to assess children's perceptions of their well-being and their experience of somatic and emotional symptoms is critical to managing their health as well as to understanding how these experiences may influence their achievement of developmental tasks and everyday functioning (Perrin and Gerrity, 1981; Brewster, 1982). The challenge, then, is to provide children themselves with a means for describing the important aspects of their physical and emotional well-being. Regardless of age, in order to complete a health survey, a person must have at least a rudimentary self-concept, understand the basic notions of health and illness, be able to pay attention, comprehend the questions, discriminate between the response alternatives, recall health experiences, and write a response.

It is known that even children as young as 5 years old can describe internal mental states such as perceptions, emotions, cognitions, and physiological states, but there was concern that they are unable until about the age of 7 or 8 to distinguish between their inner experience and the external behaviour that others see (Harter and Pike, 1984). Up to the age of five, children have difficulty in understanding basic health concepts, are incapable of adequately expressing themselves and tend to give exaggerated responses (Rebok et al., 2001).

In summary, rates of concordance between child and caregiver when rating the child's OHRQoL varied between clinical groups (Wilson-Genderson et al., 2007). Researches also suggested that when children who are younger (than 12 years) and are not able to evaluate QoL assessment due to their developmental limitation or severity of illness, parents can provide valid information about their QoL (Chang and Yeh, 2005; Hays et al., 2006). Further, in longitudinal studies data have to be obtained from parents. Consequently, caregivers collecting quality of life data for longitudinal purposes in daily practice should collect these data simply from parents (le Coq et al., 2000). Even as paediatric patient self-report is advocated, there remains a fundamental role for parent proxy-report in paediatric clinical trials and health services research (IOM, 2001; Varni et al., 2007). As the consumers of paediatric healthcare, families are uniquely positioned to give their perspectives on healthcare quality through their perceptions of paediatric health-related quality of life. Therefore, parents can be reliably used as a surrogate measure in the absence of child's self-reports (Rajasagaram et al., 2009; Khin et al., 2014).

2.5 Early Childhood Oral Health Impact Scale (ECOHIS)

QoL is important in young children because poor oral health status can affect their growth, weight, social activities, self-esteem and learning abilities (Sheiham and Tsakos, 2007). The impact can have wider repercussions not only for the present but also in adulthood (Anderson et al., 2004; Baens-Ferrer et al., 2005; Versloot et al., 2006; Pahel et al., 2007; Klaassen et al., 2008; Malden et al., 2008; Gaynor and Thomson, 2012; Erkmen et al., 2014). Also, oral and dental problems can restrict normal activities of both children and their parents/caregivers (Gift et al., 1992; WHO, 2003). Therefore, assessing parents' perceptions about how oral health problems, including symptoms, disease and its treatment influence their children's quality of life is important. Usually the

responsibility for the health of young children is borne by adults and they generally make decisions about their children's health. Thus, these influences on caregivers are also important to measure as part of assessing young children's OHRQoL.

2.5.1 Development of the Index

2.5.1.1 Conceptual and measurement model

ECOHIS is a generic measure of OHRQoL for children by a parent-administered questionnaire. It was developed by Pahel et al. (2007) and originated in USA.

The ECOHIS was developed to assess the impact of oral health problems and related treatment experiences on the QoL of preschool children aged 3-5 years old and their families. The primary objective was to develop a short instrument for use in epidemiological surveys to discriminate between children with and without dental disease experience. The ECOHIS was completed by the child's parent or primary caregiver.

ECOHIS has 2 sections which are the child impact section (CIS) and family impact section (FIS) (Figure 2.7). In the CIS, there are four domains: child symptom (1 item), child functions (4 items), child psychology and child self-image (2 items), and social interaction (2 items). In the FIS, there are two domains: parental distress (2 items) and family function (2 items). (Appendix B).

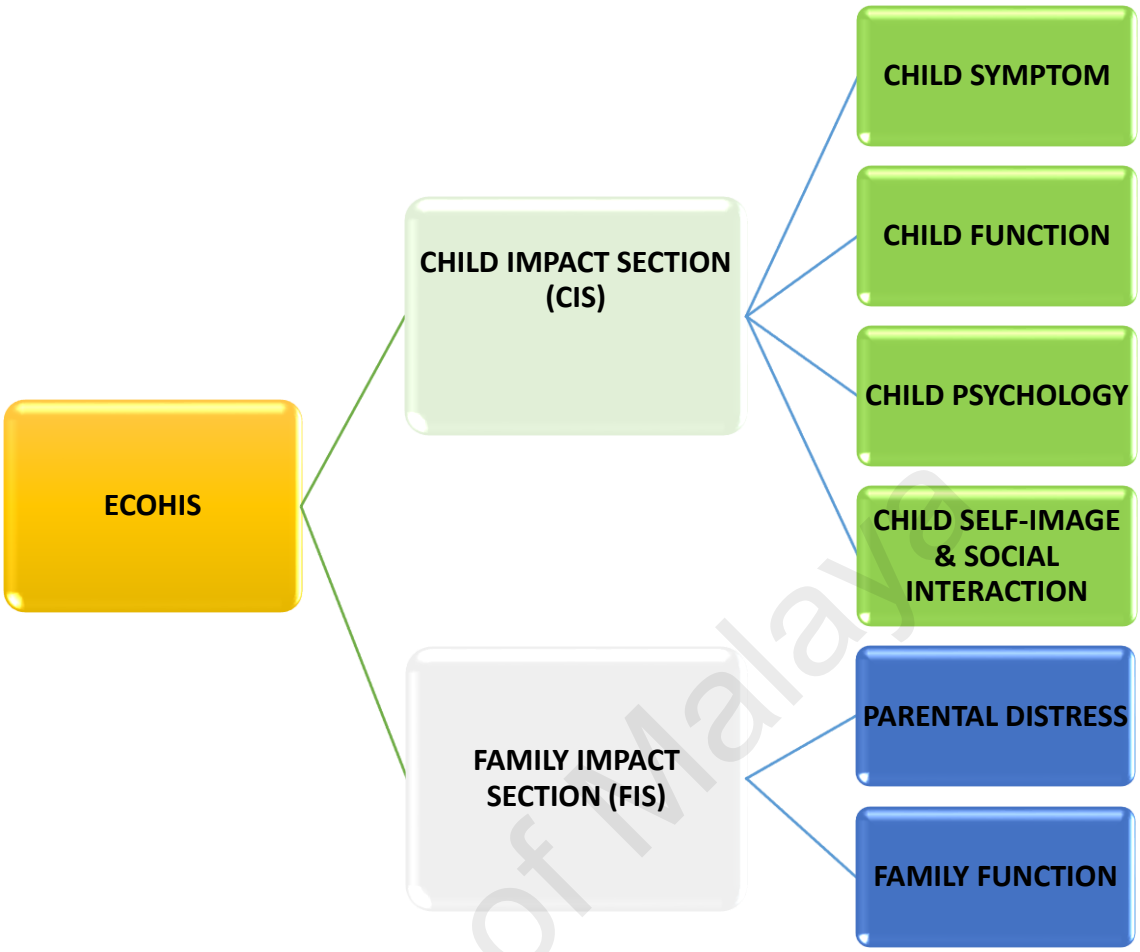

Figure 2.7: Schematic diagram of ECOHIS- each section and domains respectively

The major shortcoming of this measure is that it is based solely on proxy-ratings, which may not reflect the child's perception. The item generation also did not involve any children as the respondents are the parents.

2.5.1.2 The development of ECOHIS

Pahel et al. (2007) developed the ECOHIS following the steps shown in Figure 2.1. The authors used the methodology for developing and testing health-related quality of life instruments described by Juniper et al. (1996) and Guyatt et al. (1993) and procedures for scale development described by DeVellis (2003).

a. Item generation

A pool of 45 impact items for the initial item pool were provided by Jokovic and Locker. This item pool was previously used to generate the development of the Parental-Caregiver Perceptions Questionnaires (P-CPQ) (Jokovic et al., 2003a). These 45 items (31 child and 14 family items) represented descriptive domains of symptom, function, emotional and family/social well-being. Many of the (Jokovic et al., 2003a) items were similar to those included in the Parent form of the Child Health Questionnaire (CHQ) (Landgraf et al., 1999) and the Infant Toddler Quality of Life Questionnaire (ITQOL) (Raat et al., 2006) developed for children and adolescents 5-to-18 years of age and for infants and toddlers, respectively. Pahel et al. (2007) also reviewed generic and non-dental disease-specific quality of life instruments for preschool children to identify items relevant to children's oral health that were possibly missing from the 45-item pool. Final development of the ECOHIS used the items from the latter because items identified from the literature review were overlapped with those identified by Jokovic et al. (2003a).

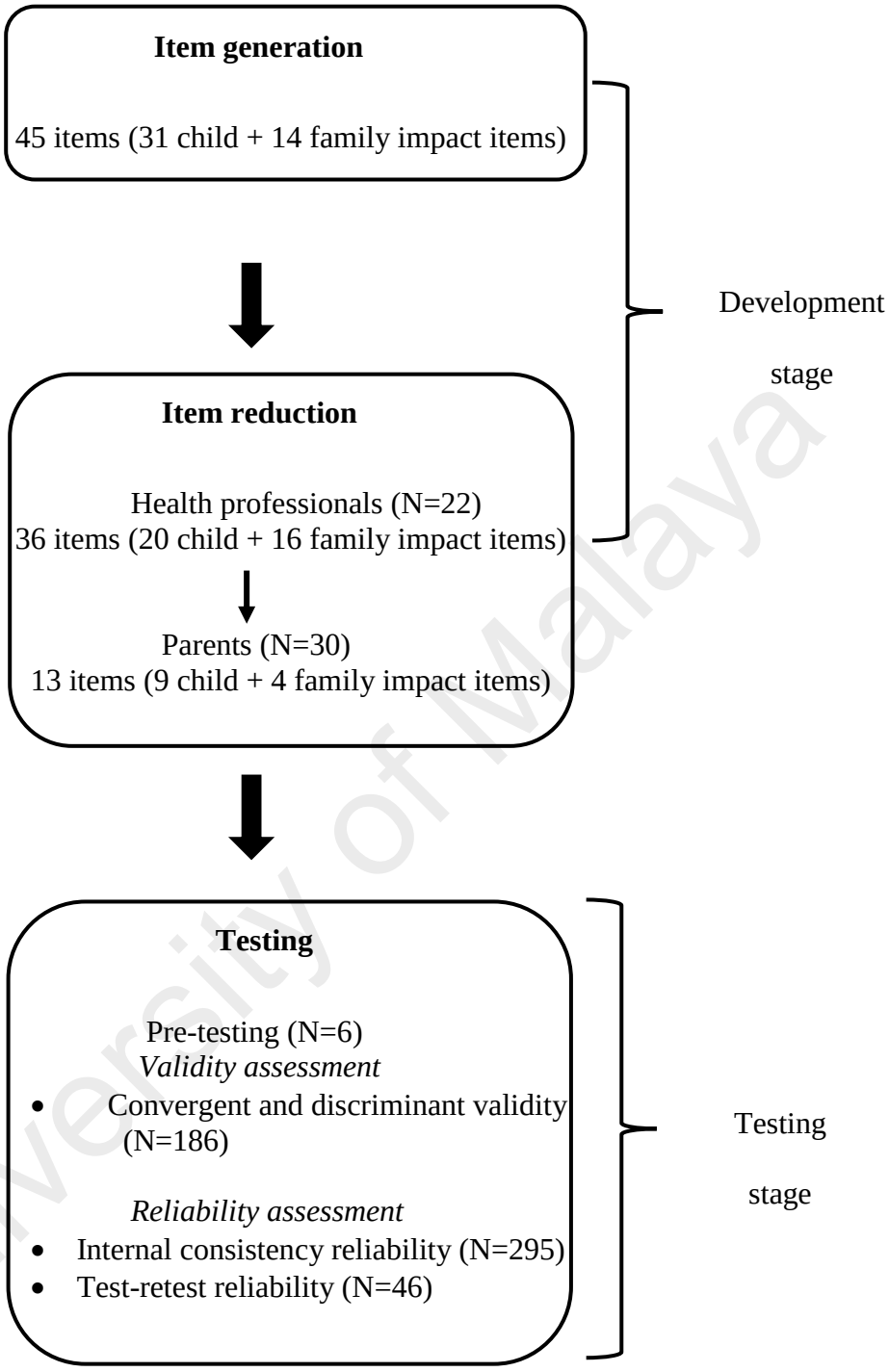

Figure 2.8: The steps in the development and initial evaluation of the ECOHIS

b. Item reduction

The item reduction stage was based on input from a convenience sample of 22 health professionals who worked with young children and their families on a routine basis or researchers in dental public health, and 30 parents of children aged 3 to 5 years old with a range of dental care needs. A modified item pool consisted of 36 items were developed by rewording, combining or excluding irrelevant items based from the responses from the health professionals. After that, the modified pool of 36 items was administered to the parents. The parents were asked to indicate which items were relevant to children of preschool age via visual analogue scales (VAS) ranging from "Not at all relevant" to "Entirely relevant".

Based on Jokovic et al. (2002) as a guide, the authors identified four descriptive domains for items included in the child impact section (symptoms, function, psychological, self -image/social interaction), and two domains for the family impact section (parental distress, family function). The items were ranked in decreasing order of "importance" based on standardised scores. The two highest ranked items in each of the six domains by at least two groups of respondents were selected for the final ECOHIS.

c. Testing

Pre-testing

Pre-testing was accomplished by administering the questionnaire to 6 parents of preschool aged children. ECOHIS was readable and easily interpreted, thus no change of format and scale were made by the authors.

Validity and Internal Consistency Reliability Assessment

The reliability and validity were analysed using data from a convenience sample of 295 parents of 5-year-old children from five high income and three low income counties in North Carolina. Parents responded to a self-completed 41-item questionnaire that included the 13-item ECOHIS and other questions relating to their child's oral health. Children were also examined for dental caries and treatment experience by standardised dental examiners.

Validity analysis

The construct validity was assessed by convergent and discriminant validity analysis of a smaller subset of parents (N=186) with complete information for the child's dental examination.

The convergent validity was evaluated on Spearman's rank order correlations: (1) between child and family ECOHIS scores and two subjective (general and dental) self-reported health measure; and (2) between the child and family sections of ECOHIS. The question for global health rating was "In general, how would you rate the overall health of your child?" The dental health rating questionnaire was "In general, how would you rate the dental health of your child?" The response options were: 1=Excellent, 2=Very good, 3=Good, 4=Fair and 5=Poor. Hypotheses regarding convergent validity were confirmed. The results showed that ECOHIS scores were significantly correlated with the global health rating. The correlation between the child and family impact sections was also statistically significant (Spearman's $r = 0.36$, $p \leq 0.001$).

Discriminant validity

In assessing the discriminant validity, two hypotheses were tested using ANOVA: (1) parents with children having dental disease and/or dental treatment experience would report higher ECOHIS scores than parents of children free from dental disease; and (2) children with more dental disease/treatment experience will have worse OHRQoL.

The results showed that children with either 1-3 or ≥ 4 decayed and/or treated teeth had higher ECOHIS scores on both sections of the ECOHIS than those who were free from dental disease. Children with ≥4 decayed and/or treated teeth had significantly higher scores on the child, but not family section of ECOHIS compared to those with 1-3 affected teeth.

Reliability analysis

Internal consistency reliability was assessed on full sample (N-295) for each of the two sections using Cronbach's alpha. Both child and family sections showed excellent results with α values of 0.91 and 0.95, respectively.

To assess test-retest reliability, the ECOHIS was administered twice to a convenience sample of 55 parents recruited from day care centres by an interval of three weeks. Intraclass correlation coefficient (ICC) was used to assess the test-retest reliability. ICC was calculated by two-way analysis of variance using data from parents who reported no dental visit or change in their child's oral health status during the 3-week interval between initial and follow-up assessments (N=46). The ICC for test-retest reliability was 0.84.

Descriptive statistic

Nearly half of the parents in reliability and validity analysis reported no impact of oral health problems, leading to strong floor effect on both sections. However, no ceiling effects were observed for either of the two sections.

Respondent and administrative burden

It is quite brief, consists of 13 questions. The mode of administration is self-administered.

Alternative forms

No alternative form of ECOHIS.

Cultural and language adaptation (translations)

ECOHIS has been translated to French (Li et al., 2008b), Chinese (Lee et al., 2009), Farsi (Jabarifar et al., 2010), Brazil (Scarpelli et al., 2011), Spanish (Noemí et al., 2012), and Malay (Hashim et al., 2015) languages using the forward-backward translation technique (Guillemin et al., 1993). Then the translated version was tested for internal and test-retest reliability; as well as convergent and discriminant validity.

2.5.2 Scoring Method

ECOHIS relies on parental ratings of 13 items grouped into two main sections: (1) the CIS; and (2) the FIS.

In the CIS, there are four domains: child symptoms (1 item), child functions (4 items), child psychology and child self-image (2 items), and social interaction (2 items). In the FIS, there are two domains: parental distress (2 items) and family function (2 items).

Because of the infrequent nature of oral health problems and the young age of children being considered, the parents was asked to consider the child's entire life span when responding to the questions. Response categories for the ECOHIS were coded: 0 = never; 1 = hardly ever; 2 = occasionally, 3 = often; 4 = very often; 5 = don't know. ECOHIS scores are calculated as a simple sum of the response codes for the child and family sections separately, after recoding all "Don't Know" (DK) responses to missing. For those with up to two missing responses on the child section or one missing on the family section, a score for the missing items was imputed as an average of the remaining items for that section. Using this criterion, it is possible for a respondent to be included in the analytic sample for one but not the other section of the ECOHIS. Parents with missing responses to more than two child items and one family item were excluded from the analysis.

This system creates a scale score ranging from 0 – 52, with higher scores indicating greater impacts and/or more problems. The score for the child and family impact sections have a possible range from 0 to 36 and from 0 to 16, respectively.

2.5.3 Reason for Choosing ECOHIS in the Study

In dental public health, oral health status indicators are useful tools for estimating oral disease levels which later can be used as a basis for developing effective oral health interventions and oral health services because they allow for determination of population needs, priority of care and permit evaluation of treatment strategies (Allen, 2003; Piovesan et al., 2009).

The ECOHIS is a measure of the impact of oral diseases on the OHRQoL of preschool children and their families. It has good validity and reproducibility in cross-sectional studies. In addition, assessing the responsiveness of the ECOHIS to change in oral health status is another key psychometric property if it is to be used as an outcome measure to

assess the effectiveness of clinical interventions (Guyatt et al., 1987). While the English ECOHIS has a limited ability to assess change (Pahel et al., 2007), the Chinese version has been shown to be responsive to changes in oral health following dental treatment (Lee et al., 2011). The difference in the degree of responsiveness of ECOHIS in different settings indicates that the same instrument may not necessarily have the same psychometric properties in a range of different populations and languages. Based on this argument, it could be said that although the Malay-ECOHIS has been validated to assess OHRQoL in surveys, its responsiveness to change has not yet been established. This must be validated before it can be used to assess changes in oral health.

By establishing the responsiveness to change characteristics of the ECOHIS, the index can be used by oral health service personnel in Malaysia as an outcome measure to evaluate treatment success under clinical interventions effectiveness. It will also be useful in oral health research related to preschool children's OHRQoL in Malaysia.

2.6 The Malay-ECOHIS

The cross-cultural adaptation of the ECOHIS into Malay version (Malay-ECOHIS) has been performed. It is valid to be used to assess OHRQoL of preschool children in Malaysia (Appendix C).

2.6.1 Assessment of psychometric properties for the Malay-ECOHIS

2.6.1.1 Linguistic translation of the original English ECOHIS into Malay language.

The translation procedure was carried out based on the guidelines described by (Acquadro et al., 2004) .The original ECOHIS instruments underwent a linguistic validation process to ensure that the Malay version (Acquadro et al., 2004):

- was conceptually equivalent to the original instrument

- was culturally relevant and acceptable to the Malaysian population
- was psychometrically comparable to the original version.

Stage 1: forward translation

The English version of the ECOHIS questionnaire was translated into the Malay language by a team of independent translators consisted of a psychologist, a paediatric dentist, dental public health specialists and experts in QoL assessment. All experts were fluent in English and Malay languages. Meeting among the experts was conducted to analyse the content and wordings of the translations. The objective was to ensure that conceptual and item equivalence between the original ECOHIS and its Malay versions were maintained throughout the process (Herdman et al., 1997).When individual translations were completed, a reconciliation session was held where the forward translators and one of the researchers, who acted as a moderator, met and decided on the agreed draft Malay-ECOHIS version.

Stage 2: Backward translation

The draft-Malay-ECOHIS was back translated into English by a language expert from the Department of Languages, University of Malaya who was proficient in both English and Malay languages. Then, the experts reconvened to compare the back translation with the original ECOHIS. After minor modifications, the experts agreed on the back translation of the Malay-ECOHIS. Small changes to the draft-Malay-ECOHIS were made accordingly before it was finalised.

2.6.1.2: Assessment of face and content validity of the Malay-ECOHIS

To ensure that the final Malay version of ECOHIS was culturally appropriate and sensitive to the Malaysian population, its face and content validity were assessed by a

small pilot study on a non-random sample of 20 mothers of 4-6 year old children at one of the kindergartens supervised by one of the authors (Guillemin et al., 1993). Content validity is concerned about the ability of the items in the questionnaire to adequately represent the relevant constructs being investigated while face validity involves checking whether the items appear to cover the intended objectives clearly and unambiguously (Fayers and Machin, 2000).The respondents were encouraged to give their feedback about their level of understanding of each question and to clarify their answers. Based on the mothers' feedback, a minor adjustment was made to the draft Malay-ECOHIS. The mode of questionnaire administration was self-administered.

2.6.1.3: The evaluation of the validity and reliability of the Malay-ECOHIS

Ethical approval for the study was granted by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya [Reference: DF CO1403/0042(P)]. Permission to conduct the study was obtained from the State Education Department, State Oral Health Division (Selangor), kindergarten teachers and parents of the children. Information about the study was given to the parents to read. A written consent from the parent was obtained before they answered the questionnaire.

The assessment of the Malay-ECOHIS psychometric properties involved 2 studies. In study 1, the Malay-ECOHIS was distributed by one of the authors to a convenient sample of 127 parents of 4-6 year old children from two public and one private kindergarten in Kelana Jaya district in the Selangor state. To assess the test-retest reliability, the scale was redistributed to 20 % of the sample after 10 days (Pahel et al., 2007). In study 2, in order to assess the relationship between the Malay-ECOHIS and clinical outcomes, the scale was distributed by the other 2 authors to 860 parents of 4–6 year old preschool

children from 25 kindergartens from 2 districts in Selangor state. Oral examinations were undertaken on the children.

Internal consistency reliability

Cronbach's alpha coefficient, inter-item correlation and corrected item-total correlation were used to assess the degree of homogeneity of the CIS and FIS. Cronbach's alpha values ≥0.70 were considered acceptable for comparison between groups (Cronbach, 1951). In this study, the Cronbach's alpha was 0.83.

The test-retest reliability test was carried out to ensure the Malay-ECOHIS would yield consistent scores when administered at two different times (Field, 2009). This was determined by the weighted kappa value for categories of Malay-ECOHIS scores and Intraclass Correlation Coefficient (ICC) in a one-way random effect parallel model for the CIS and FIS. The 95 % confidence interval was estimated. The degree of test-retest reliability was assessed based on the ICC values, i.e. ≤0.40=weak, 0.41 to 0.60= moderate, 0.61 to 0.80=good, and 0.81 to 1.00=excellent (Bartko, 1966). Arbitrary guidelines characterized kappa value over 0.75 as excellent, 0.40 to 0.75 as fair to good, and below 0.40 as poor (Fleiss, 1981). From the study, the weighted kappa value was 0.95, and ICC=0.94 respectively.

The ability of the Malay-ECOHIS to assess preschool children's OHRQoL was assessed by examining the association between Malay-ECOHIS scores and a number of subjective variables designed to indicate, both objectively and subjectively, the levels of oral health status and quality of life of the study population.

Convergent validity

The Malay-ECOHIS was tested on its ability to measure what it intended to measure (Field, 2009). In this study, the Malay-ECOHIS was intended to measure child's oral impacts which also mirrored levels of child's oral health status. Consequently, the convergent validity was tested by comparing its relationship with a suitable global oral health rating item on perceived oral health status of the child, i.e. "How do you describe your child's oral health status?" The underlying hypothesis was that parents who rated their child's oral health status as poor would score highly on the Malay-ECOHIS.

There was a trend of increasing Malay-ECOHIS scores from parents who were "very satisfied" to those who were "very unsatisfied" with their child's teeth/mouth ($p<0.001$). Similar trend was observed on parents who perceived their child's oral health status as "excellent" to those who perceived their child's oral health status as "poor" ($p<0.001$).

Construct validity

The Malay-ECOHIS was assessed by comparing its relationships with other measures that assess related constructs, i.e. perceived satisfaction on child's oral health, perceived child's treatment needs, and presence of toothache. The items used were (1) "How satisfied are you with your child's teeth/mouth?" (2) "In your opinion, would your child require any dental treatment?" and (3) "How often has your child had pain in their teeth, mouth or jaws?" The hypothesis related to the tests was that preschool children whose oral health was rated as less satisfactory and needed dental treatment and those with pain in their teeth and mouth would experience lower levels of OHRQoL and higher Malay-ECOHIS scores.

The impacts of child's oral health on his/her daily life were also closely related to the impacts on family members (Pahel et al., 2007; Piovesan et al., 2009). Parents who

perceived their child as needing dental treatment had significantly higher Malay-ECOHIS scores than those who perceived their child as not needing dental treatment. Those who were unsure had lowest Malay-ECOHIS scores compared with the other two groups of parents. The trend was statistically significantly ($p<0.001$). Parents who reported their child had toothache "very often" had significantly higher Malay-ECOHIS scores than those who reported their child had "occasional" toothache; and those who reported their child had no toothache at all ($p<0.001$). Children who never went to see the dentist because of dental problems had significantly lower Malay-ECOHIS scores than children who went to the dentist occasionally; and children who went to the dentist regularly because of dental problems ($p<0.001$).

In the construct validity test, the Malay-ECOHIS showed significant associations with children's levels of perceived oral health satisfaction, perceived oral health need, and toothache experience. These findings empirically supported the construct validity of the scale.

Discriminant validity

The Malay-ECOHIS was tested by comparing its relationship with the child's dental visits due to dental problems and the child's caries status. The hypothesis behind this was that mothers who often brought their child to the dentist for treatment were more likely to report that their child experienced dental problems. Likewise, children with caries would have significantly higher oral impacts than children with no caries.

In this study, the Malay-ECOHIS scores were skewed. Therefore, non-parametric statistics, i.e. Kruskal-Wallis and Mann Whitney were used to assess relationships between the Malay-ECOHIS and subjective/objective measures (Field, 2009). For each of the CIS, FIS, and the overall score, the mean Malay-ECOHIS scores were significantly

higher in children with caries than children without caries. The effect size for each section was small with caries-free children having better OHRQoL than children with caries. Also, there is some suggestion of floor effects for the child impacts section, parent impacts section and the overall scale which had 21 % or more scoring 0 on each section respectively.

2.6.1.4 Conclusion

This study has shown that the Malay-ECOHIS is a valid and reliable measure to assess negative impacts of oral conditions on the quality of life of 4–6 year old preschool aged children and their families in Malaysia.

2.7 Responsiveness to Change of an Index

Measures of OHRQoL are beginning to be used in oral health surveys, clinical trials and studies evaluating the outcomes of dental care programmes (Awad et al., 2000; Allen et al., 2001b). Several measures have been developed that have the potential to be used in this way (Slade et al., 1998). Although these measures are similar with respect to their conceptual basis, they differ in length, the health domains they address, and the complexity of their scoring mechanisms. In order to aid the investigator or clinician, who wishes to use a measure of OHRQoL in research or clinical practice, it is essential that the technical properties of all measures developed to date are assessed and their performance in various contexts are described.

There are two steps in selecting an appropriate measure of OHRQoL as suggested by Locker et al. (2004). The first step in selecting an appropriate measure of OHRQoL is to specify measurement goals, i.e. the exact purpose in using such a measure. The goal maybe descriptive, predictive, discriminative, or evaluative (Kirshner and Guyatt, 1985) as summarized in Table 2.3.

Table 2.3: Measurement goals of OHRQoL

Measures	Uses
Descriptive	In population-based surveys to document the prevalence or nature of health impacts
Predictive	To predict a patient's health status with respect to a current of future 'gold standard' measure
Discriminative	Distinguish between groups that differ in clinical condition or severity
Evaluative	To assess within-subject change occurring naturally or as a result of a clinical intervention

The second step is to identify a measure whose properties conform to the goals of the intended study. Ideally, these properties should have been verified in samples or contexts similar to those being studied. For example, it cannot be assumed that a measure that has been proven to be reliable and valid in cross-sectional studies will necessarily be suitable for use in assessing the outcomes of clinical interventions. While cross-sectional validity and test-retest reliability are desirable properties of evaluative measures, longitudinal validity, reproducibility, and ability to detect minimally important clinical changes are their necessary properties.

To date, the responsiveness of many measures of OHRQoL have not been established. This is a significant omission, given the increasing tendency to use OHRQoL measures as outcomes in clinical trials and evaluation studies. Establishing the responsiveness of the existing OHRQoL measures would assist investigators to select the most appropriate measure, provide a basis for estimating sample sizes, and assist health professionals to interpret the meaning of changes in scores derived from the measures (Deyo et al., 1991; Guyatt et al., 2002).

Responsiveness refers to the ability of a measure to change in relation to an expected gradient of clinical importance such as global transition ratings of changes in oral health (Locker et al., 2004), whereas sensitivity refers to the ability of a measure to identify a significant change in OHRQoL following a treatment intervention based on changes in the distribution of scores (Allen et al., 2001a). Locker (1998) described four ways of measuring change, as summarized below.

1. Before and after comparisons

It is a comparison of the distributions or means of health status variables or scores at baseline and follow-up. The advantages are simple and clear in indicating the health status of a population or patient sample. Its disadvantage is that it masks within-subject change so that positive and negative changes may cancel each other out to give the appearance of no overall change.

2. Change scores

Change scores are calculated by subtracting the score at baseline from the score at follow-up. They provide a quantitative method of assessing change, use to identify variations in change between individuals and groups and as the dependent variable in analyses.

This is the most common approach used in measuring changes in health status (Guyatt et al., 2002). Unfortunately, in spite of their apparent simplicity and logic, the use of change scores to measure change is problematic and highly controversial. Two main problems need to be considered; these concern the definition of clinically meaningful change and the psychometric properties of change scores.

i. Clinical meaning

Two solutions have been suggested for this problem of the meaning of change scores, neither of which is entirely satisfactory. The first involves the calculation of measures of responsiveness such as effect sizes and standardised response means (Kazis et al., 1989; Liang et al., 1990). These assess the sensitivity to change of health status instruments and scales. The effect size is a distribution-based measure in which the difference in mean scores at baseline and follow-up is divided by the standard deviation at baseline (Cohen, 1988). Cohen has provided benchmarks for the interpretation of effect sizes. A value of <0.2 should be considered small, a value of 0.2 – 0.7 is moderate and a value of >0.7 is considered large.

A second solution is to correlate change scores derived from health status measures to change scores derived from clinical measures (Deyo and Centor, 1986). The assumption here is that if the correlations are significant and strong, a clinically meaningful change in health status has occurred.

ii. Psychometric properties

The psychometric properties of change scores are systematically related to random errors of measurement at both baseline and follow-up and have lower reliability than the variables from which they were derived (Cronbach and Furby, 1970). This may lead to erroneous conclusions concerning the predictors of change (Linn and Slinde, 1977). Some believe that these problems are so severe that change scores should never be used in the analysis of change (Cronbach and Furby, 1970). However, this conclusion is not universally accepted. Others claim that they can be used for some analytic purposes if their reliability coefficients exceed 0.5 (Streiner and Norman, 1989). However, it is interesting to note that the issue appears to have been ignored in the literature on health

status measurement where investigators routinely use change scores to assess change in the functional and psychosocial well-being of patient populations (Jenkinson et al., 1994).

3. Global transition judgements

A global transition judgement is simply patients' overall assessment of how their oral health has changed over the reference period in question. It has been pointed out that physicians often make important clinical judgements based on patients' overall ratings of their health and how it has changed over time (Fitzpatrick et al., 1993). Moreover, a number of investigators have demonstrated close associations between global measures of health status and more complex multi-item and multidimensional scales and indexes (Rowan, 1994), so that the former have been used to assess the criterion validity of the latter (Doll et al., 1993). This close association holds for patients' self-ratings of current health status and their overall assessments of health change (Ziebland et al., 1992).

Its advantages are simple, clear and relatively easy to use in clinical practice, less problematic than quantitative measures, incorporate patients' values, and avoid what has been called the 'floor phenomenon' (Bindman et al., 1990). That is, in some studies, subjects reported a worsening of their health even though this could not be revealed by change scores since the individuals concerned had the lowest possible score at baseline. However, it may be insensitive to small or even moderate changes in the health status of populations or patients (Rowan, 1994).

4. Global transition scales

A transition scale is derived from a series of global transition judgements applied to different dimensions of health. Some investigators claimed that these transition scores are better indicators of change than raw change scores (Ziebland et al., 1992; Ziebland, 1994).

However, this is based solely on the stronger correlations with change scores obtained from clinical indicators.

2.7.1 Responsiveness to change of ECOHIS

The fact that sensitivity and responsiveness of ECOHIS had been well evaluated in the management of ECC under GA among different populations (Li et al., 2008a; Klaassen et al., 2009; Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017), may be taken as evidence of the sensitivity and responsiveness of this instrument.

Studies addressing OHRQoL among preschool children using the ECOHIS have demonstrated that dental caries exert an impact mainly on the "symptoms", "function" and "psychological" domains of the CIS as well as the "parental distress" domain of the FIS (Li et al., 2008a; Klaassen et al., 2009; Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017). The magnitude of the differences or effect size found in these studies that have used ECOHIS in preschool children were evaluated. The analysis of the effect size results in information on the real significance of an effect of an adverse health condition or intervention in addition to the concept of statistical significance (Kirk, 1996). A larger effect size denotes a greater impact of the central variable of the study on the issue that is being analysed. In these studies, ECC was found to exert a significant influence on the OHRQoL of preschool children. The discriminant validity of the ECOHIS was confirmed based on the large effect size found in the majority of studies (Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017).

Improvements in children's oral health following dental treatment under GA are reflected in the differences between the mean pre- and post-treatment of total ECOHIS scores. These studies showed significant decline following treatment under GA (Klaassen et al., 2009; Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017). The magnitude of change of total ECOHIS following dental treatment under GA was moderate to large as did the individual domain scores (Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017). Study conducted by Li et al. (2008a) reported the effect size for those reporting improvement was small, and the English ECOHIS had limited ability for responsiveness within low levels of problems.

Mean change scores of ECOHIS showed a gradient in the expected direction across categories of the global transition judgement, and the magnitude of change were moderate to large in relation to global transition judgement of oral change following dental treatment under GA, supporting the responsiveness measures (Lee et al., 2011; Erkmen et al., 2014; Abanto et al., 2016). These studies showed good longitudinal construct validity observed from those reporting improvement had positive change scores of increasing magnitude. Moreover, there were significant differences of mean change scores within categories of global transition judgements.

According to these studies, the responsiveness to change for the ECOHIS is relevant, given the increasing tendency to use OHRQoL as outcomes in clinical trials and longitudinal studies. The summary of each study is presented in Table 2.4.

Table 2.4: Summary table of studies assessing sensitivity and responsiveness to change of ECOHIS following dental treatment under GA

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Li S, Malkinson S, Veronneau J, & Allison PJ. (2008) Testing responsiveness to change for the early childhood oral health impact scale (ECOHIS). *Community Dent Oral Epidemiol 36*, 542-548.	Objective: To investigate the responsiveness to change of the ECOHIS. Study design: Prospective clinical follow-up study design Data were collected from a convenience sample of 101 parents of children attending a hospital dental clinic for dental treatment. Follow-up: After 2 weeks post-operation (trough mail)	94 subjects of 0-5 year-olds completed ECOHIS	Pre- and post-treatment distributions of ECOHIS scores were strongly distributed towards no oral health impacts. Among the 94 subjects, 51.1% reported improvement, 42.6% reported no change and 6.4% reported deterioration following treatment, using the global transition judgement. The mean ECOHIS change scores for these three groups were -0⁄9, +0.7 and +6.5 respectively, although none of the within-group changes were statistically significant. The effect size for those reporting improvement was small (0.15) but for those reporting deterioration was moderate-to-large (0.69). Sensitivity ranged from 0.61–0.79 depending on the size of the cut-off point, with a change of 3 points demonstrating the best sensitivity to false positive ratio (0.79 versus 0.41 respectively)	In this sample with low levels of problems, the ECOHIS has demonstrated some limited ability to respond to change. Further work in a larger sample with higher levels of problems is needed to investigate the instrument's ability to respond to change when it has occurred.

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Klaassen, M. A., Veerkamp, J. S., & Hoogstraten, J. (2009) Young children's Oral Health-Related Quality of Life and dental fear after treatment under general anaesthesia: a randomized controlled trial. *European journal of oral sciences, 117*(3), 273-278.	Objective: To test the hypothesis that young children's OHRQoL improves after oral rehabilitation under GA. A further aim of this study was to explore whether dental fear also changes Study design: RCT (Solomon four-group design). Follow-up: After 4- weeks post-operation (trough mail)	104 children aged 2-7 years old The ECOHIS and the Childrens Fear Survey Schedule-Dental Subscale (CFSS-DS) were used to assess OHRQoL and dental fear, respectively, before and after the rehabilitation procedures over 3 months study period (1 Apr 2007 – 15 June 2007)	The total ECOHIS score after GA was more positive in the GA group than in the control group. There was no effect found of the pre-test and there was also no interaction between the pre-test and treatment. In the total CFSS-DS scores no effects were found. The ECOHIS score of the treatment groups (mean baseline: 12.89) is significantly lower than the ECOHIS score of the control groups (mean baseline: 12.54) , so treatment under GA has effect on the ECOHIS score	The child's OHRQoL improved after treatment under GA. Furthermore, children need guidance in reducing dental fear after treatment under GA.

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Lee GH, McGrath C,Yiu CK, & King NM. (2011) Sensitivity and responsiveness of the Chinese ECOHIS to dental treatment under GA. *Community Dent Oral Epidemiol 39*, 372-377.	Objective: To investigate the sensitivity and responsiveness of the Chinese version of the Early Childhood Oral Health Impact Scale (ECOHIS) to dental treatment under GA Study design: Prospective clinical follow-up study design. A consecutive sample of primary caregivers of children with ECC attending a university hospital dental clinic for dental treatment under GA was recruited over 12-month Follow-up: After 3 months post-operation	32 primary caregivers of healthy children aged 5 and younger	Following treatment under GA, there was significant changes in ECOHIS scores ($P < 0.01$) and many of its sub-domains. The magnitude of change (effect size) of the total ECOHIS following treatment was 0.89 and among sub-domains ranged from 0.29 to 1.33. There was an observed gradient in the changes of ECOHIS scores (and effect sizes) in relation to global transition judgement of oral change following treatment, supporting the responsiveness of the measure.	The Chinese version of the ECOHIS was sensitive to dental treatment for children aged 5 years or younger with ECC under GA

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Erkmen Almaz M, Şaroğlu Sönmez I, Akbay Oba A, & Alp S. (2014) Assessing Changes in Oral Health-Related Quality of Life Following Dental Rehabilitation under General Anaesthesia. *The Journal of Clinical Paediatric Dentistry 38*.	Objective: To determine whether dental treatment under GA improved OHRQoL in preschool children, to evaluate the sensitivity and responsiveness of the Turkish version of the ECOHIS and to examine parental satisfaction with the care received Study design: Prospective clinical follow-up study design. Follow-up: After 4 weeks post-operation	98 healthy children, younger than 7-year-olds	98 children completed the follow-up survey. Between pre- and post-treatment ECOHIS scores, significant reduction was observed ($p<0.001$). The effect sizes were moderate and large (0.36 to 1.63). Global transition rating groups were compatible with statistical differences between pre- and post-treatment scores, supporting the responsiveness of the ECOHIS. 91% of parents regarded the experience to be positive.	Children's OHRQoL showed significant improvement after treatment. The majority of parents reported a high degree of satisfaction. Also, Turkish version of the ECOHIS was sensitive to dental treatment under GA for preschool children and responsive to treatment-associated changes.

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Jankauskiene B, Virtanen J.I, Kubilius R, & Narbutaite J. (2014) Oral health-related quality of life after dental general anaesthesia treatment among children: A follow-up study. *BMC Oral Health, 14*, 81.	Objective: To examine the OHRQoL of young Lithuanian children in need of DGA treatment and analyse the impact of DGA treatment on children's OHRQoL. Study design: Prospective clinical follow-up study design on 140 Lithuanian child patients over 2 years (2010-2012) of study period Follow-up: After 4 weeks post-operation	122 healthy samples younger than 6-years-old completed ECOHIS before and after 1 month follow up	Pain and eating problems among children and parents feeling upset and guilty were the most frequently reported impacts at baseline. The parents reported greater impacts on boys than on girls. The ECOHIS score decreased significantly (69.5%, $p < 0.001$) after DGA treatment, revealing a large ES for the child (1.6) and family (2.4) sections of the ECOHIS.	The OHRQoL of young Lithuanian children requiring DGA treatment is seriously impaired. Dental general anaesthesia treatment results in significant improvement of the children's OHRQoL. The children's parents also greatly appreciate this treatment modality for its positive impact on the family's quality of life

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Yawary, R., Anthonappa, R. P., Ekambaram, M., McGrath, C., & King, N. M. (2015). Changes in the oral health-related quality of life in children following comprehensive oral rehabilitation under general anaesthesia. *International Journal of Paediatric Dentistry*.	Objective: To assess changes in the oral health-related quality of life (OHRQoL), after comprehensive oral rehabilitation under GA (CORGA), among children (i) <6 years using the Early Childhood Oral Health Impact Scale (ECOHIS) and (ii) aged 6–14 years using the child oral health-related quality of life (COHRQoL) instrument. Study design: Prospective clinical follow-up study design. Follow-up: After2 weeks and 3 months post-operatio	A total of 136 healthy children were recruited. Children who had CORGA were recruited over a period of 12 months.	The overall ECOHIS scores decreased significantly ($P < 0.001$) demonstrating large effect sizes. The greatest decreases were for the domains of child oral symptoms (57.5%) and psychology (38.7%) in the child impact section (CIS) and for the domain of parental distress (38.9%) and family function (40%) in the family impact section (FIS). For COHRQoL, the overall P-CPQ and FIS scores decreased significantly for all items ($P < 0.001$), demonstrating large effect sizes. The greatest decreases were for the domains of oral symptoms (77.7%), functional limitations (74.3%), and the FIS (80.1%).	The OHRQoL of children in both age groups (<6 and 6–14 years) was significantly improved after CORGA.

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Abanto, J., Paiva, S. M., Sheiham, A., Tsakos, G., Mendes, F. M., Cordeschi, T., Vidigal E. A., Bönecker, M. (2016) Changes in preschool children's OHRQoL after treatment of dental caries: responsiveness of the B-ECOHIS. *International Journal of Paediatric Dentistry, 26*(4), 259-265.	Objective: To assess the responsiveness of the Brazilian ECOHIS (B-ECOHIS) to dental treatment of dental caries. Study design: Prospective clinical follow-up study design. Children were recruited over 4 months study period (Jan – April 2014). Follow-up: After 7-14 days post-operation	100 parents of 3-5 years old healthy children	Improvements in children's oral health after treatment were reflected in mean pre- and post-treatment B-ECOHIS scores. They declined considerably significantly from 17.4 to 1.6 ($P < 0.0001$), as did the individual domain scores ($P < 0.0001$). There were significant differences in the pre- and post-treatment scores of children who reported little improvement ($P < 0.0001$) as well as in those who reported large improvements ($P < 0.0001$). The ES and SRM based on change scores mean for total scores and for categories of global transitions judgments were large.	Dental treatment resulted in significant improvement of the preschool children's OHRQoL. The B-ECOHIS is responsive

'Table 2.4, continued'

Title, author, year, journal citation	Objectives, study design & follow-up	Sample characteristics	Outcomes/Results	Conclusion
Lanlan, L.,Hongwei, W., & Xueping, H. (2017). Oral health-related quality of life in paediatric patients under general anesthesia. *Medicine, 96*(2), 1.	Objective: To evaluate how dental treatment under GA affect the QoL of paediatric patients Study Design: Prospective pair-matched design over 3 years (Jan 2009 – Dec 2014) Follow-up: 4 weeks after post-operation	124 patients with good nutritional status 62 experimental group (28 boys, 34 girls) Mean age: 5.4 (range: 3.3-6) 62 control group (28 boys, 34 girls) Mean age: 5.6 (range: 3.6-6.3) No difference between 2 groups regarding age, sex, and severity of the disease	In both groups, items of troubled sleep and oral/dental pain scored highest, avoiding smiling/laughing and avoiding talking scored lowest before treatment. Total mean score in 2 groups was 13.1 and 13.7 respectively and no sig. difference ($p>0.05$) Total mean score was 1.9 in experiment groups after treatment and smaller compared to control group (1.9 vs 4.7, $p<0.001$) Majority of items in both groups had an apparent ES. The total mean effect in experimental group was greater than in control group (85.5% vs 65.7%, $p<0.001$)	Dental treatment under AG provide better Q of life restoration compared with treatment over multiple visits

2.8 Minimal Important Difference (MID)

One of the most important ways of describing and interpreting the significance changes in OHRQoL is through the establishment of the minimal important difference (MID). MID is "the smallest difference in score in the domain of interest that is considered to be clinically meaningful, which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" (Jaeschke et al., 1989; Nichol and Epstein, 2008; Cole et al., 2009; Masood et al., 2014). If a significant change in health status occurs due to a disease or a condition or after implementation of an intervention, patient should be able to perceive this change and regard it as an important change. Calculation of this score has been referred to as the MID (Schünemann and Guyatt, 2005). It is also termed "meaningful change," "minimal clinically significant difference," and "responder definition" (Twiss et al., 2010).

Two general approaches have been proposed in order to determine MID in OHRQoL measures: anchor- and distribution-based methods (Allen et al., 2009). This area has been recently reviewed by Tsakos et al. (2012) (Table 2.5)

Table 2.5: Example of methods used in determining MID

Approaches	Methods
Anchor-based approach	• Global health transition scale • Psychological measures • Clinical rating performance measures
Distribution-based approach	• Effect size (ES) statistic • Standard Error of Measurement (SEM) • Paired t-statistics • Half a standard deviation

2.8.1 Anchor-based approach

Anchor-based approaches link the change in OHRQoL test instrument to an already interpretable independent variable (or anchor) with known qualities to elucidate the meaning of a particular degree of change (Walters and Brazier, 2003). Potential anchors can be derived from clinical (laboratory values, psychological measures, and clinical rating performance measures) and patient based or non-clinical outcomes (global health transition scale, patient's self-reported evaluation of change, or any other OHRQoL measure).

Apart from the global rating of change, other examples of anchors in the dental setting can be status on an important and easily understood measure of function (such as chewing ability), the presence of symptoms (for example, teeth mobility), mean scores of patients with a particular diagnosis (such as anterior cross bite), disease severity (e.g., number of teeth missing), response to treatment, or the prognosis of future events such as mortality, absence from work or school, or visit to dental care. Global assessments of health change (typically measured through global health transition scales) have been the most commonly used anchor (Revicki et al., 2006). These self-report retrospective measures of change ask the respondent at follow-up if their health has changed since baseline. If so, has it changed at a small, medium, or large amount, and in what direction on a multiple Likert-type response options. Length of Likert scale can be ranged to various points. For OHRQoL measures, investigators have used different length Likert scales ranged from 15- to 3-point scale. Other measures used as "anchors" should only be used when the MID of that instrument has already been investigated or established. It should be suitably related to the testing instrument with a correlation of at least 0.5 and should cover issues of importance and relevance to the patient. The stronger the association, the more secure the inferences about interpretation of the target measure. Weak associations are liable to yield misleading results (Twiss et al., 2010).

2.8.2 Distribution-based approach

Distribution-based approaches rely on relating the difference between groups before and after treatment or between treated and untreated groups to some measure or measures of variability (Walters and Brazier, 2003). It attempts to identify a score that may be considered important above the "statistical noise" of the measure (Twiss et al., 2010). These strategies examine the underlying distribution of results with the calculation of one of the four statistics: either the effect size (ES), the standard error of measurement (SEM), one-half of the standard deviation (SD), or t-test comparisons (Walters and Brazier, 2003).

The standardised ES is the most popular distribution based approach and has been endorsed by the Cochrane Collaboration for meta-analysis (Johnston et al., 2010). It calculates the mean change as a ratio of the SD (Nichol and Epstein, 2008). Investigators may infer the relative size of change effect by using ES threshold levels developed by Cohen. The standardised ES of <0.2 should be regarded as "small," 0.2-0.7 as "moderate," and those above 0.7 as "large" (Cohen, 1988). The analysis of the ES results in information on the real significance of an effect of an adverse health condition or intervention in addition to the concept of statistical significance (Kirk, 1996). Statistical significance depends considerably on the sample size, as large samples lead to a statistically significant result, even if the association between variables is of a small magnitude without clinical relevance. Real significance is given by the description of the observed ES (Lindenau and Guimarães, 2012), which allows the reader to interpret the importance of the findings (Fritz et al., 2012).

Unlike hypothesis tests that either accept or reject differences between the groups studied, the analysis of the ES furnishes information regarding the magnitude of the relationship found between the outcome and explanatory factors. This means that the ES

is useful in determining the practical or theoretical importance of an effect and the relative contribution of different factors or the same factor under different circumstances (Fritz et al., 2012). Different ES measures are available and several may be appropriate for a given dataset (Kirk, 1996). Based on a study by Ferreira et al. (2017), the determination of the ES confirmed the discriminant validity of the ECOHIS and for most of the studies analysed, the ES was moderate to large. This means that the ECOHIS furnishes valid findings regarding the OHRQoL of preschool children with caries through the reports of parents/caregivers.

The SEM incorporates both the SD at baseline and the reliability of the instrument to represent how the observed change may be affected by random measurement error. The SEM as a useful statistic for assessing individual change on HRQoL instruments, and its use has been described for evaluating meaningful change in a number of medical, cognitive, and behavioural conditions (McHorney and Tarlow, 1995; Hays et al., 2005; Wyrwich et al., 2005). The SEM is the standard deviation of an individual score, estimated by multiplying the standard deviation for a sample by the square root of one minus its reliability coefficient (Wyrwich et al., 1999a; Wyrwich et al., 1999b). Although varying statistical thresholds have been used to determine clinically meaningful change using the SEM, recent research has reported that one SEM consistently corresponded to a minimal clinically important intra-individual change (Wyrwich et al., 1999a; Wyrwich et al., 1999b; Wyrwich and Wolinsky, 2000).

Norman et al. (1997) suggested that one-half of the baseline SD is “remarkably” similar to the calculated MID for a measure (Norman et al., 1997; Twiss et al., 2010).

The paired t-statistic is best suited to pre- and post- assessments of interventions of known efficacy. It ignores information about the variation in scores for clinically stable respondents. The responsiveness statistic looks at OHRQoL change relative to variability

for clinically stable respondents and also ignores information about variation in scores for clinically unstable responders (Nichol and Epstein, 2008).

MID estimates should be based on multiple approaches and triangulation of methods. Anchor-based methods provide preliminary meaningful estimates of an instrument's MID; distribution-based methods can support estimates drawn from anchor-based approaches and can be used in situations where anchor-based estimates are unavailable (Masood et al., 2014).

This current study will only applied the standardised ES for further analysis.

2.9 Early Childhood Caries

Early childhood caries (ECC) is defined as the presence of 1 or more decayed, missing or filled tooth surfaces in any primary tooth in a child 71 months or younger (Drury et al., 1999; Oral Health Division, 2012). ECC is the most common chronic disease in young children and may develop as soon as teeth erupt (Douglass et al., 2004). It is a significant public health problem and certain segments of society, such as the socially disadvantaged have the highest burden of disease (Vargas and Ronzio, 2006). In the US, although prevalence of caries is decreasing overall, the severity is increasing in some groups of people (Douglass et al., 2002). National oral health surveys reported that caries prevalence among 6-year olds remains high, with only a small decline from 80.9% in 1997 to 74.5% in 2007 (Oral Health Division, 2007), meanwhile among 5 year olds, the caries prevalence was 76.2% with a mean decayed, missing, and filled teeth (dmft) score of 5.6. About 55.8% of 5 year-olds had 3 or more deciduous teeth affected by caries whilst 25.3% had dmft ≥10 (Ministry of Health Malaysia, 2005). At state level, the prevalence of ECC among preschool children was even higher, i.e. 80.6% (dmf>7) in Pasir Mas in Kelantan state. Every child had an average of eleven rotten teeth each (Ruhaya et al., 2012).

Consequences of severe ECC include a higher risk of new carious lesions (Grindefjord et al., 1995; O'Sullivan and Tinanoff, 1996; Al-Shalan et al., 1997; Heller et al., 2000); hospitalizations and emergency room visits (Schwartz, 1994; Ladrillo et al., 2006); increased cost and time of treatment (Kanellis et al., 2000; Ramos-Jorge et al., 2014); risk of delayed physical growth and physical development (Ayhan et al., 1996); loss of school days and increased days with restricted activities (Gift et al., 1992; Hollister and Weintraub, 1993); and a diminished ability to learn (Schechter, 2000). OHRQoL has also been shown to be significantly correlated with ECC, i.e. children with ECC had significantly worse OHRQoL than caries free children (Filstrup et al., 2003).

The management of severe ECC is affected by the extent of the carious lesions and the compliance of the child and parent (Oral Health Division, 2012). Methods of management include prevention on good dietary practices, oral hygiene and use of fluoridated toothpaste; stabilization or temporization of the lesion; restorative treatment; dental extraction. Dental treatment under GA is a treatment option for ECC among preschool children who are extremely difficult to manage by other means.

2.10 Dental General Anaesthesia for Children

Children's perception of pain is related to cognitive development (O'Rourke, 2004; Adewale, 2012). The state of anaesthesia is defined as "the absence of sensation artificially induced by the administration of gases or the injection of drugs or a combination of both" (Welbury et al., 2012). The important feature of anaesthesia is that the patient is completely without the ability to independently maintain physiological function such as breathing and protective reflexes, and is acutely vulnerable to the loss of any foreign bodies or fluids down the throat.

The provision of dental treatment under GA falls into three main groups that is out-patient 'short case' dental chair anaesthesia, out-patient 'day stay' intubation anaesthesia

and inpatient 'hospital stay' intubation anaesthesia (Karim et al., 2008; Welbury et al., 2012).

In Malaysia, healthy preschool children with ECC undergoing dental treatment under GA were treated under day care surgery. Day Surgery is a process of care by which suitable patients are managed with admission, treatment and discharge on the same calendar day, ideally within a dedicated, ring fenced environment (Ministry of Health Malaysia, 2012b). However, there were occasions where these healthy patients; i.e. preschool children with ECC were treated under elective surgery which required admission or hospital stay depending on the OT schedule of the respective hospitals. The selection criteria is based on The American Society of Anaesthesiologists' (ASA) classification of physical status (Ministry of Health Malaysia, 2012a).

Table 2.6: ASA classification of physical status

The American Society of Anaesthesiologists' (ASA) classification of physical status
Class 1: Patient has no organic, physiological, biochemical or psychiatric disturbance. The pathological process for which surgery is to be performed is localised and does not entail a systemic disturbance. (Examples: a fit patient with an Inguinal Hernia).
Class 2: Mild to moderate, systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes. (Examples: Slightly Limiting Organic Heart Disease; Mild Diabetes; Essential Hypertension; Anaemia).
Class 3: Severe systemic disturbance or disease from whatever cause, even if it may not be possible to define the degree of disability with finality. (Examples: Severely Limiting Organic Heart Disease; Severe Diabetes with Vascular Complications; Moderate to Severe Degrees of Pulmonary Insufficiency; Angina Pectoris; Healed Myocardial Infarction).

Patient older than 75 years and children less than 6 months should not be selected. The physical factors also include patients with no obvious difficult airway features and BMI < 35 kgm-2 (Ministry of Health Malaysia, 2012a).

There are various types of patients admitted for dental treatment under GA including healthy patients with behaviour problems and patients with special needs such as those having handicapping conditions like congenital heart disease and bleeding tendencies (Ibricevic et al., 2001). Behaviour problems and inability to cooperate are the main reasons for treatment under general anaesthesia (Al-Eheideb and Herman, 2004; Karim et al., 2008) and also patients who are too young to cooperate who have ECC (Acs et al., 2001; Karim et al., 2008). Patients with medically handicapping conditions may benefit from general anaesthesia (Funakoshi et al., 1990; Karim et al., 2008) including those with intellectual disability such as autistic disorder (Klein and Nowak, 1999), cerebral palsy and mentally retarded patients (Machuca et al., 1996). Studies have shown that the quality of restoration carried out under general anaesthesia were far more better than under local analgesia since there were better moisture control and planned restoration placements (Eidelman et al., 1999; Tate et al., 2002; Lanlan et al., 2017).

GA may be required for paediatric dentistry in circumstances where (i) the use of local anaesthesia is either contraindicated, or inappropriate due to the presence of acute orofacial infection; (ii) there has been previous failure of local anaesthesia or sedation; (iii) the patient is unable to cooperate with the proposed treatment due to immaturity, disability, or language difficulties; (iv) the patient suffers from a psychological disorder such as severe anxiety; and (v) extensive treatment is required (Adewale, 2012). GA for paediatric dentistry should only be administered within a hospital setting (Pike, 2000). The Department of Health in England defines a hospital setting as being at least equivalent to that of a hospital within the NHS, including clinics and day-care facilities associated with those institutions, where the following criteria are also satisfied (i) surgery or

procedures which involve the use of general anaesthesia, with or without local anaesthesia, are regularly undertaken; (ii) trained personnel are immediately available to assist the anaesthetist with the resuscitation of a collapsed patient; (iii) facilities and staff are present to support and maintain a collapsed patient pending recovery or supervised transfer to a critical care facility that may, in some instances, be on a separate hospital site (Party, 2000; Seward, 2001).

Dental caries may have an impact on children's oral health status throughout their lives (Low et al., 1998; Erkmen et al., 2014). For the treatment of young children with many carious lesions, involvement of parental time and commitment are involved as prolonged or multiple visits are needed, which may cause a problem with behaviour management (Anderson et al., 2004; Klaassen et al., 2009; Erkmen et al., 2014). While most of the children are able to be treated in the conventional care setting, some children are too young or fail to respond to the usual behaviour management techniques (Nunn et al., 1995; Anderson et al., 2004; Malden et al., 2008; Klaassen et al., 2009; Erkmen et al., 2014). In these situations, dental treatment under GA has to be considered to alleviate pain (Klaassen et al., 2008). Researchers reported that behaviour problems and inability to cooperate were the main reasons for treatment under GA (Acs et al., 2001; Karim et al., 2008). Other study showed significantly higher number of dental procedures for healthy patients than for special needs patients due to the anxiety and fear to dental procedures among the healthy patients even though they did not have behaviour problem (Ibricevic et al., 2001; Karim et al., 2008). Nevertheless, other studies showed that some patients were treated under GA because of their dental fear or because they were too young to cooperate but otherwise healthy (Wong et al., 1997; Karim et al., 2008) and the main background of variables that may cause dental fear include social factors, personality factors and previous negative experience (Varpio and Wellfelt, 1990; Karim et al., 2008).

However for most parents, GA is seen as a dramatic departure from the traditional office-based approach for children's dental treatment. This is because GA carries a risk for morbidity and mortality, this approach can be emotionally challenging for parents who choose this option (White et al., 2003; Erkmen et al., 2014). Whereas previous studies have shown that dental treatment under GA has many beneficial effects such as: reducing toothache-related behaviours and providing better quality of life (White et al., 2003; Versloot et al., 2006; Erkmen et al., 2014), improvements involving less pain experience, abilities to eat and sleep and positive social impact (Low et al., 1998; Acs et al., 2001; White et al., 2003; Anderson et al., 2004; Klaassen et al., 2008; Erkmen et al., 2014). It also permit dentists to treat patients who otherwise could not be treated in a private practice setting, including highly anxious and/or phobic adults, pre-cooperative and uncooperative children, patients with developmental disorders, patients with muscle-control problems and patients with medical conditions that may be exacerbated by anxiety (Karim et al., 2008). Many patients opt to undergo GA to reduce stress and increase comfort (Nick et al., 2002), and some patients needed GA because of lack of cooperation as a result of age, maturity or physical or learning disability (Albadri et al., 2006).

GA for a healthy, fearful child is extremely safe and, in the long run, is the best outcome for the profession and patient (Wilson, 2004; Karim et al., 2008). Even if dental care under GA is a very effective treatment modality, it is often the last resort because of the expense and risk-benefit considerations (Savanheimo et al., 2005) and also some parents may find it hard to accept (Acs et al., 2001). One of the most important issues affecting the choice of pharmacological behaviour management is the cost and reimbursement for GA. Reimbursement for services includes dental procedures, anaesthesia costs and facilities fees, depending on whether the procedure is done in an outpatient care facility or hospital (Lee et al., 2001; Karim et al., 2008). Another issue that is generally recognized by the dental community is that the majority of the insurance

industry does not cover the cost of GA for dental procedures in children (Wilson, 2004; Karim et al., 2008).

The provision of extensive treatment under GA in some children may be justified and such services should be provided safely, effectively and efficiently in the appropriate environment (Alcaino et al., 2000). It also allows dentists to benefit from improved treatment conditions and provide a higher quality of care (Karim et al., 2008).

2.11 Conceptual Framework of Study

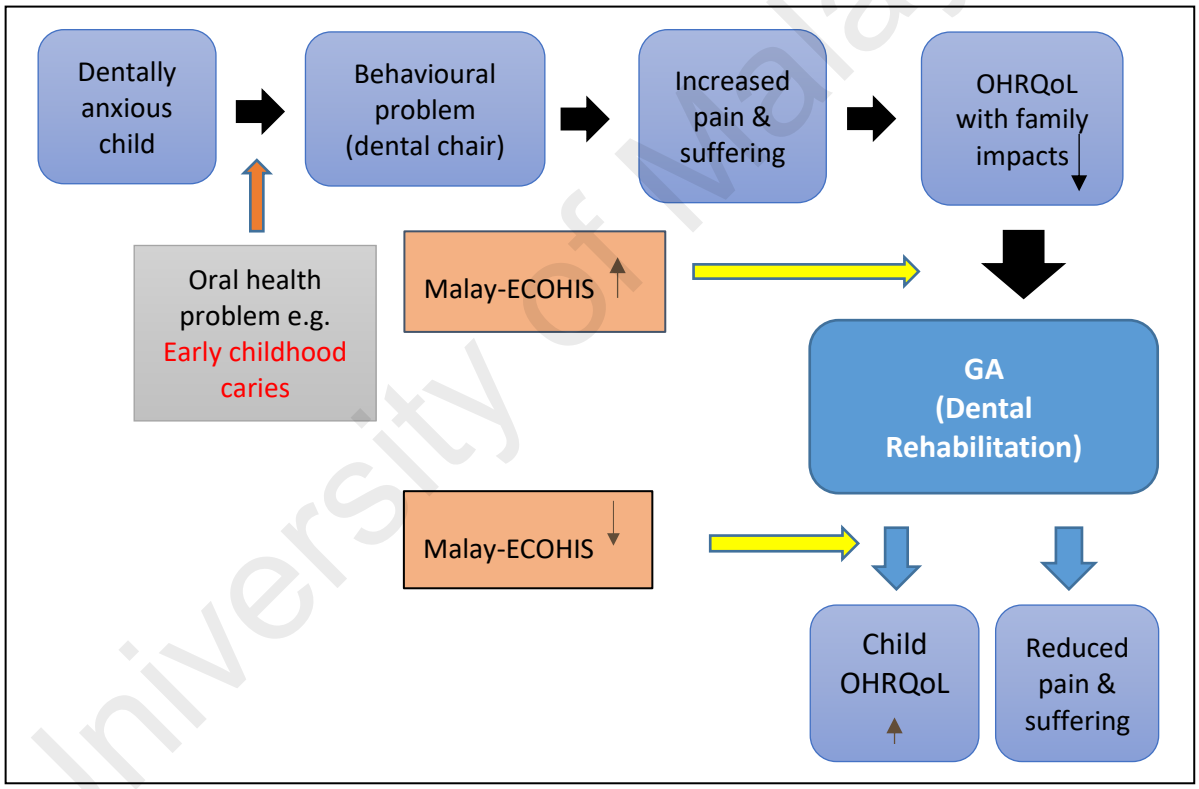

Figure 2.9: Conceptual framework of study

Previous studies have shown the ability of ECOHIS to describe OHRQoL levels in children with different oral health status (Pahel et al., 2007; Li et al., 2008b; Lee et al., 2009; Erkmen et al., 2014; Hashim et al., 2015). Although this ability is essential to measure preschool children's OHRQoL in surveys, evidence on the index's ability to demonstrate changes in OHRQoL is lacking. There is a need for the index to be able to

evaluate and demonstrate longitudinal changes in OHRQoL in individuals when change does occur, is predicted or desired, e.g. following clinical treatment/intervention. Furthermore, this ability in the index will allow it to be used as an outcome measure in evaluating treatment in oral health service (it must be sensitive and responsive to the treatment effects) (Slade, 1998; Lee et al., 2011).

Figure 2.9 shows the conceptual framework for the present study. Dentally anxious /uncooperative child with early childhood caries may lead to unsuccessful dental treatment on dental chair because of child's dental fear and the related behavioural problems. Consequently, the child may suffer from prolonged dental pain. This will impact adversely on his/her daily activities and lead to poor child's OHRQoL with family impacts. In such cases, it is recommended to treat these children under GA. Following dental treatment under GA, it is expected that the dental pain and discomfort would subside significantly. The child would feel better and be able to do his/her daily activities with lesser self and family impacts.

In the present study we measured the OHRQoL of the children using the Malay-ECOHIS before and after the treatment as shown in the Figure 1.3. We expect that the child's OHRQoL would improve and this would be reflected by lower scores of the Malay-ECOHIS. Changes in the child's OHRQoL by means of changes in the Malay-ECOHIS score would provide evidence for the Malay-ECOHIS' responsiveness and sensitivity to change in the child's OHRQoL. A global transition judgement answered by parent at follow up will provide the convergence validity of the index's ability to demonstrate changes in OHRQoL among preschool children.

In the present study, we use parents as proxy in establishing the child's OHRQoL due to the child's limitation in understanding and memorising their oral experience especially dental pain.

2.12 Summary

For the past two decades, the concept of OHRQoL has received a lot of attention from sociologists, psychologists and health professions. Most research involving the OHRQoL methodology seeks to define and identify how oral health influences an individual's life quality and overall well-being, with different instruments being developed to measure OHRQoL. The conceptual models and frameworks underlying the development of OHRQoL provide a basis for understanding the behaviour of the system being studied. With that, it allows hypothesis or prediction about how the instrument being tested should relate to other measures. The evolution culminated that instead of traditional framework, a further approach suggested by Bowling (1995) to use both an appropriate disease specific measure and a generic measure. The rationale behind it is to have a generic measure with core quality of life statements, and disease specific statements to improve responsiveness.

As the field of OHRQoL expands, a number of international studies have already begun developing measures of COHRQoL. The children are subject to numerous oral conditions that can impact on their OHRQoL. They are one of the major target groups of the oral healthcare service in many countries. The importance of OHRQoL is particularly relevant in children. Although the importance of assessing OHRQoL in children has been highlighted, constructing COHRQoL involved complex methodology and theoretical framework. Therefore, very few studies have been conducted on child populations and a few COHRQoL measures developed for children since 2002. Instruments that have been developed demonstrated appropriate questionnaire techniques, valid and reliable information which can be obtained from children. One of the instrument is the ECOHIS, developed by Pahel et al. (2007).

ECOHIS is used to assess oral impacts on the quality of life of preschool aged children and their families. It is a short instrument used to discriminate between children with and

without dental disease experience. ECOHIS relies on parental ratings of 13 items grouped into CIS and FIS sub-scales. In addition, it has good validity and reproducibility in cross-sectional studies (Pahel et al., 2007; Li et al., 2008b; Lee et al., 2009; Jabarifar et al., 2010; Scarpelli et al., 2011; Noemí et al., 2012; Hashim et al., 2015), and is one of the reasons chosen to use ECOHIS in this study. Even though a cross-cultural adaptation and its psychometric properties of the ECOHIS into Malay version (Hashim et al., 2015) has been performed, the difference in the degree of responsiveness of ECOHIS in different settings indicates that the same instrument may not necessarily have the same psychometric properties in a range of different populations and languages. The Malay-ECOHIS has been validated to assess OHRQoL in surveys, its responsiveness to change has not yet been established. Therefore, it must be validated before it can be used to assess changes in oral health.

In order to aid the investigator or clinician, to use a measure of OHRQoL in research or clinical practice, it is essential that the technical properties of all measures developed to date are assessed and their performances in various contexts are described. Therefore, establishing the responsiveness of the existing OHRQoL measures would assist investigators to select the most appropriate measure, provide a basis for estimating sample sizes, and assist health professional to interpret the meaning of changes in scores derived from the measures. The sensitivity and responsiveness of this instrument showed that the ECOHIS had been well evaluated in the management of ECC under GA among different populations (Li et al., 2008a; Klaassen et al., 2009; Lee et al., 2011; Erkmen et al., 2014; Jankauskiene et al., 2014; Yawary et al., 2015; Abanto et al., 2016; Lanlan et al., 2017). According to these studies, the responsiveness to change for the ECOHIS is relevant, given the increasing tendency to use OHRQoL as outcomes in clinical trials and longitudinal studies. Based on these, it has led to the development of the present study.

CHAPTER 3: MATERIALS AND METHODS

3.1 Study design

This longitudinal study employed a before-and-after study design on preschool children aged 2-6 years old who underwent dental treatment under GA in the Selangor state, Peninsular Malaysia.

3.2 Study Area

Malaysia at a glance

Figure 3.1: Map of Malaysia

Malaysia is a federal constitutional monarchy located in South East Asia. It has total landmass of 330,323 square kilometres with total population estimated at 31.7 million persons (Department of Statistics Malaysia, 2017). Peninsular Malaysia is separated from the states of Sabah and Sarawak by the South China Sea. To the north of Peninsular Malaysia is Thailand while its southern neighbor is Singapore. Sabah and Sarawak are

bounded by Indonesia while Sarawak also shares a border with Brunei. Malaysia consists of thirteen states and three federal territories (Figure 3.1).

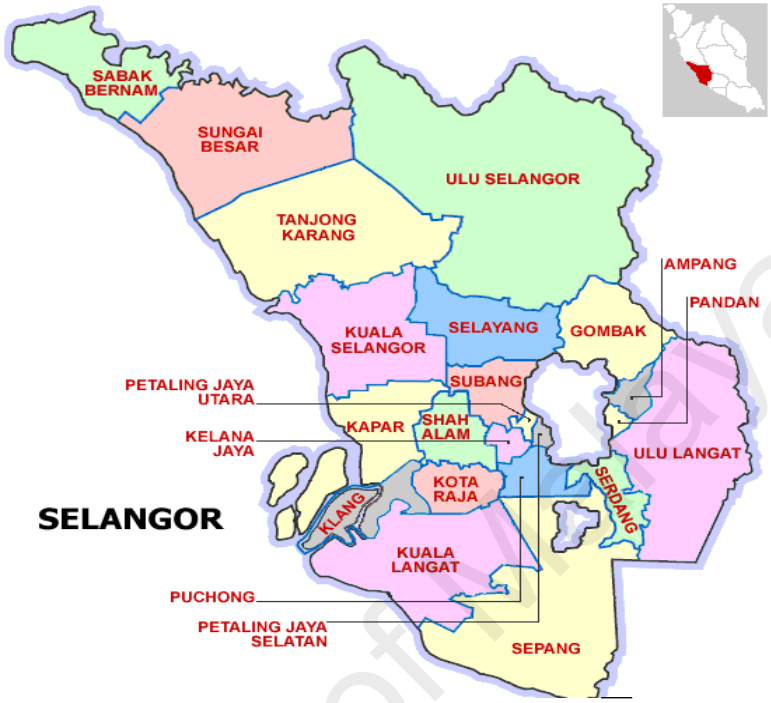

Figure 3.2: Map of Selangor

Selangor is one of the thirteen states of Malaysia (Figure 3.2). With an area of 7,930 $km^{2,}$ Selangor extends along the west coast of Peninsular Malaysia at the northern outlet of the Straits of Malacca. It is the most populated state in Malaysia with 5.386 million population (Population and Housing Census, 2010).

Selangor State Health Department (SSHD) is the headquarters of the health service under the Ministry of Health Malaysia and responsible for health services in the state. SSHD is led by State Health Director and assisted by six Deputy Directors of Health, who lead their respective division. Each division is responsible for conducting the activities in Selangor.

The six divisions are:

i. Management Division
ii. Division of Public Health,
iii. Division of Medicine,
iv. Division of Dentistry,
v. Division of Pharmaceutical Services
vi. Division of Food Safety and Quality

In addition, there are 32 centres consists of twelve hospitals, eleven district health offices and nine district oral health offices which are under the governance of the SSHD. The public hospitals involved in this study are located within Selangor state.

3.3 Target population, Sample and sampling method and sample size

3.3.1 Target population

Preschool-age children (aged 2-6 years old) who received dental treatment for ECC under GA and their parents was the target population for this study.

3.3.2. Sample and sampling method

Sample for this study was obtained from the Department of Paediatric Dentistry in public hospitals in the state of Selangor. The selected public hospitals were as follows:

i. Hospital Ampang
ii. Hospital Selayang
iii. Hospital Serdang
iv. Hospital Sungai Buloh
v. Hospital Tengku Ampuan Rahimah

The inclusion criteria were:

i. Preschool-age children diagnosed with ECC and are recommended for comprehensive dental treatment under GA (as they are either uncooperative or very young);
ii. Accompanied by a Malay-speaking parent / guardian who lives with the child most of the time.

The exclusion criteria were:

i. Preschool-age children who have serious medical condition(s); as per Table 2.6
ii. On long term medications; and
iii. Have physical / learning disabilities

The parents of the selected children acted as a proxy to answer the questionnaires before and after the children had dental treatment under GA.

In this study, a non-random sampling method was used to select participants who fulfil the inclusion and exclusion criteria to participate in the study. Whilst some researchers may view this sampling technique as inferior to random sampling techniques, there are strong theoretical and practical reasons for its use (Zina, 2004). Non-random purposive sampling reflects a group of sampling techniques that rely on the judgement of the researcher when it comes to selecting the participants who are to be studied. The main goal of this sampling technique is to focus on particular characteristics of preschool children who fit the inclusion and exclusion criteria that enable the researcher to answer the research questions. This is because, the preschool children with ECC were recruited from the waiting list to undergo dental treatment under GA in the selected five public hospitals in the state of Selangor, until the sample size of 112 or more preschool children have completed the study successfully within the 8-month of the data collection period.

Invitation letters were sent to all Heads of Department of the public hospitals to inform them of the research and to obtain permission to invite caregivers of participants, i.e. preschool children with ECC undergoing dental treatment under GA to participate in the research. All heads of departments consented to the request.

Subsequently, parents of preschool aged children scheduled for comprehensive dental treatment under GA in the Department of Paediatric Dentistry in the five public hospitals namely Hospital Ampang, Hospital Selayang, Hospital Tengku Ampuan Rahimah, Klang, Hospital Serdang and Hospital Sungai Buloh were invited to participate in the study. All parents who consented to be involved in the study were included.

3.3.3. Sample size estimation

Sample size for the study was determined using G*Power 3: a statistical power analysis programme (Faul et al., 2007). G*Power (Erdfelder et al., 1996) was designed as a general stand-alone power analysis programme for statistical tests commonly used in social and behavioural research, but also in many other disciplines that routinely apply statistical tests, including medical research (Gleissner et al., 2006).

In studies where the plan is to perform a test of hypothesis on the mean difference in a continuous outcome variable based on matched data, the hypotheses of interest are:

$$H_0 : \mu_{x-y} = 0 \text{ versus } H_1 : \mu_{x-y} \neq 0$$

where μ_{x-y} is the mean difference in the population.

The formula for determining the ES is given below (Faul et al., 2007):

$$d_z = \frac{|u_{x-y}|}{\sigma_{x-y}}$$

where u_{x-y} is the mean difference in the population and σ_{x-y} is the standard deviation of the difference in the outcome.

From the validation study of Malay-ECOHIS (Hashim et al., 2015), preschool children with ECC had a mean ECOHIS score of 18.44 (SD = ± 5.39). Based on the assumption that preschool children with ECC awaiting dental treatment under GA would have similar (if not higher) ECOHIS scores, and the assumption that the dental treatment would produce at least a 50% reduction in mean ECOHIS scores, the power analysis undertaken by G*Power 3, with a medium effect size of d_z = 0.3, α = 0.05, and power set at 0.8 gave a number of 90 participants. Considering the potential loss of 25% at follow-up, a sample of **112 preschool children was set**.

3.4 Study instrument

3.4.1 Structure of Questionnaire

Two sets of questionnaires were constructed:

i. Set 1 (pre-treatment evaluation of child's OHRQoL) (Appendix D)

The first set of the questionnaires was given to the parents of preschool children with ECC before their child received dental treatment under GA. It was distributed on the operation day at the selected public hospitals. Set 1 questionnaire comprised:

- Participant Information sheet

The Participant Information Sheet provides participants with the necessary information about the study and their rights in the research so that parents will have enough information to allow them to give an informed consent to participate in the study.

- Informed consent form

Parent will put down his/her signature to indicate consent to participate in the study and has understood the key points.

- Demographic information

The sociodemographic variables included "age, ethnic group, gender, medical problems, number of siblings and position of child in the family, relationship with the child, highest educational achievement of mother and father, and monthly household income".

- Malay-ECOHIS

The ECOHIS is an English language measure of OHRQoL. It was developed and validated in the United States. The aim is to assess the impact of oral health problems on the quality of life of preschool children and their families (Pahel et al., 2007).

This study was conducted using the Malay-ECOHIS which has been validated for use in the Malaysian setting (Hashim et al., 2015).

It consists of 13 items divided into two main parts following the original ECOHIS, i.e. child impact section (CIS) and family impact section (FIS). CIS comprises four domains, i.e. child symptom (1 item), child function (4 items), child psychology (2 items) and child self-image and social interaction (2 items). The FIS contains two domains, i.e. parental distress (2 items) and family function (2 items).

Using ECOHIS, parents reported their child's OHRQoL before their child received dental treatment under GA at the respective public hospital.

- Caries status

Dental charting from the patient information system was recorded prior to treatment under GA

ii. Set 2 (post-treatment evaluation of child's OHRQoL) (Appendix F)

The second set of the questionnaire was distributed to the same parents of the children at 4-week follow-up appointment at Paediatric Dental Specialist Clinic at the respective public hospital. This questionnaire comprised:

- Demographic information

The sociodemographic variables recorded was the child's "age and date of birth".

- Global transition judgement item

A single item with a 5-point response scale was used to assess parents' perceptions of change in their child's oral health after dental treatment under GA was performed. This global transition judgement is taken as a 'gold standard' for evaluating the responsiveness to change of QoL measures (Malden et al., 2008; Lee et al., 2011; Abanto et al., 2013).

- Malay-ECOHIS

Parents were asked to respond based on their child's oral impacts after receiving dental treatment under GA at the respective hospital.

- Type of treatment

Type of treatment provided under GA were recorded

3.5 Conduct of Study

Data collection for the study was conducted over a period of 8 months from July 2016 to March 2017. The researcher was involved in all parts of the data collection process.

The researcher approached the preschool children and their parents systematically. At the start of the day, the researcher liaised with the dental officer in-charge of each hospital to invite the respective parents of preschool children to take part in the study. The researcher remained in the operation room or admission centre until mid-day to encourage parents of the preschool children to take part in the study. Those who declined to participate were not included in the study. Eligible children were included in the study if their parents voluntarily agreed to participate when approached by the researcher at the respective hospital.

From the list of names scheduled for GA, it was possible to establish how many children were potentially available for the study at the different hospitals. A timetable which outlined the dates and operation venues was generated based on the number of potential patients and the location of the hospitals. The GA list of patients was prepared by the dental officer in-charge of each hospital and was given to researcher at least one day before the operation.

Among the five public hospitals selected in this study, some of them shared same operation day (Appendix H). Therefore, to smoothen the data collection process, the researcher communicated with all contact enumerators who were selected among dedicated dental officers in-charge before the operation day. The researcher liaised with the dental officer in-charge at the respective hospital to plan for the study sites arrangement. This was to ensure that the operation room or admission centres were accessible, convenient and appropriate for data collection. During data collection, the contact dental officer helped to disseminate information about the study to parents and

assisted them in the study. The dental officer in-charge helped parents with the self-administered questionnaire if parents did not understand on how to answer them.

Parents of preschool children were required to answer the questionnaire at two (2) different occasions (Figure 3.3). The first occasion was before their child received dental treatment under GA at the selected public hospitals; and the second occasion during the 4-week follow-up appointment at the Paediatric Dental Specialist Clinic in the same hospital.

Parents were given the Participant Information Sheet which explained about the objectives and conduct of the study. If the parents agreed to participate, they were asked to sign the informed consent form and complete the questionnaires before and after their child has received dental treatment under GA.

In Malaysia, healthy preschool children with ECC undergoing dental treatment under GA are usually treated in a day-care surgery. Day-care surgery is defined as scheduled surgical procedures provided to patients who do not require hospital stay overnight. It is a process of care by which suitable patients are managed with admission, treatment and discharge on the same day. Day-care surgery is done for diagnostic and therapeutic procedures which require local, regional, or general anaesthesia, which do not carry the risk of post-operative complications but require a period of observation in the hospital (Ministry of Health Malaysia, 2012a). However, there are occasions where healthy patients, i.e. preschool children with ECC are treated under elective surgery which will require hospital admission depending on the operation theatre (OT) schedule in the respective hospitals.

Following dental treatment under GA, the preschool children attended the 4-week post-GA follow-up appointment at the respective Paediatrics Dental Clinic. At this appointment, the set 2 questionnaire was given to the parents to fill up. The completed

questionnaires were checked for completeness by the researcher. This was done before parents and their children left the hospital. Any missing data due to incomplete records were immediately rectified with the parents.

At the end of the study, parents were given honorarium of Colgate oral health kit consisted of toothbrush, toothpaste, dental floss and moutrinse for thanking them in participating in the research and after returning the completed questionnaire to the researcher.

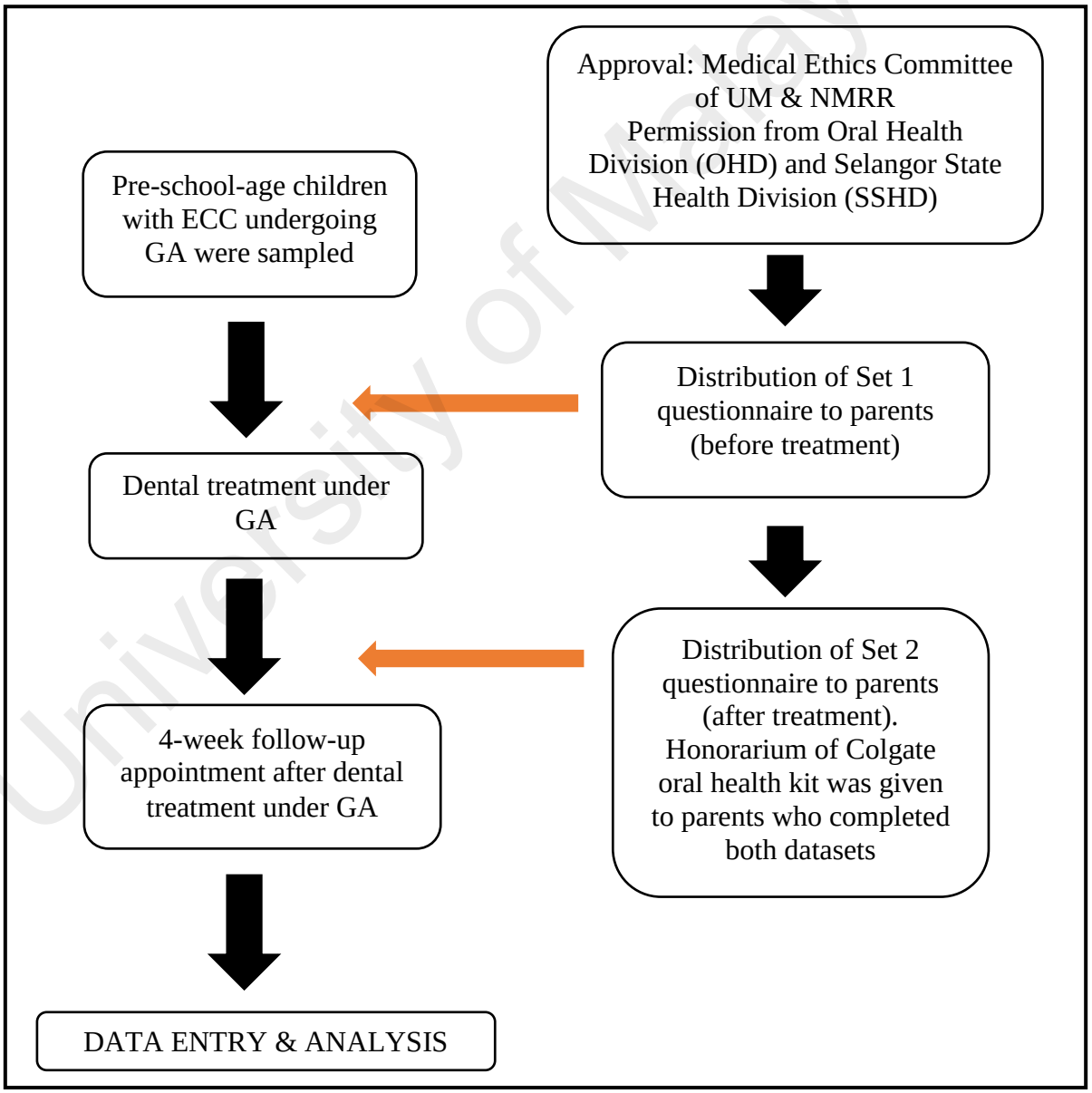

Figure 3.3: Flow chart indicating the conduct of the study

3.6 Permission and Ethics Approval

The study was ethically approved by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya [DF CO1601/0003(P)] (Appendix I) and the National Medical Research Ethics Committee [NMRR-16-381-29306(IIR)] (Appendix J).

3.7 Data handling and analysis

Quantitative data analyses were carried out based on the study objectives. Quantitative data were entered into and analysed using SPSS version 22 Software (SPSS Inc., Chicago, IL, USA). The level of statistical significance was set up at $p<0.05$. Data entry was done by the researcher.

Parents were asked whether their child experienced oral health impacts on any of the nine CIS items of ECOHIS and whether they, as parents, experienced oral health impacts on four of the FIS items. For each reported oral impact, its frequency was noted. The frequency was rated using a five-point Likert scale to record how often the impact had occurred before the GA as well as after the GA, respectively. The response scores were: 0=never, 1=hardly ever, 2=occasionally, 3=often, 4=very often, and 5=don't know. . The different score range for each domain was as follows: child symptom, range = 0 – 4; child function, range = 0 – 16; child psychology, range = 0 – 8; child self-image / social interaction, range = 0 – 8; parental distress, range = 0 – 8; and family function, range = 0 – 8. Total ECOHIS score was calculated as the sum of the response codes, after recoding all Don't Know (DK) responses as missing, following the method of data scoring proposed in the original version (Pahel et al., 2007). In cases with up to 2 missing responses in the CIS or 1 missing response in the FIS, we ascribed the score for the missing value as the average of the rest of the items for that section (Pahel et al., 2007). Subsequently, there was no case with more than 2 missing responses in the CIS or more than 1 missing item in the FIS. Total ECOHIS score ranged from 0 – 52. The CIS score

ranged from 0 – 36 and the FIS score ranged from 0 – 16. Higher scores indicate greater oral health impacts and poorer OHRQoL (Lee et al., 2011).

3.7.1 Sensitivity of Malay-ECOHIS to dental treatment under GA

The sensitivity of the Malay-ECOHIS was assessed by determining distribution changes in the scores. The pre-treatment and post-treatment mean scores were compared using Paired Samples T-Tests. Change scores were computed by subtracting post-treatment scores from pre-treatment scores. A positive change score indicates an improvement in the child's OHRQoL, and a negative change score indicates deterioration in the child's OHRQoL. The magnitude of change was determined by calculating the effect size (ES). Effect size statistics were calculated by dividing the mean of change scores by the standard deviation of the pre-treatment scores, in order to give a dimensionless measure of effect as suggested by Cohen. Effect-size statistics of <0.2 indicate a small clinically meaningful magnitude of change, 0.2– 0.7 indicate a moderate change and >0.7 indicate a large change (Cohen, 1988).

The researcher also used standardised scores in this present study so that the ECOHIS domains were comparable to see which domain(s) were mostly affected/improved by the dental treatment under GA. The average, standardised score for each domain would range from 0 - 100, so it would be easy to know whether the score is above or below the average score. The formula for determining the standardised score is (Fayers and Machin, 2007):

$$Z = (x)\ [100/(m \times k)]$$

where x = sum score

m = number of items

k = response category

3.7.2 Association between ECOHIS change scores and severity of decayed teeth (dt)

In the present study, the severity of ECC was based on the decayed (d) component of dmf index where the cut-off point was established based on the percentile and median score of the decayed teeth.

The association between mean ECOHIS change scores and severity of decayed teeth categorised by median score was calculated using independent samples T-test, meanwhile the association between mean ECOHIS change scores and severity of decayed teeth categorised by percentile score was computed using One-Way Analysis of Variance (ANOVA).

3.7.3 Correlation between Malay-ECOHIS change scores and number of decayed teeth (dt)

Pearson correlation coefficient was computed to describe the correlation between ECOHIS change scores (including CIS and FIS change scores) and the number of decayed teeth (dt) among the preschool children. Based on Cohen (1988) classification, the strength of correlation is define as: (i) "weak" if $0.1 < r < 0.3$; (ii) "moderate" if $0.3 < r < 0.5$; and (iii) "strong" if $r > 0.5$.

3.7.4. Correlation between Malay-ECOHIs change scores and number of extracted teeth

Pearson correlation coefficient was computed to describe the correlation between ECOHIS change scores (including CIS and FIS change scores) and the number of extracted teeth (dt) under the GA. Based on Cohen (1988) classification, the strength of correlation is define as: (i) "weak" if $0.1 < r < 0.3$; (ii) "moderate" if $0.3 < r < 0.5$; and (iii) "strong" if $r > 0.5$.

3.7.5 Responsiveness to change of the Malay-ECOHIS to dental treatment under GA

Responsiveness to change of the measure was assessed by determining whether the observed changes in Malay-ECOHIS scores took the form of a gradient according to the

global transition judgement reported by the parents. We grouped the data according to how the parents responded to the global transition judgement, i.e. “How has your child condition changed since before the dental treatment under GA?” The answer options were ‘worst’, ‘a little worse’, ‘no change’, ‘a little improved’ and ‘much improved’. Mean observed changes and effect sizes of ECOHIS and its sub-scales were compared between the categories of the global transition judgement. At the same time, paired samples T-Test was used to compare total ECOHIS means before and after treatment for each of the categories.

3.7.6 Establishing the Minimal Important Difference (MID) of Malay-ECOHIS

Anchor-based approaches link the change in OHRQoL test instrument to an already interpretable independent variable (or anchor) with known qualities to elucidate the meaning of a particular degree of change (Walters and Brazier, 2003). In this study, the anchor was derived from a patient-based or non-clinical outcome, i.e. a global health transition judgement item. Global assessments of health change have been the most commonly used anchor (Revicki et al., 2006). These self-report retrospective measures of change ask the respondent at follow-up if their health has changed since baseline. If so, has it changed at small, medium or large amount, and in what direction on a multiple Likert-type response options. Length of Likert scale can be ranged to various point. For OHRQoL measures, investigators have used different length Likert scales ranged from 15- to 3-point scale. It should be suitably related to the testing instrument with a correlation of at least 0.5 and should cover issues of importance and relevance to the patient. The stronger the association, the more secure the inferences about interpretation of the target measure (Twiss et al., 2010).

In order to support estimates drawn from the anchor-based approach, the standardised ES distribution-based approach was used. In this approach, the mean changes as a ratio of the standard deviation was calculated and infer the relative size of change effect by

using ES threshold levels developed by Cohen. The standardised ES of <0.2 should be regarded as “small”, 0.2 – 0.7 as “moderate” and those >0.7 as “large” (Cohen, 1988).

CHAPTER 4: RESULTS

4.1 Introduction

Preschool children aged 2-6 years old, who were under waiting list for comprehensive dental treatment of ECC under GA in the Department of Paediatric Dentistry in five public hospitals in the state of Selangor, Malaysia namely: Ampang Hospital, Selayang Hospital, Serdang Hospital, Sungai Buloh Hospital and Tengku Ampuan Rahimah Hospital were recruited into the study. The parents of the 158 preschool children were invited to answer the ECOHIS questionnaire before and after treatment of ECC under GA. Data collection stretched over an 8-month period.

In this chapter, the results are presented as follows. First the distribution of preschool children and their parents according to sociodemographic characteristics and public hospitals where they attended are described. Second, the results on the sensitive to change of the Malay-ECOHIS following treatment of preschool children's ECC under GA are presented. The types of dental treatment provided are also presented. Third, the results on responsiveness to change of the Malay-ECOHIS are shown. This will be followed by the results on the minimal important difference (MID) of Malay-ECOHIS. The chapter ends by summarising the main findings for each objective of the study.

4.2 Response rate and demographic background of participants

4.2.1 Response rate

From the proposed sample size of 112 preschool children for this study, the researcher managed to recruit 158 preschool children into the study from five public hospitals over an 8-month period of data collection. Of those, 138 parents completed the self-administered pre- and post-operative questionnaire (complete datasets), with a response

rate of 87.3%. The number of non-respondents with reasons for not participating in the study is shown in Table 4.1.

Table 4.1: Response rate of the sample

Sample	N	%
Respondents	138	87.3
Non-respondents and their reasons not participating		
No consent	3	1.9
Fail to attend follow-up appointment at Paediatric Dental Specialist Clinic after 1 month	11	7.0
Questionnaires containing incomplete items	2	1.3
Operation postponed due to infection e.g. Upper Respiratory Tract Infection (URTI) or other technical problem	4	2.5

Table 4.2 shows distribution of participants in the five public hospitals in the state of Selangor who were involved in the study. The highest number of participants were recruited from Serdang Hospital (29.7%), followed by Tengku Ampuan Rahimah Hospital (29.0%), Selayang Hospital (23.2%), Ampang Hospital (10.9%), and Sungai Buloh Hospital (7.2%).

Table 4.2: Distribution of participants by the five public hospitals involved (N=138)

Hospital	N	Percentage (%)
Ampang Hospital	15	10.9
Selayang Hospital	32	23.2
Serdang Hospital	41	29.7
Sungai Buloh Hospital	10	7.2
Tengku Ampuan Rahimah Hospital	40	29.0

4.2.2 Sociodemographic characteristics

The final sample consisted of 76 male (55.1%) and 62 female (44.9%) preschool children. Table 4.3 shows the sociodemographic characteristics of the children. The mean age of the children was 4.54 years (SD=1.01). The participants were predominantly Malay (91.3%), followed by Indian (5.8%), Chinese (2.2%) and others (0.7%). The primary caregivers involved in this study were the mothers (n=112, 81.2%) followed by the fathers (n=26, 18.8%).

Table 4.3: Sociodemographic characteristics of the preschool children (N=138)

Sociodemographic characteristic	N	Percentage (%)
Gender		
Boy	76	55.1
Girl	62	44.9
Age group, year		
2	1	0.7
3	23	16.7
4	41	29.7
5	46	33.3
6	27	19.6
Mean age (years ±SD): 4.54 ± 1.01		
Ethnicity		
Malay	126	91.3
Chinese	3	2.2
Indian	8	5.8
Others	1	0.7

Table 4.4 shows that less than half of parents were in the 31 – 35 year old age group (44.2%), followed by 36 – 40 year old age group (28.3%) and 26 – 30 year old age group (13.1%). The mean age was 34.73 (SD= ±4.76). Less than half of mothers (43.4%) and fathers (49.3%) had education up to secondary school level, respectively. The majority (68.8%) earned below Ringgit Malaysia 4,999 per month.

Table 4.4: The sociodemographic profile of the caregivers

Sociodemographic characteristics	N	Percentage (%)
Age group, year		
20-25	4	2.9
26-30	18	13.1
31-35	61	44.2
36-40	39	28.3
41-45	14	10.1
46-50	2	1.4
Mean age (years ± SD): 34.73 ± 4.76		
Educational level		
Mother		
Primary school	2	1.4
Secondary school	58	42.0
Diploma/STPM	41	29.7
University	37	26.8
Father		
Primary school	4	2.9
Secondary school	64	46.4
Diploma/STPM	32	23.2
University	38	27.5
Total family monthly income (RM)		
0 – 999	5	3.6
1,000 – 2,999	38	27.5
3,000 – 4,999	52	37.7
≥ 5,000	43	31.2

4.3 Comparing the Malay-ECOHIS scores before and after treatment

4.3.1 Sensitive to change of the Malay-ECOHIS

Table 4.5 shows the findings on pre- and post-treatment scores of the total Malay-ECOHIS. Overall, there was a statistically significant reduction (P<0.001) in the Malay-ECOHIS mean score following ECC treatment under GA, which was 68.0%.

With respect to the CIS and FIS sub-scales, there were significant score reductions of 78.9% and 66.7% following treatment under GA, respectively (P<0.001). For all domains of CIS and FIS sub-scales, statistically significant reductions were also observed after treatment (P<0.001). Overall, the CIS sub-scale had the greater reduction in mean score

(78.9%) compared to FIS sub-scale (66.7%), especially for 'child psychology' (94.1%) and 'child symptoms' (89.5%) domains of the CIS sub-scale. For FIS sub-scale domains, the reductions were lesser, i.e. "parental distress" (61.9%) and "family function" (71.4%) domains.

Overall, the magnitude of change of the Malay-ECOHIS following treatment [assessed by the effect size (ES)] was +1.0 which was considered large (ES>0.7). The ES for CIS sub-scale was also large (ES>0.7), and FIS sub-scale had moderate ES (0.2<ES<0.7). Between the two sub-scales, the magnitude of change was larger for CIS sub-scale (ES=+1.2) compared to FIS sub-scale (ES=+0.7). For all domains of CIS sub-scale, the ES were large except for 'child self-image and social interaction' domain where the ES was +0.5 which was moderate (0.2<ES<0.7). Meanwhile, both the 'parental distress' and 'family function' domains of FIS sub-scale had ES of +0.6 and +0.4, respectively, indicating moderate magnitude of change.

Table 4.5: Sensitive to change of the Malay-ECOHIS

Malay-ECOHIS domains (number of items, score range)	Pre-treatment mean (±SD)	Post-treatment mean (±SD)	P-value	Mean change score (±SD)	Reduction in score (%) **	Effect size
Child Impact Section (9 items; range 0-36)	7.6 ± 5.0	1.6 ± 2.4	<0.001*	6.0 ± 5.3	78.9	+1.2
Child symptoms (1 item; range 0-4)	1.9 ± 0.9	0.2 ± 0.5	<0.001*	1.7 ± 1.1	89.5	+1.9
Child function (4 items; range 0-16)	3.1 ± 2.5	1.1 ± 1.5	<0.001*	2.1± 2.6	67.7	+0.8
Child psychology (2 items; range 0-8)	1.7 ± 1.6	0.2 ± 0.6	<0.001*	1.6 ± 1.7	94.1	+1.0
Child self-image and Social interaction (2 items; range 0-8)	0.9 ± 1.6	0.2 ± 0.6	<0.001*	0.8 ± 1.7	88.9	+0.5
Family Impact Section (4 items; range 0-16)	2.7 ± 2.7	0.9 ± 1.3	<0.001*	1.8 ± 2.8	66.7	+0.7
Parental distress (2 items; range 0-8)	2.1 ± 2.1	0.8 ± 1.2	<0.001*	1.3 ± 2.2	61.9	+0.6
Family function (2 items; range 0-8)	0.7 ± 1.2	1.9 ± 5.5	<0.001*	0.5 ± 1.2	71.4	+0.4
Total Malay-ECOHIS score (13 items; range 0-52)	10.3 ± 7.0	2.5 ± 3.1	<0.001*	7.0± 7.3	68.0	+1.0

*statistically significant (P<0.05), Paired samples T-test

**Reduction in score (%) = $\frac{mean\ change\ score}{pre-treatment\ mean}$ x 100

Table 4.6 shows the standardised scores of the Malay-ECOHIS at pre- and post-treatment. Overall, there was a significant improvement in OHRQoL following ECC treatment under GA. The Malay-ECOHIS mean change in standardised score at post-treatment was significantly lower than that before treatment.

With respect to the CIS and FIS sub-scales, there were significant reductions in mean change of standardised score following treatment under GA, respectively ($P<0.001$). For all domains of CIS and FIS sub-scales, statistically significant reductions in mean change of standardised score were also observed after treatment ($P<0.001$). Overall, CIS sub-scale had greater reduction in mean change of standardised score (16.7 ± 14.8) compared to FIS sub-scale (11.1 ± 17.7), especially for 'child symptoms' (42.4 ± 26.4) and 'child psychology' (19.7 ± 21.1) domains of the CIS sub-scale. For FIS sub-scale domains, the reductions were lesser, i.e. "parental distress" (15.9 ± 27.4) and "family function" (6.3 ± 14.9) domains.

Table 4.6: Standardised scores of the Malay-ECOHIS at pre- and post-treatment

Malay-ECOHIS domains (number of items, score range)	**Standardised scores of pre-treatment mean (±SD)	**Standardised scores of post-treatment mean (±SD)	P-value	Mean change in standardised score (±SD)
Child Impact Section (9 items)	21.2 ± 14.0	4.4 ± 6.7	<0.001*	16.7 ± 14.8
Child symptoms (1 item)	47.6 ± 22.0	5.3 ± 13.0	<0.001*	42.4 ± 26.4
Child function (4 items)	19.2 ± 15.8	6.6 ± 9.5	<0.001*	12.5 ± 16.5
Child psychology (2 items)	21.6± 20.1	1.9 ± 7.1	<0.001*	19.7 ± 21.1
Child self-image and Social interaction (2 items)	11.5 ± 20.4	2.0 ± 7.6	<0.001*	9.5 ± 20.6
Family Impact Section (4 items)	17.0 ± 17.1	5.9 ± 8.4	<0.001*	11.1 ± 17.7
Parental distress (2 items)	25.7 ± 26.5	9.9 ± 14.8	<0.001*	15.9 ± 27.4
Family function (2 items)	8.3 ± 14.8	2.7 ± 6.3	<0.001*	6.3 ± 14.9
Total Malay-ECOHIS score (13 items)	19.9 ± 13.5	4.9 ± 6.0	<0.001*	15.0 ± 14.1

*statistically significant (P<0.05), Paired samples T-test

**please refer the formula for determining standardised score as discussed in subsection 3.7.1 (page 94)

4.3.2 Association between Malay-ECOHIS change scores and severity of decayed teeth

4.3.2.1 Association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by median score

The median score of the decayed teeth was 13.0 (Appendix K). Based on this score, the participants were divided into two categories of severity; (i) less severe group (dt score=0-13); and (ii) more severe group (dt score>13.0). It was observed that there was no statistically significant difference in mean Malay-ECOHIS change scores between the less severe group (mean=6.9, SD=6.4) and the more severe group (mean=9.0, SD=8.4) (Table 4.7).

Table 4.7: Association between Malay-ECOHIS change scores and severity of decayed teeth categorised by median score (N=138)

Severity of decayed teeth(dt)	N	Mean change score (±SD)	P-value[a]
Less severe (dt=0-13)	76	6.9 (± 6.4)	*0.100
More severe (dt>13)	62	9.0 (± 8.3)	

*Statistically significant level at P<0.05, [a]Independent samples T-test

4.3.2.2 Association between Malay-ECOHIS change scores and severity of decayed teeth categorised by percentile score

In this analysis, the severity of decayed teeth was categorised into three groups based on the percentile score, which were: (i) less severe (dt <10); (ii) severe (dt=11-16); and (iii) more severe (dt>16) (Appendix L). Table 4.9 shows that based on the p-value in the

one-way analysis of variance (ANOVA), there was no statistically significant difference in mean Malay-ECOHIS change scores across the severity levels of decayed teeth.

Table 4.8: Association between Malay-ECOHIS change scores and severity of decayed teeth categorised by percentile score (N=138)

Severity of decayed teeth (dt)	N	Mean change score (±SD)	P-value[b]
Less severe (dt<10)	37	1.2 (± 5.7)	
Severe (dt= 11-16)	71	1.6 (± 7.8)	*0.279
More severe (dt>16)	30	2.9 (± 7.9)	

*Statistically significant level at P<0.05, [b]ANOVA test

4.3.3 Correlation between Malay-ECOHIS change scores and number of decayed teeth (dt)

4.3.3.1 Correlation between total Malay-ECOHIS change scores and number of decayed teeth (dt)

Pearson correlation coefficient was computed to assess the correlation between the number of decayed teeth (dt) among preschool children and change scores of Malay-ECOHIS. The result shows that there was a weak positive correlation between the two variables and the correlation was almost statistically significant (r = 0.165; N = 138; P = 0.05) (Figure 4.1).

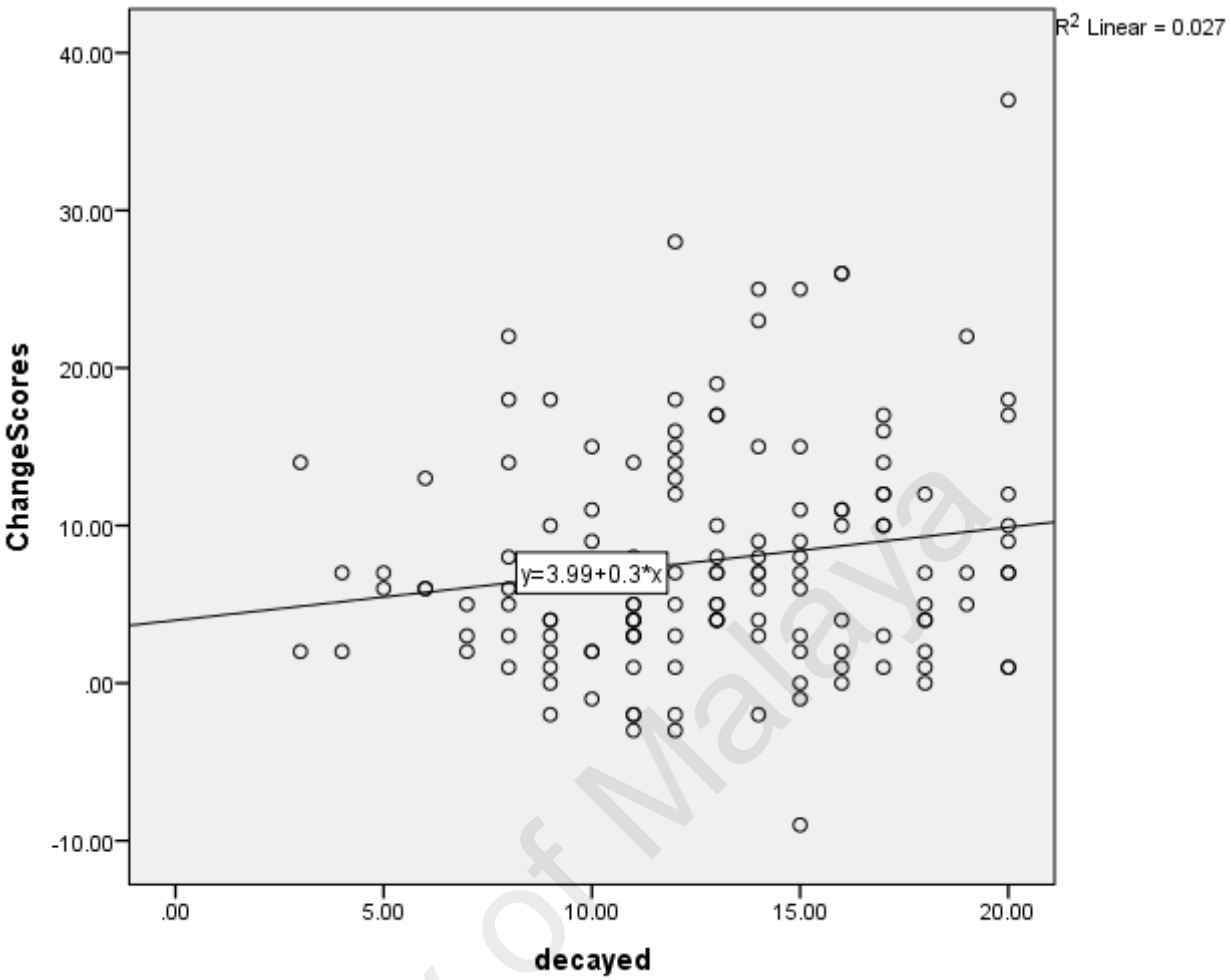

Figure 4.1: A scatterplot showing a fit line relationship between change scores of Malay-ECOHIS and number of decayed teeth

4.3.3.2 Correlation between CIS sub-scale change scores and number of decayed teeth (dt)

A Pearson correlation coefficient was computed to assess the correlation between the number of decayed teeth among preschool children and change scores of the CIS. The result shows that there was a weak positive correlation between the two variables and the correlation was statistically significant (r = 0.175; N = 138; P = 0.04). A scatterplot is shown in Figure 4.2.

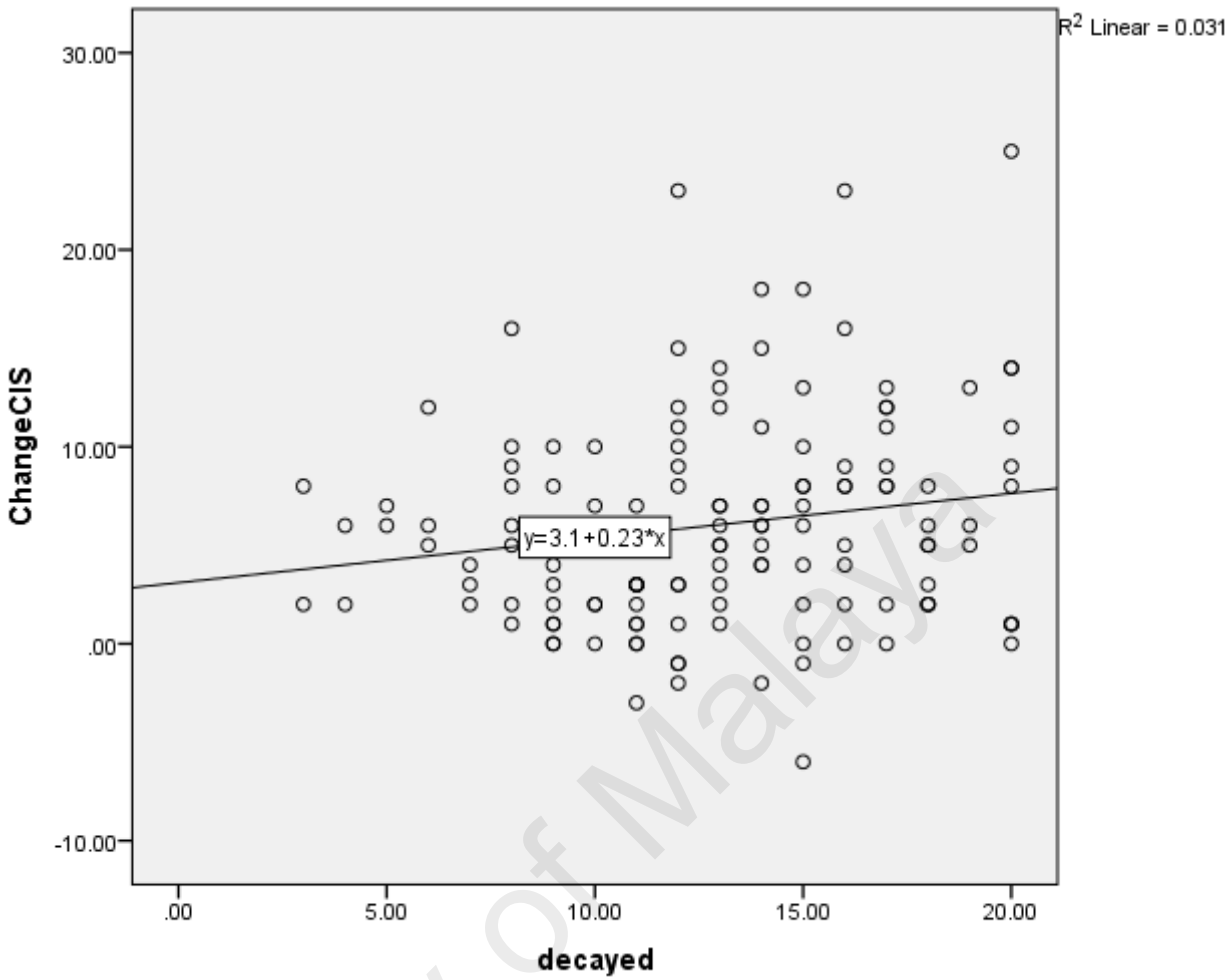

Figure 4.2: A scatterplot showing a fit line relationship between change scores of CIS and number of decayed teeth

4.3.3.3 Correlation between FIS sub-scale change scores and the number of decayed teeth (dt)

A Pearson correlation coefficient was computed to assess the correlation between the number of decayed teeth among the preschool children and change scores of the FIS. There was weak positive correlation between the two variables. However, the correlation was not statistically significant (r = 0.099; N = 138; P = 0.25). A scatterplot summarizing the result is shown in Figure 4.3.

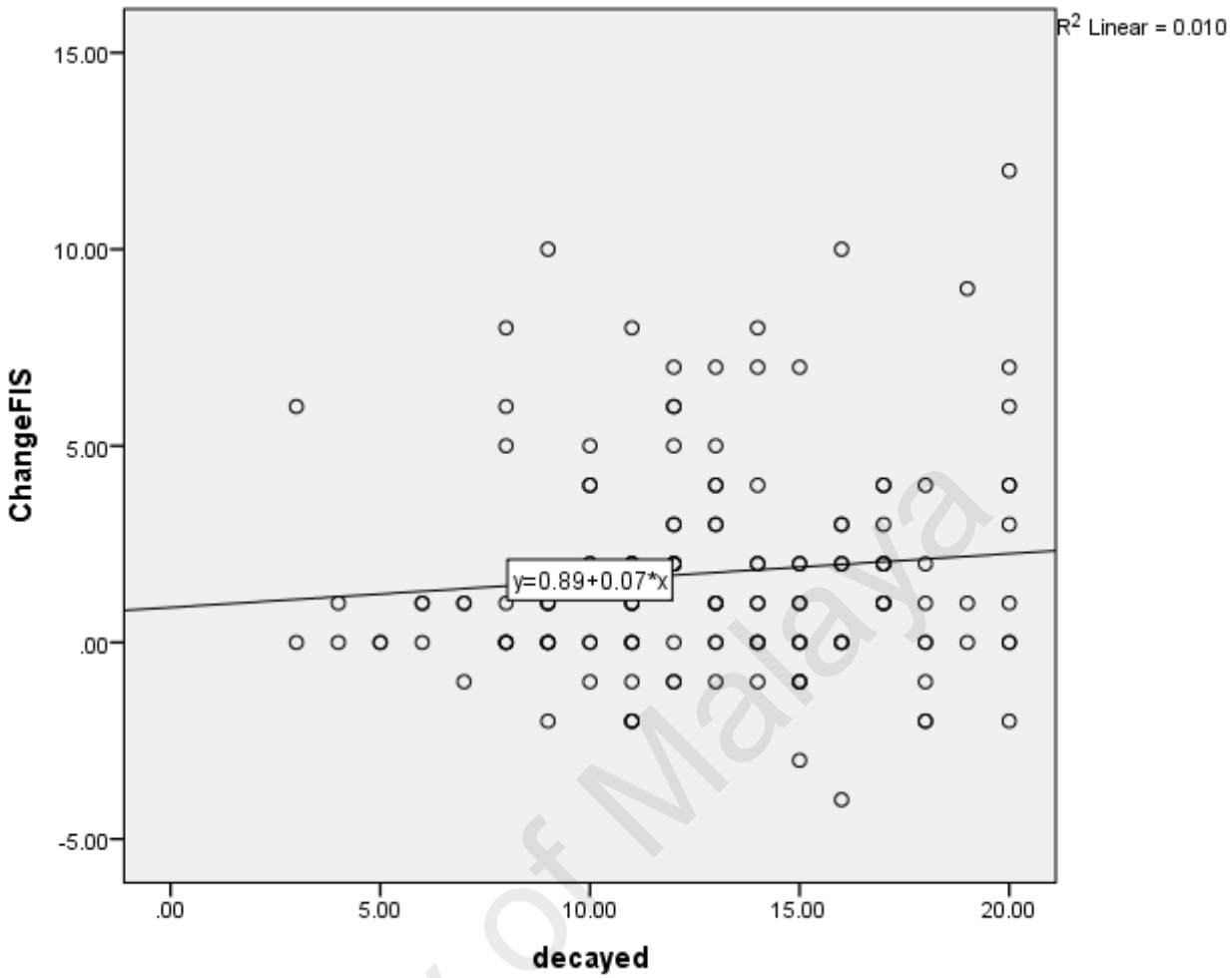

Figure 4.3: A scatterplot showing a fit line relationship between change scores of FIS and number of decayed teeth

4.3.4 Correlation between Malay-ECOHIS change scores and number of extracted teeth

The majority of treatment carried out were dental extractions (n= 137, 99.3%), followed by composite restorations (n=85, 61.6%) and fillings using glass ionomer cement (n=57, 41.3%). There were thirty seven (26.8%) stainless steel crowns and fissure sealant provided, respectively. Pulpotomy was the least provided treatment (n=5, 3.6%) to the preschool children.

Table 4.9: Treatments provided under general anaesthesia

Treatment item	Total number	Percentage (%)	Mean number (± SD)
Composite Filling	85	61.6	3.31 ± 2.11
Glass Ionomer Cement	57	41.3	2.91 ± 1.77
Stainless Steel Crown	37	26.8	2.08 ± 1.14
Pulpotomy	5	3.6	1.20 ± 0.45
Fissure Sealant	37	26.8	2.57 ± 1.63
Extraction	137	99.3	8.92 ± 4.76

A Pearson correlation coefficient was computed to assess the correlation between Malay-ECOHIS change scores and the number of extracted teeth among the preschool children following treatment under GA. There was a weak positive correlation between the two variables. However, the correlation was not statistically significant ($r = 0.129$; $N = 137$; $P = 0.134$) (Figure 4.4).

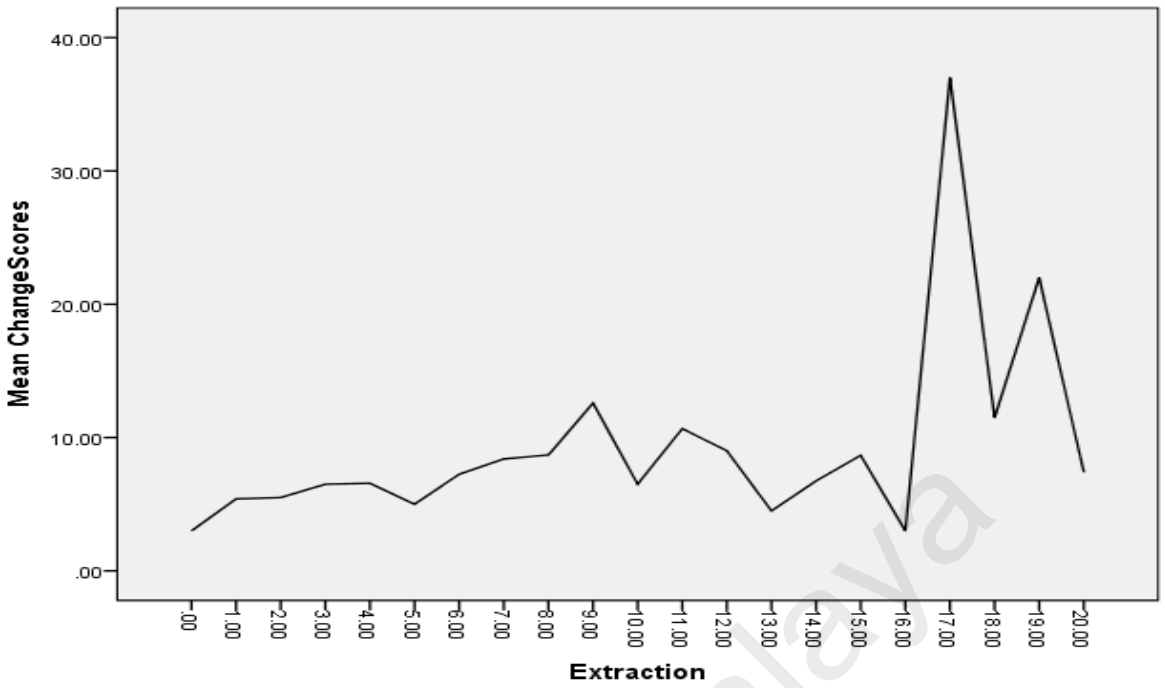

Figure 4.4: Correlation between Malay-ECOHIS change scores and number of extracted teeth

4.4 Comparing the Malay-ECOHIS change scores with a global transition judgement

4.4.1 Responsiveness to change of the Malay-ECOHIS

Based on the global transition judgement item, 37.7% (n=52) of parents reported that their child's oral health condition has 'much improved' and 62.3% (n=86) reported as 'a little improved' following dental treatment under GA. The mean pre and post-treatment scores of ECOHIS, CIS, and FIS sub-scales and their respective domains are presented in Table 4.10.

Overall, mean ECOHIS scores between pre- and post-treatment stages in the 'a little improved' and 'much improved' groups were statistically significant ($P<0.001$), respectively.

In the ‘a little improved’ group, the mean scores for all sub-scales and their respective domains showed statistically significant differences between pre- and post-treatment stages (P<0.001). The effect size of ECOHIS, CIS sub-scale and its domains with the exception of ‘child self-image and social interaction’ domain were large, respectively (ES>0.7). The ‘child self-image and social interaction’ domain of the CIS sub-scale and the FIS sub-scale and its respective domains had moderate effect size, respectively (ES = 0.3 – 0.6). The largest ES was seen on ‘child symptoms’ domain of CIS sub-scale (ES = +1.7), followed by CIS sub-scale (ES = +1.2) and total ECOHIS (ES = +1.1).

The ECOHIS score, CIS sub-scale and its respective domains (except for ‘child self-image and social interaction’ domain), FIS sub-scale and its respective domains (except for ‘family function’ domain); showed large effect size (ES>0.7), respectively. The other two domains displayed moderate effect size (ES = +0.5), respectively. The largest effect size was seen on ‘child symptoms’ domain of CIS sub-scale (ES = +2.0), followed by CIS sub-scale (ES = +1.3) and total ECOHIS (ES = +1.2).

The magnitude of change for both groups showed similar trend. However, those who reported ‘much improved’ change in their child’s oral health condition showed larger magnitude of change in all aspects compared to those who reported ‘a little improved’ in their child’s oral health condition.

There was an observed gradient in the changes of the Malay-ECOHIS scores and effect sizes across the categories of the global transition judgement where the gradient and magnitude of changes were larger in the ‘much improved’ group.

Table 4.10: Responsiveness of the Malay-ECOHIS to changes in oral health following dental treatment under GA

Malay- ECOHIS domains	Pre-treatment mean (±SD)	Post-treatment mean (±SD)	P-value	Mean change in score (±SD)	Effect size
A Little Worse (N=0)					
Worst (N=0)					
No Change (N=0)					
A Little Improved (N=86)					
Child Impact Section	6.9 ± 4.4	1.7 ± 2.5	<0.001*	5.2 ± 4.7	+1.2
Child symptoms	1.8 ± 0.9	0.3 ± 0.6	<0.001*	1.5 ± 1.8	+1.7
Child function	2.7 ± 2.2	1.0 ± 1.5	<0.001*	1.7 ± 2.3	+0.7
Child psychology	1.6 ± 1.6	0.2 ± 0.7	<0.001*	1.3 ± 1.7	+0.8
Child self-image and social interaction	0.8 ± 1.5	0.1 ± 0.6	<0.001*	0.7 ± 1.5	+0.5
Family Impact Section	2.6 ± 2.6	1.1 ± 1.5	<0.001*	1.5 ± 2.7	+0.6
Parental distress	2.0 ± 2.0	0.9 ± 1.3	<0.001*	1.1 ± 2.1	+0.6
Family function	0.6 ± 1.2	0.2 ± 0.4	0.001	0.4 ± 1.1	+0.3
Total Malay-ECOHIS score	9.5 ± 6.2	2.7 ± 3.4	<0.001*	6.7 ± 6.6	+1.1
Much Improved (N=52)					
Child Impact Section	8.8 ± 5.8	1.4 ± 2.2	<0.001*	7.3 ± 6.0	+1.3
Child symptoms	2.0 ± 0.9	0.1 ± 0.4	<0.001*	1.9 ± 1.0	+2.0
Child function	3.7 ± 2.9	1.1 ± 1.6	<0.001*	2.6 ± 3.0	+0.9
Child psychology	2.0 ± 1.7	0.1 ± 0.3	<0.001*	1.9 ± 1.7	+1.1
Child self-image and social interaction	1.1 ± 1.9	0.2 ± 0.6	0.002*	0.9 ± 1.9	+0.5
Family Impact Section	3.0 ± 3.0	0.7 ± 1.0	<0.001*	2.3 ± 3.0	+0.8
Parental distress	2.2 ± 2.2	0.6 ± 0.9	<0.001*	1.6 ± 2.3	+0.7
Family function	0.8 ± 1.2	0.1 ± 0.4	0.001*	0.6 ± 1.3	+0.5
Total Malay-ECOHIS score	11.8 ± 8.0	2.1 ± 2.7	<0.001*	9.6 ± 8.2	+1.2

*Statistically significant (P<0.05), Paired samples T-Test

Table 4.11 shows standardised scores of the Malay-ECOHIS with the global transition judgement item. In the ‘a little improved’ group, the standardised scores for ECOHIS, CIS sub-scale and its respective domains, and FIS sub-scale with its respective domains showed statistically significant reduction after dental treatment under GA. The CIS sub-scale mean score had greater reduction compared to FIS sub-scale mean score following treatment under GA.

For the group of parents who reported ‘much improved’ in their child’s oral condition following treatment, the overall ECOHIS scores, CIS sub-scale and its respective domains, FIS sub-scale and its respective domains showed significant reduction following treatment under GA. The CIS sub-scale mean score had greater reduction compared to FIS sub-scale mean score following treatment under GA.

The magnitude of change of ECOHIS between the two groups showed similar trend. The ‘much improved’ group showed greater magnitude of change for all aspects of ECOHIS and its domains following treatment under GA compared to that of the ‘a little improved’ group.

Table 4.11: Standardised scores of the Malay-ECOHIS with the global transition judgement items

Malay- ECOHIS domains	Standardised Scores pre-treatment mean (±SD)	Standardised Scores post-treatment mean (±SD)	Standardised Scores of mean change scores (±SD)
A Little Worse (N=0)			
Worst (N=0)			
No Change (N=0)			
A Little Improved (N=86)			
Child Impact Section	19.2 ± 12.3	4.6 ± 7.0	14.6 ± 13.1
Child symptoms	45.6 ± 21.8	7.0 ± 14.2	38.7 ± 27.0
Child function	16.9 ± 13.7	6.5 ± 9.1	10.4 ± 14.6
Child psychology	19.5 ± 19.5	2.6 ± 8.4	16.9 ± 20.8
Child self-image and social interaction	10.2 ± 18.2	1.6 ± 7.3	8.6 ± 18.4
Family Impact Section	16.1 ± 16.1	6.8 ± 9.4	9.3 ± 16.9
Parental distress	24.6 ± 25.5	11.3 ± 16.3	13.2 ± 26.4
Family function	7.6 ± 14.8	2.2 ± 5.5	5.4 ± 14.3
Total Malay-ECOHIS score	18.2 ± 12.0	5.3 ± 6.5	13.0 ± 12.6
Much Improved (N=52)			
Child Impact Section	24.4± 16.1	4.1 ± 6.1	20.4 ± 16.8
Child symptoms	51.0 ± 22.1	2.4 ± 10.2	48.6 ± 24.5
Child function	22.8 ± 18.4	6.7 ± 10.3	16.1 ± 18.8
Child psychology	25.0 ± 20.1	0.7 ± 3.8	24.3 ± 21.1
Child self-image and social interaction	13.7 ± 23.6	2.6 ± 8.0	11.1 ± 24.0
Family Impact Section	18.6 ± 18.7	4.6 ± 6.4	14.1 ± 18.8
Parental distress	27.6 ± 28.0	7.5 ± 11.7	20.2 ± 28.7
Family function	9.6 ± 15.0	1.7 ± 5.6	8.0 ± 15.9
Total Malay-ECOHIS score	22.6 ± 15.4	4.2 ± 5.1	18.4 ± 15.8

4.5 Establishing the Minimal Important Difference (MID)

4.5.1 Anchor-based approach

Table 4.12 shows global health transition judgement that measured change in the participants' oral health at 4-week follow up post-operatively. Participants in the 'a little improved' group who reported a small gain in oral health are then identified as undergoing a change, which the participants considered as minimally important to them. The MID for the Malay-ECOHIS was found to be 7-point change. The MID for CIS and FIS following treatment were 5-point change and 2-point change, respectively.

Table 4.12: Anchor-based approach across global health transition judgement items in the 'a little improved' group

Malay-ECOHIS domains	Mean change in score (±SD)
A Little Improved (N=86)	
Child Impact Section	5.2 ± 4.7
Child symptoms	1.5 ± 1.8
Child function	1.7 ± 2.3
Child psychology	1.3 ± 1.7
Child self-image and social interaction	0.7 ± 1.5
Family Impact Section	1.5 ± 2.7
Parental distress	1.1 ± 2.1
Family function	0.4 ± 1.1
Total Malay-ECOHIS score	**6.7 ± 6.6**

4.5.2 Distribution-based approach

For distribution-based approach which relies on the calculation of effect size, the effect sizes of 'child self-image and social interaction', 'parental distress' and 'family function' domains were between 0.2 – 0.7, indicating the magnitude of change was moderate. The effect sizes of the remaining domains and for total Malay-ECOHIS were >0.7, respectively, indicating large effect size (Table 4.13). Large effect size indicates large magnitude of change with high impact of treatment on the preschool children and family.

Table 4.13: Distribution-based approach across effect sizes of Malay-ECOHIS scores following dental treatment under GA

Malay- ECOHIS domains (number of items and possible score range)	Effect Size	The magnitude of change
Child Impact Section (9 items; range 0-36)	+1.2	Large
Child symptoms (1 item; range 0-4)	+1.9	Large
Child function (4 items; range 0-16)	+0.8	Large
Child psychology (2 items; range 0-8)	+1.0	Large
Child self-image and social interaction (2 items; range 0-8)	+0.5	Moderate
Family Impact Section (4 items; range 0-16)	+0.7	Moderate
Parental distress (2 items; range 0-8)	+0.6	Moderate
Family function (2 items; range 0-8)	+0.4	Moderate
Total Malay-ECOHIS score (13 items; range 0-52)	+1.0	Large

4.6 Summary of the main findings

The summary of the main findings are presented according to the objectives of the study.

Objective 1: Comparing the Malay-ECOHIS scores before and after treatment under general anaesthesia

Main findings:

i. Sensitive to change of the Malay-ECOHIS

- In the present study, the pre-treatment scores of Malay-ECOHIS were significantly higher than the post-treatment scores for all domains of ECOHIS.
- The CIS showed higher mean change scores than FIS. 'child symptoms', and 'child psychology' domains showed the highest mean change scores for CIS sub-scale, meanwhile 'child self-image & social interaction' was the least affected domain of CIS. For FIS, the 'family function' domain was the least affected domain.
- The mean change scores of the Malay-ECOHIS showed statistically significant reduction ($P<0.001$) following treatment under GA.

ii. Association between Malay-ECOHIS change scores and severity of decayed teeth (dt)

- Based on median and percentile scores, there were no statistically significant differences in mean Malay-ECOHIS change scores by severity of decayed teeth (dt).

iii. Correlation between Malay-ECOHIS change scores and number of decayed teeth

- Based on the Pearson correlation coefficient, there was a significant, positive correlation between number of decayed teeth (dt) and change scores of Malay-

ECOHIS (r=0.165) and CIS (r=0.175), respectively. However, the strength of correlation was weak.

- There was no significant correlation between number of decayed teeth (dt) and change scores of FIS in the present study.

iv. Correlation between Malay-ECOHIS change scores and number of extracted teeth

- Even though dental extraction was the main treatment provided under GA, it was shown that number of extraction did not change the mean change scores of the Malay-ECOHIS.

Objective 2: Comparing the Malay-ECOHIS change scores with a global transition judgement

Main findings:

i. Responsiveness to change of the Malay-ECOHIS

- Parents who perceived that their child's condition has 'a little improved' and 'much improved' after treatment had a significant change in ECOHIS scores and the magnitude of change was greater in the 'much improved' group than the 'a little improved' group.

Objective 3: Establishing the Minimal Important Difference (MID) of the scale

Main findings:

i. Anchor-based approach

- There was a 7-point change in the mean change score of ECOHIS following treatment under GA which was considered as the MID for the Malay-ECOHIS.
- The MID for CIS and FIS following treatment were 5-point change and 2-point change, respectively.

ii. Distribution-based approach

- The magnitude of change for Malay-ECOHIS was large (ES>0.7) with the effect size of 1.0. The magnitude of change for CIS (ES = 1.2) is higher than FIS (ES = 0.7).

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter will discuss the findings related to the three study objectives, i.e.

a) Evaluate the sensitivity of the Malay-ECOHIS to dental treatment of ECC under GA by:

i. Assessing changes in the distribution of Malay-ECOHIS scores before and after dental treatment under GA,
ii. Assessing the association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by the median and percentile score,
iii. Assessing the correlation between Malay-ECOHIS change scores and the number of decayed teeth.
iv. Assessing the correlation between Malay-ECOHIS change scores and the number of extracted teeth.

b) Evaluate the responsiveness of the Malay-ECOHIS to dental treatment of ECC under GA by comparing the Malay-ECOHIS change scores with a global transition judgement

c) Establish the Minimal Important Difference (MID) of the Malay-ECOHIS.

5.2 Response rate and demographic background of participants

5.2.1 Response rate

The researcher employed several measures to ensure high participation during data collection period. Even though different responses received from hospitals, such as visiting paediatric dentist on monthly basis at Ampang Hospital, and Sungai Buloh operated lesser on ECC children less than 6 years old because it is the Trauma Centre for the state of Selangor, the support from all heads of department by appointing committed dental officers in-charge smoothened the data collection procedure. The operation theatre

(OT) and admission centre staff and nurses were highly cooperative in assisting the researcher in identifying suitable patients at each of the hospitals.

In this study, 138 parents of preschool children completed the self-administered questionnaires at pre-treatment and 4-week post-treatment stages (complete datasets), with response rate of 87.3%. The main reason for dropouts was due to absence of participants on post-operative follow-up appointment after 4 weeks. With the cooperation from all dental officers in-charge, the participants were reminded of the follow-up appointments after 4 weeks through telephone call one week before the appointment. Participants who failed to attend follow-up appointments after 4 weeks were excluded from this study because they did not fulfil the follow-up requirement. Nevertheless, the follow-up rate in our study was as high as another similar study (Erkmen et al., 2014), but lower compared to other similar studies (Li et al., 2008a; Lee et al., 2011; Abanto et al., 2016).

The data were collected over the period of eight months at the five public hospitals in Selangor. The five public hospitals selected are located far apart from one to another, which ensured that all the preschool children with different ethnicity, social and cultural background, and different family dynamics were included in the study. This would enhance the external validity of the index in a multi-ethnic population of Malaysia. However, the results showed the data on ethnicity were skewed where the participants were predominantly Malay.

5.2.2 Sociodemographic characteristics of the sample

In this study, the 138 participants were 2-6 year old preschool children with ECC. The large majority were 4-5 year olds. They were recruited from the waiting list of children scheduled for dental treatment under GA at the five public hospitals in the state of Selangor. In Malaysia, dental treatment of children under GA is the last treatment option

after treatment on dental chair is not possible. This is in accordance to the current clinical practice guidelines for treating ECC under GA at public hospitals in Malaysia (Oral Health Division, 2012).

The majority of participants were Malays compared to other ethnic groups. The reason behind it could be that Malays were the majority ethnic group in Malaysia. As a result, a higher number of Malays sought dental treatment for their child under GA compared to other ethnic groups. Public oral health facilities are often preferred over private facilities because the treatment cost is reasonable, the location is convenient and they are considered as the usual place for seeking dental treatment (Oral Health Division, 2000). On the other hand, parents of other ethnic groups might prefer to go to private rather than public oral health facilities due to faster treatment provision despite higher cost.

The primary caregivers involved in this study were the mothers. In the Asian culture, mothers play the dominant role in raising the child and are involved in activities concerning the child's welfare, therefore they are more willing to participate in the study. As such, their input and understanding of the scale was important.

This study also found that many preschool children with ECC came from families whose parents had education up to secondary school level, and some had low monthly household income. These findings were in accordance with findings from other related studies that showed children from low socioeconomic status tended to have high caries experience (Locker, 2000; Reisine and Psoter, 2001; Badariah, 2005; Oral Health Division, 2007; Prakash et al., 2012).

5.3 Sensitivity of the Malay-ECOHIS to dental treatment of ECC under GA

5.3.1 Assessing changes in the distribution of Malay-ECOHIS scores before and after dental treatment under GA

The large majority of parents reported that their child had dental problems requiring treatment. This was reflected in this study by the high mean Malay-ECOHIS scores at baseline (10.3). In this respect, the baseline mean scores of other similar studies showed higher mean ECOHIS scores compared to our study (Lee et al., 2011; Abanto et al., 2016). On the other hand, the English ECOHIS showed a limited ability to be responsive due to the low levels of dental problems were reported in their sample at baseline (Li et al., 2008a). In our study, the mean change scores significantly declined following dental treatment under GA, indicating an improvement in preschool children's OHRQoL. Therefore, the Malay-ECOHIS was sensitive to changes in OHRQoL because the mean scores between pre- and post-treatment were statistically different.

The mean change score of the Malay-ECOHIS showed statistically significant reduction following treatment under GA. The mean change score was also positive for total ECOHIS, CIS, FIS and all the domains, respectively. This indicates that the Malay-ECOHIS was sensitive to improvement in OHRQoL levels. Overall, the magnitude of change of the Malay-ECOHIS following treatment which was assessed by the effect size (ES) was considered as large (ES>0.7). When comparing between CIS and FIS, the ES for CIS sub-scale was larger (ES>0.7) compared to the ES of FIS sub-scale which was moderate (0.2<ES<0.7). The magnitude of change was larger for CIS sub-scale and its respective domains except for 'child self-image and social interaction' domain, with moderate ES, compared to FIS sub-scale. A larger ES of CIS sub-scale denotes that ECC was found to give a significant impact on the OHRQoL of preschool children. It also

indicated that treatment of ECC under GA had an immediate effect on preschool children's OHRQoL compared to that of the family.

In this study, 'child symptom', 'child function', and 'child psychology' domains of CIS sub-scale had larger ES compared to FIS and its domains. Dental diseases frequently caused oral pain, oral dysfunction, i.e. difficulty in eating or drinking, and disturbed child psychology, i.e. having trouble sleeping. Therefore, the impacts on the child were felt by parents a lot more than parent impacts. These findings were consistent with findings from other similar studies (Li et al., 2008a; Lee et al., 2011; Pakdaman et al., 2014; Erkmen et al., 2014; Abanto et al., 2016; Lanlan et al., 2017). Moderate ES for 'child self-image and social interaction' domain of CIS sub-scale showed that this domain was the least affected domain in CIS sub-scale, whose finding was in accordance with other similar studies (Lee et al., 2011; Erkmen et al., 2014; Abanto et al., 2016). Possible explanations might be that a child's oral health was not important for peer-group acceptance at such a young age, and may show limits to parents' knowledge about the social aspects of a child's OHRQoL (Barbosa and Gavião, 2008; Jankauskiene and Narbutaite, 2010).

The values of the mean change scores from the standardised score of Malay-ECOHIS, showed greater reduction following dental treatment under GA for CIS sub-scale compared to FIS sub-scale. The differences in mean change scores of the standardised scores followed a similar trend and gradient to the ES of the scale.

5.3.2 Assessing the association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorised by the median and percentile score

Based on median and percentile scores, there were no statistically significant differences in mean Malay-ECOHIS change scores by severity of decayed teeth (dt), respectively. Possible explanations might be related to the detection of carious lesion during dental examination and dental charting. The progressions of carious lesions in

different stages, for example early lesion or deep severe carious lesion were charted as decayed teeth only, which provided same interpretation for decayed teeth. Therefore, the use of more precise charting techniques such as the ICDAS II or the Pulpal involvement, Ulceration due to trauma, Fistula and Abscess (PUFA/pufa) index for the detection of carious lesions may provide better clinical information in the investigation of OHRQoL in children (Leal S C et al., 2012; Gomes et al., 2014). In this study, the severity of decayed teeth was based on the number of teeth with decay and not on the number of surfaces with decay or the extent of the severity of the decay itself.

5.3.3 Assessing correlation between Malay-ECOHIS change scores and the number of decayed teeth (dt)

Correlation between the number of decayed teeth (dt) and change scores of the Malay-ECOHIS and its subscales after dental treatment under GA have been evaluated in this study. The findings showed that there was a significant, positive correlation between number of decayed teeth (dt) and change scores of Malay-ECOHIS (r=0.165) and CIS (r=0.175), respectively. However, the strength of correlation was weak, respectively. There was no significant correlation between the number of decayed teeth (dt) and change scores of FIS in the present study.

Based on the results reported by Pearson coefficient, it showed that the impact of decayed teeth was more on the child rather than on the family. Decayed teeth gave impact a lot more on the child's daily life than that of the family. Therefore, upon dental treatment under GA, parents felt that their child's OHRQoL improved significantly more than before treatment compared to that of the family. That was why significant correlation was found for CIS with near significant correlation for overall Malay-ECOHIS. It was also shown that the CIS component was sensitive to change in the severity of dental disease represented by the decayed teeth component.

5.3.4 Assessing correlation between Malay-ECOHIS change scores and the number of extracted teeth

It was also shown that in the present study, even though dental extraction was the main treatment provided under GA, number of extractions did not correlate significantly with the change scores of the Malay-ECOHIS. Possible explanations were dental extractions were carried out due to caries, retained root or exfoliating loose teeth. Some of these conditions may be symptomatic, and some may not. Therefore, change in scores of Malay-ECOHIS did not reflect a meaningful trend. Based on the results, Malay-ECOHIS is not sensitive to the types of treatment carried out under GA. Unlike dental extraction, decayed teeth were often accompanied by pain, discomfort and led to disturbances in child's daily life. Therefore, the removal of decayed teeth had improved the child's OHRQoL significantly and showed a significant correlation compared to the correlation between teeth extraction for all reasons and Malay-ECOHIS change scores.

5.4 Responsiveness of the Malay-ECOHIS to dental treatment of ECC under GA by comparing the Malay-ECOHIS change scores with a global transition judgement

In this study, parents who perceived that their child's condition has 'a little improved' and 'much improved' after treatment of ECC under GA had a significant change in Malay-ECOHIS scores and the magnitude of change was greater in the 'much improved' group than the 'a little improved' group. This explained the positive perception of the benefits of dental treatment under GA that improved a child's oral health. Dental treatment under GA has many beneficial effects such as reducing toothache-related behaviours, providing better quality of life after treatment (White et al., 2003; Versloot et al., 2006; Lanlan et al., 2017), providing less pain experience, resulting in better abilities to eat, sleep and positive social impacts (Acs et al., 2001; White et al., 2003; Anderson et al., 2004; Klaassen et al., 2008; Erkmen et al., 2014). Also, many parents opt for their

child to undergo treatment under GA as the procedure helps to reduce stress and increase comfort for both the child and parents (Nick et al., 2002) Also, some patients needed GA because they showed lack of cooperation as a result of their age, levels of maturity or due to physical or learning disability (Albadri et al., 2006).

In this study, we did not have parents who reported that their child's OHRQoL 'a little worse', 'worst' or 'no change' following treatment under GA. This finding was similar to findings in other studies that assessed the responsiveness of preschool children's OHRQoL instruments to dental treatment where the findings did not report groups with deterioration in OHRQoL following the treatment (Lee et al., 2011; Abanto et al., 2016). The findings suggest that parents perceived a greater amount of change in their child's OHRQoL following treatment under GA.

It was apparent that those who reported that their child was in the 'much improved' group showed higher ES values and mean change scores for total Malay-ECOHIS, CIS and FIS sub-scales and all their respective domains compared to those who reported ' a little improved' group. This showed that child's OHRQoL improved following dental treatment indicating a large magnitude of change in the whole measure. The changed was expected with the gradient of parent's perceptions of treatment outcome, providing evidence of the measure's responsiveness.

In addition, the Malay-ECOHIS has good longitudinal construct validity. Good longitudinal construct validity was shown by the mean change scores of Malay-ECOHIS showing the trend of change in the gradient and magnitude of ES across the global transition judgement and significance between them in both groups. This showed that the Malay-ECOHIS is responsive to measure change in relation to an expected gradient of clinical importance.

This is also reflected in the standardised scores where the mean change of standardised scores were higher in the 'much improved' group compared to the 'a little improved' group for all ECOHIS domains. The gradient of change for all ECOHIS domains followed the expected gradient across the global transition rating categories. These findings provide further evidence that the Malay-ECOHIS was responsiveness to changes in OHRQoL of clinical importance.

5.5 Establish the Minimal Important Difference (MID) of the Malay-ECOHIS

As there are no criteria to determine whether a patient with a specific OHRQoL score is mildly, moderately, or severely affected by the oral condition of interest (Jankauskiene et al., 2014), the MID is considered the smallest difference in scores that is considered important from both the clinician's and patient's point of view (Tsakos et al., 2010; Goh et al., 2016). The use of global transition scale as the anchor for the calculation of MID is deemed appropriate in clinical trials (Tsakos et al., 2012). In addition, this may be reinforced by the calculation of effect size. This is the distribution-based approach for calculating the MID value.

The MID can be best estimated using a combination of anchor- and distribution-based approaches to triangulate the values towards a single value. Anchor-based approach should be used as the primary measure and the distribution-based approach as a supportive measure (Masood et al., 2014). In the present study, there was a 7-point change in total ECOHIS scores after treatment under GA. This value is taken as the MID value for the Malay-ECOHIS. The MID values for CIS and FIS sub-scales were 5-point change and 2-point change, respectively. MID can serve as a benchmark for interpreting the preschool children treatment effects observed in Malaysia in the future. This measurement makes assessment of what is the important decision of parents towards their child's oral health.

Using the distribution-based approach, the magnitude of change (ES) for total Malay-ECOHIS was large (>0.7). This value was larger than other studies (Li et al., 2008a; Lee et al., 2011), and similar in some other studies (Erkmen et al., 2014; Jankauskiene et al., 2014; Lanlan et al., 2017). The magnitude of change for CIS was higher than that of FIS. This finding is in contrast with findings in other similar studies elsewhere (Lee et al., 2011; Erkmen et al., 2014; Cantekin K et al., 2014). This findings suggest that we can use both MID estimates in clinical intervention studies in Malaysia i.e. MID and ES.

5.6 Limitations of the study

Some issues faced during data collection period were technical issues such as last minute cancellation by patients due to upper respiratory tract infection or fever on OT day; and cancellation of GA due to disruption of water supply in Serdang Hospital. Besides this, Selayang and Serdang Hospitals underwent renovation of the OT services. Due to these disruptions, the number of patients undergoing operation was reduced.

This study was conducted in the state of Selangor, where it was considered as an urban population, and not reflect as Malaysian population as a whole. If it is to be applied in different section of population, e.g. rural area, the results predicted to be differed as OHRQoL of the preschool children are depending on the multifactorial issues such as parent-proxy and sociodemographic status.

Although most subjects who had changes in ECOHIS scores at or above the MID reported improved oral health, the chances that the ECOHIS had captured these effects correctly were moderate at best. This drawback of the anchor-based method is that it does not consider the measurement precision of the OHRQoL instrument (Crosby et al., 2003). It may be possible that clinically meaningful changes as determined by the anchor-based method will fall within the range of random variation of the OHRQoL measure applied (Crosby et al., 2003). Furthermore, subjective anchors are susceptible to recall bias

(Crosby et al., 2003). Although the use of more objective clinically relevant anchors that are proximal to the construct measured has been suggested, such clinical anchors require agreement between clinicians on what the most minimal clinically favourable effect might be for the condition studied (Tsakos et al., 2010).

CHAPTER 6: CONCLUSION

6.1 Conclusion

Based on the aim and objectives of the study, the conclusions are:

a) For objective 1:

i. The mean ECOHIS score after treatment was significantly lower than the mean ECOHIS score before treatment. This significant reduction in mean score existed for total Malay-ECOHIS, CIS, FIS, and all the sub-domains.

ii. There was no significant association between Malay-ECOHIS change scores and severity of decayed teeth (dt) categorized by median and percentile score.

iii. There was a weak, positive correlation between number of decayed teeth (dt) and Malay-ECOHIS ($r=0.165$, $p=0.05$) and CIS change scores ($r=0.175$, $p<0.05$), respectively. However, there was no significant correlation existed between number of decayed teeth (dt) and FIS change scores.

iv. There was no significant correlation between Malay-ECOHIS change scores and number of extracted teeth.

b) For objective 2:

i. Based on global health transition judgement, 62.3% of parents reported their child's oral condition as "a little improved" while 37.7% reported as "much improved" following treatment under GA with ECOHIS mean change score of 6.7 (ES=+1.1) and 9.6 (ES=+1.2), respectively.

ii. There was an observed gradient in the changes of Malay-ECOHIS scores and effect sizes in relation to global health transition judgement of oral change following treatment, supporting the responsiveness of the measure.

c) For objective 3:

The Malay-ECOHIS MID was found to be 7-point change (effect size = 1.0). The MID for CIS and FIS sub-scales following treatment was 5-point change (effect size = 1.2) and 2-point change (effect size = 0.7), respectively.

d) Overall conclusion

The Malay-ECOHIS has been empirically proven to be sensitive and responsiveness to changes in OHRQoL following dental treatment of ECC under GA. These findings indicate that Malay-ECOHIS can be used in dental treatment under GA to assess changes in OHRQoL, and may be used to assess changes in OHRQoL in other dental treatment e.g. in malocclusion interventions involving preschool children in Malaysia.

6.2 Implications of the findings and recommendations for future research

6.2.1 Implications for OHRQoL development

- ECOHIS is the only OHRQoL measure developed for preschool children. The responsiveness of the Malay-ECOHIS to changes in children's OHRQoL would allow it to be used by oral health service personnel in Malaysia as an outcome measure to assess treatment success in oral clinical interventions among Malaysian preschool children.
- The use of Malay-ECOHIS in the study showed that dental treatment has improved the OHRQoL of preschool children with ECC receiving treatment under GA.
- The Malay-ECOHIS can be used to justify treatment modalities and spending in limited oral health care financial resources in Malaysia. The treatment offered to preschool children may be justified despite the high cost if mean change score of Malay-ECOHIS after certain treatment is above the MID value.

- Also, it can be used in oral health research related to preschool children's OHRQoL in Malaysia.

6.2.2 Recommendations for future research

- As this study was carried out on an urbanized preschool children population, it may not be generalised to all preschool children in the Malaysian population especially for rural preschool children. Further studies may be conducted on different sections of the populations especially on preschool children in rural areas to confirm the sensitivity and responsiveness of the Malay-ECOHIS to dental treatment of ECC under GA.
- Future research should look into studies on the implementation of the scale, incorporating and operationalizing the scale into standard practice and procedures especially in hospital-based centres with Paediatric Dentists.
- The clinical anchor may be considered to be used in the future research, for example by using weight loss as a clinical anchor before and after treatment. The weight loss can be assessed before and after treatment to see whether this anchor was associated with improvement in OHRQoL of the preschool children.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

1. 3-minute oral presentation entitled 'Responsiveness to change of the Malay-ECOHIS following treatment of early childhood caries under general anaesthesia' at 16TH Annual Scientific Meeting & 18th AGM Of Malaysian Section IADR, at Armada Hotel, Petaling Jaya, Malaysia on 18th March 2017.