Oral-Health related Quality of Life Measures for use in Economic Evaluation in Children

Deanna Beckett

A thesis submitted for the degree of
Masters of Public Health
At the University of Otago, Dunedin
New Zealand

May 2017
Abstract

Title: Oral-Health related Quality of Life Measures for use in Economic Evaluation in Children

The first aim of this study was to investigate the availability of quality adjusted life years (QALY), for two oral health related quality of life (OHRQoL) measures, the Child Perceptions Questionnaire for 8-10-year-olds (CPQ8-10) and the Child Perceptions Questionnaire for 11-14-year-olds (CPQ11-14ISF:16), using a general health-related quality of life (HRQoL) measure, the Child Health Utility 9D (CHU-9D), that can produce utility values as a proxy.

The second aim of this study was to investigate whether the CHU-9D can be used as a Quality of Life (QoL) measure for longitudinal oral health research.

Method

Two separate studies were conducted using data from an ongoing Dunedin Randomised Control Trial (RCT), the Proximal Resin Infiltrant New Zealand study (PRINZ). Participants between seven and nine years of age, who attended one of eleven Dunedin schools, and who were registered to receive their dental care with the Bachelor of Oral Health (BOH) programme, were invited to attend. Ethical approval was obtained, as well as written parental consent, and child assent. Sociodemographic information was collected, including age, sex, deprivation, and ethnicity. Clinical data were collected through comprehensive dental examinations conducted by one of two calibrated dental therapists. Digital posterior bitewing radiographs were taken using standardised bitewing holders. The numbers of decayed, missing and filled surfaces were documented at each dental examination for both primary and permanent dentitions, along with the number of primary and permanent teeth present. The CHU-9D was administered six-monthly during the participants’ dental recall examinations. The CPQ11-14ISF:16 and CPQ8-10 measures were administered at the initial examination, and at the last dental examination prior to completing the study. Participants with a baseline CPQ measure and corresponding CHU-9D measure with clinical data were included in the first study, which investigated using the CHU-9D as a proxy to produce a QALY for the CPQ measures. Participants with at least one follow-up CHU-9D measure and corresponding clinical data were included in the second study, which
investigated whether the CHU-9D could be used as a QoL measure for longitudinal oral health related research. All data were analysed using Stata v13.

Results

82 participants aged between seven and ten were eligible for inclusion in the first study, and 87 in the second study. Because there was a large proportion of participants common to both studies, socio-economic and caries data were similar for each. Both studies had similar numbers of girls and boys, with most being 8 or 9 years of age. More than two-thirds of the children identified as NZ European, with fewer than one in five being NZ Māori. There were similar proportions of participants residing in areas of low or high deprivation, with slightly more children living in areas of medium deprivation. Caries experience was lower for NZ European participants and those living in areas of low deprivation.

For the OHRQoL measures, both CPQ8-10 and CPQ11-14ISF:16 scores showed a consistent gradient at baseline across ordinal categories of caries experience. By comparison, the CHU-9D had inconsistent utility values by caries experience category, with children in the caries-free group reporting the same QoL as those with the greatest burden of disease. Scatter plots between the CHU-9D and both the CPQ8-10 and CPQ11-14ISF:16 demonstrated a large amount of variance at both baseline and follow-up, with a correlation coefficient of -0.3 at baseline for both the CPQ8-10 and CPQ11-14ISF:16, and -0.5 at follow-up.

For HRQoL at baseline, the CHU-9D did not demonstrate a clear descending gradient in utility score across the ordinal categories of caries experience. There was a slightly more discernible pattern at times 2, 3 and 4, but it was not convincing.

Conclusions

For the first study of 82 Dunedin children between 7 and 12 years of age, the CHU-9D showed low concordance with both the CPQ8-10 and CPQ11-14ISF:16. Thus the CHU-9D was unable to be used as a proxy to calculate a QALY in this group of children.

The second study of 87 Dunedin children between 7 and 12 years of age, showed that the CHU-9D was not sensitive to caries experience at baseline, and so the measure is unable to detect or reflect change in caries experience over time.
I would like to thank my husband Kane, daughter Poppy, and stepdaughters Hayley and Piper, for all the love, patience, and encouragement they have shown me over the last two years. I am forever grateful.

To my supervisors; Associate Professor Lyndie Foster Page, Dr Claire Cameron, and Professor W Murray Thomson, I extend a heartfelt thank you for sharing your extensive knowledge, and for the time and effort you have put into guiding me through this process.

Lyndie, I would not have started this journey without your faith in my abilities. Thank you for encouraging me and giving me the opportunities that have led me to where I am today. I could not have done this without you.

Claire, your support in developing my statistical knowledge has been very much appreciated. Thank you for your constant encouragement and unwavering support that has been above and beyond the call of duty.

Murray, your input has been invaluable. Thank you for being involved with this project, and being so generous in sharing your knowledge. Your ‘red pen’ has been much appreciated.

This thesis would not have been possible without the support of my colleagues and the Faculty of Dentistry. Thank you for believing in me and investing in my professional development.
### List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Summary of mail-out responses in 2012 and 2013</td>
<td>37</td>
</tr>
<tr>
<td>Table 2</td>
<td>Summary of both mail-outs</td>
<td>37</td>
</tr>
<tr>
<td>Table 3</td>
<td>Overall response rate</td>
<td>38</td>
</tr>
<tr>
<td>Table 4</td>
<td>Participation rate for Study 1 and Study 2</td>
<td>39</td>
</tr>
<tr>
<td>Table 5</td>
<td>Baseline dental caries experience by sociodemographic characteristics</td>
<td>41</td>
</tr>
<tr>
<td>Table 6</td>
<td>Summary data on the CPQ11-14 ISF:16, CPQ8-10 and their subscales at baseline</td>
<td>43</td>
</tr>
<tr>
<td>Table 7</td>
<td>Baseline mean CPQ8-10 and CPQ11-14 scores and CHU9D by sociodemographic characteristics and caries experience</td>
<td>45</td>
</tr>
<tr>
<td>Table 8</td>
<td>Attrition analysis</td>
<td>47</td>
</tr>
<tr>
<td>Table 9</td>
<td>Mean exit CPQ8-10 and CPQ11-14 scores and CHU-9D by sociodemographic characteristics and caries experience</td>
<td>49</td>
</tr>
<tr>
<td>Table 10</td>
<td>Mean caries experience at baseline and exit by risk groups</td>
<td>53</td>
</tr>
<tr>
<td>Table 11</td>
<td>Baseline CPQ11-14 and CPQ8-20 by global oral health questions</td>
<td>55</td>
</tr>
<tr>
<td>Table 12</td>
<td>Exit CPQ11-14 and CPQ8-20 by global oral health questions</td>
<td>55</td>
</tr>
<tr>
<td>Table 13</td>
<td>CHU-9D Time 1 sociodemographic characteristics by caries experience</td>
<td>57</td>
</tr>
<tr>
<td>Table 14</td>
<td>Primary/permanent teeth present at baseline</td>
<td>58</td>
</tr>
<tr>
<td>Table 15</td>
<td>Mean CHU9D scores across the four observations</td>
<td>58</td>
</tr>
<tr>
<td>Table 16</td>
<td>Mean CHU-9D scores at each time point by sociodemographic characteristics and caries experience</td>
<td>60</td>
</tr>
<tr>
<td>Table 17</td>
<td>Attrition analysis</td>
<td>62</td>
</tr>
</tbody>
</table>
List of Figures

Figure 1. Caries in Otago vs NZ: 5-year-old mean dmft.................................................................8
Figure 2. Caries in Otago vs NZ: 5-Year-Old % Caries-Free ..........................................................8
Figure 3. Caries in Otago vs NZ: Year 8 Mean DMFT...............................................................9
Figure 4. Caries in Otago vs NZ: Year 8 % Caries-Free.............................................................9
Figure 5. QALYs: Treatment vs no treatment diagram adapted from Whitehead et.al ......17
Figure 6. Standard Gamble Diagram adapted from Drummond et al. ..........................18
Figure 7. Mapping to a QoL measure with preference weights ...........................................21
Figure 8. Comparison of the item content of the CPQ8-10 and the CPQ11-14....................32
# Table of Contents

Abstract .................................................................................................................................................. ii

Acknowledgements ............................................................................................................................... iv

List of Tables .......................................................................................................................................... v

List of Figures ......................................................................................................................................... vi

Table of Contents ................................................................................................................................... vii

Chapter 1: Review of the literature ....................................................................................................... 1

1.1 Global Burden of Oral Disease ........................................................................................................ 1

1.1.1 Background .................................................................................................................................... 1

1.1.2 Global impact ................................................................................................................................. 2

1.1.3 National impact ............................................................................................................................. 2

1.2 Child Oral Health ............................................................................................................................. 3

1.2.1 Background .................................................................................................................................... 3

1.2.2 Child oral health in New Zealand .................................................................................................. 4

1.2.3 Child oral health services in New Zealand ................................................................................... 5

1.3 New Zealand Ministry of Health Caries Prevalence Data .............................................................. 6

1.3.1 Background .................................................................................................................................... 6

1.3.2 Recording decayed, missing or filled teeth/surfaces .................................................................... 6

1.3.3 National caries data ....................................................................................................................... 7

1.3.4 Otago caries data ........................................................................................................................... 7

1.4 Oral-Health-Related Quality of Life Measures ............................................................................... 10

1.4.1 Background .................................................................................................................................... 10

1.4.2 Measuring oral-health-related quality of life for children ............................................................. 10

1.4.3 Existing oral-health-related quality of life measures for children ................................................. 12

1.5 Economic Evaluation ...................................................................................................................... 15

1.5.1 Background .................................................................................................................................... 15

1.5.2 Measuring costs and benefits of an intervention ........................................................................ 15

1.5.3 Quality-adjusted life years ........................................................................................................... 16

1.5.4 Direct methods for calculating health utility values ..................................................................... 18

1.5.5 Indirect methods for calculating utility values ........................................................................... 19
Chapter 2: Method ........................................................................................................ 26

2.1 General approach to the investigation ................................................................. 26

2.2 Sampling Procedure .............................................................................................. 26

2.2.1 Sample size ....................................................................................................... 26

2.2.2 Sample strategy .................................................................................................. 27

2.3 Caries data ............................................................................................................. 27

2.3.1 Visual examination ............................................................................................. 27

2.3.2 Radiographic observations ............................................................................... 28

2.3.3 Dental health data ............................................................................................. 28

2.4 Sociodemographic characteristics ...................................................................... 29

2.5 Quality of Life Measures .................................................................................... 30

2.5.1 HRQoL ............................................................................................................... 30

2.5.2 OHRQoL ............................................................................................................. 30

2.5.3 Global health ..................................................................................................... 33

2.5.4 Test-retest reliability ......................................................................................... 33

2.6 Inclusion Criteria ................................................................................................ 33

2.6.1 Study 1 ............................................................................................................... 33

2.6.2 Study 2 ............................................................................................................... 33

2.7 Data analysis ...................................................................................................... 34

2.7.1 Dental caries ...................................................................................................... 34

2.7.2 QoL measures .................................................................................................. 34

2.7.2.1 CPQ$_{11-12}$,ISF:16 and CPQ$_{6-10}$ .................................................................. 34

2.7.2.2 CHU-9D ......................................................................................................... 35

2.7.3 Sociodemographic characteristics .................................................................. 35

2.7.4 Study 1 ............................................................................................................... 35

2.7.5 Study 2 ............................................................................................................... 36

Chapter 3: Results .................................................................................................... 37

3.1 Analysis of participation rate .............................................................................. 37

3.1.1 PRINZ trial ....................................................................................................... 38
3.1.2 Study 1 participation ................................................................. 38
3.1.3 Study 2 participation ................................................................. 39
3.2 Baseline Data: Study 1 ................................................................. 39
  3.2.1 Sociodemographic information .................................................. 39
  3.2.2 Dental caries ............................................................................. 39
  3.2.3 OHRQoL .................................................................................. 42
  3.2.4 CPQ11-14ISF:16 ...................................................................... 42
  3.2.5 CPQ8-10 ................................................................................. 42
  3.2.6 Mean scores by sociodemographic information and caries experience .... 44
     3.2.6.1 OHRQoL measures ............................................................... 44
     3.2.6.2 HRQoL measures ................................................................. 44
  3.2.7 Attrition analysis ..................................................................... 45
3.3 Exit Data: Study 1 ........................................................................ 48
  3.3.1 Mean scores by sociodemographic information and caries experience .... 48
     3.3.1.1 OHRQoL ............................................................................. 48
     3.3.1.2 HRQoL ............................................................................. 48
  3.3.2 Relationship between OHRQoL and HRQoL .................................. 50
3.4 Baseline and Exit Data: Study 1 ...................................................... 53
  3.4.1 Test/retest reliability ................................................................. 53
3.5 Global oral health measures .......................................................... 53
  3.5.1 Self-rated oral health ................................................................. 53
  3.5.2 Impact of oral health on quality of life ....................................... 54
3.6 Baseline Data: Study 2 ................................................................. 56
  3.6.1 Sociodemographic characteristics of participants .......................... 56
  3.6.2 Caries experience .................................................................. 56
  3.6.3 Dentition status ...................................................................... 58
3.7 Longitudinal Data: Study 2 ............................................................ 58
  3.7.1 Mean CHU9D Scores ................................................................. 58
  3.7.2 Attrition Analysis ................................................................... 61

Chapter 4: Discussion ........................................................................ 63
  4.1 Findings ..................................................................................... 63
  4.2 The sample ................................................................................ 64
  4.3 Strengths and weaknesses ........................................................... 65
     4.3.1 Caries experience .................................................................. 65
     4.3.2 OHRQoL ............................................................................. 67
4.3.3 HRQoL ..................................................................................68
4.3.4 Test/retest reliability ..................................................................69

4.4 Are QALYs available for OHRQOL measures using a general health measure as a proxy? ........................................................................69

4.5 Can the CHU-9D can be used as a QoL measure for longitudinal oral health related research? ........................................................................71

4.6 Recommendations ..............................................................................71

4.7 Implications for current practice ..........................................................73

Chapter 5: Conclusion ..............................................................................74

References .............................................................................................75
Chapter 1: Review of the literature

1.1 Global Burden of Oral Disease

1.1.1 Background

The World Health Organization (WHO) defines good oral health as “A natural, functional, acceptable dentition which enables an individual to eat, speak, and socialise without discomfort, pain or embarrassment, for a lifetime, and which contributes to general well-being” (1).

Dental diseases of the oral cavity include (but are not limited to) dental caries (tooth decay), developmental defects of enamel and/or dentine, dental erosion and periodontal diseases (2). Dental caries and periodontal disease are both preventable and are currently considered the most important global oral-health burdens (2, 3).

Dental caries involves the pathological destruction of tooth tissue from cariogenic biofilm, and the progression of this disease can lead to pain and difficulty with eating, sleeping, and concentrating (2). Dental caries is multifactorial, with contributing factors including not only the presence and number of cariogenic pathogens, but also modifiable factors such as diet, poor oral hygiene, and drug and alcohol abuse. Periodontal diseases affect the gingiva (gums) and surrounding periodontium, and is a major cause of tooth loss in adult humans. Periodontal pathogens are primarily responsible for the presence of this disease, with a number of modifiable factors shown to contribute to its severity and progression, including poor oral hygiene, smoking, and drug and alcohol abuse (2, 4). Many of the modifiable risk factors for both dental caries and periodontal disease are also implicated in other chronic diseases such as diabetes, heart disease, and obesity, and they are inextricably linked to socio-economic deprivation (5, 6).

Poor oral health directly impacts on many aspects of life, including nutrition, education, mental and physical well-being, and it has been directly implicated in poor general health (2, 3, 7, 8). Untreated dental caries can result in pain, acute and chronic infection, and in some cases, death. The appearance of untreated dental caries or lost teeth due to caries can be unsightly, resulting
in stigmatisation, embarrassment, and low self-esteem. Both dental caries and periodontal disease can result in halitosis (bad breath), affecting social and personal interactions, and potentially hindering employment opportunities (2).

1.1.2 Global impact

In the World Health Report released in 2003, the WHO has identified dental diseases as the most prevalent chronic diseases worldwide, stating that at that time, an estimated 5 billion people globally suffer from untreated dental caries alone (9). Caries specifically has been identified as a major oral health problem in most industrialised countries, affecting more than two-thirds of school aged children and a great majority of adults (2, 10).

Dental diseases are the fourth most expensive condition to treat, and countries differ in the way that resources are allocated (2, 3). Because there is a relatively lower mortality rate than for other more life threatening diseases, it may not be seen as a high priority for policy makers which could affect public funding (11). In developed countries, dental care costs make up between 5% and 10% of total health care expenditure, depending on how services are subsidised (2, 4). For some more wealthy countries, there may be publicly funded oral health services; however, for many middle to low income countries, public funding is restricted to the provision of emergency care and pain relief only (2, 3). The lack of Government-funded services in these countries results in treatment of this disease being limited to individuals who can afford private dental care, resulting in the most deprived bearing the greater burden of disease (5).

In less-developed countries, over 90% of dental caries is left untreated (12). It has been estimated that if dental care was publicly funded in those countries, the cost of providing treatment for children alone would exceed their total health care budget for children (12). A call for action was put forward in 2006 by the World Congress on Preventive Dentistry, and recommendations made that countries focus on equitable access to primary oral health care, and more investment into prevention and health promotion services (13).

1.1.3 National impact

In New Zealand (NZ), dental caries has been identified by the Ministry of Health (MoH) as the country’s most prevalent chronic disease (14). Inequalities in oral health status within NZ
are well documented, with children and adults in areas of high deprivation and within ethnic minority groups known to carry a significantly greater burden of disease (14-16).

Medical and hospital care in NZ is either partially or fully funded for children and adults; however, there is currently no Government funding for dental care beyond the age of 18, despite the relationship between poor oral health, poor general health, and subsequently poorer overall well-being (15-17). For low to middle income adults, the prohibitive costs of accessing necessary treatment were the most reported barrier for not seeking dental care. However other indirect costs have been identified, including lack of transportation, inability to take time off work, difficulties organising childcare, and fear of the required treatment (dental anxiety) (14, 15).

The 2012/2013 New Zealand Health Survey identified that 55% of dentate adults in NZ did not visit a dental health care professional unless they were in pain. The numbers were significantly greater when looking at adults living in the most deprived areas (74%), Māori (76%) and Pacific Island people (78%). For the general population, 240,000 adults (7%) had one or more teeth removed in the previous 12 months, while it was 8% among Māori, 11% among Pacific Island people and 8% among adults living in the most deprived areas of NZ (18).

1.2 Child Oral Health

1.2.1 Background

Early Childhood Caries (ECC) is a term to describe dental caries in preschool children (19). It has been further defined as “the presence of one or more decayed, missing, or filled surfaces in any primary tooth, in a child of 72 months of age or younger” (20). ECC is commonly referred to as “bottle” or “nursing caries”, due to an apparent causal relationship with exposure to sugar via a bottle of sweetened beverage available to children on demand (19). Primary teeth decay at a much faster rate than permanent teeth, and poor diet, oral hygiene, and lower dental attendance can contribute to the rapid progression of the disease (19, 21).

Dental caries in early childhood has been found to be a predictor of poor long-term oral health (22, 23). The need for ongoing dental treatment as a child can lead to anxiety, fear, and avoidance of dental care as an adult (6). Many of these young children require a general
anaesthesia for treatment, and long waiting lists can result in an increase in hospital presentations for emergency interim care (21).

1.2.2 Child oral health in New Zealand

According to the 2009 New Zealand Oral Health Survey (NZOHS), approximately half of the children aged between 2 and 17 years had experienced dental caries, and yet one in five had not visited a dental professional in the previous 12 months (14). These statistics were similar to the key findings of the 2012/2013 NZ health survey, which also reported that one in four children (21%) in the 1-14 year age group had not seen a dental health professional in the previous 12 months (18). The NZ health survey also reported that 30,000 New Zealand children (4%) had teeth removed due to dental caries, infection or gum disease in the previous 12 months (18).

A 2014 review by Whyman et al. on 20 years of preventable hospital admissions, found that the national rate of NZ hospital admissions for dental care had increased nearly four-fold, from 0.76 per 1000 of population in 1990, to 3 per 1000 in 2009 (24). The rate of admission was highest in children aged 3-4 years of age, those living in areas of high deprivation, and Māori and Pacific Island people. The majority of those presenting with dental disease had complications arising from dental caries (24).

Many children in NZ are able to be treated successfully under local anaesthesia (LA) by dental therapists in the COHS. There are, however, children who are unable to cope with dental treatment. This may be due to the child being very young, high treatment requirements, or dental anxiety. These children are often referred to hospital dental departments which are able to provide treatment under general anaesthetic (GA) (21).

Lingard et al. prepared a report for the NZ Society of Hospital and Community Dentistry (NZSHCD) in 2007 on providing dental care for children under GA (21). This report showed that, once referrals were received, waiting lists for assessment were up to 8 months depending on the region that the child resides, with the wait for treatment taking up to 12 months. This delay in receiving much-needed dental treatment often contributed to an advanced progression of disease which then required more complex treatment or extractions, and resulted in ongoing intermittent pain and suffering for the child. Each year in NZ, approximately 5000 children
are treated under GA for dental caries; this is not without health risks, and comes at significant cost to the public health-care system (21).

1.2.3 Child oral health services in New Zealand

Publicly funded oral health care is available in NZ for children until the age of 18 from either dental therapists or dentists registered with the Adolescent Oral Health Service (AOHS). Preschool, primary and intermediate aged children usually access their dental care through the Community Oral Health service (COHS) which was previously known as the School Dental Service (SDS). The SDS was school-based, with many primary and intermediate schools in NZ having a dental clinic on site. This investment into dental health by the State was associated with dramatic improvements in oral health for NZ children and became a model then used in more than 50 countries around the world (16, 25).

In 2006, the New Zealand Ministry of Health released its strategic vision for oral health in NZ ‘Good Oral Health for All for Life’. It had become apparent that the outdated buildings and equipment used within the SDS were no longer meeting the requirements of modern dentistry. Increasing caseloads, changing expectations of parents, and more complex treatment options had resulted in growing arrears¹ and increased pressure on dental therapists employed within the service(1, 16). Nationally, the decline in caries prevalence appeared to have come to an end, with growing inequalities for Māori and Pacific Island children and those living in areas of high deprivation (1, 23, 26). A nationwide change in service delivery and an upgrade of facilities was subsequently undertaken, with school-based clinics being progressively decommissioned and replaced with a new community-based hub-and-spoke system that was renamed the COHS (1).

The COHS comes at a cost of approximately 80 million per year, and while the existence of a publicly-funded service has played an important role in improving dental health for children in NZ, the indirect costs and psychological barriers associated with accessing care for many families still exist (1, 8, 27). High demand for publicly-funded services in some areas of New Zealand often results in recall delays for many high-risk children. This is apparent in areas of

---

¹ Arrears is the term used by the SDS/COHS to determine the number of children who have not had a dental examination within 12 months, or had treatment completed within 14 months of their last dental visit.
greatest deprivation, where multiple treatment needs place a heavy burden on services (21). Delays in recalling children, or failure by patients to attend appointments, can result in dental caries going undiagnosed or not being treated in a timely fashion.

1.3 New Zealand Ministry of Health Caries Prevalence Data

1.3.1 Background

NZ caries statistics are collected routinely by dental therapists within the SDS/COHS, after each child’s first completed course of treatment at age 5, and at the end of their last completed treatment in year 8 (approximately 12-13 years of age). In NZ, it is usual for children to start school at the age of 5, therefore this was an age where the majority of children could be accounted for. Year 8 is the last year that children are funded under the SDS/COHS, as they are transferred to the AOHS scheme in year 9.

Year 8 data document the number of permanent teeth affected in the mouth at that time point. This is the age where many children can expect their deciduous teeth to exfoliate and new teeth to erupt, so, with the exception of the first permanent molars which erupt at six years of age, the permanent dentition is often newly erupted or not yet present (19).

1.3.2 Recording decayed, missing or filled teeth/surfaces

The caries-specific information collected is the number of ‘decayed, missing or filled teeth (dmft/DMFT)’ in the mouth. The limitations of this system are that the exact number of filled or carious surfaces in the mouth is unknown, because only the number of teeth affected is recorded, not the extent. For example, if a child had two restorations and an open carious lesion on the same tooth but on different surfaces, this would still count as a score of 1 according to the dmft/DMFT system.

A more informative system is the ‘decayed, missing, and filled surfaces’ system (dmfs/DMFS). This allows for a better understanding of the severity of caries experience, although there is debate about whether the inclusion of missing teeth or teeth restored with crowns results in an overestimation of caries experience (28). This is due to each tooth being allocated a maximum

---

2 Primary teeth are indicated by small letters (dmft), and permanent teeth are indicated by capital letters (DMFT)
number of five potential surfaces, with both crowned and extracted teeth receiving a maximum score of five regardless of the number of surfaces initially affected by caries leading to the intervention. For example, if a tooth was removed due to an abscess, this may have occurred due to caries in one or more surfaces, yet it still carries a score of five. A crown covers all surfaces of the affected tooth, yet all surfaces may not have been affected by caries (28).

1.3.3 National caries data

In 2013, the Ministry of Health (MoH) reported the mean dmft for 5-year-old children in NZ was 1.9. The District Health Board (DHB) with the highest mean dmft was Northland at 3.6, with only 34.2% of children having a caries-free primary dentition. The lowest mean dmft was seen in the Southern DHB at 1.3; this area encompasses Otago and Southland, with 63% of children having a caries-free primary dentition. For year 8 data, the average DMFT for NZ was 1.1. The DHB with the highest mean DMFT was Northland, at 1.8, with only 45% of 12-13-year-old children being caries free in the permanent dentition. The lowest was Capital and Coast DHB with a mean DMFT of 0.7, and 65.7% being caries-free in the permanent dentition.

1.3.4 Otago caries data

Otago dmft/DMFT statistics prior to 2010 were published by the MoH as an independent DHB, with more recent data including both Otago and Southland, under the newly merged Southern DHB. In 2012, the MoH reported missing some data for Southern DHB and the introduction of a new computer system was cited as the reason for this.

The Otago DHB (Southern DHB post-2010) has consistently reported a mean 5-year-old dmft lower than the national dmft (Fig1), with a higher percentage of children having a caries-free primary dentition (Fig 2). A spike in caries prevalence for the Otago region was recorded in 2009 and 2011 (Fig 2). This appeared to be a nationwide trend, however, and the difference between the local and national mean was similar to previous years (with the exception of 2010). In 2010, the national mean remained high, although that for the Southern region returned to below 1.5. A corresponding decline over the same years for the percentage of caries-free children was apparent (29).
Year 8 children in Otago have had a consistently higher DMFT than the national mean until 2010 (Fig 3). It was not until 2012, however, that the percentage of Southern children experiencing a caries-free permanent dentition was greater than the national average (Fig 4). A slight but steady decrease in mean DMFT for year 8 children has been demonstrated since
1990, and, as at 2013, Southern DHB had a mean DMFT of 1.0, with 55.4% of children having a caries-free permanent dentition (29).

Figure 3. Caries in Otago vs NZ: Year 8 Mean DMFT

![Caries in Otago vs NZ: Year 8 Mean DMFT](image)

Figure 4. Caries in Otago vs NZ: Year 8 % Caries-Free

![Caries in Otago vs NZ: Year 8 % Caries-Free](image)
Otago region has had periods of caries experience that have been both higher and lower than the national mean. Caries statistics (dmft) at 5 years of age have been consistently lower than the national average, while at year 8, caries statistics (DMFT) have historically been higher than the national average, except for the last five years. Currently, Otago is considered an area of lower caries experience (on average) than the rest of the country, and it would be a suitable area for research looking to investigate the sensitivity or responsiveness of such a measure.

1.4 Oral-Health-Related Quality of Life Measures

1.4.1 Background

The WHO defines health as “a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity” (30). From the 1960s, this shift in thinking from a medicalised treatment focus to a holistic view of health, has led to the development of HRQoL measures, which were designed to demonstrate the true impact of disease on quality of life (QoL). It was not until the early 1980s, however, that the relationship between oral health and QoL was investigated (31). The delay in exploring this area is attributed to a lack of belief by researchers at the time that poor oral health had an effect on overall quality of life (31).

The development of early OHRQoL measures involved incorporating the designs of existing HRQoL measures with current conceptual models of health, to try and create a measure that could capture the full impact of poor oral health on all aspects of health and well-being (31, 32). The subsequent establishment of multi-dimensional OHRQoL measures has allowed for research to be undertaken in this area, and an overwhelming body of evidence has since been collected supporting the hypothesis that oral health has an impact on quality of life in adults. These findings have led to further extending research into the area of OHRQoL for children.

1.4.2 Measuring oral-health-related quality of life for children

Measuring OHRQoL for children is a challenging proposition, and the ability of children to report their experiences accurately has been questioned by researchers (33). More recently, there has been a shift to research that fully involves the child, giving children an opportunity to speak for themselves. This is in line with an increasing focus on the rights of the child to be informed and consulted when dealing with health and oral health care (33).
Many previous OHRQoL studies have been ‘on’ children, using parents or adults as proxy informants, speaking for children based on their understanding of children’s perceptions (33, 34). Children mature physically, emotionally and mentally at different rates and, while some may appear capable of self-report, others may not yet have the necessary grasp of language to allow for adequate interpretation and consequent understanding of questions. Children tend to be influenced more by short-term memory recall, and may have difficulty perceiving the effect of events over an extended period (35). This could result in a dulling down of older memories, which parents may recall more vividly, or alternately, an overly strong reaction to immediate health issues which children may not be able to rationalise in context. In particular, there have been doubts that very young children (under 8 years of age) are capable of providing an accurate reporting of their own health experiences (35, 36). Conversely, parental proxy reports have limitations because their reports are based on adults’ opinions of what they ‘think’ children experience (33). Parents are generally not observing their school aged children all day, every day, so may not be in a position to report comprehensively on many aspects of their life, including school interactions, time with friends, and after-school activities (33, 36-38). A number of studies have concluded that parents generally have a low-to-moderate agreement with their children’s self-rating (33, 36, 37, 39).

Theunissen et al. (1998) tested the validity of using parents as proxy in HRQoL measures in Holland with 1,105 children aged between 8 and 11, and their parents. Both children and parents completed age-appropriate HRQoL measures, and answers were analysed. They reported that large differences can exist between the parent proxy report and the child’s self-report, with children overall giving their health a less extreme rating than their parents. Despite this, both child and parent reports were shown to be valid (35).

A study by Jokovic et al. (2004), investigating how well parents in Toronto knew their children, found that parental proxy reports and child self-reports were complementary and could, in fact, provide a wider picture of the child’s overall well-being. Parents, however, were found to be more likely to answer ‘don’t know’ to a question relating to emotional and social well-being, but were better able to report on physical ailments or limitations (37).

Having age-appropriate child self-report measures enables children to report on their own health or oral health status. This is in line with the shift to a more patient-centred model of care, embracing the belief that patients themselves are the best people to advise on their health
and wellbeing (33, 34). It also removes the added complication of observer bias, whether the observer be a parent, teacher, or interviewer, and eliminates potential discrepancies between proxy respondent and the child (34).

1.4.3 **Existing oral-health-related quality of life measures for children**

There are several OHRQoL measures for children using either self-report or adult proxy reporting systems. These include the Child Perceptions Questionnaire (CPQ) (40-42), the Child Oral Health Impacts on Daily Performance (C-OIDP) (43), the Child Oral Health Impact Profile (COHIP) (44), the Early Childhood Oral Health Impact Scale (ECOHIS) (45) and the Scale of Oral Health Outcomes for 5-year-old children (SOHO-5) (46). Currently, the most commonly used child self-report measures to examine OHRQoL are the COHIP, the C-OIDP and CPQ.

The C-OIDP is a child-appropriate adaptation of the Oral Impacts on Daily Performances scale which is commonly used with adults. It consists of only eight questions and is accompanied by pictures to aid comprehension (43).

The COHIP is a more recent measure which has 37 questions in its original form. A shorter 19-item version has more recently been validated (34). The development of the COHIP involved a comprehensive development strategy which included children and the exclusion of redundant Child Oral Health Related Quality of Life (COHRQoL) measures during its formation. This measure has included both positive as well as negative items in its development. This allows for evaluation of a more comprehensive range of health states, as both positive and negative reactions may provide useful information on an individual’s ability to cope and show resilience that may otherwise be left unmeasured. Conversely, the inclusion of positive items may complicate the interpretation of scores, especially when evaluating changes over time (34).

The CPQ is available in various forms, including the CPQ8-10 for children aged 8-10 and the CPQ11-14 for children aged 11-14. The CPQ11-14 is the most widely used, consisting of 37 items across four domains; oral symptoms, functional limitations, emotional well-being and social well-being. This measure has been rigorously tested, demonstrating solid internal consistency and test/retest reliability, performing well across various cultures and socio-economic
backgrounds, in groups with high and low caries experience (47). While the measure has performed well, the large number of items has meant that it is time-consuming for participants to complete, affecting its efficacy within clinical settings and large population-based trials (41, 48). In order to reduce the respondent burden associated with the CPQ11-14, shorter forms were developed and considered, using two alternative methods to select which items should be retained; these were the item impact method and the stepwise regression method (41, 48). The item impact method involved selecting items which were deemed to be of most importance to the patient. The regression method relied on statistical analyses of internal consistency to select a model containing items within each domain that were considered the best predictors of the overall score (41). Both methods have been used to develop 16-item short forms, each consisting of four items across four domains. Shorter 8-item forms were also developed, consisting of only two items per domain; however, these numbers are insufficient to allow for within-domain analysis. The short form CPQs developed using the item impact method are known as the CPQ11–14-ISF:16 and the CPQ11–14-ISF:8. The stepwise regression method generated the CPQ11–14-RSF:16 and CPQ11–14-RSF:8 (41).

The CPQ11–14-ISF:16 is commonly used today in place of the original CPQ11–14, because it incorporates patient preference in its development, and also has sufficient items per domain to allow for within-domain analysis and lower burden on the participants. While the CPQ11–14-ISF:16 has good evidence to support its reliability and validity, there is a need for more research examining its evaluative properties; that is, its ability to detect and represent change.

Until recently, there have been no self-report oral health measures which involve children younger than 8 years of age. The SOHO-5 was developed for use with children between five and eight years of age, and has demonstrated acceptable validity and reliability with 332 children from the United Kingdom (46). These findings support the belief that children as young as 5 years of age may be capable of valid self-report.

For longitudinal studies that involve children across various age groups, having to progress from one age-specific measure to another as they mature can be problematic, particularly during data analysis. Having one measure that could be used for children as young as 5, that is also appropriate for older children, would provide consistency in what is being measured, and ultimately offer more opportunity for longitudinal research involving children (49).
A 2011 study by Foster Page et al. investigated whether a questionnaire that incorporated both the 16-item CPQ11-14-ISF:16 and the 25-item CPQ8-10 could be used with children aged 5 to 8 (49). It showed that participants with more caries experience had significantly higher scores in the oral symptoms domain than those with less caries experience. Less significant score differences were shown for the CPQ11-14-ISF:16 in the area of functional limitations, although the CPQ8-10 performed well in this area. Overall, the authors reported that “gradients with caries experience were apparent across scores for all of the domains (except for social well-being in the CPQ11-14-ISF:16)” (49). Substantial internal consistency and reliability was apparent for both measures, with the CPQ8-10 performing slightly better than the CPQ11-14-ISF:16. This paper provided further evidence to support the contention that younger children are capable of providing their own perceptions of oral health impacts (49). This study was the first to examine the CPQ measures in children as young as 5 years of age, and the authors recommended further research in population-based samples to confirm their findings.

To date, there have been few studies measuring responsiveness to a change in oral health status in children receiving dental care in primary health care settings (50). The Brazilian version of the SOHO-5 was found to be responsive in a 2011 study by Abanto et.al, where dental treatment was provided for 154 five-to-six-year-old children living in São Paulo. This study incorporated both child self-reports and parent proxy reports at baseline and after dental treatment. Good internal and external responsiveness was demonstrated, with total SOHO-5 scores showing a significant decrease (representing an improvement) following treatment (51).

A 2015 paper by Turton et.al reported on a study evaluating the responsiveness to changing oral health status of the Khmer version of the CPQ11-14 with 140 children living in Cambodia. Basic restorative dental treatment and extractions were provided as required by dentists and dental nurses using mobile dental facilities. Baseline and follow-up CPQ11-14 scales were administered, and there was an overall small but measurable improvement in OHRQoL, leading the authors to conclude that the Khmer version of the CPQ11-14 appeared be a valid and responsive measure (52).

Further research exploring the responsiveness of child self-report QoL measures in other settings is required.
1.5 Economic Evaluation

1.5.1 Background

Worldwide, health care organisations are faced with the task of distributing limited health care resources in a fair and equitable manner. Multiple stake holders (including physicians, patients, tax payers, and pharmaceutical companies) have a vested interest in this decision making process, since the outcomes can directly influence the services provided, medicines funded, and the treatment options available in any given area of health care.

The use of economic evaluation to inform this process is increasing internationally, because it can provide decision-makers with information on the relative costs and benefits of competing alternatives. The National Institute for Care and Excellence (NICE) in the UK, the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, and PHARMAC in NZ are examples of independent expert public bodies which use economic evaluation to produce evidence-based advice on health, public health and social care to key stakeholders (53-55). Governmental agencies are relying more and more on such bodies to inform public policy and healthcare resource allocation. As such, there is now a growing expectation that researchers seek to quantify the burden of disease in an economic context, enabling decision-makers to make evidence-based decisions about the distribution of public health-care resources in a systematic and transparent manner (56, 57).

1.5.2 Measuring costs and benefits of an intervention

Measuring the true cost or benefit of a health intervention is complex and contentious. At present, countries differ in how they assess these cost/benefits, adopting either a direct healthcare cost perspective, or a more holistic societal cost perspective (58, 59).

The direct healthcare costs of treatment or a preventive regime are often more transparent and straightforward to calculate. These usually include the cost of the materials and equipment, running costs of a practice, and the cost of time (hourly rate) of the treatment provider over a set number of appointments (59). The United States, United Kingdom, and German governmental bodies have adopted this healthcare system perspective to evaluate the cost-effectiveness of health interventions for their countries (59). However, there are other societal costs that are often underestimated in such an approach.
Sweden, Finland, the Netherlands, and France have looked further into indirect expenses associated with an intervention. These include costs to the patients arising from lost time to attend one or multiple appointments, travel expenses to and from appointments, and costs of purchasing additional homecare treatments and appliances (59). While costs are fairly easy to quantify, especially from a funder’s perspective, the benefits are much more difficult to calculate. There is also the patient’s perspective to consider. Do they perceive an added benefit from the intervention? How has the intervention impacted on their quality of life? Would the benefits to them personally make it worth their while to invest time, effort and money into the proposed regime?

The most commonly required form of analysis for economic evaluation is cost-utility analysis (CUA), which is a unit of measure of ‘preference’ by the patient for a particular health state (59-61). By using preference weights reported by those affected by health conditions, over all utility values can be calculated that represent the strength of an individual’s preference for a health related outcome. This utility value provides a more accurate depiction of the improvement in quality of life, or reduction in morbidity, resulting from an intervention (59, 60, 62).

1.5.3 Quality-adjusted life years

Currently, the most acceptable unit of benefit measurement is the quality-adjusted life year (QALY). The QALY combines length of life and QoL into a single measure, which is useful for decision-making because it allows for comparison both within and across different clinical domains (57, 63).

The QALY scale uses utility values, which weight each year of life according to a patients’ preference. These values range from 0 to 1, with 0 meaning the worst possible state (death) and 1 being a state of perfect health. A score on this scale indicates the severity of the health state; for example, 0.9 is a state closer to perfect health, and it therefore has less of an impact on quality of life than 0.2 which is closer to death (60, 61). Alternative treatments for the disease may result in differing QoL outcomes, and these may be reflected in QALY scores. When combined with information on the relative costs of alternatives, the findings can be presented as incremental cost-effectiveness ratios which allow decision-makers to view the cost-effectiveness of competing alternatives. For example, if an individual was given a life
expectancy of 10 years due to their heart condition, but their QoL was only rated at 0.5 on the QALY scale, then $0.5 \times 10 \text{ years} = 5 \text{ QALYs}$. If an intervention does not increase the length of life but increases the QoL to 0.8, then $0.8 \times 10 \text{ years} = 8 \text{ QALYs}$, so they would be rated as having gained 3 QALYs from the intervention. An incremental cost-effectiveness ratio calculates the change in cost divided by the change in benefit (QALY). Therefore, if the cost of the treatment was a one-off expenditure of $10,000, the incremental cost ratio would be $10,000 \div 3 \text{ (QALYs gained)}$ which equates to $3,333$ per QALY (60, 61, 64).

Fig 5 demonstrates the QALYs gained by an individual receiving treatment that increases quality and length of life, compared to an individual who receives no treatment. The y axis shows the health utility value ranging from 1 (perfect health) to 0 (death).

*Figure 5. QALYs: Treatment vs no treatment diagram adapted from Whitehead et.al*
1.5.4 Direct methods for calculating health utility values

There are currently a number of direct and indirect systems for calculating utility or health state values. The most commonly used direct methods are the Standard Gamble (SG) System, the Time Trade Off (TTO) system, and the Visual Analogue Scale (VAS) (60, 61).

The SG system requires participants to indicate the odds at which they would be willing to take a ‘gamble’ on trading their current less-than-perfect health state for a chance at perfect health, but with a risk of a worse outcome (60, 61). Increasing and decreasing the odds between perfect health and death, and identifying at what point participants would be willing to take the gamble on trading their current health state, enables the calculation of a preference score. The underpinning theory for SG is that the worse the current health state, the more likely the individual will risk death to avoid it. This method is very complex, and participants may find it difficult and time consuming to make choices between hypothetical health states that involve a state equivalent to death as a potential outcome. Fig. 6 demonstrates the SG decision making process.

*Figure 6. Standard Gamble Diagram adapted from Drummond et al.*

The TTO method involves participants identifying what amount of time spent living with morbidity would be traded for time spent in perfect health (65). For example, would a person be willing to trade 10 years living with diabetes for 7 years of perfect health? This system includes quality of life as well as length of life. The disadvantages are that individuals may have difficulty in choosing among the variants.
A VAS is an alternative, more simplistic direct method, with participants rating their health on a single line scale that ranges from ‘best imaginable health’ to ‘worst imaginable health’. This system is easier for participants to understand than SG or TTO, however is susceptible to scaling bias, whereby participants are more likely to avoid placing themselves on the extreme ends of the scale (61).

Both the SG and TTO methods have been found to be useful in calculating utility values for adults, but they are not as useful for children. This is due to the latter having neither the cognitive development required to fully comprehend the concept of death as a consequence, nor the ability to rationalise the concept of long-term time trade-offs (56, 60, 66). The lack of a single unit preference measure for children has resulted in proxy reports and expert opinions being used, possibly invalidating the resulting QALY estimate (60).

### 1.5.5 Indirect methods for calculating utility values

Health Utilities (HU) are a commonly used health measure that use an indirect method to calculate utility values. These methods have initially used a recognised direct valuation technique (such as SG, TTO or VAS) with a subgroup of the population, and the findings have been used to calculate preference weights based on the perspectives of that group. These predetermined weights can then be applied to the health utility measure, and used for studies with other similar populations. HU measures can be generic or specific to a disease, and comprise sets of questions focussing on differing health states, designed to elicit from the participants a rating of where they feel their current health state lies. The predetermined preference weights are then applied to the responses, resulting in a utility value that can then be used to calculate a QALY.

Currently there are no oral health specific measures that can produce a preference based utility value. There are, however, generic health utility measures available. Examples of these are the EuroQol (EQ-5D), Assessment of QoL (AQoL), and the Health Utilities Index (HUI).

The EQ-5D is a widely used HU measure for cost utility analysis. It is currently available in 166 language versions (62, 67, 68) and has three forms, the most commonly reported being the original three 3-level version (EQ-5D-3L). It measures three levels of severity across the five domains of mobility, self-care, usual activities, pain/discomfort and anxiety/depression (67-
While the EQ-5D-3L has demonstrated adequate construct validity and reliability, there have been suggestions that it may lack sensitivity, leading to the EuroQoL group developing a five-level version (67, 68, 70). This version still has the same five dimensions, but participants can choose between five levels of severity within each domain instead of three. Values for this version have not yet been developed, but can be mapped to the value sets from the EQ-5D-3L (67).

The AQoL measure was designed to ensure sound construct validity and sensitivity. Originally, it encompassed five dimensions; illness, independent living, social relationships, physical senses and psychological wellbeing. Each dimension had three items and four response options (70, 71). The AQoL is currently available in four versions, which contain either 4, 6, 7 or 8 dimensions. All versions have algorithms that can estimate preference-based utility values for use in economic evaluation (71, 72).

The HUI is a family of measurement systems that is able to calculate health utility values. They are available in three versions, the most commonly used being the Mark 2 (HUI2) and Mark 3 (HUI3). Dimensions within the HUI include vision, hearing, speech, ambulation/mobility, pain, dexterity, self-care, emotion and cognition. Each dimension has between 3 and 6 levels. These measures have demonstrated good construct validity, and acceptable reliability (73).

1.5.6 Mapping OHRQoL measures to HRQoL measures

OHRQoL measures are known to be more sensitive to the impact of oral health on quality of life, but, because they do not have preference weights associated with them, utility values are unable to be produced.

Generic health measures are not as sensitive to a specific disease, because they do not contain disease specific questions. However, they can often identify a change in overall health status, which—if caries data are available—could then be attributed to an individual’s oral health status.

When a generic health measure has associated preference weights, there could be the potential to demonstrate concordance between an oral-health-specific measure and the generic health measure. By using the two measures together, the correlation between them can be explored, and if both are found to be sensitive to oral health status, the oral-health-specific measure could
map to the utility value generated by the generic measure, resulting in a QALY for use in oral health economic evaluation (see fig 7).

Figure 7. Mapping to a QoL measure with preference weights

1.5.6.1 Current literature

In 2006, Brennan et al. reported on a study (involving 375 South Australian adults) investigating linking the Oral Health Impact Profile 14 (OHIP-14) with the generic preference weighted EQ-5D. The OHIP-14 was able to map to the EQ-5D, enabling the calculation of health state values (74).

More recently, two generic health utility measures, the EQ-5D and Adult Quality of Life (AQoL), were compared to the oral-health-specific measure OHIP in 1093 Australian adults aged 30-61 years of age. The OHIP was more responsive to oral-health-related differences; however, both the EQ-5D and AQoL showed some validity, therefore may still be useful in some instances with oral-health-related research (70).
1.5.7 Child health related quality of life measures

There are currently only a few measures designed for use with children and adolescents in determining self-reported general health status. These include the Paediatric Quality of Life Inventory (PedsQL), the EuroQoL Youth (EQ-5D-Y), the CHU-9D, and the KIDSCREEN-52 (69, 75-77).

The PedsQL is a four dimension generic health measure designed for use in children from 2-18 years of age. The measure has demonstrated good construct validity and reliability; however, it relies on parental proxy reports as well as child self-reports (75, 78). Because the scoring algorithm for this measure is not preference-based, it is unable to generate utility values for use in economic evaluation.

The EQ-5D-Y is a modified version of the EQ-5D which was developed in response to the need for a child-appropriate self-reported health measure. This version retained the original five domains and adapted wording to make the questions more understandable for children as young as 8 years of age (69). A limitation of this version is that it is an adaptation of an existing adult measure and therefore did not involve children in the planning and design stage. Involving children at this point can help identify specific areas or domains that are of value to children or adolescents (69). Another limitation is that the aim of creating the EQ-5D-Y was to create a child-friendly self-report health measure, and not necessarily to calculate preference weights. Thus, the ability of the measure to produce utility values has not been fully explored (69, 79).

The KIDSCREEN-52 was the first measure of its kind that was developed using child/adolescent focus groups from multiple European countries as part of its planning. The hypothesis was that this enabled for better translation and relevance among countries and among specific age groups (76). This measure does not have an algorithm that can calculate preference-based utility scores for use in economic evaluation (80).

In response to the need for a child-friendly measure that could be completed by children and to calculate QALYs, an indirect preference-based measure—the CHU-9D—was developed by Stevens (81). This is a relatively new generic HRQoL measure that enables the calculation of utility values (77). The CHU-9D incorporates a holistic view of general health status without
a specific focus on disease (63). Children were involved throughout its development in order to ensure that it is child-centred, and it was designed to be completed by children aged 5 to 11 years (81). The measure is made up of nine dimensions (worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine and activities). Children rate their health state for each dimension by choosing one of five states depicting severity. For example, if the dimension was worried, children would choose between ‘I don’t feel worried today’, ‘I feel a little bit worried today’, ‘I feel a bit worried today’, ‘I feel quite worried today’ or ‘I feel very worried today’. Each dimension has been tested using the SG method with adults, and preference weights were able to be calculated for each health state as defined within the CHU-9D (77). Ratcliffe et al. tested the construct validity of the CHU-9D in a 2011 study with Australian adolescents aged 11-17 years. Although this measure was not developed for this age group, it still showed that it was able to discriminate among participants according to their self-reported general health (82).

In 2012, a study by Foster Page et al. compared the sensitivity of the generic health measure CHU-9D with the oral-health-related CPQ, with 140 NZ children aged between 6 and 9. Participants were part of a convenience sample of Dunedin children attending for their routine dental examinations (63). The CPQ was more sensitive than the CHU-9D specifically to dental caries, which was expected; however, the CHU-9D was still able to demonstrate a small association in the hypothesised direction, although it was not statistically significant (63). Dunedin has one of the lowest caries rates in New Zealand and this may have affected the measures’ ability to detect the impact of dental caries. Both the CHU-9D and the CPQ showed statistically significant associations with the global health question looking at impact of oral health on life, indicating that the CHU9D may be useful in future dental research.

1.5.8 Measuring responsiveness

As of 2015, the CHU-9D has never been assessed for its responsiveness to oral health status; that is, its ability to detect change in oral health over time. Repeat administration of this measure, along with collection of clinical caries data within a cohort, could allow for the detection of minimally important differences (MID) arising from treatment regimens and/or changing oral health status (83). The MID is defined as “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” (84). This varies from the previous ‘clinically important difference’ which only considered clinical data, omitting patient preferences and thereby excluding the opinions of the very people to whom the intervention would be important to (84).

1.5.9 Minimally important difference

The MID is an important concept for oral health research because it provides researchers with a tool to measure changes or differences in oral health over time, incorporating both clinical outcome measures and patient-centred perspectives (83). The CHU-9D measure’s responsiveness to oral health status has never been evaluated, and if the CHU-9D proved responsive, the findings would support its use as an outcome measure, and this which would then enable cost-utility analysis to be used in healthcare resource allocation decisions.
This thesis comprises two studies

Study 1: To investigate the development of quality adjusted life years (QALY) for oral health quality of life measures (CPQ\textsuperscript{11-14} ISF:16), using a general health measure (CHU-9D) as a proxy.

The aims of this study were:

1. To determine whether there is concordance between the CPQ\textsubscript{11-14}ISF:16, CPQ\textsubscript{8-10} and CHU-9D; and
2. If concordance is found, to consider whether the utility value produced by the general health measure could then be mapped to the oral health measure, resulting in a QALY for use in oral health economic evaluation.

Study 2: To investigate whether the CHU-9D can be used as a QoL measure for longitudinal oral health research.

The aims of this study were:

1. to determine whether the CHU-9D is sensitive to caries experience; and
2. to investigate whether the CHU-9D is responsive to changing caries experience over time.
Chapter 2: Method

2.1 General approach to the investigation

Both studies utilise information extracted from an existing data set collected within a randomised controlled trial (RCT), the Proximal Resin Infiltrant New Zealand (PRINZ) study. The PRINZ study is investigating the long term effectiveness of interproximal resin sealants, compared to traditional fluoride application, in preventing the progression of early enamel and dentine lesions in primary molars. The study commenced in 2012 and is ongoing.

Ethical approval was obtained from the Upper South A Regional Ethics Committee (URA/11/08/037).

Written parental consent and child assent was obtained.

2.2 Sampling Procedure

2.2.1 Sample size

In 2012, there were 11 Dunedin primary schools assigned to receive their dental care with the Bachelor of Oral Health (BOH) programme at the Faculty of Dentistry. Approximately 1000 children attended these schools at that time. The PRINZ study selected these schools because they represented a good cross-section of the Dunedin socio-demographic population.

Sample size calculation for the PRINZ study was based on the following parameters. Paired observations (split-mouth design), alpha = 5\%, 1 – beta = 80\%, and clinically relevant effect not to be missed = 2\%. Using the McNemar test for differences in proportions for the paired-sample design, the calculated sample size needed was 68 participants after drop-out, with an expected drop-out rate of 30\% over two years. A total of 89 children between the ages of 7 and 11 were included in the PRINZ study.

Because sample size calculations were made for the original PRINZ RCT, no power calculation was possible for the current work which used data from that study.
2.2.2 Sample strategy

Dunedin children aged between seven and nine were invited to participate in the PRINZ study. Children with compromised medical history were excluded. Participating schools were located in various areas of socio-economic deprivation within Dunedin city. Data on socio-demographic characteristics were recorded. Baseline examinations were conducted throughout 2012 and 2013.

Children with two radiographic lesions confined to the outer dentine or enamel (P3/P3) were included in the trial. The PRINZ study used a randomised split mouth technique whereby one lesion received the intervention (interproximal sealant), and the other became the control (fluoride application). Both teeth were followed six monthly until natural exfoliation. The length of time for each child in the study was dependent on the age of the child, and the stage of tooth development at the time of each baseline exam (as well as the tooth selected for the PRINZ study). For example, participants who were 9 or 10 years of age at baseline, typically had less time until their primary teeth exfoliated than children who were 7 years of age. The first primary molar exfoliates before the second primary molar, so for a 9-year-old in the study with first primary molars as the study teeth, there may be as little as 12 months before these teeth exfoliate and they are no longer followed up in the PRINZ study. Other children included at 7 years of age could potentially have up to five years before the study teeth exfoliate. For this reason, the longitudinal data collected for each participant is over varying time periods.

2.3 Caries data

Comprehensive baseline and recall dental examinations were conducted at one of two locations; the Brockville Community Satellite clinic—which is based in Brockville—and onsite at the Faculty of Dentistry. Children attending Brockville school, were seen at the satellite clinic which is located on the grounds of Brockville school.

2.3.1 Visual examination

Participants were given a comprehensive dental examination by one of two trained and calibrated dental therapists working within the BOH programme. Visual examination was conducted using a standard overhead light using a flat dental mirror, explorer and triplex air
syringe. Teeth were washed and dried, and cotton roll isolation used as required to maintain a dry field. Residual interproximal plaque was removed with an explorer or dental floss. Caries was classified clinically, by assessing the appearance of the tooth tissues. An explorer was used without pressure to evaluate the integrity of the tooth surface. Each surface was visually assessed and recorded as sound, stained, demineralised with no underlying shadow, or shadowed. Physical breakdown of the tissues were classified as either initial breakdown of enamel, open cavitation into dentine or large cavitation with obvious signs of pulp involvement.

2.3.2 Radiographic observations

At baseline, digital radiographs were taken using a standardised bitewing holder. A size 0 or 1 film was used, as appropriate for the size of the child’s mouth. Radiographs were retaken 12 monthly, with additional radiographs taken 6-monthly if clinically indicated.

Radiographic evidence of caries was classified using Mejåre’s caries classification system as follows. P0: no caries. P1: caries in the outer half of the enamel. P2: Caries extends to inner half of enamel but not into dentine. P3: Caries has reached the dentine without obvious spread into the dentine. P4: Caries into the dentine with obvious spread located within the first half of the dentine. P5: Caries has extended over half way through the dentine (see fig 8).

Fig 8. Mejåre caries classification system.

2.3.3 Dental health data

Dental health data were collected by calculating the number of decayed, missing or filled surfaces for both primary and permanent dentition (dmfs/DMFS index). Carious surfaces were identified using both visual and radiographic evidence, to enable identification of caries to a P3 level. Occlusal caries lesions that were clinically obvious, but with no clear radiographic
radiolucency, were classified as P3 (into dentine), some occlusal caries is often not visible on radiographs until the lesion is very advanced (85). If no radiographs were taken because the examination was on a 6, 18 or 30 month recall, radiographs taken at the previous examination were used. Carious lesions at a P3 level were either treated conservatively with topical fluoride, or restored. This was dependent on the caries risk status of the child, and the length of time left before tooth exfoliation. Because participants are in the process of primary tooth exfoliation and permanent tooth eruption throughout the duration of this study, the number of primary teeth remaining and permanent teeth erupted was recorded at each examination appointment. This allowed for a calculation of the number of both primary and permanent surfaces present in the mouth at each given time, so that a percentage of affected primary and secondary surfaces could be calculated. If teeth had been extracted, they were recorded as five ‘missing’ surfaces until the successor erupted.

The number of decayed, missing and filled surfaces for primary and permanent dentition were combined to enable a dmfs/DMFS calculation that represented the whole mouth.

2.4 Sociodemographic characteristics

Baseline demographic information was obtained at each child’s initial examination. Parents completed a questionnaire that included information on sex, age, ethnicity and socio-economic status. In both studies, ethnicity was recorded as NZ European, NZ Māori, Pacific Island or Other.

Deprivation was measured using the NZDep2006 Index of Deprivation (86). This is an updated version of the NZ Dep2001, NZ Dep96 and NZ Dep 91. This area-based measure combines Census data reflecting eight dimensions of material and social deprivation within a mesh block (86). A mesh block is a geographical area as defined by Statistics NZ. In 2006, the median number of people in each mesh block was 87 (86). The dimensions included in the analyses were income, employment, qualifications, home ownership, living space, transport, communication, and support. The variables in decreasing order of weight were:

People aged 18-64 receiving a means tested benefit,
People living in households with income below an income threshold,
People not living in own home,
People aged <65 living in a single parent family,
People aged 18-64 unemployed,
People aged 18-64 without any qualifications,
People living in households below a bedroom occupancy threshold,
People with no access to a telephone,
People with no access to a car.

The NZDep 2006 produces a deprivation score ranging from 1 to 10, with 1 representing the least deprived 10% of areas of NZ, and 10 representing the most deprived 10% of areas of NZ. A score of 1-3 has been classified as an area of “low deprivation”, 4-7 classified as an area of middle deprivation, and 8-10 classified as an area of high deprivation (86).

2.5 Quality of Life Measures

2.5.1 HRQoL

The generic ‘health state’ of each participant was measured using the CHU9D (77). Participants provided information on how they felt ‘today’. Nine dimensions were examined; worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine and activities. Participants rated their health state for each dimension by choosing one of five states depicting severity. The response options and initial score rating were “I don’t feel (1)”, I feel a little bit (2)”, I feel a bit (3)”, “I feel quite (4)”, or “I feel very (5)”. Each dimension has been tested using the SG method, and preference weights have been applied for each health state as defined within the CHU9D (see Appendix 3 for Stata code). Resulting scores from each health state have been combined, resulting in a utility value which sits on a scale ranging between 0 and 1, representing the overall health of the participant: a value of 1 represents perfect health, and a value of 0 is considered the equivalent of death.

The CHU9D was administered periodically throughout the study, at participants’ recall dental examinations. There was at least 6 months between each administration of the CHU9D, and up to four time points recorded for each participant, depending on the length of time they were in the PRINZ study.

2.5.2 OHRQoL

The ‘oral health state’ for each child was measured using both the CPQ11-14-ISF:16 and CPQ 8-10 (47, 49, 87). Because many of the questions were common to both measures, overlap
between the two allowed for the formulation of one questionnaire, consisting of a standardised set of 28 questions that included both the CPQ11–14-ISF:16 and CPQ 8-10 (Table 1) (49).

Participants provided information on the frequency of events in the previous four weeks. Response options and scores were: “Never” (scoring 0); “Once or twice” (1); “Sometimes” (2); “Often” (3); and “Every day or almost every day” (4). CPQ11–14-ISF:16 and CPQ 8-10 scores were computed by summing all of the item scores specific to each, and subscale scores (for four domains) were also computed. Item weights were not used. The four subscales were Oral Symptoms (OS), Functional Limitations (FL), Emotional Wellbeing (EW), and Social Wellbeing (SW). The number of items within each domain differed between the two measures, with the CPQ11–14-ISF:16 having four items per domain, and CPQ 8-10 having five for OS, FL and EW, and 10 for SW (Table 1).

Younger children were given assistance in reading questions if required, but not in responding.
**Figure 8. Comparison of the item content of the CPQ$_{8-10}$ and the CPQ$_{11-14}$**

In the past 4 weeks, how often have you (had/been) because of your teeth/mouth

<table>
<thead>
<tr>
<th>Domain</th>
<th>CPQ11-14ISF:16-specific items</th>
<th>Items common to CPQ$<em>{11-14}$ISF:16 and CPQ$</em>{8-10}$</th>
<th>CPQ$_{8-10}$ specific items</th>
</tr>
</thead>
<tbody>
<tr>
<td>OS</td>
<td>Pain in teeth/mouth</td>
<td>Difficulty eating, drinking hot/cold foods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bad breath</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouth sores</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Food caught between teeth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FL</td>
<td>Difficulty eating/drinking hot/cold foods</td>
<td>Difficulty chewing firm foods</td>
<td>Trouble sleeping</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficulty saying words</td>
<td>Trouble eating foods you like</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Taken longer to eat a meal</td>
<td></td>
</tr>
<tr>
<td>EW</td>
<td>Upset</td>
<td>Worried not at good looking</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Felt irritated/frustrated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Felt shy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concerned what people think about teeth/mouth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SW</td>
<td>Argued with children/family</td>
<td>Not wanted to speak/read loud in class</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Teased/called names</td>
<td>Missed school</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Avoided smiling/laughing</td>
<td>Hard time doing your homework</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asked questions</td>
<td>Hard time paying attention in school</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stayed away from activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Avoided being with other children</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Avoided talking with other children</td>
<td></td>
</tr>
</tbody>
</table>
Both the CPQ<sub>11–14</sub>-ISF:16 and CPQ<sub>8–10</sub> measures were issued at two time points; baseline, and at the conclusion of the study. The period of time between these two points ranged from 12 to 36 months, depending on the time the participant was in the study.

2.5.3 Global health

Children’s perceptions of their oral health were assessed using two global measures that were included in the combined CPQ<sub>11–14</sub>-ISF:16 and CPQ<sub>8–10</sub>. First they were asked to rate the health of their teeth, lips, jaws and mouth (response option: ‘Very good’, ‘Good’, ‘OK’ and ‘Poor’, scoring 1-4 respectively). Secondly, they were asked how much their teeth, lips, jaw or mouth affected their life overall (response options: ‘Not at all’, ‘A little bit’, ‘Some’ and ‘A lot’, scoring 1 – 4 respectively).

2.5.4 Test-retest reliability

The test-retest reliability of the CPQ<sub>11–14</sub>-ISF:16 and CPQ<sub>8–10</sub>, along with global health questions, were examined by reissuing the measure 1 to 2 weeks after the conclusion of the study to 20% of the participants.

2.6 Inclusion Criteria

2.6.1 Study 1

Investigating the availability of QALYs for oral health quality of life measures (CPQ<sub>11–14</sub>-ISF:16), using a general health measure (CHU-9D) as a proxy.

Participants were included in this study if they had completed a baseline CPQ measure, and had corresponding CHU-9D and clinical data from a comprehensive dental examination.

2.6.2 Study 2

Investigating whether the CHU-9D can be used as a QoL measure for longitudinal oral health-related research.
Participants were included in this study if they had completed at least one follow-up CHU-9D measure at a recall dental examination. Data from up to four recall examinations with matching CHU-9D scores were included in the analysis.

2.7 Data analysis

Data at all time points were merged and analysed using Stata Version 13.1 (88). Logic checks were performed, and the data set ‘cleaned’ as necessary. Descriptive statistics were produced, and bivariate analyses used chi-square tests associations between independent variables where appropriate. Because caries and QoL data was highly skewed, non-parametric tests (such as the Kruskal-Wallis H-test, Mann-Whitney U-test or Wilcoxin Signed-Rank test) were used to test the statistical significance of apparent differences between groups. A p-value of <0.05 was deemed statistically significant.

2.7.1 Dental caries

Carious lesions were counted if they were visible radiographically at a P3, P4, or P5 level, or if there were obvious clinical signs of caries into dentine. Caries scores were computed by summing the surfaces that presented as decayed into dentine (P3), missing or filled, to give separate dmfs and DMFS scores. Primary and permanent caries data were then combined to produce an overall dmfs/DMFS score that represented the whole mouth.

The dmfs/DMFS scores were divided into tertiles, and categorised into low, medium and high caries experience; low being a combined dmfs/DMFS of 0-2, medium 3-7, and high 8+.

Carious lesions were categorised as ‘No active caries’, ‘1 decayed surface’, ‘2 decayed surfaces’ or ‘3+ decayed surfaces’.

2.7.2 QoL measures

2.7.2.1 CPQ$_{11-14}$ISF:16 and CPQ$_{8-10}$

Individual participant scores were summed within each domain, and then a combined score of all domains was calculated to represent the overall QoL of each participant. The internal consistency/reliability of the items within each domain of the CPQ$_{11-14}$ISF:16 and CPQ$_{8-10}$ was examined using Cronbach’s alpha (α).
2.7.2.2 CHU-9D

CHU-9D scores were calculated for each health state. Pre-existing preference weights were applied to these scores to produce an overall utility value for each participant ranging from 0 to 1 (1 representing perfect health, 0 representing a state equivalent to or worse than death).

2.7.3 Sociodemographic characteristics

For both studies, caries data was analysed by sociodemographic characteristics, determine the association between caries experience and ethnicity, sex, age, and deprivation. These data are reported separately for the primary and permanent dentitions.

2.7.4 Study 1

CPQ and CHU-9D scores were examined by sociodemographic characteristics to identify whether there was a difference in mean CPQ and CHU-9D by those.

To determine whether the CHU-9D reflected a similar health state as the two CPQ measures, scores for each measure were presented by caries experience, to determine whether participants with the greatest burden of disease reported the greatest impact on quality of life across all measures.

Scatterplots were used to determine the degree of concordance between the CHU-9D, and both the CPQ11-14ISF:16 and CPQ8-10 at baseline and exit. Correlation at Time 1 and on exit was measured between both CPQ measures and the CHU-9D.

Global health questions were sorted by CPQ11-14ISF:16 and CPQ8-10 scores, to ascertain whether participants’ own perceptions of their oral health, and impact of oral health on their quality of life, were reflected in their OHRQoL scores.

Test/retest analysis was conducted on approximately 20% of participants, who completed the measures again 1-2 weeks after the final measure. Internal consistency correlation was calculated to determine if participants’ answers changed between the two times.
2.7.5 **Study 2**

The CHU-9D was reported by socio-demographic characteristics and caries experience, to identify if sex, age, ethnicity, deprivation or caries experience influenced QoL.

To compare the responsiveness of the measure over time, mean scores across each of the four time periods were analysed by sociodemographic characteristics and caries experience.
Chapter 3: Results

3.1 Analysis of participation rate

An information sheet, along with parental consent and child assent forms, was mailed out to 226 children throughout 2012, and 118 throughout 2013. The response rates to the mail-outs are shown in Table 1.

Table 1. Summary of mail-out responses in 2012 and 2013

<table>
<thead>
<tr>
<th>Response Type</th>
<th>2012 Mail-out Number (%)</th>
<th>2013 Mail-out Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent given to examine</td>
<td>149 (66)</td>
<td>79 (67)</td>
</tr>
<tr>
<td>Consent refused</td>
<td>15 (7)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>No response</td>
<td>62 (27)</td>
<td>35 (30)</td>
</tr>
<tr>
<td>Total</td>
<td>226 (100)</td>
<td>118 (100)</td>
</tr>
</tbody>
</table>

Table 2 shows a summary of responses overall for 2012 and 2013, including full consent to participate, consent refused, and those who did not respond to the mail-out. 222 participants agreed to be involved in the study, and were offered an initial assessment (including collection of baseline demographic information and a clinical and radiographic examination).

Table 2. Summary of both mail-outs

<table>
<thead>
<tr>
<th>Response</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent given to examine</td>
<td>228 (66)</td>
</tr>
<tr>
<td>Consent refused</td>
<td>19 (6)</td>
</tr>
<tr>
<td>No response</td>
<td>97 (28)</td>
</tr>
<tr>
<td>Total</td>
<td>344 (100)</td>
</tr>
</tbody>
</table>

The overall response rate is shown in Table 3. There were 228 children for whom parent consent and child assent was received. One child failed to attend the initial examination/assessment appointment, and three were unable to cope with the standardised
intra-oral radiograph equipment and therefore could not complete the required assessment. Six children withdrew consent at the examination appointment.

Table 3. Overall response rate

<table>
<thead>
<tr>
<th>Response rate</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent given to examine</td>
<td>228 (66)</td>
</tr>
<tr>
<td>Children examined</td>
<td>218 (96)</td>
</tr>
<tr>
<td>Children not examined</td>
<td>10 (4)</td>
</tr>
<tr>
<td>Consent refused</td>
<td>19 (6)</td>
</tr>
<tr>
<td>No Response</td>
<td>97 (28)</td>
</tr>
<tr>
<td>Total</td>
<td>344 (100)</td>
</tr>
</tbody>
</table>

3.1.1 PRINZ trial

After assessment, 93 children were eligible for inclusion in the PRINZ study. Two children withdrew due to not wanting to have the intervention treatment, and 91 children were subsequently included in the study.

The participation rate for both studies that utilise the data from the PRINZ trial is shown in Table 4.

3.1.2 Study 1 participation

There were missing baseline CPQ data for nine children in the PRINZ study. Thus, of the 91 children subsequently included in the RCT, only 82 (90%) had completed baseline questionnaires, and had clinical data.
3.1.3 **Study 2 participation**

To be eligible for the second study, longitudinal data were required. 87 children had completed a CHU-9D measure at baseline, as well as at least one follow up CHU-9D measure at a recall dental examination.

*Table 4. Participation rate for Study 1 and Study 2*

<table>
<thead>
<tr>
<th>Participants</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Included in PRINZ study</td>
<td>91 (100)</td>
</tr>
<tr>
<td>Missing baseline OHRQoL measures</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Missing follow up CHU-9D measures</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Total included in Study 1.</td>
<td>82 (85)</td>
</tr>
<tr>
<td>Total included in Study 2.</td>
<td>87 (97)</td>
</tr>
</tbody>
</table>

3.2 **Baseline Data: Study 1**

3.2.1 **Sociodemographic information**

Sociodemographic information is shown by clinical characteristics for children who completed the CPQ11-16SF:16 and CPQ8-10 at baseline in Table 5. There were 82 participants, with a similar number of girls and boys. Children were aged between seven and ten, with more than two-thirds (75%) being eight or nine. More than two thirds of the children identified as NZ European, with less than one in five (17%) being NZ Māori. There were slightly more children living in areas of medium deprivation, with similar numbers residing in low and high deprived areas (28% and 32% respectively).

3.2.2 **Dental caries**

The baseline dental caries experience is summarised by sociodemographic characteristics in Table 5. The overall mean dmfs in the primary dentition was 6.4 (SD = 6.8), and their scores ranged from 0 to 28. Fewer than one-fifth presented as having no detectable carious lesions. Caries experience was lower for NZ European participants and those living in areas of low deprivation. The mean dmfs score in the primary dentition was greater for males, Pacific
Islanders, and those living in areas of high deprivation. Caries experience in the permanent dentition was low, with no children presenting with a DMFS score above 4.

There were no statistically significant differences in caries experience by sex, age, deprivation or ethnicity.
## Table 5. Baseline dental caries experience by sociodemographic characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Caries Free Primary Teeth&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Mean dmfs (SD)</th>
<th>Range of observed dmfs scores</th>
<th>Caries Free Permanent Teeth&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Mean DMFS (SD)</th>
<th>Range of observed DMFS scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>82 (100)</td>
<td>15 (18)</td>
<td>6.4 (6.8)</td>
<td>70 (85)</td>
<td>0.2 (0.6)</td>
<td>0 to 4</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44 (54)</td>
<td>8 (18)</td>
<td>7.5 (7.9)</td>
<td>38 (86)</td>
<td>0.1 (0.3)</td>
<td>0 to 1</td>
</tr>
<tr>
<td>Female</td>
<td>38 (46)</td>
<td>7 (18)</td>
<td>5.1 (4.9)</td>
<td>32 (84)</td>
<td>0.3 (0.8)</td>
<td>0 to 4</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 to 8</td>
<td>39 (48)</td>
<td>8 (21)</td>
<td>6.5 (6.9)</td>
<td>33 (85)</td>
<td>0.3 (0.8)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>9 to 10</td>
<td>43 (52)</td>
<td>7 (16)</td>
<td>6.3 (6.8)</td>
<td>37 (86)</td>
<td>0.2 (0.4)</td>
<td>0 to 2</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>58 (70)</td>
<td>11 (19)</td>
<td>5.9 (6.5)</td>
<td>52 (90)</td>
<td>0.2 (0.6)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>14 (17)</td>
<td>4 (29)</td>
<td>7.3 (9.0)</td>
<td>10 (71)</td>
<td>0.4 (0.6)</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>6 (7)</td>
<td>0 (0)</td>
<td>8.5 (4.5)</td>
<td>4 (67)</td>
<td>0.7 (1.0)</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>0 (0)</td>
<td>7.5 (5.5)</td>
<td>4 (100)</td>
<td>0.0 (0.0)</td>
<td>0 to 0</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>23 (28)</td>
<td>4 (17)</td>
<td>5.0 (4.6)</td>
<td>22 (96)</td>
<td>0.0 (0.2)</td>
<td>0 to 1</td>
</tr>
<tr>
<td>Medium</td>
<td>33 (40)</td>
<td>8 (24)</td>
<td>6.1 (7.5)</td>
<td>28 (85)</td>
<td>0.2 (0.4)</td>
<td>0 to 1</td>
</tr>
<tr>
<td>High</td>
<td>26 (32)</td>
<td>3 (12)</td>
<td>8.2 (7.3)</td>
<td>20 (77)</td>
<td>0.5 (1.0)</td>
<td>0 to 4</td>
</tr>
</tbody>
</table>

<sup>a</sup>No apparent decayed, missing, filled surfaces in primary teeth at baseline

<sup>b</sup>No apparent Decayed, Missing, Filled Surfaces in permanent teeth at baseline
3.2.3 **OHRQoL**

Mean baseline scores for the CPQ₁₁⁻₁₄ISF:16, CPQ₈⁻₁₀ and their subscales are shown in Table 6. For this measure, the higher the score, the greater the impact on quality of life.

3.2.4 **CPQ₁₁⁻₁₄ISF:16**

The mean score was 11.7 (SD 8.6), with the range of observed scores between 0 and 43. No participants had the maximum score of 64, and only two (2%) had a score of 0. The subscale with the highest mean score was OS, followed by FL, EW and then SW.

For the CPQ₁₁⁻₁₄ overall, Cronbach’s alpha was 0.80, indicating acceptable reliability. When looking at subscales, the individual scores were lowest for the OS and FL at 0.44 and 0.57 respectively.

3.2.5 **CPQ₈⁻₁₀**

The overall mean score was 14.8 (1.9), with the range of observed scores between 0 and 53 (Table 6). The domain with the highest score was OS, and the lowest was EW. One participant had a score of 0, and no child had the maximum score of 100. Overall, Cronbach’s alpha was slightly lower for the CPQ₈⁻₁₀ than the CPQ₁₁⁻₁₄ at 0.76, although still indicating acceptable reliability. Individual alpha scores were lowest for the OS subscale at 0.54, with all other subscale scores close to or above 0.70.
Table 6. Summary data on the CPQ11-14SF:16, CPQ8-10 and their subscales at baseline

<table>
<thead>
<tr>
<th></th>
<th>Number of items</th>
<th>Mean score (SD)</th>
<th>Cronbach's alpha (α)</th>
<th>Range of observed scores</th>
<th>Number with score 0 (%)</th>
<th>Number with maximum score (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPQ11-14</td>
<td>16</td>
<td>11.7 (8.6)</td>
<td>0.80</td>
<td>0 to 43</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral symptoms</td>
<td>4</td>
<td>4.5 (2.6)</td>
<td>0.44</td>
<td>0 to 10</td>
<td>3 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Functional limitations</td>
<td>4</td>
<td>3.5 (3.0)</td>
<td>0.57</td>
<td>0 to 11</td>
<td>16 (20)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>4</td>
<td>2.2 (2.8)</td>
<td>0.71</td>
<td>0 to 14</td>
<td>32 (39)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Social well-being</td>
<td>4</td>
<td>1.5 (2.5)</td>
<td>0.69</td>
<td>0 to 11</td>
<td>41 (50)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>CPQ8-10</td>
<td>25</td>
<td>14.8 (11.9)</td>
<td>0.76</td>
<td>0 to 53</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral symptoms</td>
<td>5</td>
<td>5.7 (3.3)</td>
<td>0.54</td>
<td>0 to 13</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Functional limitations</td>
<td>5</td>
<td>3.1 (3.5)</td>
<td>0.68</td>
<td>0 to 16</td>
<td>25 (30)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>5</td>
<td>2.8 (3.4)</td>
<td>0.78</td>
<td>0 to 18</td>
<td>28 (34)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Social well-being</td>
<td>10</td>
<td>3.1 (4.3)</td>
<td>0.76</td>
<td>0 to 18</td>
<td>35 (43)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
3.2.6 Mean scores by sociodemographic information and caries experience

3.2.6.1 OHRQoL measures

The baseline data for both the CPQ8-10 and CPQ11-14ISF:16 are summarised by caries experience is shown in Table 7. Overall, there was a consistent gradient from caries-free to those children with the greatest burden of disease, although the differences were not statistically significant.

When examining deprivation, there was no gradient from least deprived, to most deprived, with those living in areas of low deprivation scoring higher than those living in areas of medium deprivation. While participants living in high areas of deprivation did score highest across both measures, the differences were not statistically significant.

There were no statistically significant differences when examining age, sex or ethnicity for either the CPQ8-10 or the CPQ11-14.

3.2.6.2 HRQoL measures

The baseline data for the CHU-9D are shown by caries experience in Table 7. The CHU-9D showed utility values that appear inconsistent in relation to caries experience. A gradient was present whereby children with less caries severity had lower CHU-9D scores, and those with greater severity presented with higher scores; however, this gradient appeared to be in the opposite direction than what could be expected, since children with greater caries severity had a better QoL score than those with less caries severity. When we look at ethnicity, ‘NZ Māori’ and ‘Other’ had lower CHU-9D scores than Pacific Island and NZ European participants, but these differences were not statistically significant. Participants living in the least areas of deprivation scored slightly lower than those living in areas of medium and high deprivation, but again these differences were not statistically significant.
Table 7. Baseline mean CPQ_{8-10} and CPQ_{11-14} scores and CHU9D by sociodemographic characteristics and caries experience (SD)

<table>
<thead>
<tr>
<th></th>
<th>Number (%)</th>
<th>CHU9D</th>
<th>CPQ_{8-10}</th>
<th>CPQ_{11-14}</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>82 (100)</td>
<td>0.88 (0.09)</td>
<td>14.8 (11.9)</td>
<td>11.7 (8.6)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boy</td>
<td>44 (54)</td>
<td>0.88 (0.08)</td>
<td>13.0 (10.1)</td>
<td>10.8 (8.1)</td>
</tr>
<tr>
<td>Girl</td>
<td>38 (38)</td>
<td>0.89 (0.09)</td>
<td>16.9 (13.5)</td>
<td>12.8 (9.2)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 to 8</td>
<td>39 (47)</td>
<td>0.87 (0.08)</td>
<td>18.2 (11.4)</td>
<td>13.9 (7.7)</td>
</tr>
<tr>
<td>9 to 10</td>
<td>43 (43)</td>
<td>0.89 (0.10)</td>
<td>11.8 (11.6)</td>
<td>9.7 (9.0)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>58 (71)</td>
<td>0.88 (0.08)</td>
<td>13.7 (10.3)</td>
<td>11.0 (7.6)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>14 (17)</td>
<td>0.90 (0.10)</td>
<td>18.2 (15.6)</td>
<td>14.2 (12.4)</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>6 (7)</td>
<td>0.84 (0.11)</td>
<td>22.5 (16.4)</td>
<td>15.2 (9.1)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>0.95 (0.06)</td>
<td>8.6 (4.7)</td>
<td>7.3 (2.9)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>23 (28)</td>
<td>0.86 (0.08)</td>
<td>13.4 (8.3)</td>
<td>11.1 (5.9)</td>
</tr>
<tr>
<td>Medium</td>
<td>33 (40)</td>
<td>0.89 (0.09)</td>
<td>11.1 (8.3)</td>
<td>9.0 (6.2)</td>
</tr>
<tr>
<td>High</td>
<td>26 (32)</td>
<td>0.89 (0.09)</td>
<td>20.7 (15.9)</td>
<td>15.6 (11.7)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Full dentitiona</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caries-freeb</td>
<td>14 (17)</td>
<td>0.85 (0.10)</td>
<td>9.5 (7.4)</td>
<td>7.8 (5.3)</td>
</tr>
<tr>
<td>dmfs/DMFS 0 -2</td>
<td>26 (32)</td>
<td>0.86 (0.09)</td>
<td>13.1 (11.1)</td>
<td>10.3 (8.1)</td>
</tr>
<tr>
<td>dmfs/DMFS 3 - 7</td>
<td>29 (35)</td>
<td>0.90 (0.08)</td>
<td>14.0 (9.6)</td>
<td>11.6 (7.4)</td>
</tr>
<tr>
<td>dmfs/DMFS 8+</td>
<td>27 (32)</td>
<td>0.88 (0.08)</td>
<td>17.4 (14.5)</td>
<td>13.2 (10.3)</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Full dentition active caries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No active caries</td>
<td>32</td>
<td>0.87 (0.10)</td>
<td>12.5 (9.9)</td>
<td>10.3 (7.7)</td>
</tr>
<tr>
<td>1 ‘d’ surface</td>
<td>20</td>
<td>0.87 (0.07)</td>
<td>14.7 (14.6)</td>
<td>11.4 (11.1)</td>
</tr>
<tr>
<td>2 ‘d’ surfaces</td>
<td>11</td>
<td>0.90 (0.08)</td>
<td>16.2 (12.4)</td>
<td>11.7 (7.3)</td>
</tr>
<tr>
<td>3+ ‘d’ surfaces</td>
<td>19</td>
<td>0.89 (0.08)</td>
<td>18.1 (11.5)</td>
<td>14.3 (7.8)</td>
</tr>
</tbody>
</table>

aPrimary and permanent dentition combined
bNo caries in mixed dentition (dmfs/DMFS = 0)
Low Caries – dmfs/DMFS 0 to 2
Medium Caries – dmfs/DMFS 3 to 7
High Caries – dmfs/DMFS 8+
Untreated caries – decay only in mixed dentition

3.2.7 Attrition analysis

The demographic and caries data for participants who did not complete the first study is shown in Table 8. Seven participants (9%) were lost from the study between baseline and exit. These
were two boys and five girls; five were NZ European, and two were from an area of high deprivation. Six of the seven children had experienced caries in their primary dentition, with the mean baseline dmfs of those lost being 3.0 (SD: 2.0). The mean baseline dmfs for those who remained in the study was 6.7 (SD: 7.0). Mean DMFS was very low for those remaining in the study and those lost, at 0.2 (0.6) and 0.3 (0.8) respectively. Of the seven participants lost, three left the PRINZ study before an exit CPQ measure could be administered, two moved out of the Otago region and two withdrew. Numbers of participants lost from the study were small, and there were no significant differences between children who were lost and children who were followed up.
Table 8. Attrition analysis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Time 1 sample</th>
<th>Followed up</th>
<th>Lost to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>All</td>
<td>82 (100)</td>
<td>75 (91)</td>
<td>7 (9)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boy</td>
<td>44 (54)</td>
<td>42 (56)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Girl</td>
<td>38 (46)</td>
<td>33 (44)</td>
<td>5 (71)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 &amp; 8</td>
<td>39 (48)</td>
<td>34 (45)</td>
<td>5 (71)</td>
</tr>
<tr>
<td>9 &amp; 10</td>
<td>43 (52)</td>
<td>41 (55)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>58 (70)</td>
<td>53 (71)</td>
<td>5 (71)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>14 (17)</td>
<td>13 (17)</td>
<td>1 (14)</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>6 (7)</td>
<td>5 (7)</td>
<td>1 (14)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>4 (5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>23 (28)</td>
<td>21 (28)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Med</td>
<td>33 (40)</td>
<td>30 (40)</td>
<td>3 (43)</td>
</tr>
<tr>
<td>High</td>
<td>26 (32)</td>
<td>24 (33)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Caries prevalence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary caries prevalence(^a)</td>
<td>67 (82)</td>
<td>61 (81)</td>
<td>6 (86)</td>
</tr>
<tr>
<td>Permanent caries prevalence(^b)</td>
<td>12 (15)</td>
<td>11 (15)</td>
<td>1 (14)</td>
</tr>
<tr>
<td>Caries severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean dmfs (SD) at baseline</td>
<td>6.4 (6.8)</td>
<td>6.7 (7.0)</td>
<td>3.0 (2.0)</td>
</tr>
<tr>
<td>Mean DMFS (SD) at baseline</td>
<td>0.6 (1.5)</td>
<td>0.2 (0.6)</td>
<td>0.3 (0.8)</td>
</tr>
</tbody>
</table>

\(^a\)Number of participants with decayed, missing or filled primary surfaces at baseline

\(^b\)Number of participants with Decayed, Missing or Filled permanent surfaces at baseline
3.3 Exit Data: Study 1

3.3.1 Mean scores by sociodemographic information and caries experience

3.3.1.1 OHRQoL

A gradient from those who have never experienced caries, to those with the greatest burden of disease no longer exists (Table 9). The CPQ_{11-14}:ISF:16 did demonstrate an increase in score from caries-free at 6.7 (SD 6.9) to those with medium caries at 8.4 (SD 6.2), however participants with the highest caries experience reported a better QoL, with a score of 6.9 (SD 5.5). For the CPQ_{8-10}, the scores are irregular, with caries-free participants having a mean of 8.4 (SD 9.8), increasing to 10.0 (SD 8.2) for those with medium caries experience, but then dropping to 7.4 (6.5) for those with the greatest burden of disease. The differences in caries experience for both the CPQ_{8-10} and CPQ_{11-14}:ISF:16 were not statistically significant.

3.3.1.2 HRQoL

CHU-9D scores were inconsistent when examining caries experience, with children who were caries-free, and children with high caries, both reporting similar mean scores of QoL (Table 9). Children living in areas of low deprivation had lower CHU-9D scores than those living in medium or high areas of deprivation, and Pacific Island children had the lowest score at 0.87 (SD 0.08). No statistically significant differences were found by caries experience, ethnicity, sex, age, or deprivation.
Table 9. Mean exit CPQ$_{8\text{-}10}$ and CPQ$_{11\text{-}14}$ scores and CHU-9D by sociodemographic characteristics and caries experience (SD)

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>Chu-9D</th>
<th>CPQ$_{8\text{-}10}$</th>
<th>CPQ$_{11\text{-}14}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>75 (100)</td>
<td>0.92 (0.08)</td>
<td>8.6 (7.9)</td>
<td>7.4 (6.1)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>42 (56)</td>
<td>0.91 (0.07)</td>
<td>7.5 (6.4)</td>
<td>6.7 (5.4)</td>
</tr>
<tr>
<td>Female</td>
<td>33 (44)</td>
<td>0.92 (0.09)</td>
<td>9.9 (9.4)</td>
<td>8.2 (6.8)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>53 (71)</td>
<td>0.91 (0.07)</td>
<td>7.8 (6.8)</td>
<td>6.9 (5.5)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>13 (17)</td>
<td>0.93 (0.10)</td>
<td>9.1 (7.5)</td>
<td>7.9 (6.4)</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>5 (7)</td>
<td>0.87 (0.08)</td>
<td>18.8 (14.6)</td>
<td>13.2 (8.9)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>0.96 (0.05)</td>
<td>4.8 (6.2)</td>
<td>4.8 (6.2)</td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>21 (28)</td>
<td>0.90 (0.07)</td>
<td>8.0 (5.9)</td>
<td>7.1 (5.2)</td>
</tr>
<tr>
<td>Medium</td>
<td>30 (40)</td>
<td>0.93 (0.07)</td>
<td>8.3 (7.7)</td>
<td>7.4 (6.4)</td>
</tr>
<tr>
<td>High</td>
<td>24 (32)</td>
<td>0.92 (0.09)</td>
<td>9.4 (9.7)</td>
<td>7.5 (6.5)</td>
</tr>
<tr>
<td>Full dentition$^a$</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caries free$^b$</td>
<td>19 (25)</td>
<td>0.91 (0.09)</td>
<td>8.4 (9.8)</td>
<td>6.7 (6.9)</td>
</tr>
<tr>
<td>Low caries$^d$</td>
<td>33 (44)</td>
<td>0.92 (0.08)</td>
<td>8.2 (8.5)</td>
<td>6.9 (6.4)</td>
</tr>
<tr>
<td>Medium caries$^e$</td>
<td>23 (31)</td>
<td>0.92 (0.08)</td>
<td>10.0 (8.2)</td>
<td>8.4 (6.2)</td>
</tr>
<tr>
<td>High caries$^f$</td>
<td>19 (25)</td>
<td>0.91 (0.07)</td>
<td>7.4 (6.5)</td>
<td>6.9 (5.5)</td>
</tr>
<tr>
<td>Full dentition active caries$^c$</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No active caries</td>
<td>52 (69)</td>
<td>0.91 (0.08)</td>
<td>9.4 (8.6)</td>
<td>7.8 (6.4)</td>
</tr>
<tr>
<td>1 ‘d’ surface</td>
<td>15 (20)</td>
<td>0.93 (0.06)</td>
<td>7.8 (6.6)</td>
<td>7.2 (5.8)</td>
</tr>
<tr>
<td>2 ‘d’ surfaces</td>
<td>4 (5)</td>
<td>0.90 (0.07)</td>
<td>5.0 (1.6)</td>
<td>4.8 (1.3)</td>
</tr>
<tr>
<td>3+ ‘d’ surfaces</td>
<td>4 (5)</td>
<td>0.92 (0.08)</td>
<td>4.3 (4.3)</td>
<td>4.5 (4.8)</td>
</tr>
</tbody>
</table>

$^a$Primary and permanent dentition combined  
$^b$No caries in mixed dentition (dmfs/DMFS = 0)  
$^c$Untreated caries – decay only in mixed dentition  
$^d$Low Caries – dmfs/DMFS 0 to 2  
$^e$Medium Caries – dmfs/DMFS 3 to 7  
$^f$High Caries – dmfs/DMFS 8+
3.3.2 Relationship between OHRQoL and HRQoL

The relationship between OHRQoL and HRQoL measures was explored with scatterplot graphs. The baseline CPQ\textsubscript{11,14}ISF:16 scores, and CHU-9D utility values are shown in Fig 9, with the exit scores shown in Fig 10. The baseline CPQ\textsubscript{8,10} and CHU-9D scores are shown in Fig. 11, with the exit scores shown in Fig. 12.

Perfect health is represented by 1 for the CHU-9D and 0 for the CPQ measures. A small negative correlation was observed across all scatterplots, but, there appeared to be no discernible pattern, and a large amount of variance existed.

Correlation between the CHU-9D and both the CPQ\textsubscript{8,10} and CPQ\textsubscript{11,14}ISF:16 was measured. At baseline, each CPQ measures was only moderately and negatively correlated (r= -0.3) with the CHU-9D. At follow-up, each CPQ measures was negatively correlated (r= -0.5) with the CHU-9D. Both baseline and exit correlation figures were indicative of low correlation.
Figure 9. Scatterplot of the CPQ$^{11-14}$ISF:16 and CHU-9D at baseline exit

Figure 10. Scatterplot of the CPQ$^{11-14}$ISF:16 and CHU-9D on exit
Figure 11. Scatterplot of the CPQ8-10 and CHU-9D at baseline

Figure 12. Scatterplot of the CPQ8-10 and CHU-9D on exit
3.4 Baseline and Exit Data: Study 1

When comparing mean caries experience at both baseline and follow-up (Table 10), the number of those in the low caries risk group has increased from 26 (32%) to 33 (44%). The number of children in the medium and high caries groups have dropped considerably. While the severity scores are not too dissimilar, the number of children with medium and high caries has reduced.

*Table 10. Mean caries experience at baseline and exit by risk groups*

<table>
<thead>
<tr>
<th>Caries experience</th>
<th>Baseline mean dmfs/DMFS</th>
<th>Follow-up mean dmfs/DMFS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No (%)</td>
<td></td>
</tr>
<tr>
<td>Low caries(^a)</td>
<td>26 (32)</td>
<td>0.7 (0.8)</td>
</tr>
<tr>
<td>Med caries(^b)</td>
<td>29 (35)</td>
<td>4.5 (1.4)</td>
</tr>
<tr>
<td>High caries(^c)</td>
<td>27 (33)</td>
<td>15.0 (6.3)</td>
</tr>
</tbody>
</table>

\(^a\)Low caries – dmfs/DMFS 0 to 2  
\(^b\)Medium caries – dmfs/DMFS 3 to 7  
\(^c\)High caries – dmfs/DMFS 8+

3.5.1 Test/retest reliability

18 participants completed the same questionnaire between one and two weeks after completing their final CHU-9D, CPQ\(_8\)\text{-}10 and CPQ\(_{11-14}\)ISF:16 questionnaire. Inter-related agreement between exit scores and retest scores for all three measures was low. The CPQ\(_8\)\text{-}10 and CPQ\(_{11-14}\)ISF:16 scored slight to fair agreement at Kappa 0.22 and 0.16 respectively, while the CHU-9D showed only almost no agreement at 0.01.

3.5 Global oral health measures

Responses to global oral health questions at baseline for participants who completed both CPQ measures are shown in Table 11, and exit responses are shown in Table 12.

3.5.1 Self-rated oral health

There was a statistically significant difference between the mean ‘good’ and ‘OK/poor’ categories for the CPQ\(_8\)\text{-}10 and CPQ\(_{11-14}\)ISF:16, at both baseline and exit. A consistent gradient
between all three response categories was not apparent, however, with participants who reported having ‘very good’ oral health, having higher mean CPQ\textsubscript{8-10} and CPQ\textsubscript{11-14ISF:16} scores than those who reported having ‘good’ oral health.

3.5.2 Impact of oral health on quality of life

There was a consistent gradient for both the CPQ\textsubscript{8-10} and CPQ\textsubscript{11-14ISF:16} across all three response categories, with those experiencing some/a lot of impact having worse OHRQoL at baseline and exit. There was a statistically significant difference between the ‘not at all’ and ‘a little bit’ categories for both measures.
Table 11. Baseline CPQ<sub>11-14</sub> and CPQ<sub>8-20</sub> by global oral health questions

<table>
<thead>
<tr>
<th></th>
<th>CPQ&lt;sub&gt;11-14&lt;/sub&gt; Prevalence (%)</th>
<th>CPQ&lt;sub&gt;11-14&lt;/sub&gt; Mean (SD)</th>
<th>CPQ&lt;sub&gt;8-10&lt;/sub&gt; Prevalence (%)</th>
<th>CPQ&lt;sub&gt;8-10&lt;/sub&gt; Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-rated oral health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very good</td>
<td>9 (11)</td>
<td>11.1 (9.0)</td>
<td>9 (11)</td>
<td>16.3 (14.4)</td>
</tr>
<tr>
<td>Good</td>
<td>41 (50)</td>
<td>9.0 (7.3)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>41 (50)</td>
<td>11.1 (9.8)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>OK/Poor</td>
<td>32 (39)</td>
<td>15.3 (9.0)</td>
<td>32 (39)</td>
<td>19.2 (12.3)</td>
</tr>
<tr>
<td><strong>Impact of oral health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>on quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>34 (41)</td>
<td>8.2 (7.5)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>34 (41)</td>
<td>9.4 (9.5)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>A little bit</td>
<td>38 (46)</td>
<td>13.2 (7.5)</td>
<td>38 (46)</td>
<td>17.3 (10.5)</td>
</tr>
<tr>
<td>Some/A lot</td>
<td>10 (12)</td>
<td>17.9 (11.3)</td>
<td>10 (12)</td>
<td>23.8 (16.1)</td>
</tr>
</tbody>
</table>

<sup>b</sup>p-value <0.05 Mann Whitney: The ‘good’ category differs from the ‘OK/poor’ category

<sup>c</sup>p-value <0.05 Mann Whitney: The ‘not at all’ category differs from the ‘a little bit’ and ‘some/a lot’ categories, which do not differ significantly from each other

Table 12. Exit CPQ<sub>11-14</sub> and CPQ<sub>8-20</sub> by global oral health questions

<table>
<thead>
<tr>
<th></th>
<th>CPQ&lt;sub&gt;11-14&lt;/sub&gt; Prevalence (%)</th>
<th>CPQ&lt;sub&gt;11-14&lt;/sub&gt; Mean (SD)</th>
<th>CPQ&lt;sub&gt;8-10&lt;/sub&gt; Prevalence (%)</th>
<th>CPQ&lt;sub&gt;8-10&lt;/sub&gt; Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-rated oral health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very good</td>
<td>8 (10)</td>
<td>6.4 (6.3)</td>
<td>8 (10)</td>
<td>8.6 (11.7)</td>
</tr>
<tr>
<td>Good</td>
<td>38 (46)</td>
<td>5.8 (5.2)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>38 (46)</td>
<td>6.6 (6.3)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>OK/Poor</td>
<td>29 (35)</td>
<td>9.7 (6.5)</td>
<td>29 (35)</td>
<td>11.1 (8.1)</td>
</tr>
<tr>
<td><strong>Impact of oral health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>on quality of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>30 (40)</td>
<td>5.3 (5.3)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>30 (40)</td>
<td>6.0 (6.0)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>A little bit</td>
<td>35 (47)</td>
<td>8.3 (5.6)</td>
<td>35 (47)</td>
<td>9.5 (7.8)</td>
</tr>
<tr>
<td>Some/A lot</td>
<td>10 (13)</td>
<td>10.4 (8.2)</td>
<td>10 (13)</td>
<td>13.1 (11.1)</td>
</tr>
</tbody>
</table>

<sup>b</sup>p-value <0.05 Mann Whitney: The ‘good’ category differs from the ‘OK/poor’ category

<sup>c</sup>p-value <0.05 Mann Whitney: The ‘not at all’ category differs from the ‘a little bit’ category
3.6 Baseline Data: Study 2

3.6.1 Sociodemographic characteristics of participants

The baseline characteristics of children who completed at least one follow-up CHU-9D are shown in Table 13. There were 87 participants included in this study, with similar numbers of girls and boys. At the baseline examination, children were between 7 and 10 years old, with most children (80%) being 8 or 9 years old.

More than two-thirds of the children identified as NZ European, with one-fifth being NZ Māori. There were slightly more children living in areas of medium deprivation, with similar numbers residing in low and high deprived areas.

3.6.2 Caries experience

Caries experience was lowest for NZ European participants, with similar dmfs/DMFS scores for NZ Māori, Pacific Islanders and Other. A clear gradient in the expected direction was seen for those living in areas of least deprivation, to those living in areas high areas of deprivation. This was observed with both the primary and permanent dentition. The mean dmfs score in the primary dentition was greater for males and those living in areas of high deprivation. Children aged 7 to 8 years of age were more likely to have a caries free mouth than children aged 9 to 10. Caries experience in the permanent dentition was low, with no children presenting with a DMFS score above 1. None of the observed differences were statistically significant.
### Table 13. CHU-9D Time 1 sociodemographic characteristics by caries experience

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%)</th>
<th>Caries-free in primary teeth (% dmfs = 0)</th>
<th>Mean dmfs (SD)</th>
<th>Range of observed dmfs scores</th>
<th>Caries-free in permanent teeth (% DMFS = 0)</th>
<th>Mean DMFS (SD)</th>
<th>Range of observed DMFS scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>87 (100)</td>
<td>16 (18)</td>
<td>6.2 (6.7)</td>
<td>0 to 28</td>
<td>75 (86)</td>
<td>0.2 (0.7)</td>
<td>0 to 4</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boy</td>
<td>46 (53)</td>
<td>9 (20)</td>
<td>7.2 (7.9)</td>
<td>0 to 28</td>
<td>41 (89)</td>
<td>0.1 (0.3)</td>
<td>0 to 1</td>
</tr>
<tr>
<td>Girl</td>
<td>41 (47)</td>
<td>7 (17)</td>
<td>5.2 (4.8)</td>
<td>0 to 20</td>
<td>34 (83)</td>
<td>0.4 (1.0)</td>
<td>0 to 4</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 to 8</td>
<td>46 (53)</td>
<td>10 (22)</td>
<td>5.8 (6.6)</td>
<td>0 to 25</td>
<td>40 (87)</td>
<td>0.2 (0.7)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>9 to 10</td>
<td>41 (47)</td>
<td>6 (15)</td>
<td>6.6 (6.8)</td>
<td>0 to 28</td>
<td>35 (85)</td>
<td>0.2 (0.7)</td>
<td>0 to 4</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>59 (68)</td>
<td>13 (22)</td>
<td>5.7 (6.6)</td>
<td>0 to 28</td>
<td>54 (92)</td>
<td>0.1 (0.6)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>17 (20)</td>
<td>3 (18)</td>
<td>7.2 (8.1)</td>
<td>0 to 24</td>
<td>12 (71)</td>
<td>0.5 (1.0)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>7 (8)</td>
<td>2 (29)</td>
<td>7.7 (4.3)</td>
<td>3 to 12</td>
<td>5 (71)</td>
<td>0.6 (1.0)</td>
<td>0 to 2</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>0 (0)</td>
<td>7.5 (5.5)</td>
<td>2 to 14</td>
<td>4 (100)</td>
<td>0.0 (0.0)</td>
<td>0 to 0</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>24 (28)</td>
<td>5 (21)</td>
<td>4.8 (4.6)</td>
<td>0 to 13</td>
<td>23 (96)</td>
<td>0.0 (0.2)</td>
<td>0 to 1</td>
</tr>
<tr>
<td>Medium</td>
<td>35 (40)</td>
<td>8 (23)</td>
<td>5.8 (7.4)</td>
<td>0 to 28</td>
<td>29 (83)</td>
<td>0.3 (0.7)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>High</td>
<td>28 (32)</td>
<td>3 (11)</td>
<td>7.9 (7.0)</td>
<td>0 to 25</td>
<td>23 (82)</td>
<td>0.4 (1.0)</td>
<td>0 to 4</td>
</tr>
</tbody>
</table>
3.6.3 Dentition status

The number of primary and permanent teeth present when the first CHU-9D was administered is shown in Table 15. On average, children had a mixed dentition at baseline, with 12 primary teeth and 11 permanent teeth.

<table>
<thead>
<tr>
<th>Number of teeth present</th>
<th>Mean number of teeth present (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary teeth</td>
<td>2 to 20</td>
</tr>
<tr>
<td>Permanent teeth</td>
<td>3 to 22</td>
</tr>
</tbody>
</table>

3.7 Longitudinal Data: Study 2

3.7.1 Mean CHU9D Scores

Table 16 shows the mean CHU9D utility values across each of the four observations. The mean and range of observed CHU9D scores were similar at Time 1 and 2. The mean utility scores were similar at Time 3 and 4, although the range of observed scores differed.

<table>
<thead>
<tr>
<th>CHU9D</th>
<th>Number</th>
<th>Mean Utility Value (SD)</th>
<th>Range of observed scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1</td>
<td>87</td>
<td>0.89 (0.09)</td>
<td>0.63 to 1</td>
</tr>
<tr>
<td>Time 2</td>
<td>84</td>
<td>0.89 (0.09)</td>
<td>0.63 to 1</td>
</tr>
<tr>
<td>Time 3</td>
<td>79</td>
<td>0.91 (0.09)</td>
<td>0.55 to 1</td>
</tr>
<tr>
<td>Time 4</td>
<td>73</td>
<td>0.91 (0.08)</td>
<td>0.59 to 1</td>
</tr>
</tbody>
</table>
Mean CHU-9D scores with SD over each of the four observations are shown by socio-demographic information and caries experience in Table 16. When we examine the CHU-9D by caries experience at Time 1, there does not appear to be any association between participants with low, medium, or high caries, and a change in CHU-9D scores. For Time 2, Time 3 and Time 4, we see a slightly more predictable pattern, with children who have had low or no caries experience having higher scores than children with medium or high caries experience, however these differences were not statistically significant.

NZ Māori consistently had higher CHU-9D scores than NZ European, while Pacific Island respondents had the lowest. Only at Time 2, were scores lower for those living in the greatest area of deprivation, than those living in the least deprived areas. There were no statistically significant differences when looking at gender, age, ethnicity, deprivation or caries experience.
Table 16. Mean CHU-9D scores at each time point by sociodemographic characteristics and caries experience

<table>
<thead>
<tr>
<th></th>
<th>Time 1 N (%)</th>
<th>Time 1 Mean (SD)</th>
<th>Time 2 N (%)</th>
<th>Time 2 Mean (SD)</th>
<th>Time 3 N (%)</th>
<th>Time 3 Mean (SD)</th>
<th>Time 4 N (%)</th>
<th>Time 4 Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>87 (100)</td>
<td>0.89 (0.09)</td>
<td>84 (100)</td>
<td>0.89 (0.09)</td>
<td>79 (100)</td>
<td>0.91 (0.09)</td>
<td>73</td>
<td>0.91 (0.08)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boy</td>
<td>46 (53)</td>
<td>0.88 (0.08)</td>
<td>46</td>
<td>0.89 (0.75)</td>
<td>44</td>
<td>0.90 (0.09)</td>
<td>42</td>
<td>0.91 (0.08)</td>
</tr>
<tr>
<td>Girl</td>
<td>41 (47)</td>
<td>0.89 (0.09)</td>
<td>38</td>
<td>0.90 (0.11)</td>
<td>35</td>
<td>0.91 (0.08)</td>
<td>31</td>
<td>0.90 (0.84)</td>
</tr>
<tr>
<td>Age at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 to 8</td>
<td>46 (53)</td>
<td>0.88 (0.08)</td>
<td>44</td>
<td>0.88 (0.10)</td>
<td>41</td>
<td>0.89 (0.97)</td>
<td>39</td>
<td>0.90 (0.09)</td>
</tr>
<tr>
<td>9 to 10</td>
<td>41 (47)</td>
<td>0.89 (0.09)</td>
<td>40</td>
<td>0.91 (0.08)</td>
<td>38</td>
<td>0.93 (0.72)</td>
<td>34</td>
<td>0.91 (0.08)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>59 (68)</td>
<td>0.88 (0.08)</td>
<td>58</td>
<td>0.89 (0.08)</td>
<td>56</td>
<td>0.91 (0.09)</td>
<td>52</td>
<td>0.90 (0.08)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>17 (20)</td>
<td>0.90 (0.10)</td>
<td>15</td>
<td>0.92 (0.10)</td>
<td>13</td>
<td>0.90 (0.09)</td>
<td>12</td>
<td>0.91 (0.11)</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>7 (8)</td>
<td>0.85 (0.10)</td>
<td>7</td>
<td>0.82 (0.09)</td>
<td>6</td>
<td>0.86 (0.10)</td>
<td>6</td>
<td>0.90 (0.07)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>0.95 (0.06)</td>
<td>4</td>
<td>0.94 (0.09)</td>
<td>4</td>
<td>0.97 (0.03)</td>
<td>3</td>
<td>0.98 (0.03)</td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>24 (28)</td>
<td>0.87 (0.09)</td>
<td>23</td>
<td>0.90 (0.09)</td>
<td>22</td>
<td>0.90 (0.11)</td>
<td>22</td>
<td>0.88 (0.11)</td>
</tr>
<tr>
<td>Medium</td>
<td>35 (40)</td>
<td>0.89 (0.09)</td>
<td>34</td>
<td>0.90 (0.09)</td>
<td>31</td>
<td>0.92 (0.09)</td>
<td>28</td>
<td>0.92 (0.06)</td>
</tr>
<tr>
<td>High</td>
<td>28 (32)</td>
<td>0.90 (0.08)</td>
<td>27</td>
<td>0.88 (0.10)</td>
<td>26</td>
<td>0.91 (0.07)</td>
<td>23</td>
<td>0.90 (0.08)</td>
</tr>
<tr>
<td>Full Dentitiona</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caries-freeb</td>
<td>16 (18)</td>
<td>0.87 (0.11)</td>
<td>15</td>
<td>0.91 (0.11)</td>
<td>16</td>
<td>0.92 (0.08)</td>
<td>14</td>
<td>0.91 (0.08)</td>
</tr>
<tr>
<td>Low cariesc</td>
<td>29 (33)</td>
<td>0.87 (0.09)</td>
<td>24</td>
<td>0.90 (0.95)</td>
<td>25</td>
<td>0.93 (0.07)</td>
<td>27</td>
<td>0.91 (0.09)</td>
</tr>
<tr>
<td>Medium cariesd</td>
<td>31 (36)</td>
<td>0.91 (0.08)</td>
<td>26</td>
<td>0.89 (0.09)</td>
<td>23</td>
<td>0.92 (0.08)</td>
<td>26</td>
<td>0.90 (0.08)</td>
</tr>
<tr>
<td>High cariesd</td>
<td>27 (31)</td>
<td>0.88 (0.08)</td>
<td>34</td>
<td>0.89 (0.09)</td>
<td>31</td>
<td>0.89 (0.10)</td>
<td>20</td>
<td>0.90 (0.08)</td>
</tr>
</tbody>
</table>

*aPrimary and permanent dentition combined
bNo caries in mixed dentition (dmfs/DMFS = 0)
cLow Caries – dmfs/DMFS 0 to 2
dMedium Caries – dmfs/DMFS 3 to 7
eHigh Caries – dmfs/DMFS 8+
3.7.2 Attrition Analysis

The attrition analysis for study 2 is shown in Table 17. Participants were removed if they did not have at least one follow-up recall examination with a completed CHU9D. For those included, the time spent in the study ranged from 6 to 36 months. Three children were not followed up after Time 1. One girl was excluded from the analysis as she had not completed a CHU9D measure at her subsequent recall exam, and two girls were lost as they had left the district. Of these three children, one was NZ European and two were Māori. Two had experienced caries in the primary dentition and had a mean dmfs of 2.3 (SD 2.5), and none had experienced caries in the permanent dentition. The mean dmfs of those remaining in the study was 6.4 (SD 6.7), with a mean DMFS of 0.3 (SD 0.7).

Numbers of participants lost from the study were small, and there were no significant differences between children who were lost and children who were followed up.
Table 17. Attrition analysis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Time 1 sample</th>
<th>Followed up&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Not followed up&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>All</td>
<td>87 (100)</td>
<td>84 (97)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boy</td>
<td>46 (53)</td>
<td>46 (55)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Girl</td>
<td>41 (47)</td>
<td>38 (45)</td>
<td>3 (100)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>59 (68)</td>
<td>58 (69)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>17 (20)</td>
<td>15 (18)</td>
<td>2 (67)</td>
</tr>
<tr>
<td>Pacific Island</td>
<td>7 (8)</td>
<td>7 (8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5)</td>
<td>4 (5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>24 (28)</td>
<td>23 (27)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>Med</td>
<td>35 (40)</td>
<td>34 (40)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>High</td>
<td>28 (32)</td>
<td>27 (32)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>Caries prevalence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary caries&lt;sup&gt;a&lt;/sup&gt;</td>
<td>71 (82)</td>
<td>69 (82)</td>
<td>2 (67)</td>
</tr>
<tr>
<td>Permanent caries&lt;sup&gt;b&lt;/sup&gt;</td>
<td>12 (14)</td>
<td>12 (14)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Caries severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean dmfs (SD) at baseline</td>
<td>6.2 (6.7)</td>
<td>6.4 (6.7)</td>
<td>2.3 (2.5)</td>
</tr>
<tr>
<td>Mean DMFS (SD) at baseline</td>
<td>0.2 (0.7)</td>
<td>0.3 (0.7)</td>
<td>0.0 (0.0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Number of participants with decayed, missing or filled primary teeth at baseline

<sup>b</sup>Number of participants with Decayed, Missing or Filled permanent teeth at baseline

<sup>c</sup>Participants who had at least one follow up recall examination

<sup>d</sup>Participants who did not have a follow up recall examination
4.1 Findings

In this section, the findings from the two studies will be discussed. One study determined whether there was concordance between the CHU-9D and both the CPQ8-10 and CPQ11-14ISF:16, and the other study investigated whether the CHU-9D was responsive to changing dental caries experience over time.

The first study of 82 Dunedin children between 7 and 12 years of age showed low concordance between the HRQoL measure (CHU-9D) and OHRQoL measures (CPQ8-10 and CPQ11-14ISF:16).

Mean CPQ scores (regardless of which measure) demonstrated a gradient in the expected direction when examining caries experience at baseline, although the differences were not statistically significant. Follow-up CPQ measures at the conclusion of the study showed that mean scores did not respond as expected to dental caries experience over time in this group of children. CHU-9D scores were inconsistent with respect to dental caries experience, ethnicity and deprivation. This HRQoL measure had low correlation with both the CPQ8-10 and CPQ11-14ISF:16, therefore making it inappropriate to use as a proxy to calculate a QALY in this group of children.

The second study of 87 Dunedin children between 7 and 12 years of age, showed that the CHU-9D was not sensitive to caries experience at baseline. The poor performance of the CHU9D at baseline with caries experience indicated that the measure therefore would not be responsive to change in caries experience over time. At each time point when the CHU-9D was measured, no statistically significant difference was found for caries severity (mean dmfs/DMFS). No pattern was present by caries experience, ethnicity, deprivation, sex or age.

The following sections will discuss the sample in depth, and identify any strengths and weaknesses within the study design. Both research questions will be answered
independently, followed by recommendations for future research, and implications for current practice.

4.2 The sample

It is important to establish whether the sample was representative of the population between 7 and 10 years of age in Dunedin. This can help to determine whether the findings are generalizable.

Participant data was nested within an existing RCT in Otago. Information for 89 children was available, however the number included in each study was dependent on the specific data required to answer each research question. For the first study, due to missing baseline CPQ data, only 82 participants were included. Because the second study was investigating CHU-9D responsiveness, 87 were able to be included. Overall, the participants were evenly represented with regards to sex, age, and socio-economic deprivation. There were fewer NZ Māori participants than NZ European participants, and this was a reflection of the ethnic distribution in Otago at that time.

When examining caries data for Otago, the dmft/DMFT figures were relatively representative of the Dunedin community, with Otago having a mean dmft of 1.25 in the primary dentition. Dunedin is generally considered an area of low risk for dental caries experience, and the services available for Dunedin children are provided either through a COHS clinic or the Faculty of Dentistry. The school that the child attends determines which provider is responsible for the management of their dental care.

An invitation to participate in the PRINZ study was extended to children attending schools assigned to receive their dental care from the Faculty of Dentistry. Therefore, dental care for participants included in the study may differ from those children who attend schools allocated to have their dental care provided by the COHS.

Since the Faculty of Dentistry is a teaching institution, children may be seen three or six-monthly to monitor early carious lesions if required. This means that prior to inclusion in
the study, children with high caries experience had most likely been placed on shortened recalls, where early preventive intervention or restorative treatment was able to be provided in a timely fashion. The management of the Brockville satellite clinic was transferred from the COHS to the Faculty of Dentistry in 2012, just prior to the commencement of the PRINZ study. Prior to this, the clinic was only operational for short periods (once or twice a year), and accordingly, dental recalls and provision of preventive care may have been less regular than those whose care was provided at the Faculty of Dentistry clinics.

Once included in the study, all children received six-monthly recalls regardless of caries risk status, and radiographs were taken annually to detect and/or monitor early interproximal lesions (or more frequently if required). If carious lesions were not restored, it was usually due to age, a lack of cooperation, or because it was considered possible to remineralise the lesion. Carious lesions that had progressed to a point where pain or discomfort could occur were treated. This meant that all children in the study had their oral health well managed.

4.3 Strengths and weaknesses

4.3.1 Caries experience

There was a large difference in mean caries experience between the primary and permanent dentition for both studies. This was to be expected, given the age of the children included in the studies. Primary teeth typically erupt between six months and two and a half years of age, with exfoliation usually occurring between the ages of six and twelve. Primary teeth are also smaller and less resistant to dental caries than permanent teeth. Permanent teeth begin to erupt from the age of six, with premolars and the second molars usually not erupting until approximately ten to twelve years of age. Providing a combined dmfs/DMFS score enabled the whole mouth to be assessed; however, because the permanent teeth have had less exposure to the oral cavity than the primary teeth, they have had less time to develop dental caries. If, for example, children had recently experienced multiple losses of heavily restored primary teeth due to natural exfoliation, the subsequent eruption of new and unaffected permanent teeth would result in a dmfs/DMFS score which does not adequately
reflect the lifetime caries experience of the child. This changing dentition may have influenced the QoL scores for children over time.

Using dmfs/DMFS as a measure for caries experience has limitations, as each surface of the tooth that has been affected is counted, with a maximum of five potential surfaces per tooth (28). Filled surfaces may not accurately reflect the extent of the disease, as cavity designs are often dependant on the restorative material, rather than the carious lesion. For example, if a stainless steel crown is placed on a tooth, every surface of the tooth is counted as restored, so a maximum of five surfaces is counted, even if caries had only covered two surfaces. For some younger children who have difficulty accepting dental treatment, the decision to use a stainless steel crown may be due to patient management issues rather than extent of carious activity. When restoring small interproximal carious lesions, the marginal ridge of the tooth is often compromised during cavity preparation in order to access the caries. This would mean that where only one surface (mesial or distal) had been affected by caries, a two surface preparation was required, resulting in two filled surfaces. When looking at caries severity in longitudinal studies, dmfs/DMFS scores may be higher in subsequent appointments, not due to an increase in caries experience, but because the restorative materials used have affected more surfaces than the carious lesion. This can limit the ability of the dmfs/DMFS system to detect change in caries experience over time REF.

The alternative dmft/DMFT system for measuring caries experience was considered. This involved only counting the number of teeth affected by dental caries, not the number of surfaces. This system also has its limitations, as a tooth that has had a very small restoration on a pit or fissure, would receive the same score (1) as a tooth that has been extracted due to caries (22). This limited our ability to measure the true extent of caries severity, and made it not possible to differentiate between untreated carious lesions, restored lesions, and extracted teeth. For this reason, this study used the dmfs/DMFS system, as it was more informative and allowed for a more in depth analysis of caries experience. However, the limitations of the measure were considered and accepted. Teeth that were affected due to trauma were not included in the dmfs/DMFS score.
4.3.2 OHRQoL

OHRQoL measures assess the impact overall oral health has on a child’s QoL. Dental caries is one of the most common causes of poor oral health. The questions in these measures ask children to rate how they feel about their teeth or mouth, and while children may report an impact on OHRQoL, there is always the chance that causes other than dental caries may impact on their OHRQoL. These potential confounders have been explored to ascertain if they were likely to impact on QoL scores.

Children between the age of 7 and 13 years may be exfoliating their primary teeth, and it is known that for some children, this can be painful (89). They may also have conditions such as hypomineralisation with teeth that present with post-eruptive breakdown, or hypoplasia, which can cause pain and suffering (90). Because affected teeth may erupt at any time throughout the course of the study, this was not an exclusion criteria, therefore children may have presented with hypomineralisation in the study at some point. Hypomineralisation with severe sensitivity is not particularly common (91), and it was felt that it was unlikely that there would be many children that presented with this condition.

Malocclusion (crooked teeth) and associated orthodontic treatment is known to impact on the QoL of young people (92). Children in this study were followed until their PRINZ study teeth exfoliated, which for some was up to 13 years of age. Between 10 and 13 years of age is a common time for children to commence orthodontic treatment, although it not usual for children to commence treatment prior to the exfoliation of their primary teeth. There are occasions where this may occur, however, particularly if children had no permanent successors, or on the rare occasion where early intervention was considered necessary. Orthodontics can be uncomfortable and children may report discomfort, particularly if fixed appliances have been recently adjusted (93, 94). Braces may also result in trauma to the buccal mucosa, ulcerations or gingival hypoplasia (95). At baseline examination, the children in this study would have been too young for orthodontic treatment; however, some may have commenced treatment towards the end of their participation in the study, potentially affecting follow up QoL scores. The numbers would have been low, however, and I did not feel that this was likely to affect the findings.
Accidental trauma to the teeth or mouth can result in fractures of the face, teeth or jaws, bruising, concussion or luxation of the teeth, lacerations, and lip bites. All of these may result in a poor OHRQoL score that is not influenced by dental caries (96).

Medical conditions can also affect the oral cavity, such as apthous ulcers, tonsillitis, acute necrotizing ulcerative gingivitis, or thrush (97). Poor oral hygiene can result in gingivitis, and bleeding gums on brushing (98). This can be concerning for children, and may result in a higher OHRQoL score. Additionally, the appearance of the teeth may also affect emotional wellbeing or social wellbeing (99). These conditions were not adjusted for in the analysis and may have affected the results.

This study has only investigated caries experience and OHRQoL, without measuring for the above mentioned potential confounders. It is possible for children to report a poor OHRQoL score due to their oral cavity, and yet not have experienced dental caries.

### 4.3.3 HRQoL

To investigate HRQoL, the CHU-9D asks children whether they were worried, sad, in pain, tired or annoyed, and if they have problems sleeping, completing their daily routines or participating in regular activities. This measure does not specify the cause of any of these ailments, and while children who are suffering from oral pain may report any number of these symptoms, there may be many alternative explanations. For example, a child may feel tired because he/she has had a late night, suffers from anaemia, or have had a particularly active/tiring week. If a child is worried, it may be because, for example, he/she came from a troubled or abusive background, suffers from anxiety, or has been bullied. If he/she are annoyed, it may be because he/she has missed a fun activity to attend the dental appointment, or had argued with a friend. For each domain specified, there are a multitude of reasons, not necessarily related to oral health that could influence their answers.

There are no NZ studies where the CHU-9D has been used for HRQoL research.
4.3.4 Test/retest reliability

When examining test-retest reliability, while the CPQ8-10 scored slightly better than the CPQ11-14ISF:16, both measures demonstrating only slight to fair retest reliability when participants completed the measures within two weeks of completing the study. The CHU-9D showed poor retest reliability.

Exit questionnaires for all QoL measures were administered in the clinical setting at the participant’s final recall dental examination, while retest questionnaires were completed at home and returned by post. It is possible that children may have answered differently due to being in a more relaxed, non-dental environment. It is also possible than some children may have had a dental treatment appointment after the recall examination, but prior to completing the retest questionnaire, which may have potentially altered QoL scores.

Written instructions were issued with the retest measure, requesting that children completed the measures independently, but it was not possible to monitor whether parents or siblings had influenced their answers.

It may also be possible that participant burden was too great, and children had become uninterested in completing the questionnaires with due thought and consideration.

4.4 Are QALYs available for OHRQOL measures using a general health measure as a proxy?

Previous findings have shown that the CPQ8-10 and CPQ11-14ISF:16 are sensitive to caries (47, 49). Baseline data for this study demonstrated a consistent gradient for quality of life scores from children with no caries experience, to those with the greatest burden of disease, but the observed differences were not statistically significant. On conclusion of the study, no statistically significant differences between children experiencing different levels of disease (when grouped into low, medium and high caries experience) were able to be observed, and a gradient from children with no caries experience, to those with the greatest burden of disease was no longer present. Previous NZ studies have been in older children and they have reported clear gradients in caries experience and the CPQ (49, 63). It is
possible that the difference here seen in follow-up CPQ scores was due to the ongoing short recalls and regular radiographs offered to participants that enabled timely prevention and treatment to be provided over the course of the study. Thus, if caries was present, lesions may have been small, and deemed not necessary to restore. While some children still had high dmfs/DMFS figures, any active lesions likely to cause pain would have most likely been treated. This could result in a lower impact on quality of life scores.

Another explanation could be changes in the participants occupying each caries category. Comparing caries experience data between baseline and follow-up data identified that the number of participants in the low caries risk group had increased, and that the number of children in the medium and high caries groups had decreased. While the mean dmfs/DMFS figures were not too dissimilar, the number of children with medium and high caries had reduced. The reason for this reduction was due to the loss of primary teeth, and the subsequent eruption of permanent successors. The primary teeth, at the time of exfoliation, are at the end of their natural life, and are more likely to have experienced caries. The permanent teeth are newly erupted; they are at the start of their time in the mouth and have had less opportunity to develop dental caries. However, it has been shown that children who have experienced very high caries incidence in their primary dentition may still report a greater impact on quality of life, despite the loss of these teeth, due to their previous memories of caries experience. This would be particularly relevant for those children suffering from dental anxiety (100).

When examining the CHU-9D, it was clear that QoL scores were not reflecting caries experience. A gradient similar to that for the CPQ8-10 and CPQ11-14ISF:16, from participants with no caries experience to those with high caries experience was required in order to be able to demonstrate concordance between the two measures, however, this was not the case. This low correlation was also apparent when looking at the measures on a scatterplot. If perfect concordance existed between the measures, then we would expect to see a negative correlation, with a gradient showing from the top left to the bottom right due to a perfect score for the CHU-9D being 1, whereas a perfect score for both the CPQ’s is 0. However, there was no discernible pattern between the CHU-9D and either the CPQ8-10 or CPQ11-
14ISF:16. Subsequently, the CHU-9D was unable to be used as a proxy to generate a QALY for the CPQ8-10 or CPQ11-14ISF:16 in this group of children.

4.5 Can the CHU-9D can be used as a QoL measure for longitudinal oral health related research?

The CHU-9D has been tested previously as an outcome measure for child dental health, and it was found that, while the CHU-9D detected differences in the impact of dental caries, the differences were not statistically significant (63). In the current study, the CHU-9D was not sensitive to dental caries experience, with QoL scores being inconsistent and unreliable when examining caries experience at recall. Children in the low or medium caries experience groups reported a better quality of life than children who had never experienced caries.

Since the CHU-9D was not sensitive to caries at baseline, it was not appropriate to test its responsiveness in this sample of children. The CHU-9D should not be used as a QoL measure for longitudinal oral-health-related research in this sample of children.

4.6 Recommendations

The CHU-9D in its current format is not useful for oral-health-related research in this study population.

Preference weights for the CHU9D were obtained by interviewing a UK adult population (77). While the UK is closer to NZ in many ways than the United States or China, if a measure is to be used with New Zealand children, it may be beneficial to obtain preference weights from a New Zealand child population.

Since the CHU-9D is a generic health-related measure, and does not specify the cause of change in QoL score, it is difficult to ascertain whether a decrease in score is attributed to poor oral health. Using a proven validated and responsive OHRQoL measure, such as the
CPQ11-14:ISF:16 or CPQ8-10, in conjunction with the CHU-9D is useful, as the probability of changes being oral-health-related can be determined.

Ultimately, to be able to calculate a QALY for child oral health research, it would be beneficial to have a child oral-health-specific measure with preference weights attached. This would remove the issue of non-oral health related health issues confounding the results, and would also reduce participant burden, as only one measure would be required.

For a measure to be used for economic evaluation, it needs to be a self-report measure, and aimed at children who are able to self-report. The CPQ8-10 and CPQ11-14:ISF:16 have been shown to be valid with children as young as seven, and SOHO-5 has been used with children as young as five (46, 49). For preferences to be obtained and applied, a pilot study with groups of children from several areas within NZ would be required. SG and TTO have been shown to be difficult for children to comprehend, so a VAS would be the preferred option (61).

When conducting research on the impact of dental caries, it would be beneficial to exclude participants who have oral-health-related conditions that may influence OHRQoL scores, such as hypomineralised teeth, amelogenesis imperfecta, or fixed orthodontic appliances. Trauma may also be an exclusion, particularly if it was recent. For longitudinal research, participants who present with these conditions after baseline assessment should be excluded. Alternatively, a caries specific measure, rather than a generic OHRQoL measure may be useful, to reduce oral health impacts. Development of these measures are underway but still await formal psychometric evaluation (101).

To determine whether a measure is able to detect change in caries experience over time, it would be useful to have the measure administered prior to (and six months after) the provision of dental treatment. This would help determine whether the intervention had improved the quality of life of the child. The time period suggested would allow the child sufficient time to recover from treatment, and to have a period of time with no carious lesions. Before and after a GA may be appropriate, although because it is usually pre-school children who require GA for ECC, these very young children may not be capable of self-
report (21). For older children, it is often the children who have dental anxiety who require GA for extensive dental treatment, and this could potentially create a bias when looking at OHRQoL (21). Children with dental anxiety are more likely to be distressed when recalling dental experiences, therefore previous memories and fears may influence how they score their quality of life, even if they no longer have any dental problems.

4.7 Implications for current practice

Currently, there are no OHRQoL measures that can calculate a QALY for use in economic evaluation. Having a preference-based measure that is age-appropriate and considers the perspectives of the audience it is aimed at, allows children to have a voice about their own oral health status. A QALY can subsequently be calculated, giving strength to the case that poor oral health impacts on quality of life. This can then inform decision-makers, and enable evidence-based decisions to be made about the distribution of public health-care resources in a systematic and transparent manner.
Chapter 5: Conclusion

There is a need for a QoL measure that can calculate a QALY for OHRQoL research, as this would enable researchers to quantify the burden of disease, providing important information for those who are responsible for the distribution of health care resources. There are currently no OHRQoL measures that are able to calculate a QALY, however there are generic HRQoL measures that have the potential to be used as a proxy in conjunction with existing OHRQoL measures.

In this combination of two studies, it was found that the generic CHU-9D had low correlation with either the oral-health-related CPQ8-10, or the CPQ11-14ISF:16, thus making it inappropriate to use as a proxy to calculate a QALY in this group of children.

The CHU-9D was not sensitive to caries experience at baseline, thereby invalidating the ability of the measure to detect change in caries experience over time. Because the CHU-9D does not specify a particular cause of potential suffering within each domain of the measure, there may have be many confounding factors that influenced how the children in this study responded to this non-specific health measure.

Further research is recommended, with a view to creating an oral-health-specific child QoL measure that is preference-based and able to generate a utility value for use in economic evaluation.
References


84. Schunemann HJ, Guyatt GH. Commentary - Goodbye M(C)ID! Hello MID, where do you come from? Health Serv Res. 2005;40(2):593-7.


88. StataCorp. Stata data analysis and statistical software United States of America2015 [ 
100. Merdad L, El-Housseiny AA. Do children’s previous dental experience and fear affect their perceived oral health-related quality of life (OHRQoL)? BMC Oral Health. 2017;17(1):47.

Appendix 1: List of Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>GA</td>
<td>General Anaesthesia</td>
</tr>
<tr>
<td>AOHS</td>
<td>Adolescent Oral Health Service</td>
</tr>
<tr>
<td>COHS</td>
<td>Community Oral Health Service</td>
</tr>
<tr>
<td>SDS</td>
<td>School Dental Service</td>
</tr>
<tr>
<td>DHB</td>
<td>District Health Board</td>
</tr>
<tr>
<td>MID</td>
<td>Minimally Important Difference</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Control Trial</td>
</tr>
<tr>
<td>PRINZ</td>
<td>Proximal Resin Infiltrant New Zealand</td>
</tr>
<tr>
<td>OS</td>
<td>Oral Symptoms</td>
</tr>
<tr>
<td>FL</td>
<td>Functional Limitations</td>
</tr>
<tr>
<td>EW</td>
<td>Emotional Well-being</td>
</tr>
<tr>
<td>SW</td>
<td>Social Well-being</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health Related Quality of Life</td>
</tr>
<tr>
<td>OHRQOL</td>
<td>Oral Health Related Quality of Life</td>
</tr>
<tr>
<td>COHRQoL</td>
<td>Child Oral Health Related Quality of Life</td>
</tr>
<tr>
<td>CPQ</td>
<td>Child Perception Questionnaire</td>
</tr>
<tr>
<td>CPQ\textsubscript{11-14}\text{ISF:16}</td>
<td>Child Perception Questionnaire for Children Aged 11-14, 16 Item Short Form</td>
</tr>
<tr>
<td>CPQ\textsubscript{11-14}\text{ISF:8}</td>
<td>Child Perception Questionnaire for Children Aged 11-14, 8 Item Short Form</td>
</tr>
<tr>
<td>CPQ\textsubscript{11-14}\text{RSF:16}</td>
<td>Child Perception Questionnaire for Children Aged 11-14, 16 Regression Short Form</td>
</tr>
<tr>
<td>CPQ\textsubscript{11-14}\text{RSF:8}</td>
<td>Child Perception Questionnaire for Children Aged 11-14, 8 Regression Short Form</td>
</tr>
<tr>
<td>CPQ\textsubscript{8-10}</td>
<td>Child Perception Questionnaire for Children Aged 8-10</td>
</tr>
<tr>
<td>COHIP</td>
<td>Child Oral Health Impact Profile</td>
</tr>
<tr>
<td>ECOHIS</td>
<td>Early Childhood Oral Health Impact Score</td>
</tr>
<tr>
<td>SOHO-5</td>
<td>Scale of Oral Health Outcomes for 5 Year Olds</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Care and Excellence</td>
</tr>
<tr>
<td>PHARMAC</td>
<td>Pharmaceutical Advisory Committee</td>
</tr>
<tr>
<td>CUA</td>
<td>Cost Utility Analysis</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Year</td>
</tr>
<tr>
<td>SG</td>
<td>Standard Gamble</td>
</tr>
<tr>
<td>TTO</td>
<td>Time Trade Off</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
</tr>
<tr>
<td>HU</td>
<td>Health Utility</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>European Quality of Life – 5 Dimension</td>
</tr>
<tr>
<td>EQ-5D-Y</td>
<td>European Quality of Life - 5 Dimension, for Youth</td>
</tr>
<tr>
<td>AQoL</td>
<td>Assessment of Quality of Life</td>
</tr>
<tr>
<td>HUI</td>
<td>Health Utilities Index</td>
</tr>
<tr>
<td>OHIP-14</td>
<td>Oral Health Impact Profile 14</td>
</tr>
<tr>
<td>AQoL</td>
<td>Adult Quality of Life</td>
</tr>
<tr>
<td>PedsQL</td>
<td>Paediatric Quality of Life Inventory</td>
</tr>
<tr>
<td>CHU-9D</td>
<td>Child Health Utility 9D</td>
</tr>
</tbody>
</table>
Appendix 2: Combined CPQ8-10 and CPQ11-14ISF:16 with Global Health Questions

Hello
Thanks for helping us with our study

We are doing this study to understand better things that may happen to children because of their **teeth and mouth**.

**Please Remember:**
- Don’t write your name on the questionnaire.
- This is **not a test** and there are no right or wrong answers.
- Answer as **honestly** as you can.
- No one you know will see your answers.
- Read each question **carefully** and think about the things that have happened to you **in the past 4 weeks**.
- Before you answer, ask yourself: **“Does this happen to me because of my teeth or mouth?”**
- Tick the circle that is best for you.

If you have any questions or need some help please ask the assistant or one of the staff at the clinic as we are here to help you as much as you need.

**Today’s date:**

1. Are you a boy or a girl?
   Boy  Girl

2. How old are you? ___________________________

3. When you think about your teeth or mouth, would you say that they are:
   Very good  Good  O.K.  Poor

4. How much do your teeth or mouth bother you?
   Not at all  A little bit  Some  A lot

**NOW A FEW QUESTIONS ABOUT YOUR TEETH AND MOUTH**

How often have you had:

5. Pain in your teeth or mouth in the past 4 weeks?
   Never  Once or twice  Sometimes  Often
   Everyday or almost every day
6. Sore spots in your mouth in the past 4 weeks?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

7. Pain in your teeth when you drink cold drinks or eat foods in the past 4 weeks?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

8. Food stuck in your teeth in the past 4 weeks?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

9. Bad breath in the past 4 weeks?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

10. Needed longer time than others to eat your meal because of your teeth or mouth?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

11. Had a hard time biting or chewing food like apples, corn on the cob or steak because of your teeth or mouth?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

12. Had trouble eating foods you would like to eat because of your teeth or mouth?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

13. Had trouble saying some words because of your teeth or mouth?
Never  Once or twice  Sometimes  Often
Everyday or almost every day

14. Had a problem sleeping at night because of your teeth or mouth?
Never  Once or twice  Sometimes  Often
Everyday or almost every day
SOME QUESTIONS ABOUT YOUR FEELINGS
In the past 4 weeks, how often have you:

15. Been upset because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

16. Felt frustrated because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

17. Been shy because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

18. Been concerned what other people think about your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

19. Worried that you are not as good-looking as others because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

In the past 4 weeks, how often have you:

20. Missed school because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

21. Had a hard time doing your homework because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

22. Had a hard time paying attention in school because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

23. Not wanted to speak or read out loud in class because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day
QUESTIONS ABOUT YOU BEING WITH OTHER PEOPLE
In the past 4 weeks, how often have you:

24. Tried not to smile or laugh when with other children because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

25. Not wanted to talk to other children because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

26. Not wanted to be with other children because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

27. Stayed away from activities like sports and clubs because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

28. Other children teased you or called you names because of your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

29. Other children asked you questions about your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day

30. Argued with other children or your family about your teeth or mouth?
   Never   Once or twice   Sometimes   Often
   Everyday or almost every day
Appendix 3: CHU-9D

These questions ask about you today. For each question, read all the choices and decide which one is most like you today.

Then put a tick in the box next to it like this ☑️. Only tick one box for each question. Example: Today I feel quite upset so I will tick this box.

**Upset**
- I don’t feel upset today
- I feel a little bit upset today
- I feel a bit upset today
- ☑️ I feel quite upset today
- I feel very upset today

Now think about and answer the rest of the questions below

1. **Worried**
- I don’t feel worried today
- I feel a little bit worried today
- I feel a bit worried today
- I feel quite worried today
- I feel very worried today

2. **Sad**
- I don’t feel sad today
- I feel a little bit sad today
- I feel a bit sad today
- I feel quite sad today
- I feel very sad today

3. **Pain**
- I don’t have any pain today
- I have a little bit of pain today
- I have a bit of pain today
- I have quite a lot of pain today
- I have a lot of pain today
4. **Tired**
   - I don’t feel tired today
   - I feel a little bit tired today
   - I feel a bit tired today
   - I feel quite tired today
   - I feel very tired today

5. **Annoyed**
   - I don’t feel annoyed today
   - I feel a little bit annoyed today
   - I feel a bit annoyed today
   - I feel quite annoyed today
   - I feel very annoyed today

6. **School Work/Homework (such as reading, writing, doing lessons)**
   - I have no problems with my schoolwork/homework today
   - I have a few problems with my schoolwork/homework today
   - I have some problems with my schoolwork/homework today
   - I have many problems with my schoolwork/homework today
   - I can’t do my schoolwork/homework today

7. **Sleep**
   - Last night I had no problems sleeping
   - Last night I had a few problems sleeping
   - Last night I had some problems sleeping
   - Last night I had many problems sleeping
   - Last night I couldn’t sleep at all

8. **Daily routine (things like eating, having a bath/shower, getting dressed)**
   - I have no problems with their daily routine today
   - I have a few problems with their daily routine today
   - I have some problems with their daily routine today
   - I have many problems with their daily routine today
   - I can’t do my daily routine today

9. **Able to join in activities (things like playing out with their friends, doing sports, joining in things)**
   - I can join in with any activities today
   - I can join in with most activities today
   - I can join in with some activities today
   - I can join in with a few activities today
   - I can join in with no activities today
Appendix 4: Example of Stata Code for Applying CHU-9D Preference Weights

*** b1-b9 represent the calculation for each of the 9 Sections of the baseline CHU9D ***
*** b1=worry, b2=sad, b3=annoyed, b4=tired, b5=pain, b6=sleep, b7=dailyroutine, b8=school, b9=activities ***

```stata
gen b1 = 0
gen b2 = 0
gen b3 = 0
gen b4 = 0
gen b5 = 0
gen b6 = 0
gen b7 = 0
gen b8 = 0
gen b9 = 0

***Baseline Chu 9D***
replace b1 = 0 if Worry == 1
replace b1 = 0.0227 if Worry == 2
replace b1 = 0.0227 if Worry == 3
replace b1 = 0.0227 if Worry == 4
replace b1 = 0.0227 if Worry == 5
replace b2 = 0 if Sad == 1
replace b2 = 0.0420 if Sad == 2
replace b2 = 0.0445 if Sad == 3
replace b2 = 0.0722 if Sad == 4
replace b2 = 0.0722 if Sad == 5
replace b3 = 0 if Annoy == 1
replace b3 = 0.0313 if Annoy == 2
replace b3 = 0.0313 if Annoy == 3
replace b3 = 0.0313 if Annoy == 4
replace b3 = 0.0313 if Annoy == 5
replace b4 = 0 if Tired == 1
replace b4 = 0.0479 if Tired == 2
replace b4 = 0.0479 if Tired == 3
replace b4 = 0.0479 if Tired == 4
replace b4 = 0.0479 if Tired == 5
replace b5 = 0 if Pain == 1
replace b5 = 0.0332 if Pain == 2
replace b5 = 0.0332 if Pain == 3
replace b5 = 0.1245 if Pain == 4
replace b5 = 0.1246 if Pain == 5
replace b6 = 0 if Sleep == 1
```

replace b6 = 0.0212 if Sleep == 2
replace b6 = 0.0212 if Sleep == 3
replace b6 = 0.0506 if Sleep == 4
replace b6 = 0.0907 if Sleep == 5
replace b7 = 0 if DailyRoutine == 1
replace b7 = 0.0371 if DailyRoutine == 2
replace b7 = 0.0612 if DailyRoutine == 3
replace b7 = 0.0699 if DailyRoutine == 4
replace b7 = 0.0930 if DailyRoutine == 5
replace b8 = 0 if School == 1
replace b8 = 0.0487 if School == 2
replace b8 = 0.0487 if School == 3
replace b8 = 0.0656 if School == 4
replace b8 = 0.0656 if School == 5
replace b9 = 0 if Activities == 1
replace b9 = 0.0368 if Activities == 2
replace b9 = 0.0368 if Activities == 3
replace b9 = 0.0368 if Activities == 4
replace b9 = 0.1079 if Activities == 5

***This next part generates the utility value***
gen utility = 1-(b1+b2+b3+b4+b5+b6+b7+b8+b9)