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# PUBLIC HEALTH ADVISORY COMMITTEE

## RX058: Economic Analysis of Oral Health Improvement Programmes and Interventions

Final report

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External Assessment Centre

LINDSAY CLAXTON, Research Consultant  
MATTHEW TAYLOR, Director  
MICHELLE JENKS, Research Consultant  
ALEXANDRA FILBY, Research Consultant

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**Correspondence to:** Matthew Taylor  
York Health Economics Consortium (YHEC)  
Level 2 Market Square  
University of York  
YORK  
YO10 5NH  
Tel: +44 (0)1904 323620

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# Abbreviations

ADHS	Adult Dental Health Survey
CEA	Cost-effectiveness analysis
def/DEFS	Decayed, extracted and filled deciduous/permanent surfaces
def/DEFT	Decayed, extracted and filled deciduous/permanent teeth
dft/DFT	Decayed and filled deciduous/permanent teeth
dmft/DMFT	Decayed, missing, filled deciduous/permanent teeth
d <sub>1</sub> mft/D <sub>1</sub> MFT	Non-cavitated enamel decay, missing or filled deciduous/permanent teeth
d <sub>2</sub> mft/D <sub>2</sub> MFT	Cavitated enamel decay, missing or filled deciduous/permanent teeth
d <sub>3</sub> mft/D <sub>3</sub> MFT	Cavitated dentine decay, missing or filled deciduous/permanent teeth
dmfs/DMFS	Decayed, missing, filled deciduous/permanent surfaces
EAC	External Assessment Centre
GA	General anaesthetic
HTA	HTA Health Technology Assessment
ICER	Incremental cost-effectiveness ratio
IMD	Indices of Multiple Deprivation
NHS EED	NHS Economic Evaluation Database
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NR	Not reported
OHIP	Oral Health Impact Profile
OR	Odds ratio
PH	Public Health
PHE	Public Health England
PHAC	Public Health Advisory Committee
QALY	Quality Adjusted Life Year
QATY	Quality Adjusted Tooth Year
RCT	Randomised controlled trial
RR	Relative risk
RRR	Relative risk reduction
SD	Standard deviation
SE	Standard error

# Section 1: Introduction

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## 1.1 BACKGROUND

The National Institute for Health and Care Excellence (NICE) was asked by the Department of Health to develop public health guidance for local authorities on oral health needs assessments and community oral health promotion programmes.

The guidance applies to local populations, with a particular focus on vulnerable groups at high risk of poor oral health. People at high risk of poor oral health generally live in areas that are described as socially and economically disadvantaged. Local authorities (and other agencies) define disadvantaged areas in a variety of ways. An example is the Index of Multiple Deprivation 2010. This combines economic, social and housing indicators to produce a single deprivation score. The vulnerable groups include:

- Children aged 5 years and under;
- Adults aged over 65 years;
- People on low incomes;
- People who are homeless or who frequently change the location where they live (for example, traveller communities);
- People from some black and minority ethnic groups (for example, those of South Asian origin);
- People who chew tobacco;
- People with mobility difficulties or a learning disability and who live independently in the community.

The guidance provides recommendations, which are informed by evidence of effectiveness and cost-effectiveness to promote positive oral health behaviour and prevent oral diseases.

There are three components associated with the guidance development:

1. A review of oral health improvement programmes and interventions assessing evidence of effectiveness, barriers and facilitators;
2. A review and practice survey of oral health needs assessments;
3. An economic analysis.

The Newcastle and York External Assessment Centre (EAC) has undertaken the third component only. The first component was commissioned from Bazian and the second from Cardiff University. The economic analysis complements the approach taken by Bazian in their review of the effectiveness of oral health programmes and interventions. The literature search strategy adopted consistent population and interventions terms to those used by

Bazian. This strategy was adapted as appropriate to a search on cost-effectiveness. Search sources were chosen which were not included in the effectiveness evidence review, and which were appropriate to retrieving research on cost-effectiveness from a public health perspective.

The first step in the economic analysis was to undertake a focused systematic review of published economic studies to establish if there are any high-quality economic studies that address the research questions set out in the NICE Public Health (PH) scope document and are relevant to current practice. This step was reported in a separate document which was submitted to NICE in October 2013 (Coffin *et al.* 2013).

The systematic review of cost-effectiveness evidence identified 16 papers suitable for inclusion, which all had methodological weaknesses and limited applicability to the current English context. Therefore, the review concluded that there was insufficient evidence to answer the research questions and a *de novo* economic model was recommended. This document reports this economic modelling and its findings.

## 1.2 AIMS OF THE MODELLING

The economic analysis aimed to investigate the following questions:

**Question 1:** Which community-based programmes and interventions to promote, improve, and maintain the oral health of a local community are cost-effective?

**Question 2:** Which methods and settings to deliver community-based programmes for disadvantaged populations at high risk of poor oral health are cost-effective?

It was decided that a decision-analytic model would be developed in order to estimate the expected costs and health benefits of various interventions on oral health. The costs and consequences of various interventions could then be directly compared in order to assess which are most effective and cost-effective within the limitations of relevant and available data. This model is described in full in Section 2.

In order to assess the cost-effectiveness of a particular intervention a standard unit of benefit is required in order to compare across treatment areas. For example, if we cure a certain number of cases in one disease area and avert a certain number of events in another we need a common unit in order to decide which of these outcomes is more desirable. Health economics uses the quality-adjusted life year (QALY) for this purpose. The QALY incorporates the life years gained from a treatment strategy, adjusted for the quality of life that the person experiences during those years. Quality of life is determined using measures of utility, which describe health-related quality of life, such as mobility, pain, ability to carry out usual functions of daily living, and depression, on a scale of 0 to 1, with 1 being full health and 0 being dead. For example, if a person lives for 10 years with a utility of 0.5 they will gain 5 QALYs. If they live for 4 years with a utility of 0.75 they will gain 3 QALYs.

Cost-effectiveness analysis is based on the comparison of one intervention with another, such as standard care or no intervention. In order to do this it is the *incremental* QALYs and *incremental* costs that are considered. Most new interventions are more costly and also provide more health benefits. In order to decide whether the extra health benefits are worth the extra costs of the intervention, the incremental cost-effectiveness ratio (ICER) is calculated. The ICER subtracts the cost of the current strategy from the cost of the new strategy, divided by the benefits of the current strategy subtracted from the benefits of the new strategy, in order to determine the incremental cost per unit of benefit. The formula for calculating the ICER is shown below.

$$ICER = \frac{Cost_{New\ strategy} - Cost_{Old\ strategy}}{Benefit_{New\ strategy} - Benefit_{Old\ strategy}}$$

The higher the ICER the higher the cost per QALY gained. NICE generally considered interventions with an ICER less than £20,000 per QALY gained to be cost-effective. Above this threshold, judgements around the acceptability of the intervention as an efficient use of NHS resources are made according to the degree of certainty around the ICER, how accurately changes in quality of life have been captured and how innovative the innovation in question is (NICE, 2012).

Given the likely paucity of relevant data (identified by the literature reviews) available to populate an economic model for community oral health it was decided that interim 'surrogate' outcomes would be used to predict longer-term and broader outcomes (e.g. QALYs).

The questions being answered were concerned with the cost-effectiveness of interventions to improve and maintain oral health, particularly in specific vulnerable populations. Seventeen interventions were selected to be incorporated within the economic model (described in Section 2). These interventions were identified in the effectiveness evidence review carried out by Bazian. The guideline is for local populations with a focus on vulnerable groups, and so the modelling approach was amended to cover the population over a life course approach rather than in each specific vulnerable group described in Section 1.1. Each of the 17 interventions focused on a subgroup of the population which included pre-school (or early years) children, school children, working-age adults and adults over 65 years of age. The 17 interventions are described further in Section 3.

### 1.3 METHODS

No directly applicable evidence to populate the model could be identified on either oral cancer or periodontal disease. The PHAC accepted that, given this, the economic modelling should focus on oral health improvements and maintenance as its effect on dental caries (or tooth decay) was where the relatively strongest levels of evidence lay.

A decision analytic model was developed in order to analyse the impact of a relative risk reduction of dental caries occurring as a result of each of the 17 interventions. From this, the cost per QALY for each intervention could be determined. Due to a lack of directly applicable data that would allow the economic model to calculate the cost per QALY (such as utility estimates for oral health states), various assumptions were initially used to build and populate a preliminary model and presented to the PHAC. Given this lack of appropriate data, the External Assessment Centre (EAC) advised the PHAC that the results of this model may be very limited and not provide an accurate basis to inform their decision making about the range of potential recommendations the PHAC may wish to make. The uncertainty within the preliminary model due to the large number of assumptions being made meant that, rather than a single ICER, the provision of a range of cost-effectiveness estimates based on the likely ranges of values for each input parameter were of more use to PHAC in informing their recommendations.

Therefore, taking into account the lack of directly applicable data and the limitations of the preliminary model, the methodology of the economic analysis was amended, with the alternative approach focusing on the relationship between five key parameters. The model is described fully in Section 2. Analysis I was developed using additional datasets provided by Public Health England (PHE) to estimate risks of poor oral health, and focused on selected interventions (supervised tooth brushing and fluoride varnish programmes) in a deprived community of pre-school and school children. Analysis II was developed to explore the uncertainty around the key input parameters (e.g. baseline risk of decay, quality of life) through sensitivity analyses. An additional model was developed to support Analysis II (referred to as the input calculator model), to inform likely ranges of values for the key inputs. This supporting model is described in Appendices A to D.

An alternative approach for the economic analysis would have been a cost-consequence analysis. Cost-consequence analysis reports a profile of outcomes for each intervention, but does not combine the outcomes into a single unit of effect, such as the ICER in cost-effectiveness analyses. Cost-consequence analysis is useful for interventions which have an impact on a wide range of outcomes, including both health and non-health effects. However, there is no explicit value attached to each of the different outcomes, and as such the decision-maker will have to implicitly decide which intervention represents the best value, which reduces the transparency of the process. Also, the values may reflect those of the decision-maker and not that of the general population.

In the context of this economic evaluation, many of the limitations that are associated with a cost-utility approach are also still relevant to a cost-consequence approach. These in particular are around quantifying the impact of the interventions on a clinical level and on quality of life, and around the cost of the treatment pathway and the cost of the programmes themselves. Section 2 and Section 3 describes these issues in more detail. QATYs (quality-adjusted tooth years) which are described in Appendix C may be considered to be a useful outcome measure for this approach.

## 1.4 REPORT STRUCTURE

The report comprises three further sections:

- Section 2 describes the economic model and its results;
- Section 3 provides an overview the 17 interventions identified in the Bazian review and describes how these interventions were incorporated into the economic modelling;
- Section 4 discusses the limitations of the work and advises upon future research recommendations. Summary statements are also provided.

## Section 2: Economic Analysis

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### 2.1 BACKGROUND

This section provides a summary of the top-line results from the cost-effectiveness model, as well as outlining the evidence that has been collected over the course of the development period to inform the economic analysis. It explores the key areas of uncertainty in this evidence, and our methodology for exploring these areas of uncertainty using a range of extensive sensitivity analyses.

The original aim of the model was to capture the impact of each intervention on dental and periodontal disease, and on oral cancer. However, the economic model has been redesigned to capture the costs and health benefits associated with treating dental caries only. Few studies reported outcomes relating to periodontal disease. In addition, there was a lot of uncertainty around how periodontal disease and the outcomes reported in the studies (e.g. Plaque and Gingival Index) are linked to quality of life and treatment costs and, as such, this element of oral health was excluded from the analysis. Furthermore, the effectiveness review did not capture any data on the impact of the interventions on the risk of oral cancer. There was, however, a better range of evidence for the impact on dental caries, although there was still a significant level of uncertainty due to the heterogeneity of the data reported across the studies. There are also varying levels of uncertainty around many other parameters in the economic model (including programme costs and impact on quality of life), due to a paucity of previous research and a lack of data reported in the literature.

Two approaches have been undertaken to estimate the cost-effectiveness of the interventions in the analysis. One approach looks at four specific interventions in the pre-school or school populations (Analysis I), while the other approach provides a guide on how to assess the cost-effectiveness of an intervention given a range of input parameters (Analysis II).

#### 2.1.1 Quality of Life

The key area where there is a lack of data is the impact of quality of life associated with tooth decay, including the impact of the stage and severity of decay, and of increasing the number of teeth being affected. This is compounded by the fact that the majority of the interventions will be in children where it is considered to be difficult to accurately measure quality of life associated with oral health.

Guidelines for the development of economic models in public health (as described in the CPHE Methods Manual) state that generic utility measures should be used to measure and value outcomes, since they allow for a comparison with other disease areas which may have very different health benefits. Utility weights (measured directly or indirectly) describing different health states for dental decay have, unfortunately, not been reported in the literature. The most relevant source of data for oral health impact is the Adult Dental Health

2009 survey, which reported the Oral Health Impact Profile (OHIP-14) scores for varying levels of pain in the mouth, decay and missing teeth, following an interview-administered questionnaire on a sample of adults within the UK. The OHIP-14 scores were mapped to utility estimates using a published regression analysis, further adding to the uncertainty around of quality of life estimates.

The economic model attempts to estimate the magnitude of the QALY losses associated with developing dental caries.

**Analysis I:** Utilities from otitis media have been used as a proxy for the quality of life associated with tooth loss in children. Further details of the assumptions used to calculate QALY losses associated with dental caries are provided in Section 2.3.1.

**Analysis II:** QALY losses associated with dental caries were estimated by converting oral health-related quality of life to general utilities. Oral-health related quality of life was derived from the Adult Dental Health survey (2009), which reported OHIP responses for a variety of oral health conditions. The results of this report were used to estimate the impact of dental caries associated with decay and with missing teeth. A study by Brennan and Spencer (2006) was used to map OHIP responses to generic health state values. The authors surveyed both patients and dentists and used responses to construct models of health state values. Further details on this study and the methods used to estimate the QALY loss are provided in Appendix C.

### 2.1.2 Costs

Intervention costs are very rarely reported alongside the effectiveness results of any oral health studies. The studies that report cost data are often drawn from other countries and may not be relevant to the English setting. Reported costs also vary in the level of detail, which provides further challenges for applying to alternative settings (e.g. in a smaller number of schools): some report the cost per child per year (with no data reported for adults); some provide the total cost of the programme broken down by staff and material costs. There are further limitations of extrapolating cost data from one study in one setting to a range of settings and populations since each intervention type explored in the current analysis encompasses a wide range of possible programmes, and there are some concerns that the intervention costs from a specific study may not be relevant for the broader category, especially when there is significant variation in the effectiveness impact (e.g. the cost of a fluoride varnish programme delivering two applications per year in a school in a disadvantaged area may not be appropriate for a fluoride varnish programme delivering four applications per year in a similar school in a similar area). Analysis I estimates the maximum cost of an intervention per child for a given set of input parameters. Analysis II provides a range of cost-effectiveness estimates based on a range of intervention costs.

Further information around the costs of treating dental caries that are included in the model is provided in Section 2.3.1 and Appendix B.

### **2.1.3 Effectiveness**

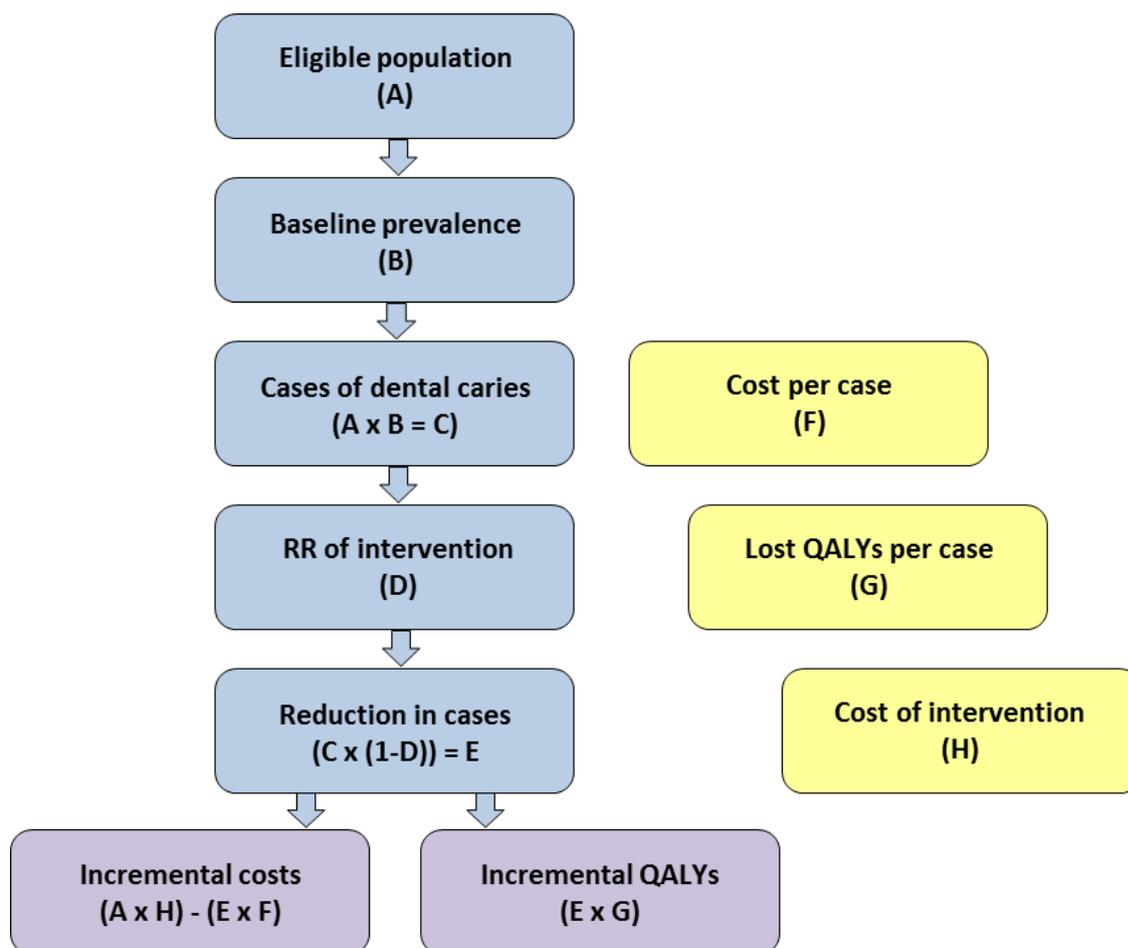
The effectiveness of the interventions on levels of decay has been reported in various ways across the identified studies, making it difficult to compare different interventions head-to-head. Most studies reported the clinical outcomes that were evaluated in the study, for example, the difference in dmft/DMFT before and after the programme, the dmft/DMFT prevented fraction, and the proportion of the study population that are caries-free before and after the programme. Few studies provided an estimate of the magnitude of the impact on the clinical outcomes, such as relative risk (RR) or odds ratios (OR). Some studies only reported intermediate outcomes relating to modifiable behaviour, such as the frequency of brushing and flossing, snacking levels, oral health knowledge and use of dental services, but this evidence is of limited use given that no quantitative data exist to link these to the impact on the patient regarding quality of life. This is described in more detail in Section 3.

## **2.2 MODEL STRUCTURE AND INPUT PARAMETERS**

A simple model was developed in order to undertake sensitivity analysis around input parameters, notably those around which there were the greatest levels of uncertainty. The structure of the model is displayed in Figure 2.1. This model is designed to handle and explore a range of scenarios.

The model structure was designed to be as simple as possible to avoid introducing unnecessary complex analysis. Although the model takes a generic approach, due to the paucity of data in this area, it was developed specifically to allow for the uncertainty in the key inputs appropriate to this project and to permit a wide range of relevant scenarios to be considered. It was judged that a less simplistic structure would increase the complexity of the results and make them less easy to interpret and limit their usefulness.

**Figure 2.1: Model structure**



The parameters that have been explored in the analyses are detailed below:

- Intervention costs (per patient);
- Baseline risk of dental caries;
- Relative risk reduction of dental caries for the intervention;
- QALY loss from each case of dental caries;
- Cost of treating each case of dental caries.

A relative risk reduction (RRR) is presented in the sensitivity analysis as an intuitive way of interpreting the effect of an intervention on the level of disease. This refers to the degree to which an intervention lowers (or increases) the risk of an event occurring. A relative risk reduction of 0 is equivalent to no effect on the rate of disease. A relative risk reduction of 10% suggests that the risk of disease has been decreased by 10% (that is, to 90% of its original level). The larger the relative risk reduction, the more the intervention reduces the risk of disease.

When assessing the impact of an intervention in a population, the baseline risk should be interpreted as the mean baseline risk of caries in the population which the programme will be delivered to (i.e. before the programme starts). Risk in a given population is likely to be heterogenous across all individuals to a certain extent, so a population with a large proportion of high risk individuals would have a higher than average baseline risk. For example, if a school is in the lower IMD quintile, then the baseline risk of caries of 39% for high risk children (see Section 2.3 for derivation of this risk) might apply to the whole school. If a school is in an average area of deprivation, 20% of children may be at high risk (with 39% risk of caries) with the remainder at moderate risk (to illustrate, at 20%). The overall baseline risk for this school would therefore be lower (roughly 24%, in this illustrative example), and the intervention should be interpreted with this baseline risk in mind.

For the remaining parameters, the approach for estimating the input varies by each analysis. In Analysis I, it was attempted to more precisely estimate the likely values for each of the parameters. Analysis II uses a range of values for each parameter.

## **2.3 ANALYSIS I: FLUORIDE VARNISH AND SUPERVISED TOOTHBRUSHING**

This analysis assessed selected interventions delivered to a high risk population; in this case, children at high risk of poor oral health (i.e. those living in disadvantaged areas).

- Fluoride varnish in pre-school children;
- Supervised tooth brushing for pre-school children (Childsmile);
- Fluoride varnish in school children;
- Supervised tooth brushing for school children.

### **2.3.1 Model Parameters**

#### **Baseline risk of caries**

Baseline risks of disease were taken from a dataset provided by the Dental Public Health Intelligence Programme, using the most deprived quintile (by IMD) to represent a high-risk population i.e. children.

- The baseline risk of dental caries for 5 year olds in the most deprived quintile is 39.6%;
- The baseline risk of dental caries for 12 year olds in the most deprived quintile is 42.4%.

#### **Quality of life**

The current analysis is likely to underestimate the benefit of intervening. The total QALY loss can only take into account the temporary reduction in quality of life from a missing tooth, and from the mortality impact of a general anaesthetic. There is a lifetime impact from a missing

tooth, but it has not been possible to include this in the current analysis because it cannot be quantified at this time.

Very few estimates of quality of life as measured by a generic instrument exist for different oral health states. As such, some members of the Committee suggested using utility estimates from a similar disease area in children as a proxy for a missing tooth. Otitis media is an infection of the middle ear that is particularly common in young children. A number of utility estimates for otitis media have been selected from different sources to inform the range of values for our analysis (see Table 2.1 for each estimate and the corresponding QALY loss). Oh *et al.* (1996) and Coco (2007) are studies of acute otitis media and, as such, reflect the short-term impact of otitis media and is considered to apply to tooth loss in terms of acute pain, disruption to individuals' and families quality of life, need for professional support and care, and in some cases attendance at secondary care settings for surgical intervention). The disutility of dental caries can vary by a number of population factors such as social group, age, race *etc.* The utility estimates presented in Table 2.1 are from studies of the general population and, therefore, may not be applicable to the more deprived and high risk quintiles.

In the absence of directly applicable data, the following assumptions are used to estimate QALY losses:

- It is assumed that having a missing tooth only will impact on quality of life.
- Of those patients with caries experience, the proportion with extraction experience (%MT>0) is used to estimate the average QALY loss per case of caries.
- 100% of 5 year olds have an extraction under general anaesthetic. Varying proportions of 12 year olds were also analysed but this was found to have very little impact on the overall QALY loss due to GA, so the rate of GA for 5 year olds was also applied to 12 year olds in this case.
- The mortality rate associated with GA is 1 in 300,000 for all age groups.
- If a patient dies as a result of GA, then they lose on average 40 QALYs. This takes into account discounting (at 1.5%) and general population mortality.
- This results in an average QALY loss of 0.00013 per extraction under GA.
- It is assumed that the disutility associated with a missing tooth lasts for 12 weeks.

It is important to note that the analysis assumes that disutility for a missing tooth lasts for 12 weeks. Although there is a lifetime impact from extraction (of both deciduous and permanent teeth), this cannot be quantified, and as such are not included in the analysis. Therefore the analysis is likely to underestimate the benefits of the intervention.

The QALY loss per case of caries takes into account the proportion of children with caries experience who have had teeth extracted (for each case of caries, the disutility of applied to the proportion who have extraction experience). ). The calculations are presented in Table 2.1.

**Table 2.1: Calculations for QALY loss**

Parameter	Value	Calculation
Baseline utility	0.94	-
Utility for missing tooth	0.72	-
Duration of disutility (weeks)	12	-
QALY loss from missing tooth	0.0508	$(0.94-0.72)*(12/52)$
Proportion of extractions under GA	100%	-
Mortality rate of GA	0.000333%	-
QALY loss if death	40	-
QALY loss from GA	0.00013	$100%*0.000333%*40$
QALY loss from missing tooth	0.0509	$0.0508 + 0.00013$
Children with caries who have extraction experience	13.91%	-
Mean QALY loss from caries	0.0071	$0.0509*13.91%$

**Table 2.2: Sources for utility estimates\* and the corresponding QALY loss per case of caries**

Source	Utility estimate	QALY loss
Oh et al. 1996	0.72	0.007
Coco 2007, Oh et al. 1996	0.79	0.005
Dakin et al. 2010	0.882	0.002

\*Taken from studies of otitis media in children

### Resource use and costs

The total costs of decay takes into account the costs associated with extraction, and the lifetime cost of a restoration.

- The cost of an inpatient tooth extraction is estimated to be £1,160 (PSSRU 2013).
- Of those patients with caries experience, the proportion with extraction experience (%MT>0) is used to estimate the average spending on extractions per case of caries.
- The cost of filling a decayed tooth accounts for the lifetime of a filling, and assumes that a certain proportion of fillings will be replaced. The estimates were obtained from the input calculator model.
- Of those patients with caries experience, the proportion with filling experience (%FT>0) is used to estimate the average spending on restorations per case of caries.
- The range of costs is generated by assuming between 1 and 3 teeth are filled.
- The average spending on caries varies by age group – a greater proportion of 5 year olds will have an extraction under general anaesthetic.

### 2.3.2 Model Interpretation

Each of the tables below presents the maximum cost per child for the intervention to be considered cost-effective at a QALY threshold of £20,000. The maximum cost per child for the intervention refers to the total cost of the intervention (for example, if an intervention

consists of two fluoride varnish applications per year for five years, then the cost per intervention refers to the five-year cost). The time horizon over which the intervention is provided is included in the results tables below, for each study that informs the effectiveness evidence.

For interventions in school children in the most deprived quintile, the baseline risk of caries is 42.4%, and a range of assumptions around the rate of extractions under GA are analysed – results are presented assuming that 50% of extractions are under GA, and 80% of extractions are under GA.

For interventions in pre-school children in the most deprived, the baseline risk of caries is 39.6%, and it is assumed that 100% of extractions are under GA.

Results are also presented for a range of QALY loss assumptions (low = 0.002, medium = 0.005, high = 0.007). For each estimate of QALY loss for each intervention, a range of intervention values are presented, which are based on varying costs of treating tooth decay.

### 2.3.3 Model Results

**Table 2.3: Cost-effectiveness of interventions for infants and pre-school children in the most deprived quintile (at £20,000 per QALY)**

Infants and Pre-school: baseline risk 39.62%		
Childsmile RRR 32% (Macpherson et al. 2013) Effectiveness assessed at three years	QALY loss	Cost-effective for maximum cost of intervention*
100% extractions under GA	Low	£27-£34
	Med	£35-£41
	High	£40-£46

\*Assumes cost of dental caries is between £175-£225

**Table 2.4: Cost-effectiveness of interventions for infants and pre-school children in the most deprived quintile (at £20,000 per QALY)**

Infants and Pre-school: baseline risk 39.62%		
Fluoride varnish RRR 43% (Moberg et al. 2005) Effectiveness assessed at three years	QALY loss	Cost-effective for maximum cost of intervention*
100% extractions under GA	Low	£37-£45
	Med	£47-£55
	High	£54-£62

\*Assumes cost of dental caries is between £175-£225

\*Assumes same risk reduction as for older children.

**Table 2.5: Cost-effectiveness of interventions for school children in the most deprived quintile (at £20,000 per QALY)**

<b>School children: baseline risk 42.4%</b>		
<b>Fluoride varnish RRR 43%</b> (Moberg et al. 2005) Effectiveness assessed at three years	<b>QALY loss</b>	<b>Cost effective for maximum cost of intervention*</b>
50% extractions under GA	Low	£35-£62
	Med	£46-£73
	High	£53-£80
80% extractions under GA	Low	£44-£71
	Med	£55-£82
	High	£62-£89

\*Range in maximum cost refers to minimum and maximum cost of caries. Assumes cost of dental caries is between £150-£300 for 50%, £200-£350 for 80%

**Table 2.6: Cost-effectiveness of interventions for school children in the most deprived quintile (at £20,000 per QALY)**

<b>School children: baseline risk 42.4%</b>		
<b>Supervised tooth brushing RRR 11%</b> (Jackson et al. 2005) 21 month programme	<b>QALY loss</b>	<b>Cost-effective for maximum cost of intervention*</b>
50% extractions under GA	Low	£9-£16
	Med	£12-£19
	High	£14-£21
80% extractions under GA	Low	£11-£18
	Med	£14-£21
	High	£16-£23

\*Assumes cost of dental caries is between £150-£300 for 50%, £200-£350 for 80%

**Table 2.7: Cost-effectiveness of interventions for school children in the most deprived quintile (at £20,000 per QALY)**

<b>School children: baseline risk 42.4%</b>		
<b>Supervised tooth brushing RRR 39%</b> (Pine et al. 2007) 30 month programme	<b>QALY loss</b>	<b>Cost-effective for maximum cost of intervention*</b>
50% extractions under GA	Low	£31-£56
	Med	£41-£66
	High	£48-£73
80% extractions under GA	Low	£40-£64
	Med	£50-£74
	High	£56-£81

\*Assumes cost of dental caries is between £150-£300 for 50%, £200-£350 for 80%

### **2.3.4 Assessment of Interventions**

These interventions are likely to most cost effective in children from deprived groups who have a higher risk of caries, so uptake should be monitored to ensure that these interventions are reaching children from deprived groups.

### Fluoride varnish in pre-school children

Assuming a baseline risk of 39.2% (which represents children aged 0-5 years in the most deprived quintile), that 100% of extractions are carried out under GA, that the QALY loss is low and the cost of treatment is £175, the overall intervention may cost up to **£37 per child** and be considered cost effective at the NICE threshold of £20,000/QALY. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£46 per child** and be considered cost effective. The study (Moberg *et al.*, 2005) used to inform this scenario reported the reduction in risk of caries (estimated to be 43%) at three years, and as such the maximum cost can be considered to be the maximum three-year cost in this instance.

### Supervised toothbrushing in pre-school children

Assuming a baseline risk of 39.2% and that 100% of extractions are carried out under GA, if the QALY loss is low and the cost of treatment is £175, the intervention may cost in total up to **£27 per child** and be considered cost effective at the NICE threshold of £20,000/QALY. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£62 per child** and be considered cost effective. The study (Macpherson *et al.*, 2013) used to inform this scenario reported the reduction in the risk of caries (estimated to be 32%) at three years, and as such the maximum cost can be considered to be the maximum three-year cost in this instance.

The investigators of this study were able to provide some limited data for the costs of the programme. There was a large variation in the annual cost per child across the different regions that the programme was delivered in. These costs ranged from less than £5 per child, to over £75. Lower costs per child were associated with a larger population in that region, so it appears that there were some economies of scale involved. The provided costs were not reported by cost component, so it is difficult to ascertain how they might apply to other tooth brushing programmes.

### Fluoride varnish in school children

Assuming a baseline risk of 42.4% (which represents children aged 5-12 years in the most deprived quintile), if 50% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£35 per child** and be considered cost effective at the NICE threshold of £20,000/QALY. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£80 per child** and be considered cost effective. If 80% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£44 per child**. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£89 per child**. The study (Moberg *et al.*, 2005) used to inform this scenario reported the reduction in risk of caries (estimated to be 43%) at three years, and as such the maximum cost can be considered to be the maximum three-year cost in this instance.

### Supervised toothbrushing in school children

Two different risk reductions have been assessed.

For a low risk reduction (Jackson *et al.*, 2005): If 50% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£9 per child** and be considered cost effective at the NICE threshold of £20,000/QALY. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£21 per child** and be considered cost effective. If 80% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£11 per child**. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£23 per child**. This programme lasted 21 months, and as such the maximum cost can be considered to be the maximum 21-month cost in this instance.

For a higher risk reduction (Pine *et al.*, 2007): If 50% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£31 per child** and be considered cost effective at the NICE threshold of £20,000/QALY. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£73 per child** and be considered cost effective. If 80% of extractions are carried out under GA, and the QALY loss is low and the cost of treatment is £175, the intervention may cost up to **£40 per child**. If the QALY loss is high and the cost of treatment is £225, the intervention may cost up to **£81 per child**. This programme lasted 30 months, and as such the maximum cost can be considered to be the maximum 30-month cost in this instance.

## 2.4 ANALYSIS II: SENSITIVITY ANALYSIS

Given the level of uncertainty around key parameters in the analysis, it would have been inappropriate to calculate single estimates of the cost-effectiveness for each intervention. Sensitivity analysis can help to determine which parameters are the key drivers of the economic evaluation, and it is used to assess the impact that changes in a certain parameter will have on the outcomes. By reporting extensive outputs from sensitivity analysis, it is possible to consider a wide range of scenarios and, as such, can increase the level of confidence that a reviewer will have in the model.

Sensitivity analysis involves varying one value in the model by a given amount, and examining the impact that the change has on the model's results. Each outcome listed below has been explored across a range of appropriate values, based on the values observed in the literature. The main model outcome can then be plotted against each possible input value to demonstrate the relationship between the input value and the model's results. This type of analysis can also be used to judge the threshold at which the main conclusions of the evaluation might change.

The following sensitivity analyses are designed to demonstrate the impact of varying combinations of the key parameters in the model. These will also help to identify potential range of values where the interventions may be considered to be cost-effective. The following section will discuss the range of evidence for each of the interventions that has been uncovered for each of the key parameters, how these compare with the range of values that is considered to be cost-effective, and whether it is appropriate to draw any conclusions about the cost-effectiveness of the interventions.

### 2.4.1 Model Parameters

Three different baseline risks of decay have been evaluated, reflecting the risk in infants (children, including very young children, under 5 years), children (aged 5 to 18), and adults (aged 18 to 65). The number of decayed teeth over the course of a lifetime reported in two national Dental Health surveys provided a guide to estimating the baseline risks of decay for each subgroup. The risk of developing caries in the infant population is estimated to be approximately 10%, and the risk in the child population is estimated to be approximately 20%. The risk of developing caries in the adult populations is estimated to be around approximately 50%.

The QALY loss and costs relating to dental caries have been estimated using the input calculator model, and are described in Appendix B and Appendix C.

Table 2.7 provides an overview of the range for each input parameter that has been included within the model.

**Table 2.7: Range of input parameter considered in sensitivity analysis**

Parameter	Inputs considered in model
Intervention cost (per patient)	£20, £40, £60, £80, £100
Baseline risk of dental caries	10%, 20%, 50%
Relative risk reduction of dental caries for the intervention	All values between 0% and 100%
QALY loss from each case of dental caries	-0.025, -0.05, -0.1
Cost of treating each case of dental caries	£75, £100, £125

### 2.4.2 Model Interpretation

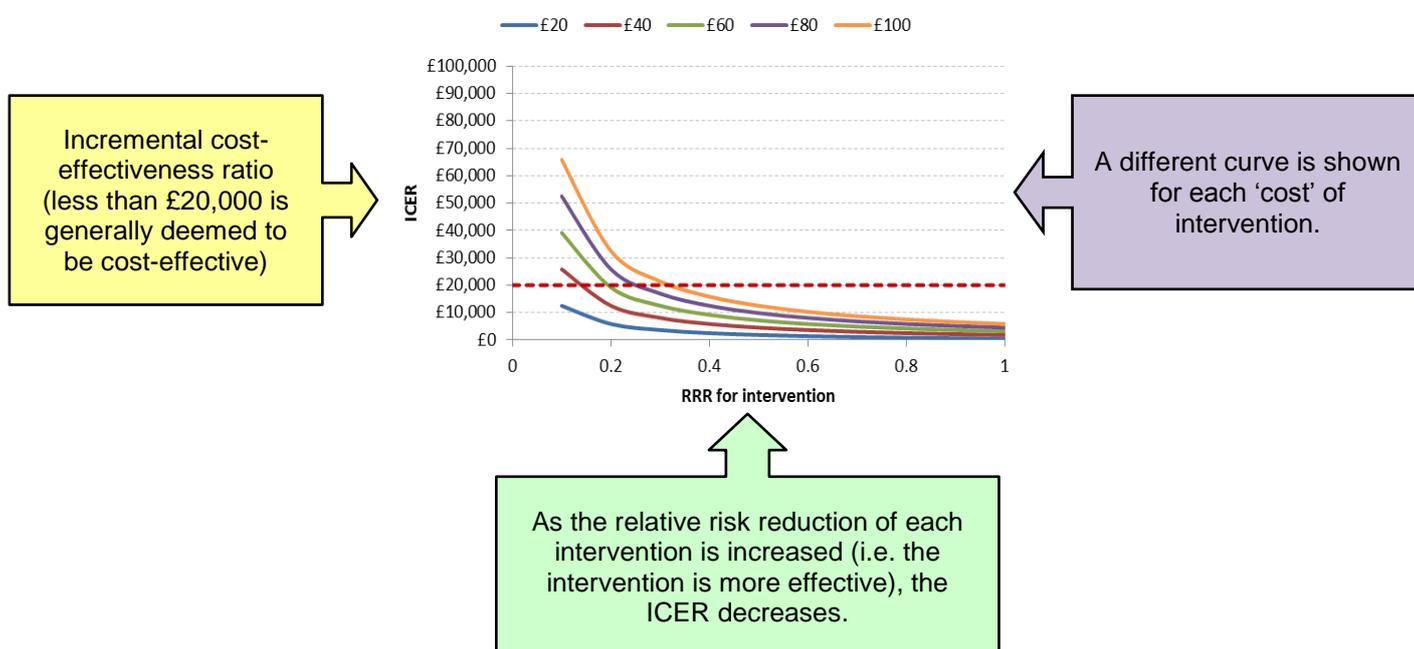
Interventions are generally considered to be cost-effective if the incremental cost-effectiveness ratio (ICER) is below £20,000. The ICER reflects the additional cost per extra unit of benefit, and is calculated as follows:

$$ICER = \frac{Cost_{Treatment} - Cost_{Comparator}}{Effectiveness_{Treatment} - Effectiveness_{Comparator}}$$

Figure 2.2 below, demonstrates how a sensitivity analysis chart can be used to explore a range of potential scenarios. In this example, an intervention that costs £40 per patient shown by the red line is likely to be cost-effective (at a £20,000 per QALY threshold) as long as the relative risk reduction of caries is greater than around 15% (i.e. the intervention lowers the risk of tooth decay by around 15%). However, an intervention that costs £100 per patient (as shown by the orange line) is only likely to be cost-effective if the relative risk

reduction of caries is greater than about 30%. The chart can, therefore, be used to show the range of potential scenarios where an intervention is likely to be cost-effective, and other scenarios where it is unlikely to be cost-effective.

**Figure 2.2: A guide to the interpretation of each graph**



Figures 2.3, 2.4 and 2.5 display the impact of varying the other parameters in the model. Figure 2.3 shows a range of scenarios for a population whose baseline risk of caries is 10%.

- The different coloured lines refer to different per-patient intervention costs.
- The top row of graphs assumes that the QALY loss resulting from a case dental caries is -0.025 QALYs. On the second and third rows this loss is changed to -0.05 and -0.10 QALYs respectively.
- Likewise, each column displays a different plausible cost of treating dental caries. In column A each episode of dental caries costs £75; this is then increased to £100 in column B and £125 per case of dental caries in column C.
- Each individual graph displays the ICER dependent on both the cost of the intervention and the relative risk reduction for that intervention.
- For example, the graph 'A1' in Figure 2.3 shows various ICERs for interventions costing between £20 and £100 with a relative risk reduction of between 0% and 100%. All of the scenarios shown on this graph have a baseline risk of caries of 10%, a cost per case of dental caries of £75 and a QALY loss associated with dental caries of -0.025.
- Figures 2.4 and 2.5 show the same charts, but for different populations with different baseline risk of caries.

The results of the sensitivity analysis can be interpreted according to the time scale that is considered to be most relevant - i.e. the PHAC can estimate QALY loss and costs over whichever time scale that is considered to be appropriate, and then the graphs in Section 2.4.3 can be used to guide discussions around whether in that circumstance the intervention is cost-effective.

### 2.4.3 Model Results

Figure 2.3: Baseline risk of caries: 10%

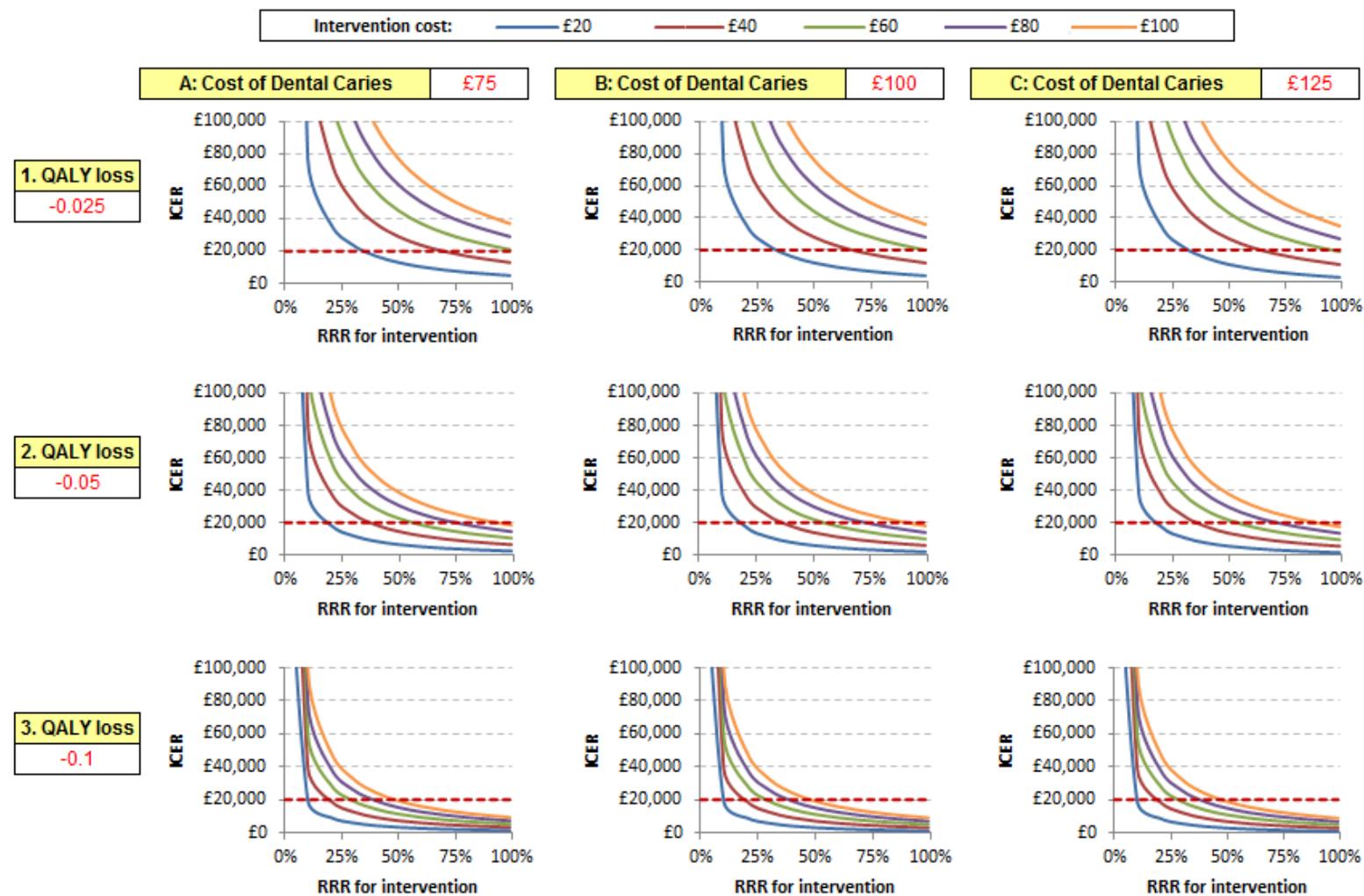


Figure 2.4: Baseline risk of caries: 20%

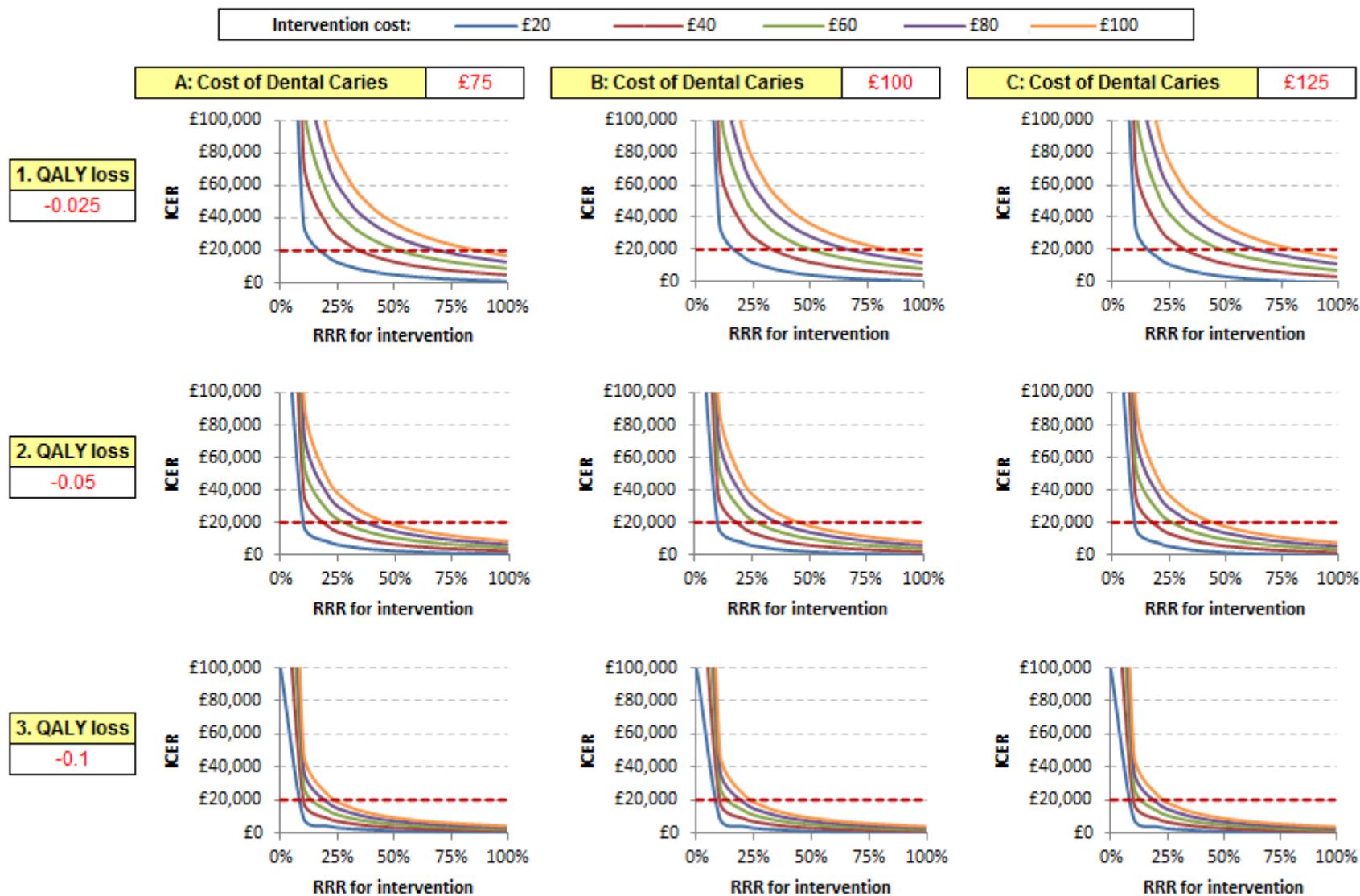
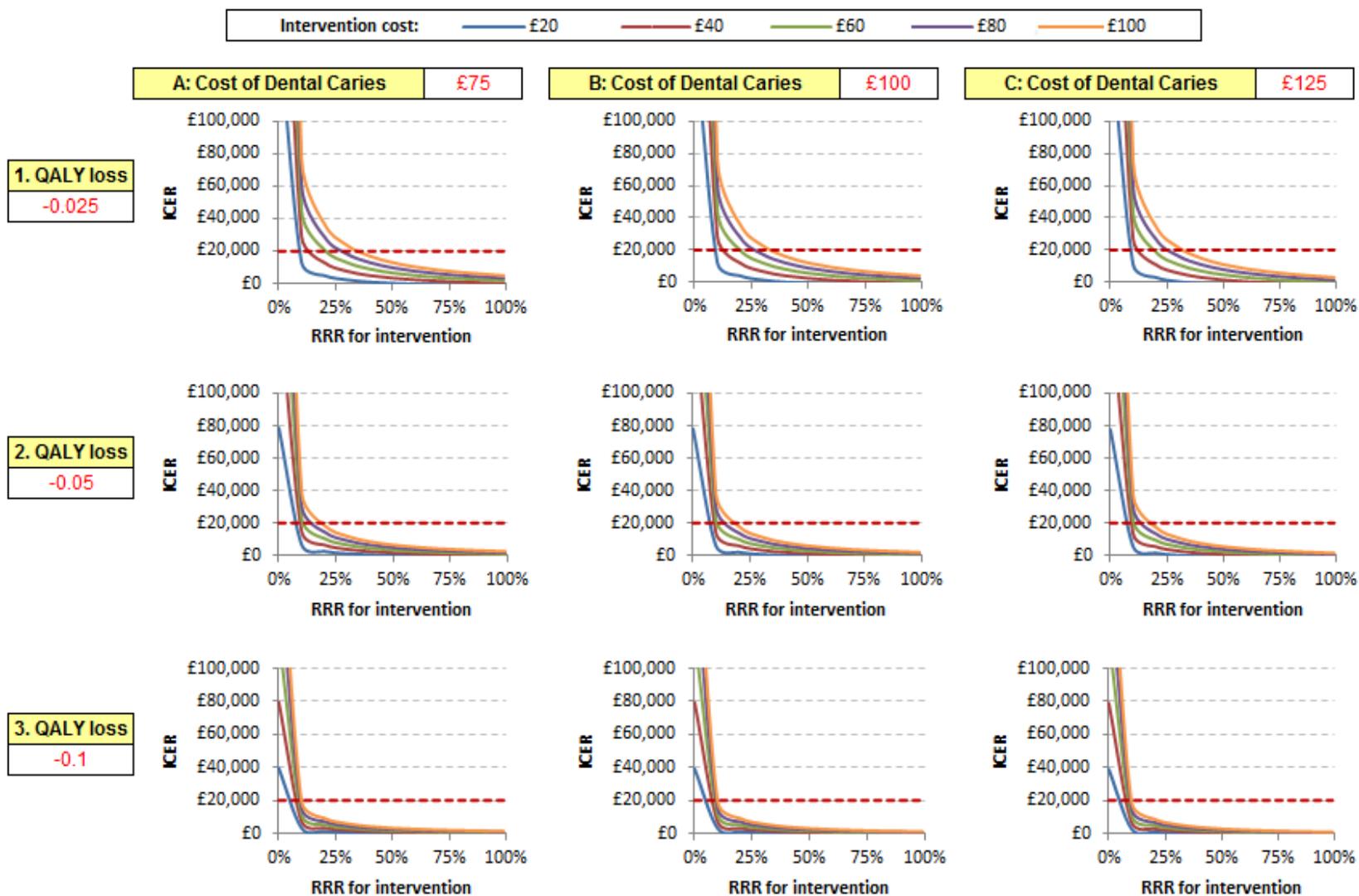


Figure 2.5: Baseline risk of caries: 50%



#### **2.4.4 Interpretation of Results**

The following observations can be drawn from the scenarios set out in Figures 2.3, 2.4 and 2.5 above.

##### **2.4.4.1 Cost per case of dental caries**

It appears from Figures 2.3, 2.4 and 2.5 that varying the cost of dental caries does not significantly impact upon the results of the model. When comparing the graphs in columns A, B and C on each of the nine rows set out above it is evident that the graphs are very similar. Considering row 1, the blue line (representing an intervention costing £20 per patient) crosses the £20,000 threshold line at around 20% RRR for the intervention on all three graphs. This consistency across the three columns occurs throughout. As such, we can infer that the cost of dental caries is not a key driver of the model's results, nor is it likely to be a key driver in the evaluation of any of the interventions.

##### **2.4.4.2 QALY loss per case of dental caries**

Various QALY losses associated with dental caries are displayed in Figures 2.3, 2.4 and 2.5. By considering the graphs across in rows 1, 2 and 3 on each Figures 2.3, 2.4 and 2.5, the impact of varying the QALY loss from -0.025 to -0.10 can be established. Across all three sheets it appears that varying the QALY loss has a relatively large impact on the results of the model, in that the higher the QALY loss, the more likely the intervention is to be cost-effective. The greater the assumed QALY loss, the less effective an intervention needs to be in order to be seen as cost-effective.

##### **2.4.4.3 Intervention cost per individual**

A range of intervention costs are provided on each of the graphs displayed in Figures 2.3, 2.4 and 2.5. The lowest cost considered is £20 per person for the total cost of the intervention (blue line), whilst the highest is £100 per person (orange line). The impact of varying the cost of the intervention within this range is shown by the shift in the ICER line as the cost changes. For instance, where the intervention costs £20 per person, the ICER line is lower (and more likely to be under the £20,000 threshold line) than where the intervention costs £100 per person. The cost of the interventions is a key driver of the model, as interventions costing £20 per person almost always cost effective provided the RRR is 25% or greater, whilst in some populations interventions costing £100 per person will never be cost effective at a £20,000 per QALY threshold.

##### **2.4.4.4 Relative risk reduction of the intervention**

The relative risk reduction of the intervention is displayed across the x axis on each graph, where 0% indicates that an intervention that does not reduce the risk of disease and 100% represents a highly effective intervention. On each graph, the ICER reduces significantly as the intervention become more effective, showing that the relative risk reduction (or effectiveness) of the intervention under consideration is a key driver of the model. The

graphs are presented so that the user can see what level of risk reduction is needed for each intervention to be cost-effective.

#### **2.4.4.5 Low baseline risk of dental caries (10%)**

Figure 2.3 represents a population with a low baseline risk of dental caries. Only where the QALY loss associated with dental caries is relatively high, or the relative risk reduction of the intervention is closer to 100% (i.e. the intervention is very effective) does the intervention become cost-effective. This occurs because only a small proportion of the population are able to benefit from the intervention and, as such, the avoided QALY loss needs to be great or the intervention highly effective, to ensure that the benefit this small number of patients gain outweighs the cost of implementing the intervention across the whole population.

#### **2.4.4.6 High baseline risk of dental caries (50%)**

Figure 2.5 represents a population with a far higher baseline risk of dental caries. Conversely, to the population with a low baseline risk, here interventions are cost-effective under a wider range of scenarios. Only where both the QALY loss associated with dental caries is low (-0.025) and the intervention is relatively ineffective (below 20% RRR) does the intervention fail to be cost-effective. This population on the whole has great potential to benefit from an intervention that will reduce incidence of dental caries, and as such this benefit outweighs the cost of implementing the intervention.

### **2.4.5 Assessment of Interventions**

The interventions that have been considered in this analysis are based around a life course approach. Most of the relevant interventions that have been identified are in children under the age of 18. The 17 interventions listed below are interpreted in the context of the sensitivity analysis shown in Section 2.4.2. The mapping of each intervention to the graphs shown in Figures 2.3, 2.4 and 2.5 aims to be indicative only and based upon very limited published literature. The effectiveness of each intervention is discussed in further detail in Section 3.

The inputs described within this section are illustrative and based on the limited published literature available. When considering specific population subgroups, the PHAC may wish to interpret cost-effectiveness results from a different graph to that suggested.

#### **2.4.5.1 Pre-school children**

- Fluoridated milk in nurseries (Stecksen-Blicks, 2009);
- Supervised brushing in nurseries (MacPhaerson, 2013);
- Oral health education in nurseries (Tubert-Jeannin, 2012);
- Multi-component oral health promotion in the community (Blair, 2005);
- Home and/or community based oral health education (Whittle, 2008 and Ellwood, 2004).

Pre-school children are likely to still have their primary teeth, and not yet have developed their permanent teeth. In this population, the baseline risk of dental caries in this population is considered to be low (due to a shorter time of exposure to cariogenic agents and behaviours etc.). It is estimated that this population would best fit within Figure 2.3, where baseline risk of dental caries is 10%. Alternatively, it has been estimated that in some sectors of society the risk of caries in infants and children is closer to 50%, and in this instance the graphs in Figure 2.5 would be more appropriate to consider. The low QALY loss and costs pictured in graph A1 of the appropriate figure may best represent this population.

The RRR associated with the each of the interventions listed above has been estimated from results reported in the literature and as such values are indicative only. All five interventions had fairly similar RRR for dental caries of between 25% and 37% compared to no intervention. If it is considered that graph A1 on Figure 2.3 is most appropriate for this population and if the intervention costs more than £40 or more per child these interventions are unlikely to be cost-effective at a £20,000 per QALY threshold. Only where the interventions above have a lower cost (at around £20 per child), or if the baseline risk of caries is significantly higher, are they likely to be cost-effective at a £20,000 threshold.

#### **2.4.5.2 School children**

- Fluoride varnish in schools (Moberg, 2005a and Hardman, 2007);
- Fluoridated milk in schools (Riley, 2005 and Ketley, 2003);
- Fluoride mouth rinse in schools (Levin, 2009);
- Supervised brushing in schools (Jackson, 2005 and Pine, 2007);
- Multi-component oral health promotion in schools with preventative treatment (Bodner, 2010);
- Addressing common risk factors in schools;
- Oral health education in schools (Piper 2012), (Pieterse, 2006), (Vanobbergen, 2004);
- Peer-to-peer oral health education in schools;
- Community oral health education;
- Home visits to improve dental care access.

School children are likely to have a mixture of primary and permanent teeth. As this population ages, primary teeth will be replaced with permanent teeth and older school children will generally have all permanent teeth. The baseline risk of dental caries is estimated to be higher in school children compared with pre-school children. It could be approximated that this population would best fit within Figure 2.4 (baseline risk of dental caries of 20%). It is unknown to what degree the QALY loss and costs associated with dental caries differs to that of pre-school children. Restorations in this age group have a relatively good survival rate compared to the older age groups (see Appendix A) and so both the QALY loss and costs associated with experiencing dental caries are comparatively low. As such, a range of low and medium estimates for cost and QALY loss could be considered, and graphs 1A, 1B, 2A and 2B on Figure 2.4 might best represent these children.

The relative risk reduction for each of the interventions listed above for school children were estimated as accurately as possible given the limited information available in the published literature. A number of interventions (addressing common risk factors; peer-to-peer education; community oral health education and home visits to improve dental care access) had unknown RRR compared to no intervention in terms of reducing incidence of dental caries. By considering graphs 1A, 1B, 2A and 2B on Figure 2.4 it is apparent more information is required to determine whether, or not these interventions will be cost-effective, i.e. the ICER is likely to be above £20,000 per QALY. Three further interventions had low estimated RRRs: supervised brushing (11%), multi-component with preventative treatment (0.04) and oral health education in schools (8%). It is evident from Figure 2.4 that these interventions are also unlikely to be cost-effective where the per-patient cost of the intervention is £20 or more, unless the QALY loss associated with each case of dental caries is greater than 10%.

The final three interventions had far higher estimated RRR. Fluoride mouth rinse had a RRR of dental caries of 21%. As such, where the QALY loss of dental caries is assumed to be -0.05 and the cost per child of the intervention is £40, or below, graphs 1A and 1B on Figure 2.4 show that the intervention would be cost-effective. If the QALY loss of dental caries is -0.1 (graphs 2A and 2B), the cost of fluoride mouth rinse could rise to £60 per patient and the intervention remain cost-effective. The estimated RRR of fluoridated milk was 31%. Considering the same four graphs on Figure 2.4 as above, where the QALY loss of dental caries is -0.05 fluoridated milk will be cost effective if the cost per child is £60, or less. Where the QALY loss is -0.1 (graphs 2A and 2B), fluoridated milk remains cost effective at all costs considered (up to £100 per child). The final intervention, fluoride varnish, had an approximate RRR of 43%. According to graphs 1A, 1B, 2A and 2B, this intervention will always be cost-effective within the ranges considered except when the QALY loss associated with dental caries is -0.05 or less and the cost of the intervention is at the highest end of the plausible range (£100).

#### **2.4.5.3 Adults of working age**

- Workplace oral hygiene education (Morishita, 2003).

Adults of working age across their lifetime are likely to have a higher baseline risk of dental caries than either school children, or pre-school children. A baseline risk of 0.5, or 50% over the course of the model, is the most plausible estimation for this subgroup of the population and as such Figure 2.5 should be considered. The only intervention identified in this population was workplace oral hygiene which had an estimated RRR of 4%. Considering the graphs on Figure 2.5 an intervention with a RRR of 4% is only cost-effective where the intervention costs £40 or less per adult and the QALY loss is -0.05 or greater (shown on rows 2 and 3), or if the intervention costs no more than £60 and the QALY loss is -0.10 or greater (shown on row 3). It is reasonable to assume that an adult with dental caries may experience a QALY loss of 0.1 or more (over their lifetime) and, as such, provided that the intervention costs no more than £40 per adult, it is likely to be cost-effective at a £20,000 per QALY threshold.

#### 2.4.5.4 Adults over 65

- Community oral health promotion (Al-Haboubi, 2012).

Similarly to adults of working age, adults over 65 are also likely to have a higher baseline risk of dental caries, of 50%. Therefore, Figure 2.5 could again be considered for this population. The literature reported one intervention for this subgroup of the population; community oral health programme, which had an estimated RRR of 8%. Where the QALY loss associated with dental caries is set at -0.05, such an intervention will be cost-effective provided that it costs £40 or less. As the assumed QALY loss caused by having dental caries increases, the cost at which the intervention becomes cost-effective reduces such that, if the QALY loss is -0.05 the intervention is cost-effective up to a cost per person of £80. Where the QALY loss was higher still, at -0.10, the community oral health programme is cost-effective at all costs per adult considered (up to £100).

#### 2.4.6 Summary of Sensitivity Analysis

Table 2.8 provides a suggestive mapping of the 17 interventions to the graphs shown in Figures 2.3, 2.4 and 2.5. It should be noted, however, that the scenarios reported in Section 2.4 of this report are presented for guidance only, and are suggested scenarios to illustrate the likelihood of the intervention being cost-effective in a range of plausible scenarios. Due to a lack of robust published evidence, it is not possible to confidently state that some, or all, of the interventions are cost-effective (or not). The user of this report is urged to use the illustrative charts and accompanying text to determine the plausibility of each intervention being cost-effective, based on the best available evidence.

## 2.4.7 Probabilistic Sensitivity Analysis

Probabilistic sensitivity analysis (PSA) provides a useful technique to quantify the level of confidence that a decision-maker has in the conclusions of an economic evaluation. NICE requests that all submissions include PSA in order to provide estimate of confidence around the model's findings.

### 2.4.7.1 Parameters varied in PSA

In addition to the economic analysis described above, a probabilistic approach was also undertaken. The probability that the intervention is likely to be cost-effective can be estimated for each combination of the parameters in the sensitivity analysis (such as for an intervention given in a high risk population). To reflect the level of uncertainty around each of the five parameters, a standard deviation was defined for each parameter. In order to calculate a random estimate for each parameter, an appropriate distribution was fitted around it, as described in Table 2.9.

**Table 2.9: Range of parameters in PSA**

Parameter	Mean*	Standard error	Distribution	Rationale
Baseline risk	10%, 20%, 50%	0.01	Beta distribution	Produces values between 0 and 1 (or 0% and 100%)
Relative risk reduction	0%, 10%, 20%, 30%, 40%	0.15	Lognormal distribution	Used for ratios
Intervention cost	£20, £40, £60, £80, £100	£15	Gamma distribution	Ensures non-negative values
QALY loss from dental caries	-0.025, -0.05, -0.1	0.015	Gamma distribution	Manipulated to ensure negative values only
Cost of dental caries	£75, £100, £125	£25	Gamma distribution	Ensures non-negative values

\*The mean value of each parameter is described in Section 2.4.

A single estimate of the probability of cost-effectiveness was calculated by generating 1,000 ICER estimates in the model by randomly generating the five key parameters according to the distributions in Table 2.3. This method was repeated for each of the scenarios described in Section 2.4.

### 2.4.7.2 Interpretation of probabilistic model

Figure 2.6 demonstrates how a PSA chart can be used to explore a range of potential scenarios. The range of intervention costs are displayed across the columns of the chart, and the range of relative risk reductions are displayed down the rows of the chart. In this example, an intervention that costs £40 per patient is more than 50% likely to be cost-effective (at a £20,000 per QALY threshold) as long as the relative risk reduction of caries is greater than around 35%. However, an intervention that costs more than £80 per patient is

a lot less likely to be cost-effective for the whole range of relative risk reduction explored in the analysis.

**Figure 2.6: A guide to the interpretation of each PSA chart**

		A: Cost of caries: £75				
		£20	£40	£60	£80	£100
1. QALY loss: -0.02	0	17%	4%	1%	0%	0%
	0.1	30%	9%	2%	1%	0%
	0.2	51%	20%	6%	2%	0%
	0.3	68%	34%	14%	4%	1%
	0.4	82%	54%	27%	13%	5%

Figures 2.7, 2.8 and 2.9 display the probability that the intervention is cost-effective in each scenario.

Figure 2.7: Probability of cost-effectiveness (baseline risk: 10%)

		A: Cost of caries: £75					B: Cost of caries: £100					C: Cost of caries: £125					
		Cost of intervention					Cost of intervention					Cost of intervention					
		£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	
1. QALY loss: -0.025	RRR	0%	8%	0%	0%	0%	0%	7%	1%	0%	0%	0%	8%	1%	0%	0%	0%
	10%	15%	2%	0%	0%	0%	18%	1%	0%	0%	0%	19%	2%	0%	0%	0%	
	20%	30%	4%	1%	0%	0%	32%	4%	1%	0%	0%	34%	5%	0%	0%	0%	
	30%	44%	8%	1%	0%	0%	47%	10%	1%	0%	0%	47%	12%	2%	0%	0%	
	40%	59%	15%	4%	1%	0%	61%	18%	4%	1%	0%	64%	21%	4%	2%	0%	
2. QALY loss: -0.05	RRR	0%	17%	2%	0%	0%	0%	15%	2%	0%	0%	0%	16%	2%	1%	0%	0%
	10%	31%	7%	1%	0%	0%	34%	7%	1%	0%	0%	35%	7%	1%	0%	0%	
	20%	51%	17%	3%	0%	0%	55%	20%	3%	0%	0%	59%	20%	4%	1%	0%	
	30%	74%	34%	9%	1%	0%	75%	36%	10%	2%	0%	73%	36%	10%	2%	0%	
	40%	86%	51%	19%	4%	1%	86%	55%	21%	7%	0%	87%	56%	23%	7%	1%	
3. QALY loss: -0.1	RRR	0%	26%	10%	4%	0%	0%	28%	12%	3%	1%	0%	28%	14%	3%	1%	0%
	10%	53%	26%	10%	2%	0%	53%	26%	8%	2%	1%	53%	27%	12%	2%	0%	
	20%	77%	55%	26%	9%	3%	77%	52%	27%	9%	2%	77%	51%	27%	10%	2%	
	30%	92%	76%	48%	25%	9%	92%	80%	52%	24%	9%	92%	79%	51%	30%	10%	
	40%	99%	92%	79%	52%	25%	98%	94%	77%	55%	26%	99%	93%	79%	53%	28%	

Figure 2.8: Probability of cost-effectiveness (baseline risk: 20%)

		A: Cost of caries: £75					B: Cost of caries: £100					C: Cost of caries: £125					
		Cost of intervention					Cost of intervention					Cost of intervention					
		£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	
1. QALY loss: -0.025	RRR	0%	17%	4%	1%	0%	0%	16%	4%	1%	0%	0%	19%	4%	0%	0%	0%
	RRR	10%	30%	9%	2%	1%	0%	32%	9%	3%	1%	0%	35%	10%	4%	0%	0%
	RRR	20%	51%	20%	6%	2%	0%	53%	21%	6%	2%	1%	55%	23%	8%	3%	0%
	RRR	30%	68%	34%	14%	4%	1%	72%	38%	16%	5%	2%	75%	44%	18%	6%	3%
	RRR	40%	82%	54%	27%	13%	5%	84%	55%	27%	12%	5%	86%	58%	31%	13%	6%
2. QALY loss: -0.05	RRR	0%	25%	11%	3%	1%	0%	27%	12%	5%	1%	0%	28%	13%	3%	1%	0%
	RRR	10%	49%	29%	12%	4%	1%	51%	26%	11%	4%	1%	53%	29%	12%	5%	1%
	RRR	20%	76%	52%	27%	12%	4%	74%	52%	26%	13%	4%	74%	53%	30%	14%	5%
	RRR	30%	90%	74%	51%	31%	10%	92%	76%	52%	34%	15%	93%	79%	54%	33%	15%
	RRR	40%	98%	92%	77%	53%	33%	98%	92%	75%	52%	34%	98%	92%	79%	57%	34%
3. QALY loss: -0.1	RRR	0%	38%	25%	15%	7%	3%	36%	26%	14%	9%	4%	37%	27%	17%	10%	4%
	RRR	10%	66%	49%	37%	25%	16%	67%	51%	37%	26%	14%	64%	52%	38%	25%	13%
	RRR	20%	87%	77%	69%	54%	32%	88%	77%	66%	52%	35%	86%	78%	67%	52%	37%
	RRR	30%	97%	95%	91%	77%	68%	98%	94%	89%	80%	70%	97%	94%	88%	83%	70%
	RRR	40%	100%	100%	99%	97%	92%	100%	99%	99%	95%	92%	100%	100%	98%	96%	92%

Figure 2.9: Probability of cost-effectiveness (baseline risk: 50%)

		A: Cost of caries: £75					B: Cost of caries: £100					C: Cost of caries: £125					
		Cost of intervention					Cost of intervention					Cost of intervention					
		£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	£20	£40	£60	£80	£100	
1. QALY loss: -0.025	RRR	0%	33%	15%	7%	4%	3%	28%	17%	8%	5%	2%	32%	18%	10%	5%	2%
	RRR	10%	55%	34%	18%	10%	6%	56%	34%	22%	12%	8%	59%	37%	21%	13%	8%
	RRR	20%	75%	57%	38%	22%	16%	80%	59%	40%	28%	16%	79%	62%	43%	30%	16%
	RRR	30%	91%	78%	59%	44%	34%	92%	78%	65%	49%	34%	94%	85%	68%	54%	37%
	RRR	40%	97%	89%	79%	62%	51%	98%	94%	82%	68%	55%	98%	94%	85%	71%	57%
2. QALY loss: -0.05	RRR	0%	39%	30%	21%	13%	9%	41%	29%	23%	15%	10%	40%	31%	22%	15%	10%
	RRR	10%	67%	53%	45%	33%	25%	68%	56%	46%	36%	25%	66%	58%	46%	34%	27%
	RRR	20%	88%	81%	75%	61%	51%	88%	81%	74%	63%	51%	89%	83%	73%	62%	51%
	RRR	30%	98%	96%	91%	85%	76%	97%	96%	93%	86%	80%	98%	96%	93%	86%	78%
	RRR	40%	100%	100%	99%	97%	94%	100%	100%	99%	98%	94%	100%	100%	99%	98%	96%
3. QALY loss: -0.1	RRR	0%	43%	38%	34%	30%	24%	48%	38%	36%	32%	23%	44%	38%	35%	31%	25%
	RRR	10%	72%	67%	61%	56%	50%	70%	64%	60%	56%	49%	69%	66%	62%	59%	50%
	RRR	20%	91%	89%	86%	83%	77%	91%	90%	86%	82%	80%	91%	89%	85%	82%	78%
	RRR	30%	98%	98%	98%	97%	95%	99%	98%	97%	97%	96%	99%	99%	96%	98%	96%
	RRR	40%	100%	100%	100%	99%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

### 2.4.7.3 Interpretation of results

The results of the PSA are largely consistent with that of the sensitivity analysis:

- **The cost of dental caries** does not appear to significantly impact upon the results of the model. This is demonstrated in Figures 2.7, 2.8 and 2.9, whereby comparing the charts in columns A, B and C shows that the likelihood of cost-effectiveness is very similar across the three columns.
- **The QALY loss** has a relatively large impact on the results of the model, in that the higher the QALY loss, the more likely the intervention is to be cost-effective. The greater the assumed QALY loss, the less effective an intervention needs to be in order to be seen as cost-effective.
- **Intervention cost** is a key driver of the model, as interventions costing £20 per person have a much higher likelihood of being cost-effective compared to interventions costing £100 per person, which have a very low likelihood of being cost-effective. Alternatively, if the cost of the intervention is held constant at £20, the likelihood that it will be cost effective increases with an increase in the baseline risk, RRR and QALYs gained.
- **The relative risk reduction** of the intervention is a key driver of the results. On each chart, the likelihood of being cost-effective increases significantly as the intervention becomes more effective.
- **A population with a low baseline risk of dental caries** is presented in Figure 2.7. Only where the QALY loss associated with dental caries is relatively high, or for scenarios where the relative risk reduction is higher (i.e. the intervention is more effective) and the cost of the intervention is low (i.e. £20 per person) does the intervention have a high likelihood of being cost-effective.
- **A population with a higher baseline risk of dental caries** is presented in Figure 2.9. The interventions are cost-effective under a wider range of scenarios. Only where both the QALY loss associated with dental caries is low (-0.025) and the intervention is relatively ineffective (below 20% RRR) does the intervention have a low likelihood of being cost-effective.

## Section 3: Evidence for Effectiveness

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### 3.1 SUMMARY

The sensitivity analyses in Section 2 explored a range of different relative risks and the impact on the likelihood of cost-effectiveness. This section explores the range of effectiveness evidence that has been identified for each intervention, which have been used to form the effectiveness evidence in Analysis I, and can be used to guide PHAC discussions around the appropriate sensitivity analysis figure to refer to in Analysis II when assessing the likelihood of cost-effectiveness for each intervention.

The review of evidence of the effectiveness of oral-health improvement programmes was conducted by Bazian in accordance with the methods set out in the CPHE Public Health Guidance Methods Manual. The main steps in the review included the identification of relevant studies by a systematic search of electronic literature databases, selection of relevant studies relating to community oral health programmes or interventions, an assessment the quality of the included studies, and data extraction from the included studies. For full details of the methods used to identify evidence for the effectiveness review, please refer to the Bazian report.

The Bazian review was used as a basis for our estimates of the relative risk of dental caries for each of the interventions. A range of evidence has been extracted from the studies identified in the review, with further details around the studies, the reported data and our interpretation provided in Sections 3.2, 3.3 and 3.4 of this report. A summary of the studies and the reported data are presented in Table 3.1. Where there was more than one study identified for each intervention, this report identifies the most appropriate study or studies to consider for the economic analysis, based on either the data quality as assessed in the Bazian review, or using our own judgement based on elements such as the setting, population size and the relevance of the reported data. Quality appraisal in the Bazian review was carried out using NICE quantitative study quality checklists, and we have aimed to explore studies that were assessed as being either [++] all or most of the NICE checklist criteria have been fulfilled, or [+] some of the checklist criteria have been fulfilled.

It may be difficult to compare the studies both within each intervention and across all interventions given that there is a wide range of data that has reported. There was a large amount of heterogeneity in the studies, such as around the time frame of the programme and the follow-up period for which outcomes were reported, different population groups (e.g. in different socioeconomic areas, different countries where the level water fluoridation may vary from that in the UK), and baseline risks of decay. There was heterogeneity particularly around the reported clinical outcomes, described below:

- Most studies reported the clinical outcomes that were evaluated in the study, for example, the difference in dmft/DMFT before and after the programme, the

dmft/DMTF prevented fraction, and the proportion of the study population that are caries-free before and after the programme.

- Where the impact on the levels of tooth decay has been evaluated by a study, different severities of decay (e.g.  $d_1$ mft,  $d_2$ mft etc.) have been reported in different studies.
- Few studies provided an estimate of the magnitude of the impact on the clinical outcomes, such as relative risk (RR) or odds ratios (OR).
- Some studies only reported intermediate outcomes relating to modifiable behaviour, such as the frequency of brushing and flossing, snacking levels, oral health knowledge and use of dental services, but this evidence is of limited use given that no quantitative data exist to link these to hard endpoints.

Given that the heterogeneity between studies will make it challenging to compare one type of programme in one study to a programme in another study, the PHAC was interested in using direct evidence from head-to-head studies of different programmes to inform an analysis. Hardman (2007) reports on an RCT assessing the effectiveness of fluoride varnish compared to the provision of oral hygiene materials (toothbrush and fluoride toothpaste) in the UK. However, the study found that there were no significant differences between each intervention group, and so the only difference between the two groups would be due to the intervention costs (which were not reported).

The long-term impact of interventions on oral health, including levels of tooth decay and gum disease across the life-course, is rarely evaluated in studies. Sufficiently powered, longitudinal studies are generally costly to fund, implement and evaluate. No published studies were identified in the literature searches for this work that demonstrated a causal relationship between oral health interventions in very young children and a reduced life time risk of dental caries. However, it is generally accepted among oral health professionals that improving oral health behaviours in young children with primary teeth may reduce their likelihood of experiencing oral disease including caries and gum disease when they have their primary teeth or their permanent successors. Improving oral health behaviours for very young children may also reduce the risk of undergoing surgery for tooth extraction with general anaesthetic, especially for children in vulnerable groups.

In order to compare the impact of different interventions, the relative risk (RR) of dental caries has been estimated from the evidence where reported in the studies and where this is possible. Some studies do not report the appropriate data to enable this (such as for those studies reported behavioural outcomes) and in these cases a relative risk cannot be estimated. This is explored in further detail in the sections below. There are however some limitations associated with this approach which is largely due to the heterogeneity of the reported data, and as such the PHAC should take this into consideration when interpreting the estimated relative risks.

**Table 3.1: Summary of data**

Patient group	Setting	Intervention	Source for Effectiveness	Effectiveness data
0-5 year olds	Pre-school / nursery	Fluoridated milk	1. Stecksen-Blicks 2009	1. Caries free primary molars and canine teeth Mean dmfs increment in molars and canine teeth
0-5 year olds	Pre-school / nursery	Supervised tooth brushing	1. Macpherson 2013	1. Difference in mean d <sub>3</sub> mft over 12yrs
0-5 year olds	Pre-school / nursery	Oral health education	1. Grant <i>et al.</i> 2010, 2. Tubert-Jeannin <i>et al.</i> 2012 3. Axelsson <i>et al.</i> 2006	1. Intervention improved scores in the immediate post-test but these were not sustained two weeks later. 2. Mean dmft. No major difference observed between 2003 and 2009. 3. Percentage of caries free three year olds increased from 35% in the early 1970 to 97% twenty years after. Mean values of deft Incidence and prevalence, but may not be for the correct age group
0-5 year olds	At home	Oral health promotion	1. Blair 2004 2. Blair 2006	1. dmft prevented fraction of 3yo and 4yo Care Index before and after (proxy for dental service utilisation) 2. Odds for tooth decay at 5yo
0-5 year olds	Community	Education programmes targeting parents/carers	1. Wennhall 2005, 2. Milgrom 2010, 3. Whittle 2008, 4. Shute 2005, 5. Yuan 2007, 6. Cruz 2012, 7. Plutzer 2008, 8. Ellwood 2004	1. Caries free at age 3 (RR) Mean DEFT Daily brushing (%) Proportion eating sweets 2. Caries free at age 2 (RR) Mean DEFT at age 3 Bleeding gums, visible plaque (%) 3. Mean DMFS at age 3, 5 4. Dental registration rates (OR) 5. Dental registration rates (%) 6. Topical fluoride use Dental service utilisation 7. Severe caries in 20m.o (OR) 8. Caries prevalence Mean caries (DMFT score, b&a)
5-10 year olds	Primary and	Fluoride varnish	1. Moberg 2005a	1. Prevented fraction of caries

Patient group	Setting	Intervention	Source for Effectiveness	Effectiveness data
	Secondary schools		2. Splieth 2011 3. Hardman 2007 4. Dohnke-Hohrmann 2004	2. Mean caries 3. Mean advanced caries (mean D <sub>3</sub> fs, d <sub>2</sub> fs, d <sub>1</sub> fs) 4. Mean DMFT (reduction after 4yrs)
5-10 year olds	Primary and Secondary schools	Milk	1. Ketley <i>et al.</i> 2003 2. Riley <i>et al.</i> 2005	1. Mean dmft, mean dmfs 2. Mean DMFT/Dt/DFS values
5-10 year olds	Primary schools	Mouthwash	1. Kaneko <i>et al.</i> 2006 2. Neko-Uwagawa <i>et al.</i> 2011 3. Levin <i>et al.</i> 2009 4. Komiyama <i>et al.</i> 2012	1. Mean DFT increment. Mean DFT. OR caries incidence 5.73 in groupd with fluoride mouthrinse and 3.47 in group without it. 2. DMFT prevalence rate and mean DMFT, percentage distribution 3. D <sub>3</sub> MFT>0 OR. Mean caries. 4. Caries prevalence, DMF person rate, DMFT index, mean caries
5-10 year olds	Primary schools	Supervised tooth brushing	1. Jackson 2005 2. Pine 2007 3. Burnett 2005 4. Wind 2005	1. Change in DMFS 2. 3-yr caries incidence (D <sub>3</sub> MFS) in teeth that were caries free and with caries at age 5 3. Caries incidence (D <sub>3</sub> MFS) in teeth that were caries free at age 5 4. Brushing frequency Brushing knowledge
5-10 year olds	Primary schools	Multi-component promotion with preventive treatment	1. Niederman 2008 2. Bodner 2010 3. Axelsson 2006	1. Caries incidence (OR) 2. Decayed (%) 3. Mean DFS and DS
5-10 year olds	Primary and Secondary schools	Addressing common risk factors	1. Freeman 2009 2. Muirhead 2011 3. Hedman 2010	1. D3cvMFT at BL and 24m follow-up 2. 2+ decayed teeth (%) 3. Tobacco use (%)
5-10 year olds	Primary schools	Oral health education	1. Vanobbergen 2004 2. Dental Health Foundation 2007 3. Pieper 2012 4. Pieterse 2006 5. Livny 2008	1. Prevalence of and average decay (DMFT) Sulcus Bleeding Index score Proportion brushing/flossing daily Proportion eating 2+ snacks Dental service utilisation (mean Restoration Index) 2. Salivary fluoride levels (proxy for brushing) Tooth brushing, snack knowledge 3. % caries free at age 12 Mean D5,6MFT

Patient group	Setting	Intervention	Source for Effectiveness	Effectiveness data
				Severity of caries Index score 4. Mean DMFS Brushing levels (% twice daily) 5. Brushing levels (% twice daily) Diet (% bringing sweets)
5-10 year olds	Primary schools	Peer-to-peer oral health education	1. Freeman 2003 2. Reinhardt 2009	1. Snacking levels Oral health knowledge 2. Time spent brushing, proportion with good technique Oral health attitude 3. Proportion with good technique, time spent brushing
5-10 year olds	Community (aged 5 – 15)	Oral health education	1. Biesbrock 2004 2. Biesbrock 2003	1. Plaque and Gingival Index Plaque, brushing or food knowledge 2. Plaque and Gingival Index Oral health knowledge
5-10 year olds	At home (aged 4 – 15)	Home visits to improve dental care access	1. Binkley 2010 2. Harrison 2003	1. Use of dental services (%claims) 2. Receiving benefits (%)
Adults	Workplace	Oral hygiene education	1. Ojima 2003 2. Morishita 2003	1. Periodontal inflammation 2. DMFT score and % high Periodontal Index after programme. No BL reported.
Adults over 65	Community	Oral health promotion and education	1. Al-Haboubi 2012 2. Marino 2004 3. Marino 2013	1. Plaque and Gingival Index, DMFS score 2. Caries, periodontal, cancer knowledge OR of flossing and brushing OR of dental service use 3. Plaque and Gingival Index Frequency of flossing

## **3.2 EVIDENCE FOR PROGRAMMES IN INFANTS AND PRE-SCHOOL CHILDREN**

### **3.2.1 Fluoridated milk**

Weak evidence suggests that a nursery based daily fluoride milk programme may be effective at reducing caries amongst younger nursery school children.

One study was identified for this intervention (Stecksen-Blicks *et al.* 2009), which was set in Sweden for pre-school age children attending day care centres. Milk supplemented with 2.5mg F/l and probiotics was provided daily for 21 months. Due to study design limitations, these results may not be representative of older nursery school children. The study attrition rate was greater than 25%, and children completing the study were, on average, younger than non-completers (mean age 42 vs. 60 months). This is due in part to difficulty with follow-up amongst older children who had left the day care centres.

The intervention had a significant effect on mean dmfs increment of the molars and canine teeth, with a mean dmfs increment of 0.3 (SD 1.8) in the intervention group and 1.6 (SD 3.1) in the comparator group, which represents a prevented fraction of 75%. This value was used to calculate a RRR, which was estimated to be 25%.

In addition to the evidence described above, a recent Cochrane review of fluoridated milk (2005) found two RCTs, one of which presented evidence for pre-school children. This study saw a significant reduction in DMFT and in dmft after three years. However the review suggests that there is insufficient evidence to include milk as a vehicle for the delivery of fluoride to vulnerable children.

### **3.2.2 Supervised tooth brushing**

Weak evidence suggests that a national daily supervised tooth brushing programme in nurseries that includes provision of fluoride toothpaste for home use is associated with significant improvements in oral health of five year old children at a population level.

One large study in the UK (Childsmile, Macpherson *et al.* 2013) involved daily supervised tooth brushing in nurseries, and distribution by nurseries of fluoride toothpaste for use at home. The intervention was provided for 12 years between 1987 and 2009. Given the study design, conclusions can only be drawn regarding the association between the implementation of the nationwide nursery based supervised toothbrushing component of Childsmile and changes in tooth decay amongst five year old children. As a nationwide programme, the ability to assess whether the reduction seen during this time period is due to the programme itself, or whether it corresponds with a secular trend in caries reduction is restricted to assessment in caries in the decade prior to implementation.

The intervention was associated with a reduction in mean  $d_3mft$  among five year old children 10 to 12 years after the programme compared to the three years prior to implementation, with a pre-programme  $d_3mft$  of 3.06 (SD 3.76), and a post-programme  $d_3mft$  of 2.07 (SD 3.16). The ratio in mean  $d_3mft$  before and after the programme was used to approximate the

relative risk of decay, and was estimated to be 0.68. From this, a RRR of 32% can be calculated.

### 3.2.3 Oral health education

Weak evidence suggests that nursery based oral health education and promotion programmes may prevent the worsening of caries amongst young children in deprived communities, but are not associated with improvements in oral hygiene, oral health knowledge or dental decay status.

Three studies were identified for this intervention;

- **Grant *et al.* 2010**, an RCT in a population of low-income children enrolled in a pre-school in the USA, consisting of a single brief oral health education;
- **Tubert-Jeannin *et al.* 2012**, a French before-and-after study of children aged 3 to 5 attending public schools in deprived areas with high caries levels, consisting of a 3-year programme aimed at improving tooth brushing habits and use of fluoridated toothpaste, educational activities on oral hygiene, nutrition and dental care directed at carers and school staff;
- **Axelsson *et al.* 2006**, a before-and-after study of children aged 3 to 5 attending kindergarten in Sweden between 1979 and 1999, consisting of a 3-year programme of educational activities on oral health, supervised tooth brushing with fluoride toothpaste, plus professional tooth cleaning and fluoride varnish (2-4 times a year) for 10% of children at the highest risk.

Tubert-Jeannin 2012 was considered by the EAC to be the most relevant and the most appropriate study to inform the analysis, particularly due to the relatively large population (n=1,073). Of the three studies, it was also reported by Bazian as having the highest quality evidence ([+]). It is also important to note that the study was undertaken in a deprived area (42.2% students were in a deprived area, 28% in semi-deprived area) and care should be taken when assessing whether this study is representative of the population considered in the decision for resource allocation.

Axelsson 2006 compared the baseline level of decay from the early 1970s to the post-programme levels, and is unlikely to reflect the baseline level of caries. Grant 2010 did not report outcomes appropriate for the model (hygiene behaviours, knowledge and attitudes).

In the Tubert-Jeannin study, programme schools were associated with a mean dmft of 1.47 (SD 2.75) before the programme vs. 1.44 (SD 2.78) after; non-programme schools were associated with a mean dmft of 0.97 (SD 2.42) before vs. 1.52 (SD 2.83) after. This suggests that the programme was associated with preventing a worsening of tooth decay.

The ratio in mean  $d_3$ mft change before and after the programme for the programme schools and the non-programme schools was used to approximate the relative risk of decay. After the baseline  $d_3$ mft of the non-programme school was adjusted, the RRR was estimated to be 37%.

### 3.2.4 Community oral health promotion with fluoride provision

Moderate evidence from two interrupted time series describing similar programmes suggests that oral health promotion campaigns delivered through multiple venues and targeting several aspects of oral health may be associated with a reduced risk of dental decay in children under the age of five living in deprived communities.

Blair *et al.* 2004 and Blair *et al.* 2005 were both interventions targeting breakfast clubs in schools and community centres, and includes the promotion of sugar free medicines in National Smile Week, snack and meal policies for schools, fruit promotion in nurseries and schools, baby bottle swap/cup provision, annual community fairs, tooth brushing schemes (e.g. in nurseries), free toothbrush and fluoride toothpaste, opportunistic oral health promotion by health visitor, oral health related competitions, child friendly dentist scheme, and parenting support baby club.

- **Blair *et al.* 2004** was targeted at residents in a severely socioeconomically deprived area of Glasgow; children aged from 3 to 5 years were included in the outcome analysis.
- **Blair *et al.* 2005** was a much larger study (n=8628) and targeted children aged under 5 in Glasgow.

Both studies were assessed by Bazian as being of a good quality ([+]). However, the EAC considered Blair 2005 to be the most relevant and the most appropriate study to inform the analysis, and was considered to produce a more robust estimate of the effect size given the larger population. The study reported lower odds of tooth decay at age 5. For the wider population, the odds ratio was estimated to be 0.66 and as such the RRR was 34%.

### 3.2.5 Home or community-based oral health education

Moderate evidence suggests that community centre based oral health promotion and education programmes delivered to low-income mothers or parents of young children (aged 2) may be effective at reducing tooth decay over approximately one year.

Moderate evidence suggests that oral health promotion and education programmes delivered by health visitors during early life home visits are no more effective than standard health visits at improving the oral health of children under the age of five, but may be associated with improvements in dental registration rates in deprived areas.

Inconsistent evidence was identified regarding the effect of oral health promotion and education materials and supplies delivered via post on tooth decay of young children; effectiveness may vary according to deprivation status and provision of fluoride toothpaste. Postal reminders of eligibility for dental services and fluoride varnish benefit programme may have no effect on dental registration or use of fluoride amongst low-income children.

Eight studies were identified for this intervention:

- **Wenhall *et al.* 2005**, a before-and-after study targeting the parent/guardian of children aged 24 to 36 months in a low socioeconomic area of Sweden. In community outreach centres, an oral health promotion programme was delivered by dental assistants during five sessions over the course of a year. The programme included oral hygiene instruction, supplies, free fluoride tablets and discounted fluoride toothpaste, dietary recommendations and problem solving.
- **Milgrom *et al.* 2010**, a cohort study targeting mothers in the USA eligible for medical and dental benefits with children aged 24 to 35 months. The programme was delivered in community centres and as home visits for one year, and included educational materials promoting dental visits for young children, plus home visits or counselling at community centres and assignment to a dental managed care programme.
- **Whittle *et al.* 2008**, an RCT targeting the parents of young children in the UK where dental health is poor. The programme consisted of a home visits dental health advice (addressing diet and toothbrushing) plus provision of a toothbrush and low fluoride toothpaste provided by a health visitor at age 8 and 20 months of age.
- **Shute and Judge, 2005**, a cohort study in the UK aimed at families of six month old children in disadvantaged areas of Glasgow. The programme consisted of a home visit delivered by Start Well health visitors.
- **Yuan *et al.* 2007**, a non-randomised controlled trial in the UK, aimed at mothers of children aged 0 to 2 years in deprived areas of Belfast with low dental registration rates. Dental health education, feeding cups, toothbrushes, fluoride toothpaste and registration vouchers were provided by community based nurses during three routine health visits over two years.
- **Cruz *et al.* 2012**, an RCT in the USA of families of low income children aged 1 to 2 years who are eligible for benefits. The programme consisted of six postcard reminders over 1 year regarding eligibility for comprehensive dental benefits.
- **Plutzer and Spencer, 2007**, an Australian RCT. The programme consisted of 3 rounds of printed guidance on oral health, oral hygiene and nutrition provided to first time mothers prenatally and over the first year of their child's life. Finger toothbrushes for children and toothbrush for mothers were included with the second and third rounds.
- **Ellwood *et al.* 2004**, an RCT set in the UK of parents of children aged 1 to 5.5 years in areas with high levels of caries. This was a programme involving health education literature, free fluoridated toothpaste every three months (440 or 1450ppm) and a toothbrush every year provided via post for 4.5 years.

Of the four studies in the UK setting, two studies (Shute 2005, Yuan 2007) reported intermediate outcomes around the rates of dental registration, which cannot be used to estimate the clinical impact of the programme.

Whittle 2008, a programme around home visits, reported mean dmfs for children in the programme and children who received normal care provided by health visitors in the area (which included advice about registering with a dentist; avoiding sugary drinks, sweets and medicine; and tooth brushing). This study was assessed as being of a good quality by Bazian ([+]). Mean dmfs was reported at age 3 (2.03 vs 2.19) and at age 5 (3.99 vs 4.84).

Age 5 outcomes for children in the intervention group were also compared to results from a standard dental census at all area schools among five year old children (dmfs: 5.94). The ratio of the mean dmfs at age 5 was used to approximate the relative risk of decay, and was estimated to be 0.67 i.e. the RRR was 33%.

Ellwood 2004, a postal programme, was also assessed as being of a good quality by Bazian ([+]). This study demonstrated that the intervention reduced the mean caries in the least deprived group (mean dmfs: 1.4 (SD 2.5) vs. 1.9 (SD 2.9)), with no effect in the most deprived areas. The relative risk in the least deprived group can be estimated by calculating the ratio of the programme dmfs and the comparator dmfs post-programme, and is approximately 0.74 (equivalent to a RRR of around 26%).

**Table 3.2: Summary of evidence for infants and pre-school children**

Intervention	Study	Evidence and estimated RR of decay	Relative risk reduction (RRR)
Fluoridated milk	Stecksen-Blicks 2009	Prevented fraction of 75% for decay	25%
Supervised brushing	MacPherson 2013	Ratio in mean $d_3mft$ before and after the programme: 0.68	32%
Oral health education	Tubert-Jeannin 2012	Ratio in mean $d_3mft$ change before and after the programme: 0.63	37%
Community oral health promotion	Blair 2005	Odds ratio for tooth decay of 0.66	34%
Community oral health education	Whittle 2008 Ellwood 2004	Ratio of mean dmfs between intervention group and control: 0.67 Ratio of mean dmfs between intervention group and control: 0.74	33% and 26%

### 3.3 EVIDENCE FOR PROGRAMMES IN SCHOOL-AGED CHILDREN

#### 3.3.1 Fluoride varnish

Moderate evidence suggests that school based fluoride varnish programmes can be effective at preventing or reducing enamel caries amongst children in deprived or at risk communities, but are less effective amongst children in non-deprived or low risk areas.

Four studies were identified for this intervention:

- **Moberg *et al.* 2005a**, an RCT in a population of students in Sweden aged 13 to 16 years. Fluoride varnish was applied by dental nurses and dental hygienists to the

approximal surfaces of teeth during the school year for three years according to 3 schedules: twice yearly, 3 times per year, and 8 times per year.

- **Splieth *et al.* 2011**, a cRCT in a population of students in Germany aged 6 to 8 years. Fluoride varnish was applied twice a year by a dental hygienist.
- **Hardman *et al.* 2007**, a cRCT in a population of students in the UK aged 6-7 (year 2) or 7-8 (year 3) attending eligible state primary schools in relatively deprived communities. Fluoride varnish was applied twice a year by dental therapists to the primary and first permanent molars.
- **Dohnke-Hohrmann, 2004**, a study of primary school children in a multicultural under-privileged area in Germany. Fluoride varnish was applied twice a year, and the outcomes assessed after four years.

Moberg 2005a was assessed to have the highest quality ([++]) evidence by Bazian, with the study fulfilling all or most of the NICE checklist criteria. Biannual application was considered to be the most appropriate intervention to include in this analysis. The study reported the prevented fraction in incident caries across the general student population, which was estimated as being 57%. This can be used to approximate the RRR of decay of 43%.

Hardman 2007 has the most relevant setting and provides an alternative good-quality (as reported by Bazian) source of data. The study demonstrated that the fluoride programme was no more effective than provision of a toothbrush and fluoride toothpaste at reducing mean advanced caries increment (mean  $d_3fs$  increment difference: 0.01 (SE 0.18); mean  $d_2fs$  increment difference: 0.28 (SE 0.20)). However it was not possible to estimate a relative risk of decay from this data given that the absolute difference in decay increment was reported rather than the proportional difference.

### 3.3.2 Fluoridated milk

Inconsistent evidence regarding the association between school-based fluoride milk schemes and dental caries was identified from one cohort study and one cross-sectional study.

Two studies were identified for this intervention:

- **Ketley *et al.* 2003**, a cohort study in the UK in a population of children aged 7 to 9 in areas of deprivation. Milk containing 0.5mg F/189ml (2.65ppm) was provided five days per week for four years.
- **Riley *et al.* 2005**, a cross sectional study of UK children aged 12 in an area of considerable deprivation. Milk containing 0.5mg F/189ml; (2.65ppm) was provided for up to 7 years. The frequency was not reported.

Riley 2005 was assessed as having the highest quality evidence by Bazian ([++]), and was considered as relevant to the economic analysis by the EAC given that it was conducted in the UK. The programme was associated with a significant reduction of caries of the first permanent molars in the group receiving fluoridated milk for seven years. The study reported the adjusted odds ratio for the increase in likelihood of the comparator group of

caries (OR: 1.71). This is equivalent to an odds ratio of 0.58 for the reduction in the risk of caries due to the programme and RRR of 32%.

Ketley 2003 also provided a good source of data (the quality was assessed as [+] by Bazian), and was also set in the UK. This study reported the mean difference in dmft increment over four years (0.40 at the tooth level and 0.38 at the surface level in primary dentition, 0.00 in the permanent molars). However it was not possible to estimate a relative risk of decay from this data given that the absolute difference in decay increment was reported rather than the proportional difference.

In addition to the evidence described above, a recent Cochrane review of fluoridated milk (2005) found two RCTs, one of which presented evidence for primary school children. The results in the trial of primary school children were not found to be significant. The review suggests that there is insufficient evidence to include milk as a vehicle for the delivery of fluoride to vulnerable children.

### 3.3.3 Fluoride mouth rinse

Moderate evidence suggests that school based fluoride mouth rinse programmes can be effective at preventing or reducing dental decay of the permanent dentition amongst school aged children living in communities with no exposure to fluoridated water.

Five studies were identified for this intervention:

- **Moberg *et al.* 2005b**, an RCT in Sweden in a population of students aged 13-16. The programme involved a dental nurse-supervised fluoride mouth rinse programme delivered for three years.
- **Kaneko *et al.* 2006**, a cohort study in Japan of primary school students. The programme involved a teacher-supervised, daily rinsing with 500ppm NaF at age 5-6, and teacher-supervised weekly rinsing with 2,000ppm NaF from age 7 to 9-10. The programme lasted for 4 to 6 years.
- **Neko-Uwagawa *et al.* 2011**, a cross-sectional study in Japan. The programme involved a teacher-supervised daily rinsing with 500ppm NaF from age 4 to 5, and then weekly with 2,000ppm NaF from age 6 to 14. Outcomes were reported when the participating students were aged 20 to 40.
- **Levin *et al.* 2009**, a cross-sectional UK study of children aged 6 to 11 years in schools with high caries prevalence. The programme involved a fortnightly rinse for 2 minutes with 0.2% NaF solution at school under supervision.
- **Komiyama *et al.* 2012**, a cross-sectional study in Japan of students attending primary schools. The programme involved weekly one minute fluoride mouth rinse with 900ppm NaF, for six years.

Levin 2009 was considered to be the most appropriate study by the EAC to estimate the impact of a fluoride mouth rinse programme. This study was based in the UK, and included a large number of participants (n=1,333). Bazian also assessed the study as contained good quality evidence ([+]). The different outcomes reported by the study were somewhat

conflicting. Across the general population of 11 year olds, there was no significant difference in mean tooth decay between rinsers and non-rinsers. When stratified by deprivation category, only rinsers in the least deprived categories were significantly more likely to be caries free compared to their non-rinsing peers. This may be due to reduced uptake of the FMR programme across Deprivation Categories. The study also reported that the programme was associated with significantly reduced likelihood of tooth decay, with the odds ratio of the likelihood of tooth decay ( $D_3MFT > 0$ ) estimated as 0.79. As such, the RRR is approximately 21%.

### 3.3.4 Supervised toothbrushing

There is moderate evidence from three cluster RCTs to suggest that daily, school based, teacher supervised tooth brushing with 1,000 to 1,450ppm fluoride toothpaste may reduce dental decay among primary school children, and weak evidence from one cluster RCT to suggest that such programmes may improve oral hygiene in the short but not long term.

Four studies were identified for this intervention:

- **Jackson *et al.* 2005**, an RCT in a population of children in their first year of primary school in a deprived area in England. The programme consisted of teacher supervised daily toothbrushing (with 1,450 ppm F toothpaste).
- **Pine *et al.* 2007**, an RCT in a population of children in their first year of primary school in a relatively deprived area in England. The programme consisted of 30 months of daily supervised tooth brushing programme with 1,000ppm fluoridated toothpaste. A toothbrush, toothpaste and a brushing chart to track twice daily brushing at home during holidays were also provided.
- **Burnett *et al.* 2004**, an RCT in a population of children attending primary school in Australia. The programme consisted of a teacher-supervised daily tooth brushing programme using low dose fluoride toothpaste for three years.
- **Wind *et al.* 2005**, a RCT in a population of children between the ages of 7 and 10 years attending elementary schools in The Netherlands. The programme consisted of daily school based supervised tooth brushing for three-years. The use of fluoridated toothpaste was not reported.

Two of the above studies were assessed by the EAC as having relevant evidence (in a UK setting, with a relatively large population), as well as being assessed as being of a good quality by Bazian ([+]).

Jackson 2005 reported that the programme was effective at reducing incident dental decay. After adjusting for baseline caries differences, the mean caries increment (dmfs and DMFS) over 21 months was 10.9% lower in the intervention than the comparator group. This is approximately equivalent to a relative risk of decay of 0.89, or a RRR of 11%.

Pine 2007 also reported that the supervised toothbrushing programme was effective at reducing incident dental decay. Compared to children in comparator classes, between baseline and 84 months follow-up, intervention children had a 30% reduction in enamel lesions ( $D_1FS$ ) of the first permanent molars. This is approximately equivalent to a relative

risk of decay of 0.70. Among children with caries at baseline, the reduction in more severe caries (D<sub>3</sub>FS) was 39%, approximately equivalent to a relative risk of decay of 0.61 or a RRR of 39%.

### 3.3.5 Multi-component oral health promotion

There is inconsistent evidence regarding the association between multi-component school based oral health programmes, which include the provision of preventive services (e.g. pit and fissure sealants) and dental caries in primary school students.

Three studies were identified for this intervention:

- **Niederman *et al.* 2008**, a cohort study set in the USA of students attending elementary schools, with a high proportion of low-income children (86.4%). Dental hygienists provided preventive services twice per year, which included prophylaxis and oral hygiene instruction, provision of toothbrushes and fluoride toothpaste, placement of glass ionomer sealants and temporary restorations in carious teeth, and fluoride varnish.
- **Bodner and Pulos, 2010**, a large before-and-after study of students attending elementary schools in the USA. The programme consisted of an oral health exam by dental hygienists and assistants, followed by preventive treatment, consisting of fluoride releasing pit and fissure sealants if required.
- **Axelsson *et al.* 2006**, a before-and-after study of students in primary and secondary school in Sweden from 1979 to 1993. Dental hygienists or dental assistants provided oral health education needs-related preventative services in school clinics.

Bodner 2010 was considered by the EAC to be the most appropriate study for the analysis, and was considered to produce a more robust estimate of the effect size given the larger population size. Bazian also reported that this study was of high quality ([++]). The programme was associated with a low uptake of sealant services, as only 18% of eligible students received sealants. The effectiveness of this intervention was largely affected by the uptake of sealants. The overall difference in DMFT was reported to be 3.02% among the general student population (corresponding for a higher percentage of first molars with decay in the programme population). Among those who received sealants, the mean difference in DMFT was reported to be -4.6% (corresponding to a lower percentage of first molars with decay in the programme population). In this population, the relative risk of decay can be estimated to be around 0.95 and therefore the RRR to be approximately 5%.

### 3.3.6 Addressing common risk factors

Inconsistent evidence was identified regarding the effectiveness of school based programmes that address common risk factors on oral health outcomes.

One study suggested that such programmes may be detrimental to the oral health of primary school children. A school based programme addressing tobacco use amongst secondary

school children at high risk for poor oral health had no effect of smoking behaviour of students.

The evidence for this intervention comprised three studies:

- **Freeman and Oliver, 2009**, a cluster non-randomised control trial in UK primary school. Participants were 9 years old and attended school in Northern Ireland in various socioeconomic areas. The intervention, Boosting Better Breaks was a dietary health promotion programme, including school milk, water and fruit during school breaks; the closing of tuck shops and removal of confectionary, cakes, biscuits or soft-drinks. Teachers provided rewards or prizes.
- **Muirhead and Lawrence, 2011**, a correlation study on students attending elementary schools in Canada that were voluntarily participating in the Healthy Schools programme. The Healthy Schools programme targeted healthy eating, physical activity, bullying prevention, personal safety, injury prevention, substance use and misuse, healthy growth and development and mental health activities. Schools were compared to regional schools that had not participated in the programme.
- **Hedman *et al.* 2010**, a cluster non-randomised controlled trial carried out on students aged between 12 and 15 years considered at high risk of oral diseases in Sweden. The intervention was a health education programme targeting tobacco use. A dental hygienist and a dental nurse delivered a 40 minute interactive lecture at the schools addressing oral health and tobacco use.

Given that each of the studies is concerned with addressing common risk factors, such as diet and tobacco use, the studies all report intermediate outcomes relating to these behaviours. Muirhead 2011 reported some conflicting evidence that suggested that a dietary intervention increased the likelihood of students having more than two decayed teeth (effect size not reported). As such, none of the studies described above reported any data that could be used to estimate the impact of the intervention on the levels of decay.

### 3.3.7 Oral health education in schools

There is moderate evidence to suggest that oral health education programmes may improve plaque and gingival health, and when combined with fluoride provision, are associated with reduced tooth decay amongst primary school children.

Five studies were included for this intervention:

- **Vanobbergen *et al.* 2004**, an RCT involving children attending primary school in Belgium with low population wide caries levels. Intervention group children and teachers attended an annual, one-hour oral health education programme which included information on oral hygiene, use of fluorides, dietary habits and dental attendance. An annual oral examination was carried out which resulted in a referral letter outlining oral status and treatment needs.
- **Dental Health Foundation, 2007**, an RCT carried out in Ireland involving children in their fourth year of primary school. The intervention was a “Winning Smiles” six

week oral health promotion programme provided by community dental staff and covering oral health, tooth brushing with fluoride toothpaste. Some school children were also sent toothbrushes and fluoridated toothpaste.

- **Pieper *et al.* 2012**, a cross-sectional study on kindergarten and primary school students in underprivileged areas of Germany. The six year intervention enhanced oral health education, provided oral hygiene instructions (four times per year) and applied fluoride varnish (four times per year).
- **Pieterse *et al.* 2006**, a before and after study in the Netherlands of children aged six to twelve. The intervention comprised an education packet on oral health, weekly fluoride mouth rinsing and teeth brushing lessons.
- **Livny *et al.* 2008**, an Israeli before and after study set of medium-low social economic status primary school children. A municipal dental health education programme delivered by a dental hygienist took place, which included provision of a toothbrush and toothpaste, three weekly education sessions of oral hygiene skills training and supervised brushing. Health education regarding the use of fluoridated toothpaste and healthy dietary habits was also provided.

Pieper 2012 and Pieterse 2006 were both assessed as being of good quality of Bazian, and reported relevant data that could be estimate to estimate the impact of the programme on dental caries.

Pieper 2012 reported significantly lower average decay in the permanent dentition, with an average D<sub>5</sub>MFT of 0.50 in the programme population and 0.77 in the comparator population. The relative risk has been approximated by calculating the ratio of the programme and comparator D<sub>5</sub>MFT (RR: 0.65). This results in a RRR of 35%.

Pieterse 2006 reported a lower mean DMFS amongst 12 year olds (0.5 vs. 2.0). The programme DMFS is a quarter of that of the comparator group. Estimating the relative risk by calculating the ratio of the two would result in an estimate of 0.25 (a 75% reduction in the risk of decay), which is a significantly larger reduction than the estimate produced by the other two studies considered for this intervention. This reflects the heterogeneity across the studies (in their populations, the type of programme), and reinforces the key message that all results should be interpreted with caution.

Vanobbergen 2004 reported data however it was assessed as poor quality by Bazian, and so the evidence should be interpreted with caution. The study reported a small effect on the average decay of the permanent dentition, with a pre-programme mean DMFT of 0.92 compared to 1.0 post-programme for the intervention group, and a pre-programme mean DMFS of 1.46 compared to 1.59 post-programme for the comparator group. The ratio of change in DMFT was used to approximate the relative risk of decay. This was estimated as being 0.92 (a RRR of 8% in decay).

The Dental Health Foundation was also assessed as having good quality evidence by Bazian and is of a relevant setting, however the study only reported outcomes around brushing and snacking behaviour and salivary fluoride levels, and as such it was not possible to estimate the programme's impact on dental caries.

### 3.3.8 Peer-to-peer education

Weak evidence suggests that peer-to-peer oral health education programmes may be associated with improved oral health knowledge and oral hygiene behaviours, but is not associated with changes in dietary behaviours amongst primary school children.

Three studies were included for this intervention:

- **Freeman and Bunting, 2003**, a UK-based RCT including children aged between 5 and 11 years from areas with high social deprivation. The intervention group participated in a three stage child-to child oral health intervention. This comprised in stage one a healthy snacking education programme for older children over 4 weeks; in stage two these children designing a healthy snacking educational programme to be provided to their younger peers and in stage 3 a one hour child-to-child educational session from the 11 year olds to the 5 years olds.
- **Reinhardt *et al.* 2009a**, a before and after study undertaken in a German primary school. Children participated in a peer-to-peer oral health tutoring programme which involved training fourth graders about dental caries and tooth brushing, and then supporting them in training first graders.
- **Reinhardt *et al.* 2009b**, reported on the same before and after study described above (Reinhardt *et al.* 2009a).

Each of the studies described above reported outcomes relating to behaviour, such as snacking levels, brushing technique, and on oral health knowledge. As such, none of the studies described above reported any data that could be used to estimate the impact of the intervention on the levels of decay.

### 3.3.9 Community oral health education

Weak evidence from two before and after studies describing similar programmes suggests that community centre based oral health promotion and education programmes that include provision of oral hygiene supplies (e.g. toothbrush and fluoride toothpaste) may be associated with improvements in plaque scores, gingival health and oral health knowledge.

The two studies identified are relevant for this intervention were:

- **Biesbrock *et al.* 2004**, a before and after study set in Chicago, USA including children between 6 and 15 years old. The intervention, “The Crest Cavity Free Zone Program”, included oral health education programme, provision of a toothbrush, toothpaste, dental floss and plaque disclosing tablets.
- **Biesbrock *et al.* 2003**, a before and after study set in Kentucky, USA involving children aged between 5 and 15 years. The intervention in this study was identical to the other study included for this intervention.

Each of the studies described above reported outcomes relating to oral health knowledge, or relating to periodontal disease such as Plaque Index or Gingival Index. As such, none of the studies described above reported any data that could be used to estimate the impact of the intervention on the levels of decay.

### **3.3.10 Home visits to improve dental care access**

There is weak evidence from one RCT and one before and after study to suggest that intensive home visits by care facilitators or coordinators may improve access to or use of dental services among low income children eligible for government funded dental care.

Two studies were identified for this intervention:

- **Binkley *et al.* 2010**, a RCT set in Kentucky, USA. Children aged 4 to 15 and enrolled in Medicaid but had not accessed a dentist through the programme in at least two years were eligible to participate in a dental care coordinator programme. Children randomised to the intervention received a home visit to discuss personal barrier to dental care access, provide information on Medicaid services and provide pamphlets and oral health products.
- **Harrison *et al.* 2003**, a before and after study set in Canada on children living in an urban, low-income neighbourhood. Three community based facilitators sent letters to parents and attended community events in order to inform families of their role in facilitating access to publicly funded dental services (the Healthy Kids programme). The facilitators then assisted families in gaining Healthy Kids funding and provided advice and assistance in choosing and attending a dentist.

Each of the studies described above reported outcomes relating to dental service utilisation. As such, none of the studies described above reported any data that could be used to estimate the impact of the intervention on the levels of decay.

**Table 3.3: Summary of evidence for school-aged children**

<b>Intervention</b>	<b>Study</b>	<b>Evidence and estimated RR of decay</b>	<b>Relative risk reduction (RRR)</b>
Fluoride varnish	Moberg 2005a	Prevented fraction in incident caries as a result of intervention: 57%	43%
Fluoridated milk	Riley 2005	Odds ratio for reduction in risk of caries due to intervention: 0.58	42%
Fluoride mouth rinse	Levin 2009	Odds ratio of likelihood of tooth decay: 0.79	21%
Supervised brushing	1. Jackson 2005 2. Pine 2007	1. Mean caries increment: 10.9% 2. Mean caries increment (dmfs and DMFS): 0.61	1. 11% 2. 39%
Multi-component promotion	Bodner 2010	Mean difference in DMFT: 0.96	4%
Addressing common risk factors	None	None	Unknown
Oral health education in schools	1. Pieper 2012 2. Pieterse 2006 3. Vanobbergen 2004	1. Ratio of post-programme DMFT: 0.65 2. Ratio of post-programme DMFT: 0.25 3. Ratio of change in DMFT: 0.92	1. 35% 2. 75% 3. 8%
Peer-to-peer education	None	None	Unknown
Community oral health education	None	None	Unknown
Home visits to improve dental care access	None	None	Unknown

### **3.4 EVIDENCE FOR PROGRAMMES IN ADULTS**

#### **3.4.1 Workplace oral hygiene**

There is weak evidence to suggest that work based oral health education and promotion programmes may be associated with improved oral health amongst employed adults.

Two studies were identified for this intervention:

- **Ojima *et al.* 2003**, an RCT of workers at a company in Japan. Employees randomised to the experimental group received access to a web-based periodontal health system which stored and displayed personalised oral health records and gave personalised advice on oral hygiene. The personalised advice was generated following two visits from a dental hygienist in the work place. The control group received the dental hygienist visits, but not access to the web-based system;
- **Morishita *et al.* 2003**, a cross-sectional study of employees from 43 companies in Japan participating in an oral health promotion programme. This included an annual clinical examination and dental health education free of charge. The study analysed those who had attended once, twice, or three times or more, and compared their oral health outcomes to employees who had not taken part in the programme.

The impact of oral hygiene programmes were estimated from Morishita 2003. There are some caveats however: no baseline outcomes were reported, and there appears to be significant differences between the outcomes for men and women. The relative risk of decay was crudely approximated by calculating the average DMFT after the programme between men and women, weighted for programme participation, and calculating the ratio of these two values. The mean post-programme DMFT for the control group was estimated to be 12.475, compared with the mean post-programme DMFT for the participants group of 12.02. Thus the relative risk was estimated to be 0.96 (a 4% RRR of decay).

No comparative risk reduction can be estimated from Ojima 2003, as this study primarily reported the effect of the programme on periodontal outcomes.

### 3.4.2 Community oral health

Weak evidence suggests that oral health interventions and education programmes may be effective at improving flossing behaviour, gingival health, dental attendance and knowledge amongst elderly individuals, but has no impact on tooth decay, brushing habits or plaque levels in this population.

Three studies were identified for this intervention:

- **Al-Haboubi *et al.* 2012**: a UK based RCT including community dwelling people aged 60 years and older who had  $\geq 6$  teeth and were not regular chewers of gum. The intervention group were prescribed and provided with six months' supply of chewing gum (100% xylitol) to use twice a day for 15 minutes each time along with instructions of how and when to use the gum. The control group continued usual oral hygiene practice.
- **Marino *et al.* 2004**, a cluster non-randomised controlled trial involving adults over 55 attending community centres in Australia. The intervention group participated in Oral Health Information Seminars which involved nine fortnightly oral health group-based seminars; provision of oral care products related to the seminar session and information sheets to reinforce learning. Control centres did not receive Oral Health Information Seminars.

- **Marino et al. 2013**, a cluster, non-randomised controlled trial based in Australia. Elderly people were recruited by social clubs and participants received Oral Health Information Seminars/Sheets for 16 weeks. This consisted of 10 oral health seminars, four one-to-one oral hygiene sessions and provision of oral health products. Comparison group participants received no oral health program.

Al-Haboubi 2012 was assessed as having good quality evidence by Bazian ([+]), and was also considered by the EAC as having the more relevant setting and reporting the more relevant outcomes for the economic analysis. The study reported the effect of the programme on tooth decay levels, as well as clinical outcomes relating to periodontal disease. The mean DMFS for the intervention (baseline vs follow-up was 85.6 (SD 28.1) vs. 88.7 (SD 26.8), and the mean DMFS for the comparator was 83.8 (SD 24.1) vs. 86.7 (SD 23.3). The ratio of change in DMFS can be used to approximate the relative risk of decay, which was estimated to be 0.92 (a RRR of 8%).

No comparative risk reduction can be estimated from Marino 2004 and Marino 2013, as these studies primarily reported the effect of the programme on oral health knowledge and behaviours (flossing and brushing).

**Table 3.4: Summary of evidence for adults**

<b>Intervention</b>	<b>Study</b>	<b>Evidence and estimated RR of decay</b>	<b>Relative risk reduction (RRR)</b>
Adults - Workplace oral hygiene education	Morishita 2003	Mean post-programme DMFT for control and intervention groups: 0.96	4%
Adults over 65 - Community oral health promotion	Al-Haboubi 2012	Ratio of change in DMFS: 0.92	8%

## Section 4: Discussion and Conclusions

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### 4.1 SUMMARY

The primary research questions for the cost-effectiveness modelling described in this report were:

**Question 1:** Which community-based programmes and interventions to promote, improve, and maintain the oral health of a local community are cost effective?

**Question 2:** Which methods and settings to deliver community-based programmes for disadvantaged populations at high risk of poor oral health are cost effective?

The 17 community based programmes and interventions included within the model were identified through a review undertaken by Bazian, using an approach taking a whole population perspective over a life course, with a focus on vulnerable groups. Therefore, the modelling approach focused upon answering the first of the questions listed above only, rather than focusing on each specific vulnerable group described in Section 1.1.

It was originally intended that a decision analytic model calculating ICERs to make comparisons between the 17 interventions would be built. This approach required that the costs and benefits of each of the interventions were quantified and health outcomes expressed as QALYs. The original model was built, however it became apparent that the paucity of data required to inform inputs into the model was so great that expressing the results of the model in a single ICER value would be of limited value. The uncertainty that existed around the results made their purpose in informing PHAC recommendations very limited.

Consequently, two alternative analyses were developed which were based on a simpler model which utilised five key parameters. The first approach (Analysis I) evaluated four specific interventions in the pre-school or school populations, and it was attempted to more precisely estimate the likely values for each of the parameters. The second analysis (Analysis II) was developed to allow ranges of inputs to be used and as such a likely *range* of results to be explored. These analyses were undertaken in order to provide the PHAC with a tool to aid their decisions around the cost-effectiveness of specific interventions. Multiple values of each of the five model input parameters were incorporated given the uncertainty around their values. The input calculator model described in Appendix A was utilised to help determine reasonable ranges for each of the inputs.

All five parameters and their values or ranges in each of the analyses are now discussed.

- **Intervention costs** were very rarely reported in any of the oral health studies identified by Bazian and on occasion when costs were reported, interventions were very specific and based outside of England and Wales meaning the costs are unlikely to be relevant to a current NHS setting. As such, the maximum cost for the intervention to be considered cost-effective (for a given range of input variables) was estimated in Analysis I, and a range of intervention costs, from £20 to £100 per person were considered in Analysis II.
- **Baseline risk of dental caries** in Analysis I were estimated from a dataset provided by the Dental Public Health Intelligence Programme, using the most deprived quintile (by IMD) to represent a high-risk population. The baseline risk of dental caries in the pre-school group was estimated to be 39.6%, and 42.4% for 12 year olds. For Analysis II, the baseline risk for each age group was approximated using the number of decayed teeth over the course of a lifetime reported in The Adult Dental Health Survey, 2009. The risk of developing caries in the infant population was estimated to be 10%, in the child population 20% and in the adult population 50%.
- **Relative risk reduction of dental caries** for each of the interventions compared to no intervention was calculated approximately where possible from information provided within the published studies. The studies were heterogeneous in terms of patient population, reported outcomes, settings, meaning it was only plausible to attempt to compare each intervention to no intervention, rather than making between intervention comparisons. The estimated RRR are reported in detail in Section 3. Four interventions of interest were selected for Analysis I, and all interventions were included in Analysis II.
- **QALY loss from each case of dental caries** could not be identified from any published literature. Analysis I used estimates from otitis media as proxies for poor oral health. In analysis II, a published regression analysis (Brennan and Spencer, 2006) mapping OHIP-14 response to utility was utilised. There were limitations with this analysis (as described in Appendix C). Losses of -0.025, -0.05 and -0.1 were considered in the analyses.
- **Cost of treating each case of dental caries** aims to capture the lifetime cost of a restoration. In a small number of patient groups (e.g. children), dental extraction may require general anaesthetic and an inpatient hospital stay costing around £1,146 (PSSRU, 2012). In the interventions in pre-school children in Analysis I, it is assumed that all children experience extractions under general anaesthetic. In Analysis II, a range of costs (£75-£125) representing the average cost of dental caries per patient were considered, which reflects the variation in costs depending on the treatment pathway that a patient takes. If a patient visits the dentist regularly and the caries is identified and treated early, the cost of treatment is likely to be low with the patient often covering most of the cost. If, however, the caries is left more extensive treatment may be required.

The results of Analysis I and Analysis II are summarised in the following summary statements. The summary statements relating to Analysis II provide an overview of the likely cost-effectiveness at given baseline risk of dental caries and RRR of the intervention in

question. It is important to reiterate that, due to the lack of robust data available to inform baseline risk of dental caries, RRR of intervention as well as other model inputs, the reader is urged to use their own judgement as to where a specific intervention in a specific subgroup of the population would fit. Interpretation of these results should be treated with caution.

**Summary statement 1: Cost-effectiveness of interventions in populations with high baseline risk of dental caries (50%)**

- A. In high risk populations, interventions with a RRR of 30% or greater (compared with no intervention), are likely to be cost-effective at a threshold of £20,000 per QALY over the range of intervention costs explored in the analysis.
- B. In high risk populations, interventions with RRR of less than 10% compared with no intervention are unlikely to be cost-effective over the range of intervention costs explored in the analysis.
- C. In high risk populations, interventions with RRR of between 10% and 30% compared with no intervention are likely to be cost-effective if the average QALY impact of the dental caries is greater than -0.05 in this population.

**Summary statement 2: Cost-effectiveness of interventions in populations with medium baseline risk of dental caries (20%)**

- A. In medium risk populations, interventions with a RRR of 75% or greater (compared with no intervention), are likely to be cost-effective at a threshold of £20,000 per QALY over the range of intervention costs explored in the analysis and the QALY loss associated with dental caries.
- B. In medium risk populations where the QALY loss associated with dental caries is -0.05 or greater, interventions with a RRR of 50% or greater are likely to be cost-effective over the range of intervention costs explored in the analysis.
- C. In medium risk populations where the QALY loss associated with dental caries is -0.1 or greater, interventions with a RRR of 25% or greater are likely to be cost-effective over the range of intervention costs explored in the analysis.
- D. In medium risk populations, interventions with RRR of less than 20% compared with no intervention are unlikely to be cost-effective over the range of intervention costs explored in the analysis.

**Summary statement 3: Cost-effectiveness of interventions in populations with low baseline risk of dental caries (10%)**

- A. In low risk populations where QALY losses are -0.025 or below for dental caries, interventions that cost more than £60 per patient are unlikely to be cost-effective for any RRR at a £20,000 per QALY threshold.
- B. In low risk populations where the QALY loss associated with dental caries is -0.1 or higher, interventions with a RRR (compared with no intervention) of 40% or higher, are likely to be cost-effective over the range of intervention costs in the analysis.
- C. In low risk populations, the cost of the intervention is a key driver. Interventions costing £20 per person or below are likely to be cost-effective provided their RRR is 30% or higher.

- D. In low risk populations, interventions costing £80 per person or higher are likely to be cost effective if they have a RRR of 50% or higher (compared with no intervention) and the QALY loss of is -0.1 or higher.

**Summary statement 4: Cost-effectiveness of supervised tooth brushing and fluoride varnish programmes in a deprived population of pre-school children**

- A. Where the QALY loss associated with dental caries is **low** (0.002), supervised toothbrushing programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £34.
- B. Fluoride varnish programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £45, when the QALY loss associated with dental caries is **low** (0.002).
- C. Where the QALY loss associated with dental caries is **high** (0.007), supervised toothbrushing programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £46.
- D. Fluoride varnish programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £62, when the QALY loss associated with dental caries is **high** (0.007).

**Summary statement 5: Cost-effectiveness of supervised tooth brushing and fluoride varnish programmes in a deprived population of school children**

- A. Where the QALY loss associated with dental caries is **low** (0.002), fluoride varnish programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £62, if 50% of extractions are under GA, or £71 if 80% of extractions are under GA.
- B. Supervised tooth brushing programmes that reduce caries by 11% are likely to be cost-effective if the total cost of the intervention per child does not exceed £16 and 50% of extractions are under GA. When the RRR increases to 39%, the maximum cost of the intervention is £56 per child. When 80% of extractions are under GA, the maximum cost for an intervention that reduces the risk of caries by 11% is £18 per child, and £64 for an intervention that is 39% effective.
- C. Where the QALY loss associated with dental caries is **high** (0.007), fluoride varnish programmes are likely to be cost-effective if the total cost of the intervention per child does not exceed £80 if 50% of extractions are under GA or £89 if 80% of extractions are under GA.
- D. Supervised tooth brushing programmes that reduce caries by 11% are likely to be cost-effective if the total cost of the intervention per child does not exceed £21 and 50% of extractions are under GA. When the RRR increases to 39%, the maximum cost of the intervention is £73 per child. When 80% of extractions are under GA, the maximum cost for an intervention that reduces the risk of caries by 11% is £23 per child, and £81 for an intervention that reduces the risk of caries y 39%.

## 4.2 RESEARCH RECOMMENDATIONS

A number of limitations were identified with the economic analysis, which may be overcome through further research. Each of these limitations and subsequent research recommendations are described below:

- Gaps in effectiveness evidence. There exists limited evidence on the effectiveness of interventions to improve oral health set in England and the existing evidence is extremely heterogeneous. Future studies should include head to head comparisons between interventions. Retrospective cohort studies providing evidence on the prevention of diseases such as oral cancer and periodontal disease would also be beneficial. If such studies could provide information on costs, or resource use, this too would be of benefit to cost-effectiveness analyses.
- Lack of utility data. Existing studies have failed to report utility data on oral health. Studies including patient reported outcome measures through established, non-disease specific tools such as EQ-5D are merited. Such data would allow QALYs to be calculated and in turn, comparisons between diseases to be made to assist in NHS resource use decisions.
- Treatment pathway of dental caries. Although, a recognised treatment pathway for dental caries exists, it assumes patients make regular visits to their dentist and therefore may represent an atypical patient. If a more typical treatment, or impact, pathway could be established, calculations such as those for the cost of dental caries may be made with more certainty.
- Gaps in intervention cost evidence. The availability evidence around the cost or resource use involved in oral health intervention is low. Reporting of the cost of interventions, or at least the resources utilised during interventions would assist in future cost-effectiveness analysis.

**Table 4.1: Data gaps for modelling**

#	Research recommendation
1	Existing evidence is very heterogeneous, and the head-to-head evidence of different oral health programmes is very limited. In addition, few studies report the <b>long-term clinical outcomes</b> in the years after the programme. In particular, it would be useful to explore the impact of programmes in children with primary teeth and how it impacts on the level of decay in their permanent teeth in the future.
2	Many <b>intermediate outcomes</b> such as oral health knowledge (e.g. knowledge for tooth brushing and flossing, awareness of oral health outcomes) and behavioural outcomes (e.g. brushing frequency, snacking levels, smoking) are collected in studies of oral health interventions. However the relationship between these and the clinical outcomes such as levels of decay and periodontal disease needs to be explored and <i>quantified</i> in order for the outcomes to provide any meaningful indication of how the intervention impacts on the patients' health.
3	<b>Programme costs</b> should be collected during the study. This should be detailed as appropriate, i.e. with costs specified for the number of patients, and for intervention cost types (staffing, materials). The targeted number and the proportion eligible with consent for the programme should also be collected.

4	<b>Quality of life</b> should be evaluated as measured by a generic instrument (e.g. EQ-5D) for different oral health states, including missing teeth, decayed and painful teeth, and restored teeth. For each of these health states, the accumulative effect (e.g. the disutility of one missing tooth compared with the disutility of three missing teeth etc.) and how this varies by tooth location should also be evaluated. Given that the majority of programmes are in school-aged children, quality of life should be evaluated in child as well as adult populations.
5	While the “typical” <b>treatment pathway</b> for dental caries has been well described, there is little data to suggest exactly how some patients (e.g. from different socioeconomic backgrounds) may deviate from this pathway. Instead of assuming that all decayed teeth receive prompt and appropriate treatment, it would be useful to know the rate at which this occurs and the proportion of teeth that are left untreated until it is required that they are extracted (with the remainder of teeth having delayed restorative treatment). Additionally, some restored teeth will experience further decay, where a proportion will require further restorative work and some will be extracted. The rate at which each of these occur will also be required for a robust analysis of the pathway.
6	There is some evidence to suggest that a significant number of children receive a general <b>anaesthetic for a tooth extraction</b> (Moles 2008). Further evidence on the annual rate of extractions under general anaesthetic, stratified by age group or year, would be required to model this robustly.
7	The impact of interventions on <b>oral cancer</b> may not be appropriate to evaluate in short-term studies, but this evidence could be collected from patient databases which contain observational long-term evidence.
8	There is currently little evidence to be able to model <b>periodontal disease</b> adequately. The impact of periodontal disease on quality of life using a general instrument (EQ-5D) is currently not known – a research recommendation may be to collect and evaluate general utility scores within a study, or conduct analyses of how measures of periodontal disease (Plaque Index, Gingival Index) are related to quality of life, for example using a regression analysis.
9	There is little epidemiological information about the progression of <b>periodontal disease</b> or longitudinal data for a UK or similar population over a sufficient period. The end-state of periodontal disease is a missing tooth: while data exists for the rate of missing teeth in general, it is not known how this relates to the periodontal status of the patient.

### 4.3 CONCLUSION

Due to the data limitations described in previous sections, providing an exact ICER figure for interventions designed to promote, improve and maintain oral health was not considered to be appropriate. Therefore, two alternative analyses have been developed. One analysis examines the impact of four interventions in a deprived population of pre-school and school children. In addition, an analysis which utilises ranges of results has been provided as a tool to assist the PHAC in providing recommendations for the range of interventions in the guidance. The PHAC is urged to use their expertise, professional experience and judgement alongside this report to ascertain realistic model inputs and, therefore, the likelihood of cost-effectiveness of a given intervention. As further data becomes available and model inputs can be established with more certainty, this report may provide more definitive answers around the cost-effectiveness of oral health interventions.

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## **APPENDIX A**

### **Model Methodology: Restoration pathway and tooth decay**

The main focus of the economic analysis is to capture the costs and benefits associated with the treatment of dental caries. The impact of varying the key parameters in the analysis is described in Section 2. An additional model, the input calculator model, has been developed in addition to the core model with the aim of providing illustrative estimates of each of these parameters. The input calculator model was based around a treatment pathway, described below, where each health state is linked to a cost impact (in Appendix B) and a quality of life impact (in Appendix C).

### Levels of tooth decay

Data from the Children’s Dental Health Survey 2003 was used to estimate the levels of decay in the general child population (Pitt and Harker, 2003). Data from the Adult Dental Health Survey was used to estimate the level of decay in the general adult population (NHS: The Information Centre, 2011).

The Children’s Dental Health Survey reported the number of teeth with “obvious decay experience” (defined as having decay into dentine and filled, otherwise sound teeth). This was reported for **primary** teeth in children aged 5 and aged 8, and for **permanent** teeth in children aged 8, 12 and 15, and presented in Table A.1 as the number of unsound teeth. The mean number of teeth that were missing due to decay was also reported for permanent teeth in children aged 8, 12 and 15. In Table A.1, the number of missing and unsound teeth in children aged eight was a combined total of the affected primary and permanent teeth.

**Table A.1 State of oral health in children**

Age	Missing teeth	Unsound teeth
Age 5	0	1.6
Age 8	0	2.0*
Age 12	0	1.1
Age 15	0.1	2

\*1.8 primary teeth, 0.2 permanent teeth

The Adult Dental Health Survey reported the mean number of total teeth for each age band, from which it was possible to estimate the number of missing teeth for each age band by assuming the mean number of adult teeth to be 30. The survey also reported the mean number of sound teeth, and the number of unsound teeth was also estimated by subtracting the number of sound teeth from the total number of teeth.

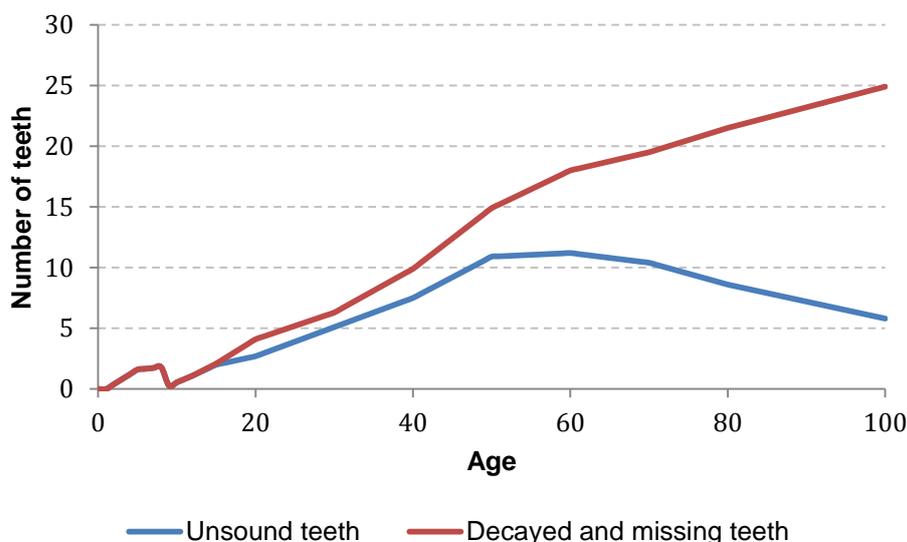
**Table A.2: State of oral health in adults**

Age	Total teeth	Missing teeth*	Sound teeth	Unsound teeth*
16-24	28.6	1.4	25.9	2.7
25-34	28.8	1.2	23.7	5.1
35-44	27.6	2.4	20.1	7.5
45-54	26.0	4	15.1	10.9
55-64	23.2	6.8	12.0	11.2
65-74	20.9	9.1	10.5	10.4
75-84	17.1	12.9	8.5	8.6
85+	14	16	6.8	7.2

\*estimated by assuming the adult mouth has 30 teeth

From these two sources of data, the mean number of unsound teeth was estimated over the lifetime. Over a course of a lifetime, some unsound teeth will become missing teeth, but it is not known the proportion of these teeth that were lost due to poor oral health and which were lost by some other means, e.g. in an accident. The number of unsound teeth and the combined number of unsound and missing teeth for each age is presented in Figure A.1. This has been estimated by assuming that the number of unsound or missing teeth refers to the midpoint of the age band (e.g. a 50 year old has 10.9 unsound teeth and a 60 year old as has 11.2 unsound teeth) and assuming that the rate of teeth affected by decay is constant between the two age points.

**Figure A.1: Lifetime unsound and missing teeth**



From this graph the number of teeth that become affected by decay each year can then be inferred. Given that the number of teeth lost due to reasons other than poor oral health is not known for the cohort, it is assumed that all missing teeth were previously decayed. A corresponding cost and QALY loss is incurred each year for each of these newly decayed

teeth, based on the patient age and the timeline of the analysis. The mechanism by which these are calculated is described in Appendix B and Appendix C, and the restoration pathway described below.

### Restoration pathway

The input calculator model attempts to capture the progression of the dental treatment of a decayed tooth, referred to as the “restorative cycle”. This cycle is well recognised having first been described by Elderton 2001. Evidence suggests that restorations have a limited life span, and that once a tooth is restored the filling is likely to be replaced many times in the patient’s lifetime. This may be due to the fact that they wear out or break, or get recurrent decay around the margins. Successive restorations placed inside the tooth tend to increase in size, leading to an increased risk of subsequent tooth fracture. Replacement restorations tend to be more complex than the initial restorations, and may have a detrimental effect on the pulp leading to the need for a root treatment. A crown may be required as the hole is too big to be filled. Eventually the crown fails and the tooth is then extracted to be replaced by a bridge which in turn may fail to be replaced by a denture. This pathway is described in Figure A.2.

**Figure A.2: Restoration pathway**



It was felt by PHAC that this represents an atypical pathway which may not be representative of some socioeconomic groups, since it is assumed that people are having regular visits to their dentist and receiving timely treatment. To account for those patients who do not have their teeth attended to regularly, the pathway was altered to allow for patients whose decayed tooth is immediately removed (perhaps due to an advanced state of decay), or to allow movement from any step of the process to an extraction. Unfortunately there is currently no published data that allows this to be accurately modelled. It is also unlikely to be a straightforward relationship, where the rate of extraction will vary by age, and the probability of going from each step of the process to a tooth extraction is unlikely to be constant (i.e. patients may be more likely to have a tooth with a crown completely removed instead of going to a root canal than a badly decayed tooth being completely removed instead of having a filling).

The input calculator model allows for these additional steps to be modelled in the treatment pathway, and also includes the rate at which newly decayed teeth are treated (assuming that treatment is delayed for a certain proportion of decayed teeth). Given that there is no published data for the value of these rates, the model allows for a range of values to be included; these are currently based on a range of assumptions, but it was considered to be useful to include these parameters in the event that evidence is published in the future and

the model will be able to be updated, or to be able to analyse a range of values to see how much it impacts on the results. A range of values for these parameters has been explored, and the corresponding impact on costs is presented in Appendix B. This can then provide a guide for PHAC as to the most plausible cost impact associated with dental caries.

The rate at which restorations were replaced was estimated from data reported in Burke *et al.* 2005. The median survival of a restoration was reported in this study for different age groups. This study investigated the outcome of direct placement restorations provided within the General Dental Services in England and Wales, and to identify the patient factors which may affect this using a database derived from patient treatment data at the Dental Practice Board. The results indicated that patients' gender was of little significance in the long-term survival of restorations, but patient age had a significant effect, with the restorations of older patients surviving less well than those of younger patients. The study does not present median survival for the younger age groups, and it appears that this is due to the fact that more than 50% of dental patients had their restoration intact at the end of the 10-year follow-up period. This indicates that the median survival for the 30-39 age group may be an underestimate for the younger age-groups and if this is the case, the illustrative QALY loss estimates in Appendix C will be too high, although the input calculator model indicates that the difference is extremely negligible.

The median restoration survival for each age group was converted to an annual probability of failure, by *i*) assuming that the median survival corresponds to a 50% probability of survival, and converting this to an annual rate of failure, and *ii*) converting this rate to an annual probability. These calculations used the following set of formulas, where probability is denoted *p* and rate is denoted *r* (Fleurence *et al.* 2007):

$$(1) r = -\frac{1}{t}(\ln(1 - p))$$

$$(2) p = 1 - e^{-rt}$$

**Table A.3: Median filling survival by patient age**

Age group	Survival (years)	Annual probability of failure
30 - 39	10.22	6.6%
40 - 49	8.39	7.9%
50 - 59	6.41	10.2%
60 - 69	5.67	11.5%
70 - 79	4.78	13.5%
80 and over	4.47	14.4%

## **APPENDIX B**

### **Costs**

## NHS dental costs

A UDA is a “Unit of Dental Activity” undertaken by an NHS dentist. A UDA depends on the type of work undertaken. A dentist is contracted by his PCT (Primary Care Trust) to do a set number of UDAs and dentists have to be within 4% of their targets.

The cost of a UDA is variable: one UDA might be worth anywhere between £15 and £25, but can be more than this or less. The actual UDA varies according to where in the country a dentist is located and the amount of work previously carried out by the dentist before the new contract. It is thought that the more desperate a PCT is for NHS dentists, the more a UDA might be worth. This analysis assumes that one UDA is costed at £25.

Dentistry is one of very few NHS services the patient pays for. Patient charges were also included in the economic model (NHS Choices, 2011).

There are three standard charges for all NHS dental treatments:

- **Band 1** - this covers an examination, diagnosis (including X-rays), advice on how to prevent future problems, a scale and polish if needed, and application of fluoride varnish or fissure sealant. Band 1 treatments are allocated 1 UDA.
- **Band 2** - This covers everything listed in Band 1 above, plus any further treatment such as fillings, root canal work or removal of teeth. Band 2 treatments are allocated 3 UDAs.
- **Band 3** - This covers everything listed in Bands 1 and 2 above, plus crowns, dentures and bridges. Band 3 treatments are allocated 12 UDAs.

**Table B.1: NHS dental costs**

Band	Treatment	Dentist costs	Patient charges
1	Examination, diagnosis	£25	£18
2	Fillings, root canal, extraction	£75	£49
3	Crowns, dentures and bridges	£300	£214

Some adults are exempt from patient charges. Children under the age of 18 do not pay for dental treatments. Table B.2 describes the proportion of adults who are exempt from paying for treatment, which has been estimated from data reported in NHS dental statistics for England: 2011/2012. NHS Dental Statistics is an annual report which brings together information on NHS dental activity in England, based on data collected through FP17 forms by NHS Dental Services (Health and Social Care Information Centre, 2012).

**Table B.2: NHS activity in adults**

Band of treatment	Exempt adults	Paying adults
Band 1 course of treatment	22.63%	77.37%
Band 2 course of treatment	35.45%	64.55%
Band 3 course of treatment	55.19%	44.81%

Other costs that might be considered in the NHS are those hospital admissions for dental care in children for the management of dental caries, as general anaesthesia is used to manage behaviour and anxiety. A significant cost is associated with extraction under general anaesthesia, and an inpatient stay for a dental extraction is estimated to cost around £1,146 (PSSRU 2012). This cost has been applied to a proportion of dental patients under the age of 16. However, the rate of extraction is very low and the impact of including this element in the costs is negligible.

A range of potential per-patient costs for different age groups, for two different time horizons are presented in Table B.3. This table refers to the costs incurred **when one tooth is affected by decay**, i.e. the cost of treating one decayed tooth. These values have been estimated using the input calculator model, and assumes that a decayed tooth follows the pathway as described in Appendix A. Future costs are discounted at a rate of 1.5% (NICE, 2012). The calculations also take into account the fact that the patient is more likely to die from natural causes as they get older, and so costs incurred in each year are weighted by the probability of being alive. Treatment costs generally increase with age due to the fact that restoration survival is largely affected by the patient age. These costs may over-estimate the actual expenditure as it does not take into account that more than one tooth may be treated at the same time, e.g. the cost of doing one filling is the same as the cost of three fillings if they are done under the same course of treatment.

There is a lower level of uncertainty around treatment costs (compared with quality of life), since dental costs are set on a national level. Two different scenarios around the rate of extraction of decayed, unfilled teeth are explored:

- Scenario one: the majority of decayed teeth are restored. The annual rate for having a decayed tooth extracted is assumed to be 1%, which represents a low rate of tooth extraction per decayed tooth.
- Scenario two: a smaller proportion of decayed teeth are restored. The annual rate for having a decayed tooth extracted is assumed to be 10%, which represents a higher rate of tooth extraction per decayed tooth.

**Table B.3: Costs per patient, by age**

Age	5 year time horizon		10 year time horizon	
	Scenario 1	Scenario 2	Scenario 1	Scenario 2
Age 5	£80.24	£73.12	£80.24	£73.12
Age 10	£93.58	£84.67	£131.44	£118.74
Age 25	£93.50	£84.60	£131.24	£118.57
Age 50	£107.98	£98.90	£175.10	£158.60
Age 65	£113.54	£103.48	£197.61	£177.70

For example, a 50-year old presenting with a decayed tooth will incur £98.90 in treatment costs over five years. This figure is estimated by assuming the probability for having the decayed tooth extracted instead of restored is 10% each year. In the same scenario, the treatment costs rise to £158.60 over ten years.

Table B.4 reports the potential **actual** costs that are incurred by a patient over a five-year or ten-year time horizon (as opposed to the potential cost of treating one case of caries that are described in Table B.3), and is based on the predicted level of tooth decay as modelled in Appendix A using the mean number of missing and unsound teeth over a lifetime (as opposed to the costs in Table B.3 which are based on one tooth affected by decay). These costs are displayed for each intervention type (stratified by age group), and for the same scenarios as described for Table B.3. A range of relative risks are explored.

**Table B.4: Per-patient actual costs, by intervention type**

Intervention type	5 year time horizon		10 year time horizon	
	Scenario 1	Scenario 2	Scenario 1	Scenario 2
Relative risk of intervention: 1.0 (0% risk reduction)				
Infants	£106.78	£97.14	242.90	220.26
School-children	£138.07	£124.98	370.43	334.69
Adults of working	£145.04	£131.80	434.90	393.87
Adults over 65	£92.75	£85.02	257.83	235.05
Relative risk of intervention: 0.9 (10% risk reduction)				
Infants	£96.10	£87.43	231.83	210.18
School-children	£124.27	£112.48	351.07	317.20
Adults of working	£130.53	£118.62	412.20	373.32
Adults over 65	£83.48	£76.52	243.67	222.15
Relative risk of intervention: 0.75 (25% risk reduction)				
Infants	£80.09	£72.86	215.21	195.07
School-children	£103.55	£93.74	332.04	290.96
Adults of working	£108.78	£98.85	378.16	342.50
Adults over 65	£69.75	£63.77	222.42	202.80

## **APPENDIX C**

### **Quality of Life**

## **Background**

Quality of life measures are included within economic models in order to measure the impact interventions have on this measure compared with the alternative. Including a quality of life component within the economic model allows for any differences between interventions in terms of their impact on quality of life to be included within decision making no matter how small these differences may be.

Oral health related problems are likely to impact upon quality of life, however, in some cases this may be to a nominal level. Where a patient experiences dental caries and requires a filling, they are likely to have reduced quality of life associated with any pain in the tooth until the tooth is treated and filled. After some initial discomfort on the day of the filling the patient's quality of life is likely to return to their normal level. In this case there is likely to be a small reduction in quality of life over a short time frame. In other cases, the impact on quality of life from oral health problems may be greater, or for a longer time frame, for instance in the case of severe dental caries. In a recent documentary there was an example of a 3 year old who had all his primary teeth removed due to decay. It was carried out under GA. The result was that he was without any teeth for several years at primary school until his adult teeth started to come through. However, for the vast majority of the disease pathway, there will be no reduction in quality of life at all - the loss of quality of life only appears at the end of the pathway where advanced decay will result in pain, and dysfunction due to tooth loss. The reduction in quality of life due to lost teeth may be either transient altogether, or be diluted over time due to people adapting to their condition, a well-documented phenomenon across all chronic diseases. Furthermore, because these events occur in the future, the impact of discounting (even at 1.5% per year) will reduce the impact even more.

It is also important to acknowledge the impact on the quality of life of young children that is associated with losing primary teeth. This includes the impact on development of the mouth or jaw if these teeth are lost prematurely, the risks associated with having teeth extracted under general anaesthetic, and dental phobia as a result of the first experiences of visiting a dentist being traumatic. However the risks associated with general anaesthesia were assessed to be small (Cochrane review of sedation, 2012) and therefore have a relatively low impact on the average population. The Cochrane review also concluded that there were no studies suitable for inclusion in the review, indicating that the full impact of general anaesthesia on mortality and morbidity is not known, and as such cannot be modelled robustly. A fairly significant number of extractions under general anaesthetic are undertaken in England, estimated to be around 34,000 in children under 17 in 2005-06, with roughly a third of these occurring in the under-5s (Moles and Ashley, 2008). But given that the economic analysis takes account of the average impact across the population that would receive an intervention (the under-5 population size in 2012 was just under 4 million), the impact on the average child is likely to be negligible.

## **Modelling**

Cost-effectiveness models are used to assess the relative benefits of a given treatment using patient outcomes and the costs incurred in achieving those outcomes. The additional cost per extra unit of benefit gained is of key interest to policy and decision makers. Benefit gained is often measured a generic health related utility measure known as a QALY which is explained further in Section 1.2. Use of the QALY allows comparisons to be made between very different health states.

### General population utility values

Baseline quality of life by age group and gender was included in the input calculator model as reported by Dolan *et al.* 1995. These utility values were applied to the 'healthy' population (unaffected by tooth decay or missing teeth) in the input calculator model, and are displayed in Table C.1.

**Table C.1: General population utility values (baseline)**

	Male	Female	All
<25	0.94	0.94	0.94
25-34	0.93	0.93	0.93
35-44	0.91	0.91	0.91
45-54	0.85	0.85	0.85
55-64	0.80	0.81	0.81
65-74	0.78	0.78	0.78
75+	0.73	0.71	0.72

### Dental caries and quality of life

There existed no health related utility scores for dental caries within the published literature, and as such, these were estimated in the input calculator model. There exist some oral health-specific instruments to measure quality of life. One of the more commonly used instruments is the Oral Health Impact Profile (OHIP-14). The total OHIP score is calculated by adding the numerical values for people's responses on the 14 questions ('Never' =0, 'Hardly ever' =1, 'Occasionally' =2, 'Fairly often' =3 and 'very often' =4). The range of values possible was from 0 (never on all 14 questions) to 56 (very often on all 14 questions). Higher scores imply a more impaired oral health-related quality of life. The Adult Dental Health survey reported OHIP responses for a variety of oral health conditions such as decayed or missing teeth, following an interview administered questionnaire on a sample of adults within the UK. Table C.2 displays the prevalence of OHIP-14 problems with different levels of oral health, including those with one or more decayed tooth, and those who have fewer than 21 teeth. A widely accepted threshold for reporting a positive OHIP-14 impact is experiencing a problem occasionally or more often, and as such the proportion experiencing oral health problems at least this frequently is reported in the ADHS and described in Table

C.2 below. For comparison with the groups in the table, the mean OHIP score for dentate adults ranged from 17.1 for those who had no decayed teeth (vs 19.2 for those with at least one decayed tooth), to 17.4 for those who have more than 21 teeth (vs 19.7 for those with fewer than 21 teeth).

**Table C.2: Illustrative OHIP-14 scores (ADHS): proportion responding with “occasionally or more often”**

<b>Dimension</b>	<b>Some decayed teeth*</b>	<b>Some missing teeth**</b>
Trouble pronouncing words	10%	18% (10% occasionally)
Sense of taste worsened	10%	18% (10% occasionally)
Painful aching in mouth	38% (24% occasionally)	41% (26% occasionally)
Uncomfortable eating	38% (24% occasionally)	41% (26% occasionally)
Felt self-conscious	28% (14% occasionally)	30% (14% occasionally)
Felt tense	28% (14% occasionally)	30% (14% occasionally)
Diet unsatisfactory	12%	15%
Interrupt meals	12%	15%
Difficulty relaxing	24% (15% occasionally)	22% (13% occasionally)
Being embarrassed	24% (15% occasionally)	22% (13% occasionally)
Irritable with other people	10%	10%
Difficulty doing usual jobs	10%	10%
Life less satisfying	9%	11%
Unable to function	9%	11%
<b>Mean total OHIP score</b>	<b>19.2</b>	<b>19.7</b>

\*At least one decayed tooth

\*\*Fewer than 21 teeth

The NICE methods guide for the development of public health guidance states that where possible cost-effectiveness analysis using QALY's should be undertaken to allow comparisons between NICE programmes (NICE, 2012). However no published literature providing utility score estimations for dental caries were available. As such, the utility score for each oral health state can be estimated within the input calculator model using a regression analysis which maps OHIP-14 score to EQ-5D. A review of the literature did not find any other studies which mapped any other oral health-specific instruments to generic quality of life.

A study by Brennan and Spencer (2006) was used to map OHIP responses to generic health state values. The authors surveyed both patients and dentists and used responses to construct models of health state values. This provided an algorithm to transform OHIP-14 scores into estimated generic health state values. The regression coefficients for each of the 14 dimensions of the OHIP-14 are shown in Table C.3. The regression model in Table C.3 is described by the authors as a continuous model, which assumes that each level of response (i.e. 'never', 'hardly ever', 'occasionally', 'fairly often' and 'very often') coded from 0 to 4 is a continuous variable. The authors of the study also considered an additional categorical model but this was found to fit less well and was not presented in this analysis.

**Table C.3: Regression coefficients for OHIP-14 to utility relationship**

Dimension	Regression coefficient	Standard error
Trouble pronouncing words	0.0154	0.025
Sense of taste worsened	0.002	0.022
Painful aching in mouth	-0.0905	0.020
Uncomfortable eating	-0.0173	0.019
Felt self-conscious	0.0281	0.026
Felt tense	0.0289	0.027
Diet unsatisfactory	0.032	0.024
Interrupt meals	-0.0337	0.025
Difficulty relaxing	-0.0187	0.030
Being embarrassed	0.0055	0.029
Irritable with other people	-0.0186	0.030
Difficulty doing usual jobs	-0.0266	0.038
Life less satisfying	-0.055	0.026
Unable to function	-0.0177	0.037
Gender (1=male)	0.0204	0.031
Age (years)	0.0002	0.001
Constant term	1.0822	0.060

For example, a female patient aged 50 answering “Occasionally” to each of the items will have their utility score estimated as such:

$$Utility = 0.0154*2 + 0.002*2 - 0.0905*2 - 0.0173*2 + 0.0281*2 + 0.0289*2 + 0.032*2 - 0.0337*2 - 0.0187*2 + 0.0055*2 - 0.0186*2 - 0.0266*2 - 0.055*2 - 0.0177*2 + 0.0204*0 + 0.0002*50 + 1.0822 = 0.76$$

While the OHIP outcomes of the Adult Dental Health Survey in Table C.2 are not presented in a format that is suitable for use in the regression analysis, they can provide a guide to the likely responses and thus the potential utility weight for each oral health state.

A range of possible utility estimates based on responses to the OHIP using the regression analysis in Table C.3 are described below:

- Where the answer ‘never’ is provided to all of the dimensions the utility score calculated is 1 (equivalent to an OHIP-14 score of 0).

- Conversely, where the answer ‘very often’ is selected for all 14 dimensions (i.e. an extreme worst case), the utility score generated is 0.49 (equivalent to an OHIP-14 score of 54).

There are some limitations with the Brennan study, some of which were discussed by the EAC and others which were mentioned by the authors of the study. As with all regression models, there is a degree of estimation error in the analysis. The authors of the study estimated the forecast error of the regression model to be 15.2%. The standard error around each regression coefficient is also presented in Table C.3. The study also only considered responses from adult dental patients, so the results of the regression may not be applicable for child populations.

As is evident from the coefficients shown in Table C.3, some of the coefficients calculated in the regression analysis by Brennan and Spencer are positive (e.g. ‘felt tense’) meaning that as the dimension occurs more often, the utility score increases. This point is counter-intuitive, and likely to be a limitation of the analysis. However it was not discussed by the authors of the paper.

The constant term is also larger than 1 (the maximum for a utility weight), suggesting that if a patient answered “never” to each question, their utility score would be above 1 (the input calculator model artificially capped the estimated utility weight at 1 so this would not occur in the analysis). There is a ceiling effect associated with the distribution of responses to the survey in the Brennan study, where a large number of respondents reported no problems, making the instrument less appropriate for milder conditions.

The authors do however mention that previous mapping studies have cautioned that the use of such mapped utility values would not be appropriate for use at the individual level and instead should be applied to analyses performed at the group level. They also noted that the participants in this study were dental patients who may have more oral disease than the general population, and may over-estimate the value of some health states.

Figure C.1 provides an illustration of how utility weight can be estimated from OHIP responses in the input calculator model. Please note that this is provided purely as an illustrative example and is not a reflection of what the EAC consider the as being the most appropriate utility estimates for the analysis.

**Figure C.1: Mapping of OHIP-14 to utility scores**

**OHIP-14 to utility relationship**

	Regression	Decayed teeth	Missing teeth
Trouble pronouncing words	0.0154	Hardly ever	Never
Sense of taste worsened	0.002	Occasionally	Never
Painful aching in mouth	-0.0905	Never	Occasionally
Uncomfortable eating	-0.0173	Never	Hardly ever
Felt self-conscious	0.0281	Occasionally	Never
Felt tense	0.0289	Fairly often	Hardly ever
Diet unsatisfactory	0.032	Occasionally	Occasionally
Interrupt meals	-0.0337	Occasionally	Fairly often
Difficulty relaxing	-0.0187	Occasionally	Very often
Been embarrassed	0.0055	Fairly often	Occasionally
Irritable with other people	-0.0186	Occasionally	Hardly ever
Difficulty doing usual jobs	-0.0266	Very often	Hardly ever
Life less satisfying	-0.055	Hardly ever	Fairly often
Unable to function	-0.0177	Occasionally	Hardly ever
		Occasionally	Very often
Sex (male)	0.0204		
Age (years)	0.0002		
Intercept	1.0822		

Source: Brennan 2006

	Decayed teeth*	Missing teeth
Utility	0.97	0.70
OHIP-14 score	26	21
Mean number of carious teeth	2.7	

\*utility of patients with at least one carious tooth

Source: Adult Dental Health Survey 2009 (Disease and Related Disorders: Table 2.1.4)

**OHIP-14 values**

Decayed teeth	19.2
Missing teeth	19.7

Source: Adult Dental Health Survey 2009 (Outcome and Impact: Table 7.2.13)

Varying the responses to each of the OHIP-14 dimensions had little impact overall health related utility, suggesting that this parameter, although uncertain is likely to have a limited impact on the model results.

The outcome of this analysis can be used to put the ranges of QALY loss in the sensitivity analyses into context. Taking, as an example, a QALY loss of -0.1 over a 10 year time horizon, i.e. 0.99 QALYs per year, the analysis can be used to determine which answers to OHIP-14 would need to be provided to generate such utility.

- Answering 'hardly ever' to all but one dimension and 'never' to the 'life less satisfying' dimension provides a utility score of 0.99 and an OHIP-14 score of 13. Therefore, if a patient lived in this health state for 10 years, they would experience a QALY loss of -0.1.
- A QALY loss of -0.1 can also be generated by considering a one year time horizon during which a patient lives with a utility of 0.9. A patient completing the OHIP-14 with answers of 'occasionally' for all dimensions except 'never' interrupting meals or having difficulty relaxing and 'hardly ever' having difficulty doing usual jobs would generate an OHIP-14 score of 23 and a utility of 0.9.

It is important to note the difference between 'utility' and 'QALYs'. Whilst we can map OHIP-14 to utility (as shown above), estimating the relationship between OHIP-14 and lost QALYs would involve modelling the complex disease pathway over longer periods of time. Therefore, using OHIP-14 to predict QALYs is somewhat more challenging. A range of alternative values has been assessed in the economic analysis in Section 2, rather than attempting to select one single estimate. The values of -0.025, -0.050 or -0.100 were chosen because it was felt that they represented a reasonable and plausible range of potential scenarios. A lower limit of zero (i.e. no utility loss) could also have been included, however that would result in no QALY gains or losses at all and, as such, cost-effectiveness ratios would be impossible to generate. It would also be possible to model QALY losses that are greater than our worst case (-0.100) but those analyses are excluded for two reasons: (i) it is unlikely that the magnitude of QALY losses will be greater than this figure due to the transient nature of the quality of life loss (i.e. it is usually incurred over short periods of time), and (ii) the sensitivity analysis below has demonstrated that, for QALY losses of 0.100 or more, the results of the model remain mostly unchanged.

The results of the sensitivity analysis in Section 2 can be interpreted according to the time scale which is considered to be most relevant - i.e. The PHAC can estimate QALY loss and costs over whichever time scale that is considered to be appropriate, and then the graphs in Section 2.4 can be used to guide discussions around whether *in that circumstance* the intervention is cost-effective. A range of potential per-patient QALY losses for different age groups, for two different time horizons are presented in Table C.4. This table refers to the QALY loss when one tooth is affected by decay. These values have been estimated using the input calculator model, and assumes that a decayed tooth follows the pathway as described in Appendix A. Future QALYs are discounted at a rate of 1.5% (NICE, 2012). Two different utility scenarios are explored:

- Scenario one: decay and missing teeth have a small impact on quality of life. The utility for having a decayed tooth is assumed to be 0.99 and the utility for having a missing tooth is assumed to be 0.95;
- Scenario two: decay and missing teeth have a larger impact on quality of life. The utility for having a decayed tooth is assumed to be 0.95 and the utility for having a missing tooth is assumed to be 0.90.

To reflect that the general health of the population will naturally deteriorate over time, the health state utility weights were applied to general population utility estimates to derive the adjusted utility scores allowing for the underlying utility of the general population. For example, an otherwise healthy 40 year old has a utility value of 0.91 (Table C.1). Assuming that the utility weight for having a decayed tooth is 0.99, a 40 year old with a decayed tooth would have a utility value of  $0.91 \times 0.99 = 0.9009$ .

Additionally, many studies in the clinical effectiveness review state that the benefits of interventions were not sustained in the long-term. The scenarios in the Table C.4 conservatively assume that each intervention reduces the risk of disease for no more than five years. An additional scenario is presented in C.5 where it is assumed that each intervention reduces the risk of disease for at least ten years (i.e. over the full 10-year time horizon). Results for the 5-year time horizon in this scenario will be identical to those in Table C.4 and are, therefore, not replicated.

**Table C.4: QALY loss per patient, by age (benefits of intervention last 5 years)**

Age	5 year time horizon		10 year time horizon	
	Scenario 1	Scenario 2	Scenario 1	Scenario 2
Age 5	-0.0205	-0.1011	-0.0362	-0.1783
Age 10	-0.0215	-0.1024	-0.0398	-0.1831
Age 25	-0.0213	-0.1012	-0.0391	-0.1802
Age 50	-0.0190	-0.0903	-0.0343	-0.1576
Age 65	-0.0172	-0.0825	-0.0306	-0.1403

**Table C.5: QALY loss per patient, by age (benefits of intervention last 10 years)**

Age	10 year time horizon	
	Scenario 1	Scenario 2
Age 5	-0.0359	-0.1783
Age 10	-0.0398	-0.1831
Age 25	-0.0391	-0.1802
Age 50	-0.0343	-0.1576
Age 65	-0.0306	-0.1403

There are limited data exploring how oral health in general impacts on quality of life, but there is even less evidence which looks at more specific scenarios. The Adult Dental Health Survey measured the OHIP score for patients with more than one tooth with decay, and with less than 21 teeth. It seems plausible that quality of life will be lower when more teeth are missing and more teeth are decayed, but unfortunately there exists no data to be able to quantify this. It is also very plausible that the location of the affected tooth in the mouth is a big factor when determining the impact on quality of life when it is affected, and for several different reasons – a missing front tooth is likely to cause embarrassment and emotional distress, and a decayed molar tooth may impact on the ability to eat and speak. People

have a tendency to adapt to their current (health) state, and it is likely that any disutility associated with decay will apply only in the short-term. For example, it may be that applying a disutility to the health state of having a filled tooth will over-estimate the benefits of treatment, given that the discomfort associated with a restoration will not apply indefinitely.

The number of teeth that become decayed and eventually extracted has been modelled over the course of a lifetime, using outcomes reported in the Children’s Dental Health report and the Adult Dental Health Survey, and described in Appendix A. One option for modelling the total QALYs that are lost from experiencing decay and missing teeth is to assume that the QALY loss estimated in Table C.4 and Table C.5 is applied to each tooth that is affected. However this approach will over-estimate the QALY loss given that it is unlikely that going from one tooth being affected to two teeth being affected will double the number of lost QALYs; that is, the utility of one decayed tooth and the utility of two decayed teeth is unlikely to differ by much. But data to suggest how the utility will vary does not exist, and in order to be fully able to model the quality of life, this is the kind of data that would be required.

Table C.6 reports the potential **actual** QALY loss that are incurred by a patient over a five-year or ten-year time horizon (as opposed to the potential QALY loss of one case of caries that are described in Table C.4), and is based on the predicted level of tooth decay as modelled in Appendix A using the mean number of missing and unsound teeth over a lifetime. The range of QALY losses are displayed for each intervention type (stratified by age group), for the same utility scenarios as described for Table C.4 and Table C.5. A range of relative risks are explored. As noted above, this analysis is likely over-estimating the potential QALY loss for each intervention, given that the additive approach for modelling multiple decayed teeth is unrealistic.

**Table C.6: Per-patient actual QALY loss associated with caries, by intervention type (benefits of intervention last 5 years)**

Intervention type	5 year time horizon		10 year time horizon	
	Scenario 1	Scenario 2	Scenario 1	Scenario 2
Relative risk of intervention: 1.0 (0% risk reduction)				
Infants	-0.0259	-0.1264	-0.0860	-0.4102
School-children	-0.0318	-0.1514	-0.1119	-0.5153
Adults of working	-0.0269	-0.1278	-0.0905	-0.4164
Adults over 65	-0.0123	-0.0588	-0.0349	-0.1613
Relative risk of intervention: 0.9 (10% risk reduction)				
Infants	-0.0234	-0.1137	-0.0747	-0.3879
School-children	-0.0286	-0.1363	-0.0973	-0.4882
Adults of working	-0.0242	-0.1151	-0.0785	-0.3942
Adults over 65	-0.0111	-0.0529	-0.0300	-0.1524
Relative risk of intervention: 0.75 (25% risk reduction)				
Infants	-0.0195	-0.0948	-0.0815	-0.3545
School-children	-0.0239	-0.1136	-0.1061	-0.4477
Adults of working	-0.0201	-0.0959	-0.0857	-0.3610
Adults over 65	-0.0092	-0.0441	-0.0329	-0.1390

**Table C.7: Per-patient actual QALY loss associated with caries, by intervention type (benefits of intervention last 10 years)**

Intervention type	10 year time horizon	
	Scenario 1	Scenario 2
Relative risk of intervention: 1.0 (0% risk reduction)		
Infants	-0.0859	-0.4096
School-children	-0.1118	-0.5148
Adults of working	-0.0883	-0.4063
Adults over 65	-0.0289	-0.1334
Relative risk of intervention: 0.9 (10% risk reduction)		
Infants	-0.0773	-0.3687
School-children	-0.1006	-0.4633
Adults of working	-0.0795	-0.3657
Adults over 65	-0.0260	-0.1200
Relative risk of intervention: 0.75 (25% risk reduction)		
Infants	-0.0644	-0.3072
School-children	-0.0839	-0.3861
Adults of working	-0.0663	-0.3047
Adults over 65	-0.0217	-0.1000

### Quality-adjusted tooth years

The OHIP-14 scores used within the model and their mapping to estimate generic utility scores made use of the best available data relating to non-disease specific health related quality of life. However, given the limitations of this data, a disease specific measure of utility was also considered within the model. Quality-adjusted tooth years (QATYs) measure tooth related quality of life on a scale of 0 to 1 whereby “0” corresponds to the worst tooth state imaginable and “1” corresponds to the best tooth state imaginable (Fyffe and Kay 1992).

The QATY scores used in the model for tooth decay and pain were taken from a study by Fyffe and Kay (1992) and those for tooth loss from Nassani and Kay (2011). These scores are shown in Table C.8.

**Table C.8: QATY score inputs for model**

Tooth state	QATY score
<i>QATY scores for tooth decay/pain*</i>	
Decayed and painful	0.57
Filled, further work required	0.87
Filled	0.90
<i>QATY scores for tooth loss (UK data service, 1998)</i>	
Anterior teeth	0.26
Premolar teeth	0.39
Molar teeth	0.44
Mean utility weighted by caries location	0.43

\*only values for molar teeth were reported, so these values were applied to all teeth

A range of potential per-patient QATY losses for different age groups, for two different time horizons are presented in Table C.9. This table refers to the QATY loss when one tooth is affected by decay. These values have been estimated using the input calculator model, and assumes that a decayed tooth follows the pathway as described in Appendix A.

**Table C.9: QATY loss per patient, by age**

Age	5 year time horizon	10 year time horizon
Age 5	-1.722	-1.722
Age 10	-1.093	-1.642
Age 25	-1.093	-1.640
Age 50	-1.092	-1.634
Age 65	-1.078	-1.582

Table C.10 reports the potential **actual** QATY loss that are incurred by a patient over a five-year or ten-year time horizon, and is based on the predicted level of tooth decay as modelled in Appendix A using the mean number of missing and unsound teeth over a lifetime. The range of QATY losses are displayed for each intervention type (stratified by age group). A range of relative risks are explored. Similarly to the QALY analysis, these values for the potential QATY loss for each intervention are likely over-estimates, given that the additive approach for modelling multiple decayed teeth is unrealistic.

**Table C.10: Per-patient actual QATY loss associated with caries, by intervention type**

<b>Intervention type</b>	<b>5 year time horizon</b>	<b>10 year time horizon</b>
Relative risk of intervention: 1.0 (0% risk reduction)		
Infants	-0.18	-0.50
School-children	-0.25	-0.86
Adults of working	-0.21	-0.68
Adults over 65	-0.09	-0.22
Relative risk of intervention: 0.9 (10% risk reduction)		
Infants	-0.16	-0.48
School-children	-0.23	-0.82
Adults of working	-0.19	-0.65
Adults over 65	-0.08	-0.21
Relative risk of intervention: 0.75 (25% risk reduction)		
Infants	-0.13	-0.45
School-children	-0.19	-0.75
Adults of working	-0.16	-0.59
Adults over 65	-0.07	-0.19

The issues with modelling QATYs are similar to the reasons listed in the section above describing general health state utilities, whereby it is expected that quality of life will be lower when more teeth are missing and more teeth are decayed, and that the location of the affected tooth in the mouth is a big factor when determining the impact on quality of life when it is affected. While there is some limited evidence for the tooth utility of different teeth being affected and with multiple teeth being affected, it is difficult to include this within the economic analysis - the total number of affected teeth over the patient's lifetime can be estimated, but not where these affected teeth are located in the mouth. In addition, the fact that the mouth contains up to 32 teeth means that any analysis attempting to capture the large number of different combinations of affected teeth would result in a highly complex model.

There is insufficient evidence to be able to generate robust estimates of the likely QATY gains for each intervention. As such, specific cost-per-QATY ICERS are not presented. However, the potential QATY gains presented in Table C.10 and the range of costs in Appendix B can be used by the PHAC to draw inferences around the likely cost per QATY for each intervention.

## **APPENDIX D**

### **Other oral health outcomes**

The original aim of the model was to capture the impact of each intervention on dental and periodontal disease, and on oral cancer. However it was decided by the EAC that the economic analysis would exclude oral cancer and periodontal disease given that no useable evidence could be identified on either outcome. Further issues around this aspect of the analysis are discussed below.

### Oral cancer

The annual risk of oral cancer by age band was obtained from Cancer Research UK incidence statistics. The risk for the younger population is very small, with no cases of oral cancer recorded for the under 10s.

**Table D.1: Risk of oral cancer by age**

Age band	Annual risk of oral cancer
0 to 4	0.0000%
5 to 9	0.0000%
10 to 14	0.0001%
15 to 19	0.0002%
20 to 24	0.0002%
25 to 29	0.0007%
30 to 34	0.0010%
35 to 39	0.0023%
40 to 44	0.0051%
45 to 49	0.0100%
50 to 54	0.0183%
55 to 59	0.0250%
60 to 64	0.0279%
65 to 69	0.0294%
70 to 74	0.0285%
75 to 79	0.0275%
80 to 84	0.0279%
85+	0.0270%

Utility weight was reported by cancer stage (Downer *et al.* 1997). The mean utility weight was then calculated, weighted by the proportion of patients diagnosed with that stage of cancer.

**Table D.2: Oral cancer quality of life**

Stage	Proportion of patients	Utility weight
Precancer	15.1%	0.92
Stage I/II cancer	46.9%	0.88
Stage III/IV cancer	38.0%	0.68
<b>Mean</b>	-	<b>0.81</b>

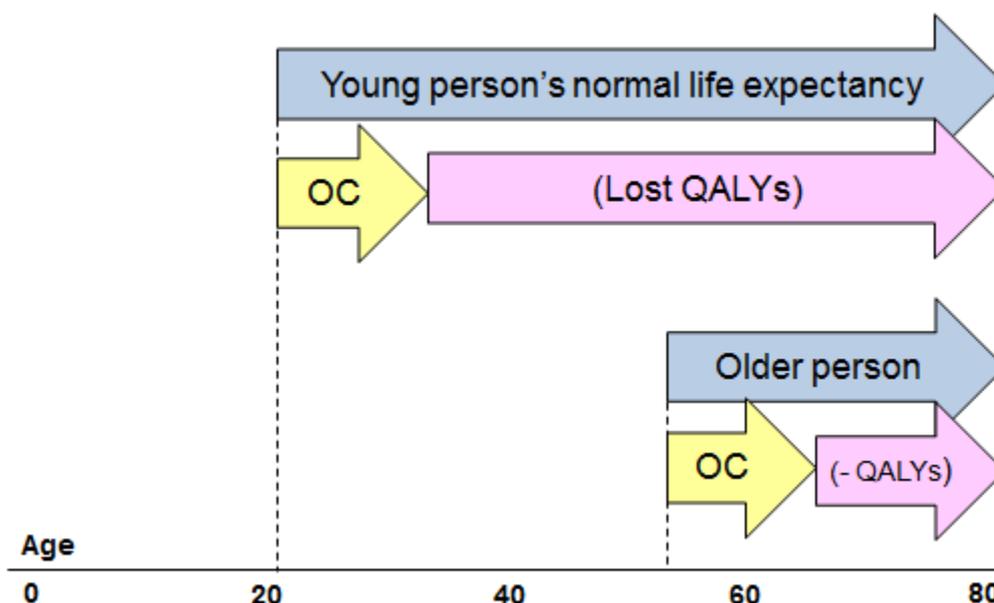
The median oral cancer survival is 5 years (Warnakulasuriya 2009). This was converted to an annual risk of death (by assuming that an exponential rate at which patients died), which was estimated to be 20%.

Management costs were obtained from the HTA for the cost-effectiveness of screening for oral cancer (Speight *et al.*, 2006):

- High first year costs (£6,444);
- Lower second and third year costs (£946, £881);
- Patients are discharged after the third year.

The modelling approach is presented in Figure D.1 below.

**Figure D.1: Oral cancer modelling approach**



The QALY loss and costs associated with a case of oral cancer have been generated based on the modelling approach described in Figure D.1.

**Table D.3: Expected cost of oral cancer**

Year	Probability alive at year end	Resource costs	Expected cost
Year 1	0.8	£6,444	£5,155.19
Year 2	0.64	£946	£596.42
Year 3	0.51	£881	£437.81

The lifetime QALY loss associated with oral cancer will inevitably vary with age. An 18 year old with oral cancer will lose approximately 30 QALYs, with their life expectancy based on UK life tables. A 40 year old with oral cancer will lose approximately 20 QALYs, and a 65 year old with oral cancer will lose approximately 10 QALYs.

Given that the rate of oral cancer in children under 10 is very low, the impact of including oral cancer in the economic analysis for the programmes in infants and pre-school children is negligible. In this age group, oral cancer is likely to be far in the future, and the costs and QALYs will be heavily discounted at this point. A similar argument can be made for children of school-age. Even for older age groups, the risk of oral cancer is still very low, and the potential QALY gains from reducing the risk of oral cancer will be smaller than that of the child population given the shorter natural life expectancy. If an intervention does have a very large effect on oral cancer (i.e. a small relative risk), it is highly unlikely to impact on the costs and QALYs.

### **Periodontal disease**

This element of oral health was excluded from the economic analysis due to a lack of understanding around how periodontal disease and the outcomes reported in the studies (e.g. Plaque and Gingival Index) are linked to quality of life and treatment costs.

Periodontal disease is generally managed at home with good brushing and flossing practices, with a scale and polish by a dental practitioner encouraged to be part of routine dental care. Generally the treatment for a tooth affected with a more advanced form of periodontal disease is extraction. There exists some data on the rates of tooth extraction in the population, but the cause is rarely reported, or is generally due to a combination of factors (some tooth decay and periodontal disease). The input calculator model aims to capture the total number of teeth missing over the course of a patient lifetime (and the associated impact on quality of life and costs), so any additional rate of tooth loss according to periodontal disease would be double-counting.

Regarding quality of life, it is understood that this is largely only affected as the disease becomes more severe and causes pain, and when this leads to a tooth being lost. A large proportion of the general population report some level of bleeding and pocketing (NHS: The Information Centre, 2011) so it is expected that the general population utility estimates should capture this. One study reports that a large proportion of patients perceive that oral health does not affect their quality of life; however there was some correlation between different symptoms associated with periodontal disease and quality of life as measured by an oral health-specific tool (Needleman, 2004).