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Impact of downward adjustment of water fluoride concentration on dental caries and fluorosis

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List of abbreviations

Abbreviation	Term
ADA	American Dental Association
AI	Adequate Intake
CCA	Community Care Area
CDC	Centers for Disease Control and Prevention
CFI	Community Fluorosis Index
CI	Confidence Interval
CPI	Community Periodontal Index
CREC	Clinical Research Ethics Committee
CWF	Community Water Fluoridation
DDE index	Developmental Defects of Enamel Index
DMFT/S	Number of decayed, missing or filled permanent teeth/surfaces
dmft/s	Number of decayed, missing or filled primary teeth/surfaces
EFSA	European Food Safety Authority
F	Fluoride
FACCT	Fluoride and Caring for Children's Teeth
F Status	Fluoridation status
Full-CWF	Lifetime exposure to domestic CWF
Full-F	Lifetime exposure to domestic CWF
GDPR	General Data Protection Regulation
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HNB	Hurdle negative binomial
IOTN	Index of Orthodontic Treatment Need
IQR	Inter-quartile range
k	Kappa Statistic

LC	Leaving Certificate
MC	Medical card
MD	Mean Difference
MIH	Molar Incisor Hypomineralisation
NC	Not calculable
NHANES	National Health And Nutrition Examination Survey
NHMRC	National Health and Medical Research Council
No-CWF	No exposure to domestic CWF
Non-F	No exposure to domestic CWF
NR	Not Reported
NSSCOH	North South Survey of Children's Oral Health
OHRQoL	Oral health-related quality of life
OHSRC	Oral Health Services Research Centre
OR	Odds Ratio
Part-CWF	Sporadic exposure to domestic CWF
PF	Prevented Fraction
PICO	Population, Intervention, Comparator, Outcome
ppm	Parts per million
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised Controlled Trial
ROBINS-I	Risk Of Bias In Non-randomised Studies – of Interventions
RoI	Republic of Ireland
RTF	Ready To Feed (infant formula)
SD	Standard Deviation
SES	Socio-Economic Status
SI	Statutory Instrument
SMD	Standardised Mean Difference

STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
TF Index	Thylstrup and Fejerskov Index
TSIF	Tooth Surface Index of Fluorosis
UK	United Kingdom
UL	Upper limit of Intake
Unknown-CWF	Exposure to domestic CWF could not be determined
U.S.	United States
WHO	World Health Organisation
95% CI	95% Confidence interval
% Agree.	Percentage agreement

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To my parents, Pat and Breda, thank you for your love and support; for ensuring that I had every opportunity and for your encouragement through each stage of my education. To my husband Mark, and my children Oisín, Aoife and Rian, thank you so much for granting me the time, space, motivation, and encouragement I needed to complete this PhD.

Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism.

Digital signature of the candidate: Patrice James

Declaration of authorship

The candidate made a major contribution to the FACCT study from its inception. She contributed to writing the grant application for the programme funding, and to the study design. The candidate was the lead researcher on workstream 1 of the FACCT study which encompassed two phases of clinical oral epidemiological fieldwork (2013-14 and 2016-17).

Phase 2 of the FACCT study in 2016-17 formed the basis for the work presented in this thesis. The candidate was responsible for preparing the study documentation and ethics submissions for phase 2 of the study, for assisting with the training and calibration and for providing supervision, direction, and support to the clinical fieldworkers during the 2016-17 fieldwork. The candidate developed the study design for the analysis of oral photographs with guidance from Professor Roger Ellwood. The candidate coordinated the process of photographic scoring and scored all the oral photographs (with duplicate scoring completed by Dr Deirdre Browne).

Multivariable regression analyses for objectives 1 and 3a were conducted early in the candidate's course of study. Dr Michael Cronin conducted the statistical analysis for objective 1 and Dr Helena Guiney conducted the preliminary statistical analysis for objective 3a with substantial input from the candidate throughout the analysis process for both objectives. The candidate completed the analysis for objective 3a and was lead author for the JDR publication "Impact of Reducing Water Fluoride on Dental Caries and Fluorosis" reporting the results of objectives 1 and 3a. The candidate conducted the regression analyses to meet objectives 2, 3b, 4a and 4b with guidance from Dr Michael Cronin. The candidate was responsible for presenting and interpreting the results of all analyses. The candidate wrote this thesis under the supervision of Professor Helen

Whelton, Professor Ivan Perry, Professor Mairead Harding, Professor Emeritus Denis O'Mullane, and Dr Michael Cronin.

Abstract

Introduction:

Community water fluoridation (CWF) was initiated in Ireland in 1964 at a concentration of 0.8 to 1 ppm fluoride. In 2007, in the context of ongoing reductions in dental caries with increasing prevalence and severity of dental fluorosis, water fluoride concentration in Ireland was adjusted to 0.6 to 0.8 ppm with the aim of reducing the prevalence and severity of dental fluorosis while maintaining reductions in dental caries.

Aim:

To determine the difference in dental caries and fluorosis levels following downward adjustment of CWF concentration.

Methods:

Ethical approval was obtained from the Clinical Research Ethics Committee (CREC) of the Cork Teaching Hospitals. A before and after study compared dental caries and fluorosis in random samples of 8-year-olds in Dublin (n=707) and Cork-Kerry (n=1,148) in 2016-17 with 8-year-olds in Dublin (n=679) and Cork-Kerry (n=565) in 2002. Dentinal caries experience in primary teeth (d_{3vc}mft(cde)) and fluorosis in permanent teeth (Dean's Index, whole mouth score) were clinically measured by trained and calibrated dentists. Standardised oral photographs were taken (8 seconds drying) for children in Cork-Kerry in 2016-17 and 2002. Fluorosis (Thylstrup-Fejerskov (TF) Index) in permanent maxillary central incisors was scored from the photographs in duplicate by two trained and calibrated dentists, blind to fluoridation status and year, with disagreements resolved by consensus. Person-level TF score was the highest score in the central incisors.

Children were categorised as having lifetime or no exposure to CWF (Full-CWF/No-CWF). Effect of examination year on dental caries prevalence (d_{3vc}mft(cde) > 0) and severity (mean d_{3vc}mft(cde) among children with caries experience) and fluorosis prevalence (Dean's 'very mild' or greater, TF 1 or greater and TF 2 or greater) were evaluated using multivariable regression controlling for the effects of other explanatory variables. Additional multivariable regression analyses evaluated the effect of CWF on dental caries prevalence and severity and fluorosis prevalence in 2002 and 2016-17, before and after the downward adjustment, respectively.

Results:

After controlling for the effects of other explanatory variables, children in Cork-Kerry in 2016-17, with lifetime exposure to CWF at 0.6 to 0.8 ppm fluoride, had lower caries prevalence (56% vs. 65%) and severity (mean d_{3vc}mft(cde) 3.7 vs. 4.2) in primary teeth than their counterparts with No-CWF. Among children with Full-CWF, there was no statistically significant difference in caries prevalence or severity between 2002 and 2016-17. In 2016-17, caries prevalence was 55% in Dublin (Full-CWF) and 56% in Cork-Kerry (Full-CWF) and mean d_{3vc}mft(cde) among children with caries was 3.4 and 3.7, respectively. Among children with No-CWF, caries severity was less in 2016-17 (mean 4.2) than 2002 (mean 4.9) ($P = 0.039$). The difference in caries severity between children with Full-CWF and No-CWF was less in 2016-17 than 2002 (Interaction $P = 0.013$), suggesting a reduced benefit for CWF in 2016-17.

In 2016-17, fluorosis prevalence (Dean's Index) was 18% in Dublin (Full-CWF) and 12% in Cork-Kerry (Full-CWF). Fluorosis was predominantly 'very mild' with no statistically significant difference between 2002 and 2016-17. Fluorosis prevalence in permanent maxillary central incisors was predominantly TF 1 and TF 2 and was lower in Cork-Kerry in 2016-17 than in 2002 at both case definitions. Among children with Full-CWF,

prevalence of TF 1 or greater was 40% in 2016-17 and 75% in 2002 (OR 0.24, 95% CI [0.17, 0.34], $P < 0.001$) and prevalence of TF 2 or greater was 15% in 2016-17 and 27% in 2002 (OR 0.50, 95% CI [0.33, 0.75], $P = 0.001$). At both time points, fluorosis prevalence measured using Dean's Index and the TF Index was higher among children with Full-CWF than their counterparts with No-CWF (2002 and 2016-17, $P < 0.001$).

Conclusion:

There was no reduction in fluorosis prevalence measured clinically using Dean's Index in 2016-17 compared with 2002. However, fluorosis prevalence in the aesthetically important maxillary central incisors measured blind to year and fluoridation status from oral photographs was reduced following downward adjustment of water fluoride concentration. Based on the cross-sectional comparison of children with Full-CWF and No-CWF in 2016-17, the lower concentration of 0.6 to 0.8 ppm fluoride is an effective caries-preventive measure. However, the before and after study indicated that downward adjustment of water fluoride concentration may have reduced the caries-preventive effect of CWF in primary teeth. Further research is needed to evaluate the impact of the downward adjustment on dental caries in permanent teeth of children and adults with CWF.

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1 Introduction

1.1 Background and rationale for the study

Dental caries represents a major global population health challenge. An estimated 2.3 billion people worldwide have untreated dental caries in permanent teeth and an estimated 532 million children worldwide have untreated dental caries in deciduous teeth (Bernabe et al. 2020). The burden of the disease falls disproportionately upon lower socioeconomic groups (Schwendicke et al. 2015; Peres et al. 2019). Untreated dental caries has a negative impact on the health-related quality of life of affected children (Sheiham 2006; Barbosa and Gavião 2008) and adults (Haag et al. 2017). Previous dental caries experience is an important predictor of dental caries in primary and permanent teeth (Zero et al. 2001). Dental caries is a chronic, progressive disease (Peres et al. 2019). Once filled, a tooth requires ongoing maintenance, repair and replacement restorations with progressive destruction of tooth tissue over time - a phenomenon known as the "tooth death spiral" (Sheiham 2002).

Community water fluoridation (CWF) is a safe and effective method of preventing and controlling dental caries (McDonagh et al. 2000; Jack et al. 2016) and has the advantage of reaching all socio-economic groups, without requiring the active participation of the individuals (O'Mullane et al. 2016). Furthermore, CWF provides an additional benefit in communities with widespread use of fluoride toothpaste (Marinho et al. 2003b). Both the prevalence and severity of dental caries has reduced in developed countries in recent decades (Glass 1982; Brunelle and Carlos 1990; Marthaler 2004; Beltrán-Aguilar et al. 2005) with exposure to fluoride in its various forms credited for making a significant contribution to these reductions (Bratthall et al. 1996; Petersson and Bratthall 1996).

However, with reductions in dental caries levels, there was a corresponding increase in the prevalence of dental fluorosis in both fluoridated and non-fluoridated communities (Pendrys and Stamm 1990; Whelton et al. 2004b; Khan et al. 2005; Beltran-Aguilar et al. 2010). Thus, the benefits of fluoride for preventing and controlling dental caries must be balanced against the risk of developing dental fluorosis from excessive ingestion and absorption of fluoride during critical periods of tooth formation. This critical period is thought to be the first 3 years of life for the aesthetically important maxillary incisors (Buzalaf and Levy 2011). The development of dental fluorosis is the only proven risk associated with CWF (McDonagh et al. 2000; Jack et al. 2016). While in many people dental fluorosis is not noticeable, at the highest levels of severity, dental fluorosis may adversely affect aesthetics and oral health related quality of life (Chankanka et al. 2010).

Ireland has a long history of CWF. CWF at a concentration of 0.8 to 1.0 parts per million (ppm) fluoride was introduced in Dublin and surrounding areas on the east coast in 1964. In subsequent years, CWF was extended to all major urban communities in Ireland. By 1976, 57% of the Irish population had a fluoridated home water supply and by 2002, 71% of the Irish population resided in areas with fluoridated water supplies (Department of Health and Children 2002). The proportion of the population with access to fluoridated water remains the same to date (Cronin et al. 2021).

Irish national surveys of children's oral health conducted in 1984 and 2002 showed an on-going reduction in the mean number of decayed, missing and filled primary and permanent teeth among 5-, 8-, 12- and 15-year-old lifetime residents of communities with and without CWF (O'Mullane et al. 1986; Whelton et al. 2006). This reduction in dental caries was accompanied by an increase in the prevalence and severity of dental fluorosis which was attributed to the availability of fluoride from toothpaste and other fluoride vehicles in addition to CWF from the mid-1970s onwards.

In response to the increased prevalence of dental fluorosis in Ireland, the Forum on Fluoridation (Department of Health and Children 2002), was established by the Minister for Health to review CWF in Ireland. In 2002, the Forum issued recommendations aimed at reducing the risk of dental fluorosis while maintaining reductions in dental caries. These recommendations included redefining the optimal level of fluoride in drinking water from 0.8 - 1.0 ppm with a target of 0.9 to 0.6 - 0.8 ppm, with a target of 0.7 ppm. Following a change to the legislation (Government of Ireland 2007), this recommendation was implemented in July 2007.

In addition, the Forum on Fluoridation issued guidance intended to reduce fluoride toothpaste ingestion in early childhood. Parents were advised:

- To brush their children's teeth with a toothbrush and tap water before age 2,
- To start using toothpaste when brushing their children's teeth from age 2 and to seek professional advice on the use of fluoride toothpaste where a child below 2 years of age is considered to be at high risk of developing dental decay,
- To supervise children aged 2 to 7 years when brushing their teeth,
- To use only a small pea sized amount of fluoride toothpaste and to make sure that children avoid swallowing the toothpaste.

Most children's toothpastes used in Ireland contained at least 1000 ppm fluoride. Although low fluoride toothpastes (500 ppm or less) were available, the guidance did not recommend their use as their effectiveness was deemed uncertain. This toothbrushing guidance remains in place following recent review of the evidence underpinning it (O'Mullane et al. 2018).

Several other countries with established CWF programmes such as Hong Kong, Singapore, Malaysia, Canada and the United States (U.S.) have also lowered the fluoride concentration of their water supplies. The adjustment in the U.S. from a range of 0.7 to

1.2 ppm fluoride varying according to the average outside ambient air temperature to 0.7 ppm fluoride for all geographic areas (U. S. Department of Health Human Services Federal Panel on Community Water Fluoridation 2015) is similar to the adjustment in Ireland. Reports from Hong Kong and Malaysia indicate a downward trend in dental fluorosis without a corresponding increase in dental caries (Lo et al. 1990; Evans and Stamm 1991; Wong et al. 2014; Lee et al. 2016; Mohd Nor et al. 2018). However, it is difficult to generalise the results of these studies to Ireland due to cultural and contextual differences.

The Fluoride and Caring for Children's Teeth (FACCT) study commenced in late 2012 with the aim of evaluating the outcome of downward adjustment of water fluoride concentration on dental caries and dental fluorosis in Irish children.

1.2 Aim

The aim of this thesis is to evaluate the outcome of downward adjustment of water fluoride concentration on dental caries in primary teeth and dental fluorosis in permanent teeth.

1.3 Objectives

1.3.1 Impact of downward adjustment of CWF concentration on dental caries

1. **Dental caries 2016-17 vs. 2002**: To compare the prevalence and severity of dental caries in primary teeth of 8-year-olds in Dublin and Cork-Kerry, born after downward adjustment of water fluoride concentration (examined in 2016-17) with children examined in the same regions in 2002 prior to the adjustment, while controlling for the effects of relevant socio-demographic and behavioural factors.

2. **Dental caries Full-CWF vs. No-CWF 2002 and 2016-17**: To compare the prevalence and severity of dental caries in primary teeth of 8-year-olds in Cork-Kerry with lifetime exposure to CWF to children with no exposure to CWF separately for 2002 (examined prior to the downward adjustment) and 2016-17 (born after the adjustment), while controlling for the effects of relevant socio-demographic and behavioural factors.

1.3.2 Impact of downward adjustment of CWF concentration on dental fluorosis

3. **Dental fluorosis 2016-17 vs. 2002:** To compare the prevalence and severity of dental fluorosis measured **a)** clinically using Dean's Index and **b)** from oral photographs using the TF Index in permanent teeth of 8-year-olds in Dublin and Cork-Kerry, born after downward adjustment of water fluoride concentration (examined in 2016-17) with 8-year-olds examined in the same regions in 2002 prior to the adjustment, while controlling for the effects of relevant socio-demographic and behavioural factors.

4. **Dental fluorosis Full-CWF vs. No-CWF 2002 and 2016-17:** To compare the prevalence and severity of dental fluorosis measured **a)** clinically using Dean's Index and **b)** from oral photographs using the TF Index in permanent teeth of 8-year-olds in Cork-Kerry with lifetime exposure to CWF to children with no exposure to CWF separately for 2002 (examined prior to the downward adjustment) and 2016-17 (born after the adjustment), while controlling for the effects of relevant socio-demographic and behavioural factors.

1.4 Thesis outline

This thesis forms part of the Fluoride and Caring for Children's Teeth (FACCT) study. The overarching aim of the FACCT study was to evaluate the outcome of the downward adjustment of water fluoride concentration in Ireland on dental caries and dental fluorosis. However, the FACCT study encompassed a variety of different components including quantitative and qualitative studies and a separate work stream (work stream 2) assessing the viability of using routinely collected data from dental electronic health records for oral health surveillance (Figure 1.1).

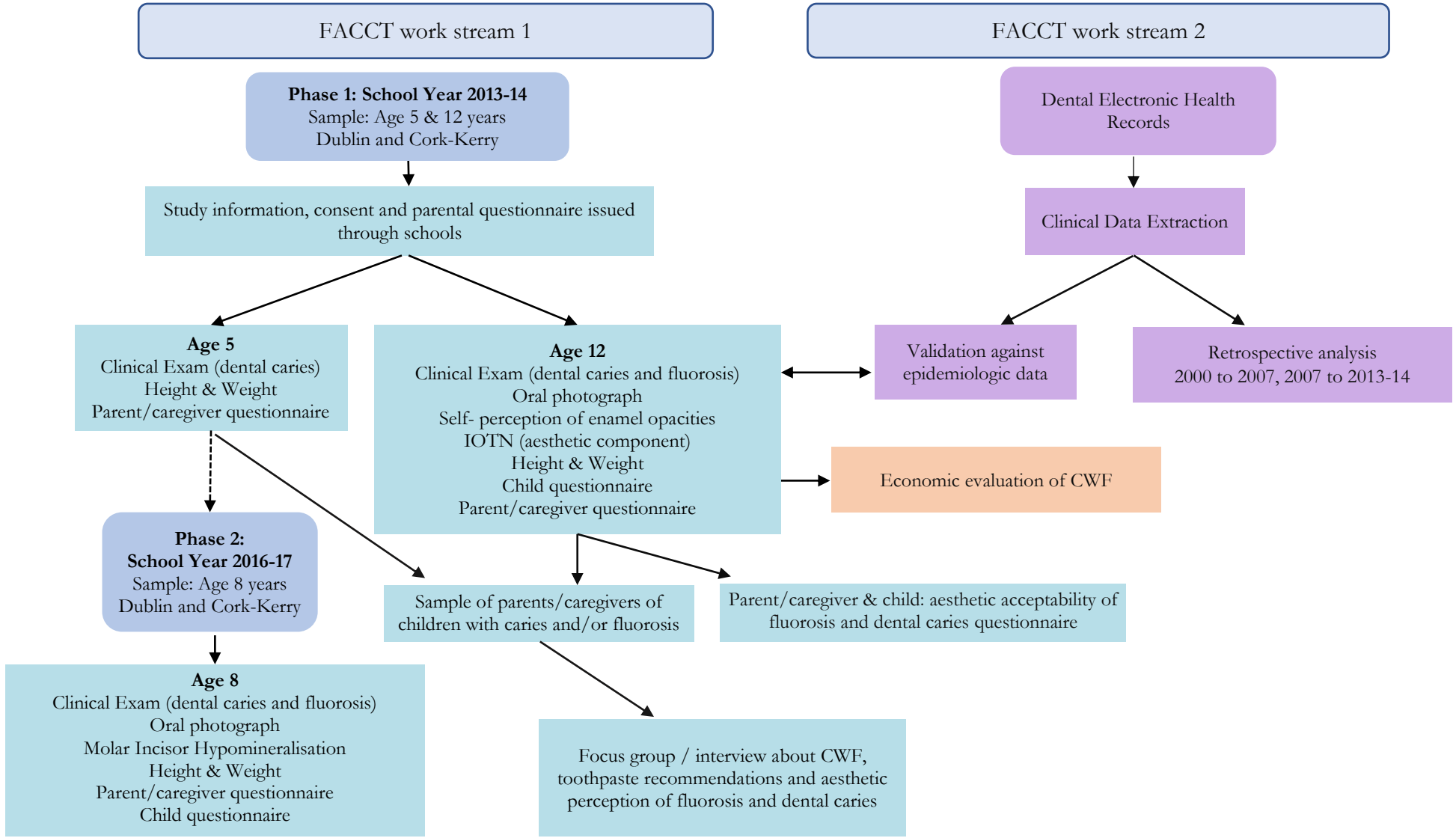
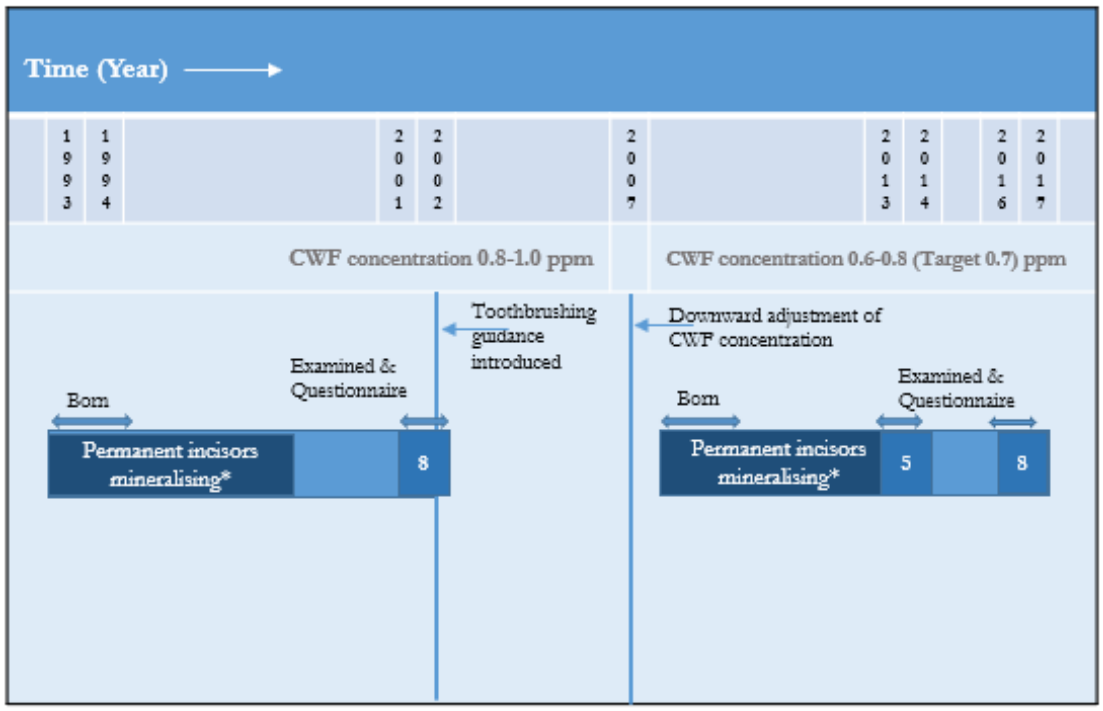


Figure 1.1: Overview of the FACCT study

The clinical oral epidemiological component of the FACCT study (work stream 1) was a cross-sectional oral health survey of a representative sample of 5- and 12-year-old children living in counties Dublin, Cork and Kerry in the school year 2013-14 (phase 1). There was a nested longitudinal study, whereby children born after downward adjustment of water fluoride concentration who participated in the study at age 5, were re-examined when they were aged 8 in 2016-17 (phase 2). These specific age groups were chosen to facilitate comparisons with data from the North South Survey of Children's Oral Health (NSSCOH) 2002. Furthermore, the initial age groups included in phase 1 of the study corresponded with the WHO index ages for population surveys (World Health Organisation 2013). In addition to the clinical examinations, oral photographs of maxillary incisors were taken according to a standardised method (Cochran et al. 2004c) for 12-year-olds examined in 2013-14 and for 8-year-olds examined in 2016-17. The clinical fieldwork protocol for the FACCT study was published in HRB Open Research (James et al. 2018) and is available in Appendix A.

This thesis relates primarily to 8-year-olds examined in 2016-17 who were participants in the longitudinal study that commenced in 2013 (FACCT phase 1) when they were 5-year-olds in their first year of primary school. These children were born after downward adjustment of water fluoride concentration (2007) and thus had lifelong exposure to the reduced water fluoride concentration. Furthermore, these children were born after introduction of toothbrushing guidance. Dental caries and dental fluorosis data for these children were compared with 8-year-olds examined in the same regions during the North South Survey of Children's Oral Health (NSSCOH) 2002 who were exposed to neither policy measure. An overview of the age groups of children included in this study and their exposure to the policy measures are shown in Figure 1.2. The study methods are explained in detail in Chapter 4.



*Mineralisation of permanent maxillary incisors complete at age 4-5 years

Figure 1.2: Overview of study groups and their exposure to the policy measures

A summary of the content of the chapters in the thesis is provided below:

- Chapter 2 is a traditional narrative review to provide the background to the topics explored in the thesis and the context in which the research questions are being answered. Because many of the topics described in chapter 2 have been comprehensively systematically reviewed, the literature review focussed on evidence from systematic reviews where they were available and on relevant primary research where there were no relevant systematic reviews.
- Chapter 3 is a systematic review of the impact of downward adjustment of water fluoride concentration on dental caries and dental fluorosis.
- Chapter 4 describes the study methods including the study setting and design, measurement of explanatory and outcome variables, examiner agreement and methods of statistical analysis.

- The study results are presented in Chapters 5, 6 and 7:
    - Chapter 5 describes the numbers and characteristics of 8-year-olds examined in the FACCT study 2016-17 and the NSSCOH 2002.
    - Chapter 6 describes the impact of downward adjustment of water fluoride concentration on dental caries prevalence and severity in primary teeth of 8-year-olds in Dublin and Cork-Kerry.
    - Chapter 7 describes the impact of downward adjustment of water fluoride concentration on dental fluorosis prevalence and severity measured clinically using Dean's Index and from oral photographs using the TF Index in 8-year-olds in Dublin and Cork-Kerry.
- Chapter 8 includes a discussion of the main findings of the study, its strengths and limitations, conclusions from the study, the implications of the results for public health and policy and recommendations for further research.

2 Background and context

2.1 Dental caries: a major public health challenge

Oral disorders including dental caries, periodontal disease, edentulousness and tooth loss are highly prevalent, affecting almost 3.5 billion people worldwide (GBD 2017 Disease and Injury Incidence and Prevalence Collaborators 2018; Bernabe et al. 2020). In the Global Burden of Disease study 2017, untreated dental caries in permanent teeth affected 2.3 billion people, while untreated dental caries in deciduous teeth affected 532 million children worldwide (Bernabe et al. 2020). The economic impact of oral diseases is staggering with direct and indirect costs due to oral diseases worldwide totalling $544 billion in 2015 (Righolt et al. 2018). Despite the substantial reduction in dental caries over the past 70 years (Marthaler 2004), dental caries continues to pose a significant challenge, particularly for lower socioeconomic groups (Schwendicke et al. 2015; Peres et al. 2019; Bernabe et al. 2020). Inequalities in oral health persist between developing and developed countries as well as within those countries (Pitts et al. 2011; Do 2012).

Dental caries is a chronic, progressive disease (Peres et al. 2019), impacting negatively on the health-related quality of life of children and adults (Sheiham 2006; Barbosa and Gavião 2008; Haag et al. 2017; Masood et al. 2017; Nora Â et al. 2018). Previous dental caries experience is the most important predictor of future disease in both the primary and permanent dentition (Zero et al. 2001). Moreover, dental caries experience in the primary dentition sets children on a steep trajectory towards further caries experience in the permanent dentition which is different from children with a caries-free primary dentition (Hall-Scullin et al. 2017). Once filled, a permanent tooth requires ongoing maintenance, repair and replacement restorations with progressive destruction of tooth tissue over time - a phenomenon known as the "tooth death spiral" (Sheiham 2002).

Recognising the substantial public health challenge posed by oral diseases, the World Health Assembly approved a landmark Resolution on Oral Health in May 2021 (Seventy-Fourth World Health Assembly 2021). The Resolution included a focus on integrating oral health into Member States' national policies, addressing key risk factors for poor oral health and an emphasis on a preventive rather than a curative approach. CWF was recognised as a safe and cost-effective community-based method for preventing dental caries. The role of topical fluoride application and fluoride toothpaste were also recognised as important components of evidence-based caries preventive efforts.

2.2 Early research on the relationship between fluoride and oral health

The hypothesis that fluoride improves the hardness of tooth enamel and provides protection against dental caries can be dated back to the late 19th century (Erhardt 1874; Dean 1943). In the early 20th century, Black and McKay noted that the susceptibility of 'mottled enamel' to dental caries was no greater than 'normal' enamel and that districts with high levels of 'mottled enamel' had "a curious absence of decay" (Black and McKay 1916; McKay and Black 1916; McKay 1925). However, studies conducted by Dean and others throughout the 1930s initially focussed on the relationship between fluoride and dental fluorosis. A classification system, which would later become known as Dean's Index, was developed for dental fluorosis measurement (Dean 1934). This research pointed to a dose response relationship between exposure to fluoride in drinking water and severity of dental fluorosis (Dean and Elvove 1935; 1936; Dean and McKay 1939). Furthermore, a water fluoride concentration of not more than 1 ppm was judged to be consistent with a level of dental fluorosis of no public health significance (Dean and Elvove 1937).

Between 1937 and 1939, significant advances were made in understanding the relationship between fluoride, dental caries and dental fluorosis when several epidemiological, biochemical and animal studies demonstrated a link between exposure to fluoride and reduced dental caries (Dean 1943). In the case of the epidemiological studies, an inverse relationship between 'mottled enamel' and dental caries in primary and permanent teeth was identified with the benefit of exposure to water fluoride also apparent in teeth without visible enamel mottling (Dean 1938).

These discoveries were followed by a large epidemiological study investigating the relationship between water fluoride concentration and dental caries in the permanent dentitions of 12- to 14-year-olds in 21 cities across four States in the U.S. (Dean et al. 1941; Dean et al. 1942; Dean 1943). Results for cities with a water fluoride concentration of 0.5 to 1.2 ppm and for cities with a water fluoride concentration of <0.5 ppm (17 of the 21 cities) are presented in Table 2.1.

Table 2.1: Summary of dental caries and fluorosis levels in 12- to 14-year-olds in 17 U.S. cities with 0.0 to 1.2 ppm fluoride

City[a]	Fluoride concentration of public water supply (ppm)	No dental caries experience	Fluorosis (Dean's Index 'very mild' or greater)
Aurora (Illinois)	1.2	23.5%	15.0%
East Moline (Illinois)	1.2	20.4%	31.6%
Maywood (Illinois)	1.2	29.8%	33.3%
Kewanee (Illinois)	0.9	17.9%	12.2%
Pueblo (Colorado)	0.6	10.6%	6.5%
Elgin (Illinois)	0.5	11.4%	4.2%
Marion (Ohio)	0.4	5.7%	6.1%
Lima (Ohio)	0.3	2.2%	2.2%
Middletown (Ohio)	0.2	1.9%	1.1%
Zanesville (Ohio)	0.2	2.6%	1.5%
Elkhart (Indiana)	0.1	1.4%	0.4%
Michigan City (Indiana)	0.1	0%	0%
Portsmouth (Ohio)	0.1	1.3%	1.3%
Quincy (Illinois)	0.1	2.4%	0.3%
Evanston (Illinois)	0.0	3.9%	1.6%
Oak Park (Illinois)	0.0	4.3%	0.6%
Waukegan (Illinois)	0.0	3.1%	0.2%

[a] Four cities with water fluoride concentration >1.2 ppm were excluded from this table.

There was a clear inverse relationship between water fluoride concentration and dental caries levels. It was also noted that as water fluoride concentration increased, dental fluorosis prevalence also increased. Based on the findings and excluding other explanations for variations in dental caries levels such as amount of sunshine, diet (apart from water), and water hardness, it was concluded that the agent responsible for the differences in dental caries and fluorosis levels across the 21 cities was the fluoride content of the water. Furthermore, a water fluoride concentration of 1 ppm was identified as the level consistent with maximum reductions in dental caries and occurrence of fluorosis of no aesthetic significance.

These studies paved the way for the next phase of research involving assessment of the effect of adjusting the fluoride concentration of drinking water to reduce dental caries.

Adjustment of the fluoride concentration of domestic water supplies to 1 ppm was first implemented in Grand Rapids, Michigan in January 1945. The impact of the introduction of water fluoridation on dental caries was assessed by comparing dental caries levels in Grand Rapids with dental caries levels in Muskegon, a city that did not have CWF. This study and several others that followed, demonstrated that the addition of fluoride to bring the concentration in drinking water to 1 ppm reduced the incidence of dental caries by approximately 50% (Department of Health and Children 2002).

2.3 Mechanism of action of fluoride for preventing dental caries

2.3.1 Pathophysiology of dental caries

As a result of microbial metabolism in the plaque biofilm, a dynamic repeated cycle of demineralisation and remineralisation takes place at the tooth surface (Fejerskov 1997). Biofilm bacteria metabolise fermentable carbohydrates, mainly free sugars, to produce organic acids (predominantly lactic acid) which diffuse into the crystalline mineral structure of the tooth causing demineralisation (Pitts et al. 2017). With the build-up of acid, the pH falls, minerals (calcium and phosphate) diffuse out of the tooth and the enamel or dentine becomes demineralised (Featherstone 1999).

With the clearance of dietary sugars from the mouth, the buffering capacity of saliva along with the diffusion of acids out of the biofilm lead to a rise in the biofilm pH within minutes favouring remineralisation of the tooth surface (Buzalaf et al. 2011). The process of demineralisation and remineralisation occurs several times throughout the day. If the equilibrium of the process is disturbed over a period of time, resulting in net loss of mineral content, an initial carious lesion (a 'white spot') develops in the tooth surface and may eventually progress to cavitation (Fejerskov 1997).

The balance between local protective factors and pathological factors determines whether an initial carious lesion will remain as it is, reverse or progress (Figure 2.1) (Featherstone 2004). Over time, the presence of free sugars, particularly sucrose, in the biofilm promote the growth of mutans streptococci, lactobacilli and other acidogenic and acid-tolerating species and improves the structural integrity of the biofilm facilitating enhanced bacterial adhesion to tooth surfaces (Marsh 1994; Paes Leme et al. 2006; Sheiham and James 2015). Thus, there is a shift towards a more cariogenic microbial profile in the biofilm. Once these cariogenic bacteria are established in the mouth, controlling the caries process can be very challenging (Featherstone 2004).

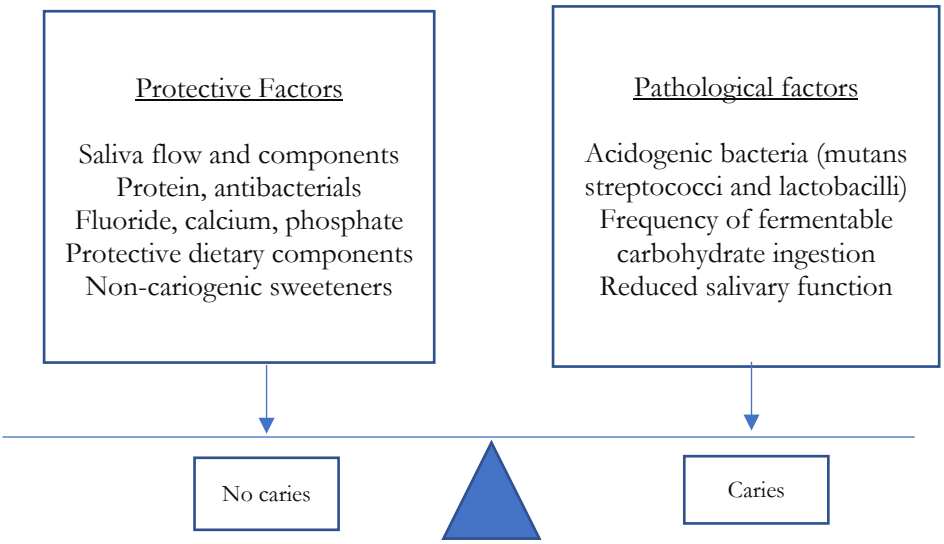


Figure 2.1: Schematic diagram of the balance between protective factors and pathological factors in the dental caries process
Reproduced from Featherstone (1999; 2004)

The predominance of local protective factors, including calcium and phosphate in saliva, fluoride and protective proteins in the pellicle and saliva promote remineralisation, halting or reversing the initial carious lesion. However, in the context of a susceptible tooth surface, if pathological factors such as cariogenic bacteria, frequent ingestion of

fermentable carbohydrates or salivary dysfunction predominate over time, the carious lesion is more likely to progress (Featherstone 2004).

Although there is clearly an interplay of several factors determining whether an initial carious lesion progresses into dentine, dietary intake of free sugars is inextricably linked with the process of dental caries development (Paes Leme et al. 2006; Moynihan and Kelly 2014; Sheiham and James 2015). Furthermore, reflecting the complex nature of the disease, the contribution of biological, genetic, social and psychological factors to the caries process must also be acknowledged (Reisine and Litt 1993; Fejerskov 1997; Selwitz et al. 2007; Vieira et al. 2014).

2.3.2 Role of fluoride in dental caries control

For many years, the cariostatic effect of fluoride was linked to a systematic effect through its ingestion via drinking water supplemented with fluoride. It was thought that fluoride exerted its effect through its incorporation into the developing enamel crystals, reducing solubility of the enamel to acid attack (McClure and Likins 1951). Subsequent research confirmed that incorporation of fluoride into the developing enamel crystals is important for dental caries prevention, particularly in pit and fissure surfaces of first permanent molars (Groeneveld et al. 1990; Singh and Spencer 2004; Singh et al. 2007). The maximum caries preventive effect is achieved with both pre- and post-eruptive exposure to fluoride but the pre-eruptive effect is less on surfaces with low susceptibility to dental caries (Groeneveld et al. 1990). With widespread reductions in dental caries levels and the introduction of effective topical caries preventive agents such as fluoride toothpaste, the topical post-eruptive effect of fluoride is now considered the most relevant (Featherstone et al. 1990; Groeneveld et al. 1990; Burt 1999; Featherstone 2000; Ten Cate and Buzalaf 2019).

The mechanism of action of fluoride for preventing dental caries can be described as follows:

Fluoride inhibits demineralisation:

During a cariogenic challenge (pH <5.5), fluoride present in the biofilm penetrates the subsurface of the tooth with the bacterial-derived acids adding to the pool of fluoride already present in the fluid surrounding the enamel crystal (Buzalaf et al. 2011). Fluoride ions in solution have a high affinity for enamel (Ogaard 1990) and adsorb strongly to the crystal surface protecting it from dissolution (Featherstone et al. 1990; Featherstone 1999). Whereas full coverage of fluoride ions will prevent dissolution, partial coverage results in partial dissolution of the enamel crystals (Buzalaf et al. 2011).

Higher concentrations of fluoride in the enamel fluid do not produce a proportionate reduction in the solubility of the crystals (Featherstone et al. 1990). Thus, to inhibit demineralisation and facilitate remineralisation, maintaining low concentrations of fluoride in saliva and the plaque biofilm over a prolonged period of time is preferable to increasing the dosage of fluoride (Featherstone et al. 1990).

Calcium fluoride (CaF_2) globules, formed following topical fluoride application, are an important source of fluoride at the enamel surface, in oral fluids and in the plaque biofilm (Rølla 1988). The formation of calcium fluoride is enhanced at low pH, as the dissolution of enamel provides the required supply of calcium ions. The calcium fluoride globules serve as a pH-controlled fluoride reservoir that is stable at neutral pH due to the adsorption of HPO_4^{2-}. With a drop in pH, the HPO_4^{2-} is lost, releasing calcium and fluoride into the oral fluids, adding to the 'pool' of available fluoride and calcium (Buzalaf et al. 2011).

Fluoride enhances remineralisation

After the cariogenic challenge, buffers in the saliva gradually increase the pH. Since saliva is supersaturated with respect to calcium and phosphate, remineralisation of the partially dissolved crystals will start to occur at pH >5.5 (Ten Cate and Buzalaf 2019). Fluoride present in the enamel fluid adsorbs onto the crystal surface attracting calcium ions. This forms a 'veneer' at the crystal surface preferentially taking up fluoride from the fluid around the crystal and excluding carbonate (ten Cate and Featherstone 1991; Featherstone 1999). The new surface is 'fluorapatite-like' with lower solubility than the carbonated apatite of the original crystal surface and is more resistant to subsequent acid attack (Featherstone 1999).

Fluoride inhibits plaque bacteria

It is proposed that when the bacteria produce acid, fluoride, taken up by the bacterial cell, can inhibit essential enzyme activity (Marquis 1990). Most of the evidence for a direct antimicrobial effect of fluoride comes from *in vitro* studies and the antimicrobial effect of fluoride *in vivo* is less certain. Producing such an effect *in vivo* is likely to require high concentrations of fluoride (Buzalaf et al. 2011).

2.4 Measurement of dental caries

The term 'dental caries' encompasses a continuum of changes in dental tissue ranging from early hypomineralisation of subsurface enamel detectable clinically as a 'white spot' lesion to frank cavitation of the tooth surface with extensive involvement of the dentine. The proportion of a population exhibiting signs of the disease is very much dependant on the cut off points chosen for measurement. For example, the expression 'caries-free' refers to individuals or sites that have not progressed to the defined stage of involvement or to cavitation (Fejerskov 1997). Therefore, rather than measuring the presence or

absence of dental caries, methods of measurement quantify the prevalence of the disease at a specified level.

Traditionally, the DMF (decayed missing filled) index, as described by the WHO (World Health Organisation 2013) was used to measure dental caries. The DMF index measures dentinal caries in addition to restored teeth and teeth that are missing due to dental caries. Thus, using the DMF index, the outcome known as 'dental caries' is a measure of current and past dental caries experience. Several other measurement systems have been developed in recent years including the International Caries Detection and Assessment System (ICDAS) (Ismail et al. 2007; ICDAS Coordinating Committee 2009), the Caries Assessment Spectrum and Treatment (CAST) instrument (Frencken et al. 2011; Frencken et al. 2013) and the Pulpal involvement Ulceration Fistula Abscess (PUFA) index (Monse et al. 2010).

ICDAS criteria integrate the best features of several existing dental caries measurement systems and extend measurement of dental caries to lesions confined to enamel. The CAST instrument includes measurement of dental caries confined to enamel and incorporates some of the features of PUFA encompassing measurement of the consequences of untreated dental caries that has progressed beyond dentine into the pulp. The PUFA index itself can be employed to complement existing dental caries indices (Monse et al. 2010) and is included as an optional additional element to ICDAS criteria (Pitts and Ekstrand 2013). The DMF index and ICDAS are described in further detail in the following sections.

2.4.1 Decayed Missing and Filled (DMF) index

The DMF index for use in epidemiological studies as described in the WHO handbook of Oral Health Surveys: Basic Methods (World Health Organisation 2013) involves

quantifying the number of teeth (or surfaces) within an individual that are decayed, missing due to decay and filled due to decay. According to WHO criteria, dental caries is recorded as present when there is a cavitated carious lesion present, undermined enamel or a detectably softened floor or wall. A CPI probe is used to remove food debris and to confirm visual evidence of dental caries on the tooth surface. Dental caries is recorded at cavitation level because at this level, examiners can be easily calibrated and high levels of reproducibility can be achieved under field conditions (Whelton et al. 2006; World Health Organisation 2013). The WHO criteria for measuring coronal dental caries are described in Table 2.2.

Table 2.2: WHO criteria for measuring coronal dental caries in permanent and primary teeth

DMF Code	Criteria
0 (A)	Sound crown - No evidence of treated or untreated clinical caries. Stages of dental caries preceding cavitation and other conditions similar to early stages of dental caries are excluded.
1 (B)	Carious crown - a lesion in a pit or fissure or on a smooth tooth surface that has an unmistakable cavity, undermined enamel or a detectably softened floor or wall, or there is a temporary restoration.
2 (C)	Filled crown with dental caries - one or more permanent restorations, and one or more areas that are decayed. There is no distinction between primary and secondary dental caries.
3 (D)	Filled crown with no dental caries - one or more permanent restorations, and no dental caries anywhere on the crown. A tooth that was crowned due to decay is included in this category.
4 (E)	Missing tooth, due to dental caries – a permanent or primary tooth that was extracted due to dental caries.
5 (-)	Permanent tooth missing due to any other reason - Absent congenitally, extracted due to orthodontic reasons, periodontal disease or trauma.
6 (F)	Fissure Sealant – a fissure sealant has been placed or the occlusal fissures have been enlarged and a composite material placed.
7 (G)	Fixed Dental prosthesis abutment, special crown or veneer.
8 (-)	Unerupted tooth (crown) – a tooth space with an unerupted permanent tooth and no primary tooth.

Codes applied to primary teeth are given in parenthesis.
Adapted from the WHO handbook of Oral Health Surveys: Basic Methods (World Health Organisation 2013)

The DMFT for an individual is calculated as the sum of the decayed (codes 1 or 2), missing (code 4 if under 30 years old) and filled (code 3) teeth as defined above with the notation DMFT indicating permanent teeth and dmft indicating primary teeth. The status of the primary or permanent dentition by tooth surface may be obtained by calculating the number of decayed, missing and filled surfaces (DMFS/dmfs).

With the declining dental caries prevalence in the Western world in recent decades, recording dental caries at cavitation level was of less use for planning services and evaluating the effectiveness of preventive programmes. In the 1990s, the British Association for the Study of Community Dentistry (BASCD) amended its criteria to include visible non cavitated dentinal caries in the dmft/DMFT count. These are lesions where dentinal caries is visible underneath the enamel but there is no detectable cavity in the enamel. Whelton (2006) expanded the WHO criteria for use in the Irish NSSCOH 2002 to include coding for visible non cavitated dentinal caries, facilitating analysis of dental caries data including (d_{3vc}mft/D_{3vc}MFT) or excluding (d_{3c}mft/D_{3c}MFT) visual dentinal caries.

Strengths and limitations of the DMF index

The advantages of the DMF index include the ability to compare results of contemporary studies with older studies that used the same index criteria to evaluate trends in dental caries prevalence over time, the ability to standardise the measurement of dentinal caries among multiple examiners, the simplicity, ease of use and efficiency of the index in the field and the amenability of the index to statistical analysis. However, measurement at the level of cavitated or visual non-cavitated dentinal lesions excludes enamel caries and thus, reflect an advanced stage of the caries process which may have limited use in planning preventive dental services or in evaluating the impact of caries preventive interventions. Furthermore, the WHO criteria do not distinguish carious lesions into dentine that can be restored from those that need more complex treatment.

2.4.2 International Caries Detection and Assessment System (ICDAS)

ICDAS was developed by an international group of experts following an 'International Consensus Workshop on Caries Clinical Trials' in 2002. The system, incorporating the

best features of several existing systems for caries detection and measurement, addressed the shortcomings of existing measurement systems that recorded only cavitated lesions and dentinal lesions (Ismail et al. 2007; Pitts and Ekstrand 2013). ICDAS criteria for coronal primary caries detection on specified tooth surfaces are based on existing knowledge about the histological extent of carious lesions, with codes 1 to 6 reflecting increasing severity of dental caries from the first visual change in enamel that can be seen only after prolonged air drying to extensive cavitation with dentine visible (Pitts and Ekstrand 2013) Table 2.3.

Table 2.3: ICDAS criteria for measuring coronal primary dental caries

ICDAS codes	Criteria
0	Sound tooth surface – either no or questionable change in enamel translucency after prolonged air drying
1	First visual change in enamel – after prolonged air drying there is a carious opacity or discoloration (white or brown lesion) visible that is not consistent with the clinical appearance of sound enamel.
2	Distinct visual change in enamel - viewed wet, there is a carious opacity (white spot lesion) and/or discoloration (white or brown lesion) that is not consistent with the normal clinical appearance of sound enamel.
3	Localised enamel breakdown due to dental caries with no visible dentine or underlying shadow
4	Underlying dark shadow from dentine with or without localised enamel breakdown.
5	Distinct cavity with visible dentine – involving less than half of the tooth surface.
6	Extensive distinct cavity with dentine visible – involving at least half of the tooth surface.

There is an option to merge the codes to measure three stages of dental caries; codes 1 and 2 indicating 'initial stage decay', codes 3 and 4 indicating 'moderate decay' and codes 5 and 6 indicating 'extensive decay' (Pitts and Ekstrand 2013). There is also an option to produce data comparable to the DMF index for teeth or surfaces with codes 5 and 6

combined being comparable to the 'D' component of the DMFT/S measure or codes 4, 5 and 6 combined bring comparable to the 'D' component of DMFT/S measure including visual dentinal caries.

The criteria for measuring coronal caries (Table 2.3) and the options for merging codes all relate to the measurement of primary dental caries. Restorations and sealants with and without dental caries are recorded using 'Caries-Associated with Restorations and Sealants' (CARS) detection criteria (ICDAS Coordinating Committee 2009). This introduces a two-digit coding method with the CARS code identifying restorations and sealants followed by the appropriate caries code. Teeth that are missing and reasons for missing teeth are also accounted for using the two-digit system.

Between 2008 and 2012, ICDAS was developed into a more comprehensive system referred to as the International Caries Classification and Management System (ICCMS) for use in clinical practice, education, research, and public health. ICDAS and ICCMS systems provide an array of resources that facilitate flexibility in the use of information about carious lesion severity and activity to derive appropriate, personalised risk-based caries management plans in clinical as well as in public health practice (Pitts and Ekstrand 2013).

Strengths and limitations of ICDAS

ICDAS is a valid and reliable index for detecting coronal caries, particularly for pit and fissure caries (Ismail et al. 2007) and is especially suited for detecting the earliest clinical signs of dental caries (Castro et al. 2018). However, ICDAS is a complex system involving one set of codes for restorations, sealants and missing teeth and another set of codes for enamel and dentinal caries, scoring each tooth surface separately wet and dry (Frencken et al. 2011; de Amorim et al. 2012; Castro et al. 2018). Thus, its application is time

consuming and the requirement for equipment to facilitate drying of teeth may be impractical for field studies, particularly in developing countries (de Amorim et al. 2012). Furthermore, its subsequent analysis is complex given the number of clinical codes recorded (Frencken et al. 2011; de Amorim et al. 2012; Castro et al. 2018). However, ICDAS/ICCMS criteria are reviewed and updated on an on-going basis and the detailed recording of the existing system is particularly suitable for use in clinical trials of caries preventive interventions (Frencken et al. 2011).

2.5 Clinical presentation of dental fluorosis

Excessive ingestion of fluoride during critical periods of tooth formation results in a mineralisation defect of enamel known as dental fluorosis. Fluorosed enamel consists of a hypomineralised subsurface zone beneath a well mineralised surface layer of enamel (Fejerskov et al. 1974; Fejerskov et al. 1977). The concentration of fluoride is increased in fluorosed enamel with increased organic content compared with normal enamel (Bhussry 1959). While mildly fluorosed enamel is more resistant to dental caries due to the high level of fluoride, severely affected enamel is weaker and more susceptible to tooth wear (Fejerskov et al. 1977) and to dental caries (DenBesten 1999).

Severity of fluorosis is related to fluoride intake and duration of exposure with increased intake and prolonged exposure linked to more severe presentations of the condition (DenBesten and Li 2011). Physiological conditions and processes such as body weight, skeletal growth and remodelling rate (rapid growth removes fluoride from the blood stream, remodelling of bone releases fluoride into the blood stream), nutrition and renal function can have an impact on the prevalence and severity of dental fluorosis (DenBesten and Li 2011). Furthermore, the influence of genetics on susceptibility or resistance to dental fluorosis has been demonstrated in experiments using mice (Everett et al. 2002; Carvalho et al. 2009; Everett et al. 2009; Charone et al. 2016). A genetic

predisposition for dental fluorosis may help to explain variations in fluorosis severity among individuals with similar fluoride intake. However, further research involving humans is required (Buzalaf 2018).

The earliest sign of fluorotic changes in enamel are thin white horizontal lines of opacity across the enamel surface corresponding to the positions of the perikymata (Fejerskov et al. 1977; Møller 1982) which may produce 'snow-capping' on the incisal or cuspal edges of newly erupted teeth. These thin opaque lines and 'snow-capping' indicate increased subsurface porosity and are more easily detected by viewing the enamel surface tangentially (Fejerskov et al. 1977). With higher levels of exposure to fluoride or prolonged exposure, the white lines become more defined and thicken (Bronckers et al. 2009) and may merge to form irregular cloudy or paper while areas (Fejerskov et al. 1977). In moderate or severe presentations of fluorosis, the deeper layers of enamel are affected with increased porosity, post eruptive enamel breakdown (Fejerskov et al. 1990) and consequent pitting and staining of the enamel (DenBesten and Li 2011).

Fluorosis presents with a bilaterally symmetrical distribution (Thylstrup and Fejerskov 1978; Manji et al. 1986). Homologous pairs of teeth tend to exhibit similar fluorosis severity, although minor variations in severity between homologous pairs of teeth have been reported. (Thylstrup and Fejerskov 1978; Levy et al. 2006). Fluorosis severity and its distribution are related to fluoride concentration and duration of exposure, the stage of ameloblast activity and individual susceptibility (Cutress and Suckling 1990).

2.6 Pathophysiology of dental fluorosis

Mature dental enamel is the hardest tissue in the body. Unlike other mineralised tissues, enamel is not remodelled after its formation and is therefore a unique substance in the body; presenting a record on eruption of the tooth several years later of the conditions

that were present when the enamel was forming. Mature enamel is highly mineralised, composed of predominantly inorganic material (96% by weight), small amounts of organic material and water (1% and 3% by weight respectively) (Berkowitz et al. 1992). The inorganic material is mainly calcium phosphate as hydroxyapatite crystals. The organic component found in developing enamel is comprised predominantly of unique amelogenin proteins with a smaller proportion of non-amelogenin proteins. These proteins are removed during amelogenesis along with water so that only small amounts of organic material and water are found in mature enamel.

Fluorosed enamel is more porous and has a higher protein content than normal enamel suggesting that fluoride affects enamel matrix degradation during tooth development (Bronckers et al. 2002). While much research has been conducted, the exact mechanisms by which fluoride induces these changes have not yet been fully elucidated. Apart from the pre-secretory stage of amelogenesis, which does not appear to be impacted by fluoride (DenBesten 1999) each stage of amelogenesis (secretary, transition and maturation) has a different susceptibility to fluoride exposure.

In the secretory stage of amelogenesis, the rows of ameloblasts retreat, a pyramidal Tomes process forms at the secreting pole of the ameloblast and hydroxyapatite crystals are formed at both the proximal and distal surfaces of the Tomes process (Berkowitz et al. 1992). Organic (enamel matrix proteins) and inorganic material (mineral) is simultaneously secreted until the full thickness of enamel has been formed. This enamel matrix is the scaffolding that will eventually form the enamel. Histologically, this forms the appearance of enamel prisms which are made up of large numbers of crystals.

At very high serum fluoride concentrations, the secretary stage of amelogenesis can be impacted by fluoride, resulting in a reduction in the enamel thickness (DenBesten and Li

2011). Several different mechanisms are suggested to explain this effect including inhibition of amino-acid uptake which in turn inhibits protein synthesis, reducing protein secretion into the matrix (DenBesten and Thariani 1992), intracellular degradation of enamel matrix proteins interrupting the transport of newly synthesised enamel matrix proteins to the extracellular space (Bronckers et al. 2002), or a direct effect of fluoride on crystal growth (DenBesten and Li 2011).

At the end of the secretory stage, there is a transition stage where the Tomes process disappears and approximately 25% of the ameloblast cells die and are phagocytosed by the remaining ameloblasts (Berkowitz et al. 1992). The enamel at this stage is structurally complete with all the features of mature enamel but is incompletely mineralised. In the maturation stage, the crystals increase in width, reducing the intercrystalline space. The ameloblasts change their morphology to alternate between having a ruffle ended or a smooth surface apposed to the enamel. The modulation between being morphologically ruffle or smooth ended facilitates resorptive and secretory stages of the maturation process where amelogenin proteins and water are removed from the enamel matrix before mineral ions are deposited to form fully calcified enamel. This degradation and removal of the enamel matrix is essential to facilitate crystal growth and normal maturation of enamel.

Fluoride is considered to impact most on the transition and maturation stages of enamel development by impacting both the number of ameloblasts and their modulation between ruffle-ended and smooth morphology (DenBesten 1999; Bronckers et al. 2009). Amelogenin proteins are retained longer during the maturation stage due to a delay in their hydrolysis and removal (DenBesten and Crenshaw 1984; DenBesten 1986) which slows crystal growth, resulting in hypomineralisation of the enamel. It is proposed that the retention of amelogenin proteins in the maturation stage is due to fluoride decreasing

the matrix proteinase activity and is dose dependant (DenBesten and Li 2011). Furthermore, it is proposed that fluoride incorporated into the crystal lattice binds amelogenin proteins, delaying their removal and inhibiting crystal growth (Tanimoto et al. 2008; DenBesten and Li 2011).

The importance of pH regulation by ameloblasts for sustained growth of hydroxyapatite crystals during amelogenesis has been highlighted (Bronckers et al. 2009; Lyaruu et al. 2014). Lyaruu et al. (Lyaruu et al. 2014) suggested a 'barrier model' where fluoride stimulates the formation of a hypermineralised band which acidifies the enamel matrix and creates a physical barrier which impairs diffusion of ions and peptides from surface to deeper layers of enamel.

2.6.1 Timing of exposure to fluoride and dental fluorosis

The first signs of calcification of the aesthetically important maxillary central incisors are visible radiographically at approximately 3 to 4 months after birth, with the maxillary lateral incisors beginning calcification slightly later at 10 to 12 months after birth (Berkowitz et al. 1992). Calcification of the crowns of the maxillary incisors is complete at approximately 4-5 years of age (Table 2.4). There is individual variation in the development of the permanent dentition and development of the permanent dentition tends to be more advanced in girls (Berkowitz et al. 1992).

Table 2.4: Chronology of tooth development and order of eruption of the permanent dentition

Tooth	First evidence of calcification	Crown completed (years)	Eruption (years)
Maxillary			
1	3-4 months	4-5	7-8
2	10-12 months	4-5	8-9
3	4-5 months	6-7	11-12
4	1½ - 1¾ years	5-6	10-11
5	2-2½ years	6-7	10-12
6	Birth	2½-3	6-7
7	2½-3 years	7-8	12-13
8	7-9 years	12-16	17-21
Mandibular			
1	3-4 months	4-5	6-7
2	3-4 months	4-5	7-8
3	4-5 months	6-7	9-10
4	1¾ - 2 years	5-6	10-12
5	2¼-2½ years	6-7	11-12
6	Birth	2½-3	6-7
7	2½-3 years	7-8	12-13
8	8-10 years	12-16	17-21

Source: Berkovitz, Holland and Moxham (Berkowitz et al. 1992)

The benefits of exposure to fluoride in terms of dental caries prevention apply across the life course whereas the risk of fluorosis is during a period of time in early childhood while the permanent dentition is mineralising. Thus, to maximise the benefits of fluoride while minimising the risk of fluorosis, it is important to identify the period of time when children are most at risk of developing dental fluorosis so that ingestion of fluoride can be minimised at this time. The period of susceptibility for the development of dental fluorosis in the entire dentition (excluding third molars) is considered to extend from birth to 6 to 8 years of age (Pendrys 1990; 1999a; Bhagavatula et al. 2016). Because of the potential aesthetic impact, the period of susceptibility of the maxillary incisors to dental fluorosis is of particular importance (Kumar et al. 2000a).

A meta-analysis of risk periods associated with dental fluorosis in maxillary permanent central incisors (Bårdsen 1999) considered studies assessing dental fluorosis where 1) fluoride was introduced at different ages during amelogenesis and 2) children exposed to fluoride from birth experienced a sudden reduction in exposure to fluoride within the first four years of life. Results from studies in group (1) demonstrated that children exposed to fluoride during the first two years of life had higher odds of developing fluorosis than those exposed to fluoride after 2 years of age (OR 7.24, 95% CI [4.71-11.13]). Duration of exposure to fluoride was also found to be an important factor in the development of fluorosis. Exposure to fluoride for more than 2 of the first 4 years of life (long exposure) was associated with increased odds of fluorosis compared with exposure for less than two of the first four years (short exposure) (OR 5.83, 95% CI [2.83-11.94]). Although the early maturation stage of amelogenesis is considered the most important for the development of fluorosis (DenBesten 1986; DenBesten and Thariani 1992), results of studies included in this review did not support any particular stage of amelogenesis being designated as the "high risk" period for the development of fluorosis.

The studies included in the Bårdsen meta-analysis (Bårdsen 1999) considered few fluoride sources and measured exposure to fluoride retrospectively. A review by Buzalaf and Levy (2011) included four reports of studies published subsequent to the Bårdsen meta-analysis. Two of these reports, from the Iowa Fluoride Study employed longitudinal measurement of fluoride intake from several sources via a parent completed questionnaire administered every 3 to 4 months from birth to 48 months (Hong et al. 2006a; Hong et al. 2006b). These found that the maxillary central incisors were most at risk of developing fluorosis from 6 to 24 months of age, although the third and fourth years of life were also important. Duration of exposure to fluoride was also important as children with higher levels of fluoride intake (>0.06 mg/kg body weight) throughout the first three years of

life were more likely to have fluorosis than children with 0, 1 or 2 years of higher fluoride intake. Two further linked studies reported the effects of an 11-month break in water fluoridation in North Carolina in the early 1990s (Burt et al. 2000; 2003). Children who were aged 1 to 3 years at the time of the interruption had lower prevalence of fluorosis in maxillary central and lateral incisors than those who were aged 4 to 5 years at the time of the interruption. Thus, sensitivity to fluoride in drinking water was greater for younger children (aged 1 to 3 years) (Burt et al. 2000). Unfortunately, results of a follow-up study of fluorosis levels in children born 1 year after resumption of water fluoridation did not support the conclusion of the earlier study (Burt et al. 2003). Nonetheless, based on the results of these studies and the existing body of evidence included in Bårdsen et al. (1999), Buzalaf and Levy (2011) recommended that fluoride intake be monitored for children within the first three years of life.

A body of evidence, including the study from Iowa (Hong et al. 2006a; Hong et al. 2006b) relating fluoride intake from several sources measured longitudinally to the development of fluorosis, supports the first two years of life as posing the highest risk of fluorosis from excessive ingestion of fluoride. The evidence also points to duration of exposure rather than a specific critical window or timing of exposure being important (Bårdsen 1999; Hong et al. 2006a; Hong et al. 2006b). However, the results of the relevant studies are not homogenous and there are some inconsistencies in the published literature. Studies have suggested later exposure to fluoride in water (Ishii and Suckling 1986) and fluoride supplements (Pendrys and Katz 1989; Pendrys et al. 1996) as being critical for the development of fluorosis, while another study suggested a gender difference in the risk period for fluorosis in maxillary central incisors with an estimate of between 15 to 24 months for males and 21 to 30 months for females (Evans and Darvell 1995). Therefore, to reduce the risk of fluorosis in the aesthetically important permanent maxillary incisors,

it seems prudent to concentrate efforts to minimise exposure to fluoride for at least the first two to three years of life.

2.7 Measurement of dental fluorosis

Enamel opacities are qualitative developmental defects of enamel, identified visually as an abnormality in the translucency of enamel. The enamel is of normal thickness with a smooth surface but the enamel subsurface is hypomineralised. The colour of the enamel can be white or can be discoloured cream, yellow or brown. Any loss of the enamel surface in teeth affected by enamel opacities is considered to be post-eruptive (Thylstrup and Fejerskov 1978). Enamel opacities can have a demarcated or diffuse appearance. Demarcated opacities have a defined and clear boundary with adjacent normal enamel. They can be white, cream, yellow or brown in colour. Diffuse opacities tend to be white; have a linear, patchy or confluent distribution and have no clear boundary with adjacent normal enamel (FDI 1992).

Measurement of developmental defects of enamel can be based on presenting appearance or their presumed aetiology and indices used to measure developmental defects of enamel can correspondingly be grouped into descriptive and specific fluorosis indices (Clarkson 1989). Descriptive indices such as the Developmental Defects of Enamel (DDE) and Al-Alousi indices (Al-Alousi et al. 1975; FDI 1982; 1992) classify enamel defects without ascribing a cause. The DDE index for example records the type and extent of enamel defects including diffuse and demarcated opacities, hypoplasia and combinations of these defects. Specific fluorosis indices, on the other hand, record changes in the enamel due to fluorosis. These indices include Dean's Index (Dean 1942), the Thylstrup and Fejerskov Index (TF Index) (Thylstrup and Fejerskov 1978; Fejerskov et al. 1988), the

Tooth Surface Index of Fluorosis (TSIF) (Horowitz et al. 1984) and the Fluorosis Risk Index (FRI) (Pendrys 1990).

Proponents of descriptive indices assert that diagnosing enamel defects as being fluoride induced is extremely difficult, particularly at low prevalence and that measurement should instead be based what is seen on examination (Goward 1976; Murray and Shaw 1979; Cutress et al. 1985; FDI 1992). On the other hand, those who favour specific fluorosis indices argue that the features of dental fluorosis are distinctive and with an appropriate classification system and methodology, can be accurately recorded without risk of confusion with non-fluoride-induced enamel defects (Fejerskov et al. 1988).

These opposing viewpoints have resulted in the development of two very different approaches to measuring developmental defects of enamel (Clarkson 1989). One approach involves the use of various criteria to distinguish between fluoride induced and non-fluoride opacities and then measurement of the fluoride-induced opacities only. This approach has been shown to be valid in studies where dental fluorosis measured without knowledge of past fluoride exposure was later found to be associated with a history of fluoride exposure (Osuji et al. 1988; Pendrys and Katz 1989; Ismail et al. 1990; Riordan and Banks 1991; Pendrys et al. 1994; Pendrys 1999b).

The other approach involves recording all enamel defects without ascribing a cause. The occurrence of diffuse enamel opacities is linked to fluoride exposure and a number of studies have established the occurrence of diffuse opacities as the discriminating factor between fluoridated and non-fluoridated areas (Suckling et al. 1985; Clarkson and O'Mullane 1989) (Suckling and Pearce 1984; Cutress et al. 1985; de Liefde and Herbison 1985; O'Mullane et al. 1986; de Liefde and Herbison 1989; Angelillo et al. 1990; Clarkson and O'Mullane 1992). Most studies of developmental defects of enamel conducted in

areas with community water fluoridation have reported increased prevalence of diffuse enamel defects but no increase in the prevalence of demarcated enamel defects compared with non-fluoridated areas (Cutress et al. 1985; Clarkson and O'Mullane 1989; Milsom and Mitropoulos 1990; Kanagaratnam et al. 2009). Therefore, if differences are found between groups with and without CWF, all else being equal, the cause of the diffuse opacities may be attributed to fluoride exposure (Clarkson 1989).

Distinguishing between fluoride and non-fluoride enamel opacities, a key part of using specific fluorosis indices, is not always straightforward. Russell (1961), developed a set of criteria to assist in the differentiation of fluoride and non-fluoride enamel opacities. These criteria are summarised in Table 2.5.

Table 2.5: Russell's criteria to aid differentiation between fluoride and non-fluoride enamel opacities

Characteristic	Milder forms of enamel fluorosis	Non fluoride enamel opacities
Area affected	Usually seen on or near tips of cusps or incisal edges.	Usually centered on smooth surface; may affect entire crown.
Shape of lesion	Resembles line shading in pencil sketch; lines follow incremental lines in enamel, form irregular caps on cusps.	Often round or oval.
Demarcation	Shades off imperceptibly into surrounding normal enamel.	Clearly differentiated from adjacent normal enamel.
Color	Slightly more opaque than normal enamel; "paper-white." Incisal edges, tips of cusps may have frosted appearance. Does not show stain at time of eruption (in these milder degrees, rarely at any time).	Usually pigmented at time of eruption; often creamy yellow to dark reddish-orange.
Gross hypoplasia	None. Pitting of enamel does not occur in the milder forms. Enamel surface has glazed appearance, is smooth to point of explorer.	Absent to severe. Enamel surface may seem etched, be rough to explorer.
Detection	Often invisible under strong light; most easily detected by line of sight tangential to tooth crown.	Seen most easily under strong light on line of sight perpendicular to tooth surface

In the following sections (2.7.1 to 2.7.5), the specific fluorosis indices relevant to this thesis; Dean's Index (Dean 1942) and the TF Index (Thylstrup and Fejerskov 1978; Fejerskov et al. 1988) are described in detail and their relative strengths and limitations for measuring fluorosis are explored. Then, clinical and photographic methods of fluorosis measurement are described.

2.7.1 Dean's Index

Dean's classification system for fluorosis was developed and refined by H. Trendley Dean and colleagues in the United States during the 1930s and early 1940s. The original classification (Dean 1934; Dean et al. 1935) included seven categories: 'normal',

'questionable', 'very mild', 'mild', 'moderate', 'moderately-severe' and 'severe'. In 1942, Dean modified the index to combine the 'moderately-severe' and 'severe' categories into one 'severe' category to form the six category index in use today (Dean 1942). The examination using Dean's Index is conducted in natural light without drying the teeth. All the teeth are examined and if fluorosis is deemed to be present, the person-level Dean's Index score is based on the two worst affected teeth. Where the two worst affected teeth are not equally affected, the classification is based on the less affected of the two teeth with the highest scores. The diagnostic criteria for Dean's Index are described in Table 2.6 and examples of Dean's Index scores 'normal' to 'severe' are presented in Figure 2.2.

Table 2.6: Diagnostic criteria for Dean's Index

Classification	Criteria
Normal	The enamel presents the usual translucent semi-vitriform type of structure. The surface is smooth, glossy, and usually of a pale creamy white colour.
Questionable	The enamel discloses slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilized in those instances where a definite diagnosis of the mildest form of fluorosis is not warranted and a classification of 'normal' not justified.
Very mild	Small, opaque, paper-white areas scattered irregularly over the tooth but not involving as much as approximately 25% of the tooth surface. Frequently included in this classification are teeth showing no more than about 1-2 mm of white opacity at the tips of the summits of the cusps of the bicuspids or second molars.
Mild	The white opaque areas in the enamel of the teeth are more extensive but do not involve as much as 50% of the tooth.
Moderate	All enamel surfaces of the teeth are affected, and surfaces subject to attrition show marked wear. Brown stain is frequently a disfiguring feature.
Severe	All enamel surfaces are affected, and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is the discrete or confluent pitting. Brown stains are widespread, and teeth often present a corroded-like appearance.



Figure 2.2: Photographs showing Dean's Index scores 'normal' to 'severe'

Source: Forum on Fluoridation Report 2002 (Department of Health and Children 2002)

To facilitate comparison of the prevalence of fluorosis across different communities with varying levels of water fluoride, Dean developed the community fluorosis index (CFI) (Dean and McKay 1939). This method assigned a weight to each of the categories of Dean's Index as follows: normal (0), questionable (0.5), very mild (1), mild (2), moderate (3), and severe (4) and yielded the average weighted score per person surveyed (Rozier 1994). However, the CFI provides little information about variation in fluorosis within a population and the community-level score may not correlate well with the individual score (Thylstrup and Fejerskov 1978; Rozier 1994). In addition, the statistical shortcomings involved in calculating a weighted average for scores on an ordinal scale where the scores are not usually normally distributed have been highlighted as have the use of an arbitrary weighting system (Thylstrup and Fejerskov 1978; Rozier 1994).

2.7.2 Thystrup and Fejerskov Index (TF Index)

Advances in understanding the histological features of dental fluorosis during the 1970s stimulated refinements of Dean's methods and the proposal of a new classification system reflecting the histopathological changes in enamel associated with fluorosis of increasing severity (Fejerskov et al. 1988). The TF Index has 10 categories graded 0 through 9 that reflect the histopathological changes in enamel associated with fluorosis of increasing severity. Thus, each score of the index represents an arbitrary point along a continuum of increasing subsurface porosity. The teeth are cleaned and dried with cotton wool or gauze and allowed to dry for 1 to 2 minutes prior to scoring each tooth present. The original index was based on clinical examination of all tooth surfaces (Thylstrup and Fejerskov 1978). However, in 1988, based on the observation that the buccal surface reflected the degree to which all surfaces were affected, the index was modified to be based only on buccal or labial tooth surfaces (Fejerskov et al. 1988). The diagnostic criteria for the TF Index are described in Table 2.7.

Table 2.7: Diagnostic criteria for the TF Index

TF 0	The normal translucency of the glossy, creamy-white enamel remains after wiping and drying of the surface.
TF 1	Thin white opaque lines are seen running across the tooth surface. The lines correspond to the position of the perikymata. In some cases, a slight 'snowcapping' of cusps/incisal edges may also be seen.
TF 2	The opaque white lines are more pronounced and frequently merge to form small cloudy areas scattered over the whole surface. 'Snowcapping' of incisal edges and cusp tips is common.
TF 3	Merging of the white lines occurs, and cloudy areas of opacity occur spread over many parts of the surface. In between the cloudy areas, white lines can also be seen.
TF 4	The entire surface exhibits a marked opacity or appears chalky white. Parts of the surface exposed to attrition or wear may appear to be less affected.
TF 5	The entire surface is opaque, and there are round pits (focal loss of the outermost enamel) that are less than 2 mm in diameter.
TF 6	The small pits may frequently be seen merging in the opaque enamel to form bands that are less than 2 mm in vertical height. In this class are also included surfaces where the cuspal rim of facial enamel has been chipped off, and the vertical dimension of the resulting damage is less than 2 mm.
TF 7	There is a loss of the outermost enamel in irregular areas, and less than half the surface is so involved. The remaining intact enamel is opaque.
TF 8	The loss of the outermost enamel involves more than half the enamel. The remaining intact enamel is opaque.
TF 9	The loss of the major part of the outer enamel results in a change of the anatomical shape of the surface/tooth. A cervical rim of opaque enamel is often noted.

2.7.3 Strengths and limitations of Dean's Index and the TF Index

The strengths of Dean's Index include its simplicity, ease of use and amenability to statistical analysis. Its long history of use facilitates comparison with previous studies back to the first studies conducted by Dean and colleagues in the 1930s. However, the index

has several important limitations. The diagnostic criteria for the classifications of Dean's Index are often criticised, in particular the lack of clarity regarding the 'questionable' category (Fejerskov et al. 1988; Clarkson 1989; Rozier 1994) which can be a source of some confusion for dental examiners and lead to difficulty diagnosing fluorosis of low severity (Fejerskov et al. 1990). Dean's Index is also criticised for its failure to distinguish between the more severe presentations of dental fluorosis (Fejerskov et al. 1988; Clarkson 1989). Basing the person level score on the most severely affected teeth measures the maximum dental effects of fluoride on the individual but is of little use when it is important to know the tooth or surface affected (Clarkson 1989; Rozier 1994). In addition, the person-level score may obscure variation in the severity of fluorosis within the individual and provides little information about the biologic effect of fluoride on the entire dentition (Thylstrup and Fejerskov 1978). Because posterior teeth tend to be more affected by fluorosis than anterior teeth, the person level Dean's Index score may underestimate fluorosis of the aesthetically important anterior teeth (Horowitz 1986; Rozier 1994). Although several modifications to Dean's Index were proposed, they did little to address the inherent limitations of the index and are not in widespread use (Clarkson 1989; Rozier 1994). Nonetheless, that the original index devised in 1942 remains in use today despite its limitations is noteworthy.

The TF Index was proposed as a more sensitive classification system than Dean's Index for evaluating the biological effect of fluoride exposure during enamel formation in areas with elevated concentrations of fluoride in drinking water. The expanded range of scores for the TF Index facilitates enhanced discrimination between severe manifestations of the condition (Thylstrup and Fejerskov 1978; Fejerskov et al. 1988; Mabelya et al. 1994). The category equivalent to Dean's Index 'severe' is broken out across TF scores 5 to 9

distinguishing between severe manifestations of fluorosis with increasing degrees of post eruptive enamel breakdown (Thylstrup and Fejerskov 1978; Fejerskov et al. 1988).

Despite the extended scale of the TF Index, Mabelya and colleagues (1994) found that the correlation between initial measurements and repeat measurements were higher for the TF Index than Dean's Index. Furthermore, on repeat measurement, the TF Index was more accurate in distinguishing between the presence or absence of fluorosis defined as TF 1 or greater (4.5% errors) than Dean's Index questionable or greater (8.4% errors). This finding reflected difficulties in consistently measuring fluorosis at the lowest levels of severity with Dean's Index, the clear criteria of the TF Index for what constitutes the earliest signs of fluorosis and drying of the teeth that facilitated the earliest enamel changes to be recorded with the TF Index.

Although drying the teeth prior to scoring with the TF Index facilitates the process of distinguishing the earliest signs of fluorosis from non-fluoride opacities, it has been suggested that drying creates an unnatural appearance and that TF 1 and TF 2 scored from dry enamel reflect very minor changes in the enamel of questionable aesthetic importance (Clarkson 1989; Ellwood et al. 1994). The increased examination time required to record a TF score for each tooth has also been reported as a disadvantage of using the index as well as remembering descriptors of the extended scale of the TF Index (Cleaton-Jones and Hargreaves 1990). However, it is considered unlikely that the full range of TF Index scores will be employed in any study; usually a range of 5 to 6 scores will suffice (Fejerskov et al. 1988).

In summary, although Dean's Index is considered suitable for a general assessment of overall fluorosis severity particularly in larger populations with water fluoride concentrations of 3 ppm or less (Wenzel and Thylstrup 1982; Cleaton-Jones and

Hargreaves 1990), the application of Dean's Index is limited in situations where detailed tooth level data are required and where it is necessary to differentiate between fluorosis at higher levels of severity or to reliably detect the earliest signs of fluorosis. In studies that directly compared the two indices, the TF Index was the index of choice due to its ease of use, its reproducibility, its versatility for measuring fluorosis at low and high severity, its ability to provide detailed information to evaluate aesthetic concerns related to individual teeth or to obtain detailed information about the effect of fluoride programmes or fluoride availability on fluorosis (Wenzel and Thylstrup 1982; Granath et al. 1985; Burger et al. 1987; Cleaton-Jones and Hargreaves 1990; Mabelya et al. 1994).

2.7.4 Clinical measurement of dental fluorosis

Measurement of dental fluorosis relies on the subjective assessment of the dental examiner and can therefore be influenced by variability in scoring and examiner drift (Whelton et al. 2004b). Furthermore, drying the teeth has a significant impact on the prevalence of fluorosis with increased drying time accentuating the appearance of diffuse opacities (Fejerskov et al. 1988; Fejerskov et al. 1990; Cochran et al. 2004b). The type of lighting used and whether the teeth are cleaned prior to scoring can also affect fluorosis measurement, particularly at low severity (Thylstrup 1978; Fejerskov et al. 1988; Whelton et al. 2004b). The angle of inspection is also an important consideration as the first signs of fluoride-induced enamel changes are more easily detected by viewing the tooth surface at a tangent (Fejerskov et al. 1977). Thus, limiting these sources of potential variability are an important aspect of producing valid and reliable estimates of fluorosis prevalence.

Indices for measuring diffuse opacities and fluorosis were developed for clinical application. Advantages of clinical measurement include the ability to examine all teeth present, to assess the distribution of any defects and to enable the examiner to vary the angle of inspection, moving their line of sight around the dental arch. Although blinding

clinical examiners to exposure to water fluoride is possible, for example by transporting study participants to a neutral venue (Jackson et al. 1985; Stephen et al. 2002), this presents logistical challenges in addition to issues of safety and consent (Pretty et al. 2012).

Standardizing clinical fluorosis measurements of different examiners within a study presents challenges as does reliably monitoring trends in fluorosis prevalence measured clinically by different examiners at different time points (Nunn et al. 1993b; Cochran et al. 2004a). A recent report by the Centers for Disease Control and Prevention (CDC) highlighted these challenges in relation to reported trends in fluorosis measured clinically using Dean's Index as part of the National Health And Nutrition Examination Survey (NHANES) 1999-2004 and 2011-2016 (Department of Health and Human Services 2019). In comparing dental examiner scores with the gold standard for the 5 examiners in 1999-2004, weighted kappa statistics for inter-examiner reliability ranged from 0.51 to 0.87 (unweighted 0.35 to 0.64) and for the four examiners in 2011-2016, kappa statistics ranged from 0.60 to 0.98 (unweighted 0.48 to 0.78). However, the proportion of participants who were re-examined by the gold standard examiner was noted to be low in both NHANES cycles (2.8% to 3.6%). In 1999-2004, kappa statistics for intra-examiner reliability ranged from 0.56 to 0.72. However, the authors noted that the differences in Dean's Index scores for the same teeth examined days apart indicated the subjectivity involved in scoring fluorosis using Dean's Index. Although the percentage agreement between the examiners and gold standard for identifying 'very mild' or greater fluorosis was high (88.8% in 1999-2004 and 89.4% in 2011 to 2016), there was substantial variability in prevalence estimates by Dean's Index category across 2-year NHANES cycles.

Although no longitudinal fluorosis prevalence data were collected as part of NHANES, data were available for 6- to 9-year-olds in 2001-04 and for 16- to 19-year-olds 10 years

later in 2011-14. The permanent dentitions of both groups mineralised during the same time frame and were likely to have experienced the same level of exposure to fluoride, facilitating analysis of the two datasets as a synthetic cohort study. The adjusted analysis revealed an increase in fluorosis prevalence in first permanent molars in the synthetic cohort between the 6- to 9-year-old age group (9.5% 'mild' or greater fluorosis) and the 16- to 19-year-old age group (46.9% 'mild' or greater fluorosis) that was not biologically plausible given that no change in fluorosis among erupted first permanent molars of the same cohort of children would be expected over time.

There was no change to the index used to measure fluorosis in 1999-2004 and 2011-2016 and only very minor changes to the examination protocol. The subjective nature of Dean's Index and variability in fluorosis measurement at the lower end of Dean's Index scale were noted by the authors of this report (Department of Health and Human Services 2019). These findings indicated that despite comprehensive training and calibration of examiners led by the same gold standard in the 1999-2004 and 2011-2016 NHANES cycles and annual retraining sessions, there may have been changes over time in the way the examiners evaluated fluorosis, affecting the validity of the fluorosis data in NHANES. The findings cast doubt on the validity of reports of increasing fluorosis prevalence based on analysis of NHANES data (Beltrán-Aguilar et al. 2005; Beltran-Aguilar et al. 2010; Wiener et al. 2018; Neurath et al. 2019) and have wider implications for other studies using clinical fluorosis measurements to monitor trends in dental fluorosis prevalence.

2.7.5 Photographic measurement of dental fluorosis

Using oral photographs to measure fluorosis offers advantages over clinical measurement by facilitating standardisation of viewing conditions, blind measurement of photographs of individuals with different levels of fluoride exposure, blind measurement of photographs from different time points, repeat measurement by different examiners

using different indices and provision of a permanent record that can allow trends in fluorosis within a population to be monitored over time (Ellwood et al. 1996; Cochran et al. 2004b; Tavener et al. 2007). These advantages must be balanced against the fact that measurement of fluorosis from photographs is best suited to incisor teeth (Nunn et al. 1993a) as the entire mouth including posterior teeth is difficult to photograph due to restricted accessibility, particularly in children. Restricting assessment of fluorosis to the anterior teeth may result in underestimation of the prevalence of fluorosis (Medina-Solis et al. 2008; Pretty et al. 2012). However, if measurement of fluorosis affecting aesthetically important teeth is the objective, then restricting the scoring to maxillary incisors or just the maxillary central incisors (of most importance aesthetically) is justified.

Photographic methods may enhance enamel opacities by magnification and can result in an increased prevalence of fluorosis being recorded (Fleming et al. 1989; Levine et al. 1989; Nunn et al. 1992; Ellwood et al. 1996; Pretty et al. 2012; Dye et al. 2018). Fluorosis prevalence will be higher if based on 'dry' compared with 'wet' teeth (Cochran et al. 2004c). The time required to position the child, insert the cheek retractors and position the camera to take the photograph will result in a certain amount of drying (Stephen et al. 2002), even if the intention is to photograph the teeth wet. Variability in drying time may become a significant challenge if more than one photographic view is taken. The issue of equipment or camera malfunction that is only discovered when photographic film is developed (Nunn et al. 1993a) has been overcome using digital cameras. Although malfunction or breakage of the digital camera is still a problem that may be encountered during fieldwork.

Although several studies reported fluorosis measured from oral photographs from the late 1970s through the 1990s (Houwink and Wagg 1979; Levine et al. 1989; Nunn et al. 1992; Nunn et al. 1993a; Holt et al. 1994; Ellwood and O'Mullane 1995; Ellwood et al.

1996; Sabieha and Rock 1998; Tabari et al. 2000), use of a variety different indices and lack of standardised methods limited the comparability of the study results (Cochran et al. 2004c). Judith Cochran (JAC) and colleagues (2004c) developed a standardised photographic method and tested its reproducibility by trained and calibrated examiners across seven European sites recording enamel opacities including fluorosis. The seven examiners used identical camera equipment and settings. A macro lens was used to produce a life size image of the teeth. A macro flash mounted at the end of the lens to avoid shadows was set to use only one tube in the 12 o'clock position to reduce specular reflection. Colour film from the same production batch was used and stored in a freezer prior to use as per manufacturer's instructions.

Children cleaned their teeth without water or toothpaste prior to being photographed and were positioned standing against a wall with the Frankfort-maxillary plane parallel to the floor. With cheek retractors inserted, children were asked to bite edge to edge. Drying time was standardised by keeping the teeth moist with cotton wool rolls up to the start of the countdown to taking the photograph. With the camera held at a 45° angle to minimise specular reflection and lip shadow, two photographs of maxillary incisors were taken 'wet' after 8 seconds and 'dry' after 105 seconds of drying.

The examiners and their assistants were trained and calibrated in the standardised photographic method before undertaking the main study involving photographing over 2,000 8-year-old children across seven European sites (Cochran et al. 2004c). Most of the 'wet' and 'dry' photographs were taken after 7 to 11 seconds and 104 to 111 seconds of drying respectively which was considered acceptable. The photographs were scored by JAC using the DDE and TF indices on a lightbox in a darkened room. Intra-examiner reproducibility (kappa scores) of the measurements from the original photographs compared with the repeat photographs taken by the same examiner ranged from 0.45 to

0.66 for the TF Index and 0.43 to 0.70 for the DDE. Inter-examiner reproducibility for the measurements from the original photographs compared with the repeat photographs taken by the Gold Standard examiner (JAC) ranged from 0.32 to 0.55 for the TF Index and 0.34 to 0.69 for the DDE.

It is worth noting that variability in scoring the original photographs compared with the repeat photographs likely reflects a certain degree of inconsistency in scoring using the TF Index and the DDE in addition to differences due to the photographic technique. The authors noted that the impact of this would be for the kappa statistics to underestimate the similarity between the original and the repeat photographs. According to the interpretation of kappa statistics proposed by Landis and Koch (1977), reproducibility of the scores from the original and the repeat photographs was in the range 'moderate' to 'substantial' for intra-examiner reproducibility for the TF Index and the DDE and in the range 'fair' to 'moderate' for inter-examiner reproducibility for the TF Index and 'fair' to 'substantial' for inter-examiner reproducibility for the DDE. The authors concluded that the photographic method was mostly robust and reproducible but depended on a high standard of training and the dedication of the examiners.

A challenge with having just one frontal photographic view of the dentition is that the lateral incisors and canines are often rotated such that they cannot be clearly visualised for scoring. Wong et al. (2005) suggested that multiple lateral view photographs could help to overcome this issue. The validity and reliability of 'five-view' (frontal, two lateral views, superior view 30° above the horizontal plane and inferior view 30° below the horizontal plane), 'three-view' (frontal and two lateral views) and 'one-view' (frontal only) sets of standardised photographs were assessed using the DDE and results compared with each other and with results of clinical examination. At the subject level, agreement between the main categories of the DDE using the 'five-view', 'three-view' and 'one-view'

and the clinical examination ranged from 'substantial' to 'almost perfect' (kappa 0.73 to 0.86). Intra-examiner reproducibility for both the clinical and photographic examinations (all sets) also ranged from 'substantial' to 'almost perfect' for subject level DDE scores (kappa 0.72 to 0.91) and for scores on the individual anterior teeth (kappa 0.71 to 0.95). The authors concluded that photographic measures were as reliable as clinical measures of recording developmental defects of enamel in the 12 anterior teeth and with no clear advantage in using the 'five-view' over the 'three-view' set suggested that one frontal view and two lateral views would be suitable for assessing developmental defects of enamel in the 12 anterior teeth. The authors also concluded that one frontal view was a suitable method for assessing developmental defects of enamel in the incisors.

A study by Tavener et al. (2007) demonstrated the importance of examiner training and standardisation of viewing conditions prior to assessing dental fluorosis from digital photographs. Ten examiners experienced in the use of the TF Index or in fluorosis measurement scored a set of 120 standardised digital oral photographs of 8- to 10-year-olds living in deprived areas of Manchester, UK with CWF levels <0.1 ppm fluoride using the TF Index. Examiners were not specifically trained or calibrated but were given the criteria and illustrations of each of the categories of the TF Index as presented in Fejerskov et al. (1988). Photographs were scored on the examiners' own computers and no attempt was made to standardise computer settings. The results indicated substantial subjectivity in the application of the TF Index. The prevalence of fluorosis diagnosed by the examiners ranged from 43% to 70% and the prevalence of TF 3 and TF 4 ranged from 2% to 13%. Consistency of the repeat measurements by each examiner was poor with intra-examiner weighted kappa scores ranging from an 0.40 to 0.77 and with six of the 10 examiners having intra-examiner weighted kappa scores < 0.6. Based on the results of this study, the authors advised caution when interpreting data regarding trends in

fluorosis prevalence and when comparing fluorosis in different populations particularly when different methods and examiners are used. Clearly, the potential for variability in the measurement of fluorosis within and between examiners in such studies is an important consideration and the importance of providing appropriate training, calibration and standardising the conditions under which fluorosis is measured cannot be overstated.

Because of the potential for examiner error in fluorosis measurement, a robust training and calibration program prior to data collection is of paramount importance. Dye et al. (2018) conducted a study to evaluate how best to train examiners to assess fluorosis from digital oral photographs. Ten examiners with different levels of experience in fluorosis measurement and two reference examiners with extensive experience in measuring fluorosis and of training examiners participated in the study (one reference examiner for the TF Index and one for Dean's Index). The examiners were divided into two groups each using either Dean's Index or the TF Index and conducted a series of training and assessment sessions including scoring fluorosis in maxillary central incisors from digital photographs on their personal laptops and clinically. The sequence of activities as undertaken by the examiners and reference examiners is outlined in Figure 2.3.

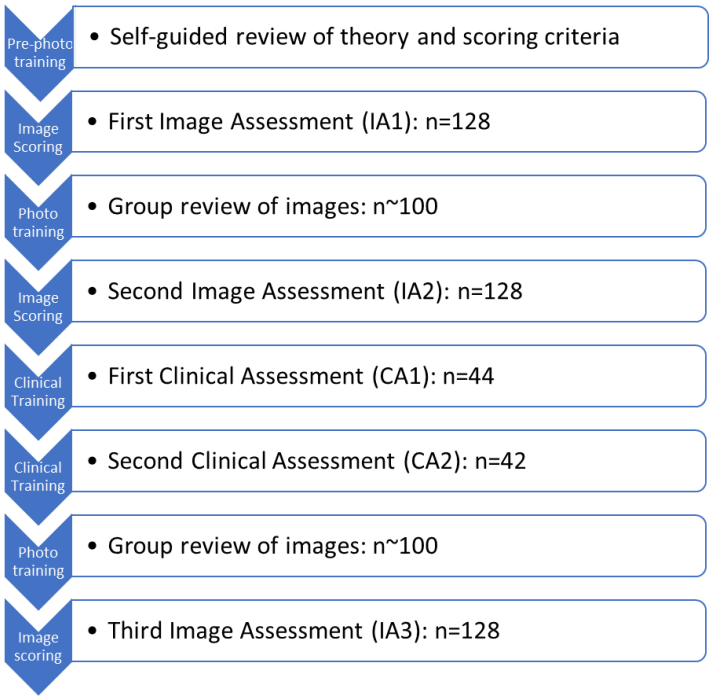


Figure 2.3: Sequence of activities as undertaken by the examiners and reference examiners and corresponding assessment periods
Source: Dye et al. (2018)

During the final Dean's Index evaluation (IA3), linear weighted kappa scores for inter-examiner agreement between each examiner and the reference examiner ranged from 0.43 to 0.69 and agreement on the diagnosis of apparent fluorosis (Dean's Index scores 'very mild' to 'moderate') ranged from 0.68 to 0.77 (unweighted kappa). For the TF Index during IA3, linear weighted kappa scores for inter-examiner agreement between each examiner and the reference examiner ranged from 0.61 to 0.77 and diagnosis of apparent fluorosis (TF scores 3-8) ranged from 0.67 to 0.89 (unweighted). Importantly, the study found that including a clinical training and assessment component did not result in improved performance when assessing fluorosis from digital photographs. For the TF Index in particular, examiner agreement with the reference examiner was found to decline when the clinical training and assessment were undertaken. However, agreement with the

reference examiners was found to improve subsequently on the final evaluation of digital photographs (IA3).

The authors concluded that although providing examiners with some theoretical background and the criteria to be used to score fluorosis may be sufficient to facilitate acceptable levels of inter-examiner agreement during scoring, there was a benefit to providing more than one training session, particularly in relation to the TF Index. The addition of a clinical training and calibration component was not thought to provide any additional benefit if the proposed study involved assessment of fluorosis from digital images. Recruiting examiners with previous experience of assessing fluorosis was found to offer a slight advantage in performance, however, minimising the number of scorers was suggested to improve inter-examiner agreement.

2.8 Aesthetic impact of dental fluorosis

There is apparently no minimum threshold for fluoride intake from water that will eliminate the occurrence of dental fluorosis (Fejerskov et al. 1990). In the context of a CWF programme, this means that a proportion of the population will inevitably develop some degree of dental fluorosis. While severe fluorosis, characterised by post eruptive enamel breakdown, has both a functional and aesthetic impact (National Research Council 2006), fluorosis associated with exposure to optimally fluoridated drinking water is generally of low severity, with a potential impact on aesthetics rather than function.

From a public health perspective, it is important to monitor the prevalence and severity of fluorosis in populations with CWF programmes. Identifying the cut point for fluorosis of aesthetic concern is challenging. Aesthetic perceptions of dental fluorosis vary 1) across different populations and cultures 2) according to the person making the judgment (e.g.,

the affected individual, the parent, a dental professional) 3) according to the attractiveness of the affected individual's dentition and facial features (National Research Council 2006).

A review by Chankanka et al. (2010) assessed the impact of dental fluorosis on aesthetics and OHRQoL. While results of older included studies regarding aesthetic perceptions of dental fluorosis produced varying results, ratings of acceptability or satisfaction tended to decline as fluorosis severity increased. More recent, higher quality studies of the impact of dental fluorosis on OHRQoL found that 'very mild' and 'mild' fluorosis did not impact negatively on OHRQoL, while 'severe' fluorosis was consistently found to have a negative impact.

Browne et al. (2008) conducted a study whereby Irish 14- to 15-year-olds rated the appearance of photographs of permanent maxillary incisors in a 'template smile' depicting one of the following: TF 0 to TF 3, very white (bleached) teeth, a demarcated opacity and dental caries. The 150 adolescents rated the photograph of the very white teeth as the most aesthetically pleasing and the dental caries photograph as the least aesthetically pleasing. Photographs of TF 0, TF 1 and TF 2 were rated similarly. Photographs of TF 3 and the demarcated opacity were also rated similarly and as less aesthetically pleasing than TF 0, TF 1 and TF 2 ($P < 0.002$). Thus, it was concluded that TF 3 was the break point at which fluorosis was aesthetically objectionable to this group of Irish adolescents.

Three previous studies (included in the Chankanka review (Chankanka et al. 2010)) evaluating aesthetic perceptions of fluorosis among children and adolescents (Hawley et al. 1996; Do and Spencer 2007a) and among university students, parents, public servants and dentists (Riordan 1993b) also identified TF 3 as the level where dental fluorosis became aesthetically unacceptable. Interestingly, two of the studies conducted in Australia (Do and Spencer 2007a) and the UK (Hawley et al. 1996) found TF 2 to be more

aesthetically pleasing than normal enamel among 8- to 14-year-olds, likely due to the whitening effect of the mildest forms of fluorosis on the teeth. The other study, conducted in Australia (Riordan 1993b) found that agreement with the statement that the teeth were pleasing declined as the TF score increased from TF 0, with some concern expressed regarding TF 2.

A larger study (McGrady et al. 2012a) with a similar design to Browne et al. (2008) conducted in fluoridated and non-fluoridated areas of the UK elicited the preferences of 1,553 11- to 13-year-olds in relation to 10 images of maxillary incisors with a variety of dental conditions overlayed onto a common base image. The conditions depicted on the images were similar to those used in the study by Browne (2008), but with the omission of TF 0, and the addition of an image of teeth shade A1, TF 4, a large demarcated opacity on both central incisors and shade A1 with a chipped incisal edge. Like the Irish study, the highest preference was for the very white teeth and the teeth with shade A1 and images with caries and large, demarcated opacities were the lowest rated images. TF 1 was ranked favourably by participants in both fluoridated and non-fluoridated areas. However, there was little difference between the rankings for the remaining images; as the TF score increased from TF 2 to TF 4, the image ratings declined. Lastly, children in the fluoridated area tended to rank images of fluorosis more favourably than those in the non-fluoridated area.

Pretty et al. (2016) reported that the proportion of 11- to 14-year-old city dwelling English children expressing dissatisfaction with the appearance of their teeth was the same among children living in fluoridated and non-fluoridated cities. However, as caries levels were higher among children without CWF, it was thought that the reasons for dissatisfaction might differ among those with CWF and those without.

Overall, there is agreement that Dean's 'moderate' or greater fluorosis or TF 3 or greater are likely to be of aesthetic concern. While some cases of 'mild' fluorosis or TF 2 may not be aesthetically pleasing, a proportion of these may improve the appearance of the teeth by making them appear whiter. The prevalence of Dean's 'moderate' or greater fluorosis among populations with lifetime exposure to CWF and widespread use of fluoride toothpaste is low. The NSSCOH 2002 reported a prevalence of 2 % 'moderate' or greater fluorosis (whole mouth score, no drying of the teeth) among 15-year-olds with lifetime exposure to CWF at a concentration of 0.8 to 1.0 ppm (Whelton et al. 2006). Prevalence of 'moderate' or greater fluorosis (maxillary incisors, scored after drying with cotton wool rolls) was 1% and 3% among 11- to 14-year-olds lifetime residents of fluoridated Newcastle and Birmingham, respectively (Pretty et al. 2016).

The benefits of CWF for caries prevention are considered to outweigh the risk of a small proportion of the population developing dental fluorosis of aesthetic concern. A study of 7,686 North Carolina schoolchildren found that while dental caries impacted negatively on child perceived and parent reported OHRQoL, dental fluorosis had little or no impact on any of the OHRQoL measures (Onoriobe et al. 2014). Furthermore, there are indications that the severity of dental fluorosis may reduce over time (Do et al. 2016; Curtis et al. 2020) due to attrition and abrasion and also possibly influenced by post eruptive changes in the enamel caused by uptake of minerals and protein from saliva (Aoba and Fejerskov 2002).

2.9 Declining prevalence of dental caries

At the 'First International Conference on the Declining Prevalence of Dental Caries' held in the U.S in June 1982, investigators from several countries in the Western World including the U.S, the U.K, Ireland, Denmark, The Netherlands, Norway, Sweden and

New Zealand presented research in support of the declining prevalence of dental caries in countries with and without CWF and oral health programmes in place (Glass 1982). For example, the mean DMFT of English 12-year-olds, living in a non-fluoridated area (Devon) reduced from 5.32 in 1971 to 2.70 in 1981 with a corresponding increase in the percentage caries-free from 5% in 1971 to 22% in 1981 (Anderson et al. 1982).

Subsequent publications provided further support for this decline in the U.S (Brunelle and Carlos 1990; Beltrán-Aguilar et al. 2005) and in Europe (Marthaler 2004; Demertzi et al. 2006). There was widespread agreement that these improvements could be attributed in large part to increased exposure to fluoride, particularly in fluoride toothpaste and through CWF programmes (Glass 1982; Brunelle and Carlos 1990; Bratthall et al. 1996; Petersson and Bratthall 1996; Marthaler 2004). Acknowledging the contribution of CWF to the decline in dental caries in the U.S., the CDC listed fluoridation of drinking water among the ten great public health achievements of the twentieth century (Centers for Disease Control and Prevention 1999a; 1999b).

2.9.1 Effectiveness of fluoride for preventing dental caries

There is a substantial body of evidence supporting the effectiveness of various fluoride vehicles including CWF, fluoride toothpaste, fluoride mouthrinse and professionally applied topical fluorides such as fluoride varnish and gel for preventing and controlling dental caries. The effectiveness of topical fluoride in mouthrinse (Marinho et al. 2016), varnish (Marinho et al. 2013) and gel (Marinho et al. 2015), combinations of topical fluorides (Marinho et al. 2004a) and their comparative effectiveness (i.e., one topical fluoride versus another) (Marinho et al. 2004b) were comprehensively reviewed in a series of Cochrane systematic reviews and will not be discussed further in this section. Evidence from systematic reviews of the effectiveness of CWF and fluoride toothpaste for preventing dental caries is summarised in Sections 2.9.1.1 and 2.9.1.2, respectively.

2.9.1.1 Community water fluoridation

2.9.1.1.1 Extent of CWF programmes

In 2012, 380 million people worldwide were served by CWF schemes (The British Fluoridation Society 2012). In Europe around 13.5 million people had CWF, including 6 million in the UK, 4.2 million in Spain, 3.3 million in Ireland and 300,000 in Serbia (The British Fluoridation Society 2012). Many other countries including the U.S., Canada, Brazil and Australia have CWF programmes. In 2016, just over 190 million people in the U.S. were served by CWF schemes (Centers for Disease Control and Prevention 2016). At this time just over 11 million people in the U.S had access to naturally fluoridated water at or above the optimum level for oral health. Taken together, 62% of the U.S population had fluoridated water.

2.9.1.1.2 Effectiveness of CWF for preventing dental caries

Evidence from several systematic reviews support CWF as an effective caries preventive strategy, beneficial for the primary and permanent dentitions and across the life course (McDonagh et al. 2000; Truman et al. 2002; Griffin et al. 2007; Rugg-Gunn and Do 2012; Iheozor-Ejiofor et al. 2015; Jack et al. 2016).

In 2000, the NHS Centre for Reviews and Dissemination at the University of York published a systematic review of water fluoridation commonly referred to as the 'York Review' (McDonagh et al. 2000). Based on 26 studies of moderate quality, the reviewers concluded that water fluoridation was effective for preventing dental caries in primary and permanent teeth. For studies in which CWF was initiated, there was an increase in the proportion of children caries free (median increase 15%, IQR [5%, 22%]) and a reduction in mean dmft/DMFT score (median 2.25 teeth, IQR 1.28, 3.63 teeth). Several

of the included studies evaluating the effect of cessation of water fluoridation on dental caries indicated an increase in caries prevalence following cessation.

Notably, the York Review excluded well conducted cross-sectional studies from the assessment of the effectiveness of water fluoridation for preventing dental caries, a decision for which the review was criticised (Downer 2007). In justifying this decision, the authors of the York Review contended that cross-sectional studies were not of an appropriate design to evaluate the effectiveness of CWF because they only show differences at one point in time, and they argued that it was not possible to tell if the differences in caries had always existed or were due to water fluoridation.

Subsequent systematic reviews on the same topic by Truman et al. (2002), Griffin et al. (2007) and Rugg-Gunn and Do (2012) all included cross-sectional studies. Based on 21 studies of varying study design, Truman et al. (2002) concluded that the 'preponderance' of evidence supported the effectiveness of CWF. Griffin et al. (2007) reported on the effectiveness of CWF for preventing dental caries in adults. Based on five studies published after 1979, a prevented fraction of 27% (95% CI, [19%, 34%]) was reported. Rugg-Gunn and Do (2012) reviewed the literature from 1990 to 2010 and concluded that although percent caries reductions were less than in studies conducted prior to 1990, reductions in caries associated with CWF were still substantial. The reviewers noted that almost all studies were cross-sectional with a concurrent control group and that methods of controlling for confounding were greatly improved in these more recent studies.

In 2015, the Cochrane Oral Health Group published a systematic review of water fluoridation (Iheozor-Ejiofor et al. 2015). The aim of the review was to update the York Review published 15 years previously and therefore similar criteria for including and excluding studies were employed, with exclusion of cross-sectional studies of the caries-preventive effectiveness of CWF. With few CWF programmes being initiated or stopped

in recent decades, most of the contemporary evidence for the effectiveness of CWF for preventing dental caries comes from studies that monitor the effectiveness of existing programmes. Thus, most contemporary studies for surveillance of existing CWF programmes are cross-sectional in design. This Cochrane review was widely criticised for these restrictive inclusion criteria and for several other issues in relation to the conduct of the review (Department of Health and Human Services 2015; Rugg-Gunn et al. 2016).

With the exclusion of contemporary cross-sectional studies, included studies of the effectiveness of CWF for preventing dental caries in the Cochrane review of water fluoridation were essentially the same as those included in the York Review. Based on these studies, the reviewers reported that initiation of water fluoridation was associated with a 35% reduction in dental caries experience in primary teeth and a 26% reduction in dental caries experience in permanent teeth. They reported an increase in the percentage caries-free of 15% in primary teeth and 14% in permanent teeth. However, the reviewers noted that most of the studies were conducted before 1975, pre-dating the introduction of fluoride toothpaste and were at high risk of bias.

In 2016, the National Health and Medical Research Council (NHMRC) in Australia, published "Health Effects of Water Fluoridation" (Jack et al. 2016) which updated their 2007 Systematic Review of the Efficacy and Safety of Fluoridation (National Health and Medical Research Council 2007). The NHMRC reviewed the dental and other health effects of water fluoridation. They included an overview of reviews on the effects of water fluoridation on dental caries and a systematic review of recent primary research studies of the effectiveness of water fluoridation for preventing dental caries, not identified by the existing reviews. The NHMRC were less restrictive than the Cochrane review of water fluoridation regarding study design and included comparative studies of any design. They acknowledged the likelihood that evidence of the effects of CWF available to decision-

makers will always come from observational studies and that some of these studies will be of low methodological quality.

The reviewers concluded that water fluoridation as implemented in Australia (0.6 to 1.1 ppm fluoride depending on climate) improves the oral health of children and adults.

2.9.1.1.3 Impact of CWF cessation on dental caries

A systematic review of the impact of CWF cessation on dental caries evaluated evidence from 15 instances of CWF cessation in 13 countries between 1956 and 2003 (McLaren and Singhal 2016). The methodological quality of the studies was mixed as were the study results. Of 12 reports that directly assessed the impact of CWF cessation on dental caries in children and young adults (included in the qualitative synthesis), nine were judged to be of at least moderate methodological quality. Of these nine studies, five found an increase in dental caries post cessation (Lemke et al. 1970; Stephen et al. 1987; Attwood and Blinkhorn 1991; Kalsbeek et al. 1993; Thomas et al. 1995), three reported no increase in dental caries (Künzel and Fischer 2000; Künzel et al. 2000; Seppä et al. 2000) and the results of the remaining study were mixed (Maupomé et al. 2001). It is noteworthy that in the three instances where there was no increase in dental caries post cessation, preventive measures such as provision of fluoride supplements and fissure sealant programmes had been initiated, which may have had an impact on the results. On balance, cessation of CWF appeared to be associated with increases in dental caries, however, the available evidence was conflicting and limited in quantity and quality.

A recently published 7-year follow-up evaluation of school children in Calgary and Edmonton, Canada (McLaren et al. 2021) reported statistically significantly higher dental caries levels in Calgary where CWF had ceased than in Edmonton which was still fluoridated. Dental caries prevalence in primary teeth and mean deft among children with

caries experience were all higher among 7-year-olds born after CWF cessation in Calgary than in Edmonton (prevalence 64.8% vs. 55.1%; mean deft 3.6 vs 2.6; mean deft among children with caries experience 5.5 vs. 4.7).

2.9.1.1.4 Effectiveness of CWF in the context of widespread use of topical fluorides

The York review (McDonagh et al. 2000) demonstrated the effectiveness of CWF in studies conducted after widespread introduction of fluoride toothpaste and other non-water sources of fluoride (after 1974). Although the relevant nine studies were of only moderate quality, they indicated a caries preventive effect for CWF over and above that of fluoride toothpaste and other fluoride vehicles. In a meta regression of data from 116 studies, Marinho et al. (2003a) found no difference in estimates of DMFS prevented fractions for topical fluorides (toothpastes, mouthrinses gels and varnishes) in groups with and without exposure to fluoridated water. This implies that CWF provides an additional benefit in communities with widespread use of topical fluorides such as fluoride toothpaste.

2.9.1.1.5 Effect of CWF on disparities in dental caries

CWF has an advantage over self-applied and professionally applied fluoride modalities in that it reaches all socio-economic (SES) groups, without requiring the active participation of the individuals (O'Mullane et al. 2016). The York review (McDonagh et al. 2000), reported some evidence that effectiveness of CWF was greater among lower SES groups. However, the reviewers recommended caution in interpreting these results because they were based on a small number of heterogeneous studies of low methodological quality. Based on three studies at high risk of bias, the Cochrane systematic review of water fluoridation (Iheozor-Ejiofor et al. 2015) was unable to draw any conclusion about the effect of CWF on disparities in dental caries according to social class. The NHMRC

review (Jack et al. 2016) included three ecological studies on this topic that were not included in previous reviews, one of acceptable quality (Public Health England 2014) and two of low quality (McGrady et al. 2012b; Lalloo et al. 2015). The reviewers concluded that the studies provided limited evidence that CWF reduces disparities in dental caries across social class.

2.9.1.2 Fluoride toothpaste

2.9.1.2.1 Effectiveness of fluoride toothpaste for preventing dental caries in permanent teeth

Widespread use of fluoride toothpaste is credited with being instrumental in bringing about the reductions in dental caries apparent since the late 1970s (Bratthall et al. 1996). According to Burt (1998), use of fluoride toothpaste is "close to an ideal public health method, in that its use is convenient, inexpensive, culturally approved and widespread".

A Cochrane systematic review of fluoride toothpastes for preventing dental caries in children and adolescents reported a D(M)FS pooled prevented fraction (PF) of 24% (95% CI [21%, 28%], $P < 0.0001$) (Marinho et al. 2003b). The pooled PF was based on the results of 70 randomised or quasi-randomised controlled trials comparing fluoride toothpaste at any concentration, frequency of application, amount or duration of use with placebo (non-fluoride) toothpaste. The results suggested a substantial caries preventive benefit for fluoride toothpaste in permanent teeth of children and adolescents. Meta regression revealed that the PF was higher with increased fluoride concentration, higher caries levels at baseline and with increased frequency of toothbrushing. In addition, unsupervised toothbrushing was found to be less effective than supervised toothbrushing. (PF -10%, 95% CI [-17%, -4%], $P = 0.001$). The prevented fraction for fluoride toothpaste use was similar in studies conducted in fluoridated and non-fluoridated areas suggesting that fluoride toothpaste provided a benefit in addition to that provided by CWF.

A systematic review by Twetman et al. (2003), published in the same year as the Cochrane systematic review reported similar findings. A PF of 25% (95% CI [20%, 28%]), based on the results of 26 randomised or controlled clinical trials comparing fluoride toothpaste with placebo, provided strong evidence in support of the effectiveness of daily fluoride toothpaste use for preventing dental caries in the young permanent dentition. Higher concentration fluoride toothpaste (1500 ppm F) was reported to be more effective than 1000 ppm fluoride toothpaste and supervised toothbrushing to be more effective than unsupervised toothbrushing.

A Cochrane systematic review of fluoride toothpastes of different concentrations for preventing dental caries (Walsh et al. 2019) reported results from a network meta-analysis of 81 studies including comparisons of seven fluoride toothpaste concentrations. The reviewers reported that fluoride toothpaste of 1000 to 1250 ppm fluoride (High certainty, 55 studies, SMD -0.28, 95% CI [-0.32 to -0.25]) and 1450-1500 ppm fluoride (Moderate certainty, four studies, SMD -0.36, 95% CI [-0.43 to -0.29]) were effective at reducing the D(M)FS increment in children and adolescents compared with non-fluoride toothpaste. Similarly, the authors reported moderate certainty evidence that fluoride toothpaste of 1000 or 1100 ppm fluoride reduced DMFS increment in permanent teeth of adults compared with non-fluoride toothpaste (three studies, 2,162 participants, MD -0.53, 95% CI [-1.02 to -0.04]). Although the reviewers did not draw any conclusions regarding the relative effectiveness of specific fluoride toothpaste concentrations, they did report a strong dose response relationship between fluoride toothpaste concentration and the caries preventive effect in permanent teeth of children and adolescents. The magnitude of the effect estimate was noted to increase the greater the difference between the reference (lower concentration or no-fluoride) and the higher fluoride concentration toothpastes.

2.9.1.2.2 Effectiveness of fluoride toothpaste for preventing dental caries in primary teeth

All the systematic reviews mentioned previously (Marinho et al. 2003b; Twetman et al. 2003; Walsh et al. 2019) noted the lack of high-quality studies of the effectiveness of fluoride toothpaste in the primary dentition. Furthermore, fluoride concentration is an important consideration when assessing effectiveness in the primary dentition because young children tend to swallow much of the toothpaste placed on the brush (Bentley et al. 1999; Cochran et al. 2004b) increasing the risk of developing dental fluorosis (Wong et al. 2010).

The Cochrane systematic review by Walsh et al. (2019) included eight studies of the caries preventive effect of fluoride toothpaste of various concentrations in primary teeth. There was moderate certainty evidence from one study (998 participants) (Fan et al. 2008) that 1500 ppm fluoride toothpaste was effective at reducing the dmfs increment in primary teeth compared with non-fluoride toothpaste (MD -1.86, 95% CI [-2.51, -1.21]). The study by Davies et al. (2002) provided moderate certainty evidence that 1450 ppm fluoride toothpaste was more effective than 440 ppm fluoride toothpaste at reducing both the dmft increment (2,362 participants, MD -0.34, 95% CI [-0.59, -0.09]) and the proportion of children developing new caries (2,362 participants, RR 0.87, 95% CI [0.81, 0.94]). There was moderate certainty evidence from two studies (Winter et al. 1989; Vilhena et al. 2010) of no difference in the effectiveness of 1055-1100 ppm fluoride toothpaste and 500-550 ppm fluoride toothpaste (MD -0.05, 95% CI -0.38, 0.28). The certainty of the remaining evidence in relation to the effect of fluoride toothpaste in the primary dentition was judged to be low. Walsh and colleagues highlighted the need for further studies with head-to-head comparisons of the effectiveness of lower versus higher fluoride concentration toothpaste in the primary dentition.

This Cochrane systematic review by Walsh and colleagues (2019) provided the highest quality summary of the effectiveness of fluoride toothpaste in the primary dentition and the most up to date. Other recent systematic reviews of the effectiveness of fluoride toothpaste in the primary dentition and of the relative effectiveness of low versus higher fluoride concentration toothpastes in the primary dentition (Santos et al. 2013; Wright et al. 2014) reviewed many of the same studies as the Cochrane review but employed less rigorous methods. These systematic reviews were mentioned here for completeness but will not be discussed further.

In conclusion, there is little doubt regarding the effectiveness of toothpaste with at least 1000 ppm fluoride for preventing dental caries in populations with and without CWF and exposure to other fluoride sources. However, evidence from head-to-head comparisons of toothpastes with different fluoride concentrations, particularly low (< 1000 ppm F) compared with standard concentration (≥ 1000 ppm F) toothpastes is lacking. High quality studies assessing the risk benefit of using toothpaste with different fluoride concentrations in the primary dentition are needed.

2.10 Increasing prevalence of dental fluorosis

When CWF was first introduced in the U.S., water was the predominant source of fluoride in the population. In Dean's 21 Cities Study, conducted in the late 1930s and early 1940s, the range of Dean's Index 'very mild' or greater among 12- to 14-year-olds in the four communities with a water fluoride concentration in the range 0.9 to 1.2 ppm was 12% to 33% (Dean et al. 1942). Among the 10 communities with ≤ 0.3 ppm water fluoride, the prevalence of Dean's 'very mild' or greater ranged from 0% to 2.2%.

By the 1980s, an increased prevalence of fluorosis was reported in some communities in the U.S. (Leverett 1986; Szpunar and Burt 1988; Beltran-Aguilar et al. 2002). Comparing

a sample of 1986-87 NIDR survey data for 12- to 14-year-olds with data from Dean's 21 Cities study, Beltran-Aguilar (2002) reported an increase in fluorosis prevalence among children with optimal water fluoride (OF, adjusted to between 0.7 and 1.2 ppm) and suboptimal water fluoride (SF, < 0.7 ppm). Prevalence of Dean's 'very mild' or greater fluorosis in the 1986-87 sample was 26% among children with OF and 16% among children with SF. Based on North American studies published in the 1980s, Pendrys and Stamm (1990) concluded that while fluorosis appeared to have increased among children living in optimally fluoridated areas, the proportionate increase in fluorosis was higher among North American children living in non-fluoridated areas. This finding indicated the impact of increasing exposure to fluoride in North American children from non-water sources such as fluoride supplements and fluoride toothpaste.

Further increases in fluorosis prevalence and severity were subsequently reported in the U.S. (Rozier 1999; Beltrán-Aguilar et al. 2005; Beltran-Aguilar et al. 2010; Wiener et al. 2018). In 12- to 15-year-olds, prevalence of Dean's 'very mild' or greater fluorosis increased from 22.6% in 1986-87 to 40.7% in 1999-2004 (Beltran-Aguilar et al. 2010). Subsequently, an increase in Dean's 'very mild' or greater fluorosis was reported among 16- to 17-year-olds between NHANES 2001-02 (29.7%) and 2011-12 (61.3%) (Wiener et al. 2018). Increases in fluorosis prevalence and severity were reported in other parts of the world during the 1990s and early 2000s including in South and Western Australia (Riordan 1993a; Whelton et al. 2019) and in Ireland (Whelton et al. 2006).

While there is agreement regarding the increase in fluorosis prevalence and severity with exposure to fluoride from multiple sources, particularly among children without CWF, the presence and magnitude of recently reported increases in fluorosis prevalence is a subject of some debate. A recent analysis of NHANES data by Neurath et al. (2019) reported a large increase in fluorosis in in 12- to 15-year-olds in the U.S. in 2011-12

compared with 1986-87 and 1999-2004 surveys. Prevalence of 'moderate' fluorosis was reported to have increased from 3.3% in 1999-2004 to 27.9% in 2011-12 and prevalence of 'severe' fluorosis from 0.4% to 2.6%. The authors concluded that the increase in 2011-12 was consistent with exposure to a combination of fluoridated water, infant formula reconstituted with fluoridated water and ingestion of fluoride toothpaste. However, a subsequent report by the Centers for Disease Control and Prevention (CDC) (Department of Health and Human Services 2019) indicated that the magnitude of these increases was not biologically plausible and suggested that there may have been changes over time in the way the examiners evaluated fluorosis, affecting the validity of the fluorosis data in NHANES (for a description of the CDC report see Section 2.7.4). These findings cast doubt on the validity of the reported increase in fluorosis described by Neurath (Neurath et al. 2019) and others (Wiener et al. 2018) and have wider implications for analyses of fluorosis trends based on analysis of NHANES data described previously in this section.

2.10.1 Risk factors for dental fluorosis

With the availability of fluoride from multiple sources, a balance must be struck between the benefits of using fluorides for caries prevention and the risk of developing dental fluorosis of aesthetic concern. The risk of fluorosis in permanent teeth is due to excessive ingestion and absorption of fluoride during critical periods of tooth formation. This risk period is considered to extend from birth to age 6 to 8 years for the entire permanent dentition excluding the third permanent molars (Pendrys 1990; 1999a). For the aesthetically important maxillary central incisors, this risk period is considered to extend through the first 2 to 3 years of life (Buzalaf and Levy 2011).

In relation to the risk of fluorosis in infants and young children, total fluoride intake from all sources must be considered. Accurate measurement of total fluoride intake is

challenging and it is not yet known the level of fluoride intake that causes dental fluorosis (Hong et al. 2006b). The empirical evidence provided by Dean and colleagues in the 1930s and 1940s formed the basis for an 'optimal' level of fluoride intake which was closely linked to the average dietary intake of fluoride at a water fluoride level of 1 ppm. This 'optimal' fluoride intake of 0.05 mg F/kg body weight per day is widely accepted by health authorities throughout the world. The European Food Safety Authority (EFSA) and many other health authorities worldwide have set 0.05 mg F/kg body weight per day as the level for Adequate Intake (AI) of fluoride in children and adults (Mejàre 2018). According to the EFSA this is the level at which the "caries preventive effect approached its maximum whilst the risk of dental fluorosis approached its minimum" (EFSA NDA Panel 2013).

The EFSA considered 'moderate' fluorosis as the level of fluorosis that was an adverse effect. To minimise the occurrence of 'moderate' fluorosis, the EFSA set the Tolerable Upper Intake Level (UL, the maximum amount of fluoride that can be consumed safely over a long period of time) for fluoride in children aged 1 to 8 years at 0.1 mg F/kg body weight per day (EFSA 2005). This threshold had been previously adopted by the U.S. Institute of Medicine (Institute of Medicine (IOM) 1997).

A review of studies reporting total fluoride intake found that in many of the studies, the 'optimal' level of 0.05 mg F/kg body weight per day was exceeded (Clarkson et al. 2010). Spencer et al (2018) reported that a large proportion of children drinking water fluoridated at 1 ppm have a total fluoride intake exceeding the AI and that reasonable proportions of these children have a fluoride intake that exceeds the UL. Spencer et al. (2018) pointed to the 'Exceedance Conundrum'; that despite exceeding these thresholds, the prevalence of 'moderate' and 'severe' fluorosis remained very low in these

populations. Therefore, it has been suggested that the AI and UL values for fluoride intake in children, could safely be revised upwards (Rugg-Gunn 2018; Spencer et al. 2018).

The findings of well conducted cohort, case control and cross-sectional studies provide evidence of the association between exposure to fluoride via different fluoride vehicles and dental fluorosis. Four major risk factors for fluorosis are consistently identified in the literature: CWF (McDonagh et al. 2000; Iheozor-Ejiofor et al. 2015; Jack et al. 2016), fluoride toothpaste (Wong et al. 2010), infant formula (Hujoel et al. 2009) and fluoride supplements (Ismail and Hasson 2008). These risk factors are described in detail in the following sections 2.10.1.1 to 2.10.1.4.

2.10.1.1 Community water fluoridation

From the earliest days of research into the association between water fluoride concentration and dental caries, it was known that exposure to fluoride during mineralisation of the permanent dentition was associated with dental fluorosis. The York systematic review of public water fluoridation ('York Review') (McDonagh et al. 2000) systematically reviewed adverse outcomes of water fluoridation including dental fluorosis and general health effects. Inclusion criteria for fluorosis studies were less stringent than those employed for the dental caries aspect of the review and included comparative studies of any design. Most of the included studies were cross-sectional in design and their quality was judged to be poor, with the results at risk of observer bias and with failure to control for confounding.

Studies where fluoride was present in water naturally or artificially at any concentration (not higher than 5 ppm) were considered for inclusion. Of the 88 included studies, 20 compared participants with artificially fluoridated water at a range of 0.6 to 1.2 ppm with either low (< 0.3 ppm) or high (4 to 7 ppm) naturally occurring water fluoride. Fourteen

studies did not report whether the study areas were artificially or naturally fluoridated. The remaining 54 studies involved areas with naturally occurring water fluoride.

The authors reported a significant dose response relationship between water fluoride concentration and the proportion of participants with fluorosis (defined as a Dean's Index, TF Index, TSIF or DDE score greater than zero). The prevalence of fluorosis (e.g., Dean's 'questionable' or greater or TF 1 or greater) was estimated to be 48% (95% CI [40%, 57%]) at a water fluoride concentration of 1 ppm and 42% (95% CI [34%, 51%]) at a water fluoride concentration of 0.7 ppm. The cut off used in this review for the prevalence of fluorosis that may be of aesthetic concern of TF 3 or greater (translated by the reviewers to Dean's 'mild' or greater) was informed by the results of the study by Hawley (1996) (described in Section 2.8). Using this cut off, the prevalence of fluorosis of aesthetic concern was estimated to be 12.5% (95% CI [7.0%, 21.5%]) at a water fluoride concentration of 1 ppm and 10% (95% CI [5.0%, 17.9%]) at a water fluoride concentration of 0.7 ppm. Regarding other negative effects of water fluoridation on general health, the quality and quantity of the evidence was noted to be poor. There was no association between water fluoridation and bone fracture or cancer.

In updating the York Review, the Cochrane systematic review of water fluoridation (Iheozor-Ejiofor et al. 2015) used generally the same methods as the York Review but had a narrower remit whereby adverse effects other than dental fluorosis (i.e., general health effects) were not considered. Based on studies of both naturally occurring and artificially adjusted fluoride in water, the Cochrane review re-affirmed that an increase in the fluoride concentration of water supplies was associated with an increased prevalence of fluorosis. This dose-response effect was established in the early studies conducted by Dean and colleagues in the US (Dean and Elvove 1935; 1936; Dean and McKay 1939) and was also shown in the York Review (McDonagh et al. 2000). Based on 40 studies

reporting fluorosis for a water fluoride concentration up to 5 ppm, the Cochrane review estimated that at a concentration of 0.7 ppm water fluoride approximately 12% (95% CI [8%, 17%]) of participants would have fluorosis of aesthetic concern (defined by the reviewers as Dean's Index 'mild' or greater or TF 3 or greater). These studies were deemed to be at high risk of bias.

The 2016 NHMRC (Australian) systematic review of the health effects of water fluoridation (Jack et al. 2016) included a critical appraisal of the evidence on dental fluorosis included in the Cochrane systematic review of water fluoridation and a systematic review of other health effects of water fluoridation. The reviewers reiterated the results of the Cochrane review and noted that all the included studies were at high risk of bias, being observational studies, with a general lack of consideration for potential confounding by other sources of fluoride such as fluoride supplements and toothpaste. Although the Cochrane systematic review (Iheozor-Ejiofor et al. 2015) was well conducted and achieved a high score using AMSTAR, the reviewers outlined several limitations in relation to the fluorosis section of the review and the applicability of the findings to the Australian context. The water fluoride concentrations and fluorosis prevalence in many of the included studies were much higher than those seen in the context of a CWF programme. The cut offs used for fluorosis and for fluorosis of aesthetic concern (the same as those used in the York Review) had the potential to overestimate the 'harm' of fluorosis. Dean's 'mild' fluorosis is not considered to adversely affect aesthetics or to have an impact on OHRQoL (Chankanka et al. 2010). Finally, the applicability of the evaluation of the dose-response relationship between water fluoride concentration and dental fluorosis to the situation in Australia where water is artificially fluoridated at a low concentration (0.6 to 1.1 ppm fluoride depending on climate) was unclear.

The NHMRC systematic review of other health effects of water fluoridation reported limited evidence of no association between the water fluoride concentration used in Australia and IQ in children and adults, delayed tooth eruption, tooth wear, osteosarcoma, Ewing sarcoma, total cancer incidence, hip fracture or Down syndrome. The NHMRC reviewers concluded that water fluoridation as implemented in Australia increases the number of people who experience dental fluorosis but does not appear to be associated with any other significant harm.

2.10.1.2 Fluoride toothpaste

A Cochrane systematic review of topical fluoride as a cause of dental fluorosis (Wong et al. 2010) included 25 studies assessing the relationship between fluoride toothpaste use in children under the age of 6 years and dental fluorosis. The review included two RCTs, one cohort study, six case-control studies and 16 cross-sectional studies. Apart from one RCT (Tavener et al. 2006) and one case-control study (Osuji et al. 1988) at low risk of bias, all the other studies were judged to be at moderate or high risk of bias. Fluorosis was defined as present with a TF Index or TSIF score greater than zero or with a Dean's Index score of 'Questionable' or greater.

Two RCTs conducted in non-fluoridated areas compared fluorosis prevalence following use of low and standard concentration fluoride toothpastes. One RCT (Tavener et al. 2006) comparing toothpaste with 440 ppm fluoride and 1450 ppm fluoride reported a reduction in fluorosis with use of the lower concentration toothpaste (OR 0.59, 95% CI [0.44, 0.79]. The other RCT (Holt et al. 1994) reported a reduction in fluorosis prevalence with use of 550 ppm compared with 1000 ppm fluoride toothpaste (OR 0.75 [0.57, 0.99]).

Two case control studies at low (Osuji et al. 1988) and moderate (Skotowski et al. 1995) risk of bias assessed the effect of commencing toothbrushing with fluoride toothpaste after 24 months of age compared with before. One study (Osuji et al. 1988), conducted

in a fluoridated area reported a statistically significant reduction in fluorosis when toothbrushing commenced after 24 months (OR 0.09, 95% CI [0.04, 0.24]). The other study (Skotowski et al. 1995), conducted in a non-fluoridated area, found no statistically significant difference between the groups (OR 0.70, 95% CI [0.31, 1.60]). Pooled results from five cross-sectional studies conducted in a mix of fluoridated and non-fluoridated areas found no statistically significant difference between commencing toothbrushing with fluoride toothpaste before or after 24 months of age (OR 0.92, 95% CI [0.71, 1.18]). Pooled results for five cross-sectional studies in predominantly non fluoridated areas (4 of the 5 studies) indicated a reduction in fluorosis when toothbrushing commenced after 12/14 months compared with before (OR 0.70, 95% CI [0.57, 0.88]).

There was no statistically significant difference in fluorosis prevalence associated with brushing twice a day or more often compared with once a day or less often (three cross-sectional studies, OR 0.88, 95% CI [0.71, 1.08]). Similarly, there was no statistically significant difference in fluorosis prevalence with use of a small compared with a medium or large amount of toothpaste (three cross-sectional studies, OR 0.92, 95% CI [0.67, 1.28]).

The reviewers concluded that there was weak unreliable evidence that starting to use fluoride toothpaste before 12 months of age was associated with increased fluorosis. They suggested that if the risk of developing fluorosis is a concern, fluoride toothpaste with a concentration less than 1000 ppm could be considered for children under 6 years of age. They emphasised that decisions regarding fluoride toothpaste use in young children should include 'balanced consideration' of both the benefits and the risks (Wong et al. 2010).

While this systematic review (Wong et al. 2010) was conducted according to the rigorous Cochrane methodology, some limitations were identified. That the case definition of

fluorosis included scores of Dean's Index 'questionable' or greater and TF 1 or greater limits the applicability of the results to public health and the development of oral health policy. Furthermore, of the 25 included studies, evidence from only 13 studies contributed data to the meta-analyses. Although the results of the remaining 13 studies with limited or missing data not included in the meta-analysis were summarised in a table, this evidence does not appear to have been formally considered as part of the review or its conclusions. Of note, several studies that reported fluorosis measured using the Fluorosis Risk Index (Pendrys and Katz 1989; Pendrys et al. 1994; 1996; Pendrys and Katz 1998; Franzman et al. 2006) were not included in the analysis because the surface level scores could not be represented in the meta-analyses.

A systematic review published after the Cochrane systematic review assessed the efficacy and safety of fluoride toothpaste in children younger than 6 years of age (Wright et al. 2014). This systematic review identified two additional studies (Vallejos-Sánchez et al. 2006; Pendrys et al. 2010) and reached generally the same conclusions as the Cochrane Review.

Another systematic review of the effect of low and standard concentration fluoride toothpastes on dental caries and fluorosis (Santos et al. 2013) pooled the results of the RCTs by Tavener (2006) and Holt (1994), which were both conducted in non-fluoridated areas. Based on the pooled RR for fluorosis at TF ≥ 3 (RR 0.32, 95% CI [0.03, 2.97]), the reviewers concluded that low fluoride toothpastes did not reduce the risk of aesthetically objectionable fluorosis in upper permanent anterior teeth. This interpretation of the evidence was challenged, and it was suggested that evidence of the relative effect of low and standard concentration fluoride toothpastes on risk of fluorosis was unclear and that there was a lack of evidence from fluoridated areas (Buzalaf et al. 2013).

2.10.1.3 Infant formula

Whereas the fluoride concentration of breastmilk and cow's milk is low (Koparal et al. 2000), infant formula powders and ready to feed (RTF) infant formula can contain appreciable levels of fluoride because of the manufacturing process (Ericsson and Ribelius 1971; Singer and Ophaug 1979; Silva and Reynolds 1996). Furthermore, fluoride is introduced into the infant formula through reconstituting powdered infant formula with fluoridated water. Following recognition of the variable and sometimes high concentration of fluoride in infant formula in the U.S. (Ericsson and Ribelius 1971; Singer and Ophaug 1979), manufacturers in the U.S responded in 1979 by reducing the fluoride concentration of RTF and powdered formula (Feigal 1983; Levy 1994). In the late 1990s, industry in Australia also responded to calls to reduce the fluoride concentration in infant formula (Riordan 2002; Do and Spencer 2007b; Clifford et al. 2009). A recent analysis of the fluoride concentration of RTF and powdered infant formula brands available in the U.K, reconstituted with non-fluoridated water found a low concentration of fluoride and a corresponding low contribution towards total daily fluoride intake (Bussell et al. 2016). With the reduction in the intrinsic fluoride concentration of the formula, fluoride intake now depends very much on the fluoride concentration of the water used for their reconstitution (Zohoori et al. 2012; Bussell et al. 2016).

A systematic review assessing the effect of infant feeding on dental fluorosis (Hujoel et al. 2009) reported that infant formula consumption during infancy can increase the risk of developing a detectable level of dental fluorosis in permanent teeth. In the included studies, dental fluorosis was measured using a variety of different indices and with different case definitions for fluorosis. In this review 'fluorosis' referred to 'the presence of at least some detectable level of enamel fluorosis' according to any index or case definition. Based on the results of 17 studies, the odds of fluorosis were 80% higher

among children who ingested infant formula compared with those who ingested breastmilk or cow's milk (OR 1.8, 95% CI [1.4, 2.3]).

The authors noted the presence of statistically significant heterogeneity, likely reflecting differences between the studies regarding the use of formula (amount, frequency, and duration of use), the fluoride concentration of the formula and differences in exposure to other sources of fluoride. A meta regression indicated that an increase in water fluoride of 1 ppm was associated with a 67% increase in the odds of fluorosis associated with infant formula (OR 1.67%, 95% CI [1.18, 2.36]).

It was considered likely by the reviewers that the association between infant formula and fluorosis was overstated because there was evidence of publication bias, where studies that found a statistically significant association were more likely to have been published. In addition, many of the studies failed to control for other important sources of fluoride exposure in infancy and early childhood such as fluoride toothpaste and supplement use.

In Ireland, the risk of 'moderate' dental fluorosis in the permanent dentition from exposure to fluoride in infant formula reconstituted with fluoridated water (average yearly fluoride concentration below 1.03 ppm F) is estimated to be very low (Anderson et al. 2004; FSAI 2018), and it is considered safe for powdered infant formula to be reconstituted with fluoridated water (Department of Health and Children 2002). In Australia, formula is considered safe for consumption by infants when reconstituted with fluoridated or non-fluoridated water (Australian Research Centre for Population Oral Health 2006). The ADA "Evidence-based clinical recommendations regarding fluoride intake from reconstituted infant formula and fluorosis" (Berg et al. 2011) were informed by the systematic review of the effect of infant feeding on dental fluorosis (Hujoel et al. 2009), a study by Spencer (Spencer and Do 2008) and results from the Iowa Fluoride Study (Levy et al. 2010). The ADA recommended that where parents or caregivers of

infants have opted for infant formula as the main source of nutrition, continued use of formula reconstituted with fluoridated water can be suggested while being cognisant of the potential risk of dental fluorosis development. Where the potential risk of dental fluorosis development is of concern, RTF formula, powered or liquid concentrate formula reconstituted with water that is fluoride free or low in fluoride were suggested (Berg et al. 2011).

2.10.1.4 Fluoride supplements

Fluoride supplements in the form of fluoride tablets and drops were initially introduced as a caries preventive measure for individuals without CWF. The idea was that the systemic and topical delivery of 1 mg fluoride would approximate a child's fluoride intake from drinking optimally fluoridated water (Whelton et al. 2019). Although effective at preventing caries in the permanent dentition, the effectiveness of fluoride tablets, drops and lozenges for preventing caries in the primary dentition is unclear (Ismail and Hasson 2008; Tubert-Jeannin et al. 2011). Use of fluoride supplements in the early years of life increases the risk of 'mild' to 'moderate' fluorosis with the first year of life being the most important (Ismail and Hasson 2008). Indeed, use of fluoride supplements in non-fluoridated areas of the U.S. played a role in the increased prevalence of fluorosis recorded in non-fluoridated areas in the 1980s and 1990s (Pendrys and Katz 1989; Pendrys et al. 1996).

Given that the main effect of fluoride is topical and post eruptive (Burt 1999; Featherstone 2000; Fejerskov 2004), that the effect of fluoride is maximised when a low concentration is maintained in the oral cavity (Featherstone et al. 1990), and that fluoride supplements increase the risk of dental fluorosis (Ismail and Hasson 2008), continued use of fluoride supplements in young children is difficult to justify. However, fluoride supplements continue to be used for children at high risk of developing caries in many

parts of the world including the U.S, New Zealand and parts of Europe (O'Mullane et al. 2016). While use of fluoride supplements in children with a fluoridated water supply is generally not recommended, the minimum age for commencing fluoride supplement use and the dosage schedules vary considerably across jurisdictions (O'Mullane et al. 2016). In many other countries including those with CWF programmes, use of fluoride supplements has been superseded by discretionary topical fluoride vehicles such as fluoride toothpaste. For example, in Australia and Ireland, use of fluoride supplementation was no longer recommended by the end of the 20th century (Department of Health and Children 2002; Australian Research Centre for Population Oral Health 2006).

2.11 Fluoride and oral health in Ireland

2.11.1 Rationale for introducing CWF in Ireland

Pre-fluoridation baseline studies conducted in Ireland between 1961 and 1963 provided a strong rationale for the initiation of CWF in Ireland. Five-year-olds had on average 5.6 decayed (cavitated) missing or filled primary teeth ($d_{3c}mft$) and 12-year-olds had on average 4.7 decayed (cavitated), missing or filled permanent teeth ($D_{3c}MFT$). Cavitated dentinal caries was widespread affecting the primary dentitions of 85% of 5-year-olds and the permanent dentitions of 94% of 12-year-olds (O'Mullane et al. 1986). On initiation of CWF in Ireland in 1964, a fluoride concentration of 0.8 to 1.0 ppm was considered optimal to achieve an acceptable balance between caries prevention and the occurrence of fluorosis. CWF is mandatory in Ireland; local authorities have a statutory obligation to fluoridate public water supplies to within the range of concentrations specified in the legislation (Government of Ireland 1960; 2007).

2.11.2 Trends in dental caries and fluorosis following introduction of CWF

2.11.2.1 Introduction of fluoride toothpaste and other fluoride vehicles

In the first decade of CWF in Ireland, fluoride added to drinking water was the predominant source of fluoride in the population. Local surveys conducted at the time provided early evidence of the effectiveness of CWF for preventing dental caries (Collins and O'Mullane 1970; O'Hickey 1976; O'Hickey and Pigott 1983). From the mid-1970s, other vehicles for delivering fluoride for caries prevention including fluoride toothpaste were introduced in Ireland. Hence from the 1980s onwards, most people with CWF were exposed to fluoride from water and toothpaste. Fluoride toothpaste provides additional caries prevention to that provided by CWF (Marinho et al. 2003b). However, exposure

to fluoride from multiple sources brought about an increase in the risk of developing dental fluorosis.

2.11.2.2 The National Survey of Children's Dental Health 1984

The National Survey of Children's Dental Health in 1984 demonstrated a substantial decline in the prevalence of dental caries in Irish schoolchildren in the 20 years since the introduction of CWF (O'Mullane et al. 1986). The improvements were most pronounced among younger children and among those with lifetime exposure to CWF (Table 2.8).

Table 2.8: Percentage of 5-year-olds (primary teeth) and 12-year-olds (permanent teeth) with no known dental caries experience and mean $d_{3c}mft/D_{3c}MFT$ (cavitated) in 1961-63 and 1984 (All health boards)

	5-year-olds			12-year-olds		
	1961-63	1984		1961-63	1984	
Caries Outcome		Full-CWF	No-CWF		Full-CWF	No-CWF
% caries-free*	15%	52%	38%	6%	23%	15%
Mean $d_{3c}mft/D_{3c}MFT$	5.6	1.8	3.0	4.7	2.6	3.3

Adapted from "Children's Dental Health in Ireland 1984"
* $d_{3c}mft/D_{3C}MFT = 0$

The prevalence of fluorosis recorded clinically using Dean's Index in 1984 was negligible. Among 8-year-old lifetime residents of fluoridated areas 5% had 'questionable' fluorosis and 1% had 'very mild' fluorosis (O'Mullane et al. 1986).

2.11.2.3 The Dental Health Action Plan 1994

In 1994, the Dental Health Action Plan formalised the aims and health objectives of the dental service in Ireland for the first time in the history of the State (Department of Health 1994). Acknowledging the success of CWF for improving oral health, a key part of the Dental Health Action Plan was a commitment to invest in maintaining and expanding the infrastructure needed to fluoridate the public water supplies. There was also a commitment to promote wider use of fluorides, encouraging regular daily use of fluoride toothpaste by the whole population over three years of age.

2.11.2.4 The North South Survey of Children's Oral Health 2002

By 2002, approximately 71% of the population resided in communities served with CWF (Whelton et al. 2004a) and fluoride toothpastes represented 95% of toothpaste sales in Ireland (Arnadóttir et al. 2004). The North South Survey of Children's Oral Health (NSSCOH) 2002 showed an on-going reduction in dental caries levels among 5-, 8-, 12- and 15-year-old lifetime residents in communities with and without CWF (Figures 2.4 and 2.5). Children with lifetime exposure to CWF in 2002 had significantly lower dental caries levels than those without (Whelton et al. 2006).

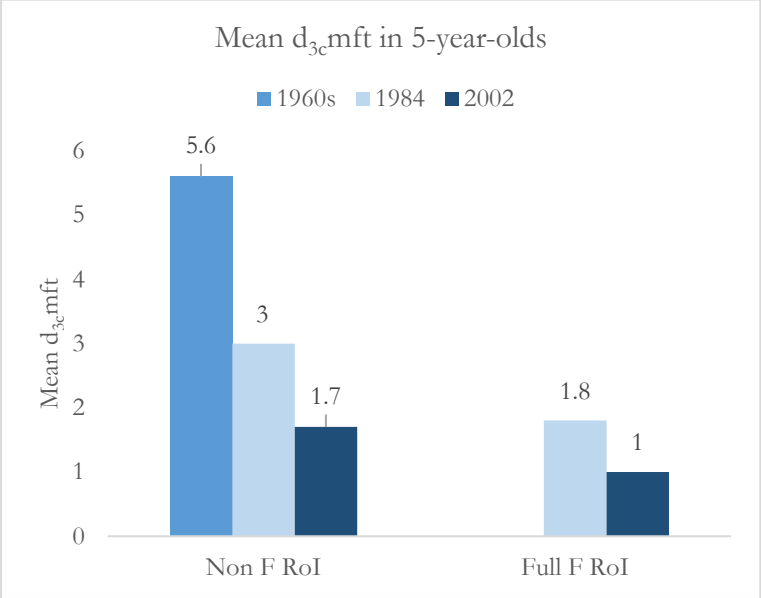


Figure 2.4: Mean d_{3c}mft among 5-year-olds by fluoridation status in 1961-63 (non-fluoridated only), 1984 and 2002

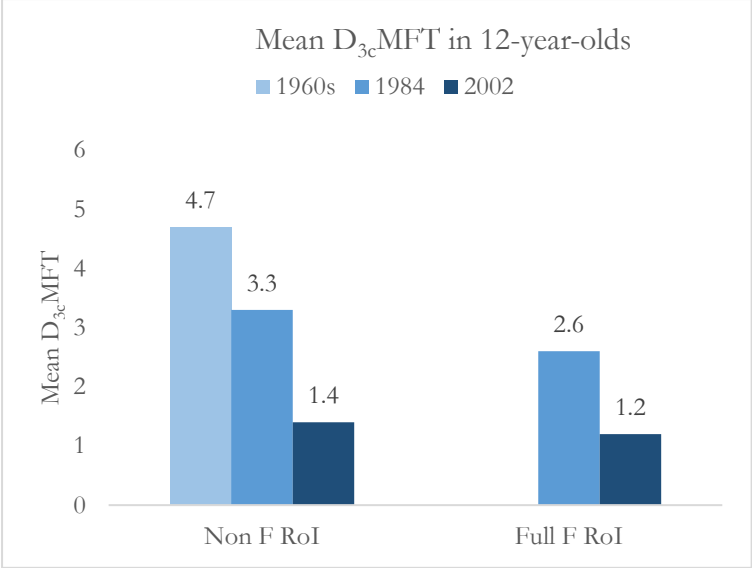


Figure 2.5: Mean D_{3c}MFT among 12-year-olds by fluoridation status in 1961-63 (non-fluoridated only), 1984 and 2002

However, this on-going reduction in dental caries was accompanied by an increase in dental fluorosis. In 1984, 6% of 8-year-olds and 5% of 15-year-olds with CWF had Dean's Index scores 'questionable' or greater (O'Mullane et al. 1986). In 2002, using the same measurement criteria, the prevalence of Dean's 'questionable or greater' was 24% in 8-year-olds and 38% in 15-year-olds with CWF (Figure 2.6) (Whelton et al. 2006). This increase in fluorosis reflected increased exposure to fluoride from sources other than water. It is important to note that most of the increase occurred in the barely perceptible 'questionable' and 'very mild' categories of Dean's Index and that the percentage of children with scores at the higher end of the scale ('moderate' or 'severe') was low (1–2%) (See Figure 2.2 for photographs of Dean's Index scores 'normal' to 'severe'). Although the increase in fluorosis was evident among children with and without CWF, the prevalence of fluorosis was significantly higher among 8- and 15-year-old children with CWF compared to their counterparts without ($P < 0.0001$) (Whelton et al. 2006).

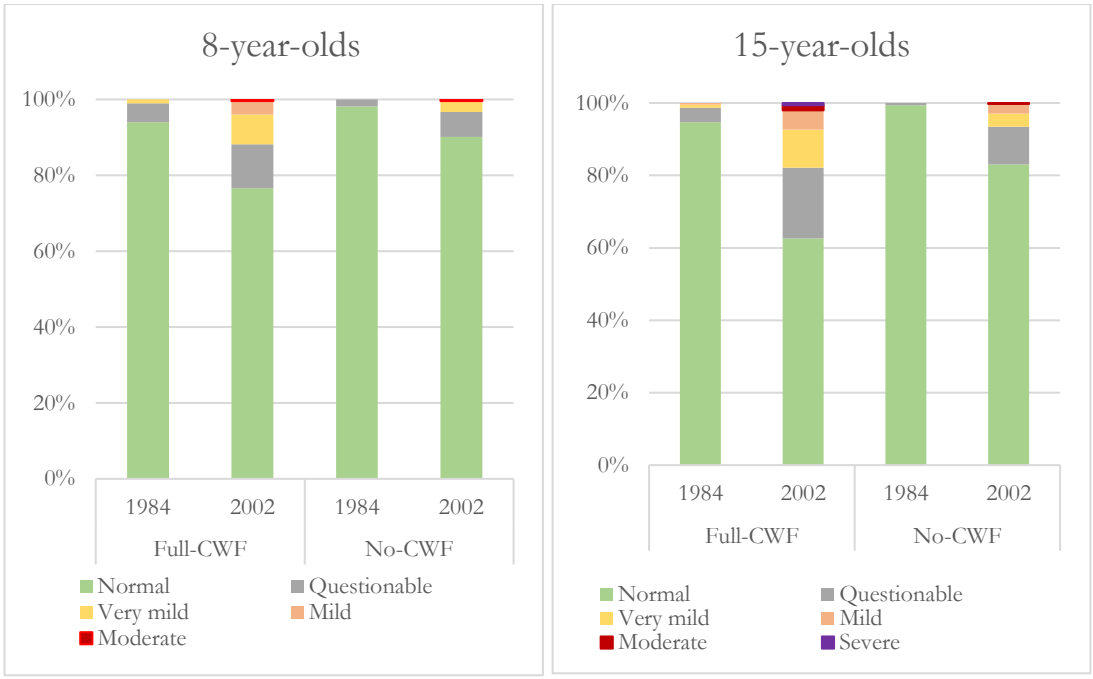


Figure 2.6: Dean's Index scores for 8- and 15-year-olds with Full-CWF and No-CWF in 1984 and 2002

2.11.3 The Forum on Fluoridation Report 2002

In 2000, the Forum on Fluoridation (hereafter 'the Forum') was established by the Minister for Health to review CWF in Ireland. In 2002, the Forum issued a number of recommendations aimed at minimising the occurrence of dental fluorosis while maintaining reductions in dental caries (Department of Health and Children 2002). It was recommended that the optimal level of fluoride in drinking water be redefined from 0.8 to 1.0 ppm to 0.6 to 0.8 ppm, with a target value of 0.7 ppm. This adjustment was implemented in 2007 after the required change to the legislation (Government of Ireland 2007).

The following recommendations regarding use of fluoride toothpaste were also issued by the Forum in 2002:

- Parents are advised not to use toothpaste when brushing their children's teeth until the age of 2 years. Prior to this age parents should brush their children's teeth with a toothbrush and tap water. Professional advice on the use of fluoride toothpaste should be sought where a child below 2 years of age is considered to be at high risk of developing dental decay.
- Parents are advised to supervise children aged 2 to 7 years when brushing their teeth and to ensure that only a small pea sized amount of fluoride toothpaste is used and that swallowing of the paste is avoided.

Most children's toothpastes marketed in Ireland contained at least 1000 ppm fluoride. Although low fluoride toothpastes (500 ppm or less) were available, the Forum did not recommend their use as their effectiveness was deemed uncertain. The toothbrushing guidance outlined above remains in place following recent review of the evidence underpinning it (O'Mullane et al. 2018).

The Forum considered all discretionary fluoride sources but focussed on fluoride toothpaste as the most important. The Forum noted that fluoride supplements (such as fluoride tablets and drops) were a risk factor for fluorosis in young children. However, they noted that the availability and use of fluoride supplements in Ireland did not appear to be an issue.

The Forum report included a probabilistic estimation of fluoride intake from formula reconstituted with fluoridated water (at 0.8 to 1.0 ppm F) by Irish infants aged 0 to 4 months (Department of Health and Children 2002; Anderson et al. 2004). The mean exposure of infants to fluoride from formula on any one day (acute exposure model) was estimated to be between 0.11 and 0.14 mg/kg body weight (95^{th} percentiles 0.20 and 0.26 respectively). The mean daily exposure to fluoride for infants exclusively formula fed over the first four months of life (chronic exposure model) was estimated to be between 0.106

and 0.170 mg/kg body weight per day. The authors concluded that there was a very low risk of 'moderate' dental fluorosis in the permanent dentition of infants exposed to these levels of fluoride from infant formula. Importantly, the authors noted that the fluoride concentration of formula had a small impact on daily fluoride intake; the fluoride concentration of the water used to reconstitute the powdered formula had the biggest influence on the estimates of fluoride intake.

These estimates by Anderson and colleagues (Anderson et al. 2004) were higher than those reported in the longitudinal Iowa Fluoride Study (Levy et al. 1995; Levy et al. 2002). However, the estimates were made in the absence of any information about the formula feeding practices of Irish infants and the conservative assumptions applied to the models likely overestimated fluoride intake from formula reconstituted with fluoridated water. Moreover, the prevalence of 'moderate' or greater fluorosis was only 2% among 15-year-old lifetime residents of fluoridated areas in Ireland in the NSSCOH 2002 (Whelton et al. 2006).

The Forum concluded that infant formula reconstituted with fluoridated water was not an important risk factor for the development of 'moderate' fluorosis in Ireland. They recommended that where infants are formula fed, formula could continue to be reconstituted with boiled tap water or alternatively, ready to feed (RTF) formula could be used. The Forum recommended ongoing monitoring of fluoride intake in infants and of dental fluorosis prevalence in children.

2.11.4 Context and rationale for the FACCT study

Following publication of the Forum recommendations, there was a period of rapid population growth in Ireland. The population increased from 3.9 million in 2002 to 4.2 million in 2006 with a further increase to 4.6 million in 2011 (Central Statistics Office).

The rapid population growth from 2002 onwards coincided with a period of unprecedented economic growth and prosperity. However, on foot of the first signs of the global financial crisis in 2007, Ireland experienced a steep economic downturn that would last for five years, with rising unemployment rates and falling disposable incomes.

The implementation of the downward adjustment of water fluoride concentration in 2007 coincided with this economic recession, and there followed several years in which the population had a greater reliance on public health measures and public dental services to prevent and treat dental diseases. As Ireland began to emerge from the economic recession in 2012, the outcome of the change to this important public health measure was not known and it was considered essential to determine whether the change was associated with the desired effect of reducing dental fluorosis levels whilst maintaining the reductions in dental caries levels reported in recent decades.

The Fluoride and Caring for Children's Teeth (FACCT) study commenced in late 2012 with the aim of evaluating the outcome of downward adjustment of water fluoride concentration on dental caries and dental fluorosis in Irish children. The focus of this thesis is on the outcome of the downward adjustment on dental caries in primary teeth and dental fluorosis in permanent teeth of 8-year-olds.

The timeframe for the development and publication of the new Irish Oral Health Policy Smile agus Sláinte (Department of Health 2019), coincided with the conduct of the FACCT study. The policy was evidence-informed by research commissioned by the Department of Health with the preliminary results of the FACCT study contributing to policy development. Maintaining water fluoridation and developing appropriate advice on toothpaste use, in line with evidence were identified as priorities in the Policy.

Although several other countries with established CWF programmes such as Hong Kong, Singapore, Malaysia, Canada and the United States (U.S.) have lowered the fluoride concentration of their water supplies, there is little evidence regarding the impact of these minor adjustments on dental caries and fluorosis. **Chapter 3** reports the results of a systematic review of the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis.

The methods employed to determine the impact of the downward adjustment on dental caries in primary teeth and dental fluorosis in permanent teeth in Ireland are reported in **Chapter 4**, the results of the study in **Chapters 5, 6 and 7** and discussion of the results in **Chapter 8.**

3 Systematic review of the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis

3.1 Abstract

Background

Community water fluoridation (CWF) is an effective population-level caries preventive measure. In the context of exposure to fluoride from additional sources such as fluoride toothpaste, several countries with CWF programmes adjusted the water fluoride concentration downwards with the aim of reducing dental fluorosis while maintaining the caries-preventive benefit of CWF.

Aim:

To assess the impact of downward adjustment of CWF concentration on dental caries and dental fluorosis.

Methods:

The protocol for the review was registered with PROSPERO. PubMed, Web of Science and Scopus databases were searched from inception to March 2022 for English language publications. Grey literature databases were searched for relevant studies. Studies of any design with a dental caries or dental fluorosis outcome, comparing groups exposed to a downward adjustment in CWF concentration with historical or concurrent control groups exposed to the higher CWF concentration were considered for inclusion. Studies including control groups with no exposure to CWF (such as controlled before and after studies) were also considered. Two review authors independently screened the search results and assessed the risk of bias of the included studies using ROBINS-I. One review

author extracted data and a second review author checked the accuracy of data extraction. The results were summarised narratively. The certainty of the body of evidence was independently assessed by two review authors using GRADE.

Results

Three studies at serious risk of bias evaluating CWF adjustments in Hong Kong and Malaysia were included. In Hong Kong, adjustment from 1.0 to 0.7 ppm fluoride in 1978 was associated with a reduction in 'very mild' or greater fluorosis and a reduction in the prevalence of diffuse opacities in children. A further adjustment to 0.5 ppm fluoride in 1988 was associated with a reduction in the prevalence of diffuse opacities. In Malaysia, adjustment from 0.7 to 0.5 ppm fluoride was associated with a non-statistically significant reduction in 'very mild' or greater fluorosis. Dental caries levels in Malaysian children with lifetime exposure to the reduced water fluoride concentration were lower than among children with no exposure to CWF.

Conclusions

There was very low-quality evidence of a reduction in dental fluorosis following downward adjustment of CWF. There was insufficient evidence to draw a conclusion regarding the impact of downward adjustment of CWF concentration on dental caries.

3.2 Introduction

In the first half of the 20th century, Dean and colleagues demonstrated that within U.S. communities with varying concentrations of naturally occurring water fluoride, higher water fluoride concentrations were associated with lower dental caries levels and higher prevalence of dental fluorosis (Dean et al. 1941; Dean et al. 1942; Dean 1943). A water fluoride concentration of 1 ppm was identified as the 'optimal' concentration consistent with achieving the best balance between maximising the caries-preventive benefits of fluoride and minimising the occurrence of dental fluorosis of aesthetic or public health concern (Dean 1944).

Community water fluoridation (CWF) and widespread use of fluoride toothpaste are credited with being instrumental in reducing the prevalence and severity of dental caries in the second half of the 20th Century (Brunelle and Carlos 1990; Bratthall et al. 1996). However dental caries is still highly prevalent among children and adults and is a significant challenge, particularly for lower socioeconomic groups (Kassebaum et al. 2015; Schwendicke et al. 2015; Peres et al. 2019; Bernabe et al. 2020). A substantial body of evidence supports the caries preventive effectiveness of CWF (McDonagh et al. 2000; Iheozor-Ejiofor et al. 2015; Jack et al. 2016). Drinking optimally fluoridated water and ingesting food prepared with it maintains a low concentration of fluoride in saliva and the biofilm inhibiting demineralisation during a cariogenic challenge and promoting remineralisation (Featherstone et al. 1990; Cury and Tenuta 2008). Furthermore, incorporation of fluoride into the developing enamel crystals (pre-eruptively) provides enhanced protection for pits and fissures (Singh and Spencer 2004; Singh et al. 2007) which are not easily accessible to topical fluorides. CWF is cost effective (Truman et al. 2002; Ran and Chattopadhyay 2016; Cronin et al. 2021), benefitting the primary and permanent dentitions across the life course (McDonagh et al. 2000; Griffin et al. 2007;

Iheozor-Ejiofor et al. 2015; Jack et al. 2016). It benefits all socio-economic groups, without requiring the active participation of the individuals (O'Mullane et al. 2016). Concurrent use of fluoride toothpaste provides caries prevention additional to CWF (Marinho et al. 2003b).

Use of CWF for caries prevention is inevitably accompanied by the occurrence of a certain amount of dental fluorosis (Fejerskov et al. 1990). Thus, the benefits of CWF must be balanced against the risk of developing dental fluorosis from excessive ingestion and absorption of fluoride during critical periods of tooth formation. For the aesthetically important maxillary central incisors, this critical period extends through the first 2 to 3 years of life (Buzalaf and Levy 2011). However, dental fluorosis associated with exposure to optimally fluoridated water and fluoride toothpaste is generally 'very mild' or 'mild' (Whelton et al. 2006; Pretty et al. 2016), a level considered to have little or no impact on aesthetics or oral health-related quality of life (Chankanka et al. 2010).

From the late 1980s, with exposure to fluoride from several different sources, the prevalence and severity of dental fluorosis increased (Szpunar and Burt 1987; Pendrys and Stamm 1990; Riordan 1993a; Clark 1994; Rozier 1999; Whelton et al. 2006). In response, several countries with CWF programmes including Hong Kong, Singapore, Malaysia, Canada, Ireland and the U.S. re-defined the 'optimal' water fluoride concentration at a lower level with the fluoride concentration determined according to climate and exposure to other sources of fluoride. These adjustments reduced fluoride intake from water, reducing total fluoride ingestion and absorption with the aim of reducing dental fluorosis while maintaining the caries preventive benefit of CWF.

Systematic reviews of CWF initiation and cessation studies provide evidence of the effectiveness of CWF for preventing dental caries and the dose response relationship between water fluoride concentration and dental fluorosis (McDonagh et al. 2000;

Iheozor-Ejiofor et al. 2015; Jack et al. 2016; McLaren and Singhal 2016). Partial defluoridation of a water supply is associated with a clear reduction in dental fluorosis (Horowitz et al. 1967; Horowitz and Heifetz 1972). However, there is little evidence regarding the impact of minor adjustments to the fluoride concentration of existing CWF programmes on dental caries and fluorosis.

The aim of this systematic review was to assess the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis.

3.3 Methods

The protocol for the review was registered with PROSPERO (CRD42021254666) (James et al. 2021). This review follows the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) (Page et al. 2021).

3.3.1 Types of studies

Comparative studies of any design were considered for inclusion in the review. Although randomised controlled trials are the gold standard for evaluating healthcare interventions (Schulz et al. 2010), this design is often not feasible for evaluating complex public health interventions (Sterne et al. 2016). Thus, non-randomised studies of interventions (defined as quantitative studies estimating the effectiveness of an intervention (harm or benefit) that do not use randomisation to allocate individuals to intervention or comparator groups (Reeves et al. 2021)) were expected to provide the best available evidence regarding the impact of adjustments to water fluoride concentration. Systematic reviews and narrative (non-systematic) reviews were excluded.

The following PICO structure was used to determine eligibility of studies for inclusion:

3.3.2 Participants

Studies involving children or adults were considered for inclusion.

3.3.3 Intervention

The concentration of fluoride in artificially fluoridated water supplies varies worldwide according to context but is usually in the range of 0.5 to 1.0 ppm fluoride (O'Mullane et al. 2016). Studies where participants were exposed to downward adjustment of water fluoride concentration were included. For the purposes of this review, downward adjustment was defined as the controlled reduction of the fluoride concentration of an artificially fluoridated water supply. The water supply must have remained fluoridated (>0.4 ppm fluoride) after the adjustment. Defining a water fluoride concentration of 0.4 ppm or less as non-fluoridated is consistent with the arbitrary cut off used in the Cochrane systematic review of water fluoridation (Iheozor-Ejiofor et al. 2015).

Although lifetime exposure to the reduced water fluoride concentration in the intervention group was desirable, studies where participants had part of life exposed to the reduced water fluoride concentration were also considered for inclusion. Where participants had part of life exposed to the intervention, the relationships between dental development, duration and timing of exposure and the outcomes were considered.

Studies of the impact of temporary interruptions to water fluoridation, uncontrolled reductions in water fluoride concentration and studies of the impact of cessation of CWF programmes were excluded.

3.3.4 Comparison

Studies with historical or concurrent control groups exposed to the higher water fluoride concentration i.e., not exposed to the downward adjustment were considered for

inclusion. Also, studies with control groups with no exposure to CWF (such as in controlled before and after studies) were considered for inclusion.

3.3.5 Outcomes

The difference in dental caries and/or the proportion caries-free measured using any appropriate index such as the dmf/DMF Index (decayed, missing or filled teeth or surfaces) or ICDAS (International Caries Detection and Assessment System) in primary or permanent dentitions.

The difference in dental fluorosis or diffuse enamel opacities in permanent teeth measured using any appropriate index including Dean's Index, the Thylstrup-Fejerskov (TF) Index or the Developmental Defects of Enamel (DDE) Index.

3.3.6 Identification of studies

PubMed, Web of Science and Scopus bibliographic databases were searched from inception to March 2022 for English language publications using a search strategy developed for PubMed and adapted for Web of Science and Scopus (Appendix B, Tables B 1-B 3). The PubMed search was limited to studies involving humans. The grey literature databases: Grey Literature Report and Electronic Thesis Online Service (EThOS) were searched from inception to March 2022 for studies relevant to the review and for comprehensive reports of relevant studies identified through searching bibliographic databases. Google scholar was searched for relevant studies and grey literature such as government reports. An unrestricted search of the Cochrane Database of Systematic reviews was conducted for relevant systematic reviews. Reference lists of included studies and relevant systematic reviews were searched for further relevant studies. Personal contacts were emailed to identify relevant unpublished, on-going, or planned studies. All

searches were re-run prior to the final analysis and any further relevant studies assessed for inclusion.

3.3.7 Selection of studies

The list of records identified through systematic searching were merged and duplicates removed. The records were screened against the inclusion criteria for the review by two review authors (PJ and MH) independently and in duplicate to identify potentially eligible records. Full text copies of all potentially eligible studies were assessed to identify those that met the inclusion criteria. Multiple reports of the same study were linked under one study title. Disagreements regarding eligibility were resolved by discussion with a third review author (DOM) if necessary. Endnote reference management software and Microsoft Excel were used to manage the search results and to record decisions about inclusion and exclusion of studies.

3.3.8 Data extraction and management

Data extraction was performed by one review author (PJ) and checked by a second review author (MH).

The following data were extracted from the included studies:

Characteristics of the study: Country, study location and setting, climate, study design, study duration (if applicable), criteria for inclusion in the study, sampling procedures, recruitment procedures.

Characteristics of participants: Number of participants in intervention and comparator groups, demographic characteristics of participants in intervention and comparator groups.

Information about exposure to CWF: Date/year of downward adjustment, water fluoride concentration before and after downward adjustment, how exposure to CWF was measured, duration and timing of exposure in study participants.

Information about other explanatory variables including potential confounders: Exposure to other (non-water) sources of fluorides e.g., fluoride toothpaste (toothbrushing behaviours) and other fluoride modalities, dietary behaviours, utilisation of dental treatment/preventive services.

Information about outcomes: Outcomes reported (for dental caries and/or fluorosis), indices used to measure the outcomes, training and calibration of examiners.

Statistical analysis: Identification of potential confounders, statistical analysis methods and how confounders were handled in the analysis.

Other information: Details of sample size calculation, source of funding, conflicts of interest.

3.3.9 Assessment of internal validity of the included studies

Risk of bias of the included studies was assessed using the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool. Two review authors assessed the risk of bias independently and in duplicate with disagreements resolved by discussion or consultation with a third review author (DOM) if necessary.

ROBINS-I is a domain-based tool that assesses risk of bias across seven domains:

1. Bias due to confounding

2. Bias in selection of participants into the study

At intervention:

3. Bias in classification of interventions

Post-intervention:

4. Bias due to deviations from intended interventions

5. Bias due to missing data

6. Bias in measurement of outcomes

7. Bias in selection of the reported result

For each study, domain-level judgements, and an overall risk of bias judgement across domains were reported for each outcome as 'Low risk', 'Moderate risk', 'Serious risk', 'Critical risk' or 'No information'.

Important confounders were age, gender, socio-economic status, use of fluoride toothpaste/other fluoride modalities (before age 2 to 3 years for fluorosis), infant feeding, diet, utilisation of dental treatment/preventive services (dental caries).

Important co-interventions were oral health promotion activities or changes in policy regarding use of other fluoride modalities commencing with or after downward adjustment of water fluoride concentration.

3.3.10 Presentation of results

Key features of the included studies in relation to study design, participants, intervention, comparison and outcome were tabulated to facilitate comparison of these elements across the studies and to assess clinical and methodological diversity. A narrative summary of the evidence was presented in text.

Heterogeneity (variation in effect estimates beyond chance (Higgins et al. 2022)) was assessed from the forest plot 1) visually by inspecting the effect estimates, their confidence intervals and the magnitude and direction of the intervention effects and 2)

statistically based on the Chi^2 test ($P < 0.1$ was interpreted as providing evidence of heterogeneity of intervention effects) and the I^2 statistic. The I^2 statistic was interpreted according to guidance provided in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2022) as follows:

- 0% to 40%: might not be important
- 30% to 60%: may represent moderate heterogeneity
- 50% to 90%: may represent substantial heterogeneity
- 75% to 100%: considerable heterogeneity

3.3.11 Assessment of the certainty of the body of evidence

The certainty of the body of evidence was independently assessed by two review authors using the GRADE approach (https://www.gradeworkinggroup.org). The GRADE quality of the evidence could be judged as 'high', 'moderate', 'low' or 'very low'. Recent guidance for using GRADE with ROBINS-I suggested that the certainty of the body of evidence begins as 'high' and is downgraded as appropriate for risk of bias, indirectness, imprecision, inconsistency, and publication bias (Schünemann et al. 2019). Lack of randomisation results in the certainty of evidence being downgraded by at least two levels to low or very low certainty except where plausible confounders or other biases increase the certainty in the effect of the intervention or where the study has special design features that reduce the impact of selection bias and confounding (Schünemann et al. 2019). Furthermore, where there is a large effect or presence of a dose response gradient, the extent of rating down may be lowered. The approach to using GRADE and presenting the GRADE assessment when the results are summarised narratively (i.e., there is no pooled effect estimate from a meta-analysis) was informed by Murad et al. (2017).

3.4 Results

3.4.1 Results of the search

The PRISMA flow diagram is presented in Figure 3.1. Database searches and searches of other sources yielded 2.695 records after de-duplication. Titles and abstracts were screened against the inclusion criteria for the review by two review authors independently and in duplicate, discarding 2,664 records. Full-text copies of 31 records were assessed, and 25 were excluded with reasons (Appendix B, Table B 4). Therefore, three studies (six records) met the inclusion criteria for the review (Appendix B, Table B 5).

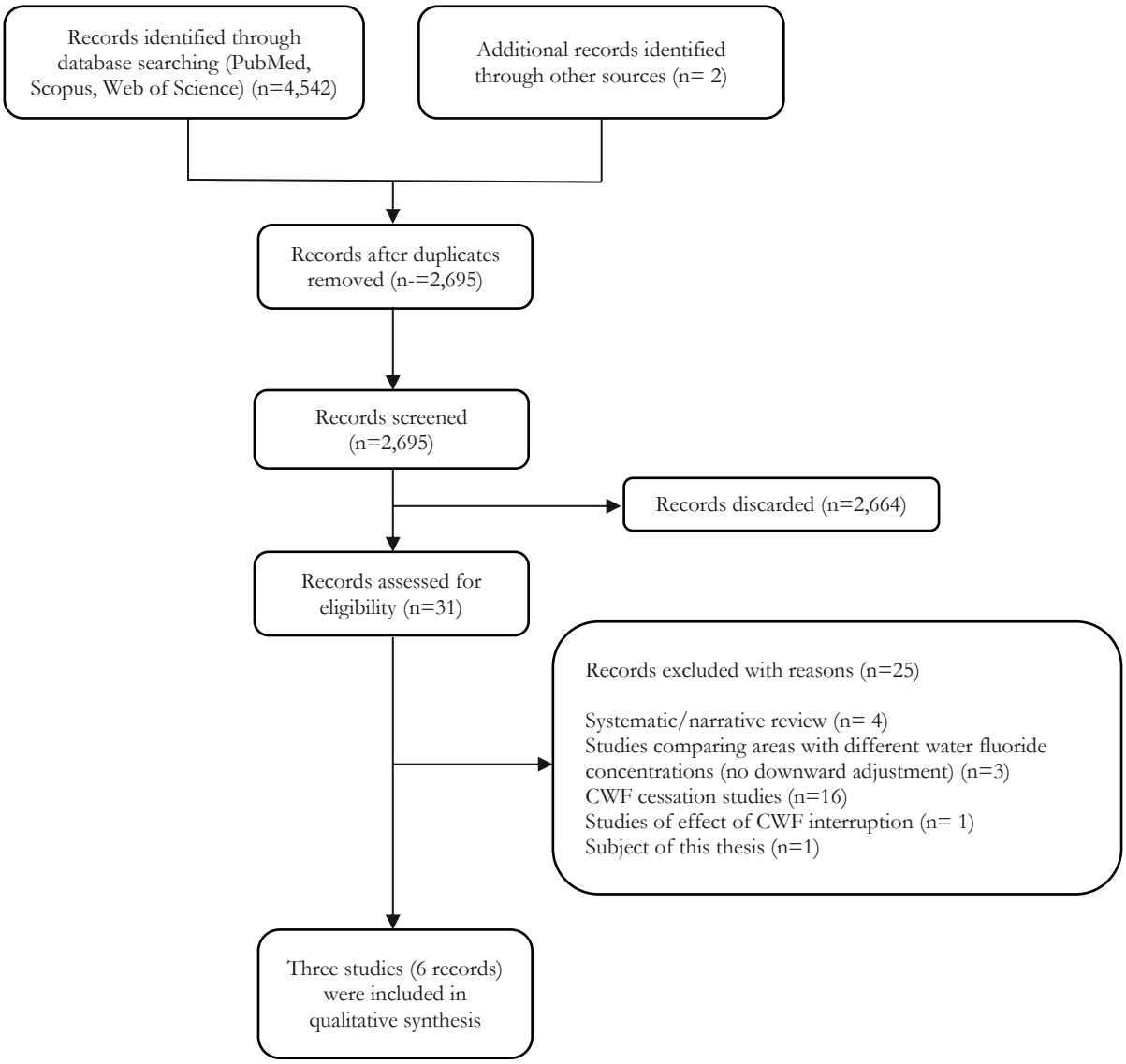


Figure 3.1: PRISMA flow diagram

3.4.2 Characteristics of included studies

Three studies met the inclusion criteria for the review; two conducted in Hong Kong (Evans and Stamm 1991; Wong et al. 2014) and one in Malaysia (Mohd Nor et al. 2018). Tables describing the characteristics of the included studies are presented in Appendix B, Tables B 6-8. A summary of the main features of the included studies is presented in Table 3.1.

In Hong Kong, the fluoride concentration of urban water supplies was adjusted downwards from 1.0 to 0.7 ppm fluoride in 1978 with a further reduction to 0.5 ppm fluoride in 1988. Two studies from Hong Kong (Evans and Stamm 1991; Wong et al. 2014) evaluated the impact of the downward adjustments. Evans and Stamm (1991) used a cross-sectional study design to measure dental fluorosis in permanent maxillary right central incisors using Dean's Index in successive cohorts of 7- to 12-year-old children whose maxillary central incisors mineralised before, during and after the initial (1978) downward adjustment. Wong and colleagues (2014) presented an analysis of the prevalence of diffuse opacities in permanent maxillary incisors measured from oral photographs of 12-year-olds across four successive cross-sectional studies in 1983, 1991, 2001 and 2010, whose permanent maxillary incisors mineralised at 1.0, 0.7, 0.5 and 0.5 ppm fluoride, respectively.

In Malaysia, the fluoride concentration of the public water supply was adjusted downwards from 0.7 to 0.5 ppm fluoride in 2005 (Oral Health Division Ministry of Health Malaysia 2006). Using a cross-sectional study design, Mohd Nor and colleagues (2018) assessed dental caries and fluorosis levels among 9-year-olds with lifetime exposure to 0.5 ppm fluoride, 12-year-olds with exposure to 0.7 ppm fluoride for approximately the first 2 years of life and exposure to 0.5 ppm fluoride thereafter and control groups of 9- and 12-year-olds with no exposure to CWF.

Table 3.1: Summary of included studies

Study	Country (Climate)	CWF adjustment ppm F (year)	Study design	Age	Outcome measurement	Results
Evans 1991	Hong Kong (Sub-tropical)	1.0 to 0.7 (1978)	Cross-sectional study: Data collected at one point in time (June 1985) for successive cohorts of children born 1973 to 1978 whose maxillary incisors mineralised before during and after downward adjustment.	7-12	Fluorosis: Dean's Index Prevalence of Dean's 'very mild' or greater, permanent maxillary right central incisor, clinical Community Fluorosis Index (CFI) was calculated from Dean's Index scores.	Born / Age in 1985 / Exposure to adjustment / Prevalence Fluorosis / CFI 1973 / 12 / Pre / 64% / 1.008 1974 / 11 / Pre / 61% / 0.967 1975 / 10 / Mixed / 58% / 0.975 1976 / 9 / Mixed / 51% / 0.821 1977 / 8 / Mixed / 49% / 0.793 1978 / 7 / Post / 47% / 0.750 Multiple regression analysis of CFI on cohort and gender showed that the reduction in fluorosis was statistically significant (P = 0.001)
Wong 2014	Hong Kong (Sub-tropical)	1.0 to 0.7 (1978) 0.7 to 0.5 (1988)	Repeated cross-sectional study: Analysis of oral photographs taken during epidemiological surveys in 1983, 1991, 2001, 2010 for 12-year-olds with exposure to different water fluoride concentrations.	12	Fluorosis: modified DDE index Prevalence and severity of diffuse opacities in permanent maxillary central and lateral incisors, from photographs	Year photographed / F concentration (ppm F) / Prevalence of at least one diffuse opacity / Prevalence of diffuse confluent type 1983 / 1.0 / 89% / 23% 1991 / 0.7 / 49% / 12% 2001 / 0.5 / 32% / <1% 2010 / 0.5 / 42% / 2% The reduction in prevalence of diffuse opacities between 1983 and 1991 was statistically significant but there was an increase in prevalence between 2001 and 2010. Prevalence of diffuse confluent subtype reduced from 1983 to 2001.
Mohd Nor 2018	Malaysia (Tropical)	0.7 to 0.5 (2005)	Cross-sectional study: Data collected at one point in time for 12-year-olds with CWF born in 2003, 2 years prior to the adjustment (0.7 ppm F for first 23-35 months of life and 0.5 ppm thereafter) and 9-year-olds with CWF born in 2006 after the adjustment (lifetime exposure to 0.5 ppm F). Included control groups of 9- and 12-year-olds with no CWF.	9 and 12	Fluorosis: Dean's Index Prevalence of Dean's 'very mild' or greater, permanent maxillary central incisors, from photographs	Fluoridated (F), % fluorosis / Non-Fluoridated (NF), % fluorosis / % Difference F vs. NF Age 12 (Pre), 38% / Age 12, 5% / Pre 34% Age 9 (Post), 32% / Age 9, 7% / Post 25% Chi-square P=0.139 / Chi-square P=0.344 Among children with CWF there was a non-statistically significant reduction in fluorosis prevalence following the downward adjustment. The difference in fluorosis prevalence between F and NF was less following the downward adjustment.
					Caries: ICDAS-II, clinical $D_{1-6}MFT$: dental caries at all levels $D_{4-6}MFT$: dental caries into dentine	Age 12 / Mean $D_{1-6}MFT$ / Mean $D_{4-6}MFT$ / % $D_{4-6}MFT$ >0 F / 2.01 (SD 2.19) / 0.47 (SD 0.97) / 26% NF / 2.83 (SD 2.74) / 1.31 (SD 1.81) / 54% Age 9 / Mean $D_{1-6}MFT$ / Mean $D_{4-6}MFT$ / % $D_{4-6}MFT$ >0 F / 1.15* (SD 1.55) / 0.40 (SD 0.96) / 25% NF / 1.44* (SD 1.70) / 0.73 (SD 1.17) / 40% F vs. NF, all comparisons P<0.001 except * P = 0.021 (Mann Whitney U test)

3.4.3 Risk of bias of included studies

Based on risk of bias judgments across the seven domains of ROBINS-I, all three included studies were at serious risk of bias overall (Table 3.2). The risk of bias judgements for the three included studies are reported in detail in Appendix B, Tables B 9-11.

Table 3.2: Summary of risk of bias of included studies assessed using ROBINS-I

	Evans 1991	**Wong 2014**	**Mohd Nor 2018**	
Domain	**Fluorosis**	**Fluorosis**	**Fluorosis**	**Caries**
Bias due to confounding	Moderate	Serious	Serious	Serious
Bias in selection of participants into the study	Moderate	Moderate	Moderate	Moderate
Bias in classification of interventions	Low	Moderate	Moderate	Serious
Bias due to deviations from intended interventions	Low	No information	No information	No information
Bias due to missing data	Serious	Low	Low	Low
Bias in measurement of outcomes	Serious	Moderate	Moderate	Serious
Bias in selection of the reported result	Moderate	Moderate	Serious	Moderate
Overall judgement	**Serious risk**	**Serious risk**	**Serious risk**	

3.4.3.1 Bias due to confounding

Two studies (Wong et al. 2014; Mohd Nor et al. 2018) were judged to be at serious risk of bias due to confounding because there was no control for confounding in the main analyses relevant to this review. The remaining study (Evans and Stamm 1991) was judged to be at moderate risk of bias due to confounding.

3.4.3.2 Bias in selection of participants into the study

Selection of participants into the study was based on characteristics of the participants several years after the downward adjustment (i.e., area of residence, being enrolled in primary school). Therefore, some children who were exposed to the downward

adjustment and would have been eligible for selection into the studies were likely to have moved away and not been included in the studies. However, the reasons that children moved away were unlikely to have been related to the downward adjustment (the intervention) or to the outcomes of interest. Thus, all three included studies were judged to be at moderate risk of bias in selection of participants into the study.

3.4.3.3 Bias in classification of interventions

Measurement of exposure to the downward adjustment in two of the included studies (Wong et al. 2014; Mohd Nor et al. 2018) was based solely on the official month and year of adjustment and the CWF concentrations set by the authorities, with the analyses restricted to lifetime residents of the study areas. These two studies were judged to be at moderate risk of bias for this domain. Evans and Stamm (1991) was the only study to report the actual mean water fluoride concentrations before and after the adjustment. In this study (at low risk of bias for this domain), although mean water fluoride concentrations did not exactly correspond to official concentrations in the 48 months before (0.82 rather than 1 ppm) and after (0.63 ppm rather than 0.7 ppm) the adjustment, mean water fluoride concentration was lower by approximately 0.2 ppm in the 48 months following the adjustment.

3.4.3.4 Bias due to deviations from intended interventions

There was no information available to judge whether the intervention was implemented as planned in two of the included studies (Wong et al. 2014; Mohd Nor et al. 2018). Furthermore, no information was provided regarding implementation of any co-interventions with or after downward adjustment of water fluoride concentration. Evans and Stamm (1991) was judged to be at low risk of bias for this domain because there was evidence that the downward adjustment of 0.2 ppm fluoride was implemented in 1978 and it was unlikely that co-interventions involving fluoride toothpaste were implemented

at that time, as the study predated the widespread availability of this product in Hong Kong.

3.4.3.5 Bias due to missing data

Risk of bias due to missing data was judged to be low in two of the included studies (Wong et al. 2014; Mohd Nor et al. 2018). In the remaining study (Evans and Stamm 1991), the exclusion of a large proportion of younger children whose maxillary central incisors were not adequately erupted (20% of those examined), could have introduced a serious risk of bias. This is because the proportion of missing data differed across the groups and the reason for missing data was associated with exposure to the downward adjustment i.e., the younger children had the most exposure to the reduced water fluoride concentration. However, the trend of decreasing fluorosis prevalence across the age cohorts provides some evidence that the findings were robust to the missing data for younger participants.

3.4.3.6 Bias in measurement of outcomes

In Wong et al. (2014), measurement of diffuse opacities from photographs was conducted blind to water fluoride concentration. However, the risk of misclassification of the outcome (because the DDE Index measures diffuse enamel opacities rather than fluorosis) meant that this study was judged to be at moderate risk of bias for this domain. Mohd Nor et al. (2018), was judged to be at moderate risk of bias for measurement of the fluorosis outcome. Although the three examiners measuring dental fluorosis from photographs were not aware of whether the children lived in fluoridated or non-fluoridated areas, awareness of the dental age of the children could have compromised blinding to exposure to the downward adjustment of water fluoride concentration. However, in the same study, the examiner measuring dental caries was not blind to the age of the children (i.e., their exposure to the downward adjustment) or their exposure to CWF. Therefore, measurement of the dental caries outcome in this study was judged to

be at serious risk of bias. The study by Evans and Stamm (1991) was judged to be at serious risk of bias for this domain because of lack of blinding of the clinical fluorosis measurement. These examinations could not be conducted blind to the age of the children and younger children had progressively less exposure to water fluoride when the permanent maxillary incisors were mineralising.

3.4.3.7 Bias in selection of the reported result

None of the included studies had an associated protocol or statistical analysis plan. For two of the studies (Evans and Stamm 1991; Wong et al. 2014), the outcomes were clearly defined and there was no indication of selective reporting of results from among the analyses. These two studies were judged to be at moderate risk of bias for this domain. However, reporting of the fluorosis outcome for Mohd Nor et al. (2018) was judged to be at serious risk of bias, because the clinical Dean's Index scores were not reported.

3.4.4 Impact of downward adjustment of CWF concentration on dental fluorosis

All three included studies reported a reduction in the prevalence of dental fluorosis following downward adjustment of water fluoride concentration (Figure 3.2). There was 'considerable' heterogeneity between the results of studies evaluating adjustment from 1.0 to 0.7 ppm fluoride (1^2 96%, $P < 0.001$) and 'substantial' heterogeneity between the results of studies evaluating adjustment from 0.7 to 0.5 ppm fluoride (1^2 76%, $P = 0.04$) reflecting clinical and methodological diversity between the studies (Appendix B, Figure B 1). Visually, there was no overlap of the 95% confidence intervals for the evaluation of the downward adjustment from 1.0 to 0.7 ppm fluoride in Hong Kong (Wong et al. 2014) and the same adjustment in Hong Kong reported by Evans and colleagues (Evans and Stamm 1991). There was poor overlap of the 95% confidence intervals for the evaluation of the downward adjustment from 0.7 to 0.5 ppm fluoride in Hong Kong (Wong et al.

2014) and the same adjustment reported by Mohd Nor and colleagues in Malaysia (Mohd Nor et al. 2018). There was no clear difference in effect between studies evaluating adjustment from 1.0 to 0.7 ppm fluoride and those evaluating adjustment from 0.7 to 0.5 ppm fluoride (test for subgroup differences; $P = 0.21$) (Appendix B, Figure B 1). As there was no obvious explanation for the heterogeneity, it was not considered appropriate to pool the results of the studies. Instead, results for fluorosis were displayed in a forest plot but without a summary estimate of effect as suggested by Reeves (2021) (Figure 3.2).

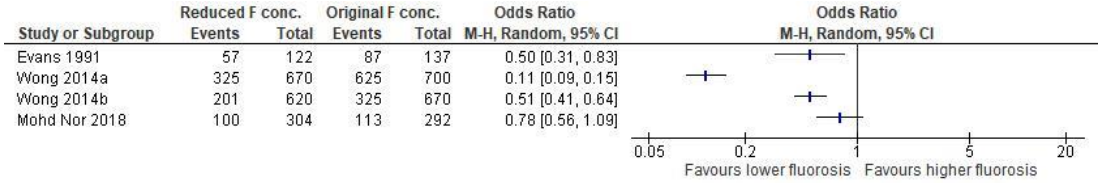


Figure 3.2: Forest plot for comparison of dental fluorosis prevalence with reduced versus original (higher) CWF concentration

Data from Wong et al. (2014) was entered in the forest plot twice to illustrate the results evaluating two different adjustments within the same study (Wong 2014a is adjustment from 1.0 to 0.7 ppm fluoride and Wong 2014b is 0.7 to 0.5 ppm fluoride).

Hong Kong

The initial adjustment from 1.0 ppm to 0.7 ppm fluoride was evaluated in 1985 in successive representative cohorts of children aged 7 to 12, whose maxillary central incisors mineralised before, during and after the downward adjustment (Evans and Stamm 1991). The prevalence of clinical Dean's Index scores 'very mild' or greater in maxillary right central incisors reduced from 64% in 12-year-olds whose maxillary incisors mineralised prior to the adjustment to 47% in 7-year-olds born after the adjustment. Subsequent analysis by Wong et al. (2014) of oral photographs taken for representative samples of 12-year-olds in 1983, 1991, 2001 and 2010 showed that the prevalence and severity of diffuse opacities in maxillary incisors measured using the Developmental

Defects of Enamel (DDE) Index (FDI 1992) declined between 1983 and 2001 coinciding with the downward adjustment of water fluoride concentration. An increase in the prevalence of diffuse opacities was recorded between 2001 and 2010 when the fluoride concentration of water had remained at 0.5 ppm fluoride. The authors indicated that this increase in the prevalence of diffuse opacities was likely related to ingestion of fluoride from sources other than water.

Malaysia

There was a non-statistically significant reduction in the prevalence of dental fluorosis (Dean's 'very mild' or greater) in maxillary central incisors from 38% in 12-year-olds exposed to 0.7 ppm fluoride for approximately the first two years of life and 0.5 ppm fluoride thereafter to 32% in 9-year-olds with lifetime exposure to 0.5 ppm fluoride (Mohd Nor et al. 2018) (Table 3.1). In addition, there was less of a difference in fluorosis prevalence between fluoridated and non-fluoridated areas among 9-year-olds (25%) compared with 12-year-olds (34%). Fluorosis prevalence was higher in 9- and 12-year-olds with CWF compared with their counterparts with No-CWF.

3.4.5 Impact of downward adjustment of CWF concentration on dental caries

One study, from Malaysia, addressed the impact of downward adjustment of water fluoride concentration on dental caries (Mohd Nor et al. 2018). Dental caries data for 9- and 12-year-olds could not be compared due to differences in the permanent teeth present at the time of the examination and the chronic progressive nature of dental caries i.e., that dental caries experience increases with age. Thus, dental caries levels in children exposed to the downward adjustment could not be compared with dental caries levels in those exposed to the higher concentration of water fluoride for approximately the first

two years of life and to the reduced water fluoride concentration thereafter. However, mean $D_{1-6}MFT$, mean $D_{4-6}MFT$ and the proportion of children with $D_{4-6}MFT>0$ was lower among 9- and 12-year-olds with CWF (at either concentration) compared with their counterparts living in non-fluoridated areas (Table 3.1). Similar results were reported for the primary dentition (data not shown).

3.4.6 Certainty of the body of evidence

The certainty of the body of evidence in relation to the impact of downward adjustment of water fluoride concentration on dental fluorosis was rated as very low quality (Table 3.3).

Table 3.3: GRADE summary of findings in relation to the impact of downward adjustment of water fluoride concentration on dental fluorosis

Intervention	Outcome	Effect	Number of participants (studies)	Certainty
Downward adjustment of CWF concentration	Dental fluorosis assessed using two different indices	All 3 studies showed a reduction in fluorosis	2,845 (3 non-randomised studies)	⊕◯◯◯ VERY LOW (due to risk of bias and indirectness)

An initial rating of 'high' quality was applied to the body of evidence which was then downgraded two levels due to lack of randomisation, the consequent risk of selection bias and the lack of control for confounding in the three included studies. The evidence was downgraded by one more level due to indirectness of the body of evidence; two of the four comparisons involved populations who only had exposure to water fluoride and no exposure to other sources of fluoride such as fluoride toothpaste. This reduces the applicability of the body of evidence to contemporary populations with exposure to fluoride from several different sources including water. The GRADE evidence profile for the impact of downward adjustment of water fluoride concentration on dental fluorosis is shown in Appendix B Table B 12.

There was insufficient evidence regarding the impact of downward adjustment of water fluoride concentration on dental caries for the GRADE system to be used.

3.5 Discussion

3.5.1 Summary of main results

There was very low quality evidence from three studies (Evans and Stamm 1991; Wong et al. 2014; Mohd Nor et al. 2018) that adjusting the water fluoride concentration downward was associated with a reduction in dental fluorosis. Results from Hong Kong indicated a reduction in 'very mild' or greater fluorosis and a reduction in the prevalence and severity of diffuse enamel opacities in maxillary incisors following the adjustment from 1.0 to 0.7 ppm fluoride (Evans and Stamm 1991; Wong et al. 2014). The subsequent adjustment from 0.7 to 0.5 ppm fluoride was associated with a more modest but statistically significant reduction in the prevalence of diffuse opacities in maxillary incisors (Wong et al. 2014). Results from Malaysia indicated a non-statistically significant reduction in 'very mild' or greater fluorosis in central incisors of children with lifetime exposure to 0.5 ppm fluoride compared with children with exposure to 0.7 ppm for approximately the first two years of life and 0.5 ppm thereafter (Mohd Nor et al. 2018).

There was a dearth of information regarding the impact of downward adjustment of water fluoride concentration on dental caries. One study (Mohd Nor et al. 2018) showed that children with lifetime exposure to the reduced water fluoride concentration (0.5 ppm fluoride) and children with exposure to the higher water fluoride concentration (0.7 ppm fluoride) to approximately age two and 0.5 ppm fluoride thereafter had lower dental caries levels than children with no exposure to CWF.

3.5.2 **Discussion of main results**

In the two countries studied, reducing water fluoride concentration reduced dental fluorosis. All three studies evaluated changes in fluorosis in the aesthetically important maxillary incisors. The studies employed two different indices (Dean's Index and the DDE Index) to measure dental fluorosis or diffuse enamel opacities clinically or from standardised oral photographs. The overall direction of the effect of downward adjustment on dental fluorosis was consistent across the three studies, although the magnitude of the effect varied. The statistical heterogeneity between the studies likely reflected the methodological diversity of the studies, the differential effect of bias and differences in the populations studied. Thus, the studies were not considered 'similar enough' for results to be combined. Instead, the dental fluorosis results were displayed in a forest plot with summary estimates suppressed as advised by Reeves et al.(2021).

The one study that reported the impact of downward adjustment of water fluoride concentration on dental caries was hampered by its inability to compare dental caries levels in the pre- and post-adjustment groups due to the difference in their ages (age 12 and age 9 respectively). Furthermore, 12-year-olds with CWF had exposure to the reduced water fluoride concentration for their entire lives apart from the first 2 years. Although CWF has a pre-eruptive effect through the incorporation of fluoride into developing enamel (Groeneveld et al. 1990; Singh and Spencer 2004; Singh et al. 2007), the main effect of CWF is considered to be post-eruptive through its topical effect (Burt 1999; Featherstone 2000; Ten Cate and Buzalaf 2019). Thus, for a dental caries outcome, the 12-year-olds provided at best a measure of partial exposure to the pre-adjustment water fluoride concentration.

Measurement of exposure to the downward adjustment based on the CWF concentration set by the authorities and the month and year of the adjustment assumed consistency

between the 'optimal' water fluoride concentration (and control range, if applicable) and the fluoride concentration of water suppling the study participants. Evans and Stamm (1991) reported mean water fluoride concentrations approximately 0.2 ppm fluoride below the official water fluoride concentration both before and after the downward adjustment. In a recent publication linked to the Malaysian study, Mohd Nor (2021) reported that water quality reports showed water fluoride concentration in the fluoridated area consistently at 0.5 ± 0.2 ppm fluoride after the adjustment. However, no information was provided regarding the water fluoride concentration in the fluoridated area prior to the downward adjustment.

Compliance with the 'optimal' concentration of water fluoride and the control range of acceptable concentrations varies across jurisdictions, water supply services, and over time. In the U.S. over a five-year period, water fluoride concentration was maintained within ±0.15 ppm of the recommended water fluoride concentration in three-quarters of fluoride-adjusted community water systems (Barker et al. 2017). Furthermore, systems serving larger populations were better able to maintain average water fluoride concentration within a narrow control range than systems serving small populations. An analysis of water fluoride concentration in two of five English water companies supplying artificially fluoridated water found wide variation in water fluoride concentration between different water suppliers and over time (Moore et al. 2020). The results indicated that between 28% and 78% of water samples spanning an 18- to 36-year time frame were within the optimal range of 0.7 to 1.0 ppm fluoride. A recent systematic review reported that more than half of public water supplies in Brazilian cities had fluoride concentrations outside the acceptable range (Rosário et al. 2021). These reports highlight the importance of verifying the water fluoride concentration before and after an adjustment as it may deviate from the official water fluoride concentration.

The rationale for downward adjustment of water fluoride concentration has been questioned on the basis that it may reduce the caries preventive effect of CWF for the entire population to reduce ingestion of fluoride at a critical period in early childhood (Spencer and Do 2016). An alternative approach was adopted by the Australian health authorities in the early 1990s. Rather than reducing water fluoride concentration, policies targeted reductions in exposure to discretionary sources of fluoride from infant formula powders containing high levels of fluoride, fluoride supplementation regimens and ingestion of fluoride toothpaste (Australian Research Centre for Population Oral Health 2006). Several years later, a statistically significant reduction in the prevalence of fluorosis was found in children born after implementation of the policy measures (Riordan 2002; Do and Spencer 2007b).

3.5.3 Quality of the evidence

Systematic reviews of healthcare interventions have traditionally focussed on evidence from RCTs as being at lower risk of bias than non-randomised studies. However, not every important question about healthcare interventions can be answered using an RCT. In the case of complex or population-level interventions such as those involving CWF, conducting an RCT is neither feasible nor ethical. The main advantage of an RCT design is the randomisation process, which if performed correctly, controls for confounders (both known and unknown) and produces groups for comparison that are similar apart from the intervention under study. Non-randomised studies are subject to the same limitations and biases as RCTs but to a greater extent (Jack et al. 2016). In particular, with lack of randomisation of participants to intervention and comparator groups, identifying potential confounders and controlling for them in the analysis is central to minimising the risk of bias in non-randomised studies.

The earliest opportunity for definitive evaluation of the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis is when the first cohort of children born after the adjustment can be examined for the outcome of interest. For fluorosis, this evaluation can only occur upon emergence of the permanent incisors at 7 to 8 years of age. This presents challenges for researchers evaluating the impact of downward adjustment of water fluoride concentration.

Although all three included studies could be classified as cross-sectional or repeated cross-sectional studies, the particulars of the study designs varied. Evans and Stamm (1991) collected data at one point in time for groups of children of different ages whose permanent maxillary central incisors mineralised before, during and after downward adjustment of water fluoride concentration from 1.0 to 0.7 ppm fluoride. This was an efficient method of data collection and minimised the impact of background temporal changes that could have impacted the results. This study design also facilitated assessment of trends in fluorosis prevalence among similar groups of children with incrementally less exposure to water fluoride. However, challenges were posed by the large proportion of partially erupted central incisors among the younger age-groups, the inability to fully blind the examiner and the possibility that fluorosis levels might have reduced over time (from age 7 to age 12) due to physiological wear of the enamel. As noted by the authors, any reduction in fluorosis over time would have favoured a finding of no difference between the older and younger groups, which was not the case in this study. Participants in this study did not have access to fluoride toothpaste when their maxillary incisors were mineralising. Lack of control for confounding due to fluoride toothpaste use is therefore not considered a major limitation of this study.

Wong et al. (2014) used a repeated cross-sectional study design, utilising oral photographs taken during periodic oral health surveys in Hong Kong, to evaluate trends in the

prevalence and severity of diffuse opacities among 12-year-olds with exposure to different water fluoride concentrations. The analysis included data from four time points from 1983 to 2010 with measurement of diffuse opacities conducted blind to the year the photograph was taken. There was the potential for misclassification of the outcome, as the chosen index (the DDE Index (FDI 1992)) does not specifically measure fluorosis. Furthermore, there was no control group without exposure to CWF and there was no control for confounding in this study. The importance of having a control group with no CWF and of considering the effect of confounding is evidenced by the trend of increasing prevalence of diffuse opacities between 2001 and 2010 at a time when the water fluoride concentration remained at 0.5 ppm fluoride. Evidence from other studies conducted in Hong Kong point to increasing early use of fluoride toothpaste from the early 2000s onwards as a likely cause for this increase (Chan 2002, Wong 2012).

Mohd Nor et al. (2018) used a cross-sectional study design to measure dental fluorosis and dental caries in children with lifetime or partial exposure to the reduced water fluoride concentration and children with no exposure to CWF. Fluorosis was assessed blind to exposure to CWF from oral photographs. On the other hand, measurement of dental caries was not blind to exposure to CWF as the examiner would have been aware of the location where the examinations were taking place.

The investigators collected information on many explanatory variables yet failed to control for any of them in the analyses central to answering their main research question (for list of explanatory variables, see Appendix B Table B 8). There were several important differences in socio-demographics, use of infant formula and fluoride toothpaste among Malaysian children living in fluoridated and non-fluoridated areas that could have impacted on the fluorosis and caries outcomes. Furthermore, no information was collected regarding frequency of intake of dietary sugars or use of dental services in the

study populations. Therefore, comparisons of dental caries and fluorosis levels in Malaysian children living in fluoridated and non-fluoridated areas that did not control for confounding were particularly prone to bias.

3.5.4 Potential biases in the review process

To minimise bias in the review process, the methods to be used in the review were documented prior to the conduct of the systematic database searches and the review protocol registered with Prospero on July 19th, 2021. The only change to the protocol was the decision to use Google Scholar rather than OpenDOAR for the grey literature search. The protocol stated that where results for dental caries and fluorosis were available within the same jurisdiction or country, the risk benefit balance within that specific context would be assessed. While outcome data for both dental caries and fluorosis were reported for Malaysia, assessment of the impact of the downward adjustment on dental caries was of such limited value, that no comment could be made regarding the risk benefit balance in the Malaysian context.

A thorough, objective, and reproducible search of a range of sources was conducted to identify as many eligible studies as possible, as recommended by the Cochrane Handbook of Systematic Reviews (Higgins et al. 2022). Our resources did not extend to assessing eligibility or translation of non-English language publications. This restricted search may have resulted in important non-English language reports being excluded from the review. However, this is thought to be unlikely due to the small number of countries that have implemented the intervention (downward adjustment) and the comprehensive search for evidence relating to adjustments in these countries.

3.5.5 Agreements and disagreements with other reviews

Mohd Nor and colleagues (Mohd Nor et al. 2020) systematically reviewed the impact of cessation of water fluoridation or reduction of the level of fluoride in public water supplies on dental fluorosis. A comprehensive search was conducted restricted to English language publications. Study quality was evaluated using the validity assessment checklist used in the York Review (McDonagh et al. 2000). The three included studies evaluating the impact of reduction of water fluoride concentration on fluorosis were the same as those included in the present review (Evans and Stamm 1991; Wong et al. 2014; Mohd Nor et al. 2018). In addition, three studies of the effect of water fluoridation cessation on dental fluorosis in China (Wei and Wei 2002), Brazil (Buzalaf et al. 2004) and Canada (Clark et al. 2006) were included. Two of these studies showed a reduction in fluorosis after cessation (Wei and Wei 2002; Clark et al. 2006) and one showed an increase in fluorosis (Buzalaf et al. 2004). Despite the substantial heterogeneity (I^2=98%, P = 0.001), results of all six studies were pooled in a meta-analysis. The overall pooled effect estimate showed that dental fluorosis was higher before CWF cessation or reduction of water fluoride concentration compared with after (OR 3.25, 95% CI [1.34, 7.85]).

No systematic reviews of the impact of downward adjustment of water fluoride concentration on dental caries were identified. The impact of CWF cessation on dental caries in 13 countries between 1956 and 2003 was systematically reviewed by McLaren and Singhal (2016). The available evidence was conflicting and limited in quantity and quality (for a summary, see Section 2.9.1.1.3). On balance, cessation of CWF was associated with an increase in dental caries.

3.5.6 Implications for research

Despite decisions by several countries to reduce water fluoride concentration, there is a scarcity of information regarding the impact of these policy changes on dental caries and

fluorosis. Well-conducted studies of the impact of downward adjustment of water fluoride concentration in different climates, in the context of widespread exposure to other fluoride sources, incorporating accurate measurement and control for confounding are required. The absence of any robust evidence of the impact of downward adjustments on the effectiveness of CWF for preventing dental caries represents a major gap in our knowledge and is a priority issue to be addressed.

Evaluating the impact of downward adjustment of water fluoride concentration on oral health outcomes must be carefully planned as there is a limited time frame within which to collect appropriate data in relation to the pre-adjustment outcome measures. Recent reductions in CWF concentrations that have yet to be evaluated include those in Canada, Ireland and the U.S. The most recent downward adjustment in the U.S. in 2015 from a range of 0.7 to 1.2 ppm fluoride varying according to the average outside ambient air temperature to 0.7 ppm fluoride for all geographic areas (U. S. Department of Health Human Services Federal Panel on Community Water Fluoridation 2015) has the potential to affect almost 200 million people provided with artificially fluoridated water in the U.S. (Centers for Disease Control and Prevention 2016). Thus, appropriate evaluation of the impact of the adjustment in the U.S. is of paramount importance. The impact of the downward adjustment in Ireland from 0.8 - 1.0 ppm to 0.6 - 0.8 ppm fluoride on dental caries and fluorosis is the focus of this thesis.

3.6 Conclusion

There was very low quality evidence that adjusting water fluoride concentration downwards was associated with a reduction in fluorosis. Due to the limited quantity and quality of the available evidence, no conclusion could be drawn regarding the impact of downward adjustment of water fluoride concentration on dental caries.

4 Methods

The aims and objectives of the study were presented in Chapter 1, Sections 1.2 and 1.3. The study methods relate to 8-year-olds, born after downward adjustment of water fluoride concentration, examined in FACCT phase 2 in 2016-17 and a comparator group of 8-year-olds examined in the North South Survey of Children's Oral Health (NSSCOH) 2002 (Whelton et al. 2006). This chapter has four main sections: 1) Ethics, data protection and study design, 2) Measurement of explanatory variables, 3) Measurement of outcome variables and 4) Statistical analysis.

4.1 Ethics, data protection and study design

4.1.1 Ethical approval

Ethical approval for the Fluoride and Caring for Children's Teeth (FACCT) study was obtained from the Clinical Research Ethics Committee (CREC) of the Cork Teaching Hospitals (https://www.ucc.ie/en/crec/). Approval letters from CREC are presented in Appendix C. Written informed consent was obtained from parents and child assent from 8-year-olds.

4.1.2 Data protection

This thesis was written in part-delivery of the aims and objectives of the FACCT study, which included comparison of data collected as part of FACCT with data collected during the NSSCOH 2002. Both FACCT and the NSSCOH 2002 commenced prior to the introduction of the General Data Protection Regulation (GDPR).

4.1.2.1 FACCT

The FACCT study protocols, subject information leaflet, informed consent process, and documentation of informed consent were designed to comply with the requirements of the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003; Data Protection (Access Modification) (Health) Regulations, 1989 (S.I. No.82 of 1989); Data Protection (Access Modification) (Social Work) Regulations, 1989 (S.I. No.83 of 1989); Council Directive on the Protection of Individuals with Regard to Processing of Personal Data (Directive 95/46/EC) (W).

Following the introduction of GDPR, and the Data Protection Act 2018, a review was undertaken to assess whether on-going processing of the data would be compliant with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (as amended). Using the instruments 1) *Health Research Regulations Checklist* and 2) *Explicit Consent Checklist for Researchers* (Appendix C), it was concluded that the study was compliant, because parents/guardians of participants in FACCT gave explicit consent to the processing of their child's data for the specified purposes, in line with the requirements of the Health Research Regulations.

4.1.2.2 NSSCOH 2002

The NSSCOH dataset was fully and irrevocably anonymised, thereby falling outside the scope of GDPR.

4.1.3 Study reporting

The reporting of this study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al. 2008).

4.1.4 Study setting

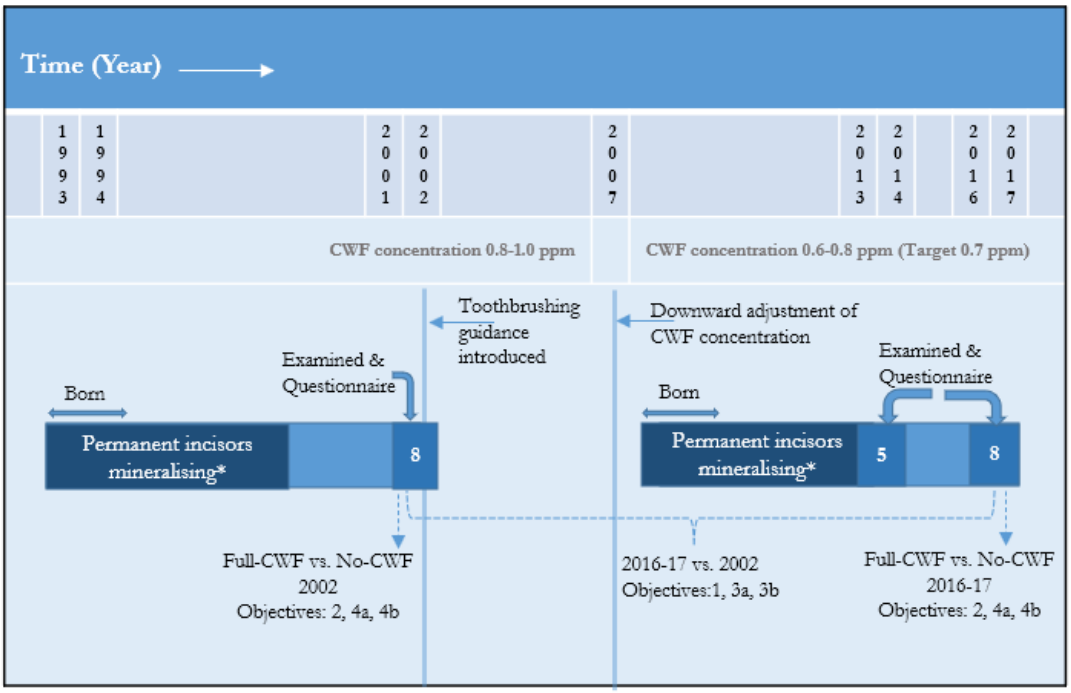
In 2016-17, 71% of the Irish population had access to community water fluoridation (CWF) (Cronin et al. 2021), with the remainder supplied by non-fluoridated water schemes or private wells. This study was conducted in Counties Dublin, Cork and Kerry (Figure 4.1). Over one quarter of the population of Ireland (28%) resided in Dublin with CWF, while 15% of the population of Ireland resided in Counties Cork and Kerry with a mix of areas with and without CWF (Central Statistics Office 2017).



Figure 4.1: Map of Ireland showing FACCT study locations

4.1.5 Study design

The aim of this thesis was to evaluate the outcome of the downward adjustment of water fluoride concentration in Ireland on dental caries in primary teeth and dental fluorosis in permanent teeth. An overview of the age groups of children included in the study, their exposure to the downward adjustment in water fluoride concentration (2007) and the Forum toothbrushing recommendations (2002) and the main comparisons presented in the thesis are shown in Figure 4.2.



*Mineralisation of permanent maxillary central incisors commences at approximately 2-3 months after birth and is complete at age 4-5 years

Objective 1: Dental caries, clinical, primary teeth (d_{3vc}mft(cde)), age 8 2016-17 vs age 8 2002

Objective 2: Dental caries, clinical, primary teeth (d_{3vc}mft(cde)), age 8 Full-CWF vs. No-CWF 2002 and 2016-17

Objective 3a: Fluorosis, Dean's Index, clinical, permanent teeth, age 8 2016-17 vs. age 8 2002

Objective 3b: Fluorosis, TF Index, measured from photographs, permanent maxillary central incisors, age 8 2016-17 vs. age 8 2002

Objective 4a: Fluorosis, Dean's Index, clinical, permanent teeth, age 8 Full-CWF vs. No-CWF 2002 and 2016-17

Objective 4b: Fluorosis, TF Index, measured from photographs, permanent maxillary central incisors, age 8 Full-CWF vs. No-CWF 2002 and 2016-17

Figure 4.2: Overview of study groups and main comparisons

This thesis focussed on 8-year-olds examined in Dublin and Cork-Kerry in 2016-17 (FACCT phase 2) who were participants in a longitudinal study that commenced in 2013-14 (FACCT phase 1) when they were 5-year-olds (in their first year of primary school). These children were born after downward adjustment of water fluoride concentration and thus had lifelong exposure to the reduced water fluoride concentration. In this thesis, using a before and after study design, dental caries in primary teeth and dental fluorosis in permanent teeth of 8-year-olds 2016-17 were compared with 8-year-olds examined in Dublin and Cork-Kerry as part of the cross-sectional NSSCOH 2002 before the

downward adjustment of water fluoride concentration (Figure 4.2, Objectives 1, 3a and 3b).

Concurrent control groups with no exposure to CWF were available in 2002 and 2016-17 in Cork-Kerry, facilitating controlled before-and–after studies in this region. However, as domestic water supplies throughout urban Dublin were fluoridated, no concurrent control group was available in Dublin at either time point.

For each time point (2002 and 2016-17), in Cork-Kerry, additional analyses were carried out to evaluate differences in the prevalence and severity of dental caries in primary teeth and dental fluorosis in permanent teeth of children with Full-CWF compared with No-CWF (Figure 4.2, Objectives 2, 4a and 4b) and to identify factors associated with dental caries and fluorosis in Cork-Kerry.

4.1.6 Study sample

The FACCT study was designed to facilitate comparison with data from the NSSCOH 2002. Thus, similar sampling methods were used in both studies. The method used to select the sample of 5-year-olds in the FACCT study 2013-14 (phase 1) is described in the following sections.

4.1.6.1 Selection of schools

Samples of 5-year-olds in 2013-14 were selected using multi-stage, stratified, cluster random sampling with school as the primary sampling unit. A list of primary schools in Dublin and Cork-Kerry in the school year 2011-12 (the most recent data available at the time the sample was drawn) formed the sampling frame for the study. Schools for children with special educational needs were not included in the sampling frame. Thus, children in Junior Infants (aged 4-6 years) attending randomly selected primary schools in Dublin and Cork-Kerry in the school year 2013-14 were eligible to participate in the FACCT study.

All schools in Dublin received a fluoridated water supply. For the Cork-Kerry schools, on the basis that children attending a school with a non-fluoridated water supply were more likely to live in a household without CWF, the sampling frame was stratified by the fluoridation status of the school water supply. The sampling frame for Dublin and Cork-Kerry was stratified by Community Care Area (CCA) (n=11: 6 in Dublin, 5 in Cork-Kerry) and school size (with similar sized schools in each of three strata). CCA was no longer used to define administrative areas for delivery of primary healthcare services at the time of the study in 2013. However, the use of CCA as the smallest geographic unit for sampling replicated the sampling method used in the NSSCOH 2002, facilitating direct comparison between the two datasets. Randomly selected schools were selected to participate in the study.

Each selected school was contacted, informed about the study and their willingness to participate ascertained. Where schools declined participation, a replacement school of the same size and fluoridation status was selected within the same CCA.

4.1.6.2 Selection of children within schools

4.1.6.2.1 Schools with a fluoridated water supply

The number of boys and girls in schools with a fluoridated water supply to whom consent forms were issued was decided *a priori* by the study statistician. These children were randomly selected within schools by the examining teams using a random number generating software programme. In instances where there was more than one class within a school year (e.g., more than one Junior Infant class in the same school), a class was randomly selected. If insufficient numbers of children were present in the first class selected, another class was randomly selected until the required number of children to issue consent forms was obtained. Children who were not selected to participate received

a letter to advise parents/caregivers about the random selection process and to inform them that their child was not selected to participate in the study.

4.1.6.2.2 Schools with a non-fluoridated water supply

The total number of 5-year-olds attending schools with a non-fluoridated water supply in 2011-12 was very close to the actual number required to meet the non-fluoridated sample size, therefore examining teams issued consent forms to all eligible children attending these schools.

4.1.6.3 Sample size

4.1.6.3.1 Sample size calculations

Sample size calculations were based on prevalence of dental fluorosis measured clinically using Dean's Index and mean dmft for children examined in Dublin and Cork-Kerry in the NSSCOH 2002. The calculations were directed towards answering the main research questions of the FACCT study related to clinical measures of dental fluorosis and dental caries:

1. Is there a difference in the prevalence of dental fluorosis in children whose permanent teeth mineralised with a water fluoride concentration of 0.6 to 0.8 ppm F compared with children whose permanent teeth mineralised with a water fluoride concentration of 0.8 to 1.0 ppm fluoride?
2. Is water fluoridation at the lower level of 0.6 to 0.8 ppm fluoride effective for preventing dental caries in primary teeth?

The target sample size of 424 8-year-olds with CWF in Cork-Kerry, 424 8-year-olds with no CWF in Cork-Kerry and 497 8-year-olds with CWF in Dublin had in excess of 80% power, at a 5% level of significance, to demonstrate that:

- the proportion of children with lifetime exposure to CWF with Dean's Index scores 'normal' in each region had increased by at least 5% since 2002.
- mean dental caries levels were at least 20% lower in children with lifetime exposure to CWF compared with children with no exposure to CWF in Cork-Kerry in 2016-17.

The sample size outlined above had 80% power to demonstrate a difference in d_{3vc}mft(cde) of 20% in Dublin and Cork-Kerry for children with CWF in 2016-17 relative to 2002.

4.1.6.3.2 Adjustments to sample size

The sample size was increased by 40% to account for the design effect due to using a cluster sampling technique. The sample was also increased to account for participants being classified as having neither Full-CWF nor No-CWF (20%) and for non-response (35%). As the 5-year-olds were re-examined at age 8, the sample was further increased to account for loss to follow-up during the subsequent three years (20%) (Table 4.1).

Table 4.1: Adjustments to FACCT sample size of 5-year-olds 2013-14

Region	Fluoridation Status	n	Design effect + 40%	Loss to follow up 20%	Neither Full-CWF/No-CWF 20%	Non-response 35%	Final n to issue consents to
Dublin	**Full-CWF**	497	696	870	1087	1673	**1673**
Cork-Kerry	**Full-CWF**	424	594	742	928	1427	**1427**
	No-CWF	424	594	742	928	1427	**1427**
	Total	**1345**	**1884**	**2354**	**2943**	**4527**	**4527**

4.1.7 Study documents

Each child selected to participate was given a FACCT study pack. The pack contained the following:

1 Study information leaflet

2 Parent/guardian consent and child assent form

3 Residential history form

4 Medical history form

5 Parent questionnaire

Copies of FACCT study information leaflets, consent/assent forms, residential history forms, medical history forms and parent questionnaires are available in Appendix D and in the Clinical Fieldwork Protocol [supplemental files] (James et al. 2018)).

Consent forms and questionnaires were previously piloted with parents and children in local Cork schools (representing a spectrum of socio-economic groups), to assess content, terminology, presentation, clarity and respondent burden, and were amended accordingly. Each document in the consent pack was labelled with a unique subject number barcode. This barcode served to link each subject's consent form and parent/caregiver questionnaire. The subject number barcode was assigned centrally by the Oral Health Services Research Centre (OHSRC) at the beginning of the study in 2013-14. The subject number barcode linked records for children examined in 2013-14 and 2016-17. Contact details for the OHSRC and the web address for the FACCT study were provided on the study information leaflet so that parents could clarify any aspects of the study before deciding whether to consent.

Parents/guardians who permitted their child to participate in the study returned the completed documentation to the school in the envelope provided. Returned documents

were evaluated by the examining team for positive consent/assent and to ensure that there was no medical reason to exclude the child from clinical examination.

Eligible children whose parents or guardians returned a completed consent/assent form and a completed medical history form were included in the study. Eligible children whose parents did not consent, who did not assent in writing (8-year-olds only), or who were unable or unwilling to participate on the day were not examined. Children with any medical condition that meant their participation in the study would pose a risk to their health or wellbeing were not examined.

Returning incomplete documentation did not preclude inclusion in the study provided that the consent/assent form and medical history form were completed. Every effort was made to obtain missing residential history information via follow-up phone calls with parents/caregivers who consented to be contacted by the study team. Children whose parents/caregivers did not complete or partially completed the parent questionnaire were included in the study; however, missing data may have resulted in the child's data being excluded from some of the statistical analyses.

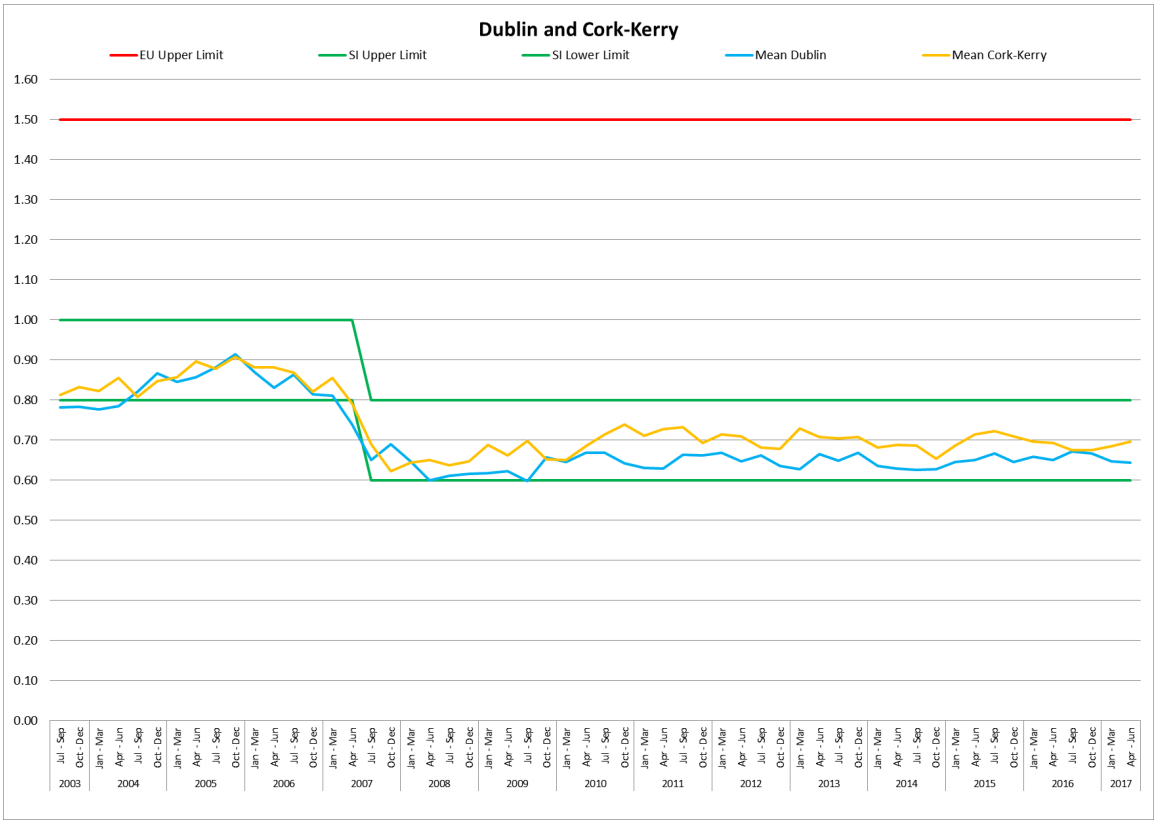
Documentation and questionnaires returned by parents/caregivers of 5-year-olds who were not clinically examined in phase 1 of FACCT in 2013-14 for example, because they were absent or refused to be examined on the day, were retained and follow-up was attempted when they were aged 8 in 2016-17.

The Irish language is the first official language of Ireland and the Official Languages Act 2003 (Government of Ireland 2003) promotes its use for official purposes. Therefore, all study documents were translated into Irish by Ionad na Gaeilge Labhartha, University College Cork and made available to parents/caregivers and participating children on request during the study.

4.2 Measurement of explanatory variables

4.2.1 Measurement of exposure to CWF

Data from mandatory monitoring of fluoride levels in public water supplies in Ireland confirmed that the downward adjustment was implemented from mid-2007 (Figure 4.3).



Note: SI upper and lower limits were the limits of CWF concentration specified in the legislation (SI = Statutory Instrument)

Figure 4.3: Quarterly mean water fluoride concentration (ppm F) for Dublin and Cork-Kerry from July 2003 to June 2017

4.2.1.1 FACCT 2016-17

Parents detailed their child's full residential history. Exposure to CWF was classified individually based on the fluoride concentration of water supplying the child's current and all previous addresses. The Irish Water website (https://www.water.ie/help/water-quality/) was used to facilitate this process which was completed after clinical examination by researchers not involved in clinical fieldwork. Participants were classified

as having lifetime exposure (Full-CWF), no exposure (No-CWF), sporadic exposure (Part-CWF), or unknown exposure (Unknown-CWF) to CWF.

- Children with Full-CWF resided at addresses continuously supplied by water fluoridated at > 0.4 ppm fluoride from at least 6 months old to the date of the dental examination.
- Children with No-CWF resided at addresses continuously supplied by non-fluoridated water at ≤ 0.4 ppm fluoride from at least 6 months old to the date of the dental examination.
- Children who had sporadic exposure to CWF or whose exposure could not be determined were classified Part-CWF or Unknown-CWF respectively and were not considered further in this study.

Further information about the classification of fluoridation status can be found in Appendix E.

4.2.1.2 NSSCOH 2002

In 2002, classification of exposure to CWF was the same in principle as in the FACCT study. Classification of exposure to CWF in 2002 included lifetime exposure (Full-CWF), no exposure (No-CWF), sporadic exposure (Part-CWF), or 'unknown' exposure to CWF (Not recorded) which corresponded with the categorisation used in FACCT.

In 2002, classification of the children's fluoridation status according to a defined protocol was completed by the examining teams, whereas in FACCT (phase 1 and 2), this classification was completed after clinical examination by researchers not involved in clinical fieldwork. Furthermore, with the passage of time, access to new resources including the Irish Water website (https://www.water.ie/help/water-quality/) facilitated

use of more sophisticated and accurate methods for classifying fluoridation status in the FACCT study.

4.2.2 Measurement of other explanatory variables

4.2.2.1 FACCT 2016-17

Socio-demographic and oral health behaviours data were collected in 2013-14 (at age 5, FACCT phase 1) and 2016-17 (at age 8, FACCT phase 2) via a parent-completed questionnaire (Available in Appendix D and in the clinical fieldwork protocol [supplemental files] (James et al. 2018)).

The questionnaire at age 5 included questions about:

- Parental medical card ownership and highest level of education attained by parents/caregivers,
- Age of commencing toothbrushing with fluoride toothpaste, toothbrushing behaviours at age < 2 years, age 2-3 and age 5 (the time of questionnaire administration) and use of other fluoride modalities such as fluoride tablets or drops,
- Dietary habits including infant feeding practices,
- Dental attendance.

A medical card is a means-tested benefit provided by the Irish State to applicants who meet criteria based on income, expenses, marital status, dependants, and other circumstances. Approximately one-third of the population of Ireland are eligible for a medical card (PCRS). Parental medical card ownership was used in the present study and in previous Irish oral health surveys (Whelton et al. 2006; Parnell et al. 2007) as a measure of socio-economic disadvantage.

Responses to questions about toothpaste use in infancy and early childhood and relevant infant feeding practices collected when the children were 5-year-olds were used in the analysis of data for 8-year-olds 2016-17. These questions were not repeated in the follow-up parent questionnaire at age 8.

The questionnaire at age 8 included questions about:

- Parental medical card ownership and highest level of education attained by parents/caregivers,
- Toothbrushing behaviours at age 8 and use of other fluoride modalities such as fluoride tablets or drops,
- Dietary habits,
- Dental attendance.

4.2.2.2 NSSCOH 2002

Socio-demographic and oral health behaviours data were collected for 8-year-olds in 2002 via a parent-completed questionnaire (Appendix D).

The questionnaire included questions about:

- Parental medical card ownership,
- Age of commencing toothbrushing, toothbrushing behaviours and use of other fluoride modalities such as fluoride tablets or drops at age 8,
- dietary habits,
- dental attendance.

4.3 Measurement of outcome variables

4.3.1 Sequence of the clinical examinations

The clinical examinations for 8-year-olds in the NSSCOH 2002 and the FACCT study were conducted according to the sequences presented in Table 4.2. In the NSSCOH 2002 and in FACCT phase 2 in 2016-17, Dean's Index was measured clinically after measurement of height and weight and the Developmental Defects of Enamel (DDE) index. Furthermore, oral photographs were taken after clinical fluorosis measurement in both studies. Thus, potential differences in drying time that could affect comparability of the fluorosis measurements were minimised. In both the NSSCOH 2002 and the FACCT study, assessment of dental caries was the final component of the clinical examination.

Table 4.2: Sequence of clinical examinations 2002 and 2016-17

Sequence	Age Group and year	
	8-Year-Olds 2002	**8-Year-Olds 2016-17**
1	Height and Weight	Height and Weight
2	DDE	DDE
3	Dean's Index*	Dean's Index*
4	Oral photographs*	Molar Incisor Hypomineralisation (MIH)
5	Assessment of dental trauma	Oral photographs*
6	Oral hygiene assessment	Dental caries*
7	Dental caries*	

*Components of the clinical examinations in each year that are relevant to this thesis

4.3.2 Clinical measurement of dental caries and fluorosis (Dean's Index)

4.3.2.1 FACCT 2016-17

4.3.2.1.1 Training and calibration

An experienced gold standard examiner (Professor Helen Whelton) trained the 12 dental examiners in 2016-17, supported during the training and calibration by two experienced

assistant gold standard examiners (Professor Mairead Harding and Dr Marie Tuohy). Dentists' training consisted of a combination of desk-based training and primary school based clinical training. The desk-based component of the training included a combination of small group interactive teaching sessions based around epidemiological measurement of dental caries, dental fluorosis and developmental defects of enamel and discussion of photographs and slides of dental fluorosis. The dentists' training in recognising and scoring dental fluorosis with Deans Index (Dean 1942) was supplemented by an online fluorosis training tool (Whelton et al. 2014). The online tool included a series of training sessions and a final calibration session. The dentists' calibration results from the online fluorosis tool were used by the study team to monitor each dentist's progress during the training. In the school-based calibration session following school-based training, dental examiners were required to achieve kappa values above 0.6 indicating at least substantial agreement with the gold standard examiners (Landis and Koch 1977; McHugh 2012) on scores for dental caries and fluorosis prior to commencing fieldwork. Examiners who did not achieve a kappa value above 0.6 in the school-based calibration exercise for dental fluorosis continued training with the online fluorosis tool until they could consistently achieve a kappa value above 0.6 in the online calibration.

During training, dentists and dental nurses were introduced to the protocol for recording the indices, including the correct positioning of the child and examiner and the procedures involved in organising and conducting oral epidemiological fieldwork. They were guided through the procedures involved in setting up a clinical examination station in a school. During the school-based training, the dental nurses assisted the dentists and recorded the dentists' clinical scores. A fieldwork manual (available at: https://www.ucc.ie/en/media/research/ohsrc/FACCTFieldworkmanual2016_2017.pdf) and video resource (available at:

https://www.ucc.ie/en/ohsrc/research/facct/educationalresourcesfordentalprofessionals/) explaining the procedures involved in organising and conducting oral epidemiological fieldwork were produced and made available to assist the examining teams during clinical fieldwork.

Dental examiners assisted by dental nurses conducted clinical examinations in schools between November 2016 and May 2017. Clinical data were entered directly to a dedicated laptop computer using a software package designed for the NSSCOH 2002 and modified for the FACCT study. The two assistant gold standard examiners in 2016-17 were the 'roving' gold standard examiners deployed to monitor inter-examiner agreement during the FACCT fieldwork. Approximately 5% of the children were re-examined for dental caries and fluorosis during the fieldwork to monitor both inter- and intra-examiner agreement.

4.3.2.1.2 Dental caries

Dental caries in primary teeth was measured using WHO criteria (World Health Organisation 2013) modified to include visible non-cavitated dentinal caries (d_{3vc}mft, 'v' indicating 'visual caries') (Whelton et al. 2006). Children were examined supine on a table covered with a foam camping mat with a disposable head rest cover. The teeth were examined wet. A WHO Community Periodontal Index (CPI) probe (World Health Organisation 2013) was used to remove plaque and food debris and/or to confirm cavitation. Lighting was provided by a portable dental light source ('Daray' lamp (www.daray.co.uk). WHO criteria and their modification to include non-cavitated carious lesions into dentine were described in Section 2.4.1. The codes used during the clinical examination and the clinical record form are presented in Appendix D.

Dental caries experience was reported as the proportion of children with decayed, missing or filled primary canines, first and second primary molars (prevalence, $d_{3vc}mft(cde)>0$) and mean $d_{3vc}mft(cde)$ among children with caries experience (severity).

4.3.2.1.3 Dental fluorosis (Dean's Index)

Dental fluorosis in permanent teeth was measured using Dean's Index (Dean 1942) according to a standard protocol. Children were examined upright, facing a window without drying the teeth. After assessing all permanent teeth present, examiners assigned a person-level score of 'normal', 'questionable', 'very mild', 'mild', 'moderate' or 'severe' based on the condition of the two most severely affected teeth or the lesser affected tooth if the two most severely affected teeth were not equally affected (World Health Organisation 2013). The diagnostic criteria for recording Dean's Index were presented in Table 2.6. The case definition for dental fluorosis was a Dean's Index score 'very mild' or greater.

4.3.2.2 NSSCOH 2002

4.3.2.2.1 Training and calibration

Dental examiners assisted by dental nurses conducted clinical examinations in schools between January and June 2002. The same gold standard examiner as in the FACCT study (Professor Helen Whelton) trained the 11 dental examiners in Dublin and Cork-Kerry, supported during the training and calibration by experienced assistant gold standard examiners. The structure of the training programme was similar in 2002 and in FACCT. A summary of the main features of the training and calibration programmes in 2002 and 2016-17 are summarised in Table 4.3.

In 2002, dental examiners were required to achieve kappa values above 0.4 indicating at least moderate agreement with the gold standard examiners before commencing clinical

fieldwork. The minimum threshold for examiner agreement was lower in the NSSCOH 2002 than in the FACCT study (Kappa > 0.4 vs. > 0.6 respectively). However, this was the standard interpretation of Kappa at the time according to the arbitrary divisions described by Landis and Koch (Landis and Koch 1977). Inter- and intra-examiner agreement were monitored during the 2002 fieldwork.

Table 4.3: Details of training and calibration 2002 and 2016-17

Training and calibration before commencement of fieldwork	**2002**	**2016-17**
Dental nurses trained to use direct data entry software on dedicated laptop computers	√	√
Video resource "Setting up for School Dental Examinations"	x	√
Small group interactive teaching sessions for dentists	√	√
Group discussion and individual scoring of photographs of dental caries, dental fluorosis and other developmental defects of enamel by dentists.	√	√
Use of training and calibration components of the online fluorosis training tool ' e-training for Dean's Index' (Whelton et al. 2014)	x	√
School based clinical training	√	√
Final calibration based on clinical scores in school-based calibration exercise	√	√
Minimum acceptable level of agreement with gold standard examiners during calibration exercise	0.4 'moderate agreement*'	0.6 'substantial agreement*^'

* (Landis and Koch 1977), ^ Moderate agreement (McHugh 2012)

4.3.2.2.2 Dental caries

Dental caries in primary teeth was measured using WHO criteria (World Health Organisation 2013) modified to include visible non-cavitated dentinal caries (d_{3vc}mft, 'v' indicating 'visual caries'). The protocol for measuring dental caries was identical in 2002 and in FACCT 2016-17 as described in Section 4.3.2.1.2

4.3.2.2.3 Dental fluorosis (Dean's Index)

Dental fluorosis in permanent teeth was measured using Dean's Index (Dean 1942) according to the same standard protocol described previously for FACCT 2016-17 (Section 4.3.2.1.3).

4.3.3 Photographic measurement of dental fluorosis (TF Index)

Assessment of dental fluorosis using oral photographs addresses the subjective nature of clinical assessment of dental fluorosis, by allowing the assessment to be conducted by an independent researcher blind to the fluoridation status of the subjects. Furthermore, photographic measurement of fluorosis facilitates repeat measurement by the same or different examiners and provides a permanent record that can be used to assess temporal trends in dental fluorosis.

Oral photographs were taken for 8-year-olds in Dublin and Cork-Kerry during the FACCT study. During the NSSCOH 2002, oral photographs were taken for 8-year-olds in Cork-Kerry but not in Dublin. Although the Cork-Kerry photographs for 2002 were scored using Dean's Index (anterior teeth) in 2007, the results were not analysed or presented at that time. In FACCT and the NSSCOH, the photographs were taken using the same standardised photographic method modified from the technique developed by Judith Cochran and colleagues (Cochran et al. 2004c) as described in Section 2.7.5. The following sections outline the methods used to measure dental fluorosis in maxillary central incisors from oral photographs of 8-year-olds in 2016-17 and 2002 using the TF Index.

4.3.3.1 FACCT 2016-17

Digital oral photographs of the incisor teeth were taken for 8-year-olds during the 2016-17 clinical fieldwork. Dental examiners were trained to photograph the incisor teeth according to a standardised photographic procedure which was modified from the method developed by Cochrane et al. (Cochran et al. 2004c). Teeth were photographed using a Canon EOS 1100D digital camera with a Sigma 105mm macro lens and Sigma EM140-DG macro ring flash for even lighting. The photographs were centered on the midline between the maxillary central incisors and taken from approximately 30 degrees

(between 30 and 45 degrees) above the incisal edge to reduce lip shadow. The magnification ratio was set at 1:1.5. The field of the photograph included the maxillary and mandibular incisors with the child biting in the edge-to-edge position. Two photographs were taken of each child. The teeth were photographed 'wet' after 8 seconds of drying to record the appearance of the teeth under normal conditions and 'dry' after 60 seconds of drying to allow detection of dental fluorosis at the lowest levels of severity. Further information about the photographic method can be found in the fieldworkers' manual (https://www.ucc.ie/en/media/research/ohsrc/FACCTFieldworkmanual2016_2017.pdf).

4.3.3.2 NSSCOH 2002

Although the NSSCOH 2002 included representative samples of children from all counties in Ireland, oral photographs of the incisor teeth were taken for children in selected counties rather than for the national sample of children. Oral photographs were taken for 8-year-olds in Cork-Kerry during the NSSCOH 2002 according to a modification of the standardised method described by Cochrane et al. (Cochran et al. 2004c) (as described in Section 4.3.3.1). These photographs were used in the FACCT study. Dublin was not selected for oral photographs in the NSSCOH 2002.

In the NSSCOH 2002 one photograph was taken for each child, after 8 seconds of drying. The photographs were taken using photographic film and converted into slides. To ensure comparability of the images from 2016-17 and 2002 for dental fluorosis scoring and to facilitate blinding to year, the 2002 slides were professionally digitised for the present study to match the format of the oral photographs taken during the FACCT study.

4.3.3.3 Training and calibration for photographic measurement of dental fluorosis

The candidate (PJ, Examiner 1) and Dr Deirdre Browne (Examiner 2) undertook the photographic measurement of dental fluorosis. Both examiners had previous experience of using the TF Index as outlined below:

- In September 2014, both examiners were trained and calibrated in the clinical and photographic application of the TF Index as part of a study in Newcastle upon Tyne, UK to assess training methodology and to select a group of scorers to assess photographs of dental fluorosis from the 2013–14 National Health and Nutrition Examination Survey (NHANES). Professor Roger Ellwood was the gold standard for the TF Index during the training programme which was described in detail by Dye et al. (2018).
- Examiner 2 was previously trained and calibrated in the use of the TF Index by Professor Roger Ellwood and gained extensive experience in employing the TF Index clinically and from oral photographs while undertaking her PhD (Browne 2008).

Both examiners were re-calibrated to the gold standard examiner (Professor Roger Ellwood) during a 1-day training session at the OHSRC, Cork in December 2018. During the training, photographs of permanent maxillary incisors were viewed on a computer monitor, scored using the TF Index and discussed. A set of 120 photographs were scored by Professor Roger Ellwood to be used for further training (the 'training set'). A set of 30 photographs of 8-year-olds were selected from the 'training set' to be used as a 'calibration set'. These 30 photographs were removed from the 'training set' and scored by Examiner 1 and 2 the week following the training to measure agreement between each examiner and the gold standard in advance of commencing scoring of the 2016-17/2002 photographs. Percentage agreement on the person level TF Index score was 90% for

Examiner 1 and 97% for Examiner 2. Kappa scores were 0.87 and 0.96 for Examiner 1 and 2 respectively indicating almost perfect agreement between the examiners and the gold standard examiner in advance of commencing scoring of the 2016-17/2002 photographs.

4.3.3.4 Preparation of photographs for scoring

Whereas two photographs (one 'wet, one' dry') were taken for each 8-year-old in 2016-17, only one photograph was taken for each 8-year-old in 2002 after 8 seconds of drying ('wet'). Therefore, the photographic comparison of dental fluorosis 2016-17 versus 2002 focussed on the teeth photographed 'wet'. Although the TF Index was designed for use after drying the teeth, scoring dental fluorosis on teeth photographed 'wet' reflects the prevalence of dental fluorosis most relevant for public health, as these images most closely approximate the appearance of the maxillary central incisors under real-life conditions. The process used to prepare the photographs for scoring is outlined in Figure 4.4.

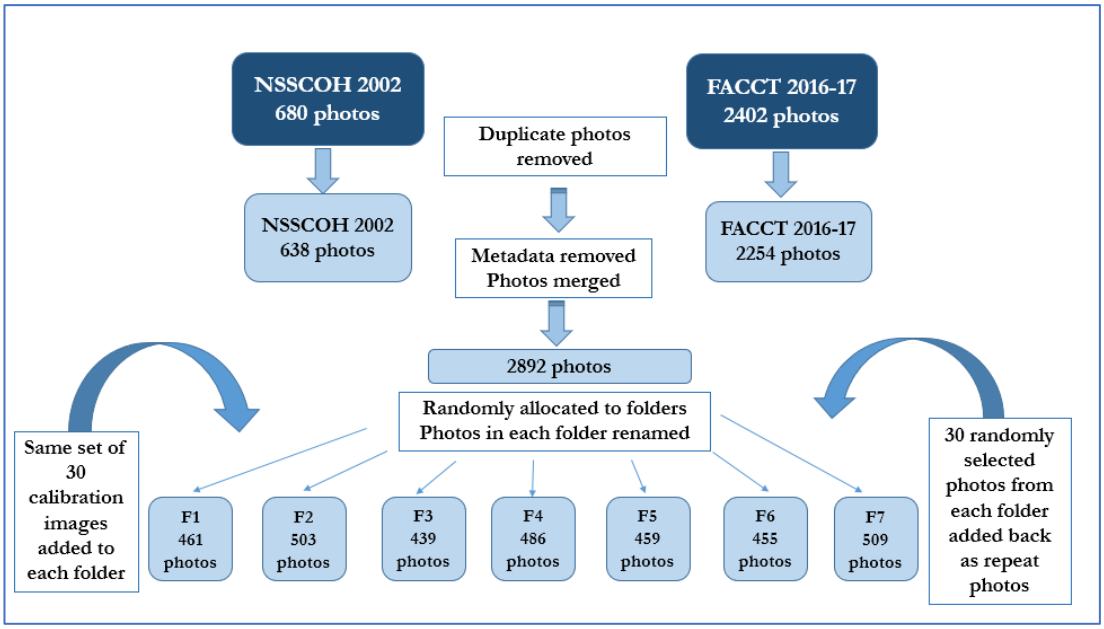


Figure 4.4: Preparation of photographs of 8-year-olds 2002 and 2016-17 for scoring

Photographs for children examined in Dublin and Cork-Kerry during FACCT phase 2, 2016-17 (n=2,254) and in Cork-Kerry in 2002 (n=638) were prepared for scoring by a researcher not involved with scoring the photographs (Darragh Beecher). Duplicate photographs and all identifying or descriptive data (metadata) associated with each photograph were removed. To ensure blinding to year, a solid black box was applied to cover the date/time stamp on the 2002 photographs (Figure 4.5) and the same box was applied to the FACCT photographs in the same position.

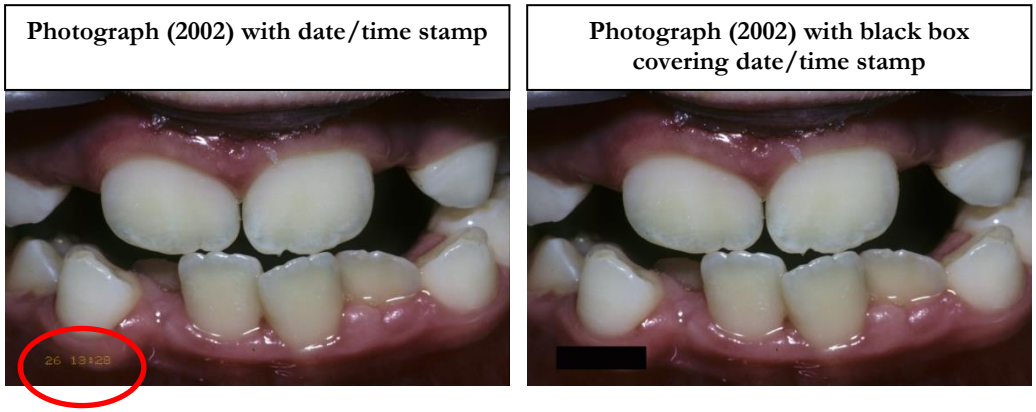


Figure 4.5: Example of a 2002 photograph before and after application of the solid black box

To facilitate measurement of inter-examiner reliability between the two examiners and the gold standard examiner throughout the scoring process, the photographs (n=2,892) were randomly allocated into seven folders. The set of 30 photographs scored by the gold standard examiner and used in the initial calibration (the 'calibration set') were added to each folder so that the same 30 images were randomly distributed throughout each of the seven folders. This enabled any potential 'examiner drift' during the process of scoring the photographs to be detected.

In addition, 30 photographs from each folder were randomly selected by an automated computer process and added back to the same folder as random repeat photographs (total 210/2,892, 7%). Photographs within each folder were randomly renamed with a 5-digit number to maintain blinding.

4.3.3.5 Dental fluorosis measurement (TF Index)

The labial surfaces of the permanent maxillary central incisors were scored independently and in duplicate by the two examiners using the TF Index (Thylstrup and Fejerskov 1978) as modified by Fejerskov et al. (1988) Measurement criteria for the TF Index were presented in Table 2.7.

Examiners used identical laptop computers linked to identical monitors with the same viewing settings. The examiners scored the photographs in separate locations, but each examiner standardised their own viewing conditions (i.e., the same location/room with low ambient lighting). Teeth were excluded from scoring if they were less than one-third erupted, if there were fixed appliances in place or if the labial surface of the tooth was not fully visible for any other reason (e.g., large restoration or non-fluoride opacity).

The photographs were scored from September to December 2019. Disagreements on the TF scores were resolved by consensus in January and February 2020. Where consensus

could not be reached, the gold standard examiner (Roger Ellwood) assigned the scores. After agreeing consensus scores, a person level score for each child was calculated based on the highest score in the maxillary central incisors. Two case definitions for dental fluorosis were used based on the person level score: TF 1 or greater and TF 2 or greater. The TF scores were linked to the original clinical record for each child in the FACCT and 2002 datasets. Although the scored photographs included children with Full-CWF, No-CWF, Part-CWF and Unknown-CWF at both time points, subsequent analysis focussed only on scores for children with Full-CWF or No-CWF in 2016-17 and 2002.

Intra-examiner agreement was calculated for each examiner using percentage agreement and kappa scores for the 210 randomly repeated photographs across the seven folders. Inter-examiner agreement was calculated for each examiner using percentage agreement and kappa scores for the 30 'calibration set' photographs in each of the seven folders. Results for intra-examiner and inter-examiner agreement are presented in Section 4.3.4.2.

4.3.4 Examiner agreement

4.3.4.1 Clinical measurement of dental caries and fluorosis (Dean's Index)

4.3.4.1.1 Age 8 2016-17: Dental caries and fluorosis (Dean's Index)

Percentage agreement and kappa scores for repeat dental caries and fluorosis examinations conducted during clinical fieldwork in 2016-17 are presented by examiner in Table 4.4.

Table 4.4: Dental caries and fluorosis (Dean's Index, clinical) in 8-year-olds 2016-17: Intra-examiner and inter-examiner agreement during clinical fieldwork

	Dental caries						Dental fluorosis (Dean's Index score)					
	Intra-examiner agreement			Inter-examiner agreement			Intra-examiner agreement			Inter-examiner agreement		
Region / Examiner	n[a]	% Agree	k	n[a]	% Agree	k	n[b]	% Agree	k	n[b]	% Agree	k
Dublin												
A	1158	97	0.77	1470	98	0.80	11	82	0.69	14	71	0.43
B	733	>99	0.96	1976	98	0.88	6	83	0.71	19	89	0.73
C	986	99	0.87	1583	98	0.81	10	80	0.57	15	100	1.00
D	914	99	0.89	1655	99	0.83	9	100	1.00	16	88	0.74
Cork-Kerry												
A	635	100	1.00	306	99	0.89	6	nc	nc	3	nc	nc
B	1034	99	0.92	1629	98	0.55	10	90	0.80	16	94	0.76
C	726	>99	0.99	2072	97	0.80	7	100	1.00	20	95	0.81
D	2539	99	0.94	1179	99	0.92	24	100	1.00	11	100	1.00
E	2693	99	0.96	1509	98	0.77	26	96	0.92	15	93	0.63
F	2984	99	0.87	1319	98	0.76	29	100	1.00	13	nc	nc
G	1268	97	0.84	1643	97	0.81	12	100	1.00	16	75	0.56
H	1228	99	0.93	1565	98	0.85	12	92	0.82	15	93	0.64

[a] Number of tooth surfaces
[b] Number of children
k= kappa score
% Agree = percentage agreement
nc = not calculable because the number of observations were insufficient or due to the absence of variation in the scores

For dental caries, repeat examinations yielded intra-examiner percentage agreement of between 97% and 100% and kappa scores ranging from 0.77 to 1.00 (median 0.92). Inter-examiner percentage agreement for dental caries ranged from 97% to 99% with kappa scores ranging from 0.55 to 0.92 (median 0.81). These kappa scores indicated substantial to almost perfect intra-examiner agreement and moderate to almost perfect inter-examiner agreement according to the interpretation suggested by Landis and Koch (1977).

For dental fluorosis, repeat examinations yielded intra-examiner percentage agreement on Dean's Index score ('normal', 'questionable', 'very mild', 'mild' or 'moderate') of between 80% and 100% with kappa scores ranging from 0.57 to 1.00 (median 0.92). Inter-examiner

percentage agreement on Dean's Index score ranged from 71% to 100% with kappa scores ranging from 0.43 to 1.00 (median 0.74). These results indicated moderate to almost perfect intra- and inter-examiner agreement.

4.3.4.1.2 Age 8 2002: Dental caries and fluorosis (Dean's Index)

Percentage agreement and kappa scores for repeat dental caries and fluorosis examinations conducted during clinical fieldwork in 2002 are presented by examiner in Table 4.5. For dental caries, repeat examinations yielded intra-examiner percentage agreement of between 98% and 100% and kappa scores ranging from 0.86 to 1.00 (median 0.97) indicating almost perfect intra-examiner agreement. For dental fluorosis, repeat examinations yielded intra-examiner percentage agreement on Dean's Index score of between 65% and 100% and kappa scores ranging from 0.40 to 1.00 (median 0.67) indicating fair to almost perfect intra-examiner agreement. Although inter-examiner agreement with gold standard examiners was monitored in 2002, results of inter-examiner agreement for dental caries and fluorosis were unavailable.

Table 4.5: Dental caries and fluorosis (Dean's Index, clinical) in 8-year-olds 2002: Intra- examiner agreement during clinical fieldwork

	Intra-examiner agreement					
	Dental caries			Dental fluorosis (Dean's Index score)		
Region						
Examiner	**n[a]**	**% Agree**	**k**	**n[b]**	**% Agree**	**k**
Dublin						
A	1807	99	0.88	17	65	0.52
B	432	>99	0.91	4	100	1.00
C	103	100	1.00	1	nc	nc
D	412	100	1.00	4	nc	nc
E	1142	>99	0.98	11	100	1.00
F	564	99	0.86	9	89	0.73
Cork-Kerry						
A	212	100	1.00	2	nc	nc
B	319	>99	0.97	6	83	0.67
C	1763	100	1.00	17	94	nc
D	319	98	0.90	3	67	0.40
E	432	>99	0.95	5	80	0.58

[a] Number of tooth surfaces
[b] Number of children
k= kappa score
% Agree = percentage agreement
nc = not calculable because the number of observations were insufficient or due to the absence of variation in the scores

4.3.4.2 Photographic measurement of dental fluorosis

4.3.4.2.1 Dental fluorosis (TF Index) 2016-17 and 2002

Intra-examiner agreement for the 2016-17/2002 set of photographs was measured from 210 photographs randomly selected to be re-scored by each of the two examiners as described in Section 4.3.3.4. Thirteen photographs were excluded from the kappa calculation, four where there was disagreement between the examiners about whether the photograph was of suitable quality to be scored and nine where both maxillary central incisors were unerupted or less than one third erupted. Calculation of intra-examiner agreement was based on each examiner's repeat person-level scores for the same 197 photographs. Percentage agreement was 84% for Examiner 1 (PJ) and 87% for Examiner

2 (DB). Kappa scores were 0.72 and 0.77 for Examiner 1 and 2 respectively indicating substantial intra-examiner agreement.

The same set of 30 photographs scored by the gold standard examiner (the 'calibration set') were randomly distributed through each of the seven folders (210 photographs in total across the seven folders) as described in Section 4.3.3.4. Percentage agreement and kappa scores for inter-examiner agreement between each examiner and the gold standard examiner are presented for each of the seven folders of 2016-17/2002 photographs in Table 4.6.

Table 4.6: Dental fluorosis (TF Index): Inter-examiner agreement between each examiner and the gold standard examiner for photographic scores of 8-year-olds (2016-17 and 2002 combined, person-level score)

	Dental Fluorosis (TF Index)				
	Inter-examiner agreement				
		Examiner 1 vs. Gold standard		Examiner 2 vs. Gold standard	
Folder no.	n	% Agreement	kappa	% Agreement	kappa
1	30	80	0.74	63	0.53
2	30	97	0.96	77	0.70
3	30	90	0.87	77	0.69
4	30	77	0.69	83	0.78
5	30	93	0.91	80	0.73
6	30	87	0.83	80	0.74
7	30	87	0.83	77	0.69
Total	210	-	-	-	-

For Examiner 1, percentage agreement with the gold standard examiner was between 77% and 97% and kappa scores ranged from 0.69 to 0.96 (median 0.83) across the seven folders indicating substantial to almost perfect agreement with the gold standard examiner during the scoring. For Examiner 2, percentage agreement with the gold standard examiner was between 63% and 83% and kappa scores ranged from 0.53 to 0.78 (median 0.70) across the seven folders indicating moderate to substantial agreement with the gold standard examiner during the scoring.

4.4 Statistical analysis

4.4.1 Introduction

Children whose parents/caregivers reported they had ever taken fluoride tablets or drops were excluded from all analyses. Analyses were restricted to children with Full-CWF and No-CWF. Dublin and Cork-Kerry represented two distinct geographic areas within Ireland. Dublin is a large urban area where over one-quarter of the Irish population resided at the time of the FACCT study (Central Statistics Office 2017), while 15% of the Irish population lived in Counties Cork and Kerry with a mix of smaller urban areas and rural areas. Therefore, Dublin and Cork-Kerry were sampled, described, and analysed separately. Explanatory variables included those relevant to dental caries and fluorosis from the FACCT parent-completed questionnaire at age 5 (phase 1, 2013-14) and age 8 (phase 2, 2016-17) and the NSSCOH parent-completed questionnaire at age 8 (2002) (Appendix D).

A summary of the statistical methods employed to meet the objectives are presented in Table 4.7 and the statistical methods are described in detail in Sections 4.4.2 to 4.4.7. All explanatory variables considered relevant to each outcome were included in the multivariable regression models regardless of their statistical significance in univariate analysis. Therefore, the statistical methods described here relate to the multivariable regression analyses. Univariate analyses of the association between each of the explanatory variables and 1) dental caries and 2) dental fluorosis were conducted for objective 2 (dental caries), 4a (Dean's Index) and 4b (TF Index) and are reported in Appendix F.

Table 4.7: Overview of statistical methods used to meet the objectives

Outcome	Statistical model	Objective	Multivariable regression analyses
Dental caries prevalence (d_{3vc}mft(cde)>0) Dental caries severity (mean d_{3vc}mft(cde) among children with caries experience)	HNB regression[ab]	1	2016-17 vs. 2002 ▪ Dublin Full-CWF ▪ Cork-Kerry Full-CWF ▪ Cork-Kerry No-CWF ▪ Cork-Kerry Full-CWF and No-CWF combined with Interaction Year and CWF
		2	Cork-Kerry ▪ Full-CWF vs No-CWF 2002 ▪ Full-CWF vs No-CWF 2016-17
Dental fluorosis: Dean's Index Very mild or greater, whole mouth score, measured clinically	Logistic regression[b]	3a	2016-17 vs. 2002 ▪ Dublin Full-CWF ▪ Cork-Kerry Full-CWF ▪ Cork-Kerry No-CWF ▪ Cork-Kerry Full-CWF and No-CWF combined with Interaction Year and CWF
		4a	Cork-Kerry ▪ Full-CWF vs No-CWF 2002 ▪ Full-CWF vs No-CWF 2016-17
Dental fluorosis: TF Index TF 1 or greater, TF 2 or greater Maxillary central incisors, measured from photographs	Logistic regression[b]	3b	2016-17 vs. 2002 ▪ Cork-Kerry Full-CWF ▪ Cork-Kerry No-CWF ▪ Cork-Kerry Full-CWF and No-CWF combined with Interaction Year and CWF
		4b	Cork-Kerry ▪ Full-CWF vs No-CWF 2002 ▪ Full-CWF vs No-CWF 2016-17

[a] Hurdle negative binomial regression.
[b]All explanatory variables considered relevant to the outcomes were included in the multivariable regression models regardless of their statistical significance in univariate analyses.

Relevant explanatory variables were identified based on the literature review and the results of the NSSCOH 2002, and categorical responses were grouped, where appropriate, for the regression analyses. Although the aim of the study was to evaluate the outcome of downward adjustment of water fluoride concentration on dental caries and fluorosis, introduction of toothbrushing guidance in 2002 also had the potential to affect dental caries and fluorosis levels in children born after their introduction. To account for this, reported age of commencing fluoride toothpaste use was controlled for

in all multivariable regression analyses for dental caries and fluorosis. Other reported toothbrushing behaviours before age 2 such as frequency of toothbrushing and a history of eating or licking toothpaste were controlled for in multivariable regression analyses of fluorosis outcomes in 2016-17 (comparable information was not collected in 2002).

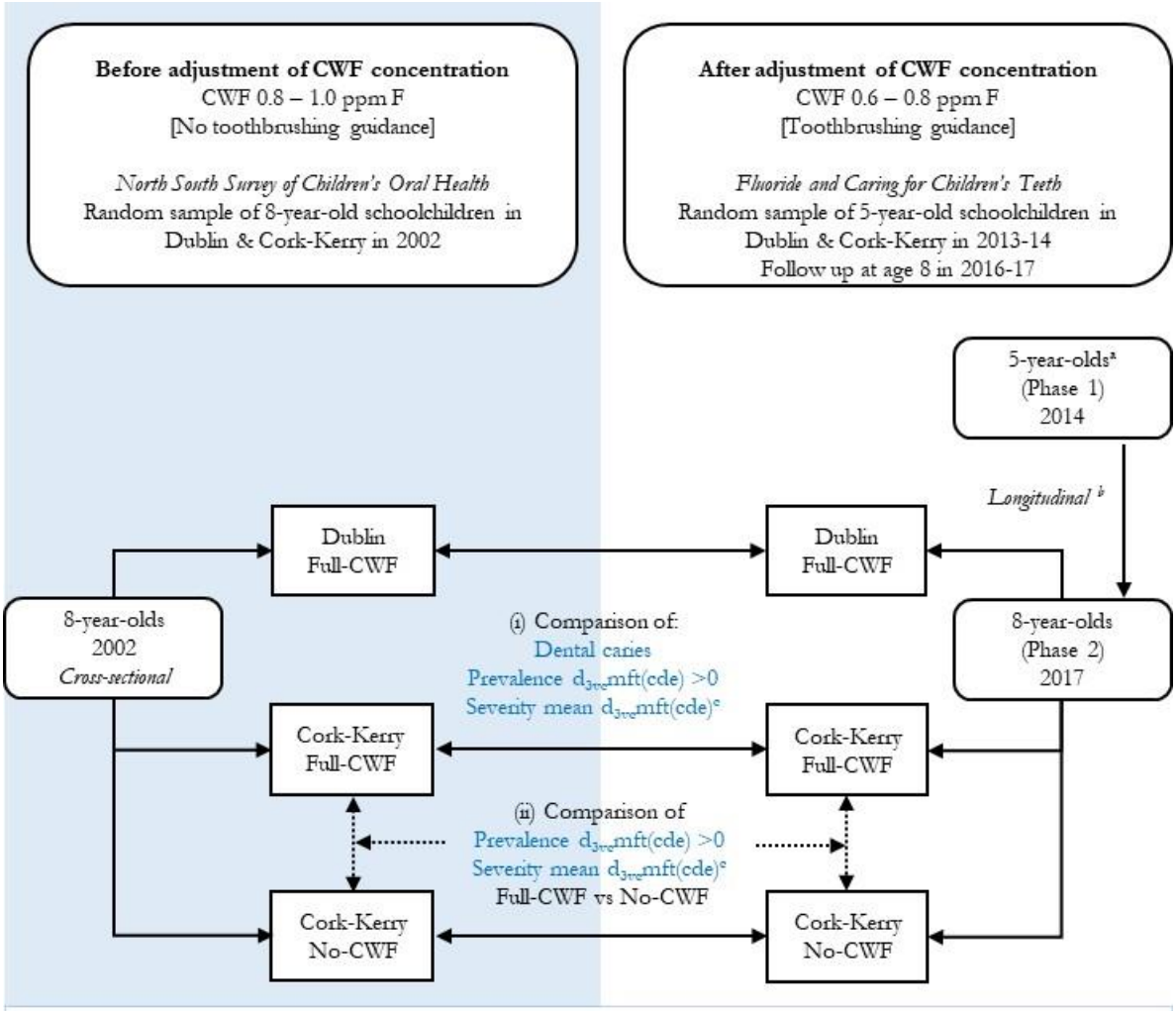
Father's education at age 8 was excluded from the 2016-17 analyses due to the high proportion of missing responses (Dublin Full-CWF 14% missing, Cork-Kerry Full-CWF 10% missing). A wider set of explanatory variables were included in the 2016-17 regression analyses than in 2002 reflecting the additional information collected via parent-completed questionnaire in the FACCT study.

Weighting was not used in the statistical analyses because 1) the emphasis was on multivariable comparisons rather than on estimation of means and proportions, 2) weighted estimates of means/proportions for the combined Cork-Kerry and Dublin regions are not representative of any geographical/administrative entity and in particular, would not be representative of the Republic of Ireland, 3) hurdle models are a two-stage statistical modelling process, in which the analysis sets/populations differ between the two stages and thus, are not amenable to application of weights.

Data were analysed using STATA (IC Version 14.2) and SAS (Version 9.4) software. Significance level was $P < 0.05$.

4.4.2 Objective 1: Dental caries 2016-17 vs. 2002

The design of the before and after study to assess differences in the prevalence and severity of dental caries in primary teeth of 8-year-olds in FACCT 2016-17 compared with 8-year-olds in the NSSCOH 2002 is shown in Figure 4.6.



(i) Analyses of association between year of examination and caries prevalence and severity in Dublin Full-CWF, Cork-Kerry Full-CWF and Cork-Kerry No-CWF
(ii) Analyses to test the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) in Cork-Kerry
[a] Information about age first used toothpaste collected via a parent-completed questionnaire at age 5 (2013-14) was used in the analysis at age 8 (2016-17)
[b] 5-year-olds who participated in phase 1 of the FACCT study in 2013-14 were invited to participate in phase 2 in 2016-17
[c] Severity of caries was mean $d_{3ve}mft(cde)$ among children with caries experience

Figure 4.6: Study design to assess differences in dental caries in primary teeth of 8-year-olds in FACCT 2016-17 vs. NSSCOH 2002 (Objective 1)

Differences in dental caries prevalence and severity in primary teeth of 8-year-olds with Full-CWF and No-CWF in 2016-17 compared with 2002 were tabulated and described narratively. Relevant data from the FACCT and NSSCOH 2002 datasets were combined with the main explanatory variable, year of examination (2016-17 or 2002), used to differentiate between the two datasets. An overview of the analyses, including details of the explanatory variables included in the multivariable hurdle negative binomial (HNB) regression models, is presented in Table 4.8.

The HNB model is particularly suited to dental caries data as it takes account of the positively skewed distribution and the large number of zero values indicating individuals without caries experience (Hofstetter et al. 2016). The HNB model part 1 models dental caries prevalence i.e., the presence or absence of dental caries. In individuals without caries experience, the 'hurdle' is not cleared. Thus, the HNB model part 2 models the amount (or severity) of dental caries in individuals with caries experience. The odds ratio (OR) was the measure of association reported for part 1 of the HNB. For part 2, the percentage difference in mean d_{3vc}mft(cde) was reported.

Table 4.8: Overview of analyses for comparison of dental caries 2016-17 vs. 2002 (Objective 1)

Dental Caries Age 8 2016-17 vs. Age 8 2002		
	(i)	**(ii)**
Dataset	1) Dublin (Full-CWF) 2016-17 and 2002 combined 2) Cork-Kerry (Full-CWF) 2016-17 and 2002 combined 3) Cork-Kerry (No-CWF) 2016-17 and 2002 combined	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17 and 2002
Analysis method	Multivariable regression with the HNB[a] model Separate regression models for 1) 2) and 3) above Interactions tested between year of examination and all other explanatory variables for 1) 2) and 3) above	Multivariable regression with the HNB[a] model with interaction term (Year and Fluoridation Status)
Outcome variables	HNB Part 1: Caries prevalence (proportion with d_{3vc}mft(cde)>0) HNB Part 2: Caries severity (mean d_{3vc}mft(cde) among children with caries experience)	HNB Part 1: Caries prevalence (proportion with d_{3vc}mft(cde)>0) HNB Part 2: Caries severity (mean d_{3vc}mft(cde) among children with caries experience)
Main explanatory variable	Year (2016-17 vs. 2002)	Interaction term Year and CWF
Other explanatory variables	Age Medical card[b] Age first used toothpaste[c] Frequency of toothbrushing at age 8 Amount of toothpaste at age 8 Rinse method after toothbrushing at age 8 Sweet foods/drinks between meals at age 8 Age at first visit to the dentist	Age Medical card[b] Age first used toothpaste[c] Frequency of toothbrushing at age 8 Amount of toothpaste at age 8 Rinse method after toothbrushing at age 8 Sweet foods/drinks between meals at age 8 Age at first visit to the dentist

(i) Analyses of association between year of examination and caries prevalence and severity in Dublin Full-CWF, Cork-Kerry Full-CWF and Cork-Kerry No-CWF
(ii) Analyses to test the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) in Cork-Kerry

[a] HNB= Hurdle Negative Binomial

[b] Medical card ownership was used in this study to indicate socio-economic disadvantage

[c] Parent reported at age 5 in 2013-14 in FACCT dataset All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

Multivariable regression with the HNB model assessed the association between year of examination and caries prevalence (HNB Part 1) and severity (HNB Part 2), controlled for the effects of other explanatory variables (Table 4.8 (i)). Separate analyses were conducted for children in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-

Kerry with No-CWF. In each regression model, two-way interactions were tested between year of examination and all other explanatory variables to assess whether any differences in dental caries prevalence or severity between 2002 and 2016-17 depended on any of the other explanatory variables.

A separate multivariable HNB Model for Cork-Kerry Full-CWF and No-CWF combined assessed differences in caries prevalence and severity between children with Full-CWF and No-CWF in 2016-17 versus 2002 by testing the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) (Table 4.8 (ii)).

4.4.3 Objective 2: Dental caries Full-CWF vs. No-CWF 2002 and 2016-17

Dental caries prevalence and severity in primary teeth of 8-year-olds in Cork-Kerry with Full-CWF and No-CWF in 2002 and 2016-17 were tabulated and described narratively. Multivariable regression with the HNB model assessed the association between CWF and dental caries prevalence (HNB Part 1) and severity (HNB Part 2) separately for 2002 and 2016-17, controlled for the effects of other explanatory variables. In each regression model, two-way interactions were tested between fluoridation status (Full-CWF or No-CWF) and all other explanatory variables to assess whether differences in dental caries prevalence or severity between children with Full-CWF and No-CWF depended on any of the other explanatory variables.

An overview of the analyses including details of the explanatory variables included in the regression models are presented in Table 4.9.

Table 4.9: Overview of analyses for comparison of dental caries Full-CWF vs. No-CWF 2002 and 2016-17 (Objective 2)

	Dental Caries Full-CWF vs. No-CWF 2002 (Age 8)	**Dental Caries Full-CWF vs. No-CWF 2016-17 (Age 8)**
Dataset	Cork-Kerry (Full-CWF and No-CWF combined) 2002	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17
Analysis method	Multivariable regression with the HNB[a] model Interactions tested between CWF and all other explanatory variables	Multivariable regression with the HNB[a] model Interactions tested between CWF and all other explanatory variables
Outcome variables	HNB Part 1: Caries prevalence (proportion with d_{3vc}mft(cde)>0) HNB Part 2: Caries severity (mean d_{3vc}mft(cde) among children with caries experience)	HNB Part 1: Caries prevalence (proportion with d_{3vc}mft(cde)>0) HNB Part 2: Caries severity (mean d_{3vc}mft(cde) among children with caries experience)
Main explanatory variable	CWF (Full-CWF vs. No-CWF) at Age 8	CWF (Full-CWF vs. No-CWF) at Age 8
Other explanatory variables	Age Medical Card[b] Age first used toothpaste Frequency of toothbrushing at age 8 Amount of toothpaste at age 8 Rinse method after toothbrushing at age 8 Sweet foods/drinks between meals at age 8 Age at first visit to the dentist	Age Medical Card[b] Mother's Education Age first used toothpaste[c] Frequency of toothbrushing at age 8 Amount of toothpaste at age 8 Rinse method after toothbrushing at age 8 Sweet foods/drinks between meals at age 8 Type of water child usually drinks Regularly took baby bottle into bed[c] Age weaned to cup/mug[c] Age at first visit to the dentist

[a] HNB= Hurdle Negative Binomial

[b] Medical card ownership was used in this study to indicate socio-economic disadvantage

[c] Parent reported at age 5 in 2013-14 in FACCT dataset All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

4.4.4 Objective 3a: Dental fluorosis (Dean's Index) 2016-17 vs. 2002

Dental fluorosis prevalence and severity measured using Dean's Index (clinical, whole mouth score) in 2002 and 2016-17 were tabulated and described narratively. The case definition of dental fluorosis was Dean's Index 'very mild' or greater. Dental fluorosis prevalence was modelled using logistic regression analysis with the OR as the measure of association. Differences in dental fluorosis severity were not assessed in multivariable analysis for Dean's Index because numbers of children with 'mild' or 'moderate' fluorosis, were too small to be considered as separate categories or grouped together as 'mild' or greater.

The design of the before and after study to assess differences in the prevalence of dental fluorosis (Dean's Index 'very mild' or greater) in 8-year-olds in FACCT 2016-17 compared with 8-year-olds in the NSSCOH 2002 is shown in Figure 4.7.

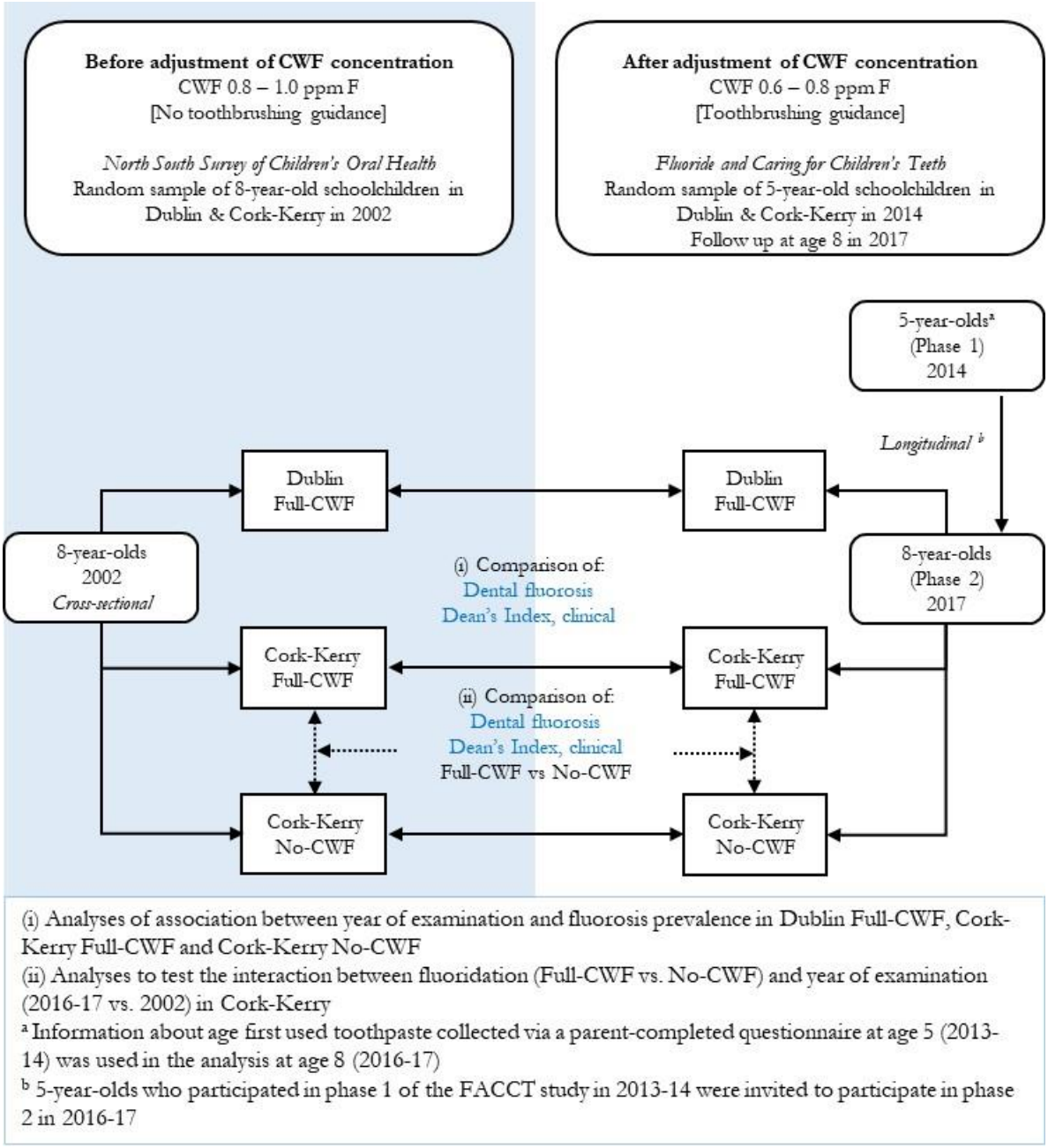


Figure 4.7: Study design to assess differences in dental fluorosis (Dean's Index, clinical) in 8-year-olds in FACCT 2016-17 vs. NSSCOH 2002 (Objective 3a)

Relevant data from the FACCT and NSSCOH 2002 datasets were combined with the main explanatory variable, year of examination (2016-17 or 2002), used to differentiate between the two datasets. Separate analyses were conducted for children in Dublin with Full-CWF, Cork-Kerry with Full-CWF and in Cork-Kerry with No-CWF. An overview

of the analyses including details of the explanatory variables included in the logistic regression models is presented in Table 4.10.

Table 4.10: Overview of analyses for comparison of dental fluorosis (Dean's Index) 2016-17 vs. 2002 (Objective 3a)

Dental Fluorosis (Dean's Index) Age 8 2016-17 vs. Age 8 2002		
	(i)	**(ii)**
Dataset	1) Dublin (Full-CWF) 2016-17 and 2002 combined 2) Cork-Kerry (Full-CWF) 2016-17 and 2002 combined 3) Cork-Kerry (No-CWF) 2016-17 and 2002 combined	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17 and 2002
Analysis method	Multivariable logistic regression Separate regression models for 1) 2) and 3) above Interactions tested between year of examination and all other explanatory variables for 1) 2) and 3) above	Multivariable logistic regression with interaction term (Year and Fluoridation Status)
Outcome variable	Fluorosis Prevalence: Dean's Index 'very mild' or greater vs. 'normal'/'questionable'	Fluorosis Prevalence: Dean's Index 'very mild' or greater vs. 'normal'/'questionable'
Main explanatory variable	Year of examination (2016-17 vs. 2002)	Interaction term Year and CWF
Other explanatory variables	Age Gender Medical card[a] Age first used toothpaste[b]	Age Gender Medical card[a] Age first used toothpaste[b]

(i) Analyses of association between year of examination and fluorosis prevalence in Dublin Full-CWF, Cork-Kerry Full-CWF and Cork-Kerry No-CWF

(ii) Analyses to test the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) in Cork-Kerry

[a] Medical card ownership was used in this study to indicate socio-economic disadvantage.

[b] Parent reported at age 5 in 2013-14 in FACCT dataset All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

Multivariable logistic regression assessed the association between year of examination and dental fluorosis prevalence (Dean's Index 'very mild' or greater), controlled for the effects of other explanatory variables (Table 4.10 (i)). In each regression model, two-way interactions were tested between year of examination and all other explanatory variables to assess whether any differences in fluorosis prevalence between 2002 and 2016-17 depended on any of the other explanatory variables.

A separate multivariable logistic regression model for Cork-Kerry Full-CWF and No-CWF combined assessed differences in dental fluorosis prevalence (Dean's Index 'very mild' or greater) between children with Full-CWF and No-CWF in 2016-17 versus 2002 by testing the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) (Table 4.10 (ii)).

4.4.5 Objective 3b: Dental fluorosis (TF Index) 2016-17 vs. 2002

Dental fluorosis prevalence and severity in maxillary central incisors measured using the TF Index (2002 and 2016-17) were tabulated and described narratively. Two case definitions for dental fluorosis were based on the maximum score in the maxillary central incisors: TF 1 or greater and TF 2 or greater. The OR was the measure of association reported in the logistic regression analyses. The number of children with TF 3 or greater was too small to be considered as a separate category in the regression analysis. However, the two case definitions of dental fluorosis modelled in multivariable logistic regression analyses reflected different levels of dental fluorosis severity (TF 1 or greater and TF 2 or greater). Identical multivariable logistic regression analyses were conducted for dental fluorosis defined as TF 1 or greater and TF 2 or greater. The analyses relate to Cork-Kerry only, because oral photographs were not taken for children in Dublin during the NSSCOH 2002.

The design of the before and after study to assess differences in the prevalence of dental fluorosis in maxillary central incisors of 8-year-olds in FACCT 2016-17 compared with 8-year-olds in the NSSCOH 2002 is shown in Figure 4.8.

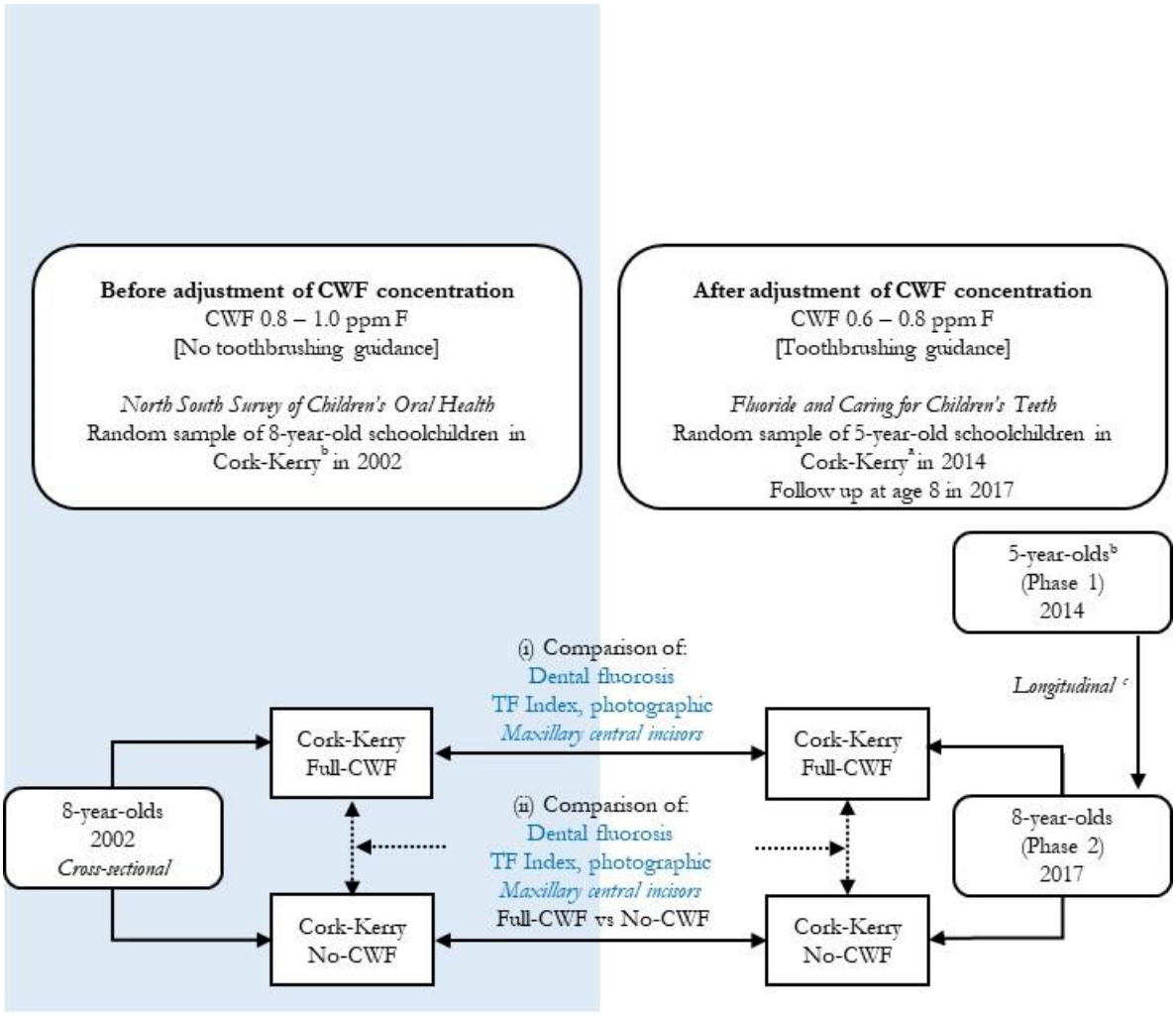


Figure 4.8: Study design to assess differences in dental fluorosis (TF Index, from photographs) in 8-year-olds in FACCT 2016-17 vs. NSSCOH 2002 (Objective 3b)

Relevant data for Cork-Kerry from the FACCT and NSSCOH 2002 datasets were combined with the main explanatory variable, year of examination (2016-17 or 2002), used to differentiate between the two datasets. Separate analyses were conducted for children in Cork-Kerry with Full-CWF and with No-CWF. An overview of the analyses

including details of the explanatory variables included in the logistic regression models is presented in Table 4.11

Table 4.11: Overview of analyses for comparison of dental fluorosis in maxillary central incisors (TF Index) 2016-17 vs. 2002 (Objective 3b)

Dental Fluorosis (TF Index) 2016-17 vs. 2002		
	(i)	**(ii)**
Dataset	1) Cork-Kerry (Full-CWF) 2016-17 and 2002 combined 2) Cork-Kerry (No-CWF) 2016-17 and 2002 combined	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17 and 2002
Analysis method	Multivariable logistic regression Separate regression models for groups 1) and 2) above and for TF 1 or greater and TF 2 or greater Interactions tested between year of examination and all other explanatory variables for groups 1) and 2) above and for both case definitions of dental fluorosis	Multivariable logistic regression with interaction term (Year and Fluoridation Status) Separate regression models for TF 1 or greater and TF 2 or greater
Outcome variables	Fluorosis prevalence (maxillary central incisors) 1) TF 1 or greater vs. TF 0 2) TF 2 or greater vs. TF 0 and 1	Fluorosis prevalence (maxillary central incisors) 1) TF 1 or greater vs. TF 0 2) TF 2 or greater vs. TF 0 and 1
Main explanatory variable	Year of examination (2016-17 vs. 2002)	Interaction term Year and CWF
Other explanatory variables	Age Gender Medical card[a] Age first used toothpaste[b]	Age Gender Medical card[a] Age first used toothpaste[b]

(i) Analyses of association between year of examination and fluorosis prevalence in Cork-Kerry Full-CWF and Cork-Kerry No-CWF

(ii) Analyses to test the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) in Cork-Kerry

[a] Medical card ownership was used in this study to indicate socio-economic disadvantage

[b] Parent reported at age 5 in 2013-14 in FACCT dataset. All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

Multivariable logistic regression assessed the association between year of examination and dental fluorosis prevalence for each case definition of dental fluorosis (TF 1 or greater and TF 2 or greater) controlled for the effects of other explanatory variables (Table 4.11 (i)). In each regression model, two-way interactions were tested between year of examination and all other explanatory variables to assess whether any differences in

fluorosis prevalence between 2002 and 2016-17 depended on any of the other explanatory variables.

Separate logistic regression models for Cork-Kerry Full-CWF and No-CWF combined assessed differences in dental fluorosis prevalence for each case definition of dental fluorosis between children with Full-CWF and No-CWF in 2016-17 versus 2002 by testing the interaction between fluoridation (Full-CWF vs. No-CWF) and year of examination (2016-17 vs. 2002) (Table 4.11 (ii)).

4.4.6 Objective 4a: Dental fluorosis (Dean's Index) Full-CWF vs. No-CWF 2002 and 2016-17

Multivariable logistic regression assessed the association between CWF and dental fluorosis prevalence (Dean's Index 'very mild' or greater) in Cork-Kerry, separately for 2002 and 2016-17, controlling for the effects of other explanatory variables. In each regression model, two-way interactions were tested between fluoridation status (Full-CWF or No-CWF) and all other explanatory variables to assess whether differences in fluorosis prevalence between children with Full-CWF and No-CWF depended on any of the other explanatory variables.

An overview of the analyses including details of the explanatory variables included in the multivariable regression models is presented in Table 4.12.

Table 4.12: Overview of analyses for comparison of dental fluorosis (Dean's Index) Full-CWF vs. No-CWF 2002 and 2016-17 (Objective 4a)

	Dental fluorosis (Dean's Index) Full-CWF vs. No-CWF 2002 (Age 8)	**Dental Fluorosis (Dean's Index) Full-CWF vs. No-CWF 2016-17 (Age 8)**
Dataset	Cork-Kerry (Full-CWF and No-CWF combined) 2002	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17
Analysis method	Multivariable logistic regression Interactions tested between CWF and all other explanatory variables	Multivariable logistic regression Interactions tested between CWF and all other explanatory variables
Outcome variable	Fluorosis Prevalence: Dean's Index 'very mild' or greater vs. 'normal'/'questionable'	Fluorosis Prevalence: Dean's Index 'very mild' or greater vs. 'normal'/'questionable'
Main explanatory variable	CWF (Full-CWF vs. No-CWF)	CWF (Full-CWF vs. No-CWF)
Other explanatory variables	Age Gender Medical card[a] Age first used toothpaste	Age Gender Medical card[a] Mother's Education Age first used toothpaste[b] Frequency of toothbrushing before age 2[b] Amount of toothpaste before age 2[b] Eats/licks toothpaste before age 2[b] Breastfed[b]

[a] Medical card ownership was used in this study to indicate socio-economic disadvantage

[b] Parent reported at age 5 in 2013-14 in FACCT dataset All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

4.4.7 Objective 4b: Dental fluorosis (TF Index) Full-CWF vs. No-CWF 2002 and 2016-17

Multivariable logistic regression assessed the association between CWF and dental fluorosis prevalence (maxillary central incisors, TF 1 or greater and TF 2 or greater) in Cork-Kerry, separately for 2002 and 2016-17, controlling for the effects of other explanatory variables. In each regression model, two-way interactions were tested between fluoridation status (Full-CWF or No-CWF) and all other explanatory variables to assess whether any differences in fluorosis prevalence between children with Full-CWF and No-CWF depended on any of the other explanatory variables.

An overview of the analyses including details of the explanatory variables included in the regression models is presented in Table 4.13.

Table 4.13: Overview of analyses for comparison of dental fluorosis in maxillary central incisors (TF Index) Full-CWF vs. No-CWF 2002 and 2016-17 (Objective 4b)

	Dental fluorosis (TF Index) Full-CWF vs. No-CWF 2002	**Dental fluorosis (TF Index) Full-CWF vs. No-CWF 2016-17**
Dataset	Cork-Kerry (Full-CWF and No-CWF combined) 2002	Cork-Kerry (Full-CWF and No-CWF combined) 2016-17
Analysis method	Multivariable logistic regression Separate regression models for TF 1 or greater and TF 2 or greater Interactions tested between CWF and all other explanatory variables	Multivariable logistic regression Separate regression models for TF 1 or greater and TF 2 or greater Interactions tested between CWF and all other explanatory variables
Outcome variables	Fluorosis prevalence (maxillary central incisors) 1) TF 1 or greater vs. TF 0 2) TF 2 or greater vs. TF 0 and 1	Fluorosis prevalence (maxillary central incisors) 1) TF 1 or greater vs. TF 0 2) TF 2 or greater vs. TF 0 and 1
Main explanatory variable	CWF (Full-CWF vs. No-CWF)	CWF (Full-CWF vs. No-CWF)
Other explanatory variables	Age Gender Medical card[a] Age first used toothpaste	Age Gender Medical card[a] Mother's Education Age first used toothpaste[b] Frequency of toothbrushing before age 2[b] Amount of toothpaste before age 2[b] Eats/licks toothpaste before age 2[b] Breastfed[b]

[a] Medical card ownership was used in this study to indicate socio-economic disadvantage

[b] Parent reported at age 5 in 2013-14 in FACCT dataset All other explanatory variables in 2016-17 and 2002 were parent reported at age 8

5 Results: Characteristics of the children

This chapter describes the numbers and characteristics of children examined in the FACCT study 2016-17 and in the NSSCOH 2002.

1. The flows of 8-year-olds through the FACCT study and the NSSCOH 2002 are outlined.
2. The number of children clinically examined for dental caries and fluorosis in 2016-17 and 2002 and the number of children included in the analysis of dental fluorosis measured from oral photographs at each time point are outlined.
3. Socio-demographic characteristics and oral health behaviours of 8-year-olds born after downward adjustment of water fluoride concentration (examined 2016-17) are described.
4. Socio-demographic characteristics and oral health behaviours of 8-year-olds born after downward adjustment of water fluoride concentration (examined 2016-17) are compared with 8-year-olds examined in the same regions in 2002 prior to the adjustment.

5.1 Description of the samples

5.1.1 FACCT Age 8 2016-17

The flow of 5- and 8-year-olds through FACCT phase 1 (2013-14) and 2 (2016-17) respectively and the samples analysed for each outcome are outlined in Figure 5.1. Of 4,215 5-year-olds invited to participate in FACCT phase 1 in 2013-14, 3,054 consented to participate (response rate 72%). In phase 2 in 2016-17, of 2,674 8-year-olds invited to participate 2,380 (89%) consented.

Of the 4,215 children initially invited to participate at age 5 in phase 1 of FACCT, 2,308 (55%) were followed-up at age 8 and examined clinically for dental caries and 2,304 (55%) for fluorosis (Dean's Index, clinical) in phase 2 in 2016-17.

In 2016-17, 2,315 8-year-olds were examined clinically for dental caries or fluorosis in Dublin and Cork-Kerry. In Dublin, 89% of children had Full-CWF (n=707). In Cork-Kerry, 25% of children had Full-CWF (n=376) and 51% had No-CWF (n=772) (Figure 5.1).

Analyses of dental caries included 1,849 children, 704 in Dublin, 375 in Cork-Kerry with Full-CWF and 770 in Cork-Kerry with No-CWF. Analyses of dental fluorosis, measured using Dean's Index, included 1,846 children, 703 in Dublin, 371 in Cork-Kerry with Full-CWF and 772 in Cork-Kerry with No-CWF (Figure 5.1).

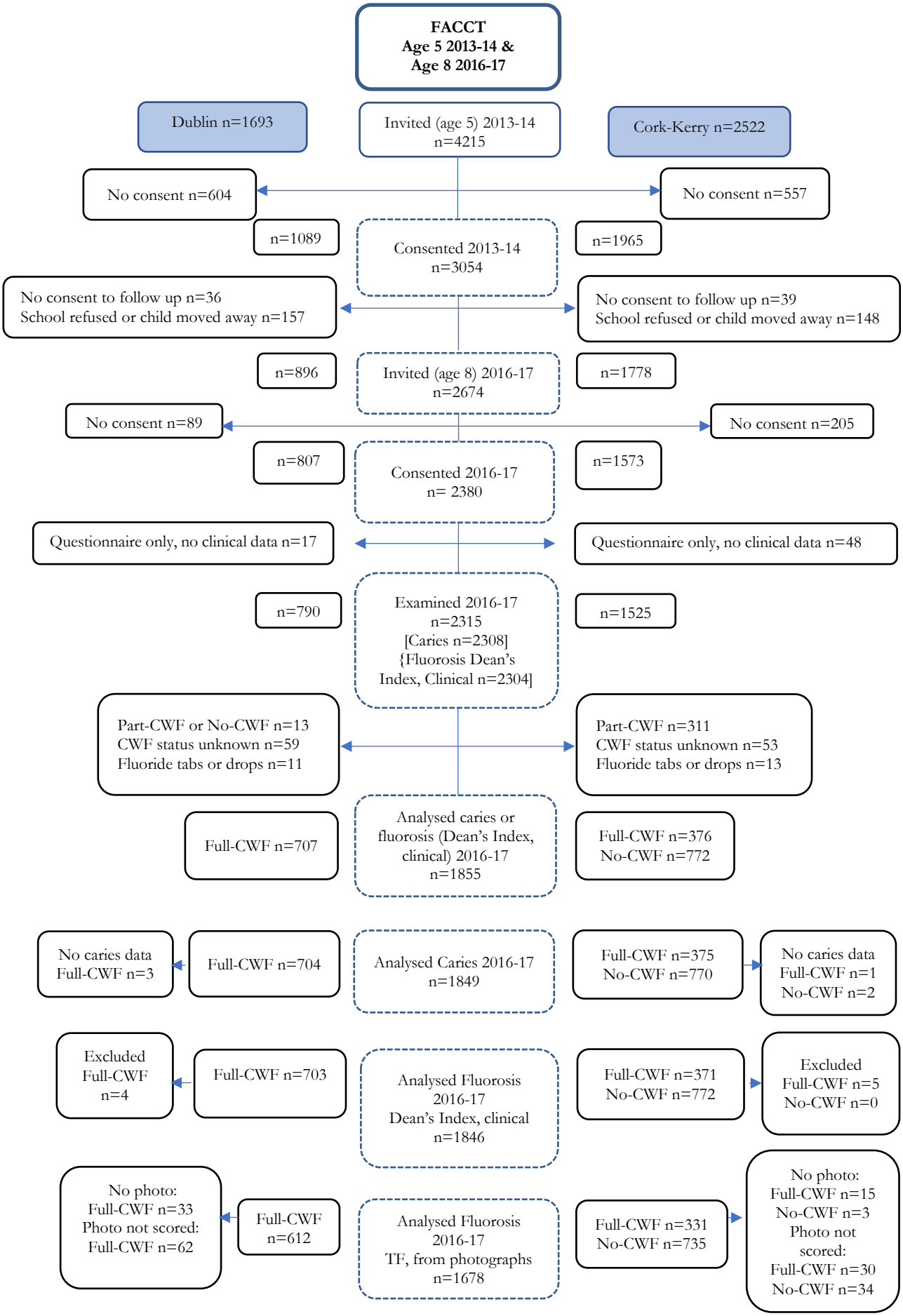


Figure 5.1: Flow of 5- and 8-year-olds through the FACCT study and numbers analysed for each outcome

Of 707 children with Full-CWF examined in Dublin in 2016-17, 612 (87%) were included in the analyses of dental fluorosis measured from photographs using the TF Index. In Cork-Kerry, 331 children with Full-CWF out of 376 children examined (88%) and 735 children with No-CWF out of 772 examined (95%) were included in the TF Index analyses.

In Dublin 2016-17, photographs were not available for 5% of children and photographs of a further 9% of children could not be scored. Among children with Full-CWF in Cork-Kerry 2016-17, photographs were not available for 4% of children and photographs for a further 8% could not be scored. Among children with No-CWF in Cork-Kerry 2016-17 photographs were not available for 0.6% of children and photographs for a further 4% could not be scored. The most common reason that photographs could not be scored in 2016-17 was unerupted or partially erupted (less than one-third) permanent maxillary central incisors (Table 5.1).

Table 5.1: Summary of reasons that children with oral photographs in 2016-17 were excluded from the analysis

Reason photograph not scored	Dublin Full-CWF	Cork-Kerry Full-CWF	Cork-Kerry No-CWF
Permanent maxillary central incisors unerupted or partially erupted (less than one-third)	49	29	26
Fixed orthodontic appliance in situ	0	0	1
Poor image quality	13	1	7
Total	**62**	**30**	**34**

Socio-demographic characteristics of children in Dublin and Cork-Kerry whose parents consented to participate in 2013-14 and of children who were followed up and examined in 2016-17 were similar (Table 5.2 and 5.3). However, there were a higher proportion of dependants of medical card/GP card holders among children who were lost to follow-up in both regions in 2016-17 compared with those who consented to participate in the study in 2013-14 and who were examined in 2016-17.

Table 5.2: Socio-demographic characteristics at baseline (2013-14) for children in Dublin who consented at age 5 in phase 1 (Consented 2013-14), children who were followed-up and examined in phase 2 (Examined 2016-17) and children who consented in phase 1 but were not examined in phase 2 (Lost to follow-up 2016-17)

	Dublin				
	Consented 2013-14	Examined 2016-17		Lost to follow-up 2016-17	
	All	All	Full-CWF	All	Full-CWF
Characteristic	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Gender					
Female	542 (50)	413 (52)	386 (54)	129 (43)	97 (40)
Male	546 (50)	376 (48)	335 (46)	170 (57)	145 (60)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total	**1088 (100)**	**789 (100)**	**721 (100)**	**299 (100)**	**242 (100)**
Age* (phase 1)	5.2 (0.4)	5.2 (0.4)	5.2 (0.4)	5.2 (0.4)	5.1 (0.4)
MC/GP visit card					
Yes	424 (39)	275 (35)	250 (35)	149 (50)	127 (52)
No	646 (59)	504 (64)	462 (64)	142 (47)	111 (46)
Missing	18 (2)	10 (1)	9 (1)	8 (3)	4 (2)
Total	**1088 (100)**	**789 (100)**	**721 (100)**	**299 (100)**	**242 (100)**

*mean (SD)
MC/GP visit card=Medical card or GP visit card. Used in this study to indicate socio-economic disadvantage
Total number consented 1088 rather than 1089 as reported in Figure 5.1 because parents/caregivers of one child consented and completed residential history only. No demographic information was available for this child. Numbers for phase 2 differ slightly from those reported in Figure 5.1 because by necessity, socio-demographic variables, and fluoridation status for phase 1 (age 5) rather than phase 2 (age 8) were used to generate this table. Numbers examined 2016-17 in 'All' include all children (all F status categories) who had a dental caries or fluorosis examination in Dublin in phase 2; 'Full-CWF' includes only children categorised Full-CWF in Dublin in phase 1 (age 5).

Table 5.3: Socio-demographic characteristics at baseline (2013-14) for children in Cork-Kerry who consented at age 5 in phase 1 (Consented 2013-14), children who were followed-up and examined in phase 2 (Examined 2016-17) and children who consented in phase 1 but were not examined in phase 2 (Lost to follow-up 2016-17)

	Cork-Kerry						
	Consented 2013-14	Examined 2016-17			Lost to follow-up 2016-17		
	All	All	Full-CWF	No-CWF	All	Full-CWF	No-CWF
Characteristic	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gender							
Female	993 (51)	795 (52)	214 (53)	401 (50)	198 (45)	67 (45)	86 (54)
Male	969 (49)	731 (48)	188 (47)	394 (50)	238 (54)	83 (55)	73 (46)
Missing	1 (0)	0 (0)	0 (0)	0 (0)	1 (<1)	0 (0)	0 (0)
Total	**1963 (100)**	**1526 (100)**	**402 (100)**	**795 (100)**	**437 (100)**	**150 (100)**	**159 (100)**
Age* (phase 1)	5.3 (0.4)	5.4 (0.4)	5.3 (0.4)	5.4 (0.4)	5.3 (0.4)	5.2 (0.4)	5.4 (0.4)
MC/GP visit card							
Yes	652 (33)	467 (31)	150 (37)	193 (24)	185 (42)	69 (46)	56 (35)
No	1273 (65)	1032 (68)	244 (61)	591 (74)	241 (55)	78 (52)	100 (63)
Missing	38 (2)	27 (2)	8 (2)	11 (1)	11 (3)	3 (2)	3 (2)
Total	**1963 (100)**	**1526 (100)**	**402 (100)**	**795 (100)**	**437 (100)**	**150 (100)**	**159 (100)**

*mean (SD)
Percentages may not sum to 100 due to rounding.
MC/GP visit card=Medical card or GP visit card. Used in this study to indicate socio-economic disadvantage.
Total number consented 1963 rather than 1965 as reported in Figure 5.1 because parents/caregivers of two children consented and completed residential history only. No demographic information was available for these children.
Numbers for phase 2 differ slightly from those reported in Figure 5.1 because by necessity, socio-demographic variables, and fluoridation status for phase 1 (age 5) rather than phase 2 (age 8) were used to generate this table.
Numbers examined 2016-17 in 'All' include all children (all F status categories) who had a dental caries or fluorosis examination in Cork-Kerry in phase 2; 'Full-CWF' and 'No-CWF' include only children categorised Full-CWF or No-CWF in Cork-Kerry in phase 1 (age 5).

5.1.2 NSSCOH Age 8 2002

The flow of 8-year-olds through the NSSCOH 2002 and the samples analysed for each outcome are outlined in Figure 5.2. Of 2,021 children invited to participate, 1,372 were clinically examined in Dublin and Cork-Kerry (response rate of 68%). In Dublin, 94% of children examined had Full-CWF. In Cork-Kerry, 51% of children examined had Full-CWF and 36% had No-CWF.

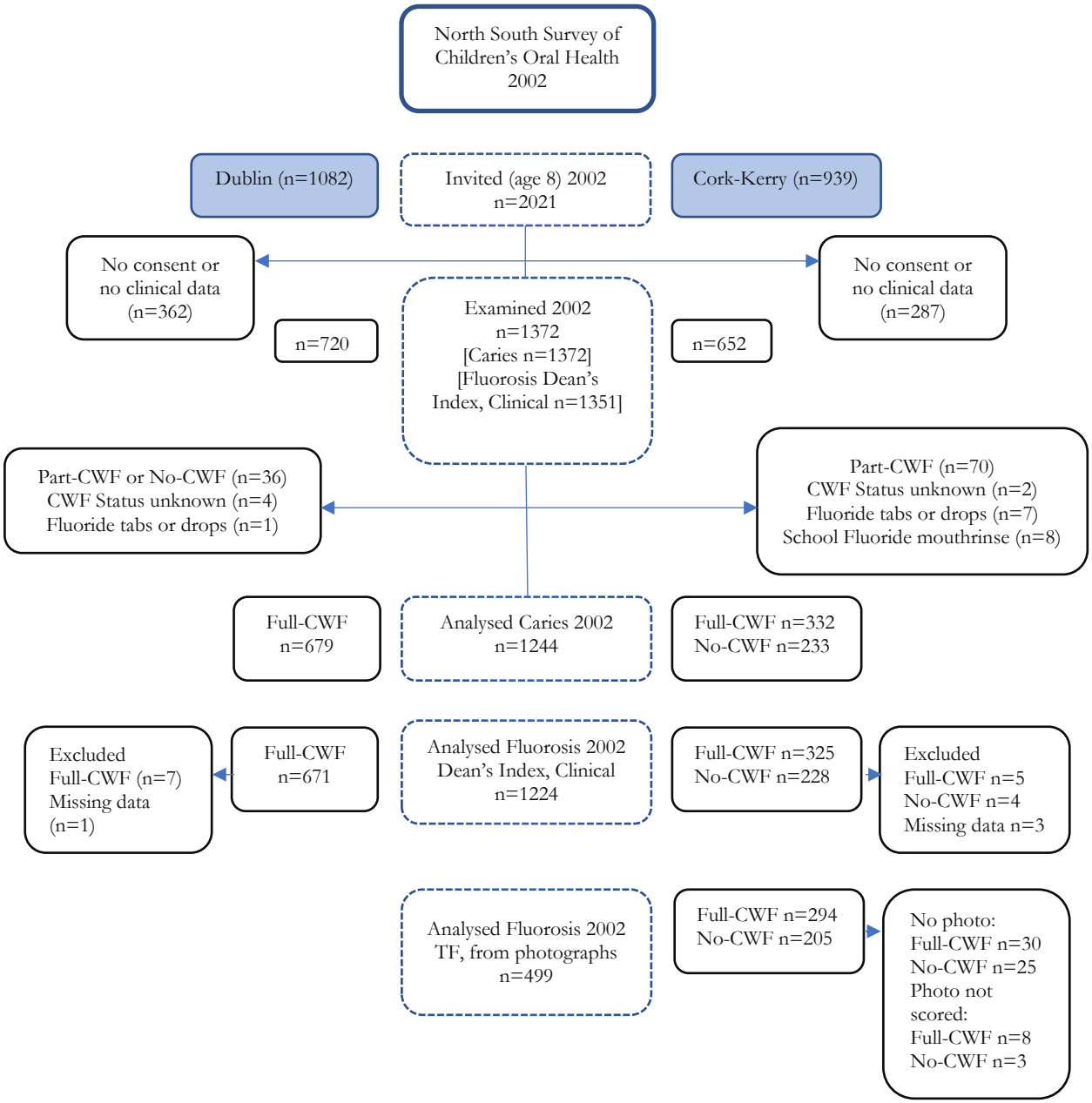


Figure 5.2: Flow of 8-year-olds through the NSSCOH 2002 and numbers analysed for each outcome

In total, 1,244 children with Full-CWF or No-CWF in Dublin and Cork-Kerry were included in the dental caries analyses, 679 in Dublin with Full-CWF, 332 in Cork-Kerry with Full-CWF and 233 in Cork-Kerry with No-CWF. Analyses for Dean's Index measured clinically included 1,224 children, 671 in Dublin with Full-CWF, 325 in Cork-Kerry with Full-CWF and 228 in Cork-Kerry with No-CWF. Sample size in Cork-Kerry No-CWF was smaller in 2002 than in 2016-17 because the No-CWF sample in Cork-Kerry 2002 contributed to a national No-CWF sample, whereas the FACCT study was powered to demonstrate differences (Full-CWF vs No-CWF) within Cork-Kerry.

In 2002, oral photographs were available for children examined in Cork-Kerry but not for children examined in the Dublin region. Of 565 children with Full-CWF or No-CWF examined for dental caries in Cork-Kerry in 2002, 499 (88%) were included in the analyses of dental fluorosis measured from photographs using the TF Index. The analyses included 294 children with Full-CWF and 205 with No-CWF in Cork-Kerry in 2002. Photographs were not available for 10% of the Cork-Kerry sample. The proportion of children missing photographs was similar among children with Full-CWF (9%) and No-CWF (11%). Photographs for 11 children (2%), could not be scored. Reasons that photographs could not be scored are summarised in Table 5.4. The number of images that could not be scored was considerably lower in 2002 than in 2016-17. This was likely due to the oral photographs in 2002 being screened at the time of the NSSCOH, with only the images deemed suitable for scoring being converted into slides.

Table 5.4: Summary of reasons that children with oral photographs in 2002 were excluded from the analysis

Reason photograph not scored	Cork-Kerry Full-CWF	Cork-Kerry No-CWF
Permanent maxillary central incisors unerupted or partially erupted (less than one-third)	2	3
Dental plaque obscuring tooth surface	1	0
Poor image quality	5	0
Total	**8**	**3**

5.2 Characteristics of 8-year-olds 2016-17

5.2.1 Socio-demographic characteristics

The socio-demographic characteristics of children born after downward adjustment of water fluoride concentration, examined for dental caries or fluorosis in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2016-17 are presented in Table 5.5. Mean age and gender balance were similar in both regions and for children with Full-CWF and No-CWF. Approximately one-third of the population of Ireland are eligible for a medical card (PCRS). In Dublin Full-CWF and Cork-Kerry Full-CWF, the proportion of children who were dependants of medical card holders was 29% and 30%, respectively. Among children with No-CWF in Cork-Kerry, the proportion of children who were dependants of medical card holders was lower (20%), indicating that there may have been lower levels of deprivation among children with No-CWF than among their counterparts with Full-CWF in Cork-Kerry. Similarly, a higher proportion of mothers of children with No-CWF in Cork-Kerry attained a diploma/certificate or higher than among children with Full-CWF in Cork-Kerry. There was a high proportion of missing data in relation to father's education in 2016-17, particularly among children with Full-CWF in Dublin (14%) and Cork-Kerry (10%).

Table 5.5: Socio-demographic characteristics of 8-year-olds examined in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2016-17

	Dublin Full-CWF	Cork-Kerry Full-CWF	Cork-Kerry No-CWF
Characteristic	**n (%)**	**n (%)**	**n (%)**
Total examined	707	376	772
Age[a]	8.2 (0.3)	8.3 (0.4)	8.4 (0.4)
Gender			
Female	383 (54)	198 (53)	392 (51)
Male	324 (46)	178 (47)	380 (49)
Missing	0 (0)	0 (0)	0 (0)
Medical card ownership[b]			
Medical card	206 (29)	111 (30)	158 (20)
No Medical card	486 (69)	257 (68)	603 (78)
Missing	15 (2)	8 (2)	11 (1)
Mothers' education			
Leaving Certificate[c] or less	189 (27)	101 (27)	174 (23)
Diploma/Cert or higher	492 (70)	256 (68)	580 (75)
Missing	26 (4)	19 (5)	18 (2)
Fathers' education[d]			
Leaving Certificate[c] or less	196 (28)	113 (30)	290 (38)
Diploma/Cert or higher	413 (58)	226 (60)	439 (57)
Missing	98 (14)	37 (10)	43 (6)

Data are for children who had a dental caries or fluorosis examination in 2016-17 (n=1855)
Percentages may not sum to 100 due to rounding.
[a] mean (SD), no missing data
[b] Medical card ownership was used in this study to indicate socio-economic disadvantage
[c] Attainment of Leaving Certificate indicates completion of second level education
[d] Not included in multivariable regression analyses due to the high proportion of missing data

5.2.2 Toothbrushing behaviours

Toothbrushing behaviours of 8-year-olds born after downward adjustment of water fluoride concentration, examined in 2016-17 are presented for each region and category of fluoridation status in Table 5.6. Information about toothbrushing behaviours before age 2 was collected via the parent completed questionnaire at age 5 in FACCT phase 1 2013-14. Information about toothbrushing behaviours at age 8 was collected via the parent completed questionnaire in phase 2 of FACCT in 2016-17.

Toothbrushing behaviours were similar in both regions and for children with Full-CWF and No-CWF except in Cork-Kerry No-CWF where a lower proportion of parents reported noticing their child eating or licking toothpaste sometimes or often before age 2 (41%) compared with parents of children in Cork-Kerry with Full-CWF (54%) (Table 5.6).

Despite advice to delay commencing fluoride toothpaste use until after 24 months of age, 80% of parents in 2016-17 across both Full-CWF and No-CWF groups indicated that they first used toothpaste with their child at ≤24 months (Table 5.6). Approximately one-quarter of parents reported toothbrushing at least twice a day under age 2. Almost three-quarters of parents reported their child toothbrushing at least twice a day at age 8. Most parents reported their child using a pea-sized amount of toothpaste or less before age 2. More than half of parents of children with Full-CWF reported noticing their child eating or licking toothpaste before age 2 (Table 5.6).

Table 5.6: Toothbrushing behaviours of 8-year-olds examined in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2016-17

	Dublin Full-CWF	Cork-Kerry Full-CWF	Cork-Kerry No-CWF
Characteristic	**n (%)**	**n (%)**	**n (%)**
Total examined	707	376	772
Age first used toothpaste			
≤ 24 months	568 (80)	303 (81)	618 (80)
> 24 months[a]	133 (19)	68 (18)	145 (19)
Missing	6 (<1)	5 (1)	9 (1)
Frequency of toothbrushing (< age 2)			
Once a day or less	491 (69)	273 (73)	559 (72)
Twice a day or more	193 (27)	93 (25)	182 (24)
Missing	23 (3)	10 (3)	31 (4)
Frequency of toothbrushing (age 8)			
Once a day or less	195 (28)	97 (26)	204 (26)
Twice a day or more	498 (70)	271 (72)	561 (73)
Missing	14 (2)	8 (2)	7 (<1)
Amount of toothpaste (< age 2)			
Pea-sized[a] or less	654 (93)	351 (93)	718 (93)
> Pea-sized	17 (2)	9 (2)	15 (2)
Missing	36 (5)	16 (4)	39 (5)
Amount of toothpaste (age 8)			
Pea-sized or less	600 (85)	305 (81)	642 (83)
> Pea-sized	88 (12)	60 (16)	114 (15)
Missing	19 (3)	11 (3)	16 (2)
Eats/Licks toothpaste (< age 2)			
Often/Sometimes	352 (50)	204 (54)	315 (41)
Never[a]	304 (43)	149 (40)	397 (51)
Missing	51 (7)	23 (6)	60 (8)
Rinse method after toothbrushing (age 8)			
Glass	147 (21)	84 (22)	209 (27)
Other[b] or no rinse	547 (77)	284 (76)	555 (72)
Missing	13 (2)	8 (2)	8 (1)

Data are for children who had a dental caries or fluorosis examination in 2016-17 (n=1855)
Percentages may not sum to 100 due to rounding
[a] Recommended from 2002 onwards
[b] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

5.2.3 Dietary behaviours and dental attendance

Dietary behaviours and dental attendance of 8-year-olds born after downward adjustment of water fluoride concentration, examined in 2016-17 are presented for each region and category of fluoridation status in Table 5.7. Among children in Dublin and Cork-Kerry with Full-CWF, frequency of snacking on sweet foods or drinks between meals was similar with over half of children snacking on sweet foods or drinks more than once a day between meals (54% Dublin Full-CWF, 53% Cork-Kerry Full-CWF). The proportion of children snacking on sweet foods or drinks more than once a day between meals was slightly lower among children in Cork-Kerry with No-CWF (44%).

Parent's responses in relation to the type of water the child usually drinks varied across regions and according to fluoridation status. The proportion of children reported to usually drink tap water was highest among children with No-CWF in Cork-Kerry (67%) and lowest among children with Full-CWF in Cork-Kerry (45%) (Table 5.7). Conversely, the proportion of children reported to usually drink bottled water was highest among children with Full-CWF in Cork-Kerry (23%) and lowest among children with No-CWF in Cork-Kerry (14%). In Dublin among children with Full-CWF, half of children (51%) were reported to usually drink tap water and 18% to usually drink bottled water.

Approximately half of children were breastfed, with similar proportions breastfed in Dublin and Cork-Kerry (Table 5.7). In Dublin, 39% of parents reported that their child had regularly taken a baby bottle into bed. In Cork-Kerry, 44% of children with Full-CWF and 33% of children with No-CWF were reported to have regularly taken a baby bottle into bed. Over 80% of children in Dublin and Cork-Kerry were weaned from the breast or baby bottle to a cup or mug before 12 months or between age 1 and 2 years.

At the time of the study, the first opportunity for children in Ireland to avail of free routine dental care was in second class at age 7-9, although treatment for relief of pain was available free of charge to children under age 16 years. By phase 2 of the study in 2016-17, a large proportion of the children (40% Dublin Full-CWF, 40% Cork-Kerry Full-CWF, 35% Cork-Kerry No-CWF) had either first attended the dentist at age 7 or older or had never attended the dentist (Table 5.7).

Table 5.7: Dietary behaviours and dental attendance of 8-year-olds examined in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2016-17

	Dublin Full-CWF	Cork-Kerry Full-CWF	Cork-Kerry No-CWF
Characteristic	**n (%)**	**n (%)**	**n (%)**
Total examined	707	376	772
Sweet foods or drinks between meals (age 8)			
≥ 4 times a day	68 (10)	32 (9)	48 (6)
2-3 times a day	308 (44)	165 (44)	296 (38)
Once a day or less	312 (44)	164 (44)	411 (53)
Missing	19 (3)	15 (4)	17 (2)
Type of water child usually drinks			
Tap	364 (51)	169 (45)	516 (67)
Tap and bottled	182 (26)	103 (27)	120 (16)
Bottled	127 (18)	88 (23)	108 (14)
Missing or does not drink water	34 (5)	16 (4)	28 (4)
Ever breastfed			
Yes	367 (52)	204 (54)	381 (49)
No	337 (48)	170 (45)	386 (50)
Missing	3 (<1)	2 (<1)	5 (<1)
Regularly took a baby bottle into bed			
Yes	273 (39)	166 (44)	255 (33)
No	426 (60)	206 (55)	509 (66)
Missing	8 (1)	4 (1)	8 (1)
Age weaned to cup or mug			
After 2 years old	93 (13)	51 (14)	106 (14)
≤ 2 years old	584 (83)	316 (84)	645 (84)
Missing	30 (4)	9 (2)	21 (3)
Age at first visit to the dentist			
≤ 4 years old	166 (23)	92 (24)	238 (31)
5-6 years old	222 (31)	119 (32)	244 (32)
≥7 years old	102 (14)	84 (22)	148 (19)
Never	186 (26)	67 (18)	122 (16)
Missing	31 (4)	14 (4)	20 (3)

Data are for children who had a dental caries or fluorosis examination in 2016-17 (n=1855)
Percentages may not sum to 100 due to rounding

5.3 Comparison of socio-demographics and oral health behaviours of 8-year-olds 2016-17 with 8-year-olds 2002

This thesis includes a comparison of dental caries and fluorosis in 8-year-olds 2016-17 born after downward adjustment of water fluoride concentration with 8-year-olds examined prior to the adjustment. The Report of the Forum on Fluoridation 2002 included several recommendations in relation to use of fluoride toothpaste in infancy and early childhood (See Section 2.11.3). Information about age the child first used toothpaste was available from both the FACCT study and the NSSCOH 2002, facilitating assessment of any change in this behaviour following introduction of the 2002 toothbrushing recommendations. Questions about sociodemographic characteristics and other oral health behaviours included in parent-completed questionnaires in both studies facilitated assessment of other changes since 2002.

Characteristics of children examined in Dublin (Full-CWF), Cork-Kerry Full-CWF and Cork-Kerry No-CWF in 2002 and 2016-17 are presented in Table 5.8. Mean age and gender balance of the groups was similar across regions and fluoridation status at both time points. The proportion of children in 2002 who were dependants of medical card holders was 20% in Dublin Full-CWF, 24% in Cork-Kerry Full-CWF and 17% in Cork-Kerry No-CWF. In 2016-17, the proportion of children who were dependants of medical card holders was 29% in Dublin Full-CWF, 30% in Cork-Kerry Full-CWF and 20% in Cork-Kerry No-CWF. At both time points, the proportion of children who were dependants of medical card holders was lower in Cork-Kerry No-CWF than in Cork-Kerry Full-CWF.

Table 5.8: Characteristics of 8-year-olds examined in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2002 and 2016-17

	Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
	2002	2017	2002	2017	2002	2017
Characteristic	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total examined	679	707	332	376	233	772
Age[a]	8.3 (0.4)	8.2 (0.3)	8.4 (0.5)	8.3 (0.4)	8.5 (0.4)	8.4 (0.4)
Gender						
Female	319 (47)	383 (54)	183 (55)	198 (53)	130 (56)	392 (51)
Male	360 (53)	324 (46)	149 (45)	178 (47)	103 (44)	380 (49)
Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Medical card ownership[b]						
Medical card	139 (20)	206 (29)	80 (24)	111 (30)	39 (17)	158 (20)
No Medical card	532 (78)	486 (69)	251 (76)	257 (68)	193 (83)	603 (78)
Missing	8 (1)	15 (2)	1 (<1)	8 (2)	1 (<1)	11 (1)
Age first used toothpaste[c]						
Before 12 months	179 (26)	109 (15)	97 (29)	54 (14)	55 (24)	122 (16)
12-18 months	251 (37)	318 (45)	132 (40)	169 (45)	97 (42)	323 (42)
19-24 months	117 (17)	141 (20)	55 (17)	80 (21)	25 (11)	173 (22)
> 24 months[d]	123 (18)	133 (19)	43 (13)	68 (18)	54 (23)	145 (19)
Missing	9 (1)	6 (<1)	5 (2)	5 (1)	2 (<1)	9 (1)
Frequency of toothbrushing (age 8)						
Once a day or less	286 (42)	195 (28)	128 (39)	97 (26)	103 (44)	204 (26)
Twice a day or more	387 (57)	498 (70)	202 (61)	271 (72)	127 (55)	561 (73)
Missing	6 (<1)	14 (2)	2 (<1)	8 (2)	3 (1)	7 (<1)
Amount of toothpaste (age 8)						
Pea-sized or less	289 (43)	600 (85)	161 (48)	305 (81)	92 (39)	642 (83)
> Pea-sized	381 (56)	88 (12)	170 (51)	60 (16)	138 (59)	114 (15)
Missing	9 (1)	19 (3)	1 (<1)	11 (3)	3 (1)	16 (2)
Rinse method after toothbrushing (age 8)						
Glass	181 (27)	147 (21)	99 (30)	84 (22)	91 (39)	209 (27)
Other[e] or no rinse	483 (71)	547 (77)	232 (70)	284 (76)	137 (59)	555 (72)
Missing	15 (2)	13 (2)	1 (<1)	8 (2)	5 (2)	8 (1)
Sweet foods or drinks between meals (age 8)						
≥ 4 times per day	74 (11)	68 (10)	19 (6)	32 (9)	13 (6)	48 (6)
2-3 times per day	321 (47)	308 (44)	163 (49)	165 (44)	90 (39)	296 (38)
Once a day or less	275 (41)	312 (44)	148 (45)	164 (44)	127 (55)	411 (53)
Missing	9 (1)	19 (3)	2 (<1)	15 (4)	3 (1)	17 (2)
Age at first visit to the dentist						
≤ 4 years old	165 (24)	166 (23)	94 (28)	92 (24)	67 (29)	238 (31)
5-6 years old	189 (28)	222 (31)	115 (35)	119 (32)	87 (37)	244 (32)
≥7 years old	182 (27)	102 (14)	87 (26)	84 (22)	58 (25)	148 (19)
Never	122 (18)	186 (26)	30 (9)	67 (18)	17 (7)	122 (16)
Missing	21 (3)	31 (4)	6 (2)	14 (4)	4 (2)	20 (3)

Percentages may not sum to 100 due to rounding. [a]mean (SD), no missing data [b] Medical card ownership was used in this study to indicate socio-economic disadvantage [c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age of first using toothpaste in 2013-14 (collected at age 5) [d] Recommended from 2002 onwards [e] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

While there were indications that a lower proportion of parents in 2016-17 first used toothpaste with their child before 12 months of age than in 2002, there was little change over time in the overall proportion of parents with Full-CWF and No-CWF who indicated that they first used toothpaste with their child at ≤ 24 months (80% of parents in 2016-17 and between 76% and 86% of parents in 2002) (Table 5.8).

Compared with 2002, a higher proportion of children in 2016-17 brushed at least twice a day and a lower proportion in 2016-17 used a glass to rinse after toothbrushing. There was a notable increase in the proportion of 8-year-olds in 2016-17 using a pea-sized amount of toothpaste or less compared with 2002 (Figure 5.3).

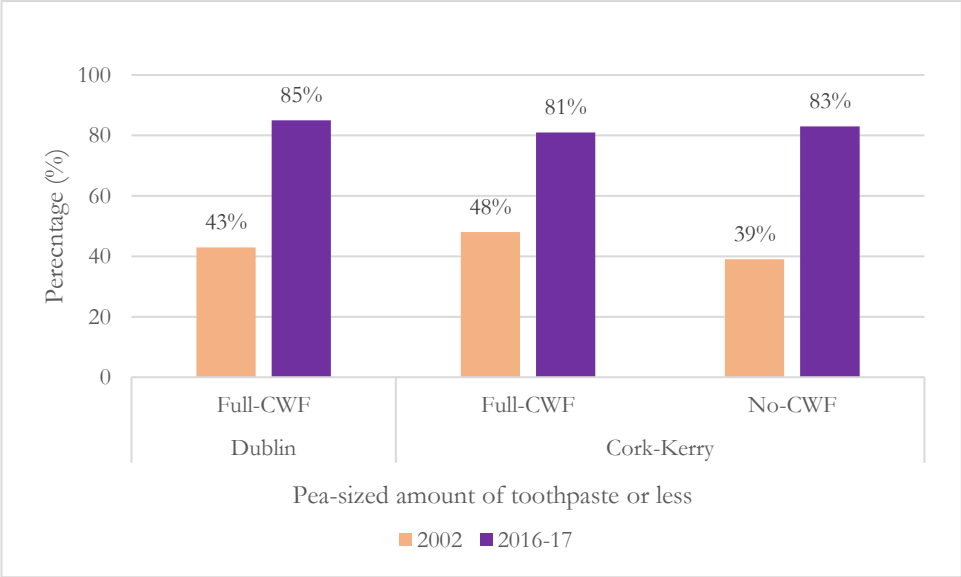


Figure 5.3: Percentage of 8-year-olds using a pea-sized amount of toothpaste or less in 2002 compared with 2016-17

The proportion of children snacking on sweet foods or drinks more than once a day between meals was similar in 2002 and 2016-17. Snacking on sweet foods or drinks more than once a day between meals was reported for more than half of children with Full-CWF in Dublin (58% in 2002 and 54% in 2016-17) and Cork-Kerry (55% in 2002 and

53% in 2016-17). This proportion was slightly lower among children in Cork-Kerry with No-CWF at both time points (45% in 2002 and 44% in 2016-17).

The proportion of children at either time point who first visited the dentist at age 7 or older or who had not visited the dentist at the time of the study varied slightly by year, region and fluoridation status, from 32% among children with No-CWF in Cork-Kerry 2002 to 45% among children with Full-CWF in Dublin 2002.

5.4 Summary of findings

In 2016-17, 2,315 8-year-olds were examined clinically for dental caries or fluorosis in Dublin and Cork-Kerry. In Dublin, 89% of children examined had Full-CWF, while in Cork-Kerry 25% of children examined had Full-CWF and 51% had No-CWF. Most of the children with Full-CWF in Dublin (87%) and Cork-Kerry (88%) and with No-CWF in Cork-Kerry (95%) were included the analyses of dental fluorosis measured from oral photographs.

In 2002, 1,372 8-year-olds were clinically examined in Dublin and Cork-Kerry. In Dublin, 94% of children examined had Full-CWF, while in Cork-Kerry 51% of children examined had Full-CWF and 36% had No-CWF. Oral photographs were only available for children examined in Cork-Kerry in 2002. Of the children with Full-CWF or No-CWF examined in Cork-Kerry in 2002, 88% were included in the analyses of dental fluorosis measured from oral photographs.

Despite advice to delay commencing fluoride toothpaste use until after 24 months of age, there was little change over time in the proportion of parents who indicated that they first used toothpaste with their child at ≤ 24 months. Furthermore, in 2016-17 among children

with Full-CWF, more than half of parents reported noticing their child eating or licking toothpaste before age 2.

Other changes in toothbrushing behaviours over time were evident. A higher proportion of children in 2016-17 brushed at least twice a day and a lower proportion used a glass to rinse after toothbrushing. Furthermore, a higher proportion of 8-year-olds in 2016-17 used a pea-sized amount of toothpaste or less compared with 2002.

Snacking on sweet foods or drinks more than once a day between meals was reported for more than half of children with Full-CWF in Dublin and Cork-Kerry, the proportion being slightly lower among children with No-CWF in Cork-Kerry. More than one-third of children in 2016-17 and 2002 had either first visited the dentist at age 7 or older or had never visited the dentist at the time of the study.

6 Results: Dental caries

This chapter describes the impact of downward adjustment of water fluoride concentration on dental caries prevalence and severity in primary teeth of 8-year-olds living in Dublin and Cork-Kerry.

1. The prevalence and severity of dental caries in primary teeth of 8-year-olds born after downward adjustment of water fluoride concentration (examined in 2016-17) and 8-year-olds examined in 2002 prior to the downward adjustment are described.
2. Caries prevalence and severity in primary teeth of 8-year-olds in Dublin and Cork-Kerry in 2016-17 are compared with 8-year-olds in the same regions in 2002 **(Objective 1)**.
3. Differences in the prevalence and severity of dental caries in primary teeth of 8-year-olds with Full-CWF compared with No-CWF in Cork-Kerry in 2002 and in 2016-17 are evaluated **(Objective 2)**, and factors associated with dental caries in this region at each time point are identified.

In FACCT 2016-17, 1,849 8-year-olds with Full-CWF or No-CWF were clinically examined for dental caries; 704 in Dublin with Full-CWF, 375 in Cork-Kerry with Full-CWF and 770 in Cork-Kerry with No-CWF (Figure 5.1). Dental caries measurements for 8-year-olds 2016-17 were compared with 1,244 8-year-olds in 2002; 679 in Dublin with Full-CWF, 332 in Cork-Kerry with Full-CWF and 233 in Cork-Kerry with No-CWF (Figure 5.2).

6.1 Dental caries prevalence and severity 2002 and 2016-17

This section provides an overview of the prevalence and severity of dental caries in primary teeth of 8-year-olds examined in the NSSCOH 2002 and in the FACCT study 2016-17. Dental caries was reported as the proportion of children with d_{3vc}mft(cde)>0 (prevalence) and mean d_{3vc}mft(cde) among children with caries experience (severity). Measurement of dental caries was at the dentine level of involvement and included both cavitated and visible non-cavitated dentinal carious lesions.

At both time points, more than half of 8-year-olds with Full-CWF in Dublin (54% in 2002, 55% in 2016-17) and Cork-Kerry (55% in 2002, 56% in 2016-17) had at least one decayed missing or filled primary canine, first or second primary molar (Table 6.1). Among children with No-CWF in Cork-Kerry, 73% in 2002 and 65% in 2016-17 had at least one decayed missing or filled primary canine, first or second primary molar.

Table 6.1: Dental caries experience in primary teeth of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 and 2016-17

	d_{3vc}mft(cde)[a]									
	Children with caries experience						Children with and without caries experience			
	2002			2016-17			2002		2016-17	
Region	n	%	mean[b] (SD)	n	%	mean[b] (SD)	n	mean[c] (SD)	n	mean[c] (SD)
Dublin										
Full-CWF	368	54	3.3 (2.1)	388	55	3.4 (2.3)	679	1.8 (2.2)	704	1.9 (2.4)
Cork-Kerry										
Full-CWF	182	55	3.5 (2.2)	209	56	3.7 (2.4)	332	1.9 (2.4)	375	2.1 (2.6)
No-CWF	169	73	4.9 (2.6)	497	65	4.2 (2.5)	233	3.5 (3.1)	770	2.7 (2.8)

[a] WHO criteria modified to include visible non-cavitated dentinal caries ('v' indicating 'visual caries')
[b] Mean d_{3vc}mft(cde) among children with caries experience
[c] Mean d_{3vc}mft(cde) for the full sample of children examined including children with and without caries experience
% = caries prevalence, percentage of children with d_{3vc}mft(cde)>0
SD = standard deviation

Mean d_{3vc}mft(cde) among children with Full-CWF who had experienced dental caries in their primary teeth ranged from 3.3 (SD 2.1) in Dublin 2002 to 3.7 (SD 2.4) in Cork-

Kerry 2016-17. Among children with No-CWF in Cork-Kerry, mean d_{3vc}mft(cde) was 4.9 (SD 2.6) in 2002 and 4.2 (SD 2.5) in 2016-17.

The contribution of decayed, missing and filled components to the mean d_{3vc}mft(cde) of children who had experienced dental caries is presented in Table 6.2. In 2002, the contribution of decayed teeth to the mean d_{3vc}mft(cde) was 47% in Cork-Kerry No-CWF, 54% in Cork-Kerry Full-CWF and 67% in Dublin Full-CWF. In 2016-17, decayed teeth accounted for 66% and 65% of the mean d_{3vc}mft(cde) in Cork-Kerry No-CWF and Full-CWF respectively and 76% of the mean d_{3vc}mft(cde) in Dublin Full-CWF.

Table 6.2: Mean number of decayed (d_{3vc}t(cde)), missing (mt(cde)) and filled (ft(cde)) teeth and proportion of dental caries reported as untreated (% d_{3vc}t(cde)) among 8-year-olds with caries experience in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 and 2016-17

Region (Fluoridation Status)	d_{3vc}t(cde)	mt(cde)	ft(cde)	d_{3vc}mft(cde)	% d_{3vc}t
2002					
Dublin (Full-CWF)	2.2 (1.7)	0.7 (1.3)	0.3 (0.9)	3.3 (2.1)	67%
Cork-Kerry (Full-CWF)	1.9 (2.0)	0.4 (0.9)	1.3 (1.6)	3.5 (2.2)	54%
Cork-Kerry (No-CWF)	2.3 (2.1)	1.0 (1.8)	1.5 (1.9)	4.9 (2.6)	47%
2016-17					
Dublin (Full-CWF)	2.6 (1.9)	0.4 (1.2)	0.4 (1.0)	3.4 (2.3)	76%
Cork-Kerry (Full-CWF)	2.4 (2.0)	0.6 (1.4)	0.7 (1.2)	3.7 (2.4)	65%
Cork-Kerry (No-CWF)	2.7 (2.2)	0.6 (1.4)	0.8 (1.3)	4.2 (2.5)	66%

6.2 Dental caries in Dublin and Cork-Kerry 2016-17 vs. 2002 (Objective 1)

In this section, dental caries prevalence and severity in 8-year-olds in Dublin and Cork-Kerry born after downward adjustment of water fluoride concentration are compared with children in the same regions in 2002 prior to the downward adjustment. The results presented in this section in relation to objective 1 were published in the Journal of Dental Research in 2021 (Appendix A).

The prevalence and severity of dental caries in primary teeth of 8-year-olds in each region in 2002 and 2016-17 are summarised in Figure 6.1.

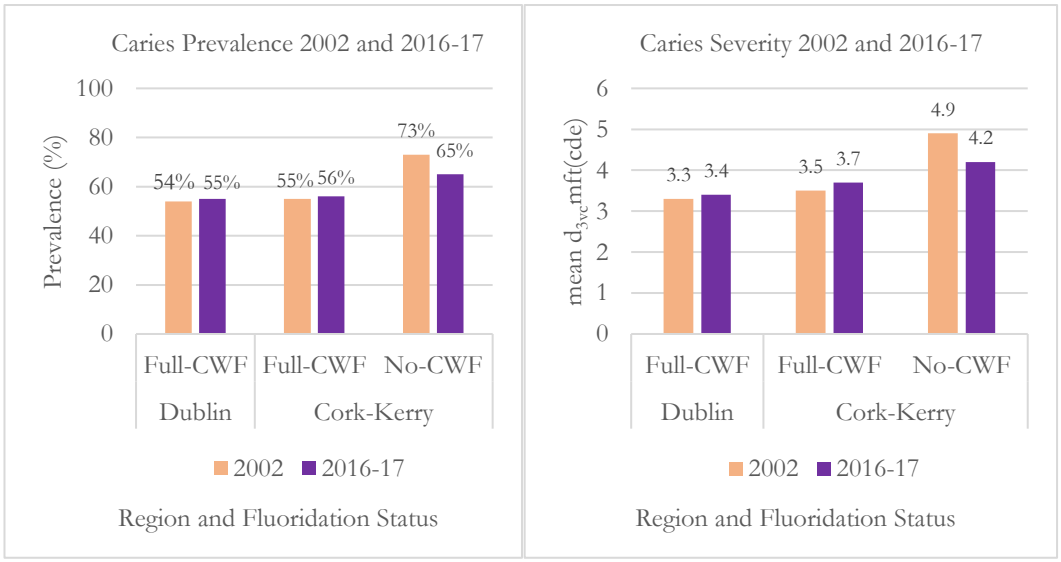


Figure 6.1: Dental caries prevalence (% with d_{3vc}mft(cde)>0) and severity (mean d_{3vc}mft(cde) among children with caries experience) in primary teeth of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 compared with 2016-17

In Dublin (Full-CWF), dental caries prevalence was 55% in 2016-17 compared with 54% in 2002. Among children with caries experience in Dublin, mean d_{3vc}mft(cde) was 3.4 (SD 2.3) in 2016-17 compared with 3.3 (SD 2.1) in 2002. Multivariable hurdle negative binomial (HNB) regression analysis revealed no statistically significant difference in either the prevalence (OR 1.14, 95%CI [0.87, 1.49], $P = 0.350$) or severity (increase in mean 5%,

95% CI [-9%, 21%], P = 0.487) of dental caries among children in Dublin in 2016-17 relative to 2002 (Table 6.3).

Table 6.3: Multivariable HNB regression analysis of the association between year of examination and prevalence and severity of dental caries (d_{3vc}mft(cde)) in primary teeth of 8-year-olds in Dublin with Full-CWF

	Dublin Full-CWF			
	Prevalence of caries (HNB model part 1) n=1291		Severity of caries (HNB model part 2) n=699	
Explanatory Variables	**OR (95% CI)**	***P* value**	**Mean (%) (95% CI)**	***P* value**
Year (2016-17 vs. 2002)	**1.14 (0.87, 1.49)**	**0.350**	**5 (-9, 21)**	**0.487**
Age	1.15 (0.86, 1.55)	0.347	1 (-13, 18)	0.877
Medical card[a] (yes vs. no)	1.71 (1.29, 2.27)	<0.001	23 (7, 40)	0.003
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	0.53 (0.39, 0.73)	<0.001	-3 (-16, 12)	0.675
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.51 (1.17, 1.94)	0.001	16 (2, 33)	0.021
Amount of toothpaste at age 8 (pea-sized or less vs. full brush)	0.99 (0.75, 1.31)	0.956	7 (-8, 24)	0.388
Rinse method after toothbrushing at age 8 (glass vs. other[d] or no rinse)	1.12 (0.85, 1.47)	0.421	6 (-8, 22)	0.393
Sweet foods or drinks between meals at age 8				
≥ 4 times a day	2.30 (1.51, 3.52)	<0.001	34 (10, 63)	0.004
2-3 times a day	1.69 (1.33, 2.16)	<0.001	13 (-1, 30)	0.072
Once a day or less	Reference		Reference	
Age at first visit to the dentist				
≤ 4 years old	2.51 (1.79, 3.52)	<0.001	76 (44, 114)	<0.001
5-6 years old	1.88 (1.37, 2.59)	<0.001	46 (20, 77)	<0.001
≥ 7 years old	1.76 (1.24, 2.50)	0.002	21 (-2, 49)	0.082
Never	Reference		Reference	

OR = Odds ratio
Mean (%) = the percentage change in mean d_{3vc}mft(cde)
The main explanatory variable was year of examination (Year). The OR and Mean (%) for the other explanatory variables represented the association between each explanatory variable and the prevalence and severity of dental caries controlled for the effect of the other explanatory variables
[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage
[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[c] Recommended from 2002 onwards
[d] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

In Dublin (Full-CWF) 2002 and 2016-17 combined, explanatory variables associated with higher prevalence of dental caries were parental medical card ownership, toothbrushing once a day or less often (vs. twice a day or more often), having sweet foods or drinks more than once a day between meals and having visited the dentist (vs. never) (Table 6.3). First using toothpaste at ≤ 24 months (vs. > 24 months) was associated with lower

prevalence of dental caries. In relation to severity of dental caries, parental medical card ownership, toothbrushing once a day or less often (vs. twice a day or more often), having sweet foods or drinks four times a day or more often between meals (vs. once a day or less often) and having visited the dentist at age 6 years or younger (vs. never) were associated with higher mean d_{3vc}mft(cde).

Among children in Cork-Kerry with Full-CWF, caries prevalence was 56% in 2016-17 compared with 55% in 2002 (Figure 6.1). Among children with caries experience, mean d_{3vc}mft(cde) was 3.7 (SD 2.4) in 2016-17 compared with 3.5 (SD 2.2) in 2002. Multivariable HNB regression analysis revealed no statistically significant difference in the prevalence (OR 1.25, 95% CI [0.88, 1.78], $P = 0.207$) or severity (increase in mean 7%, 95% CI [-9%, 27%], $P = 0.424$) of dental caries among children with Full-CWF in Cork-Kerry in 2016-17 relative to 2002 (Table 6.4).

Table 6.4: Multivariable HNB regression analysis of the association between year of examination and prevalence and severity of dental caries (d_{3vc}mft(cde)) in primary teeth of 8-year-olds in Cork-Kerry with Full-CWF

	Cork-Kerry Full-CWF			
	Prevalence of caries (HNB model part 1) n=663		Severity of caries (HNB model part 2) n=369	
Explanatory Variables	**OR (95% CI)**	***P* value**	**Mean (%) (95% CI)**	***P* value**
Year (2016-17 vs. 2002)	**1.25 (0.88, 1.78)**	**0.207**	**7 (-9, 27)**	**0.424**
Age	1.58 (1.07, 2.32)	0.021	-8 (-24, 11)	0.376
Medical card[a] (yes vs. no)	1.45 (0.99, 2.10)	0.053	34 (14, 58)	0.001
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	0.80 (0.51, 1.25)	0.332	-17 (-31, 1)	0.061
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.47 (1.03, 2.10)	0.033	13 (-4, 33)	0.138
Amount of toothpaste at age 8 (pea-sized or less vs. full brush)	0.91 (0.63, 1.31)	0.605	-1 (-17, 18)	0.912
Rinse method after toothbrushing at age 8 (glass vs. other[d] or no rinse)	1.38 (0.95, 1.99)	0.090	14 (-3, 35)	0.119
Sweet foods or drinks between meals at age 8				
≥ 4 times a day	1.73 (0.91, 3.29)	0.092	26 (-4, 66)	0.094
2-3 times a day	1.52 (1.10, 2.12)	0.012	12 (-5, 31)	0.168
Once a day or less	Reference		Reference	
Age at first visit to the dentist				
≤ 4 years old	1.82 (1.07, 3.09)	0.027	87 (40, 150)	< 0.001
5-6 years old	1.77 (1.06, 2.93)	0.028	79 (35, 136)	< 0.001
≥ 7 years old	1.09 (0.64, 1.86)	0.757	31 (-4, 78)	0.087
Never	Reference		Reference	

OR = Odds ratio
Mean (%) = the percentage change in mean d_{3vc}mft(cde)
The main explanatory variable was year of examination (Year). The OR and Mean (%) for the other explanatory variables represented the association between each explanatory variable and the prevalence and severity of dental caries controlled for the effect of the other explanatory variables
[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage
[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[c] Recommended from 2002 onwards
[d] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

In Cork-Kerry Full-CWF 2002 and 2016-17 combined, explanatory variables associated with higher caries prevalence were increasing age (within the age range 7-9), toothbrushing once a day or less often (vs. twice a day or more often), having sweet foods or drinks two to three times a day between meals (vs. once a day or less often) and first visiting the dentist at age 6 or younger (vs. never) (Table 6.4). In relation to severity of dental caries, parental medical card ownership and first visiting the dentist at age 6 or younger (vs. never) were associated with higher mean d_{3vc}mft(cde).

Among children with No-CWF in Cork-Kerry, the difference in dental caries prevalence in 2016-17 (65%) compared with 2002 (73%) was not statistically significant (OR 0.77, 95% CI [0.52, 1.13], $P = 0.179$) (Table 6.5). However, among children with caries experience, the reduction in mean d_{3vc}mft(cde) from 4.9 (SD 2.6) in 2002 to 4.2 (SD 2.5) in 2016-17 was statistically significant. Mean d_{3vc}mft(cde) was 13% lower among 8-year-olds with No-CWF in 2016-17 than in 2002 (reduction in mean 13%, 95% CI [1%, 24%], $P = 0.039$).

Table 6.5: Multivariable HNB regression analysis of the association between year of examination and prevalence and severity of dental caries (d_{3vc}mft(cde)) in primary teeth of 8-year-olds in Cork-Kerry with No-CWF

	Cork-Kerry No-CWF			
	Prevalence of caries (HNB model part 1) n=941		Severity of caries (HNB model part 2) n=622	
Explanatory Variables	**OR (95% CI)**	***P* value**	**Mean (%) (95% CI)**	***P* value**
Year (2016-17 vs. 2002)	**0.77 (0.52, 1.13)**	**0.179**	**-13 (-24, -1)**	**0.039**
Age	0.85 (0.58, 1.24)	0.394	-3 (-15, 11)	0.664
Medical card[a] (yes vs. no)	1.15 (0.79, 1.67)	0.467	17 (3, 32)	0.012
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	0.90 (0.63, 1.30)	0.587	-6 (-17, 6)	0.324
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.50 (1.09, 2.08)	0.013	9 (-2, 21)	0.111
Amount of toothpaste at age 8 (pea-sized or less vs. full brush)	1.27 (0.88, 1.82)	0.199	-6 (-18, 7)	0.342
Rinse method after toothbrushing at age 8 (glass vs. other[d] or no rinse)	1.39 (1.01, 1.91)	0.044	2 (-9, 13)	0.771
Sweet foods or drinks between meals at age 8				
≥ 4 times a day	2.25 (1.17, 4.34)	0.016	30 (8, 57)	0.006
2-3 times a day	1.83 (1.35, 2.48)	<0.001	17 (5, 30)	0.004
Once a day or less	Reference		Reference	
Age at first visit to the dentist				
≤ 4 years old	2.36 (1.52, 3.66)	<0.001	87 (50, 132)	<0.001
5-6 years old	3.80 (2.43, 5.94)	<0.001	76 (42, 118)	<0.001
≥ 7 years old	2.08 (1.30, 3.32)	0.002	51 (20, 91)	0.001
Never	Reference		Reference	

OR = Odds ratio
Mean (%) = the percentage change in mean d_{3vc}mft(cde)
The main explanatory variable was year of examination (Year). The OR and Mean (%) for the other explanatory variables represented the association between each explanatory variable and the prevalence and severity of dental caries controlled for the effect of the other explanatory variables
[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage
[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[c] Recommended from 2002 onwards
[d] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

In Cork-Kerry No-CWF 2002 and 2016-17 combined, explanatory variables associated with higher caries prevalence were toothbrushing once a day or less often (vs. twice a day or more often), using a glass to rinse after toothbrushing (vs. other rinse method or no rinse), having sweet foods or drinks more than once a day between meals and visiting the dentist (vs. never) (Table 6.5). In relation to severity of dental caries, parental medical card ownership, having sweet foods or drinks more than once a day between meals and visiting the dentist (vs. never) were associated with higher mean d_{3vc}mft(cde).

There were no statistically significant interactions between year of examination (2016-17 vs. 2002) and any of the other explanatory variables in the HNB regression models for Dublin Full-CWF, Cork-Kerry Full-CWF or Cork-Kerry No-CWF.

A separate multivariable HNB regression model for Cork-Kerry Full-CWF and No-CWF combined was tested for interaction between fluoridation status (Full-CWF vs No-CWF) and year of examination (2016-17 vs 2002) to determine whether the association between CWF and dental caries depended on year of examination. (Appendix F Table F 1). This analysis was restricted to Cork-Kerry because the Dublin sample had Full-CWF and therefore no comparison of Full-CWF and No-CWF could be conducted for the Dublin region. The difference in dental caries prevalence between children with Full-CWF and No-CWF in Cork-Kerry was similar in 2002 and 2016-17 (Interaction $P = 0.098$) (Figure 6.2 and Appendix F Table F 1). However, among children with caries experience, the difference in mean d_{3vc}mft(cde) between children with Full-CWF and No-CWF was less in 2016-17 than 2002 (Interaction $P = 0.013$).

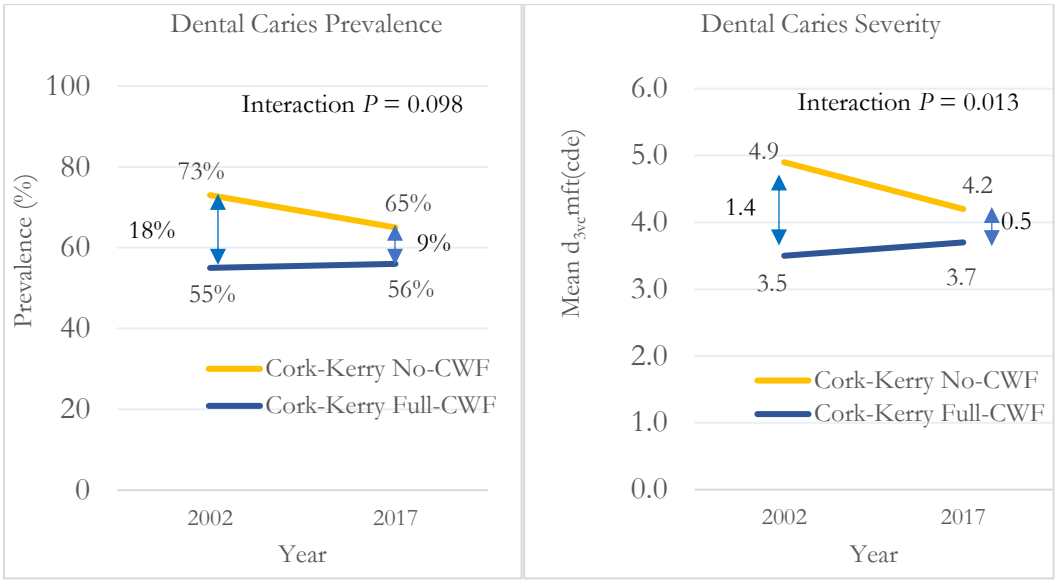


Figure 6.2: Difference in dental caries prevalence (% with d_{3vc}mft(cde)>0) and severity (mean d_{3vc}mft(cde) among children with caries experience) between children with Full-CWF and No-CWF in 2002 vs. 2016-17

[Note: These are actual prevalence and severity data, not model-adjusted]

6.3 Dental caries Full-CWF vs. No-CWF Cork-Kerry 2002 and 2016-17 (Objective 2)

This section describes the effectiveness of CWF for preventing and controlling dental caries in primary teeth of 8-year-olds in 2002, before the downward adjustment of water fluoride concentration and in 2016-17 after the adjustment. Differences in the prevalence and severity of dental caries in primary teeth of 8-year-olds with Full-CWF compared with No-CWF in the Cork-Kerry region in both 2002 and 2016-17 were assessed using multivariable HNB regression analysis. Although exposure to CWF was the main explanatory variable in the multivariable analyses, other explanatory variables were statistically significant in the multivariable models in 2002 and 2016-17. The association between these other explanatory variables and dental caries prevalence and severity in Cork-Kerry are described in Section 6.3.1. The results of univariate analyses are reported in Appendix F, Table F 2. Dental caries prevalence and severity in primary teeth of 8-year-olds in Cork-Kerry with Full-CWF and No-CWF in 2002 and 2016-17 are summarised in Figure 6.3.

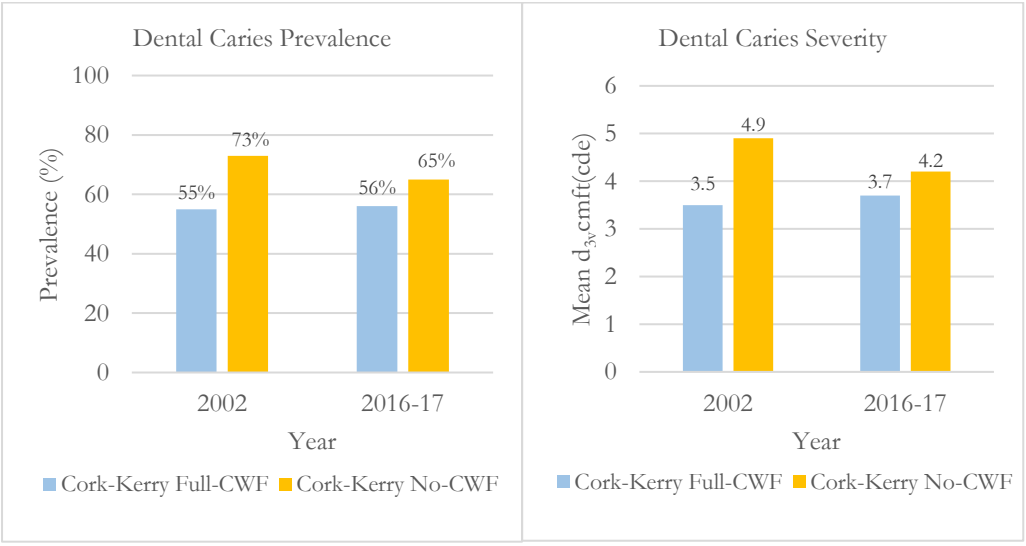


Figure 6.3: Dental caries prevalence (% with d_{3vc}mft(cde)>0) and severity (mean d_{3vc}mft(cde) among children with caries experience) in primary teeth of 8-year-olds in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17

At both time points, after controlling for the effects of other explanatory variables, differences in the prevalence and severity of dental caries between 8-year-olds with Full-CWF and No-CWF were statistically significant (Table 6.6).

In Cork-Kerry 2002, among children with Full-CWF (0.8 to 1.0 ppm F), caries prevalence was 55% compared with 73% among children with No-CWF (Figure 6.3). In multivariable HNB regression analysis, the odds of dental caries were 50% lower among children with Full-CWF than among children with No-CWF (OR 0.50, 95% CI [0.34, 0.74], $P < 0.001$) (Table 6.6). Mean d_{3vc}mft(cde) among children with caries experience was 3.5 (SD 2.2) among children with Full-CWF and 4.9 (SD 2.6) among children with No-CWF (Figure 6.3). In multivariable HNB regression analysis, mean d_{3vc}mft(cde) was 31% lower (95% CI [21%, 40%], $P < 0.001$) among children with Full-CWF in Cork-Kerry than among children with No-CWF (Table 6.6). There were no statistically significant interactions between CWF and any of the other explanatory variables in 2002. This meant that the difference in the prevalence and severity of dental caries between children with Full-CWF and No-CWF in 2002 did not depend on any of the other explanatory variables.

In Cork-Kerry 2016-17, among children with Full-CWF (0.6 to 0.8 ppm F), dental caries prevalence was 56% compared with 65% among children with No-CWF (Figure 6.3). In multivariable HNB regression analysis, the odds of dental caries were 39% lower among children with Full-CWF than among children with No-CWF (OR 0.61, 95% CI [0.46, 0.83], $P = 0.001$) (Table 6.6). Mean d_{3vc}mft(cde) among children with caries experience was 3.7 (SD 2.4) among children with Full-CWF compared with 4.2 (SD 2.5) among children with No-CWF (Figure 6.3). In multivariable HNB regression analysis, mean d_{3vc}mft(cde) was 18% lower (95% CI [7%, 28%], $P = 0.002$) among children with Full-CWF in Cork-Kerry than among children with No-CWF (Table 6.6). There were no

statistically significant interactions between CWF and any of the other explanatory variables in 2016-17. This meant that the difference in the prevalence and severity of dental caries between children with Full-CWF and No-CWF in 2016-17 did not depend on any of the other explanatory variables.

Table 6.6: Multivariable HNB regression analysis of the association between CWF and dental caries (d_{3vc}mft(cde)) in primary teeth of 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Cork-Kerry Full-CWF and No-CWF 2002				Cork-Kerry Full-CWF and No-CWF 2016-17			
	Prevalence of caries (HNB model part 1) n=540		Severity of caries (HNB model part 2) n=333		Prevalence of caries (HNB model part 1) n=989		Severity of caries (HNB model part 2) n=607	
Explanatory Variables	**OR (95%CI)**	***P* value**	**Mean % (95% CI)**	***P* value**	**OR (95%CI)**	***P* value**	**Mean % (95% CI)**	***P* value**
CWF (Full-CWF vs. No-CWF)	**0.50 (0.34, 0.74)**	**<0.001**	**-31 (-40, -21)**	**<0.001**	**0.61 (0.46, 0.83)**	**0.001**	**-18 (-28, -7)**	**0.002**
Age	1.61 (1.06, 2.44)	0.024	-9 (-23, 7)	0.249	0.97 (0.67, 1.42)	0.894	-4 (-18, 13)	0.623
Medical card[a] (yes vs. no)	1.12 (0.71, 1.78)	0.618	16 (-3, 37)	0.101	1.27 (0.88, 1.82)	0.206	16 (1, 32)	0.034
Mother's Education (LC or less[b] vs. Diploma/Certificate or higher)	-	-	-	-	1.11 (0.78, 1.58)	0.570	16 (1, 32)	0.029
Age first used toothpaste[c] (≤ 24 months vs. >24 months[d])	0.80 (0.48, 1.35)	0.409	-17 (-31, -2)	0.029	0.95 (0.67, 1.36)	0.780	-3 (-16, 12)	0.663
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.12 (0.77, 1.63)	0.567	13 (-2, 29)	0.097	1.80 (1.29, 2.51)	0.001	9 (-3, 24)	0.158
Amount of toothpaste at age 8 (pea-sized vs. full brush)	0.93 (0.64, 1.35)	0.699	-3 (-16, 12)	0.656	1.28 (0.87, 1.86)	0.207	-3 (-17, 14)	0.688
Rinse method after toothbrushing at age 8 (glass vs. other[e] or no rinse)	1.07 (0.72, 1.57)	0.750	9 (-5, 26)	0.222	1.54 (1.11, 2.14)	0.010	1 (-11, 14)	0.921
Sweet foods or drinks between meals at age 8								
≥ 4 times a day	1.24 (0.54, 2.86)	0.609	-2 (-27, 31)	0.882	2.30 (1.24, 4.25)	0.008	36 (12, 66)	0.002
2-3 times a day	1.15 (0.79, 1.67)	0.475	-2 (-15, 13)	0.778	1.98 (1.47, 2.68)	<0.001	19 (5, 34)	0.005
Once a day or less	Reference	-	Reference	-	Reference	-	Reference	-
Type of water child usually drinks (tap vs tap and bottled or bottled)	-	-	-	-	1.18 (0.88, 1.59)	0.276	2 (-10, 15)	0.800
Regularly took baby bottle into bed (yes vs. no)	-	-	-	-	1.47 (1.10, 1.97)	0.009	7 (-4, 20)	0.226
Age weaned to cup/mug: (after age 2 vs. before age 2)	-	-	-	-	1.27 (0.84, 1.94)	0.256	1 (-14, 18)	0.896
Age at first visit to the dentist								
≤ 4 years old	2.15 (1.07, 4.35)	0.033	54 (10, 113)	0.011	2.19 (1.45, 3.31)	<0.001	87 (50, 132)	<0.001
5-6 years old	2.11 (1.07, 4.16)	0.031	52 (10, 109)	0.012	2.96 (1.96, 4.47)	<0.001	67 (35, 107)	<0.001
≥ 7 years old	1.07 (0.53, 2.15)	0.854	17 (-17, 65)	0.378	1.94 (1.25, 3.01)	0.003	46 (16, 84)	0.001
Never	Reference	-	Reference	-	Reference	-	Reference	-

Results of univariate analysis are reported in Appendix F, Table F 2. OR = Odds ratio, Mean (%) = the percentage change in mean d_{3vc}mft(cde)

[a] Medical card ownership is used in this study to indicate socio-economic disadvantage. [b] LC= Attainment of Leaving Certificate indicates completion of second level education. [c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5) [d] Recommended from 2002 onwards [e] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

6.3.1 Association between other explanatory variables and dental caries in Cork-Kerry in 2002 and 2016-17

The association between other explanatory variables and dental caries prevalence and severity in Cork-Kerry in 2002 and 2016-17 is shown in Table 6.6.

6.3.1.1 Socio-demographic variables

In 2002, within the age range of 7 to 9 years, increasing age was associated with higher caries prevalence (OR 1.61, [95% CI 1.06, 2.44], $P = 0.024$). In 2016-17, medical card ownership and mothers' highest level of education being Leaving Certificate were associated with higher mean d_{3vc}mft(cde) (increase in mean 16%, 95% CI [1%, 32%], $P = 0.034$ and 16%, 95% CI [1%, 32%], $P = 0.029$ respectively).

6.3.1.2 Toothbrushing variables

In 2002, first using toothpaste at ≤ 24 months was associated with lower mean d_{3vc}mft(cde) (reduction in mean 17%, 95% CI [2%, 31%], $P = 0.029$). In 2016-17, toothbrushing once a day or less often (vs. twice a day or more often) and rinsing with a glass after toothbrushing (vs. other rinse method or no rinse) were associated with higher caries prevalence (OR 1.80, 95% CI [1.29, 2.51], $P = 0.001$; OR 1.54, 95% CI [1.11, 2.14], $P = 0.010$, respectively).

6.3.1.3 Dietary behaviours and dental attendance

In 2016-17, regularly taking a baby bottle into bed was associated with higher caries prevalence (OR 1.47, 95% CI [1.10, 1.97], $P = 0.009$). In addition, in 2016-17, having sweet foods or drinks more than once a day between meals (vs. once a day or less often) was associated with higher prevalence and severity of dental caries. In 2002 and 2016-17, having first visited the dentist at age 6 years or younger was associated with higher prevalence and severity of dental caries.

6.4 Summary of findings

At both time points, more than half of 8-year-olds with Full-CWF in Dublin (54% in 2002, 55% in 2016-17) and Cork-Kerry (55% in 2002, 56% in 2016-17) had at least one decayed missing or filled primary canine, first or second primary molar. Among children with No-CWF in Cork-Kerry, 73% in 2002 and 65% in 2016-17 had at least one decayed missing or filled primary canine, first or second primary molar.

Objective 1: Among 8-year-olds with Full-CWF in Dublin and Cork-Kerry, there was no statistically significant difference in the prevalence or severity of dental caries in primary teeth following downward adjustment of water fluoride concentration (Table 6.7). However, among 8-year-olds with No-CWF, there was a reduction in caries severity within the same time frame and the difference in caries severity between children with Full-CWF and No-CWF was less in 2016-17 than in 2002.

Table 6.7: Summary of multivariable HNB regression analyses of the association between year of examination and dental caries in primary teeth (d_{3vc}mft(cde)) of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

		Caries Prevalence (HNB model part 1)			Caries Severity (HNB model part 2)		
Region Fluoridation Status	**Year**	**n**	**OR (95% CI)**	***P* value**	**n**	**Mean % (95% CI)**	***P* value**
Dublin Full-CWF	2016-17	1291	1.14 (0.87, 1.49)	0.350	699	5 (-9, 21)	0.487
	2002		Reference			Reference	
Cork-Kerry Full-CWF	2016-17	663	1.25 (0.88, 1.78)	0.207	369	7 (-9, 27)	0.424
	2002		Reference			Reference	
Cork-Kerry No-CWF	2016-17	941	0.77 (0.52, 1.13)	0.179	622	-13 (-24, -1)	0.039
	2002		Reference			Reference	

HNB = Hurdle Negative Binomial
OR = Odds ratio
Mean % = Percentage change in mean d_{3vc}mft(cde)

Objective 2: In Cork-Kerry, 8-year-olds with Full-CWF examined prior to the downward adjustment (in 2002) and 8-year-olds with Full-CWF born after the adjustment (examined in 2016-17) had lower caries prevalence and severity in primary teeth than their counterparts with No-CWF (Table 6.8).

Table 6.8: Summary of multivariable HNB regression analyses of the association between CWF and dental caries in primary teeth (d_{3vc}mft(cde)) of 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

Region	F Status	Caries Prevalence (HNB model part 1)			Caries Severity (HNB model part 2)		
		n	OR (95% CI)	*P* value	n	Mean % (95% CI)	*P* value
Cork-Kerry 2002	Full-CWF	540	0.50 (0.34, 0.74)	<0.001	333	-31 (-40, -21)	<0.001
	No-CWF		Reference			Reference	
Cork-Kerry 2016-17	Full-CWF	989	0.61 (0.46, 0.83)	0.001	607	-18 (-28, -7)	0.002
	No-CWF		Reference			Reference	

HNB = Hurdle Negative Binomial
OR = Odds ratio
Mean % = Percentage change in mean d_{3vc}mft(cde)

Multivariable HNB regression analyses of data for 8-year-olds in Cork-Kerry in 2002 and 2016-17, identified several socio-demographic and modifiable behavioural factors including toothbrushing and dietary habits as being associated with caries prevalence and severity.

7 Results: Dental fluorosis

This chapter describes the impact of downward adjustment of water fluoride concentration on dental fluorosis in permanent teeth of 8-year-olds living in Dublin and Cork-Kerry. Results for dental fluorosis based on a whole mouth score measured clinically using Dean's Index are presented in Section 7.1. Results for dental fluorosis in permanent maxillary central incisors measured from oral photographs using the TF index are presented in Section 7.2.

7.1 Dental fluorosis: Dean's Index

This section describes the prevalence and severity of dental fluorosis measured clinically using Dean's Index in 8-year-olds living in Dublin and Cork-Kerry in 2002 and 2016-17 and the impact of downward adjustment of water fluoride concentration on dental fluorosis in 8-year-olds living in Dublin and Cork-Kerry.

1. The prevalence and severity of dental fluorosis measured clinically using Dean's Index in permanent teeth of 8-year-olds born after downward adjustment of water fluoride concentration (examined in 2016-17) in Dublin and Cork-Kerry and 8-year-olds examined in the same regions in 2002 prior to the downward adjustment are described.
2. Dental fluorosis prevalence in 8-year-olds in Dublin and Cork-Kerry in 2016-17 is compared with 8-year-olds in the same regions in 2002 **(Objective 3a).**
3. Differences in the prevalence of dental fluorosis in 8-year-olds with Full-CWF compared with No-CWF in Cork-Kerry in 2002 and 2016-17 are assessed **(Objective 4a)**, and factors associated with dental fluorosis in this region at each time point are identified.

In FACCT 2016-17, 1,846 8-year-olds with Full-CWF or No-CWF were clinically examined for dental fluorosis; 703 in Dublin with Full-CWF, 371 in Cork-Kerry with Full-CWF and 772 in Cork-Kerry with No-CWF (Figure 5.1). Dental fluorosis measurements for 8-year-olds 2016-17 were compared with 1,224 8-year-olds in 2002; 671 in Dublin with Full-CWF, 325 in Cork-Kerry with Full-CWF and 228 in Cork-Kerry with No-CWF (Figure 5.2).

7.1.1 Dental fluorosis prevalence and severity (Dean's Index) 2002 and 2016-17

This section provides an overview of the prevalence and severity of dental fluorosis in permanent teeth of 8-year-olds examined clinically for dental fluorosis in the NSSCOH 2002 and in the FACCT study in 2016-17. The Dean's Index measurement was based on a whole mouth score. The prevalence of dental fluorosis (defined as Dean's Index 'very mild' or greater) and the distribution of Dean's Index scores in 2002 and 2016-17 are reported in Table 7.1.

Table 7.1: Dental fluorosis prevalence (Dean's Index 'very mild' or greater, clinical) and distribution of Dean's Index scores in permanent teeth of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 and 2016-17

Dental Fluorosis Prevalence (Dean's Index)	Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
	2002	2016-17	2002	2016-17	2002	2016-17
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Normal/Questionable	85 (567)	82 (576)	87 (283)	88 (328)	97 (222)	95 (732)
Very mild or greater	15 (104)	18 (127)	13 (42)	12 (43)	3 (6)	5 (40)
Total	**100 (671)**	**100 (703)**	**100 (325)**	**100 (371)**	**100 (228)**	**100 (772)**
Dean's Index score[a]						
Normal	73 (488)	63 (441)	75 (245)	63 (232)	86 (196)	79 (613)
Questionable	12 (79)	19 (135)	12 (38)	26 (96)	11 (26)	15 (119)
Very mild	11 (75)	14 (99)	8 (25)	9 (34)	3 (6)	5 (38)
Mild	4 (24)	4 (26)	5 (17)	2 (8)	0 (0)	<1 (2)
Moderate	< 1 (5)	<1 (2)	0 (0)	<1 (1)	0 (0)	0 (0)
Total	**100 (671)**	**100 (703)**	**100 (325)**	**100 (371)**	**100 (228)**	**100 (772)**

[a] No cases of 'severe' dental fluorosis were recorded

In Dublin (Full-CWF), dental fluorosis prevalence was 15% in 2002 and 18% in 2016-17. Among children with Full-CWF in Cork-Kerry, dental fluorosis prevalence was 13% in 2002 and 12% in 2016-17. Dental fluorosis prevalence among children with No-CWF in Cork-Kerry was 3% in 2002 and 5% in 2016-17. At both time points, dental fluorosis was predominantly 'very mild' and among children with Full-CWF and No-CWF, the proportions with 'mild' or 'moderate' fluorosis were ≤5% and <1% respectively.

7.1.2 Dental fluorosis (Dean's Index) in Dublin and Cork-Kerry 2016-17 vs. 2002 (Objective 3a)

In this section, dental fluorosis prevalence in 8-year-olds in Dublin and Cork-Kerry in 2016-17, born after downward adjustment of water fluoride concentration is compared with children in the same regions in 2002, prior to the downward adjustment. The results presented in this section in relation to objective 3a were published in the Journal of Dental Research in 2021 (Appendix A).

The prevalence of dental fluorosis in 8-year-olds with Full-CWF and No-CWF in each region in 2002 and 2016-17 are summarised in Figure 7.1.

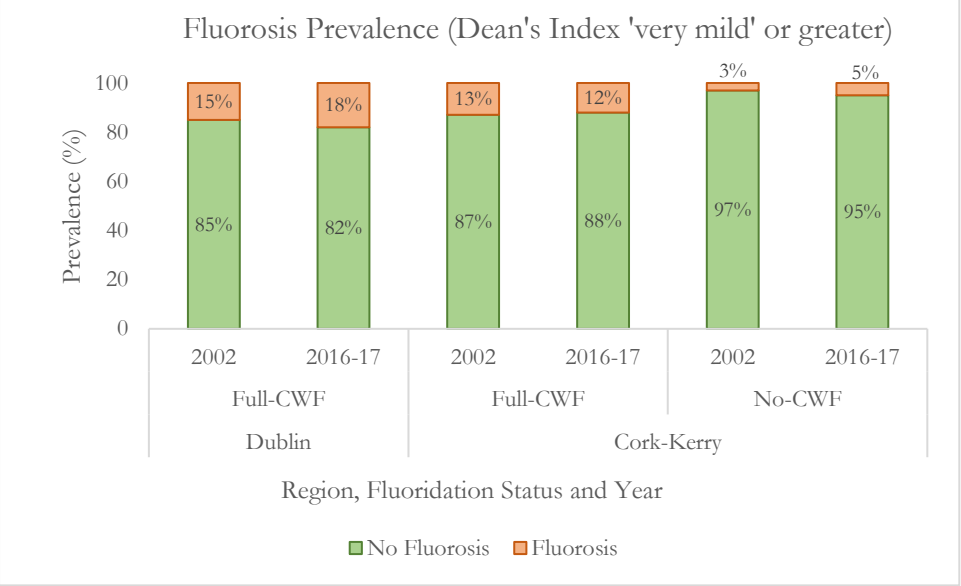


Figure 7.1: Dental fluorosis prevalence (Dean's Index 'very mild' or greater, clinical) in permanent teeth of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 compared with 2016-17

In Dublin (Full-CWF), the prevalence of dental fluorosis was 18% in 2016-17 and 15% in 2002 but the difference was not statistically significant in the multivariable logistic regression analysis (OR 1.16, 95% CI [0.87, 1.56], $P = 0.312$) (Table 7.2). Similarly, among children with Full-CWF in Cork-Kerry, the prevalence of dental fluorosis was 12% in 2016-17 and 13% in 2002 and with no statistically significant difference in prevalence over time (OR 0.93, 95% CI [0.59, 1.48], $P = 0.771$). The prevalence of dental fluorosis among children with No-CWF in Cork-Kerry was 5% in 2016-17 and 3% in 2002. The difference was not statistically significant (OR 1.97, 95% CI [0.82, 4.73], $P = 0.129$).

In Dublin (Full-CWF) 2002 and 2016-17 combined, being female (vs. male) was associated with higher prevalence of 'very mild' fluorosis or greater. There were no statistically significant interactions between year of examination and any of the other

explanatory variables in the logistic regression models for Dublin Full-CWF, Cork-Kerry Full-CWF or Cork-Kerry No-CWF. This meant that the difference in the prevalence of dental fluorosis (Dean's Index 'very mild' or greater) between children in 2002 and 2016-17 did not depend on any of the other explanatory variables.

Table 7.2: Multivariable logistic regression analyses of the association between year of examination and prevalence of dental fluorosis (Dean's 'very mild' or greater) among 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

	Dental fluorosis (Dean's Index 'very mild' or greater, clinical)					
	Dublin Full-CWF n=1338		Cork-Kerry Full-CWF n=678		Cork-Kerry No-CWF n=979	
Explanatory Variables	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
Year (2016-17 vs. 2002)	**1.16 (0.87, 1.56)**	**0.312**	**0.93 (0.59, 1.48)**	**0.771**	**1.97 (0.82, 4.73)**	**0.129**
Age	0.84 (0.58, 1.21)	0.337	1.45 (0.86, 2.43)	0.164	0.60 (0.26, 1.36)	0.221
Gender (female vs. male)	1.55 (1.16, 2.08)	0.003	1.06 (0.66, 1.70)	0.801	1.44 (0.78, 2.66)	0.244
Medical card[a] (yes vs. no)	1.06 (0.76, 1.48)	0.736	0.95 (0.56, 1.60)	0.845	1.62 (0.83, 3.15)	0.157
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	1.29 (0.87, 1.91)	0.211	1.94 (0.90, 4.15)	0.090	0.94 (0.45, 2.00)	0.882

The main explanatory variable was year of examination (Year). The OR (odds ratio) for the other explanatory variables represented the association between each explanatory variable and the prevalence of dental fluorosis controlled for the effect of the other explanatory variables.

[a] Medical card was used in this study as a measure of socio-economic disadvantage

[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[c] Recommended from 2002 onwards

A separate multivariable logistic regression model for Cork-Kerry Full-CWF and No-CWF combined was tested for interaction between fluoridation status (Full-CWF vs. No-CWF) and year of examination (2016-17 vs 2002) to determine whether the association between CWF and dental fluorosis depended on year of examination (Appendix F, Table F 3). This analysis was restricted to Cork-Kerry because the Dublin sample had Full-CWF and therefore no comparison of Full-CWF and No-CWF could be conducted in the Dublin region. The interaction was not statistically significant ($P = 0.094$) indicating that the difference in dental fluorosis prevalence between children with Full-CWF and No-CWF was similar in 2016-17 and 2002 (Figure 7.2).

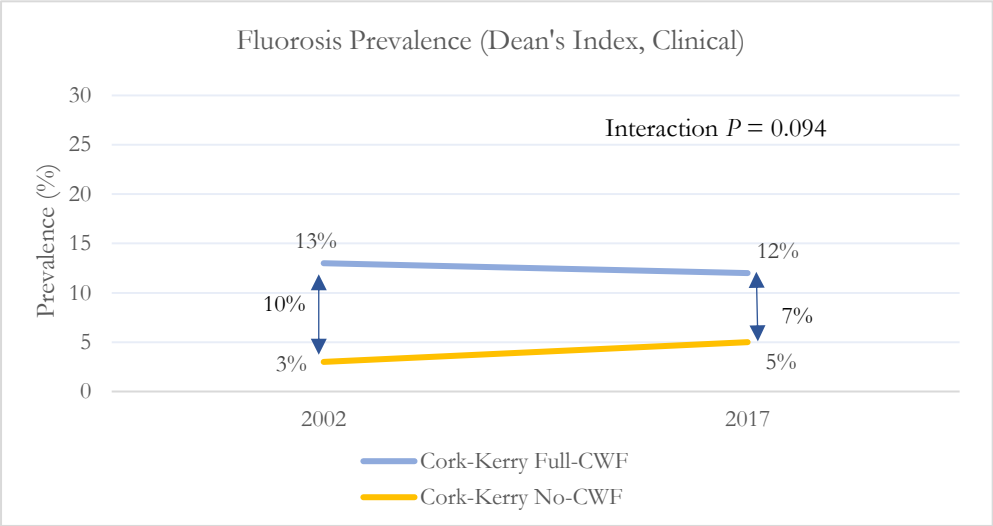


Figure 7.2: Difference in dental fluorosis prevalence (Dean's Index, clinical) between children with Full-CWF and No-CWF in 2002 vs. 2016-17

[Note: These are actual prevalence data, not model-adjusted]

7.1.3 Dental fluorosis (Dean's Index) Full-CWF vs. No-CWF Cork-Kerry 2002 and 2016-17 (Objective 4a)

This section evaluates the difference in dental fluorosis prevalence (Dean's Index 'very mild' or greater) in 8-year-olds with Full-CWF compared with No-CWF in the Cork-Kerry region in 2002 and 2016-17 using multivariable logistic regression analysis. Although exposure to CWF was the main explanatory variable in the multivariable analyses, other explanatory variables were statistically significant in the multivariable models. The association between these other explanatory variables and dental fluorosis in Cork-Kerry are described in Section 7.1.3.1. The results of univariate analyses are reported in Appendix F, Table F 4.

Dental fluorosis prevalence among 8-year-olds in Cork-Kerry with Full-CWF and No-CWF in 2002 and 2016-17 is summarised in Figure 7.3.

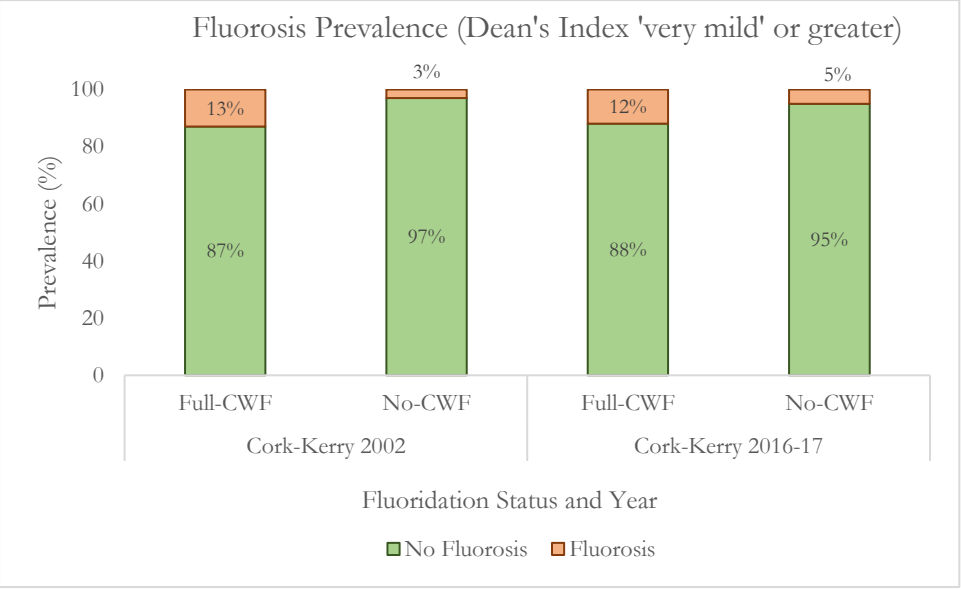


Figure 7.3: Dental fluorosis prevalence (Dean's Index 'very mild' or greater, clinical) in permanent teeth of 8-year-olds in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17

At both time points, after controlling for the effects of other explanatory variables, the difference in dental fluorosis prevalence between 8-year-olds with Full-CWF and No-CWF was statistically significant ($P < 0.001$) (Table 7.3)

Table 7.3: Multivariable logistic regression analyses of the association between CWF and dental fluorosis (Dean's Index 'very mild' or greater) in permanent teeth of 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Cork-Kerry (Full-CWF and No-CWF combined)			
	Prevalence of dental fluorosis Dean's Index, 'very mild' or greater			
	2002 n=546		2016-17 n=992	
Explanatory Variables	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
CWF (Full-CWF vs. No-CWF)	**5.61 (2.32, 13.55)**	**<0.001**	**2.57 (1.58, 4.17)**	**<0.001**
Age	1.13 (0.61, 2.11)	0.695	1.09 (0.57, 2.11)	0.791
Gender (female vs. male)	1.07 (0.58, 1.99)	0.820	1.26 (0.77, 2.04)	0.353
Medical card[a] at age 8 (yes vs. no)	0.88 (0.42, 1.86)	0.743	1.25 (0.72, 2.19)	0.423
Mother's Education at age 8 (LC or less[b] vs. Diploma/Cert or higher)	-	-	1.40 (0.79, 2.46)	0.249
Age first used toothpaste[c] (vs. >24 months[d])				
Before 12 months	1.54 (0.52, 4.54)	0.430	2.39 (1.08, 5.26)	0.031
Between 12 and 18 months	1.77 (0.64, 4.90)	0.269	0.97 (0.46, 2.03)	0.926
Between 19 and 24 months	1.13 (0.32, 3.96)	0.846	0.61 (0.25, 1.50)	0.282
Frequency of toothbrushing before age 2 (≥ twice a day vs. ≤once a day)	-	-	1.68 (1.01, 2.81)	0.046
Amount of toothpaste before age 2 (pea-sized[d] or less vs. >pea-sized)	-	-	1.15 (0.25, 5.33)	0.859
Eats/licks toothpaste before age 2 (often or sometimes vs. never[d])	-	-	0.95 (0.58, 1.54)	0.822
Breastfed (yes vs. no)	-	-	1.21 (0.74, 1.98)	0.444

Results of univariate analyses are reported in Appendix F Table F 4
OR = Odds ratio
[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage
[b] LC=Leaving Certificate. Attainment of Leaving Certificate indicates completion of second level education
[c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[d] Recommended from 2002 onwards

In Cork-Kerry 2002, among children with Full-CWF (0.8 to 1.0 ppm F), dental fluorosis prevalence was 13% compared with 3% among children with No-CWF (Figure 7.3). In multivariable logistic regression analysis, the odds of fluorosis were 461% higher among children with Full-CWF than among children with No-CWF (OR 5.61, 95% CI [2.32, 13.55], $P < 0.001$) (Table 7.3). There were no statistically significant interactions between CWF and any of the other explanatory variables in 2002.

In Cork-Kerry 2016-17, among children with Full-CWF (0.6 to 0.8 ppm F), dental fluorosis prevalence was 12% compared with 5% among children with No-CWF (Figure 7.3). In multivariable logistic regression analysis, the odds of fluorosis were 157% higher among children with Full-CWF than among children with No-CWF (OR 2.57, 95% CI [1.58, 4.17], $P < 0.001$) (Table 7.3). There were no statistically significant interactions between CWF and any of the other explanatory variables in 2016-17.

7.1.3.1 Association between other explanatory variables and dental fluorosis (Dean's Index) in Cork-Kerry in 2002 and 2016-17

Exposure to CWF was the main explanatory variable in the multivariable analyses presented in Table 7.3. The only other explanatory variables that were statistically significant in the multivariable regression models at either time point were age first used toothpaste and frequency of toothbrushing under age 2 years in Cork-Kerry 2016-17. First using toothpaste before 12 months (vs. after 24 months) was associated with higher prevalence of fluorosis (OR 2.39, 95% CI [1.08, 5.26], $P = 0.031$). In addition, in 2016-17, toothbrushing twice a day or more often under age 2 years compared with once a day or less often was associated with higher prevalence of fluorosis (OR 1.68, 95% CI [1.01, 2.81], $P = 0.046$).

7.1.4 Summary of findings

At both time points, dental fluorosis was predominantly 'very mild' and the prevalence of 'mild' or 'moderate' fluorosis was low.

Objective 3a: Among 8-year-olds with Full-CWF in Dublin and Cork-Kerry, there was no difference in dental fluorosis prevalence measured clinically with Dean's Index between 2002 and 2016-17, indicating that there was no difference in the prevalence of dental fluorosis following downward adjustment of water fluoride concentration (Table 7.4).

Table 7.4: Summary of multivariable logistic regression analyses of the association between year of examination and dental fluorosis (Dean's Index 'very mild' or greater, clinical) in permanent teeth of 8-year-olds in Dublin with Full-CWF, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

		Dental fluorosis (Dean's Index 'very mild' or greater, clinical)		
Region	**Year**	**n**	**OR (95% CI)**	***P* value**
Dublin Full-CWF	2016-17	1338	1.16 (0.87, 1.56)	0.312
	2002		Reference	
Cork-Kerry Full-CWF	2016-17	678	0.93 (0.59, 1.48)	0.771
	2002		Reference	
Cork-Kerry No-CWF	2016-17	979	1.97 (0.82, 4.73)	0.129
	2002		Reference	

OR = Odds ratio

Objective 4a: In Cork-Kerry, children with Full-CWF examined prior to the downward adjustment (in 2002) and children with Full-CWF born after the downward adjustment (examined in 2016-17) had higher prevalence of dental fluorosis than their counterparts with No-CWF (Table 7.5).

Table 7.5: Summary of multivariable logistic regression analyses of the association between CWF and dental fluorosis (Dean's Index 'very mild' or greater, clinical) in permanent teeth of 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

		Dental fluorosis (Dean's Index 'very mild' or greater, clinical)		
Region and Year	**Fluoridation Status**	**n**	**OR (95% CI)**	**P value**
Cork-Kerry 2002	Full-CWF	546	5.61 (2.32, 13.55)	<0.001
	No-CWF		Reference	
Cork-Kerry 2016-17	Full-CWF	992	2.57 (1.58, 4.17)	<0.001
	No-CWF		Reference	

OR = Odds ratio

In Cork-Kerry in 2016-17, first using toothpaste before 12 months (vs. after 24 months) and toothbrushing twice a day or more often under age 2 years (vs. once a day or less often) were associated with higher prevalence of 'very mild', 'mild' or 'moderate' fluorosis.

7.2 Dental fluorosis: TF Index

This section describes the prevalence and severity of dental fluorosis in permanent maxillary central incisors measured from photographs using the TF Index in 8-year-olds living in Cork-Kerry in 2002 and in Dublin and Cork-Kerry in 2016-17 and the impact of downward adjustment of water fluoride concentration on dental fluorosis in 8-year-olds in Cork-Kerry.

1. The prevalence and severity of dental fluorosis in permanent maxillary central incisors of 8-year-olds born after downward adjustment of water fluoride concentration (examined in 2016-17) in Dublin and Cork-Kerry and 8-year-olds examined in Cork-Kerry in 2002 prior to the downward adjustment are described.
2. Dental fluorosis prevalence in permanent maxillary central incisors of 8-year-olds in Cork-Kerry in 2016-17 is compared with children in the same region in 2002 **(Objective 3b)**.
3. Differences in the prevalence of dental fluorosis in permanent maxillary central incisors of children with Full-CWF compared with No-CWF in Cork-Kerry in 2002 and 2016-17 are evaluated **(Objective 4b),** and factors associated with dental fluorosis in this region at each time point identified.

Objectives 3b and 4b relate to Cork-Kerry only, because oral photographs were not taken for children in Dublin during the NSSCOH 2002.

The 2016-17 analyses included 612 8-year-olds in Dublin with Full-CWF, 331 in Cork-Kerry with Full-CWF and 735 in Cork-Kerry with No-CWF (Figure 5.1). Dental fluorosis measurements for 8-year-olds in Cork-Kerry 2016-17 were compared with 8-year-olds in the same region in 2002. Comparator groups in Cork-Kerry 2002 included 294 8-year-olds with Full-CWF and 205 with No-CWF (Figure 5.2).

7.2.1 Dental fluorosis prevalence and severity in maxillary central incisors (TF Index) in 2002 and 2016-17

This section provides an overview of the prevalence and severity of dental fluorosis in maxillary central incisors of 8-year-olds in the NSSCOH 2002 and in the FACCT study in 2016-17. The person-level TF score was the highest score in the maxillary central incisors. The prevalence of dental fluorosis, defined as a person-level score of TF 1 or greater or TF 2 or greater and the distribution of the TF Index scores for 2002 and 2016-17 are reported in Table 7.6. The descriptive criteria for each of the TF Index scores was previously described in Section 2.7.2, Table 2.7.

Table 7.6: Dental fluorosis prevalence (TF 1 or greater, TF 2 or greater) in permanent maxillary central incisors and distribution of TF Index scores (person-level score from photographs based on highest score in maxillary central incisors) among 8-year-olds in Dublin with Full-CWF in 2016-17, Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 and 2016-17

Dental Fluorosis Prevalence (TF Index)	Dublin[a] Full-CWF	Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
	2016-17	2002	2016-17	2002	2016-17
	% (n)	% (n)	% (n)	% (n)	% (n)
TF 0	59 (360)	25 (73)	60 (197)	41 (84)	86 (635)
TF 1 or greater	41 (252)	75 (221)	40 (134)	59 (121)	14 (100)
Total	**100 (612)**	**100 (294)**	**100 (331)**	**100 (205)**	**100 (735)**
TF 0 or 1	83 (506)	73 (216)	85 (282)	92 (189)	96 (709)
TF 2 or greater	17 (106)	27 (78)	15 (49)	8 (16)	4 (26)
Total	**100 (612)**	**100 (294)**	**100 (331)**	**100 (205)**	**100 (735)**
TF Score[b]					
TF 0	59 (360)	25 (73)	60 (197)	41 (84)	86 (635)
TF 1	24 (146)	49 (143)	26 (85)	51 (105)	10 (74)
TF 2	13 (79)	20 (59)	11 (35)	7 (15)	3 (20)
TF 3	4 (23)	5 (15)	4 (13)	<1 (1)	<1 (6)
TF 4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TF 5	<1 (4)	1 (4)	<1 (1)	0 (0)	0 (0)
Total	**100 (612)**	**100 (294)**	**100 (331)**	**100 (205)**	**100 (735)**

[a]There were no oral photographs for the Dublin sample in the NSSCOH 2002
[b]No case of TF 4 or TF>5 was recorded

In 2002 and 2016-17, dental fluorosis was predominantly TF 1 and TF 2. No scores of TF 4 were recorded and the highest score recorded at any time point was TF 5. The proportion of children at either time point with TF 3 or greater was ≤6% among children with Full-CWF and <1% among children with No-CWF.

7.2.1.1 TF 1 or greater

The prevalence of TF 1 or greater in maxillary central incisors of children in Dublin with Full-CWF was 41% in 2016-17 (Table 7.6). Among children with Full-CWF in Cork-Kerry, the prevalence of TF 1 or greater was 75% in 2002 and 40% in 2016-17. Among children with No-CWF in Cork-Kerry the prevalence of TF 1 or greater was 59% in 2002 and 14% in 2016-17.

7.2.1.2 TF 2 or greater

The prevalence of TF 2 or greater in maxillary central incisors of children in Dublin with Full-CWF was 17% in 2016-17 (Table 7.6). Among children with Full-CWF in Cork-Kerry, the prevalence of TF 2 or greater was 27% in 2002 and 15% in 2016-17. Among children with No-CWF in Cork-Kerry, the prevalence of TF 2 or greater was 8% in 2002 and 4% in 2016-17.

7.2.2 Dental fluorosis (TF Index) in maxillary central incisors in Cork-Kerry 2016-17 vs. 2002 (Objective 3b)

In this section, dental fluorosis prevalence (TF 1 or greater and TF 2 or greater) in maxillary central incisors of children in Cork-Kerry in 2016-17, born after downward adjustment of water fluoride concentration is compared with children in the same regions in 2002 prior to the downward adjustment.

7.2.2.1 TF 1 or greater

The prevalence of TF 1 or greater in permanent maxillary central incisors of children with Full-CWF and No-CWF in Cork-Kerry 2002 and 2016-17 is summarised in Figure 7.4

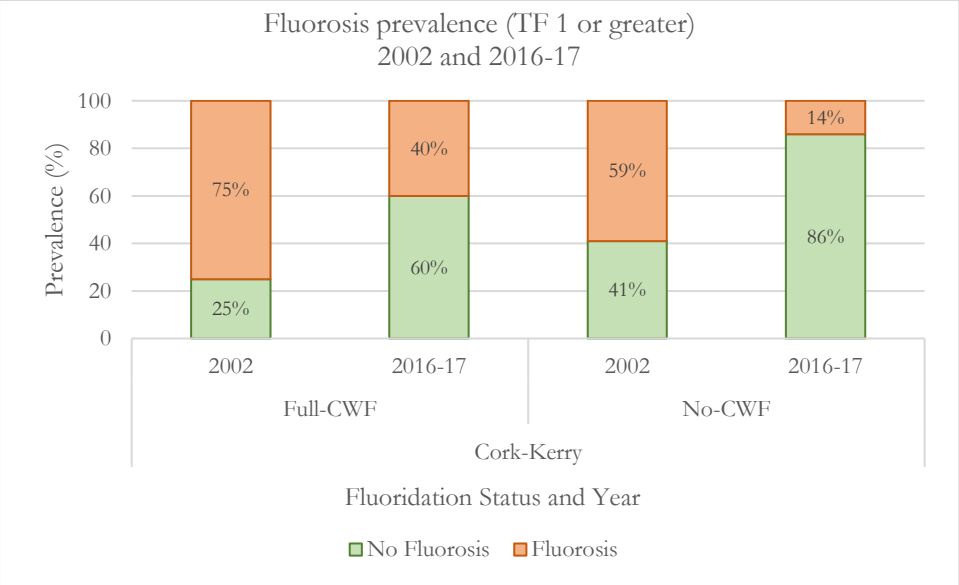


Figure 7.4: Dental fluorosis prevalence (TF 1 or greater, measured from photographs) in permanent maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 compared with 2016-17

In Cork-Kerry, among 8-year-olds with Full-CWF, the reduction in the prevalence of TF 1 or greater from 75% in 2002 to 40% in 2016-17 (Figure 7.4) was statistically significant after controlling for the effects of other explanatory variables. The odds of fluorosis at TF 1 or greater were 76% lower among children in Cork-Kerry with Full-CWF in 2016-17 than in 2002 (OR 0.24, 95% CI [0.17, 0.34], $P < 0.001$) (Table 7.7).

Similarly, among children in Cork-Kerry with No-CWF, the reduction in the prevalence of TF 1 or greater from 59% in 2002 to 14% in 2016-17 was statistically significant in multivariable analysis. The odds of fluorosis at TF 1 or greater were 89% lower among children in Cork-Kerry with No-CWF in 2016-17 than in 2002 (OR 0.11, 95% CI [0.08, 0.16], $P < 0.001$).

In Cork-Kerry No-CWF 2002 and 2016-17 combined, parental medical card ownership (vs. no medical card) was associated with lower prevalence of dental fluorosis at TF 1 or greater. There were no statistically significant interactions between year of examination and any of the other explanatory variables. This meant that the difference in the prevalence of dental fluorosis (TF 1 or greater) between children in 2002 and 2016-17 did not depend on any of the other explanatory variables.

Table 7.7: Multivariable logistic regression analyses of the association between year of examination (2016-17 vs. 2002) and dental fluorosis prevalence (TF 1 or greater, measured from photographs) in maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

	TF 1 or greater			
	Cork-Kerry Full-CWF n=608		Cork-Kerry No-CWF n=920	
	OR (95% CI)	***P* value**	**OR (95% CI)**	***P* value**
Year (2016-17 vs. 2002)	**0.24 (0.17, 0.34)**	**<0.001**	**0.11 (0.08, 0.16)**	**<0.001**
Age	0.86 (0.57, 1.28)	0.451	0.92 (0.59, 1.45)	0.730
Gender (female vs. male)	1.30 (0.91, 1.85)	0.143	1.31 (0.93, 1.85)	0.123
Medical card[a] (yes vs. no)	1.00 (0.68, 1.47)	0.991	0.58 (0.36, 0.93)	0.023
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	1.38 (0.86, 2.20)	0.185	1.11 (0.73, 1.70)	0.619

OR = Odds ratio

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage

[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[c] Recommended from 2002 onwards

A separate multivariable logistic regression model for Cork-Kerry Full-CWF and No-CWF combined was tested for interaction between fluoridation status (Full-CWF vs. No-CWF) and year of examination (2016-17 vs 2002) to determine whether the association between CWF and prevalence of TF 1 or greater depended on year of examination

(Appendix F, Table F 5). The interaction was statistically significant ($P = 0.002$) indicating that the association between CWF and the prevalence of TF 1 or greater depended on year of examination. This meant that the difference in dental fluorosis prevalence (TF 1 or greater) between children with Full-CWF and No-CWF was greater in 2016-17 than in 2002 (Figure 7.5).

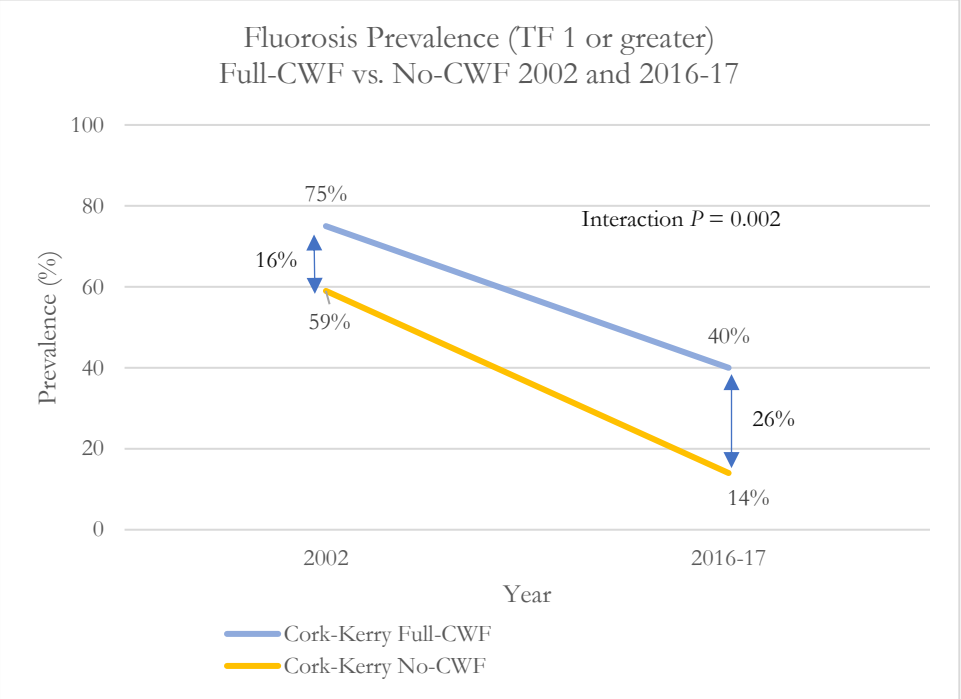


Figure 7.5: Difference in dental fluorosis prevalence (TF 1 or greater, measured from photographs) in permanent maxillary central incisors of 8-year-olds with Full-CWF and No-CWF in 2002 and 2016-17

[Note: These are actual prevalence data, not model-adjusted]

7.2.2.2 TF 2 or greater

The prevalence of TF 2 or greater in permanent maxillary central incisors of children with Full-CWF and No-CWF in Cork-Kerry 2002 and 2016-17 is summarised in Figure 7.6

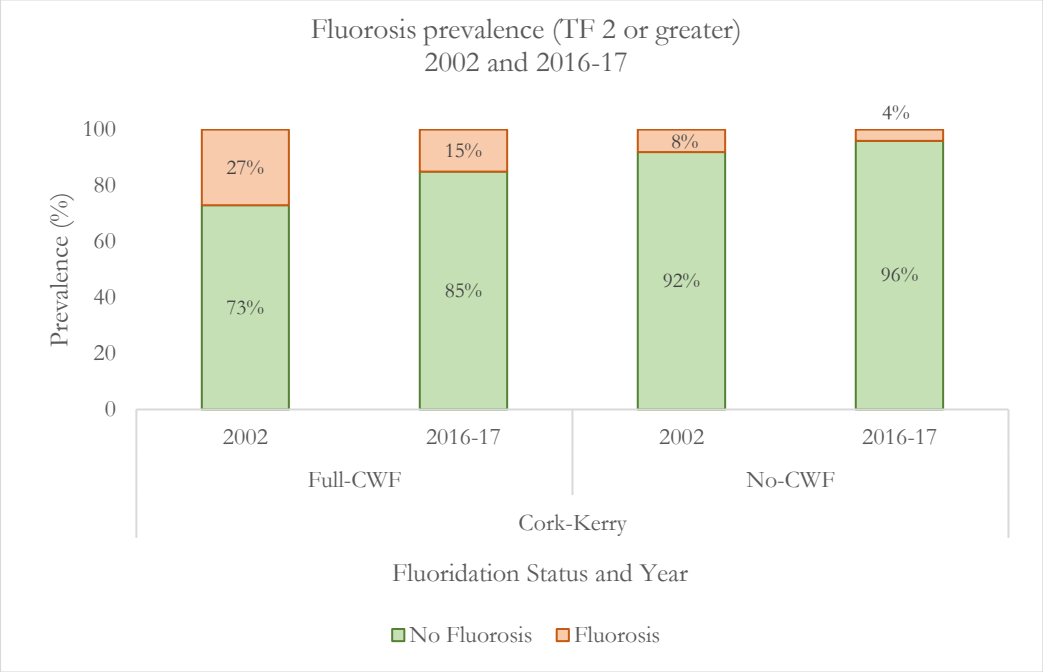


Figure 7.6: Dental fluorosis prevalence (TF 2 or greater, measured from photographs) in permanent maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF in 2002 compared with 2016-17

In Cork-Kerry, among 8-year-olds with Full-CWF, the reduction in the prevalence of TF 2 or greater from 27% in 2002 to 15% in 2016-17 (Figure 7.6) was statistically significant after controlling for the effects of other explanatory variables. The odds of fluorosis at TF 2 or greater were 50% lower among children in Cork-Kerry with Full-CWF in 2016-17 than in 2002 (OR 0.50, 95% CI [0.33, 0.75], $P = 0.001$) (Table 7.8).

Similarly, among children in Cork-Kerry with No-CWF, the reduction in the prevalence of TF 2 or greater from 8% in 2002 to 4% in 2016-17 was statistically significant in multivariable analysis. The odds of fluorosis at TF 2 or greater were 51% lower among

children in Cork-Kerry with No-CWF in 2016-17 than in 2002 (OR 0.49, 95% CI [0.26, 0.95], $P = 0.036$).

There were no statistically significant interactions between year of examination and any of the other explanatory variables. This meant that the difference in the prevalence of dental fluorosis (TF 2 or greater) between children 2002 and 2016-17 did not depend on any of the other explanatory variables.

Table 7.8: Multivariable logistic regression analyses of the association between year of examination (2016-17 vs. 2002) and dental fluorosis prevalence (TF 2 or greater, measured from photographs) in maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

	TF 2 or greater			
	Cork-Kerry Full-CWF n=608		Cork-Kerry No-CWF n=920	
	OR (95%CI)	***P* value**	**OR (95%CI)**	***P* value**
Year (2016-17 vs. 2002)	**0.50 (0.33, 0.75)**	**0.001**	**0.49 (0.26, 0.95)**	**0.036**
Age	0.69 (0.44, 1.09)	0.111	2.13 (0.95, 4.77)	0.067
Gender (female vs. male)	1.18 (0.78, 1.78)	0.434	1.09 (0.58, 2.06)	0.779
Medical card[a] (yes vs. no)	0.84 (0.53, 1.33)	0.453	0.57 (0.22, 1.48)	0.246
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	1.56 (0.83, 2.93)	0.166	1.13 (0.52, 2.45)	0.753

OR = Odds ratio

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage

[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[c] Recommended from 2002 onwards

A separate multivariable logistic regression model for Cork-Kerry Full-CWF and No-CWF combined was tested for interaction between fluoridation status (Full-CWF vs. No-CWF) and year of examination (2016-17 vs 2002) to determine whether the association between CWF and prevalence of TF 2 or greater depended on year of examination (Appendix F, Table F 5). The interaction between fluoridation status and year of examination was not statistically significant ($P = 0.749$) indicating that the difference in dental fluorosis prevalence (TF 2 or greater) between children with Full-CWF and No-CWF was similar in 2016-17 and 2002 (Figure 7.7).

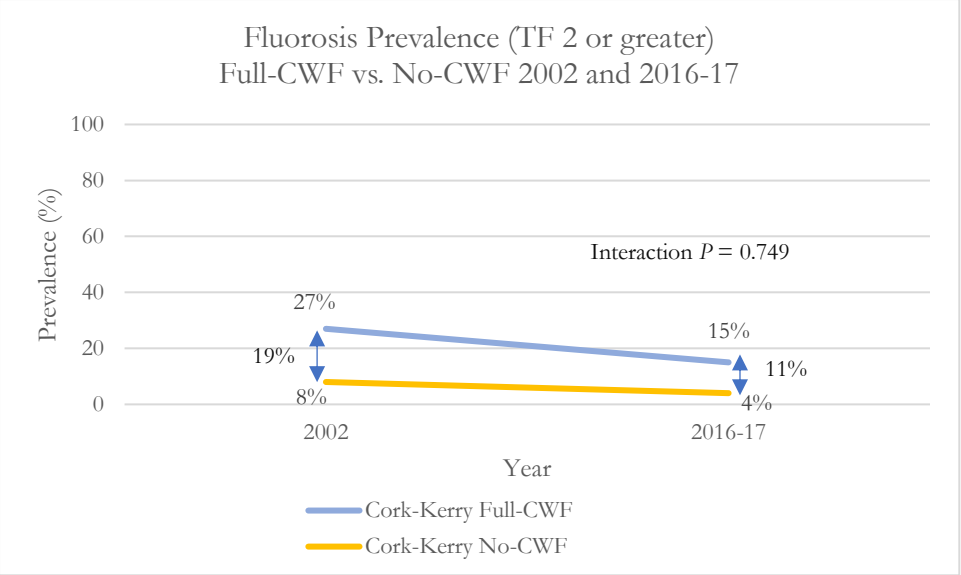


Figure 7.7: Difference in dental fluorosis prevalence (TF 2 or greater, measured from photographs) in maxillary central incisors of 8-year-olds with Full-CWF and No-CWF in 2016-17 versus 2002

[Note: These are actual prevalence data, not model-adjusted]

7.2.3 Dental fluorosis (TF Index) in maxillary central incisors Full-CWF vs. No-CWF Cork-Kerry 2002 and 2016-17 (Objective 4b)

This section evaluates the difference in dental fluorosis prevalence in maxillary central incisors of 8-year-olds with Full-CWF compared with No-CWF in the Cork-Kerry region in 2002 and 2016-17 using multivariable logistic regression analysis. Although exposure to CWF was the main explanatory variable in the multivariable logistic regression analyses, other explanatory variables were statistically significant in the regression models. The association between these other explanatory variables and dental fluorosis in Cork-Kerry are described in Section 7.2.3.3. The results of univariate analyses are reported in Appendix F, Table F 6.

7.2.3.1 TF 1 or greater

Prevalence of TF 1 or greater in maxillary central incisors of children in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17 is summarised in Figure 7.8.

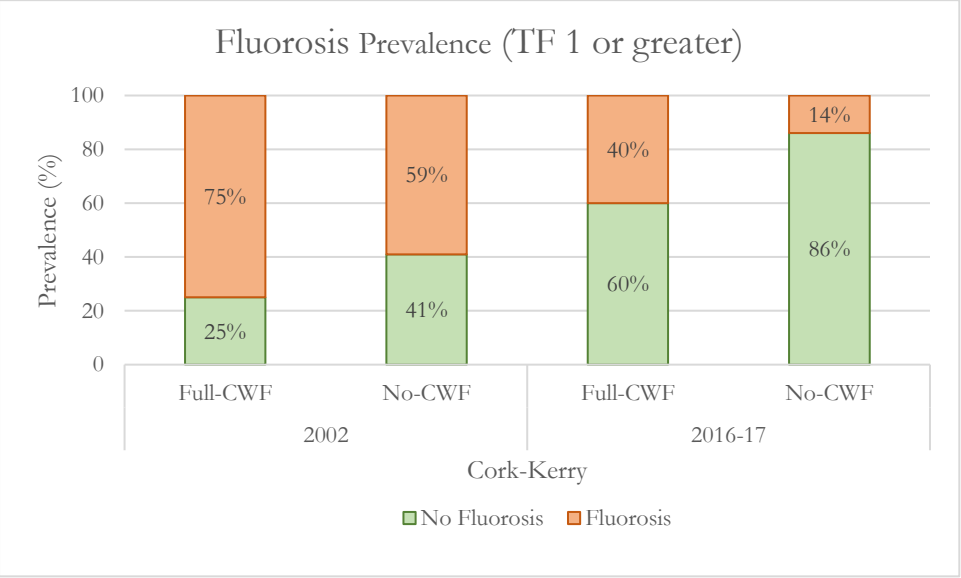


Figure 7.8: Dental fluorosis prevalence (TF 1 or greater, measured from photographs) in permanent maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17

In 2002 and 2016-17, after controlling for the effects of other explanatory variables, the difference in the prevalence of TF 1 or greater between children with Full-CWF and No-CWF was statistically significant ($P < 0.001$) (Table 7.9).

In Cork-Kerry 2002, among children with Full-CWF (0.8 to 1.0 ppm F), the prevalence of TF 1 or greater was 75% compared with 59% among children with No-CWF (Figure 7.8). In multivariable logistic regression analysis, the odds of fluorosis in maxillary central incisors were 112% higher among children with Full-CWF than among children with No-CWF (OR 2.12, 95% CI [1.42, 3.15], $P < 0.001$) (Table 7.9). There were no statistically significant interactions between CWF and any of the other explanatory variables. This meant that in 2002, the difference in fluorosis prevalence (TF 1 or greater) between children with Full-CWF and No-CWF did not depend on any of the other explanatory variables.

Table 7.9: Multivariable logistic regression analyses of the association between CWF and dental fluorosis prevalence (TF 1 or greater, TF 2 or greater, scored from photographs) in maxillary central incisors of children in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Cork-Kerry (Full-CWF and No-CWF combined)									
	2002 (n=494)				2016-17 (n=918)					
	TF 1 or greater		TF 2 or greater		TF 1 or greater			TF 2 or greater		
Explanatory Variables	OR (95%CI)	*P* value	OR (95%CI)	*P* value	Explanatory Variables	OR (95% CI)	*P* value	Explanatory Variables	OR (95% CI)	*P* value
CWF (Full-CWF vs No-CWF)	2.12 (1.42, 3.15)	<0.001	4.22 (2.35, 7.57)	<0.001	MC Yes[e]	10.50 (4.71, 23.41)	<0.001	Toothbrushing ≥ twice a day before age 2[f]	15.43 (5.41, 43.10)	<0.001
					MC No	4.26 (2.91, 6.24)	<0.001	Toothbrushing ≤once a day before age 2	3.85 (1.99, 7.47)	<0.001
Age	0.76 (0.50, 1.15)	0.193	0.61 (0.37, 1.01)	0.053	-	0.96 (0.60, 1.54)	0.875	-	1.70 (0.80, 3.58)	0.165
Gender (female vs. male)	1.53 (1.03, 2.26)	0.034	1.19 (0.73, 1.93)	0.485	-	1.23 (0.87, 1.73)	0.244	-	1.09 (0.63, 1.88)	0.752
Medical card[a] (yes vs. no)	0.83 (0.51, 1.34)	0.447	0.95 (0.53, 1.68)	0.853	Full-CWF[e]	1.25 (0.72, 2.19)	0.431	-	0.62 (0.30, 1.26)	0.184
					No-CWF	0.51 (0.25, 1.03)	0.060	-		
Mother's education (LC[b] or lower vs. Diploma/Certificate or higher)	-	-	-	-	-	0.73 (0.47, 1.23)	0.154	-	1.19 (0.61, 2.30)	0.613
Age first used toothpaste[c] (vs. >24 months[d])										
Before 12 months	0.84 (0.46, 1.54)	0.572	0.99 (0.45, 2.16)	0.973	-	1.34 (0.74, 2.43)	0.338	-	2.07 (0.79, 5.37)	0.137
Between 12 and 18 months	1.04 (0.60. 1.82)	0.887	1.28 (0.62, 2.65)	0.504	-	1.14 (0.69, 1.89)	0.614	-	1.38 (0.58, 3.27)	0.465
Between 19 and 24 months	0.76 (0.37, 1.53)	0.436	0.65 (0.25, 1.68)	0.369	-	0.91 (0.51, 1.60)	0.736	-	0.95 (0.35, 2.55)	0.915
Frequency of toothbrushing before age 2 (≥ twice/day vs. ≤once/day)	-	-	-	-	-	1.63 (1.11, 2.39)	0.013	Full-CWF[f]	3.19 (1.58, 6.43)	0.001
								No-CWF	0.79 (0.28, 2.22)	0.656
Amount of toothpaste before age 2 (pea-sized[d] or less vs. >pea-sized)	-	-	-	-	-	0.63 (0.21, 1.90)	0.417	-	0.51 (0.12, 2.18)	0.364
Eats/licks toothpaste before age 2 (often/sometimes vs. never[d])	-	-	-	-	-	1.47 (1.04, 2.08)	0.028	-	0.88 (0.51, 1.52)	0.653
Breastfed (yes vs. no)	-	-	-	-	-	1.05 (0.74, 1.48)	0.786	-	1.60 (0.91, 2.81)	0.101

Results of univariate analyses are reported in Appendix F Table F 6.

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage [b] LC=Leaving Certificate. Attainment of Leaving Certificate indicates completion of second level education. [c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5) [d] Recommended from 2002 onwards

[e] Interaction CWF and Medical card *P*=0.045; [f] Interaction CWF and frequency of toothbrushing before age 2 *P*=0.027. Hence Odds Ratios (OR) are reported separately. See interaction plots Figures 7.9 and 7.11.

In Cork-Kerry 2016-17, among children with Full-CWF (0.6 to 0.8 ppm F), the prevalence of TF 1 or greater was 40% compared with 14% among children with No-CWF (Figure 7.8). In multivariable logistic regression analysis, the prevalence of fluorosis (TF 1 or greater) in maxillary central incisors was higher among children with Full-CWF than among children with No-CWF ($P < 0.001$) (Table 7.9). The association between CWF and dental fluorosis (TF 1 or greater) depended on parental medical card ownership (Interaction $P = 0.045$). Therefore, for the association between CWF and dental fluorosis (TF 1 or greater) in 2016-17, odds ratios were presented for dependants of medical card and non-medical card holders separately.

The difference in dental fluorosis prevalence (TF 1 or greater) was more pronounced among dependants of medical card than non-medical card holders (Interaction $P = 0.045$).

- Among dependants of medical card holders, the odds of fluorosis at TF 1 or greater were 950% higher among children with Full-CWF than among children with No-CWF (OR 10.50, 95% CI [4.71, 23.41], $P < 0.001$).
- Among dependants of non-medical card holders, the odds of fluorosis at TF 1 or greater were 326% higher among children with Full-CWF than among children with No-CWF (OR 4.26, 95% CI [2.91, 6.24], $P < 0.001$).

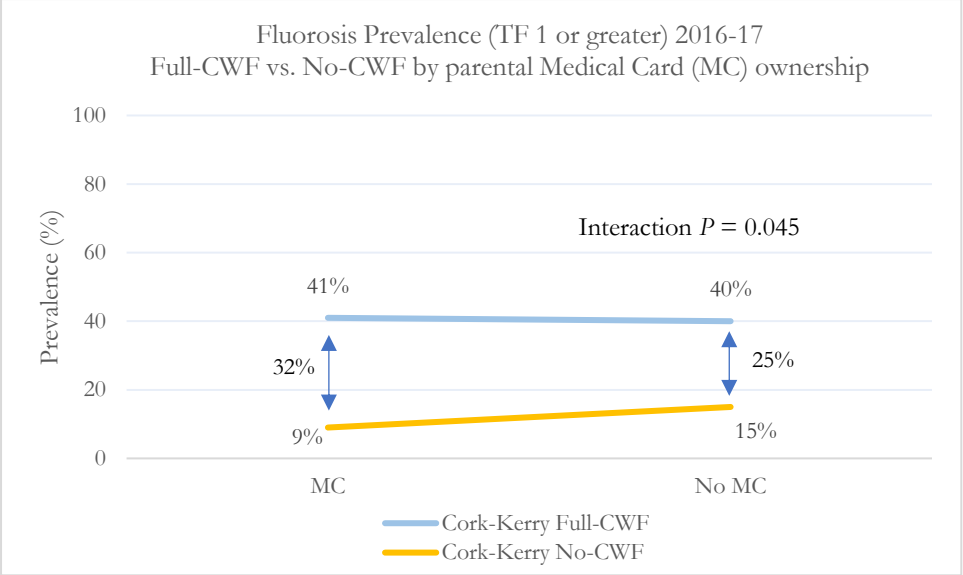


Figure 7.9: Difference in dental fluorosis prevalence (TF 1 or greater, measured from photographs) between 8-year-olds with Full-CWF and No-CWF according to parental medical card (MC) ownership

[Note: These are actual prevalence data, not model-adjusted]

7.2.3.2 TF 2 or greater

Prevalence of TF 2 or greater in maxillary central incisors of children in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17 is summarised in Figure 7.10.

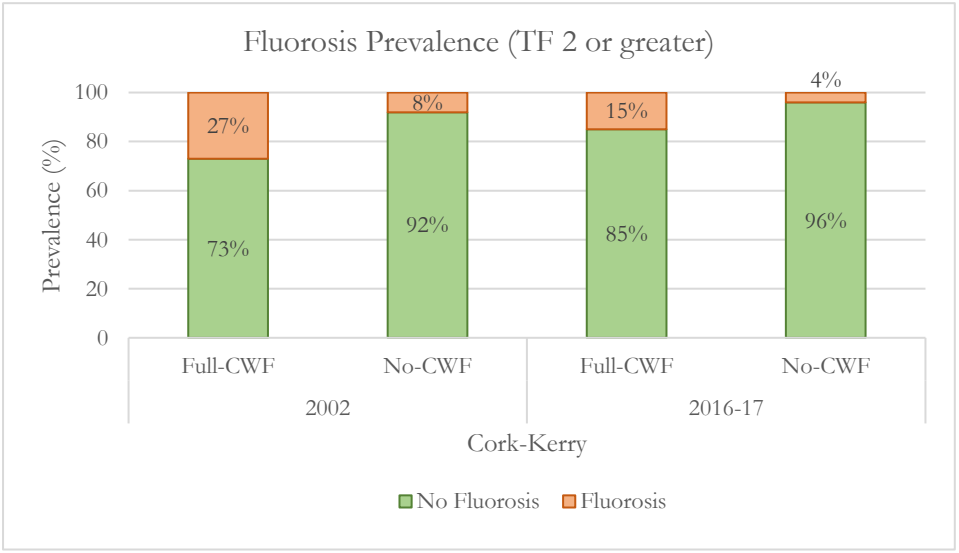


Figure 7.10: Dental fluorosis prevalence (TF 2 or greater, measured from photographs) in permanent maxillary central incisors of 8-year-olds in Cork-Kerry with Full-CWF compared with No-CWF in 2002 and 2016-17

At each time point, after controlling for the effects of other explanatory variables, the difference in the prevalence of TF 2 or greater between children with Full-CWF and No-CWF was statistically significant ($P < 0.001$) (Table 7.9).

In Cork-Kerry 2002, among children with Full-CWF (0.8 to 1.0 ppm F), the prevalence of TF 2 or greater was 27% compared with 8% among children with No-CWF (Figure 7.10). In multivariable logistic regression analysis, the odds of fluorosis (TF 2 or greater) in maxillary central incisors were 322% higher among children with Full-CWF than among children with No-CWF (OR 4.22, 95% CI [2.35, 7.57], $P < 0.001$) (Table 7.9). There were no statistically significant interactions between CWF and any of the other explanatory variables. This meant that in 2002, the difference in fluorosis prevalence (TF 2 or greater) between children with Full-CWF and No-CWF did not depend on any of the other explanatory variables.

In Cork-Kerry 2016-17, among children with Full-CWF (0.6 to 0.8 ppm F), the prevalence of TF 2 or greater was 15% compared with 4% among children with No-CWF (Figure 7.10). In multivariable logistic regression analysis, the odds of fluorosis (TF 2 or greater) in maxillary central incisors were higher among children with Full-CWF than among children with No-CWF ($P < 0.001$) (Table 7.9). The association between CWF and dental fluorosis (TF 2 or greater) depended on frequency of toothbrushing under age 2 (Interaction $P = 0.027$). Therefore, for the association between CWF and dental fluorosis (TF 2 or greater) in 2016-17, odds ratios were presented separately for children who brushed twice a day or more often under age 2 and children who brushed once a day or less often under age 2.

The difference in dental fluorosis prevalence was more pronounced among children who brushed twice a day or more often under age 2 than among those who brushed once a day or less often under age 2 (Interaction $P = 0.027$) (Figure 7.11).

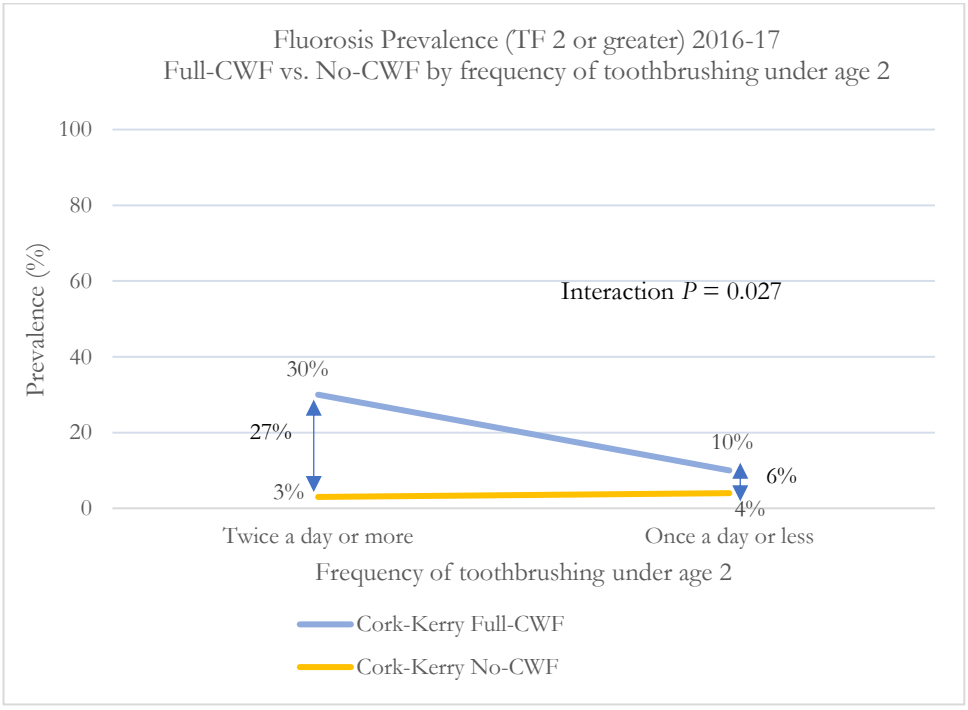
- Among children who brushed twice a day or more often under age 2, the odds of fluorosis at TF 2 or greater were 1,443% higher among children with Full-CWF than among children with No-CWF (OR 15.43, 95% CI [5.41, 43.10], $P < 0.001$) (Table 7.9).
- Among children who brushed once a day or less often under age 2, the odds of fluorosis at TF 2 or greater were 285% higher among children with Full-CWF than among children with No-CWF (OR 3.85, 95% CI [1.99, 7.47], $P < 0.001$) (Table 7.9).
- 

Figure 7.11: Difference in dental fluorosis prevalence (TF 2 or greater, measured from photographs) between 8-year-olds with Full-CWF and No-CWF according to frequency of toothbrushing under age 2

[Note: These are actual prevalence data, not model-adjusted]

7.2.3.3 Association between other explanatory variables and dental fluorosis (TF Index) in Cork-Kerry 2002 and 2016-17

The association between other explanatory variables and dental fluorosis prevalence in Cork-Kerry 2002 and 2016-17 are shown in Table 7.9.

7.2.3.3.1 Socio-demographic variables

In 2002, being female (vs. male) was associated with increased prevalence of fluorosis at TF 1 or greater (OR 1.53, 95% CI [1.03, 2.26], $P = 0.034$).

7.2.3.3.2 Toothbrushing variables:

In 2016-17, toothbrushing twice a day or more often under age 2 years compared with once a day or less often was associated with higher prevalence of fluorosis at TF 1 or greater in maxillary central incisors (OR 1.63, 95% CI [1.11, 2.39], $P = 0.013$) (Table 7.9).

In 2016-17, the association between frequency of toothbrushing under age 2 years and fluorosis at TF 2 or greater depended on CWF (Interaction $P = 0.027$).

- Among children with Full-CWF, the odds of fluorosis at TF 2 or greater were 219% higher among children who brushed twice a day or more often under age 2 than among children who brushed once a day or less often under age 2 (OR 3.19, 95% CI [1.58, 6.43], $P = 0.001$).
- Among children with No-CWF, there was no difference in the odds of fluorosis at TF 2 or greater between children who brushed twice a day or more often and children who brushed once a day or less often under age 2 (OR 0.79, 95% CI [0.28, 2.22], $P = 0.656$).

In 2016-17, eating or licking toothpaste sometimes or often under age 2 years compared with never was associated with a 47% increase in the odds of fluorosis (TF 1 or greater) in maxillary central incisors (OR 1.47, 95% CI [1.04, 2.08], $P = 0.028$).

7.2.4 Summary of findings

At both time points, dental fluorosis was predominantly TF 1 or TF 2 and the prevalence of scores TF 3 or greater was low.

Objective 3b: Among children with Full-CWF or No-CWF in Cork-Kerry, dental fluorosis prevalence in maxillary central incisors at both case definitions was lower in 2016-17 (after downward adjustment) compared with 2002 (Table 7.10).

Table 7.10: Summary of multivariable logistic regression analyses of the association between year of examination and dental fluorosis (TF 1 or greater, TF 2 or greater, measured from photographs) in permanent teeth of 8-year-olds in Cork-Kerry with Full-CWF and Cork-Kerry with No-CWF

			Dental fluorosis			
			TF 1 or greater		TF 2 or greater	
Region	Year	n	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Cork-Kerry Full-CWF	2016-17	608	0.24 (0.17, 0.34)	<0.001	0.50 (0.33, 0.75)	0.001
	2002		Reference		Reference	
Cork-Kerry No-CWF	2016-17	920	0.11 (0.08, 0.16)	<0.001	0.49 (0.26, 0.95)	0.036
	2002		Reference		Reference	

OR = Odds ratio

Objective 4b: In Cork-Kerry, children with Full-CWF examined prior to the adjustment (in 2002) and children with Full-CWF born after the downward adjustment (examined 2016-17) had higher prevalence of dental fluorosis at both case definitions than their counterparts with No-CWF (Table 7.11).

Table 7.11: Summary of multivariable logistic regression analyses of the association between CWF and dental fluorosis (TF 1 or greater, TF 2 or greater, measured from photographs) in 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

Case definition dental fluorosis	Region and Year	n	Explanatory variables		OR (95% CI)	*P* value
TF 1 or greater	Cork-Kerry 2002	494	Full-CWF	-	2.12 (1.42, 3.15)	<0.001
			No-CWF	-	Reference	
	Cork-Kerry 2016-17	918	Full-CWF	MC[ab] Yes	10.50 (4.71, 23.41)	<0.001
			No-CWF		Reference	
			Full-CWF	MC No	4.26 (2.91, 6.24)	<0.001
			No-CWF		Reference	
TF 2 or greater	Cork-Kerry 2002	494	Full-CWF	-	4.22 (2.35, 7.57)	<0.001
			No-CWF	-	Reference	
	Cork-Kerry 2016-17	918	Full-CWF	≥twice a day[c]	15.43 (5.41, 43.10)	<0.001
			No-CWF		Reference	
			Full-CWF	≤once a day	3.85 (1.99, 7.47)	<0.001
			No-CWF		Reference	

OR = Odds ratio

[a] Medical card ownership was used in this study to indicate socio-economic disadvantage

[b] Interaction CWF and Medical card *P*=0.045; [c] Interaction CWF and frequency of toothbrushing before age 2 *P*=0.027. Hence ORs are reported separately.

In Cork-Kerry, among children with Full-CWF or No-CWF born after the adjustment (examined 2016-17), eating or licking toothpaste sometimes or often under age 2 years (vs. never) and toothbrushing twice a day or more often under age 2 years (vs. once a day or less) were associated with higher prevalence of dental fluorosis at TF 1 or greater. Among children with Full-CWF born after the adjustment, toothbrushing twice a day or more often under age 2 years (vs. once a day or less) was associated with higher prevalence of dental fluorosis at TF 2 or greater, whereas among children with No-CWF born after the adjustment, there was no association between frequency of toothbrushing under age 2 years and dental fluorosis at TF 2 or greater.

8 Discussion

This chapter presents a summary of the main findings of the study (Section 8.1) and discussion of the main findings in relation to dental fluorosis (Section 8.2) and dental caries (Section 8.3). The strengths and limitations of the study are outlined (Section 8.4) and conclusions drawn regarding the risk benefit balance of downward adjustment of water fluoride concentration in Ireland (Section 8.5). Lastly, the public health and policy implications of the findings are outlined (Section 8.6) and recommendations made for further research (Section 8.7).

8.1 Main findings

Dean's Index measured clinically based on a whole mouth score indicated no difference in dental fluorosis in permanent teeth of 8-year-olds following downward adjustment of water fluoride concentration. However, results for dental fluorosis in permanent maxillary central incisors, measured from oral photographs using the TF Index, indicated a reduction in dental fluorosis at TF 1 or greater and TF 2 or greater since 2002.

Among children with Full-CWF there was no difference in dental caries prevalence or severity following downward adjustment of water fluoride concentration. However, among children with No-CWF, dental caries severity was lower in 2016-17 than in 2002 and the difference in caries severity between children with Full-CWF and No-CWF was less after the adjustment than in 2002. Despite improvements in the oral health of children with No-CWF, dental caries prevalence and severity were still lower among children with Full-CWF in 2016-17, establishing the effectiveness of CWF at the lower concentration of 0.6 to 0.8 ppm fluoride for preventing dental caries in primary teeth.

8.2 Impact of downward adjustment of CWF concentration on dental fluorosis

8.2.1 Discretionary sources of fluoride in Ireland

In assessing the impact of downward adjustment of water fluoride concentration in Ireland on fluorosis, any potential changes in total fluoride intake from other sources must also be considered. While exposure to CWF is a risk factor for the development of dental fluorosis (McDonagh et al. 2000; Iheozor-Ejiofor et al. 2015; Jack et al. 2016), discretionary sources of fluoride such as fluoride toothpaste, supplements and infant formula reconstituted with fluoridated water are also recognised risk factors for fluorosis (Ismail and Hasson 2008; Hujoel et al. 2009; Wong et al. 2010).

As outlined in Chapter 2 (Section 2.11.3), the availability and use of fluoride supplements is not considered to be an issue in Ireland. In the present study, the small number of children whose parents reported they had ever used fluoride supplements (n = 8 (<1%) in 2002, n = 24 (1%) in 2016-17) were excluded from all analyses.

Infant formula reconstituted with fluoridated water is not considered an important risk factor for 'moderate' fluorosis in Ireland (Department of Health and Children 2002; Anderson et al. 2004; FSAI 2018). Although the concentration of fluoride in infant formula powders and RTF infant formula was high in the past due to the manufacturing process (Ericsson and Ribelius 1971; Singer and Ophaug 1979; Silva and Reynolds 1996), industry subsequently reduced the intrinsic fluoride concentration of infant formula (Levy 1994; Clifford et al. 2009). A recent study of infant formula brands available in the U.K (similar to those marketed in Ireland) found low concentrations of fluoride in infant formula reconstituted with non-fluoridated water (Bussell et al. 2016). Thus, any risk of fluorosis with infant formula consumption nowadays depends on the fluoride

concentration of the water used for its reconstitution (Anderson et al. 2004; Zohoori et al. 2012).

At least 80% of children included in the analyses for the present study were fed with infant formula at some stage during the period of risk for the development of fluorosis in the maxillary incisors. In 2016-17, 81% of children in Dublin and 86% in Cork-Kerry were either formula fed from birth or from 6 months of age. In 2002, 88% of children in Dublin and 87% in Cork-Kerry were fed with infant formula at some stage in infancy. In 2016-17, almost 90% of parents in Cork-Kerry and over 80% of parents in Dublin reported reconstituting infant formula with tap water that was not filtered to remove fluoride. Consequently, any risk of fluorosis associated with ingestion of fluoride from infant formula was closely linked to domestic exposure to CWF and thus accounted for in the analyses.

Recommendations in Ireland since 2002 are not to use fluoride toothpaste before age 2 unless advised to by a health professional. The Dental Health Foundation Ireland (https://www.dentalhealth.ie/), promotes official oral health messages using different strategies to engage with the public and the dental profession. As dental visiting was low in Ireland among infants and young children (Whelton et al. 2006; Parnell et al. 2007), advice from dental health professionals regarding use of fluoride toothpaste in early childhood was unlikely to be timely. The results of the present study suggest that adherence to the recommendation not to use fluoride toothpaste before age 2 was low. Approximately four-fifths of parents in the NSSCOH 2002 and in FACCT reported that they started to brush their child's teeth with toothpaste before age 2.

A higher proportion of 8-year-olds reportedly brushed twice a day or more often in 2016-17 compared with 2002. Changes over time in frequency of toothbrushing in infancy and early childhood could not be assessed because this information was not collected in 2002.

However, the increased frequency of toothbrushing in 8-year-olds in 2016-17 may be indicative of increased frequency of toothbrushing in the first 2 to 3 years of life, when the incisors were at risk of developing fluorosis. Even with the apparent reduction since 2002 in the amount of toothpaste used, much of the toothpaste placed on the brush is ingested by children under 30 months of age (Cochran et al. 2004b). Furthermore, more than half of parents of children with Full-CWF in 2016-17 reported noticing their child eating or licking toothpaste before age 2. After controlling for the effect of lifetime exposure to CWF at 0.6 to 0.8 ppm fluoride and other explanatory variables, first using toothpaste before 12 months, toothbrushing twice a day or more often before age 2 and eating or licking toothpaste sometimes or often before age 2 were risk factors for fluorosis in Cork-Kerry in 2016-17 (Tables 7.3 and 7.9). Therefore, with most children using fluoride toothpaste before age 2, a shift over time towards more frequent toothbrushing with fluoride toothpaste in infancy and early childhood could have contributed to increased ingestion of fluoride from toothpaste in the contemporary cohort.

On the other hand, a lower proportion of parents in 2016-17 reported first using toothpaste with their child before 12 months of age compared with 2002, and there was a considerable increase in the proportion of parents who indicated that their 8-year-old used a pea-sized amount of toothpaste. Furthermore, over 90% of parents in 2016-17 reported their child using a pea-sized amount of toothpaste or less before age 2. These reported changes in oral health behaviours had the potential to reduce fluoride ingestion and dental fluorosis even if the water fluoride concentration remained unchanged.

It is difficult to predict on balance how these reported changes in oral health behaviours might have affected dental fluorosis prevalence. One interpretation of the finding of no difference in dental fluorosis prevalence following the downward adjustment, as measured clinically using Dean's Index, is that fluoride ingestion from toothpaste

increased in the period since 2002, offsetting the expected reduction in fluorosis. Conversely, if fluoride ingestion and absorption from discretionary sources reduced over time or even stayed the same, the reduction in fluoride ingestion and absorption due to the adjustment in water fluoride concentration could have brought about a reduction in fluorosis such as that reported from photographic measurement of fluorosis in maxillary central incisors using the TF Index. However, it is not known the extent to which the parent reported toothbrushing behaviours reflected parents' knowledge or children's behaviours. Moreover, information about oral health behaviours before age 2 were collected several years later when the children were aged 5 and 8 in FACCT and the NSSCOH 2002 respectively, which may have affected the accuracy of the information.

In the present study, children classified as having No-CWF should have been minimally impacted by the downward adjustment in water fluoride concentration. While they never had a fluoridated domestic water supply, they would have had some exposure to water fluoride through the diffusion or 'halo' effect from food and beverages manufactured in fluoridated areas and from exposure to CWF while outside the home. Therefore, trends in fluorosis prevalence among children with No-CWF provided some information about background temporal trends in fluorosis influenced predominantly by exposure to discretionary sources of fluoride rather than exposure to CWF.

These trends mirrored the findings for Dean's Index and the TF Index among children with Full-CWF. There was no difference in the prevalence of Dean's 'very mild' or greater among children with No-CWF in Cork-Kerry following the downward adjustment. Here, the non-statistically significant increase in fluorosis was supportive of increased exposure to fluoride from toothpaste in the period between 2002 and 2016-17. Conversely, fluorosis measurement using the TF Index among children with No-CWF in Cork-Kerry revealed a statistically significant reduction in the proportion of children with TF 1 or

greater and TF 2 or greater in maxillary central incisors following the downward adjustment. This is supportive of a reduction in fluoride ingestion from fluoride toothpaste and/or a reduction in fluoride ingestion via the diffusion effect between 2002 and 2016-17.

8.2.2 Comparison of findings for dental fluorosis measured clinically with Dean's Index and from photographs using the TF Index

Dental fluorosis was measured clinically using Dean's Index to facilitate comparison with results from the NSSCOH 2002. Furthermore, recognising the importance of measuring dental fluorosis in the aesthetically important teeth and the significant advantages of photographic measurement of dental fluorosis over clinical measurement, particularly in relation to blinding of examiners, photographic measurement was also employed.

The TF Index was chosen for the photographic fluorosis measurement because it offered several advantages over Dean's Index. These included its suitability for measuring fluorosis at individual tooth level (facilitating measurement of fluorosis in maxillary central incisors), its usefulness for detecting fluorosis at the lowest levels of severity and its reproducibility (Wenzel and Thylstrup 1982; Granath et al. 1985; Burger et al. 1987; Cleaton-Jones and Hargreaves 1990; Mabelya et al. 1994).

Although the two approaches to fluorosis measurement differed, it was envisaged that the impact of the downward adjustment on dental fluorosis would correspond, at least in terms of the direction of the effect, if any. Clinical measurement using Dean's Index indicated that there was no difference in the prevalence of dental fluorosis in 8-year-olds with Full-CWF in Dublin and Cork-Kerry following downward adjustment of water fluoride concentration. However, fluorosis measured from oral photographs using the TF Index indicated a reduction in fluorosis in maxillary central incisors of 8-year-olds

with Full-CWF in Cork-Kerry. Measurements of fluorosis prevalence among children who never had a fluoridated domestic water supply (No-CWF) offered the opportunity to assess background temporal trends in fluorosis among children minimally impacted by the downward adjustment. Among children with No-CWF, there was no difference in the prevalence of 'very mild' or greater fluorosis measured using Dean's Index and a reduction in dental fluorosis in maxillary central incisors measured using the TF Index.

8.2.2.1 Differences in the teeth that were the basis for the person-level fluorosis score

Person-level Dean's Index scores were based on the condition of the two worst affected of all the permanent teeth present (or the lesser affected if the two worst affected teeth were not equally affected), whereas the person-level TF score reflected the condition of the worst affected maxillary central incisor. Although the teeth that were the basis for the Dean's Index score were not reported, it is likely that in many cases the Dean's Index score was based on the maxillary central incisors. This is because maxillary incisors tend to be more affected by fluorosis than first permanent molars (Fejerskov et al. 1977; Larsen et al. 1985; Larsen et al. 1987; Levy et al. 2006) with mandibular incisors least affected (Fejerskov et al. 1977; Manji et al. 1986; Levy et al. 2006; Medina-Solis et al. 2008). In the present study, almost all children (>95%) in 2002 and 2016-17 had at least one maxillary central incisor present, whereas only two-thirds had at least one maxillary lateral incisor present.

8.2.2.2 Case definition of fluorosis and choice of Index

The absolute reduction in fluorosis in Cork-Kerry was more marked at the level of TF 1 or greater (75% in 2002 to 40% in 2016-17) than at TF 2 or greater (27% in 2002 to 15% in 2016-17). Therefore, with fluorosis defined as Dean's Index 'very mild' or greater, it is plausible that Dean's Index failed to detect a statistically significant reduction at the lowest

levels of severity. The Dean's Index 'questionable' category was not included in the case definition for fluorosis. Dean and colleagues defined fluorosis incidence as the proportion of children with 'very mild' fluorosis or greater (Dean and Elvove 1935; 1936; 1937; Dean and McKay 1939). Later, the diagnostic criteria for the 'questionable' category of Dean's Index were criticised for a lack of clarity (Fejerskov et al. 1988; Clarkson and O'Mullane 1989; Rozier 1994) leading to difficulty standardising the measurement of the earliest signs of dental fluorosis (Fejerskov et al. 1990). On the other hand, the TF Index presents a set of clear criteria defining the categories at the low end of the scale. Consequently, the TF Index is more sensitive than Dean's Index for detecting the presence of fluorosis of low severity (TF 1 or greater) (Granath et al. 1985; Mabelya et al. 1994; Rozier 1994).

However, the exclusion of the 'questionable' category from the case definition for fluorosis and the greater sensitivity of the TF Index for detecting fluorosis of low severity would not fully explain the finding of no difference in the prevalence of Dean's 'very mild' or greater following downward adjustment of water fluoride concentration when there was a statistically significant reduction in the proportion with TF 2 or greater in maxillary central incisors. The criteria for assigning Dean's Index and TF Index scores differ considerably. Most notably, Dean's Index scores are based on the proportion of the tooth surface affected by fluorosis whereas TF Index scores reflect histopathological changes in the enamel associated with fluorosis of increasing severity. These differences result in substantial overlap of TF and Dean's Index scores, particularly at the lower end of both scales. For example, one study showed that TF 2 corresponded with Dean's Index scores 'questionable', 'very mild', 'mild' and 'moderate' (Wenzel and Thylstrup 1982) whereas another study showed that TF 2 corresponded with Dean's Index scores 'normal', 'questionable' and 'very mild' (Mabelya et al. 1994). Importantly, both studies demonstrated good agreement between TF 2 and Dean's 'very mild' scores (Wenzel and

Thylstrup 1982; Mabelya et al. 1994). Therefore, it could be expected that a reduction in TF 2 or greater would also be detected using a case definition of 'very mild' or greater with Dean's Index.

Mabelya (1994) found that the measurement error on repeat clinical examination by the same examiner was lower for the TF Index than for Dean's Index. Furthermore, in the same study, the TF Index was found to be more accurate in distinguishing between the presence or absence of fluorosis than Dean's Index. For fluorosis measured from oral photographs, Pretty et al. (2012) found inter-examiner reliability to be higher for the TF Index (linear weighted kappa 0.74) than for Dean's Index (linear weighted kappa 0.50). In studies that directly compared the two indices, the TF index was preferred over Dean's index for its ease of use, its reproducibility, it's suitability for measuring fluorosis of low and high severity and its ability to provide detailed information to evaluate aesthetic concerns related to individual teeth (Wenzel and Thylstrup 1982; Granath et al. 1985; Burger et al. 1987; Cleaton-Jones and Hargreaves 1990; Mabelya et al. 1994).

8.2.2.3 Validity and reliability of Dean's Index applied clinically

The CDC recently highlighted the subjectivity of clinical fluorosis measurement with Dean's Index in two NHANES cycles (1999-2004 and 2011-2016) (Department of Health and Human Services 2019). Even with the same gold standard examiner during both cycles and a comprehensive training and calibration programme, standardising fluorosis measurements across multiple examiners within and between NHANES cycles was reported to be challenging. The findings of the CDC report suggested that there may have been changes over time in the way fluorosis was measured that affected the validity of fluorosis data collected in the NHANES surveys. This cast doubt on estimates of fluorosis prevalence reported in 1999-2004 and 2011-2016 and on published papers based

on these data that reported an increase in fluorosis prevalence, such as a recent paper by Neurath et al. (2019).

In the present study and in the NSSCOH 2002, examiners were trained and calibrated in the use of Dean's Index by the same experienced gold standard examiner (Professor Helen Whelton). Although kappa scores for intra-examiner reliability ranged from 0.40 to 1.00 in 2002 and from 0.57 to 1.00 in 2016-17, most examiners at each time point achieved at least substantial within-examiner agreement during the fieldwork (kappa >0.60). Likewise, although kappa values for agreement between the examiners and the gold standard in 2016-17 ranged from 0.43 to 1.00, most examiners achieved at least substantial agreement with the gold standard examiner during the fieldwork (kappa >0.60).

The strength of intra- and inter-examiner reliability reported for Dean's Index in other studies is variable but is generally consistent with the levels of agreement achieved by examiners in the present study. For example, the following kappa values for intra-examiner reliability for repeat clinical fluorosis examinations with Dean's Index have been reported: 0.76 and 0.83 (Evans 1989), 0.69 (Mabelya et al. 1994) and 0.89 (weighted) (Mohd Nor et al. 2016). Evans and Stamm (1991) reported kappa values for intra-examiner reliability for repeat clinical fluorosis examinations with Dean's Index conducted on the same day of 0.86. However, levels of agreement for repeat examinations conducted one and four months later were lower (0.68 and 0.57, respectively). Kumar (2000b) reported kappa values for inter-examiner reliability on the subject level Dean's Index score of 0.67, 0.68 and 0.76 for three examiners conducting clinical fluorosis examinations.

However, in the present study, the number of repeat clinical examinations conducted by many of the examiners in 2002 and 2016-17 was below the minimum of 25 subjects specified by the WHO Oral Health Surveys Basic Methods (World Health Organisation 2013) and no measure of intra- or inter-examiner reliability could be calculated for several examiners because there were insufficient repeat clinical examinations or lack of variation in the Dean's Index scores (i.e., all children with repeat examinations were 'normal'). Moreover, misclassification of the Dean's Index score by the few examiners who failed to achieve satisfactory intra- or inter-examiner reliability during the fieldwork could potentially bias the overall estimates of fluorosis prevalence at each time point. Differential misclassification of fluorosis, for example, due to awareness of the children's exposure to CWF, could overestimate or underestimate fluorosis. Non-differential/random misclassification, where misclassification of fluorosis occurred in the same proportions of participants in each of the comparison groups could obscure differences between the groups due to increased variability in scoring. Importantly, in the present study, non-differential misclassification of fluorosis in 2002 and 2016-17 could potentially have biased the results towards the null and might help to account for the finding of no difference in fluorosis measured using Dean's Index between 2002 and 2016-17.

8.2.2.4 Clinical compared with photographic measurement of fluorosis

Although indices for measuring fluorosis were developed for clinical use, photographic methods offer several advantages including the ability to image the teeth using standardised photographic methods, facilitation of blind outcome assessment, repeated measurements by several examiners and provision of a permanent record of fluorosis for monitoring temporal trends (Ellwood et al. 1996; Cochran et al. 2004a; Tavener et al. 2007).

Several studies have compared clinical with photographic methods for measuring fluorosis using Dean's Index or the TF Index (Ellwood et al. 1996; Tabari et al. 2000; Pretty et al. 2012; Mohd Nor et al. 2016). While the results of these studies are not directly applicable to the present study where fluorosis was measured clinically and photographically using different indices, they demonstrated that satisfactory agreement could be achieved between fluorosis scored clinically and from oral photographs.

However, the prevalence of fluorosis scored from photographs tends to be higher than fluorosis scored clinically (Ellwood et al. 1996; Sabieha and Rock 1998; Pretty et al. 2012) with drying of the teeth and magnification of enamel defects contributing to the increased prevalence of fluorosis recorded using the photographic method (Fleming et al. 1989; Levine et al. 1989; Nunn et al. 1992; Ellwood et al. 1996; Cochran et al. 2004c; Pretty et al. 2012; Dye et al. 2018). Although in the present study oral photographs were taken without drying the teeth after clinical measurement with Dean's Index and before the clinical dental caries examination, a certain amount of drying of the teeth was to be expected while positioning the child and the cheek retractors and during the 8 seconds leading up to taking the photograph. This small amount of drying coupled with the magnification of the images for scoring on the laptop monitor suggest that fluorosis scored from photographs in the present study was likely to be higher than fluorosis scored clinically. However, the higher prevalence of fluorosis detected from photographs would affect measurement in 2002 and 2016-17 in the same way and would not be expected to have an important impact on the evaluation of the impact of the downward adjustment on fluorosis measured from photographs. However, it is plausible that changes in the prevalence and severity of fluorosis were more likely to be detected with the photographic method of fluorosis measurement used in the present study than with clinical measurement.

8.2.2.5 Validity and reliability of the TF Index, measured from photographs

In the present study, oral photographs taken according to the same standardised method in Cork-Kerry in 2002 and 2016-17 were scored for fluorosis using the TF Index. Blinding to fluoridation status and year of examination eliminated any potential bias due to knowledge of the child's exposure to CWF or their exposure to the downward adjustment. Scoring the 2002 and 2016-17 photographs contemporaneously ensured consistency of the measurement at both time points. Given the low severity of fluorosis in Ireland, examiner thresholding (i.e., differences between examiners in the application of the index criteria) could have had an important impact on the results, being more of an issue at the lower end of the scale (Tavener et al. 2007; Pretty et al. 2012). The subjectivity of fluorosis measurement and the impact of examiner thresholding were minimised by ensuring that the two examiners agreed regarding each person level score. Use of consensus scores for fluorosis measured from photographs has been reported in other studies (McGrady et al. 2012c; Mohd Nor et al. 2016).

Whereas competing demands during clinical fieldwork including the length of the school day and the limit on the number of times a child can be examined clinically, can limit the opportunity to conduct repeat clinical examinations to monitor validity and reliability, the photographic method provided greater flexibility for repeat measurements. Based on the repeat scores for each examiner for 197 photographs, kappa values (unweighted) for intra-examiner reliability were 0.72 and 0.77 for Examiner 1 and 2 respectively indicating substantial intra-examiner reliability in the measurement of the person-level TF score.

Unweighted kappa scores reflect exact agreement between the measures, with zero weight given to disagreements regardless of the magnitude of the disagreement. For example, any agreements on TF score would feature (given a weight of 1) and any disagreements would not feature (given a weight of zero) in the kappa calculation. On the other hand,

weighted kappa scores give partial credit for 'near misses'; for example, when disagreement by one category of the TF Index is given a weight of 0.75 rather than zero, disagreement by two categories is given a weight of 0.5, and disagreement by three categories is given a weight of 0.25.

To compare the intra-examiner reliability of the two examiners in the present study with results from other similar studies, linear weighted kappa values were calculated for the two examiners using linear pre-recorded weights in STATA (StataCorp 2015) as described above. Weighted kappa values for Examiner 1 and 2 were 0.77 and 0.83, respectively. These values compared well with reliability measures reported in other similar studies reporting weighted kappa values (Tavener et al. 2006; McGrady et al. 2012b), although the weighting system used was not reported in either study. In a study of 11- to 13-year-old lifetime residents of fluoridated Newcastle and non-fluoridated Manchester, McGrady (2012b) reported a weighted kappa of 0.75 for repeat subject level scores (highest TF score in maxillary central incisors) for the single examiner based on 98 photographs. Tavener (2006) reported a weighted kappa of 0.73 for 127 repeat subject level scores (highest score in maxillary central incisors) measured by the single examiner from digital oral photographs of 8- to 10-year-olds in non-fluoridated parts of North West England.

In the present study, the strength of the agreement between each of the examiners and the gold standard examiner during the photographic scoring was predominantly substantial to almost perfect (kappa >0.60) (Landis and Koch 1977). Although the percentage agreement and kappa values varied during the scoring, agreement with the gold standard examiner was consistent and the variability in the kappa scores reduced as the scoring progressed, indicating that 'examiner drift' during the scoring was unlikely to be an issue.

8.2.2.6 Comparison with results of other studies

Based on the results of three studies conducted in Hong Kong and Malaysia, a systematic review of the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis (Chapter 3) concluded that there was very low quality evidence that adjusting water fluoride concentration downwards was associated with a reduction in fluorosis. In Hong Kong, adjustment from 1.0 to 0.7 ppm fluoride in 1978 was associated with a reduction in 'very mild' or greater fluorosis and a reduction in the prevalence of diffuse opacities in children (Evans and Stamm 1991; Wong et al. 2014). A further adjustment from 0.7 to 0.5 ppm fluoride in 1988 was associated with a further reduction in the prevalence of diffuse opacities (Wong et al. 2014). In Malaysia, adjustment from 0.7 to 0.5 ppm fluoride in 2005 was associated with a non-statistically significant reduction in 'very mild' or greater fluorosis.

All three studies found that the prevalence of fluorosis or diffuse enamel opacities in maxillary central incisors (Evans and Stamm 1991; Mohd Nor et al. 2018) or all four maxillary incisors (Wong et al. 2014) was lower following downward adjustment of water fluoride concentration. In the Malaysian study, although the difference in fluorosis prevalence in maxillary central incisors of children with exposure to 0.7 ppm fluoride compared with 0.5 ppm in the first two years of life was not statistically significant, the results tended towards a lower level of fluorosis in the group of children with lifetime exposure to the reduced water fluoride concentration. Moreover, that study may have been underpowered to detect a difference in fluorosis between the two groups with CWF as the sample size calculation was based on comparing fluorosis in children with and without CWF. Thus, the results of these studies conducted in Hong Kong and Malaysia agree with the results of the present study which found a reduction in the prevalence of fluorosis at TF 1 or greater and TF 2 or greater in maxillary central incisors following downward adjustment of water fluoride concentration.

In contrast, the results for Dean's Index in the present study, indicated no statistically significant difference in fluorosis following the downward adjustment. Indeed, if 'questionable' fluorosis had been included in the case definition for fluorosis in the present study, the results would have indicated a substantial increase in fluorosis prevalence. Thus, the results obtained using Dean's index applied clinically using a whole mouth score were not in agreement with the results of other similar studies.

In the present study, lifetime exposure to CWF as well as early and inappropriate use of fluoride toothpaste in infancy and early childhood were risk factors for fluorosis measured using Dean's and the TF Index, which is consistent with the findings of systematic reviews of the relevant literature (McDonagh et al. 2000; Wong et al. 2010; Iheozor-Ejiofor et al. 2015; Jack et al. 2016). The finding that first using fluoride toothpaste before 12 months of age was associated with fluorosis (Dean's 'very mild' or greater) was also reported in the Cochrane systematic review by Wong and colleagues (2010). Although in the present study, frequency of toothbrushing before age 2 was identified as a risk factor for fluorosis using both Dean's and the TF Index, this behaviour was not found to be associated with fluorosis in a meta-analysis of three studies reported in the Cochrane systematic review (Wong et al. 2010). However, other studies included in the Cochrane systematic review (but not the meta-analysis) found associations between toothbrushing twice a day or more often before age 2 or from birth to age 8 and fluorosis among children living in both fluoridated and non-fluoridated areas (Pendrys et al. 1994; 1996; Pendrys and Katz 1998).

Lastly, fluorosis measurement using the TF Index identified eating or licking toothpaste sometimes or often before age 2 as a risk factor for fluorosis at TF 1 or greater. This finding is consistent with the findings of epidemiological studies conducted in South and

West Australia which identified eating, licking, or 'liking' toothpaste as strong risk factors for fluorosis (Riordan 1993a; Spencer and Do 2008)

8.2.2.7 Conclusions

The choice of fluorosis index and method of measurement depend upon the aim of the study (Ellwood et al. 1994; Whelton et al. 2004b). The present study aimed to assess the impact of downward adjustment of water fluoride concentration in Ireland on dental fluorosis. The primary fluorosis outcome was the whole mouth person-level Dean's Index score, facilitating comparison with fluorosis measured according to the same method in the NSSCOH 2002. However, prevalence of 'moderate' fluorosis in Ireland is low and 'severe' fluorosis is rarely documented (Whelton et al. 2006). Most cases of dental fluorosis in Ireland are of low severity, with a small proportion potentially of aesthetic concern. Therefore, in achieving the study aim, it was important that measurement of fluorosis also considered changes in the prevalence of fluorosis in the aesthetically important teeth following the downward adjustment.

The TF Index offers several advantages over Dean's Index, including the clarity of the criteria for measuring fluorosis of low severity, facilitation of individual tooth measurements and superior reproducibility (Wenzel and Thylstrup 1982; Granath et al. 1985; Burger et al. 1987; Cleaton-Jones and Hargreaves 1990; Mabelya et al. 1994). The photographic method facilitates blind outcome assessment, minimising bias in measurement of the outcome; one of the main sources of bias in comparative studies. Studies that have compared clinical with photographic methods have reported a satisfactory level of agreement between the two approaches (Ellwood et al. 1996; Tabari et al. 2000; Pretty et al. 2012; Mohd Nor et al. 2016), suggesting that either method could be used to produce a valid and reliable estimate of fluorosis prevalence. However, drying the teeth and magnifying the photograph for scoring can enhance the appearance of

enamel opacities (Ellwood et al. 1996; Pretty et al. 2012), making them easier to detect using the photographic method.

Before and after studies such as the present study are prone to bias from differential measurement of the outcome before compared with after the intervention (Sterne et al. 2021). Challenges standardising clinical fluorosis measurement over time were recently highlighted in relation to the NHANES surveys in the U.S. (Department of Health and Human Services 2019) where despite intensive training and calibration with the same gold standard examiner, suspected variability in how fluorosis was measured over time cast doubt on the accuracy of large tranches of fluorosis prevalence data collected over many years. In the present study, despite the substantial commitment to training and calibrating the clinical examiners in 2002 and 2016-17, changes over time in the way fluorosis was measured could not be ruled out. On the other hand, the photographic method used in the present study with blinding to the year that the photograph was taken ensured that fluorosis was measured in the same way at both time points and was not influenced by examiners' knowledge of exposure to CWF or to the year the photograph was taken.

In the present study, the results obtained using the two different methods of fluorosis measurement were not consistent with each other. The discrepant findings were considered unlikely to be due to differences in the teeth that were the basis for the person-level score. The lower cut off of TF 1 or greater compared with Dean's 'very mild' or greater and the enhanced clarity of the TF Index for measuring fluorosis of low severity might explain the statistically significant reduction in fluorosis at TF 1 or greater in maxillary central incisors that was not detected with clinical Dean's Index scores. Use of the photographic method may have enhanced the appearance of the diffuse opacities, increasing the likelihood that changes in the prevalence and severity of fluorosis would be detected with this method. However, given the concordance between TF 2 and Dean's

'very mild' categories (Wenzel and Thylstrup 1982; Mabelya et al. 1994), this would not fully explain the discrepancy between the findings for Dean's 'very mild' or greater compared with TF 2 or greater nor would it explain the higher proportion with Dean's 'questionable' in 2016-17 compared with 2002 which is opposite to the trend recorded with the TF Index in the maxillary central incisors. Furthermore, the findings of the present study, of a reduction in fluorosis in maxillary central incisors following downward adjustment of water fluoride concentration were consistent with the results of other studies evaluating the impact of such adjustments on fluorosis, while the findings for Dean's Index differed. Lack of standardisation of clinical measurement using Dean's Index between 2002 and 2016-17 might help to explain the discrepant findings at the level of Dean's Index 'very mild' or greater and TF 2 or greater by biasing the results for Dean's Index towards the null.

The impact of downward adjustment of water fluoride concentration on dental fluorosis measured from oral photographs using the TF Index was at lower risk of bias compared with clinical measurement using Dean's Index. This indicates that the results obtained using the TF Index are likely to be closer to the truth than the results from Dean's Index. Therefore, the next section focusses on an in-depth discussion of the fluorosis results obtained from the TF Index measured from oral photographs.

8.2.3 Impact of downward adjustment of CWF concentration on dental fluorosis in maxillary central incisors

8.2.3.1 Summary of main findings

Among children with Full-CWF, the prevalence of dental fluorosis in maxillary central incisors that was potentially of aesthetic concern was low following downward adjustment of water fluoride concentration (<5% in Dublin and Cork-Kerry in 2016-17). In Cork-Kerry, there was a marked reduction in the proportion of children with fluorosis at TF 1

or greater from 75% in 2002 to 40% in 2016-17. Similarly, there was a large reduction in fluorosis at this level among children with No-CWF (59% in 2002 to 14% in 2016-17). The reduction in fluorosis prevalence at TF 1 or greater predominantly related to a reduction in the barely perceptible TF 1 score. While the prevalence of fluorosis at TF 2 or greater was much lower than the prevalence of TF 1 or greater at both time points, prevalence of TF 2 or greater essentially halved following the downward adjustment among children with Full-CWF (27% to 15%) and No-CWF (8% to 4%).

This reduction in fluorosis in maxillary central incisors of 8-year-olds following downward adjustment of water fluoride concentration is consistent with what was expected considering the established dose response relationship between water fluoride concentration and dental fluorosis (Dean and Elvove 1935; 1936; Dean and McKay 1939; McDonagh et al. 2000). While there were some changes in reported toothbrushing behaviours among 8-year-olds with Full-CWF since 2002, for example higher proportions toothbrushing twice a day or more often and using a pea-sized amount of toothpaste or less, it is not known how these parent-reported behaviours at age 8 reflected parents' knowledge or children's behaviours or how they related to toothbrushing behaviours when the children's maxillary central incisors were mineralising and at risk of developing fluorosis (i.e., to approximately age 3 years). Although a lower proportion of parents in 2016-17 reported first using toothpaste with their child before 12 months of age compared with 2002, there was little change in commencement of fluoride toothpaste use at ≤24 months following introduction of toothbrushing guidance. It is noteworthy that following downward adjustment of water fluoride concentration, inadvertent ingestion of fluoride toothpaste before age 2 by frequent toothbrushing or deliberately through eating and licking toothpaste were associated with fluorosis. Furthermore, the present study revealed that toothbrushing twice a day or more often before age 2 was only a risk factor

for fluorosis at TF 2 or greater among children with lifetime exposure to CWF and not among children with No-CWF. This finding highlights the additive effect of exposure to fluoride from both CWF and standard concentration fluoride toothpaste (at least 1000 ppm F) in infancy and early childhood on fluorosis.

Several aspects of the fluorosis results obtained from oral photographs are discussed in Sections 8.2.3.2 to 8.2.3.4.

8.2.3.2 Aesthetic considerations

Several studies, including one conducted among Irish adolescents, identified TF 3 as the level where dental fluorosis may be of aesthetic concern (Riordan 1993b; Hawley et al. 1996; Do and Spencer 2007a; Browne 2008). In the present study, following downward adjustment of water fluoride concentration, the proportion of children with Full-CWF with at least one maxillary central incisor scored TF 3 or 5 was <5% in both Dublin and Cork-Kerry. Changes in the severity of fluorosis at the level of TF 3 or greater following the downward adjustment were not evaluated using logistic regression analysis due to the small number of cases in this category. Although two case definitions for fluorosis reflecting different levels of severity were included in the analyses (TF 1 or greater, TF 2 or greater), statistically significant reductions in dental fluorosis measured using these two case definitions predominantly reflected reductions in TF 1 and TF 2 respectively rather than reductions in the proportion of children with TF 3 or greater. Thus, the majority of fluorosis in maxillary central incisors was at worst TF1 and TF 2, which are regarded as being barely perceptible to the untrained eye (Figures 8.1 and 8.2) with little or no impact on OHRQoL (Chankanka et al. 2010). Fluorosis at this level may even be considered more aesthetically pleasing than normal enamel (TF 0), presumably by making the enamel appear whiter (Hawley et al. 1996; Do and Spencer 2007a).



Figure 8.1: Examples of person level score TF 1



Figure 8.2: Examples of person level score TF 2

The proportions of children with TF 3 or greater (Figure 8.3) were low at both time points, with little change over time among children with Full-CWF despite the reduction in water fluoride concentration. Tavener (2007) aptly described the use of digital photographs of maxillary central incisors as a 'keyhole' view of the dentition. Differential diagnosis of fluorosis at any level of severity would be greatly enhanced by being able to assess the entire dentition. Furthermore, the importance of confirming a history of significant fluoride exposure before making a diagnosis of fluorosis as emphasised by Cutress and Suckling (1990) was not possible in the present study due to examiner blinding. Although there was a risk of misclassifying fluorosis at the level of TF 3 or greater in the present study, blinding ensured that any misclassification would have been non-differential, affecting prevalence estimates in 2002 and 2016-17 to a similar degree. In addition, distinguishing between fluoride and non-fluoride opacities is more challenging at low rather than high levels of fluorosis severity (Cutress and Suckling 1990; Pendrys 1999b). Moreover, in line with expectations, prevalence of scores TF 3 or greater

was higher among children with Full-CWF compared to children with No-CWF at both time points and was similar among children in both fluoridated groups in 2016-17.



Figure 8.3: Examples of person-level score TF 3

While the fluoride concentration of water is well controlled, most toothpastes marketed in Ireland contain at least 1000 ppm fluoride with the potential for considerable amounts of fluoride toothpaste to be ingested in infancy and early childhood, particularly with unsupervised use. Thus, an explanation for the lack of a reduction in fluorosis at TF 3 or greater could be that the risk of developing fluorosis at this level relied more on excessive ingestion of fluoride from toothpaste than on the fluoride concentration of the water supply. Use of fluoride toothpaste in early life is clearly a risk factor for fluorosis (Wong et al. 2010) with fluoride toothpaste contributing in large part to total fluoride ingestion from age 16 to 36 months (Levy et al. 2010). However, measuring exposure to discretionary sources of fluoride using parent questionnaires is likely to have low accuracy in identifying the interplay of factors associated with more severe presentations of fluorosis. Furthermore, the small proportion of children with higher fluorosis severity in optimally fluoridated areas will always pose a barrier to robust statistical analyses at the level of TF 3 or greater. The present study highlighted the increased risk of fluorosis of at least TF 2 among children with CWF, toothbrushing twice a day or more often before age 2.

Recent studies have indicated that the prevalence and severity of fluorosis and diffuse enamel opacities tended to reduce or 'fade out' over time (Do et al. 2016; Curtis et al. 2020). These changes are thought to be due to attrition, abrasion and possibly influenced by post eruptive changes in the enamel caused by uptake of minerals and protein from saliva (Aoba and Fejerskov 2002). Do et al. (2016) reported on the natural history of dental fluorosis among 8- to 13-year-old Australian children examined in 2003-04 and followed-up in 2011-12. Of 22 children with TF 2 or TF 3 in 2003-04, 46% (10) were scored TF 2 or TF 3 on follow-up, while 32% (7) were scored TF 1 and 23% (5) were scored TF 0. Therefore, in the present study, it is plausible that the proportion with TF 3 or greater in their maxillary central incisors would reduce into adolescence and adulthood.

8.2.3.3 Fluorosis prevalence in 2002 and 2016-17

In Cork-Kerry in 2002, three-quarters of 8-year-olds with Full-CWF had fluorosis at TF 1 or greater on their maxillary central incisors. Cochran and colleagues (2004a) reported the prevalence of fluorosis in a random sample of 324 8-year-olds in fluoridated Cork city in 1997-98. Fluorosis was scored blind using the TF Index from oral photographs taken according to the validated standardised technique developed by the author of the study (Cochran et al. 2004c). In common with the present study, the same standardised photographic technique was used, and the person-level TF score was based on the highest score on either maxillary central incisor. However, the Cochran study scored 'dry' photographs taken after 105 seconds of drying rather than the 'wet' photographs that were the basis for the TF scores in the present study. Nonetheless, the frequency distributions of TF scores were similar in both studies (Figure 8.4), albeit higher at the level of TF 1 and TF 2 in 1997-98. This likely reflected the longer drying time facilitating enhanced discernment of the earliest signs of fluorosis in the 1997-98 study. Furthermore,

the prevalence of TF 1 was high in both studies providing support for the high prevalence of TF 1 in 2002 reported in the present study.

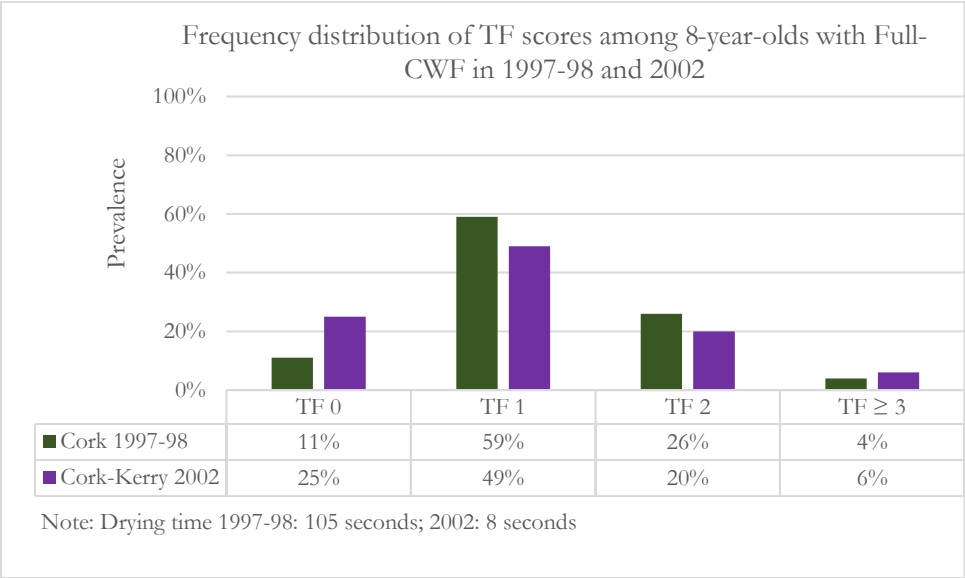


Figure 8.4: Frequency distribution of TF scores in maxillary central incisors of 8-year-olds with CWF measured from photographs in Cork 1997-98 and Cork-Kerry 2002

The prevalence of diffuse enamel opacities is the distinguishing factor between fluoridated and non-fluoridated areas (Cutress et al. 1985; Clarkson and O'Mullane 1989; Clarkson and O'Mullane 1992). However, in 2002, the prevalence of TF 1 in maxillary central incisors was similar in fluoridated and non-fluoridated areas (Full-CWF 49%, No-CWF 51%). The TF index only distinguished between children with Full-CWF and No-CWF at the level of TF 2 and TF 3.

A high prevalence of barely perceptible diffuse enamel opacities among children with Full-CWF and No-CWF in Cork-Kerry was also reported in the NSSCOH 2002, where a similar proportion of children with Full-CWF and No-CWF had Dean's Index scores 'Questionable' (12% and 11% respectively) (Figure 8.5). In the NSSCOH 2002, it was only at the level of Dean's 'very mild' and 'mild' that a distinction could be seen regarding

the prevalence of fluorosis among children with Full-CWF at 0.8 to 1.0 ppm fluoride and children with No-CWF.

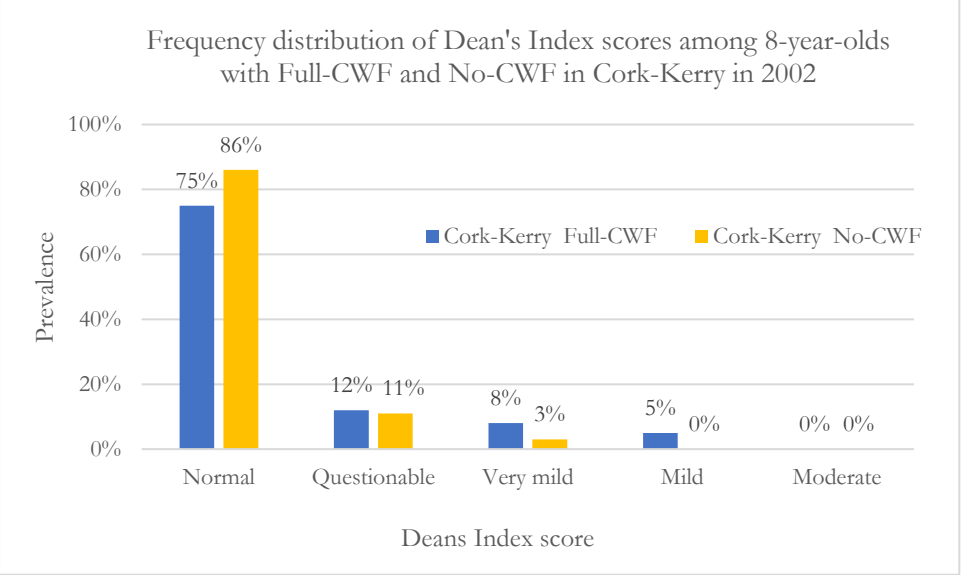


Figure 8.5: Frequency distribution of Dean's Index scores among 8-year-olds with Full-CWF and No-CWF in Cork-Kerry in 2002

The high prevalence of TF 1 among children with No-CWF in 2002 suggests that exposure to fluoride toothpaste in infancy and early childhood was sufficient to result in fluorosis of low severity. Furthermore, the impact of the diffusion effect and the effect of children consuming fluoridated water outside the home on fluorosis is likely to have been greater in 2002 than in 2016-17, reflecting the higher concentration of water fluoride in 2002.

In 2016-17, the frequency distributions of TF scores among children with Full-CWF in Dublin and Cork-Kerry were remarkably similar (Figure 8.6) which is consistent with children in both regions being exposed to the same water fluoride concentration and reported oral health behaviours among children with Full-CWF being similar in both regions. In the context of blind fluorosis measurement, the consistency of the prevalence

measures in 2016-17 among children with Full-CWF instil confidence in the accuracy of fluorosis measurement from the 2016-17 photographs.

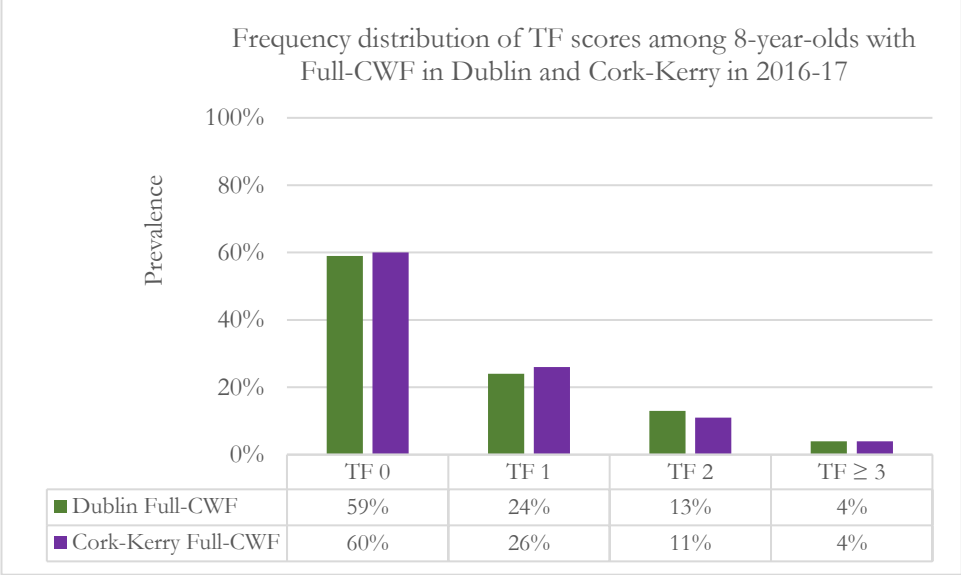


Figure 8.6: Frequency distribution of TF scores in maxillary central incisors of 8-year-olds with Full-CWF measured from photographs in Dublin and Cork-Kerry in 2016-17

8.2.3.4 Reductions in fluorosis among children with Full-CWF and No-CWF following downward adjustment of water fluoride concentration

There were substantial reductions in fluorosis among children in Cork-Kerry with Full-CWF and No-CWF following downward adjustment of water fluoride concentration. Reductions in fluorosis among children with Full-CWF can be explained by the reduction in water fluoride concentration. Compliance with reducing water fluoride concentration was excellent. The control ranges used in Ireland were 0.8 to 1.0 ppm fluoride prior to the downward adjustment and 0.6 to 0.8 ppm fluoride after the adjustment. Given the upper and lower limits of the control ranges at both time points, the downward adjustment could have been up to 0.4 ppm fluoride while remaining compliant with the legislation. This may help to explain the large reduction in fluorosis among children with

Full-CWF that did not appear to be offset by any of the reported changes in toothbrushing behaviours between 2002 and 2016-17.

However, the reduction in fluorosis prevalence among children with No-CWF between 2002 and 2016-17 is more difficult to explain. While there was a reduction in the proportion of children with fluorosis defined as TF 1 or greater and TF 2 or greater, the magnitude of the reduction in the prevalence of TF 1 among children with No-CWF from 59% in 2002 to 14% in 2016-17 was particularly striking. As the impact of downward adjustment of water fluoride concentration would be expected to be minimal among children without a fluoridated domestic water supply, reductions in fluorosis among children with No-CWF suggested reduced exposure to fluoride from discretionary sources between 2002 and 2016-17.

Although there were some changes in reported toothbrushing behaviours and use of fluoride toothpaste between 2002 and 2016-17 (as described in Section 8.2.1), some of the changes suggested increases in fluoride ingestion while others suggested reductions in fluoride ingestion with no clear indication of how, on balance, the changes might have affected total fluoride ingestion from toothpaste. Moreover, parent-reported oral health behaviours had several limitations. The extent to which the responses reflected parental knowledge or child behaviours is not known and accuracy of information regarding use of fluoride toothpaste in infancy may have been affected by poor parental recall. Thus, it is possible that there were reductions in fluoride ingestion from fluoride toothpaste in the reference period that were not identified using parent questionnaires.

Furthermore, it is possible that the diffusion effect, which has not been quantified in the Irish population, had a large impact on barely perceptible levels of fluorosis (TF 1). If this were the case, the reduction in water fluoride concentration might have contributed to a reduction in fluorosis at the level of TF 1 among children with No-CWF.

The difference in dental fluorosis prevalence at TF 1 or greater between children with Full-CWF and No-CWF was greater in 2016-17 than in 2002 (Figure 7.5, Interaction P = 0.002). This finding was surprising, given that a lessening of the difference in fluorosis prevalence between children with Full-CWF and No-CWF would have been expected following downward adjustment of water fluoride concentration. This statistically significant interaction was influenced by the reduction in fluorosis prevalence (TF 1 or greater) between 2002 and 2016-17 being greater among children with No-CWF than among children with Full-CWF.

As it is relatively straightforward to classify addresses that never had a fluoridated domestic water supply as having No-CWF, misclassification of exposure to CWF at either time point is least likely among children with No-CWF and is unlikely to explain the findings. However, classification of exposure to CWF in 2016-17 was aided by access to a detailed electronic database of current and historical water fluoride concentrations for addresses in the study areas. Thus, classification of exposure to CWF is likely to have been more accurate in 2016-17 than in 2002. This is evidenced by the lower proportion of children in 2016-17 that met the criteria for having Full-CWF (25%) compared with 2002 (51%). As children with Part-CWF were likely to have lower levels of fluorosis than children with Full-CWF, classification of a proportion of children with Part-CWF as Full-CWF in 2002 could have underestimated fluorosis prevalence among children classified as having Full-CWF in 2002. If this were the case, it would have underestimated the difference in fluorosis prevalence between children with Full-CWF and No-CWF in 2002, which would help to explain the difference in differences found in the present study.

Another explanation could be a greater reduction in fluoride ingestion and absorption between 2002 and 2016-17 among children with No-CWF than among children with Full-CWF. Although there were slight differences in reported toothbrushing behaviours

between children with Full-CWF and No-CWF in Cork-Kerry in 2002 (see Table 5.8), reported toothbrushing behaviours were remarkably similar among children with Full-CWF and No-CWF in Cork-Kerry in 2016-17 (see Table 5.6) with one exception. Among children with No-CWF, a lower proportion of parents reported noticing their child eating or licking toothpaste before age 2 compared with parents of children with Full-CWF. Information about eating or licking toothpaste was not collected in 2002, therefore it is not known whether this suggests a reduction in fluoride ingestion that occurred only among children with No-CWF between 2002 and 2016-17.

That the reduction in fluorosis at TF 1 or greater was more pronounced among children with No-CWF than among children with Full-CWF could also suggest that there were temporal changes in the underlying characteristics of the populations under study. Fluorosis was measured before and after downward adjustment of water fluoride concentration in populations with and without lifetime exposure to CWF. Such a study design is prone to selection bias, if the characteristics of the participants changed over time and if the changes differed between exposed and unexposed groups (Sterne et al. 2021). Although the analysis of the difference in fluorosis prevalence between children with Full-CWF and No-CWF in 2002 compared with 2016-17 was modelled using multivariable logistic regression to control for the effect of other explanatory variables, the explanatory variables available for inclusion in the model were limited by the small number of variables relevant to fluorosis in 2002. Therefore, the possibility of residual confounding cannot be ruled out.

8.2.4 Concluding comments on the impact of downward adjustment of CWF concentration on dental fluorosis

The dose response relationship between water fluoride concentration and dental fluorosis is well established (Dean and Elvove 1935; 1936; Dean and McKay 1939; McDonagh et

al. 2000). Therefore, 'all other things being equal', a reduction in dental fluorosis would be expected to occur among children with Full-CWF following downward adjustment of water fluoride concentration. There appeared to be low adherence to the main recommendation of the Forum on Fluoridation in relation to age of commencing fluoride toothpaste use. Furthermore, although there were some changes in reported oral health behaviours of 8-year-olds between 2002 and 2016-17, the net impact of these changes on fluorosis prevalence is difficult to determine.

A scenario whereby increasing fluoride ingestion from toothpaste since 2002 offset the expected reduction in dental fluorosis following the downward adjustment, resulting in no difference over time in fluorosis prevalence measured clinically using Dean's Index cannot be ruled out. However, the lower risk of bias associated with blind fluorosis measurement from oral photographs suggested a more likely scenario; that regardless of any changes in fluoride toothpaste use over time, downward adjustment of water fluoride concentration was associated with a statistically significant reduction in fluorosis at TF 1 or greater and TF 2 or greater in the aesthetically important maxillary central incisors.

Although the present study did not detect a reduction in the proportion of children with fluorosis in maxillary central incisors which may be of aesthetic concern (TF 3 or greater) following the adjustment, the proportion of children with fluorosis at this level was low at both time points. Fluorosis in 8-year-olds associated with exposure to CWF at 0.6 to 0.8 ppm fluoride and widespread use of fluoride toothpaste was predominantly TF 1 or TF 2; a level which is considered to have little or no impact on aesthetics or OHRQoL (Chankanka et al. 2010).

8.3 Impact of downward adjustment of CWF concentration on dental caries

8.3.1 Summary of main findings

This study demonstrated that following downward adjustment of water fluoride concentration, CWF at a concentration of 0.6 to 0.8 ppm fluoride with a target of 0.7 ppm fluoride was an effective caries-preventive measure for children living in a temperate climate with widespread use of fluoride toothpaste. That there was no difference in the prevalence or severity of dental caries in primary teeth of 8-year-olds with lifetime exposure to CWF born after the downward adjustment compared with 8-year-olds examined before the adjustment could indicate that the caries preventive effect of CWF was maintained following the downward adjustment. However, a reduction in dental caries severity among children with No-CWF in 2016-17 compared with 2002 was not observed among children with Full-CWF despite similar reported oral health behaviours in children with Full-CWF and No-CWF in 2016-17. Moreover, the difference in dental caries severity between children with Full-CWF and No-CWF (the 'difference in differences') was less in 2016-17 than in 2002 (Figure 6.2). These results suggest that the caries-preventive effect of CWF in primary teeth may have reduced following downward adjustment of water fluoride concentration.

8.3.2 Role of fluoride toothpaste in maintaining reductions in dental caries following downward adjustment of CWF concentration

Maintaining the caries preventive effect of CWF despite a reduction in water fluoride concentration required that exposure to topical fluoride modalities, especially fluoride toothpaste, were optimised. The effectiveness of fluoride toothpaste for preventing caries is firmly established (Marinho et al. 2003b; Walsh et al. 2019). In theory, simply toothbrushing with fluoride toothpaste twice a day or more often could maintain

adequate levels of fluoride in saliva to achieve substantial reductions in dental caries (Hausen 2004). However, in 2002, only 58% of 8-year-olds were reported to brush their teeth at least twice a day. Comparison with our nearest neighbours in the United Kingdom (U.K) in 2003, suggested that in the early 2000s a lower proportion of children brushed their teeth at least twice a day in the Republic of Ireland (RoI) (58%) compared with the U.K (78%) (Lader et al. 2005; Whelton et al. 2006) (Figure 8.7).

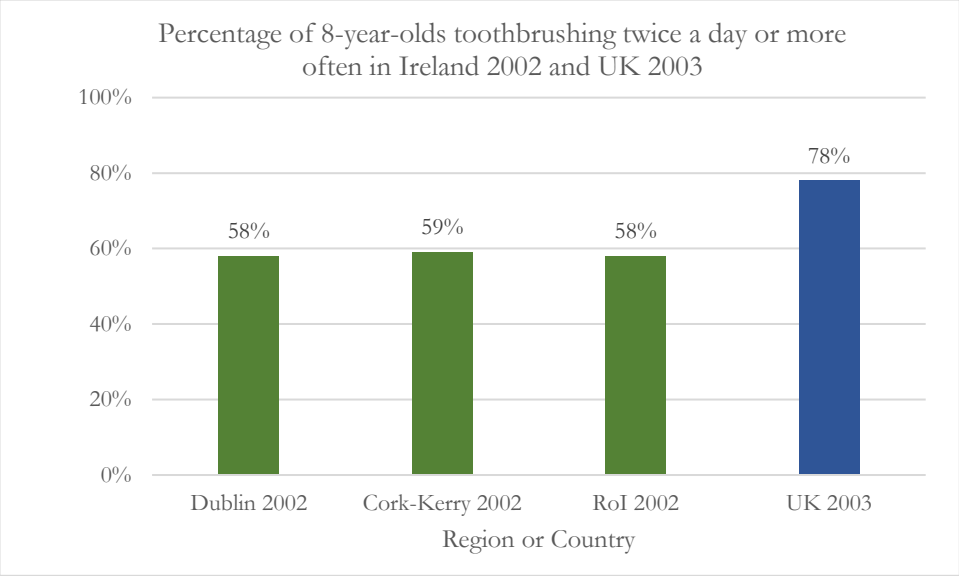


Figure 8.7: Percentage of 8-year-olds toothbrushing twice a day or more often in Ireland 2002 and in the UK 2003

Furthermore, although there were regional differences in dental caries levels between different parts of the U.K, dental caries levels in permanent teeth of 8, 12 and 15-year-olds were lower overall among children in the U.K in 2003 than among RoI children with and without CWF in 2002 (Figure 8.8) and greater reductions in dental caries levels had been recorded in the UK since 1983-84 than in RoI (Whelton et al. 2006). Therefore, following the NSSCOH 2002, it appeared that exposure to topical fluoride through twice daily toothbrushing with fluoride toothpaste was not yet optimised in Ireland and that

there was the potential for improvements in toothbrushing behaviours to further reduce dental caries levels among Irish children.

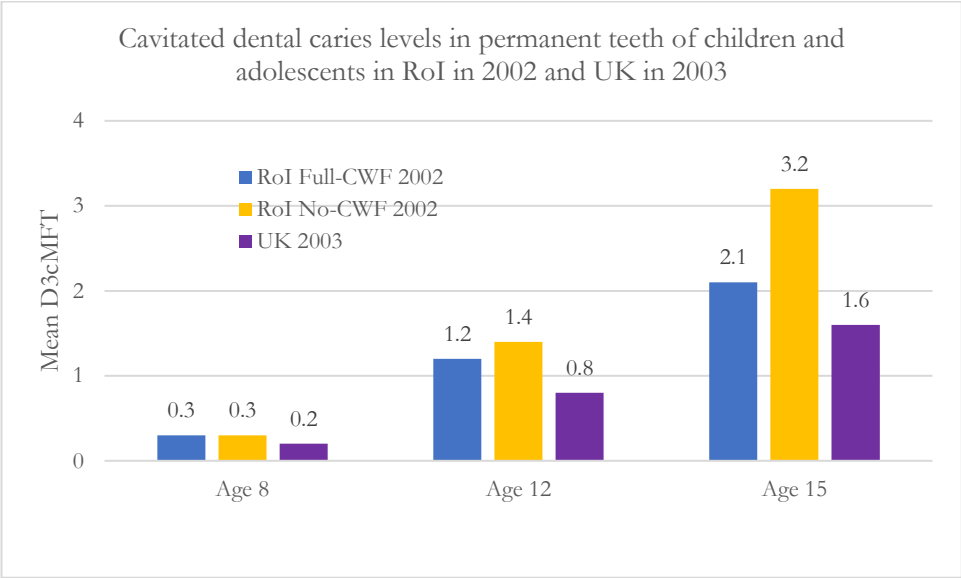


Figure 8.8: Cavitated dental caries levels in permanent teeth of children and adolescents in RoI in 2002 and UK in 2003
Source: (Whelton et al. 2006)

By 2016-17, the proportion of 8-year-olds reportedly toothbrushing at least twice a day had increased to between 70% and 73%, depending on region. Furthermore, in the present study, toothbrushing once a day or less often (compared with twice a day or more often) was consistently associated with increased prevalence and/or severity of dental caries after controlling for other explanatory variables (Tables 6.3, 6.4, 6.5 and 6.6). Thus, it is plausible that increased frequency of toothbrushing could help to explain the reduced severity of dental caries among children with No-CWF. Improvements were not apparent among children with Full-CWF despite similar reported oral health behaviours. Increased frequency of tooth brushing could have compensated, at least in part, for the reduced exposure to fluoride from water offsetting any potential deterioration in dental caries levels in primary teeth of children with Full-CWF.

Maintaining reductions in dental caries following downward adjustment of water fluoride concentration assumes that optimal use of fluoride toothpaste will be sufficient to compensate for the reduction in the pre-eruptive effect of fluoride. The pre-eruptive effect of fluoride on developing enamel, which was once thought to be the mainstay of its effectiveness, is now considered less relevant for caries prevention than maintaining low concentrations of fluoride in saliva, the plaque biofilm and at the tooth surface to facilitate the topical effects of fluoride (Featherstone et al. 1990; Ten Cate 1990). However, the pre-eruptive effect of fluoride remains an important part of its mechanism of action with the highest reductions in dental caries when both pre- and post-eruptive exposure to fluoride (CWF) are present (Groeneveld et al. 1990; Singh and Spencer 2004; Singh et al. 2007).

8.3.3 Rationale for maintaining reductions in dental caries following downward adjustment of CWF concentration

The association between water fluoride concentration and DMFT is described as negative curvilinear (Spencer et al. 2018). Below 3 ppm fluoride, there is essentially a dose-response relationship between water fluoride concentration and DMFT; as water fluoride concentration increases, DMFT decreases. However, at fluoride concentrations of approximately 3 ppm, DMFT starts to level off and may even start to increase (EPA 2010). Thus, at water fluoride concentrations consistent with CWF, an increase in dental caries levels could plausibly follow a reduction in water fluoride concentration.

The decision to reduce the water fluoride concentration is underpinned by the hypothesis that despite reduced exposure to water fluoride, reductions in caries can be maintained in the context of widespread use of fluoride toothpaste (Department of Health and Children 2002; U. S. Department of Health Human Services Federal Panel on Community Water

Fluoridation 2015). However, the available evidence in support of this hypothesis is limited.

The rationale for the 2015 decision to reduce the water fluoride concentration in the U.S. was based, in part, on the findings of Heller et al. (1997). This study, analysing data for 18,755 5- to 17-year-old participants in the 1986-87 National Survey of Oral Health in U.S. School Children (NIDR survey), found that mean dfs and DMFS decreased with increasing water fluoride concentration from 0 to 0.7 ppm and plateaued between 0.7 and 1.2 ppm fluoride. The same study demonstrated that Dean's Index scores 'very mild' or greater increased with increasing water fluoride concentration.

With apparently no additional benefit to be gained from exposure to CWF at a concentration above 0.7 ppm, and with additional research indicating no association between children's water intake and outdoor air temperature (Sohn et al. 2001; Beltrán-Aguilar et al. 2015), a downward adjustment from 0.7 to 1.2, depending on climate to 0.7 ppm fluoride for all temperature zones in the U.S was recommended.

Spencer and Do (2016) were critical of the finding of little additional gain in caries-prevention associated with increasing exposure to water fluoride from 0.7 to 1.2 ppm fluoride. Water fluoride concentration in the U.S. was tailored to the average maximum daily temperatures of different geographic areas with the aim of delivering the same caries-preventive effect in all geographic areas according to the calculation proposed by Galagan and Vermillion (1957). Notwithstanding results of recent studies indicating that differences in water consumption were not as dependant on climate as previously thought (Sohn et al. 2001; Beltrán-Aguilar et al. 2015), that the water fluoride concentration was adjusted to account for variation in water intake might help to explain the reported levelling of caries reductions between 0.7 and 1.2 ppm fluoride.

The policy decision in the U.S was also influenced by the reduction in fluorosis following downward adjustment of water fluoride concentration in Hong Kong in 1978 without a concurrent increase in dental caries (Lo et al. 1990; Evans and Stamm 1991). Evidence in support of no increase in dental caries following the downward adjustment came from Lo et al. (1990). This study compared the results of a cross-sectional study of dental caries in 6 to 12-year-olds examined in Hong Kong in 1986 (8 years after the reduction from 1.0 to 0.7 ppm) with the results of several earlier cross-sectional studies conducted through the 1960s and in the early 1980s. The results demonstrated that dental caries levels were lower in the 1980s than in the 1960s. However, the impact of downward adjustment of water fluoride concentration on dental caries in Hong Kong was not specifically evaluated in this study (Lo et al. 1990) or in subsequent cross-sectional surveys of dental caries in Hong Kong (Evans and Lo 1992; Wei et al. 1993; Chu et al. 1999; Chu et al. 2012). Furthermore, all the participants in these cross-sectional studies had exposure to CWF. Therefore, it is not known what trends in dental caries levels would have been in the absence of CWF or if no downward adjustments had taken place. That there was no increase in dental caries within 8 years of the adjustment does not necessarily mean that the downward adjustment did not have an impact on dental caries.

8.3.4 Comparison with results of other studies

In a systematic review of the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis (Chapter 3), no conclusion could be drawn regarding the impact on dental caries due to the limited quantity and quality of the available evidence. The one study that evaluated the impact of the downward adjustment from 0.7 to 0.5 ppm fluoride in Malaysia on dental caries found that mean $D_{1-6}MFT/d_{1-6}mft$, mean $D_{4-6}MFT/d_{4-6}mft$ and the proportion of children with $D_{4-6}MFT>0/d_{4-6}mft>0$

were lower among 9-year-olds with CWF at 0.5 ppm fluoride compared with their counterparts living in non-fluoridated areas (Mohd Nor 2017; Mohd Nor et al. 2018).

The results of the present study are consistent with the results from the Malaysian study (Mohd Nor 2017; Mohd Nor et al. 2018) in demonstrating the effectiveness of CWF for preventing dental caries following downward adjustment of water fluoride concentration.

Associations in the present study between socio-economic disadvantage and both higher prevalence and severity of dental caries are consistent with the established social gradient in health and disease, where increasing socio-economic disadvantage is associated with a progressively higher burden of ill health (Marmot and Bell 2011). A systematic review by Schwendicke (2015) confirmed that low socioeconomic position was associated with higher risk of having carious lesions or caries experience in primary or permanent teeth.

In the present study, the benefits of fluoride toothpaste for preventing dental caries in primary teeth were evident in the associations between frequency of toothbrushing at age 8 and dental caries in multivariable regression models for both Dublin and Cork-Kerry. Considering the recommendation for children under the age of 2 years to refrain from using fluoride toothpaste, it is notable that there were associations in the multivariable regression models between first using fluoride toothpaste before age 2 and lower caries prevalence (Dublin 2002 and 2016-17 combined, Table 6.3) and severity (Cork-Kerry 2002, Table 6.6).

In Dublin and Cork-Kerry, among children with Full-CWF and No-CWF there was a consistent association between snacking on sweet foods or drinks more than once a day between meals and increased prevalence and severity of dental caries. The key role that frequent exposure to free sugars plays in the aetiology of dental caries is undisputed but often underemphasised in contemporary caries preventive programmes (Sheiham and

James 2015). While fluoride increases the threshold for the dental caries process to progress to cavitation, there is a limit to what fluoride can achieve in terms of caries prevention (Zero 2004). This is evidenced in the present study by the fact that despite CWF and a high proportion of children brushing at least twice a day with fluoride toothpaste, more than half of the children at both time points had experienced dental caries in their primary dentition.

In Cork-Kerry in 2016-17, regularly taking a baby bottle into bed was associated with higher caries prevalence in the primary dentition (OR 1.47, 95% CI [1.10, 1.97], $P = 0.009$). This variable was related to nocturnal bottle feeding rather than to the content of the bottle which could have been infant formula, milk or sugar sweetened beverages. While consumption of liquids containing free sugars from a baby bottle is associated with increased risk of Early Childhood Caries (ECC) (Moynihan et al. 2019), there is a lack of consensus regarding the association between frequent intake of infant formula from a baby bottle and ECC (Arora et al. 2011). However, several studies have reported associations between nocturnal feeding with a baby bottle (regardless of the content of the bottle) and ECC (Ollila et al. 1998; Campus et al. 2007; Bahuguna et al. 2013; Olczak-Kowalczyk et al. 2020).

The present study revealed a consistently strong association between ever visiting the dentist and higher prevalence and severity of dental caries reflecting a pattern of dental attendance for caries-related problems. Indeed, among 8-year-olds examined in 2016-17, the proportion whose first visit to the dentist was for relief of pain or because the parent felt treatment was needed was 17% in Dublin Full-CWF, 23% in Cork-Kerry Full-CWF and 18% in Cork-Kerry No-CWF (data not shown).

While these findings may seem counterintuitive, they should be interpreted in the context of dental service availability and utilisation for young children in Ireland at the time of

the FACCT study and the NSSCOH 2002. Routine primary dental care for children of school-going age in Ireland was provided free of charge by the Public Dental Service (PDS) at ages 8, 10 and 12 in 2nd, 4th and 6th class respectively with provision of emergency services to all children up to 16-years-old (Department of Health 1994; Woods et al. 2017). Although private dental services for children were available, routine private attendance was not the norm, particularly for younger children (Whelton et al. 2006; Parnell et al. 2007). Thus, the first opportunity for these children to avail of free routine dental care was at age 7 to 9 years (i.e., at the time the clinical examinations for both studies were conducted). However, this system is due to change with implementation of the recent Irish Oral Health Policy which aims to reduce caries in the primary dentition through early access to preventive services (Department of Health 2019).

The contribution of the 'decayed' or 'd' component (% $d_{3vc}t$) to the $d_{3vc}mft(cde)$ was high at both time points indicating a high level of untreated dentinal caries in primary teeth of the study participants. Given that provision of the first school dental examination was at age 7 to 9 years and the reliance on the public dental service for preventive and restorative treatment, bias due to differential provision of caries preventive or treatment services is not considered an important source of bias in this study.

8.3.5 Concluding comments on the impact of downward adjustment of CWF concentration on dental caries

At water fluoride concentrations consistent with CWF, the dose response relationship between water fluoride and dental caries indicates that reductions in water fluoride concentration could lead to increases in dental caries. The rationale for reducing water fluoride concentration to reduce dental fluorosis is underpinned by the hypothesis that reductions in dental caries can be maintained in this context through widespread use of fluoride toothpaste. However, evidence in support of this hypothesis is weak.

Furthermore, evidence of the impact of downward adjustment of water fluoride concentration on dental caries is limited in both quantity and quality (see Chapter 3).

In the early 2000s, frequency of toothbrushing with fluoride toothpaste was lower and dental caries levels higher among Irish 8-year-olds with Full-CWF and No-CWF than among UK 8-year-olds (Lader et al. 2005; Whelton et al. 2006). Thus, it appeared that further reductions in dental caries levels could be achieved by optimising fluoride toothpaste use among Irish children.

The present study indicated that the proportion of 8-year-olds reportedly toothbrushing at least twice a day increased between 2002 and 2016-17. A reduction in the severity of dental caries in primary teeth was recorded among children with No-CWF in Cork-Kerry between 2002 and 2016-17. However, the present study indicated no difference over time in the prevalence and severity of dental caries in primary teeth of children with Full-CWF. Increased exposure to fluoride through increased frequency of tooth brushing between 2002 and 2016-17 may have contributed to the reduction in dental caries in primary teeth of children with No-CWF. In the context of reduced exposure to water fluoride, increased exposure to fluoride through increased frequency of tooth brushing could have offset any potential deterioration in dental caries levels in primary teeth of children with Full-CWF.

Following downward adjustment of water fluoride concentration in Ireland, CWF remained an effective caries preventive measure. Furthermore, dental caries levels did not increase following the adjustment. However, trends in dental caries among children with No-CWF suggest that reductions in dental caries levels among children with Full-CWF may have been forgone by implementing the downward adjustment.

8.4 Strengths and limitations

There are many situations where it may not be appropriate or feasible to conduct a randomised controlled trial (RCT) (Black 1996) and there is increased recognition of the role that observational studies can play in informing evidence-based decisions in healthcare (Black 1996; O'Mullane et al. 2012). If treatment effects are sufficiently large and consistent, carefully conducted observational studies may provide more compelling evidence than poorly conducted RCTs (Guyatt 2008).

In the case of water fluoridation programmes, the use of randomised controlled trials is rightly regarded to be problematic in terms of difficulty in randomising individuals or population groups to receive fluoridated or non-fluoridated water (McDonagh et al. 2000). Therefore, non-randomised studies such as prospective cohort studies, controlled before and after studies and cross-sectional studies must be relied upon for evidence of the effectiveness and safety of this population-level intervention.

In the present study, a before and after study design utilised historical data collected during the cross-sectional NSSCOH 2002 prior to the downward adjustment of water fluoride concentration and data collected from children born just after the downward adjustment. However, introduction of toothbrushing guidance in 2002 also had the potential to impact dental caries and fluorosis levels in children born after the adjustment. Furthermore, as with any before and after study, there was the potential for the characteristics of the populations to change over time. Although the results suggested that adherence to the recommendation not to use fluoride toothpaste before age 2 was low and multivariable analysis controlled for differences between the groups being compared (including age the children first used fluoride toothpaste), the presence of residual confounding cannot be ruled out. Thus, the results of each separate study (2002

and 2016-17) are likely to be at lower risk of bias than the temporal comparisons between the studies.

Participants were selected into the present study based on their age and the geographic areas where they lived. Some children who were exposed and not exposed to the downward adjustment of water fluoride concentration were likely to have moved away before selection of participants into the study. Thus, some eligible children were not included in the study. The risk of bias associated with selection of participants into the study is unavoidable in any non-randomised study where there is a time lag between implementation of the intervention and selection of participants into the study and was outlined in Chapter 3 in relation to other studies evaluating the impact of downward adjustment of water fluoride concentration (Evans and Stamm 1991; Wong et al. 2014; Mohd Nor et al. 2018). However, the reasons children were not included in the studies were unlikely to be related to the intervention or the outcomes and therefore, this is not considered to be an important source of bias in the present study.

A major strength of this study was the meticulous individual classification of exposure to CWF. Exposure of FACCT participants to CWF was classified individually based on the fluoride concentration of water supplying the child's current and all previous addresses. Furthermore, data from mandatory monitoring of fluoride levels in Irish public water supplies confirmed that the water fluoride concentration was adjusted downwards from 0.8 - 1.0 to 0.6 - 0.8 ppm fluoride in mid-2007. These data indicated that the intervention (the downward adjustment) was delivered as intended. A further strength was clinical assessment of dental caries and fluorosis using identical protocols at both time points with training led by the same experienced gold standard examiner. Also, control groups at both time points facilitated assessment of temporal trends in dental caries and fluorosis

in children with No-CWF. Multivariable regression controlled for any differences in demographics or oral health behaviours between the groups being compared.

A limitation of the study was that examiners measuring dental caries and fluorosis clinically were not blind to participants' fluoridation status because transporting children to a neutral venue was not logistically feasible. In FACCT, although examiners likely knew whether the child's school was in a fluoridated or non-fluoridated area, risk of bias was mitigated by ensuring that examiners were not aware of the child's exposure to CWF throughout their lives. A further limitation of the study was that the evaluation of the impact of the downward adjustment on dental caries was restricted to the primary dentition (primary canines and molars). However, when considered in the context of a public dental service that first offers routine primary dental care to children at age 7 to 9 (Department of Health 1994; Woods et al. 2017), where routine attendance privately is not the norm (Whelton et al. 2006; Parnell et al. 2007), the low risk of confounding due to differences in the provision of preventive and treatment services, strengthens the findings of the present study. Furthermore, there is a clear link between dental caries in the primary dentition and dental caries in the permanent dentition (Zero et al. 2001; Hall-Scullin et al. 2017) with caries experience in second primary molars strongly predicting caries experience in the young permanent dentition (Skeie et al. 2006).

The advantages of fluorosis measurement from oral photographs were manifold. Firstly, the same standardised photographic technique was used at both time points. Secondly, the methods facilitated blinding to both fluoridation status and exposure to the downward adjustment. Thirdly, photographs taken in 2002 and 2016-17 were scored contemporaneously, ensuring that the method of outcome assessment was the same before and after the intervention. Lastly, the photographic method facilitated valid and reliable measurement of fluorosis in the aesthetically important maxillary central incisors,

of most relevance to public health in countries with low fluorosis severity associated with optimally fluoridated water and use of fluoride toothpaste.

The main limitation of the photographic method of measuring fluorosis in the present study was the inability to assess the impact of the downward adjustment on dental fluorosis in Dublin (Full-CWF), where over one-quarter of the Irish population resided. This was because photographs were not taken for 8-year-olds in the Dublin region in the NSSCOH 2002. However, the similarity in the frequency distribution of TF scores in maxillary central incisors of children with Full-CWF in 2016-17 in Dublin and Cork-Kerry (Section 8.2.3.3, Figure 8.6), and the similarly in the proportion with Dean's 'very mild' or greater fluorosis among children with Full-CWF in both regions in 2002 (Figure 8.9) suggest that the impact of the downward adjustment on fluorosis in maxillary central incisors of children in Dublin may have been similar to the reduction in Cork-Kerry.

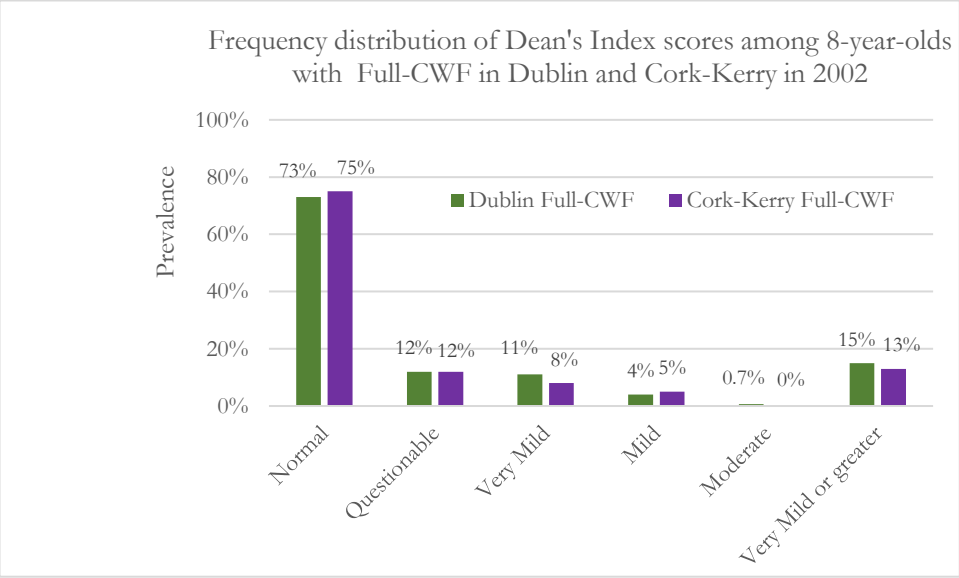


Figure 8.9: Frequency distribution of Dean's Index scores of 8-year-olds with CWF measured clinically in Dublin and Cork-Kerry in 2002

A further limitation of the photographic method as employed in this study was the differences in the technologies used to image the maxillary central incisors at each time point. Whereas both sets of photographs were taken according to the same standardised method, it is not known whether the images taken using photographic film in 2002, converted into slides and later digitised for use in the present study were fully comparable with the digital images taken in the FACCT study. Although not noticed by either examiner at the time of scoring, it is possible that subtle differences in the quality of the images in 2002 and 2016-17 might have impacted the measurement of fluorosis. However, given the similarity of fluorosis prevalence among children with Full-CWF photographed in Cork in 1997 (Cochran et al. 2004a) and as measured in the present study from photographs taken in 2002 and later digitised (Figure 8.4), it seems unlikely that the digitisation process had an important impact on the fluorosis measurement in 2002. Therefore, differences in the technologies used to image the maxillary central incisors are considered unlikely to have had an important impact on the results.

The rationale for basing the person level score on the highest score in the maxillary central incisors was to record all cases of fluorosis that were potentially of cosmetic importance, even if only one maxillary central incisor was affected at this level. Several other studies have used this case definition for fluorosis (Ellwood et al. 1996; Cochran et al. 2004a; Tavener et al. 2006; Tavener et al. 2007; Spencer and Do 2008; McGrady et al. 2012b; Do et al. 2016). The drawback of this approach was the potential for overscoring fluorosis prevalence, particularly at TF 1. If only one maxillary central incisor was affected (e.g., one maxillary central incisor scored TF 1 and the other scored TF 0) a diagnosis of fluorosis may not have been warranted. Furthermore, when present, fluorosis generally affects all teeth to some degree (Fejerskov et al. 1988) and examining the entire dentition to determine the presence of fluorosis is an important part of fluorosis measurement

regardless of the index employed. However, it was not possible to confirm the diagnosis of fluorosis within the limited field of view presented by the one frontal photograph. However, fluorosis tends to affect homologous pairs of teeth similarly (Thylstrup 1978; Wenzel and Thylstrup 1982; Levy et al. 2006) and in the present study, 88% of children had the same TF (consensus) score (TF 0 to 5) on the two maxillary central incisors.

The strengths and limitations of clinical fluorosis measurement with Dean's Index in the context of the present study were addressed in Section 8.2.2. Briefly, while clinical measurement with Dean's Index in 2016-17 facilitated assessment of the impact of downward adjustment of water fluoride concentration by comparison with fluorosis recorded according to the same methods in the NSSCOH 2002, lack of examiner blinding to exposure to CWF and the potential for differences in how fluorosis was measured in 2002 and 2016-17 meant that this outcome was likely to be at higher risk of bias than fluorosis measured from photographs using the TF Index.

The lower proportion of children classified as having Full-CWF in 2016-17 (25%) compared with 2002 (51%) (See Figures 5.1 and 5.2), reflected improvements in access to electronic data for classification of lifetime exposure to CWF. Thus, a proportion of children classified as Full-CWF in Cork-Kerry 2002 may have had Part-CWF. A sensitivity analysis indicated that re-classifying Part-CWF 2002 as Full-CWF or No-CWF did not change the overall findings for dental caries (Objective 1), or fluorosis measured using Dean's Index (Objective 3a) or the TF Index (Objective 3b) (Appendix G). Thus, any potential misclassification of exposure to CWF in 2002 was considered unlikely to have had an important impact on the results.

A limitation of the present study was that one-quarter of children who consented to participate in the study at age 5 in 2013-14 were not clinically examined or photographed

at age 8 in 2016-17. The higher proportion of dependents of medical card/GP card holders among children lost to follow-up in Dublin and Cork-Kerry suggested that participants in 2016-17 were of higher socio-economic status than the sample who originally consented to participate in the study in 2013-14. A similar phenomenon was reported in the longitudinal Iowa Fluoride Study, where children who remained in the study several years on tended to be from a more affluent background than those who were lost to follow-up (Levy et al. 2003; Warren et al. 2009).

In the present study, there were indications that parental medical card ownership was associated with lower levels of fluorosis at TF 1 or greater, but this association was only seen among children with No-CWF in Cork-Kerry (See Table 7.7). An association between socio-economic disadvantage and lower risk of developing fluorosis has been reported in other studies (Pendrys and Katz 1989; Ellwood and O'Mullane 1994; Rock and Sabieha 1997; Tabari et al. 2000). However, in the present study parental medical card ownership was controlled for in the multivariable regression analyses and no statistically significant association between parental medical card ownership and dental fluorosis was seen at the level of TF 2 or greater. Any impact on fluorosis of the 2016-17 sample being more affluent than the sample originally selected is considered to be slight and might have led to the earliest signs of fluorosis being overestimated in Cork-Kerry, particularly among children with No-CWF.

Parental medical card ownership was associated with higher caries prevalence and severity in Dublin and with higher caries severity in Cork-Kerry (See Tables 6.3, 6.4, 6.5 and 6.6). Lower levels of deprivation among the 2016-17 sample might have resulted in dental caries being underestimated. If dental caries levels were higher than measured in 2016-17 among children with Full-CWF there would have been either no difference or an increase in dental caries in 2016-17 relative to 2002, reinforcing the findings in relation to trends

among children with Full-CWF. Among children with No-CWF, dental caries levels being higher in 2016-17 would lessen the magnitude of reductions in dental caries seen in this group in 2016-17 compared with 2002.

In common with any prospective study, loss to follow up during the study can be a substantial challenge. While the research question could have been answered using a cross-sectional study of 8-year-olds in 2016-17, advantages of using a longitudinal study design included collection of information about use of fluoride toothpaste in infancy and early childhood and residential history to age 5 in 2013-14, reducing the risk of bias due to poor parental recall.

8.5 Conclusions regarding the risk benefit balance of the downward adjustment of CWF concentration

In adjusting the water fluoride concentration downwards, the desired outcome was to reduce the prevalence of fluorosis while maintaining reductions in dental caries. Water fluoride has both a systemic and a topical caries preventive effect. It was anticipated that reductions in dental fluorosis could be achieved through reduced ingestion and absorption of fluoride from water in infancy and early childhood while the reduction in the topical effect of CWF would be compensated for in all age groups by widespread use of fluoride toothpaste. Furthermore, reductions in fluoride toothpaste ingestion in infancy and early childhood were sought by the introduction of toothbrushing recommendations. Although the main recommendation was to defer commencing fluoride toothpaste use until after 24 months of age, the present study indicated little change in age of first using fluoride toothpaste following introduction of this recommendation.

The impact of downward adjustment of water fluoride concentration on dental fluorosis was measured clinically using Dean's Index and from photographs using the TF Index. While there was no difference in fluorosis prevalence defined as Dean's 'very mild' or greater following the adjustment, there was a statistically significant reduction in the prevalence of fluorosis in maxillary central incisors defined as TF 1 or greater and TF2 or greater. However, as the photographic method was at lower risk of bias than the clinical method, it is concluded that there was a reduction in fluorosis prevalence among children with Full-CWF and No-CWF following downward adjustment of water fluoride concentration. Fluorosis in maxillary central incisors was predominantly TF 1 and TF 2, a level which is considered to have little or no impact on aesthetics or OHRQoL (Chankanka et al. 2010). Although there was little change in the prevalence of scores TF 3 or greater in maxillary central incisors between 2002 and 2016-17, the prevalence of fluorosis at this level was low and the trend of increasing severity of fluorosis that prompted introduction of the Forum on Fluoridation recommendations has stabilised suggesting that fluorosis of aesthetic concern is not currently a public health problem in Ireland.

This study demonstrated that CWF at 0.6 to 0.8 ppm fluoride is an effective caries-preventive measure in a temperate climate against a background of widespread fluoride toothpaste use. Eight-year-olds with Full-CWF born after the adjustment (examined in 2016-17) had lower caries prevalence and severity in primary teeth than their counterparts with No-CWF. There was no increase in dental caries in primary teeth of children with Full-CWF following downward adjustment of water fluoride concentration. However, reductions in dental caries among children with No-CWF and the lessening of the difference in dental caries between children with Full-CWF and No-CWF in 2016-17

compared with 2002 suggested that downward adjustment of water fluoride concentration may have reduced the caries-preventive effect of CWF.

In the present study, risk of bias due to the before and after study design and the consequent time lapse between the pre- and post-intervention measurements must be acknowledged. There was the potential for changes in the characteristics of the populations over time that were not controlled for in multivariable analysis to affect the results. In relation to dental fluorosis, the robust methodology used to measure fluorosis from photographs and the magnitude of the reductions in dental fluorosis prevalence instil confidence in the findings. Considering secular trends in oral health behaviours and dental caries levels among UK children (Lader et al. 2005), the expectation was for continued reductions in dental caries among Irish children between 2002 and 2016-17. Therefore, from a public health perspective, that reductions in dental caries among children with No-CWF between 2002 and 2016-17 were not seen in children with Full-CWF is of concern.

The rationale for lowering the concentration of fluoride in water supplies has been questioned on the basis that it potentially reduces the benefit in terms of caries prevention for the entire population across the life course to reduce the risk of fluorosis at a critical period in early childhood (Spencer and Do 2016). An alternative approach adopted in Australia in the early 1990s was to maintain the water fluoride concentration while targeting reductions in exposure to discretionary sources of fluoride, including toothpaste, infant formula powders containing fluoride and fluoride supplementation (Australian Research Centre for Population Oral Health 2006). The policy measures included advice to delay commencing toothpaste use until after 24 months of age and to use a pea-sized amount of low-concentration (400-550 ppm) fluoride toothpaste to age 7. Assessment of fluorosis levels in children born before and after implementation of the

policy measures found a statistically significant reduction in the prevalence of fluorosis (Riordan 2002; Do and Spencer 2007b). An increase in the use of low-concentration fluoride toothpaste was thought to be largely responsible for the reduction. However, studies of the caries-preventive effect of low-concentration fluoride toothpastes in primary teeth have produced conflicting results (Walsh et al. 2019) and further research is warranted (O'Mullane et al. 2018).

The decision to reduce water fluoride concentration in Ireland was made in 2002, in the context of ongoing reductions in dental caries and increases in both the prevalence and severity of dental fluorosis among Irish children. Furthermore, the wider context included somewhat alarming reports of increasing fluorosis levels in other countries with CWF programmes (the U.S. and Australia) (Pendrys and Stamm 1990; Riordan and Banks 1991; Riordan 1993a; Rozier 1999; Beltran-Aguilar et al. 2002). The decision to adjust the water fluoride concentration in Ireland downwards was carefully considered and was justified at the time. However, whereas dental fluorosis does not progress and may decline in severity over time (Do et al. 2016; Curtis et al. 2020), caries development in the primary dentition sets children on a steep trajectory towards further disease experience in the permanent dentition (Hall-Scullin et al. 2017). The results of the present study suggest that reductions in dental fluorosis may have been achieved at the cost of forfeiting further reductions in dental caries levels among children with CWF.

This is the first study to compare both dental caries and fluorosis levels among children with lifetime exposure to the higher water fluoride concentration and children with lifetime exposure to the reduced water fluoride concentration. Fluorosis prevalence in the aesthetically important maxillary central incisors reduced following downward adjustment of water fluoride concentration. Based on the cross-sectional comparison of children with Full-CWF and No-CWF in 2016-17, the lower concentration of 0.6 to 0.8 ppm fluoride

is an effective caries-preventive measure. However, the before and after study indicated that downward adjustment of water fluoride concentration may have reduced the caries-preventive effect of CWF in primary teeth. Considering the findings of this study, evaluating the impact of the downward adjustment on dental caries in permanent teeth of children and adults with CWF is a priority for further research.

8.6 Public health and policy implications

- Downward adjustment of water fluoride concentration reduced fluorosis prevalence in the aesthetically important maxillary central incisors. However, the adjustment may have reduced the benefit of CWF for preventing dental caries in primary teeth. These findings suggest a potential reduction in the effectiveness of CWF from childhood across the life course. Further research is needed to determine the impact of downward adjustment of water fluoride concentration on dental caries in the permanent dentitions of children and adults.
- Following downward adjustment of water fluoride concentration, fluorosis was predominantly TF 1 or TF 2 and the prevalence of scores TF 3 or greater was low. These findings suggest that fluorosis is unlikely to be a public health problem in Ireland.
- Although fluorosis defined as TF 1 or greater and TF 2 or greater reduced following adjustment of CWF concentration, there was little change in fluorosis at the level which may be of aesthetic concern (TF 3 or greater). This suggests that fluorosis at TF 3 or greater was little affected by the downward adjustment of water fluoride concentration. However, in the present study fluorosis was measured in newly erupted maxillary central incisors and the severity of fluorosis is likely to reduce over time. Therefore, the proportion with TF 3 or greater is likely to be less in older children and young adults. If reductions at the level of

TF 3 or greater are desired, efforts should focus on reducing ingestion of fluoride toothpaste in infancy and early childhood.

- In evaluating the risks and benefits of fluoride toothpaste use in children under age 2 years, policymakers should take the following findings of the present study into consideration:
    - that despite advice to delay commencing fluoride toothpaste use until after 24 months, 80% of parents in 2016-17 with Full-CWF and No-CWF indicated that they first used toothpaste with their child at ≤24 months,
    - the association between first using fluoride toothpaste at ≤24 months and reduced dental caries prevalence in primary teeth,
    - the association between toothbrushing with fluoride toothpaste twice a day or more often at ≤24 months and fluorosis at TF 2 or greater among children with lifetime exposure to CWF.
- Despite having an effective population level caries preventive intervention in place, dental caries was still a public health problem among children with Full-CWF. This suggests that CWF and fluoride toothpaste use are not sufficient to ensure optimal oral health in children. A multifaceted approach targeting the social determinants of health is required to reduce the burden of dental caries among those living in fluoridated areas.
- The higher prevalence and severity of dental caries among children with No-CWF compared with those with Full-CWF represents an oral health inequality that must be addressed.

8.7 Recommendations for further research

- The present study makes a valuable contribution to the body of evidence regarding the impact of downward adjustment of water fluoride concentration on dental caries and fluorosis. However, there is still a scarcity of information regarding the impact of this policy change, particularly in relation to dental caries in permanent teeth.
    - In Ireland, evaluating the impact of the downward adjustment on dental caries in permanent teeth of children and adults is a priority for further research.
        - Further analysis of the FACCT study data could include evaluation of the impact of downward adjustment of water fluoride concentration on dental caries in first permanent molars of 8-year-olds in Dublin, Cork and Kerry.
    - Further information regarding the impact of downward adjustment of water fluoride concentration on dental fluorosis in Ireland could come from comparing fluorosis in maxillary central incisors of 12-year-olds in Dublin and Cork-Kerry, photographed in phase 1 of FACCT in 2013-14 (whose permanent incisors mineralised at a CWF concentration of 0.8 to 1.0 ppm fluoride) with fluorosis in maxillary central incisors of 8-year-olds in Dublin and Cork-Kerry, photographed in phase 2 of FACCT in 2016-17 (whose permanent incisors mineralised at a CWF concentration of 0.6 to 0.8 ppm fluoride).
    - In other countries, evaluation of recent or future downward adjustments of water fluoride concentration should:

        - be planned well in advance of the downward adjustment as there is a limited time frame within which to collect appropriate data in relation to pre-adjustment outcome measures,
        - ideally include more than one outcome measurement before and after the intervention to allow characterisation of trends and patterns in the outcome data. Inclusion of a control group is desirable to facilitate a 'difference in differences' analysis.
        - ensure accurate individual measurement of exposure to CWF in study participants,
        - include accurate measurement and control for important confounders and other explanatory variables.

- In the present study, toothbrushing behaviours in infancy and early childhood were parent-reported when the children were aged 5 or 8 years. Information about toothbrushing behaviours of Irish children should be collected from birth to age 3 to provide accurate information to inform policy regarding the benefits and risks of fluoride toothpaste use in infancy and early childhood. Ideally this information should:
    - be collected as part of a longitudinal study (birth cohort),
    - include measurement of total fluoride ingestion and absorption from all sources,
    - incorporate evaluation of dental caries in primary teeth and dental fluorosis on emergence of the permanent teeth.
- Use of low fluoride toothpaste in early childhood offers the opportunity to reduce dental fluorosis while maintaining the caries preventive benefit of fluoride toothpaste. Well conducted RCTs are required. These should evaluate the effectiveness of low fluoride toothpaste of at least 500 ppm fluoride compared

with toothpaste with at least 1000 ppm fluoride for preventing dental caries in primary teeth with adequate follow up to allow measurement of fluorosis on eruption of the permanent maxillary incisors.

- Future monitoring of the prevalence and severity of dental fluorosis in Ireland should include oral photographs taken according to a standardised method and scored using the TF Index in addition to or as a replacement for clinical measurement using Dean's Index.
- If clinical measurement of fluorosis using Dean's Index is used in future Irish studies:
    - the number of repeat examinations conducted by each examiner and by the gold standard examiner should be sufficient to demonstrate the validity and reliability of the clinical fluorosis measurement,
    - repeat measurements should include a variety of different Dean's Index scores,
    - for intra-examiner reliability, repeat measurements should be conducted on a different day (if possible) to minimise recall.
- The development of optical or digital technology, artificial intelligence or machine learning programmes to reduce subjectivity and bias in the measurement of fluorosis are recommended. Until such a time as a suitable objective method of fluorosis measurement becomes available, the photographic method of fluorosis measurement described in the present study is suggested as a valid and reliable method that minimises the inherent subjectivity of fluorosis measurement.
- There is some evidence internationally that the prevalence of fluorosis can reduce or 'fade out' over time (Do et al. 2016; Curtis et al. 2020). Therefore, longitudinal changes in the severity of fluorosis in Irish children, particularly in maxillary central incisors scored TF 3 or greater (potentially of aesthetic concern), are of

interest from a public health perspective. The present study offers the opportunity to re-photograph the children examined in 2016-17 when they are several years older (e.g., at age 15 in 2023/24) to evaluate longitudinal changes in the prevalence and severity of dental fluorosis, blind to TF score at age 8 and to fluoridation status.

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Appendix A: Published papers

Fluoride And Caring for Children's Teeth (FACCT): Clinical Fieldwork Protocol.

James P, Harding M, Beecher T, Parnell C, Browne D, Tuohy M, Kavanagh D, O'Mullane D, Guiney H, Cronin M, Whelton H. Fluoride And Caring for Children's Teeth (FACCT): Clinical Fieldwork Protocol. HRB Open Res. 2018 Feb 28;1:4. doi: 10.12688/hrbopenres.12799.1. PMID: 32002500; PMCID: PMC6973526

Available at: https://hrbopenresearch.org/articles/1-4/v1

Abstract

Background: The reduction in dental caries seen between Irish national surveys of children's oral health in 1984 and 2002 was accompanied by an increase in the prevalence of enamel fluorosis. To minimise the risk of enamel fluorosis in Irish children, in 2007, the level of fluoride in drinking water was reduced from 0.8-1.0 ppm to 0.6-0.8 ppm fluoride. Recommendations on the use of fluoride toothpastes in young children were issued in 2002. Fluoride and Caring for Children's Teeth (FACCT) is a collaborative project between the Oral Health Services Research Centre, University College Cork and the Health Service Executive dental service, with funding from the Health Research Board.

Aim: FACCT aims to evaluate the impact and the outcome of the change in community water fluoridation (CWF) policy (2007) on dental caries and enamel fluorosis in Irish schoolchildren, while also considering the change in policy on the use of fluoride toothpastes (2002).

Methods/Design: A cross-sectional study with nested longitudinal study will be conducted in school year (SY) 2013-2014 by trained and calibrated dental examiners in primary schools in counties Dublin, Cork and Kerry for a representative sample of children

born either prior to or post policy changes; age 12 (born 2001) and age 5, (born 2008). Five-year-olds will be followed-up when they are 8-year-olds (SY 2016-2017). The main explanatory variable will be fluoridation status of the children (lifetime exposure to CWF yes/no). Information about other explanatory variables will be collected via parent (of 5-, 8- and 12-year-olds) and child completed (8- and 12-year-olds only) questionnaires. The main outcomes will be dental caries (dmf/DMF Index), enamel fluorosis (Dean's Index) and oral health-related quality of life (OHRQoL). Multivariable regression analyses will be used to determine the impact and outcome of the change in CWF policy on oral health outcomes controlling for other explanatory variables.

Keywords

water fluoridation, prevention, dental caries, enamel fluorosis, public health, oral health-related quality of life, Dean's Index, DMF Index, dmf index

Background

Community water fluoridation (CWF) has been the cornerstone of dental caries (tooth decay) prevention in the Republic of Ireland (RoI) since the 1960s and has played an important role in the improvement in oral health of children (O'Mullane et al., 1986, Whelton et al., 2006, Parnell et al., 2007) and adults (Whelton et al., 2007). Reviews of the scientific literature have also confirmed the effectiveness of CWF in the control of dental caries (McDonagh et al., 2000, Centers for Disease Control and Prevention, 2001, Australian Government National Health and Medical Research Council, 2007, Rugg-Gunn and Do, 2012, Iheozor-Ejiofor et al., 2013). Apart from an increased incidence of enamel fluorosis, studies have concluded that there is no credible or definitive evidence linking CWF with negative health outcomes (McDonagh et al., 2000, Australian Government National Health and Medical Research Council, 2007, Sutton et al., 2015).

Of the total population of 4.5 million in the RoI, approximately 71% reside in communities served with fluoridated water supplies (Whelton et al., 2006). Fluoride toothpastes, first introduced in the 1970s and in widespread use by the 1980s, now represent 95% of toothpaste sales in most developed countries, including Ireland (Department of Health and Children, 2002). Hence most people with CWF are exposed to fluoride from water and toothpastes. National surveys of children's oral health conducted in 1984 (O'Mullane et al., 1986) and 2001-2002 (Whelton et al., 2006) showed an on-going reduction in dental caries levels among 5-, 8-, 12- and 15-year-old lifetime residents in communities with and without CWF. Children with lifetime exposure to CWF had significantly lower dental caries levels than those without. This reduction in dental caries was accompanied by an increase in enamel fluorosis (marks on the teeth associated with fluoride intake during tooth development) levels. In 1984, 6% of 8-year-olds and 5% of 15-year-olds with CWF had some sign of enamel fluorosis. In 2001-2002, using the same measurement criteria, the prevalence of enamel fluorosis was 24% in 8-year-olds and 36% in 15-year-olds. It is important to note that most of the increase occurred in the barely perceptible "Questionable" category of Dean's Index (Dean, 1934) and the percentage of children with scores at the higher end of the scale ('Moderate' / 'Severe') was low (1–2%). The prevalence of enamel fluorosis was significantly higher among 8- and 15-year-old children with CWF compared to their counterparts without ($p<0.0001$) (Whelton et al., 2006).

In response to these findings, in 2002 the Forum on Fluoridation, which was established by the Minister for Health to review CWF in Ireland, issued a number of recommendations aimed at minimising the risk of enamel fluorosis (Department of Health and Children, 2002). These recommendations included the following:

- In the light of the best available scientific evidence, the Fluoridation of Water Supplies Regulations, 1965 should be amended to redefine the optimal level of fluoride in drinking water from the present level (0.8 to 1.0 ppm) to a level of 0.6 to

0.8 ppm, with a target value of 0.7 ppm. (This recommendation was implemented in 2007.)

- Parents should be advised not to use toothpaste when brushing their children's teeth until the age of 2 years. Prior to this age parents can brush their children's teeth with a toothbrush and tap water. Professional advice on the use of fluoride toothpaste should be sought where a child below 2 years of age is considered to be at high risk of developing dental decay.
- Parents should supervise children aged 2 to 7 years when brushing their teeth and should ensure that only a small pea sized amount of fluoride toothpaste is used and that swallowing of the paste is avoided.

The effect of these major policy changes on children's oral health will be evaluated as part of the Health Research Board funded Collaborative Applied Research project **F**luoride **A**nd **C**aring for **C**hildren's **T**eeth (FACCT) study.

Aim of the FACCT study

The primary aim of the FACCT study is to evaluate the impact and the outcome of the change in CWF policy (2007) on dental caries and enamel fluorosis in Irish children, while also considering the change in policy on the use of fluoride toothpastes (2002).

This is the protocol for the collection, management and analysis of clinical and questionnaire data for children living in counties Dublin, Cork and Kerry in school year (SY) 2013-2014 (Wave 1) and SY 2016-2017 (Wave 2) to meet the primary aim of the FACCT study.

The FACCT study also includes an evaluation of the aesthetic acceptability of enamel fluorosis and dental caries, and the full CARG/2012/34 grant includes an economic evaluation of CWF and an assessment of the potential of electronic oral health records to generate oral health data that can be used to monitor trends in oral health which will be described elsewhere. An outline of the FACCT study is presented in Figure 1.

Objectives

1. To measure the level of dental caries in primary teeth of a representative sample of children aged 5 with and without lifetime exposure to CWF in Dublin, Cork and Kerry in SY 2013-2014.

2. To measure the level of dental caries and enamel fluorosis in permanent teeth of a representative sample of children aged 12 with and without lifetime exposure to CWF in Dublin, Cork and Kerry in SY 2013-2014.

3. To re-examine the 5-year-old children when they are aged 8 (SY 2016-2017) to measure the level of dental caries (primary and permanent teeth) and enamel fluorosis (permanent teeth).

4. To assess children's oral health knowledge, attitudes and behaviour via parental/caregiver questionnaires and self-administered questionnaires (12-year-olds SY 2013-2014; 8-year-olds SY 2016-2017) and to link oral health knowledge, attitudes and behaviour with clinical oral health measures.

5. To compare the level of dental caries in primary teeth of children aged 5 with and without lifetime exposure to CWF (SY 2013-2014) with the level of dental caries recorded in primary teeth of children aged 5 in the corresponding areas in the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006).

6. To compare the level of dental caries in permanent teeth of children aged 12 with and without lifetime exposure to CWF (SY 2013-2014) with the level of dental caries

recorded in permanent teeth of children aged 12 in the corresponding areas in the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006).

7. To compare the level of dental caries (primary teeth) and enamel fluorosis (permanent teeth) in children aged 8 years with and without lifetime exposure to fluoridated water (SY 2016-2017) with the level of dental caries and enamel fluorosis recorded in children aged 8 in the corresponding areas in the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006).

8. To examine the relationship between CWF and dental caries in 5- and 12-year old children (SY 2013-2014) and 8-year-old children (SY 2016-2017) in the study areas whilst controlling for other explanatory variables such as age, gender, oral health behaviours and deprivation.

9. To estimate the impact of oral health on the oral health-related quality of life (OHRQoL) of 12-year old children and their parents in SY 2013-2014, and on 8-year-olds and their parents in SY 2016-2017.

Secondary objective

To measure the weight and height of 5-, 8- and 12-year-olds and compare with BMI measured for the same age groups in 2002 as part of the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006).

Methods

Study Design

This is a cross-sectional oral health survey of a representative sample of children aged 5 and 12 living in counties Dublin, Cork and Kerry in SY 2013-2014. This is a nested longitudinal

study, whereby children who consent to participate in the study at age 5 will be re-examined when they are aged 8 (SY 2016-2017).

The study will compare the primary oral health outcomes dental caries and enamel fluorosis between children with lifetime exposure to CWF ("fluoridated") and children without lifetime exposure to CWF ("non-fluoridated").

The specific age groups are chosen to correspond with the WHO index ages for population surveys (World Health Organisation, 2013) and to allow back comparisons with data from previous Irish oral health surveys.

Children aged 5 in SY 2013-2014 (and aged 8 in SY 2016-2017) were born in 2008-2009 subsequent to both the introduction of recommendations on the use of fluoride toothpastes in young children (2002) and the reduction in the level of fluoride in piped public water supplies (2007), and thus have had full exposure to both policy changes since birth.

Children aged 12 in SY 2013-2014 were born in 2001-2002 at the time that recommendations on the use of fluoride toothpastes in young children were being introduced (2002) and 6 years before the reduction in the level of fluoride in public piped water supplies (2007). Thus children living in areas with CWF throughout their lives had partial exposure to both policy changes. Their permanent teeth mineralised with water fluoride at the higher level of 0.8–1 ppm fluoride but their permanent teeth were exposed to a reduced topical effect fluoride from approximately age 6 onwards.

Study location

The study will be conducted in counties Dublin, Cork and Kerry in the RoI. Dublin was selected because over a quarter (28%) of the population of Ireland resides in Dublin (Central Statistics Office, 2011) and it is served by large water treatment plants with an excellent record of control of CWF at the recommended levels. CWF is provided throughout Dublin. Cork and Kerry were selected to represent areas with and without CWF.

Ethical Approval

Ethical approval for the training and calibration of dental examining teams and for data collection, will be obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, prior to the commencement of the study. Informed consent will be obtained from the parents/guardians of participating children and assent from 8- and 12-year-old children.

Participants

Children in Junior Infants (aged 4–6 years) and 6th class (aged 11–13 years) in SY 2013-2014 attending randomly selected primary schools in counties Dublin, Cork and Kerry will be eligible to participate in the study.

Selection of schools

The sample of schools will be drawn using stratified cluster random sampling. A list of primary schools in Dublin, Cork and Kerry in SY 2011-2012 (the most recent data available at the time the sample is drawn) will form the sampling frame for the study. Schools for children with special educational needs will not be included in the sampling frame. All schools in Dublin receive a fluoridated water supply. For the Cork and Kerry schools, on the basis that children attending a school with a non-fluoridated water supply are more likely to live in a household without CWF, the sampling frame will be stratified by the fluoridation status of the school water supply, classified as fluoridated or non-fluoridated by the Principal Dental Officers of the Cork and Kerry regions. The sampling frame for Dublin, Cork and Kerry will be stratified by Community Care Area/Dental Area (n=11: 6 in Dublin, 5 in Cork/Kerry) and school size (small, medium and large). The use of community care/dental area as the smallest geographic unit for sampling replicates the sampling method used in the North South Survey of Children's Oral Health in 2002 (Whelton et al., 2006) and will allow

direct comparison between the two data sets. Randomly selected schools with an even distribution of gender will be approached to participate in the study.

Each selected school will be contacted, informed about the study and their willingness to participate ascertained. Where schools decline participation, a replacement school of the same size and fluoridation status will be selected within the same Community Care Area/Dental Area.

Sample size

The sample size calculation is based on prevalence and central tendency data for Dublin, Cork and Kerry obtained in the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006).

5-year-olds

Sample sizes of 5-year-olds will have in excess of 80% power, at a 5% level of significance, to demonstrate that:

- Mean dental caries levels are at least 20% lower in children with lifetime exposure to CWF compared with children without lifetime exposure to CWF living in Cork/Kerry in 2013-2014.
- In Cork/Kerry, the proportions of 8-year-old children (2016-2017) with lifetime exposure to CWF with no enamel fluorosis has increased by at least 5% from 2002.
- In Dublin, the proportion of 8-year-old children (2016-2017) with no enamel fluorosis has increased by at least 5.25% from 2002. Furthermore, the sample size will allow an estimate of the proportion of 8-year-old children with no enamel fluorosis to within 2.5%.

12-year-olds

Sample sizes of 12-year-olds in Cork/Kerry will have in excess of 80% power, at a 5% level of significance, to demonstrate that:

- Mean dental caries levels are at least 20% lower in children with lifetime exposure to CWF compared with children without lifetime exposure to CWF living in Cork/Kerry in 2013-2014.
- Sample sizes of 12-year-olds for Dublin will have sufficient precision to estimate caries levels in 2013-2014.

Adjustments to the sample size

The sample size is inflated by 40% to account for the design effect due to using a cluster sampling technique. As the 5-year-olds will be re-examined at age 8, the 5-year-old sample is further adjusted to account for loss to follow-up during the subsequent three years (20%). The sample is also adjusted to account for participants being classified as neither "fluoridated" nor "non-fluoridated" (20%) and for non-response (35%) (Table 8.1).

Selection of children within schools

Schools with a fluoridated water supply

The number of boys and girls in schools with a fluoridated water supply to be issued consent forms will be decided *a priori* by the study statistician. These children will be randomly selected within these schools by the examining teams using a random number generating software programme. In instances where there are a number of different classes within one school year (e.g. four different 6th classes in the same school), a class will be randomly selected. If insufficient numbers of children are present in the first class selected, another class will be randomly selected until the required number of children to issue consent forms is obtained. Children who are not selected to participate will receive a letter to advise parents/caregivers about the random selection process and to inform them that their child was not selected.

Schools with a non-fluoridated water supply

The total number of 5- and 12-year-old children attending schools with a non-fluoridated water supply in SY 2011-2012 is very close to the actual number required to meet the non-fluoridated sample size, therefore examining teams will issue consent packs to all eligible children attending these schools.

Consent and study documents

Each child who is selected to participate will be given a FACCT study pack to take home to their parents/caregivers. The pack will contain the following:

- **Study Information leaflet**
- **Parent/guardian consent and child assent form**
- **A parent questionnaire** comprising:
    - a residential history and type of water supply at each address (to establishing if the child has had lifelong exposure to fluoridated or non-fluoridated water supplies)
    - a brief child medical history to ensure suitability for examination
    - a questionnaire about the child's oral health behaviours and demographic details
    - Short form of the Parental-Caregivers Perceptions Questionnaire (P-CPQ) (Jokovic et al., 2003, Thomson et al., 2013).
- In Cork/Kerry a small **water bottle** with instructions about returning a home tap water sample will be included in the pack.

Copies of FACCT information leaflets, consent/assent forms, residential history forms and parent/caregiver questionnaires for 2013-2014 and 2016-2017 are available as supplementary files.

The consent forms and questionnaires will be piloted with parents and with 12-year-old children in local Cork schools (representing a spectrum of socio-economic groups), to assess content, terminology, presentation, clarity and respondent burden, and will be amended accordingly. The parent/caregiver questionnaires will be colour coded by age group to easily distinguish between the different age groups in the study. Each document in the consent pack will be labelled with a unique subject number barcode; this barcode will serve to match each subject's consent form and parent/caregiver questionnaire. The subject number barcode will be assigned centrally by the Oral Health Services Research Centre (OHSRC). Contact details for the OHSRC and the web address for the FACCT study will be provided on the study information leaflet so that parents can clarify any aspects of the study before deciding whether to consent.

Parents/guardians who permit their child to participate in the study will return the completed consent/assent form, medical history form, residential history form and questionnaire to the school in the envelope provided. Returned documents will be evaluated by the examining team for positive consent/assent and to ensure that there is no medical reason to exclude any child.

Eligible children whose parents/guardians return a completed consent/assent form and a completed medical history form will be included in the study. Eligible children whose parents do not consent or who do not assent in writing (8- and 12-year-olds only), or who are unable or unwilling to participate on the day (all age groups) will not be examined. Children with any medical condition that would mean their participation in the study would pose a risk to their health or wellbeing will also be excluded.

Returning incomplete paperwork will not preclude inclusion in the study provided that the consent/assent form and medical history form are completed. Every effort will be made to obtain missing residential history information via follow-up phone calls with

parents/caregivers (who consent to be contacted by the study team). Children whose parents/caregivers do not complete or partially complete the parent survey will be included in the study; however, the child's oral health data may consequently be excluded from some of the statistical analyses.

Paperwork and questionnaires returned by parents/caregivers of 5-year-old children who are not clinically examined (because they are absent on the day the examining team visit the school or because the child refuses to be examined on the day) will be retained and we will attempt to follow-up these children when they are aged 8 in SY 2016-2017.

Translation of study documents

The Irish language is the first official language of Ireland and the Official Languages Act 2003 promotes its use for official purposes. Therefore, all study documents will be translated into Irish by Ionad na Gaeilge Labhartha (University College Cork) and made available to parents/caregivers and participating children during the study.

A number of validated instruments will be translated into Irish for use in the study. In the case of these validated instruments (Parental-Caregivers Perceptions Questionnaire-P-CPQ (short form; (Jokovic et al., 2003, Thomson et al., 2013)), Child Perceptions Questionnaire for children aged 8 to 10 years old – $CPQ_{8\text{-}10}$ (long form; (Jokovic et al., 2004)), and Child Perceptions Questionnaire for children aged 11 to 14 years old – $CPQ_{11\text{-}14}$ (short form; (Foster Page et al., 2008, Jokovic et al., 2006)) a safeguard will be introduced to ensure the meaning of the validated instruments will be unchanged by the translation into Irish. The translated instruments will be back-translated into English by a second professional translator blind to the original English version. The original English versions and the back translated English versions will then be compared. The Irish wording will be adjusted where necessary to ensure that the meaning of the validated instruments is unchanged by the translation process.

Data Protection

UCC is the data controller for all data collected in the course of this study. The study will comply with the requirements of the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003. A detailed submission will made to the Office of the Data Protection Commissioner (ODPC) in relation to management of sensitive personal data collected as part of the FACCT study.

Training of examining teams

The examining teams will be trained in advance of the fieldwork. Dentists and dental nurses will be instructed in the overall design of the study and in the procedures involved in organising and conducting oral epidemiological fieldwork. A video resource explaining the procedures involved in organising and conducting oral epidemiological fieldwork will be produced and made available to assist the examining teams. Dental nurses will be trained to use direct data entry software on dedicated FACCT clinical laptops. Dentists will be trained in a series of small group interactive teaching sessions based around epidemiological measurement of dental caries, enamel fluorosis and developmental defects of enamel, including discussion of photographic images of enamel fluorosis. The dentists' training in recognising and scoring enamel fluorosis with Dean's Index (Dean, 1934) will be supplemented by an online fluorosis training tool (Whelton et al., 2014). Further school-based training and calibration to gold standard examiners will be undertaken in a local Cork school, involving clinical examination of children.

Manuals will be produced in 2013-2014 and 2016-2017 to assist the examining teams to organise and conduct the oral epidemiological fieldwork (Copies of the manuals are available as supplementary files).

Inter-examiner agreement will be determined using Kappa statistics and percentage agreement (Po). The arbitrary divisions provided by Landis and Koch (1977) will be used as

a guide in interpreting the Kappa statistics. Dentists will be required to achieve Kappa values above 0.6 indicating at least substantial agreement with the gold standard examiner for the dmf/DMF Index, Dean's Index and the DDE Index before commencing clinical fieldwork.

Data collection

Parent/caregiver questionnaire

Oral health behaviours and socio-demographic factors

The parent/caregiver questionnaire will be used to collect information about other explanatory variables, such as children's oral health behaviours and socio-demographic factors. The questionnaire will include questions about age of commencing toothbrushing with fluoride toothpaste, frequency of brushing and amount of toothpaste used at different points in the child's life (under 2 years, at 2–3 years and at the time of the survey). Parents/caregivers will also be asked about use of other fluoride modalities such as fluoride mouthrinse and fluoride tablets or drops. Information will be collected regarding snacking frequency and frequency of intake of sugar sweetened beverages. Parents/caregivers will be asked about infant feeding practices, type of infant formula used and source of water used to make up infant formula. Additional questions will be included regarding parental perceptions about the appearance of their child's teeth and dental attendance. Responses to questions about healthcare cover and parental education will be used to determine a measure of socio-economic status to be used in the analysis.

Parental-Caregivers Perceptions Questionnaire (P-CPQ)

Included in the FACCT parent/caregiver questionnaire is the short form version of the Parental-Caregiver Perceptions Questionnaire for children aged 6 to 14 years old ($P\text{-}CPQ_{6\text{-}14}$) (Jokovic et al., 2003, Thomson et al., 2013).

Child oral health-related quality of life (COHRQoL) and oral health behaviours questionnaire

Twelve-year-olds (SY 2013-2014) will complete a child oral health-related quality of life questionnaire (CPQ_{11-14} (short form) (Jokovic et al., 2006, Foster Page et al., 2008) and oral health behaviours questionnaire. Eight-year-olds (SY 2016-2017) will complete a child oral health-related quality of life questionnaire (CPQ_{8-10} (long form) (Jokovic et al., 2004) and oral health behaviours questionnaire. The questionnaires will be completed on a dedicated secure laptop computer prior to the children's dental examination. Electronic versions of each questionnaire will be created using Microsoft Access, in English and Irish. For 8-year-olds, the questionnaire will be accompanied by a voice-over to reduce the likelihood of difficulties associated with low literacy.

Clinical Examination

Eligible children will be examined in their school by a trained and calibrated dentist assisted by a trained dental nurse. A fieldwork manual (available as a supplementary file) will be available to assist examining teams in conducting the clinical examinations. School visits will be arranged at a time that suits the school staff. Clinical data will be entered directly on to a dedicated laptop computer using a software package designed for the North South Survey of Children's Oral Health (Whelton et al., 2006) and modified for this study. The examining team will confirm the child's name, signed parent/guardian consent and child's willingness to take part in the study. A new clinical record will be created in the direct data entry system, and the child's unique subject number barcode – which has been assigned centrally by the OHSRC and appears on the child's consent/assent form – will be scanned by a member of the examining team.

The dental nurse will enter the child's first and surname, gender, date of birth (from the consent form) and will also ask the child's age. The school name, school roll number,

examiner ID and dental nurse ID numbers will also be entered before the clinical examination commences.

Sequence of clinical examination

The clinical examinations for each age group will be conducted in the following order:

Sequence	Age Group (School Year)		
	5-Year-Olds (2013-2014)	8-Year-Olds (2016-2017)	12-Year-Olds (2013-2014)
1	Height and Weight	Height and Weight	Height and Weight
2	Dental caries	DDE	Self-perception of enamel opacities
3		Dean's Index	DDE
4		MIH	Dean's Index
5		Oral photographs	Oral photographs
6		Dental caries	IOTN– aesthetic component
7			Dental caries

Dental caries

Dental caries will be measured in 5-year-old children initially in 2013-2014 (primary teeth) and in the primary and permanent teeth of the same children when they are aged 8 in 2016-2017. Dental caries will be measured in the permanent teeth of 12-year-old children in 2013-2014. The dental caries examination will be performed in a similar manner to the procedure used in the North South Survey of Children's Oral Health 2002 (Whelton et al., 2006) by a trained and calibrated dentist. Data will be entered by a trained dental nurse onto a dedicated clinical laptop.

Each child will lie on a table covered with a foam camping mat, with a clean disposable head rest cover under their head. The teeth will be examined wet, and a WHO Community Periodontal Index (CPI) probe (World Health Organisation, 2013) will be used to remove plaque and food debris and/or to confirm cavitation. Lighting will be provided by a portable dental light source ('Daray' lamp: (www.daray.co.uk)). Dental caries will be measured at the dentine level of involvement (d_{3c}mft/s and D_{3c}MFT/S), according to WHO examination

criteria (World Health Organisation, 2013). These criteria will be expanded to include coding for non-cavitated dentinal caries, where caries is visible as a shadow under the enamel but does not have a detectable cavity through the enamel (d_{3vc}mft/s and D_{3vc}MFT/S, 'v' indicating 'visual' caries). Tooth surfaces with fixed braces or bands (i.e. banded/covered tooth surfaces) will be excluded from this examination. Parents of children for whom an urgent need for dental treatment is noted will be notified by the examining team.

Enamel fluorosis

Dean's Index

Enamel fluorosis will be recorded in the permanent teeth of 8-year-olds (2016-2017) and 12-year-olds (2013-2014) using Dean's index (Dean, 1934).

Dean's index records fluorosis at the level of the subject, i.e. it is a whole mouth score. The procedure used to record Dean's Index is the same as that used in the 1984 and 2001-2002 national surveys of children's oral health (O'Mullane et al., 1986, Whelton et al., 2006). The child will be examined in the upright position, facing natural light, with the examiner facing the child with his or her back to the light (window). Teeth with orthodontic bands or brackets will be excluded.

All teeth will be examined for fluorosis, and if fluorosis is present, Dean's Index will be scored on the condition of the two most severely affected teeth. If the two teeth are not equally affected, the less affected tooth will be scored.

Oral photographs of incisor teeth

Assessment of fluorosis using photographs addresses the subjective nature of clinical assessment of fluorosis, by allowing the assessment to be conducted by an independent researcher who is blind to the fluoridation status of the subjects. For this study, dental examiners will be trained to take digital oral photographs of the incisor teeth according to a

standardised photographic procedure (a modified version of that developed by Cochran et al. (2004)). These digital oral photographs of the incisor teeth will be assessed by an experienced researcher at the OHSRC, using the Thylstrup Fejerskov (TF) index (Thylstrup and Fejerskov, 1978) as modified by Fejerskov et al. (1988).

The teeth will first be photographed "wet" to record the appearance of the teeth under normal conditions. This is important from a public health perspective, as the use of photographs can enhance minor defects, particularly if the teeth are dry, and could lead to an overestimate of the prevalence of defects. The teeth will also be photographed "dry" to allow detection of fluorosis at the very lowest levels of severity.

The teeth will be photographed using a Canon EOS 1100D digital camera with a Sigma 105mm macro lens and Sigma EM140-DG macro ring flash for even lighting. The photographs will be taken from approximately 30 degrees above the perpendicular to reduce lip shadow. In practice, this is a subjective assessment and where doubt occurs, the examiner should bear in mind that it is better to over-estimate the camera angle and be slightly steeper. Photographs will be expected to fall between 30^{o} and 45^{o} above the incisal edge of the tooth. The reproduction will be set at 1:1, or life-size. Further information regarding the method used to photograph the incisor teeth can be found in the fieldworker manuals 2013-2014 and 2016-2017 provided as supplemental files.

To avoid any possibility of difficulty identifying the photograph associated with a particular child due to incomplete record keeping or loss of paper-based records, four images will be taken per child: the first and fourth images will be of the child's barcode from the consent form and the second and third images will be of the child's teeth. This will ensure that at all times, the image and subject number can be matched simply by sorting all images by the time and date when they were taken.

DDE (Developmental Defects of Enamel):

Not all opacities of enamel are fluorosis. It is important to distinguish between developmental defects of enamel that are not typical of fluorosis, and those that are measured using the fluorosis indices, since non-fluorotic opacities could affect the appearance of teeth, and consequently influence perceptions of aesthetic acceptability and quality of life. The DDE index (Clarkson and O'Mullane, 1989) records the presence of any enamel opacities or defects in the quantity or quality of enamel without attributing a cause.

The index tooth surfaces to be examined using the DDE in this study are the labial surfaces of the maxillary first pre-molar, canine and incisor teeth and the buccal surfaces of the mandibular first permanent molars.

Molar Incisor Hypomineralisation

Molar-Incisor hypomineralisation (MIH) is a developmental condition resulting in enamel defects in first permanent molars and permanent incisors. Enamel defects can range from mild opacities, white or yellow in colour, to severe enamel involvement, which breaks down rapidly shortly after tooth emergence (Daly and Waldron, 2009). In addition to being of public health importance due to the symptoms associated with it and the complexity of treating the condition, MIH could potentially be confused with the 'moderate' and severe Dean's Index scores. Therefore examiners will be trained to recognise the condition and to note the presence or absence of MIH in the clinical record.

Self-perception of enamel opacities

Measurement of self-perceived enamel opacities will be recorded according to the procedure outlined in the NHS Dental Epidemiology Programme Oral Health Survey of 12-year-old children, 2008-2009 National Protocol (www.nwph.net/dentalhealth/). The examining teams will be provided with a laminated page showing three sets of photographs, showing groups of teeth with varying types of appearance.

The examiner will ask each 6th class child:

Question	***Response*** (entered into the clinical record)
"Do you have any white marks on your front teeth that won't brush off? "	*Yes* *No* *Don't know*
For those who say **"Yes",** the examiner then asks: **"Does the appearance of these white marks bother you?"**	*Yes* *No* *Don't know*
The examiner shows three sets of photographs showing groups of teeth with varying types of appearance. **All children** are then asked **"Thinking about white marks on teeth, do you think your front teeth look more like those in this group, or the ones in this group, or this group?"**	*Photograph set N* *Photograph set S* *Photograph set A* *Don't know*

Index of Orthodontic Treatment Need – aesthetic component (IOTN)

The IOTN has two components which independently measure the need for orthodontic treatment based on aesthetic grounds and on dental health grounds. In the FACCT study, only the aesthetic component will be used to control for impact on quality of life and on perceptions of aesthetics that are due to malocclusion rather than caries or fluorosis. A set of ten special colour photographs will be used to gauge the Aesthetic Component.

To measure the Aesthetic Component of the IOTN:

- The child is seated upright and the examiner views the teeth from in front of the child. The examiner asks the child to close together on their back teeth, then retract the lips to expose the anterior teeth.
- The dental attractiveness is then rated using the 10-point Aesthetic Component scale:
    - **Grades 1-4** represent no need for orthodontic treatment
    - **Grades 5-7** represent a borderline need
    - **Grades 8-10** represent a definite need for orthodontic treatment on aesthetic grounds.

- The anterior teeth should be rated on their dental attractiveness as seen, rather than specific morphological similarity to the photographs. Stained teeth, enamel fractures and gingival inflammation should be ignored.

Height and Weight

Children's height will be measured using Leicester Height Measure and weight will be measured using a calibrated Tanita professional weight scales. Measurements of height and weight will be taken in a sensitive and confidential manner.

Ensuring consistency of outcome measurement during the study

To measure intra-examiner agreement, 5% of the children will be examined twice by the same dental examiner for the relevant clinical indices within a 1–7 day interval. The dental examiner will not know, *a priori,* which child is going to be examined twice. Where the initial and repeat examinations are conducted on the same day, examining teams will be advised to allow maximum time between the child's first examination and the re-examination to minimise recall bias.

Duplicate examinations for dmf/DMF, height and weight will be conducted for all age groups. Additional duplicate measurements will vary depending on the age of the child. Where relevant, duplicate examinations will be conducted for Dean's Index, DDE Index, IOTN aesthetic component, self-perception of enamel opacities and Molar Incisor Hypomineralisation. For 5% of subjects, a repeat oral photograph will be taken by the same examiner.

To measure inter-examiner agreement, 5% of the children will be re-examined by a gold standard examiner for all relevant indices. Duplicate examinations will be facilitated by

arranging for the gold standard examiner to visit at least one school together with the dental examiner in each study area to examine the children.

Intra-examiner and inter-examiner agreement will be determined using Kappa statistics and percentage agreement (Po). The arbitrary divisions provided by Landis and Koch (1977) will be used as a guide in interpreting the Kappa statistics.

Classification of fluoridation status

Monthly sample results concerning the level of fluoride in each fluoridated water supply in Dublin, Cork and Kerry will be compiled from the beginning of 2000 (the likely earliest date of birth of a 6th class child in SY 2013-2014). Records will be updated continuously until fieldwork ends in 2017. Maps of distribution networks and data concerning changes to distribution systems will be gathered from engineers, initially up to mid-2014, and again up to mid-2017. Each child's residential history will be analysed to establish if it meets the criteria for being classified as fluoridated or non-fluoridated; if not, children will be classified as part-fluoridated, or unknown where data are incomplete or where children have lived abroad. A more detailed description of the rules used in classifying the fluoridation status of each child and the rationale for same is available as a supplementary file.

Data analysis and statistical plan

The impact of CWF on dental caries experience adjusted for the effect of behavioural and socio-demographic factors, will be assessed by conducting multivariable regression analyses using appropriate statistical models. The negative binomial hurdle model (NB-Hurdle), the Poisson Regression Model (PRM) and the Negative Binomial Regression Model (NBRM) will be considered. Model selection will be guided by tests such as the Likelihood-ratio (LR) test, Vuong test, Akaike's Information Criterion (AIC) and the Bayesian Information Criterion (BIC).

The main explanatory variable in the regression analyses will be the fluoridation status of the child, categorised as 'fluoridated', where the child has always resided in an area with CWF, and 'non-fluoridated', where the child has never resided in an area with CWF. The analyses will be adjusted for variables such as age, gender, toothbrushing practices, use of toothpaste, whether the child was breastfed, frequency of snacking (sweet foods or drinks), attendance at the dentist, and socioeconomic status.

The impact of CWF on enamel fluorosis adjusted for the effect of behavioural and socio-demographic factors, will be assessed using logistic regression analyses. The analyses will be adjusted for variables such as age, gender, toothbrushing practices, use of toothpaste, whether the child was breastfed and where relevant, type of water used to make up infant formula.

The conventional p-value of < 0.05 will be chosen as the level of significance for all statistical calculations.

Interactions between all explanatory variables will be tested using moderated multiple regression. Only interaction terms significant at the 5% level in moderated multiple regression will be included in the final analyses. Stata SE 10 (StataCorp, 2007), SAS Version 9 or IBM SPSS Version 23 will be used to analyse the data.

To estimate the impact of oral health on oral health-related quality of life (OHRQoL) of children and their parents the subscale and total scale scores from the validated instruments employed in the study will be correlated with dental caries and enamel fluorosis levels.

The study results will be reported in accordance with the STROBE guidelines for reporting of observational studies (von Elm et al., 2014)

Dissemination and communication of study results

FACCT results and outcomes will be disseminated to collaborators, policyholders, dental and health professionals and the public, including the school bodies who will be associated with the conduct of FACCT research, through oral presentations, written reports and information leaflets. Presentations including conference proceedings such as slides of study results and scientific posters and leaflets of study results will be posted on the FACCT website (facct.ucc.ie). Key study results will be written up and submitted for publication in peer reviewed journals.

Competing Interests

No competing interests were disclosed.

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Supplementary material:

The following documents contained in the FACCT consent packs in 2013-2014 and 2016-2017 are available as supplementary files at https://hrbopenresearch.org/articles/1-4/v1

- FACCT information leaflet 2013-2014
- FACCT information leaflet 2016-2017
- FACCT consent/assent form 2013-2014
- FACCT consent/assent form 2016-2017
- FACCT residential history form 2013-2014
- FACCT residential history form 2016-2017
- FACCT parent/caregiver questionnaire Junior Infants (age 4-6) 2013-2014
- FACCT parent/caregiver questionnaire 6th class (age 11-13) 2013-2014
- FACCT parent/caregiver questionnaire 2nd class (age 7-9) 2016-2017

The rules that guided the classification of the fluoridation status of each child and the rationale for the classification system used are available as supplementary files at https://hrbopenresearch.org/articles/1-4/v1

FACCT Fluoridation Status Rules

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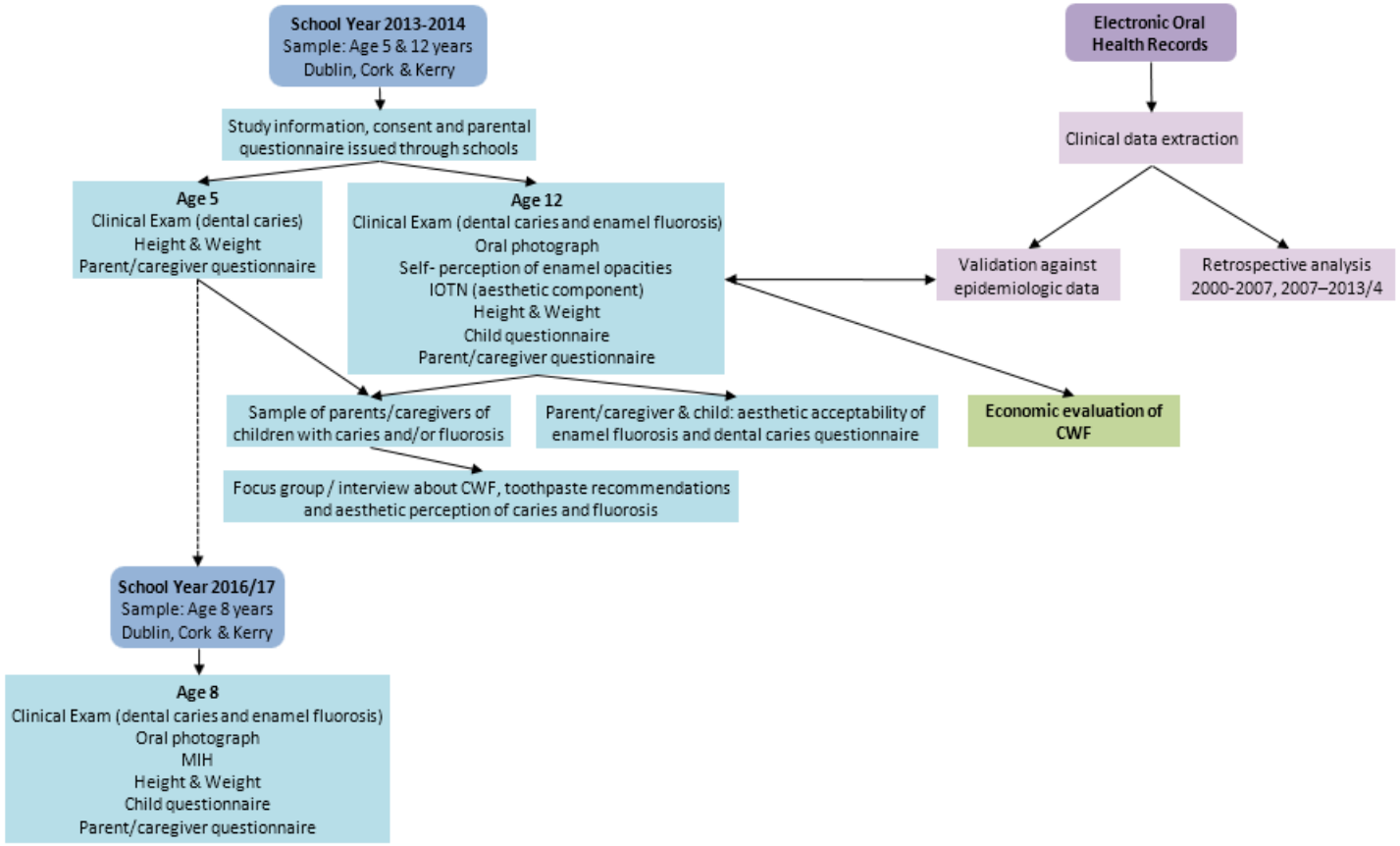
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Table 8.1. FACCT sample size adjustments

Age	Region	Fluoridation Status	n	Design effect + 40%	Loss to follow up 20%	Neither F nor NF 20%	Non-response 35%	Final n to issue consents to
5	Dublin	Full	497	696	870	1087	1673	**1673**
	Cork/Kerry	Full	424	594	742	928	1427	**1427**
		Non	424	594	742	928	1427	**1427**
12	Dublin	Full	432	605	605	756	1163	**1163**
	Cork/Kerry	Full	442	619	619	774	1190	**1190**
		Non	442	619	619	774	1190	**1190**
TOTAL			**2661**	**3725**	**4196**	**5245**	**8070**	**8070**

Figure 1. Schematic of the FACCT Study



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Impact of Reducing Water Fluoride on Dental Caries and Fluorosis.

James P, Harding M, Beecher T, Browne D, Cronin M, Guiney H, O'Mullane D, Whelton H. 2021. Impact of Reducing Water Fluoride on Dental Caries and Fluorosis. J Dent Res. 100(5):507-514.

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A supplemental appendix to this article is available.

Keywords: Water fluoridation, Dean's Index, fluoride toothpaste, dental health surveys, prevalence, public health.

Note: This is the authors' final version of the article first published online on December 21 2020. The permanent link for the article is https://doi.org/10.1177/0022034520978777.

Abstract:

Introduction: Guidance intended to reduce fluoride toothpaste ingestion in early childhood was introduced in Ireland in 2002. In 2007, water fluoride concentration was adjusted from 0.8-1.0 to 0.6-0.8 ppm.

Objective: To determine the difference in caries and fluorosis levels following introduction of these two policy measures.

Methods: A before and after study compared caries and fluorosis in random samples of 8-year-olds in Dublin (n=707) and Cork-Kerry (n=1148) in 2017 with 8-year-olds in Dublin (n=679) and Cork-Kerry (n=565) in 2002. Dentinal caries experience (primary teeth, d_{3vc}mft(cde)) and fluorosis (permanent teeth, Dean's ≥ 'very mild') were clinically measured. Lifetime exposure to community water fluoridation (CWF) was classified as 'Full-CWF'/'No-CWF'. Effect of examination year on caries prevalence and severity and fluorosis prevalence was assessed using multivariable regression adjusting for other explanatory variables.

Results: There was little change in commencement of fluoride toothpaste use at ≤24 months following introduction of toothbrushing guidance. Among children with Full-CWF, there was no statistically significant difference in caries prevalence or severity between 2017 and 2002. In 2017, caries prevalence was 55% in Dublin (Full-CWF) and 56% in Cork-Kerry (Full-CWF) and mean d_{3vc}mft(cde) among children with caries was 3.4 and 3.7, respectively. Caries severity was less in 2017 (mean 4.2) than 2002 (mean 4.9) among children with No-CWF ($P = 0.039$). The difference in caries severity between children with Full-CWF and No-CWF was less in 2017 than 2002 (Interaction $P = 0.013$), suggesting a reduced benefit for CWF in 2017. In 2017, fluorosis prevalence was 18% in Dublin (Full-CWF) and 12% in Cork-Kerry (Full-CWF). Fluorosis was predominantly 'very mild' with no statistically significant difference between 2017 and 2002.

Conclusion: CWF at 0.6-0.8 ppm is an effective caries-preventive measure. Results suggested low uptake of toothbrushing guidance, a reduced caries-preventive effect for CWF in primary teeth and no reduction in fluorosis following introduction of the policy measures.

Introduction:

Dental caries presents a major public health challenge especially for lower socio-economic groups (Bernabe et al. 2020) for which community water fluoridation (CWF) is a safe and effective strategy (Jack et al. 2016). CWF reaches all socio-economic groups without active participation of individuals (O'Mullane et al. 2016). Fluoride toothpaste provides caries prevention additional to CWF (Marinho et al. 2003). The benefits of fluoride for preventing caries must be balanced against the risk of developing dental fluorosis from fluoride ingestion during amelogenesis. Moderate and severe fluorosis may adversely affect aesthetics and oral health-related quality of life (OHRQoL) (Chankanka et al. 2010).

Following introduction of CWF at 0.8–1.0 ppm fluoride (Government of Ireland 1960) and increasing use of fluoride toothpaste, there was a substantial decline in caries in Irish children (O'Mullane et al. 1986). However, by 2002, with 71% of the population supplied by CWF and fluoride toothpaste widely used, dental fluorosis had increased, particularly among children with lifetime exposure to CWF (Whelton et al. 2006). This prompted two new policy measures aimed at minimising the occurrence of dental fluorosis while maintaining reductions in caries. Firstly, with fluoride toothpastes holding over 95% of the market in Ireland, guidance was introduced in 2002 to reduce ingestion of fluoride toothpaste in early childhood (Department of Health and Children 2002). Parents were advised to delay commencing toothpaste use until after age 24 months and to supervise toothbrushing using a small pea-sized amount of toothpaste up to age 7. The majority of children's toothpastes used in Ireland contained at least 1000 ppm fluoride. Although low fluoride toothpastes (500 ppm or less) were available, the guidance did not recommend their use as their effectiveness was deemed uncertain. This toothbrushing guidance remains in place following recent review of the evidence underpinning it (O'Mullane et al. 2018). Secondly, in 2007, the fluoride concentration of public water supplies was adjusted downwards to a range of 0.6-0.8 ppm fluoride with a target of 0.7 ppm.

Several other countries with CWF such as Hong Kong, Singapore, Malaysia, Canada and the United States (U.S.) have also lowered water fluoride concentration. The adjustment in the U.S. from a range of 0.7-1.2 to 0.7 ppm fluoride (U.S.H.H.S. 2015) is similar to that in Ireland. Reports from Hong Kong and Malaysia indicate a downward trend in dental fluorosis without an increase in caries (Evans and Stamm 1991; Wong et al. 2014; Lee et al. 2016; Mohd Nor et al. 2018). However, it is difficult to generalise the results of these studies due to cultural and contextual differences.

This paper reports on the Fluoride and Caring for Children's Teeth (FACCT) study, which aimed to evaluate the impact of downward adjustment of water fluoride concentration and introduction of toothbrushing guidance on caries and fluorosis in Ireland. The objectives were to determine if there was a difference in 1) the prevalence and severity of caries in primary teeth and 2) the prevalence of fluorosis in permanent teeth of children born after introduction of the policy measures compared with children examined in the same regions in 2002 in the North South Survey of Children's Oral Health (Whelton et al. 2006), prior to introduction of the policy measures.

Methods

Ethical approval (Clinical Research Ethics Committee of the Cork Teaching Hospitals, ECM 5 (2) 07/05/13), written informed consent from parents/guardians, and child assent were obtained. This manuscript follows STROBE guidelines (von Elm et al. 2008).

Study setting and design:

In 2017, 71% of the Irish population had access to CWF, the remainder supplied by non-fluoridated water schemes or private wells. This study was conducted in Counties Dublin, Cork and Kerry. One quarter of the population of Ireland reside in Dublin (Central Statistics Office 2017) with CWF, while Counties Cork and Kerry have a mix of areas with and without CWF.

Using a before and after study design (Figure), caries in primary teeth and fluorosis in permanent teeth of 8-year-olds 2017 were compared with 8-year-olds 2002. At both time points, children were aged 7-9 (fourth year of primary school). Eight-year-olds in 2017 were participants in a longitudinal study that commenced in 2014 (FACCT phase 1) when they were 5-year-olds (first year of primary school). The methods of the FACCT study and the 2002 survey were previously reported (Whelton et al. 2006; James et al. 2018). As domestic water supplies throughout urban Dublin are fluoridated, no concurrent control group was available in Dublin. However, concurrent control groups with no exposure to CWF were available in 2002 and 2017 in Cork-Kerry, facilitating a controlled before-and–after study in this region. Eight-year-olds examined in 2017 were born after introduction of toothbrushing guidance (2002) and downward adjustment of water fluoride concentration (2007) and thus had lifelong exposure to both policy measures. Conversely, 8-year-olds in 2002 had exposure to neither policy measure.

Study sample:

Samples were selected in 2002 and 2014 using the same method of multistage stratified cluster random sampling with school as the primary sampling unit. For children with CWF in 2017, the target sample size of 424 8-year-olds in Cork-Kerry and 497 8-year-olds in Dublin had in excess of 80% power, at a 5% level of significance, to demonstrate that the proportion of children with Dean's Index scores 'normal' in each region had increased by at least 5% since 2002. This sample size had 80% power to demonstrate a difference in d_{3vc}mft(cde) of 20% in Dublin and Cork-Kerry for children with CWF in 2017 relative to 2002.

Measurement of exposure to CWF

Data from mandatory monitoring of fluoride levels in public water supplies in Ireland confirmed that the downward adjustment was implemented from mid-2007 (Appendix

Figure 1). Parents detailed their child's full residential history. Exposure to CWF in 2002 and 2017 was classified individually based on the fluoride concentration of water supplying the child's current and previous addresses. Participants were classified as having lifetime exposure (Full-CWF), no exposure (No-CWF), sporadic exposure (Part-CWF), or 'unknown' exposure to CWF. Analyses reported here relate to children with Full-CWF and No-CWF.

In 2002, following a defined protocol, examining teams classified the fluoridation status of children in their area, whereas in FACCT, this classification was completed after clinical examination by researchers not involved in clinical fieldwork. In principle, classification of exposure to CWF was the same in FACCT and 2002 surveys. However, with the passage of time, access to new resources including the Irish Water website (https://www.water.ie/water-supply/water-quality/) facilitated use of more sophisticated methods for classifying fluoridation status in the FACCT study.

Measurement of dental caries and fluorosis:

Dental examiners assisted by dental nurses conducted clinical examinations in schools January-June 2002 and November 2016-May 2017. The same experienced gold standard examiner (HW) supported by assistant gold standard examiners, trained and calibrated different groups of examiners in 2002 and 2017 (Appendix Table 1). Methods for measuring caries and fluorosis were identical in 2002 and 2017 as described previously (James et al. 2018). Teeth were not dried for either examination. Caries in primary teeth was measured using WHO criteria (World Health Organisation 2013) modified to include visible non-cavitated dentinal caries (d_{3vc}mft, 'v' indicating 'visual caries') (Whelton et al. 2006). Caries experience was reported as the proportion of children with decayed, missing or filled primary canines, first or second primary molars (prevalence, d_{3vc}mft(cde)>0) and mean d_{3vc}mft(cde) among children with caries experience (severity). For fluorosis, a person-level Dean's Index score was assigned following assessment of all permanent teeth present (Dean 1942). Case definition for fluorosis was a Dean's Index score 'very mild' or higher.

Measurement of other explanatory variables:

Socio-demographic and oral health behaviours data were collected in 2002, 2014 (at age 5, FACCT phase 1) and 2017 (at age 8, FACCT phase 2) via a parent-completed questionnaire. Relevant explanatory variables common to the 2002 and FACCT data sets were identified, and categorical responses grouped for analysis (Table 1).

Statistical Analysis:

Repeat examinations during fieldwork yielded intra-examiner kappa scores for caries ranging from 0.86 to 1.00 (median 0.97) in 2002 and 0.77 to 1.00 (median 0.92) in 2017 and for fluorosis from 0.40 to 1.00 (median 0.67) in 2002 and 0.57 to 1.00 (median 0.92) in 2017. Although inter-examiner reliability with gold standard examiners was monitored in 2002, kappa scores are unavailable. In 2017, kappa scores for inter-examiner reliability for caries ranged from 0.55 to 0.92 (median 0.81) and for fluorosis from 0.43 to 1.00 (median 0.74).

Multivariable regression with a negative binomial Hurdle Model (HNB) assessed the association between year of examination and prevalence and severity of caries, adjusted for the effect of other relevant explanatory variables. The HNB is a two-part model which assesses 1) the association between year of examination and caries prevalence and 2) the association between year of examination and caries severity among children with caries experience. Differences between children with Full-CWF and No-CWF in Cork-Kerry were compared (2017 vs 2002) by testing the interaction between fluoridation (Full-CWF vs No-CWF) and year of examination.

Multivariable logistic regression assessed the association between year of examination and prevalence of fluorosis, adjusted for the effect of other relevant explanatory variables. Differences in severity were not assessed because numbers with 'mild' and 'moderate' fluorosis were too low to be considered separately.

Interactions between year of examination and all other explanatory variables were tested but none were statistically significant. The lower proportion of children examined in 2017 with Full-CWF (25%) compared with 2002 (51%) (Appendix Figures 2 and 3), reflected improvements in access to electronic data for classification of lifetime exposure to CWF. Thus, a proportion of children classified as Full-CWF in Cork-Kerry 2002 may have had Part-CWF. A sensitivity analysis indicated that re-classifying Part-CWF 2002 as Full-CWF or No-CWF did not change the overall findings (Appendix Table 2). Thus, any potential misclassification of exposure to CWF in 2002 was considered unlikely to have had an important impact on the results. Data were analysed using STATA (IC Version 14.2) and SAS (Version 9.4) software.

Results

The flow of participants through FACCT and 2002 surveys are outlined in Appendix Figures 2 and 3. The response rate was 68% in 2002 and 72% for phase 1 of FACCT (2014). Of 4215 children invited to participate in phase 1 of FACCT, 2308 (55%) were examined for caries and 2304 (55%) for fluorosis in phase 2 (2017). Characteristics of children whose parents consented to participate in 2014 and of children who were followed up and examined in 2017 were similar (Appendix Table 3). Of children examined in Dublin, 94% in 2002 and 89% in 2017 had Full-CWF. Of those examined in Cork-Kerry 51% in 2002 and 25% in 2017 had Full-CWF, whereas 36% in 2002 and 51% in 2017 had No-CWF.

Approximately one-third of the population are eligible for a medical card (PCRS). The proportion of the samples in 2002 and FACCT surveys who were dependants of medical card holders was 21% and 26%, respectively (Table 1). Compared with 2002, a higher proportion of children in 2017 brushed at least twice a day and used a pea-sized amount of toothpaste or less. However, despite advice to delay commencing fluoride toothpaste use until after 24 months, 80% of parents in 2017 with Full-CWF and No-CWF indicated that they first used toothpaste with their child at ≤24 months compared with 76%-86% in 2002.

In Dublin (Full-CWF), caries prevalence was 55% in 2017 compared with 54% in 2002. Among children with caries experience, mean d_{3vc}mft(cde) was 3.4 (SD 2.3) in 2017 compared with 3.3 (SD 2.1) in 2002 (Table 2). Multivariable regression revealed no statistically significant difference in either the prevalence or severity of caries in Dublin children (Full-CWF) in 2017 relative to 2002 (Table 3). Results were similar among children with Full-CWF in Cork-Kerry. Among children with No-CWF in Cork-Kerry, caries prevalence and mean d_{3vc}mft(cde) were higher at both time points compared with their Full-CWF counterparts. The difference in caries prevalence among children with No-CWF in Cork-Kerry in 2017 (65%) relative to 2002 (73%) was not statistically significant. However, among children with caries, the reduction in mean d_{3vc}mft(cde) from 4.9 (SD 2.6) in 2002 to 4.2 (SD 2.5) in 2017 was statistically significant (reduction in mean 13%, CI 1 to 24) (Table 3). The difference in caries prevalence between children with Full-CWF and No-CWF in Cork-Kerry was similar in 2002 and 2017 (Interaction $P = 0.098$). However, among children with caries experience, the difference in caries severity between children with Full-CWF and No-CWF was less in 2017 than 2002 (Interaction $P = 0.013$).

Among children with Full-CWF in Dublin, fluorosis prevalence was 18% in 2017 and 15% in 2002 and in Cork-Kerry it was 12% in 2017 and 13% in 2002 (Table 4). Fluorosis prevalence among children with No-CWF in Cork-Kerry was 5% in 2017 and 3% in 2002. None of the differences were statistically significant (Table 3).

Other explanatory variables associated with increased prevalence and/or severity of caries in 2002/2017 were medical card ownership, brushing once/day or less (vs twice/day or more), having sweet foods/drinks more than once a day between meals, and visiting the dentist (vs never) (Appendix Tables 4-6). In Dublin (Full-CWF), first using toothpaste at ≤24 months was associated with reduced prevalence of caries (Appendix Table 4). In Dublin (Full-CWF), being female (vs male) was associated with increased prevalence of fluorosis (Appendix Table 7).

Discussion

Following introduction of the policy measures, there was no increase in caries but the expected reduction in dental fluorosis was not observed. Although fluorosis prevalence was low with little or no impact on OHRQoL (Chankanka et al. 2010), the latter findings suggest that reduction in fluoride absorption in early childhood was not achieved.

As compliance with reducing fluoride levels in water was excellent, the findings could be explained by increased ingestion of fluoride from discretionary sources. As fluoride supplements and infant formula reconstituted with fluoridated water are not considered important risk factors for fluorosis in Ireland (Department of Health and Children 2002; Anderson et al. 2004; FSAI 2018), the most important source of discretionary fluoride is fluoride toothpaste. Knowledge about certain desirable oral health behaviours such as brushing twice a day, using a pea-sized amount of toothpaste and not to use a glass to rinse after toothbrushing increased since 2002. However, acknowledging the risk of recall bias, there was low uptake of advice in relation to age of commencing fluoride toothpaste use. The Dental Health Foundation Ireland (dental health.ie), promotes official oral health messages using different strategies to engage with the public and the dental profession. As dental visiting was low in Ireland among infants and young children (Whelton et al. 2006; Parnell et al. 2007), advice from dental health professionals regarding use of fluoride toothpaste in early childhood was unlikely to be timely. Children under age 30 months ingest much of the toothpaste (Cochran et al. 2004), thus increased toothbrushing frequency could have compensated for reduced exposure to water fluoride, offsetting a reduction in dental fluorosis.

Toothpaste use in early childhood and increased frequency of toothbrushing could also help to explain the reduced severity of caries in children with No-CWF. A similar trend in caries was not apparent in children with Full-CWF despite similar reported toothbrushing behaviours in children with Full-CWF and No-CWF in 2017. These trends indicate that the

caries-preventive effect of CWF may have reduced following adjustment of water fluoride concentration.

The majority of children at both time points had experienced caries in their primary dentition. The first opportunity for these children to avail of free routine dental care was at age 7-9. Attending the dentist was associated with increased caries levels in primary teeth reflecting a pattern of dental attendance for caries-related problems. The recent Irish Oral Health Policy aims to reduce caries in the primary dentition through early access to preventive services (Department of Health 2019).

Randomised controlled trials are often not feasible when evaluating complex public health interventions (Jack et al. 2016). A major strength of this pragmatic study was the thorough individual classification of exposure to CWF. A further strength was assessment of caries and fluorosis using identical protocols at both time points with training led by the same experienced gold standard examiner. Also, control groups at both time points facilitated assessment of temporal trends in caries and fluorosis in children with No-CWF. Multivariable regression controlled for any differences in demographics or oral health behaviours between the groups being compared.

However, the study has some limitations. Firstly, examiners were not blind to participants' fluoridation status because transporting children to a neutral venue was not logistically feasible. In FACCT, although examiners likely knew whether the child's school was in a fluoridated or non-fluoridated area, risk of bias was mitigated by ensuring that examiners were not aware of the child's exposure to CWF throughout their lives. Secondly, a shortcoming of Dean's Index as applied in this study is that the teeth that were the basis for the whole mouth score were not recorded. Therefore, fluorosis affecting the aesthetically important maxillary incisors could not be quantified. The impact of the policy measures on fluorosis measured from photographs is underway, focussing on maxillary permanent incisor

teeth. This will facilitate blind scoring and allow assessment of the impact of the policy measures on fluorosis in aesthetically important teeth.

Although a downward trend in dental fluorosis without a corresponding increase in caries was reported in Hong Kong and Malaysia following downward adjustment of water fluoride concentration (Evans and Stamm 1991; Wong et al. 2014; Lee et al. 2016; Mohd Nor et al. 2018), comparison with our results is hampered by the adjustments involving different concentrations of fluoride, different climates, methodological differences between the studies and cultural and contextual differences between the populations. An alternative approach adopted in Australia in the early 1990s to maintain the water fluoride concentration while targeting reductions in exposure to discretionary sources of fluoride, was successful in achieving a reduction in fluorosis prevalence (Riordan 2002; Do and Spencer 2007), with increased use of low-concentration fluoride toothpaste shown to be largely responsible for the reduction (Do and Spencer 2007). Studies of the caries-preventive effect of low-concentration fluoride toothpastes in primary teeth have produced conflicting results (Walsh et al. 2019) and further research is warranted.

Lowering the fluoride level of CWF has been questioned on the basis that it reduces the benefit for caries prevention across the life course in order to reduce the risk of dental fluorosis in early childhood (Spencer and Do 2016). Caries development in the primary dentition sets children on a steep trajectory towards further disease experience in the permanent dentition (Hall-Scullin et al. 2017). Dental fluorosis, on the other hand, does not progress and may decline in severity over time (Do et al. 2016; Curtis et al. 2020). The trend of increasing fluorosis that prompted introduction of the policy measures has stabilised. CWF at 0.6-0.8 ppm fluoride is an effective caries-preventive measure. However, there are indications that downward adjustment of water fluoride concentration has reduced the caries-preventive effect of CWF. Evaluating the impact of the downward adjustment on caries in permanent teeth of children and adults with CWF is a priority for further research.

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Author Contributions:

P James contributed to conception, design, data acquisition, analysis and interpretation, drafted and critically revised the manuscript. M Harding contributed to conception, design, data acquisition, analysis and interpretation, drafted and critically revised the manuscript.

T Beecher contributed to conception, design, data acquisition and critically revised the manuscript. D Browne contributed to conception, design and critically revised the manuscript. M Cronin contributed to conception, design, analysis and interpretation and critically revised the manuscript. H Guiney contributed to analysis and interpretation and critically revised the manuscript. D O'Mullane contributed to conception, design, analysis and interpretation, drafted and critically revised the manuscript. H Whelton contributed to conception, design, data acquisition, analysis and interpretation and critically revised the manuscript. All authors gave their final approval and agree to be accountable for all aspects of the work.

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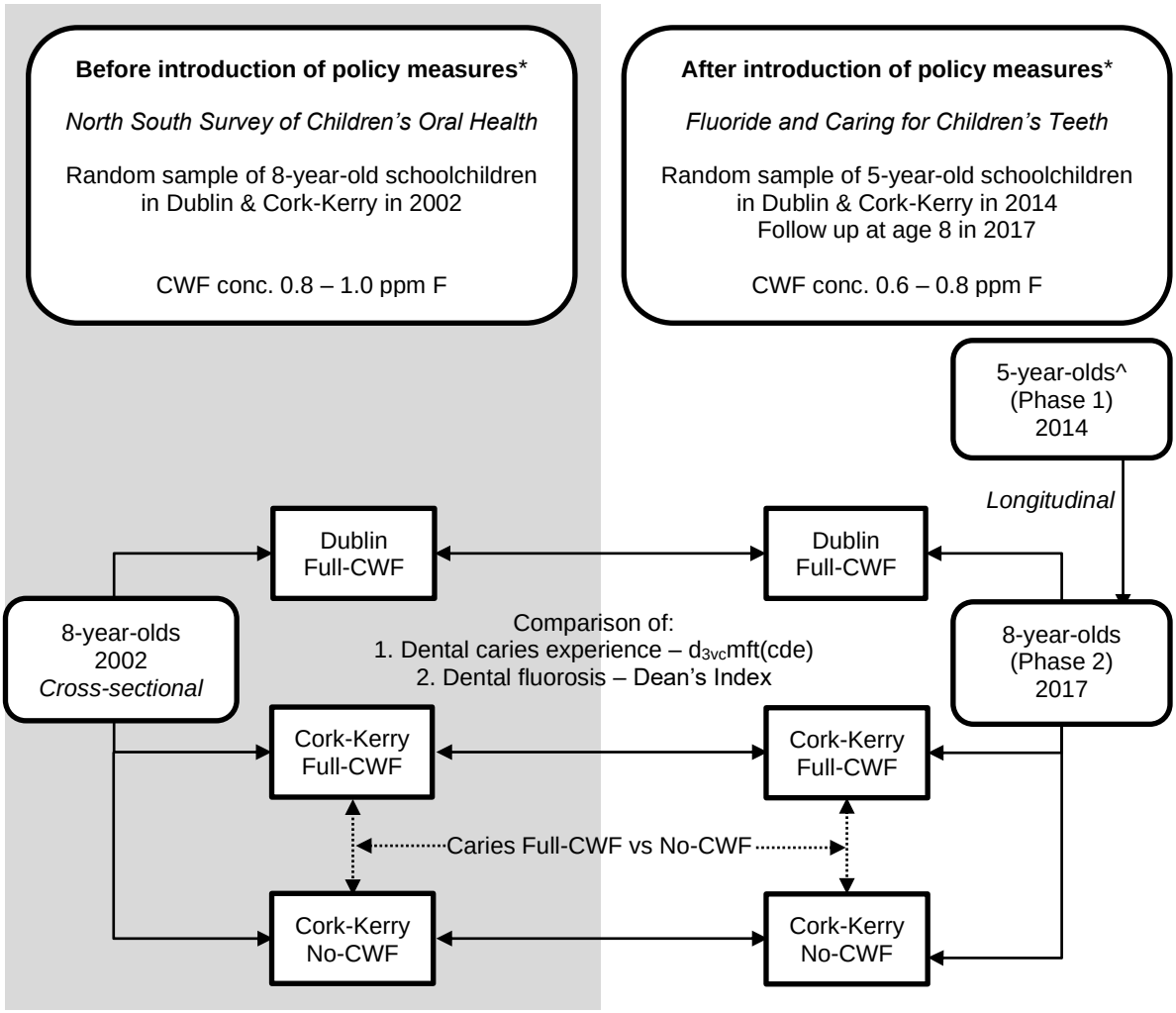


Figure: Overview of study design

*****Toothbrushing guidance in 2002 & downward adjustment of CWF concentration in 2007
^Information about age first used toothpaste collected via parent-completed questionnaire at age 5 (2014) used in analysis at age 8 (2017)

Table 1: Characteristics of 8-year-olds examined in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2002 and 2017

	Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
	2002	2017	2002	2017	2002	2017
Characteristic	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total examined	679	707	332	376	233	772
Gender						
Female	319 (47)	383 (54)	183 (55)	198 (53)	130 (56)	392 (51)
Male	360 (53)	324 (46)	149 (45)	178 (47)	103 (44)	380 (49)
Age*	8.3 (0.4)	8.2 (0.3)	8.4 (0.5)	8.3 (0.4)	8.5 (0.4)	8.4 (0.4)
Economic disadvantage[ǂ]						
Medical card	139 (20)	206 (29)	80 (24)	111 (30)	39 (17)	158 (20)
No Medical card	532 (78)	486 (69)	251 (76)	257 (68)	193 (83)	603 (78)
Missing	8 (1)	15 (2)	1 (<1)	8 (2)	1 (<1)	11 (1)
Age first used toothpaste∞						
≤ 24 months	547 (81)	568 (80)	284 (86)	303 (81)	177 (76)	618 (80)
> 24 months^	123 (18)	133 (19)	43 (13)	68 (18)	54 (23)	145 (19)
Missing	9 (1)	6 (<1)	5 (2)	5 (1)	2 (<1)	9 (1)
Age at first visit to the dentist						
≤ 4 years old	165 (24)	166 (23)	94 (28)	92 (24)	67 (29)	238 (31)
5-6 years old	189 (28)	222 (31)	115 (35)	119 (32)	87 (37)	244 (32)
≥7 years old	182 (27)	102 (14)	87 (26)	84 (22)	58 (25)	148 (19)
Never	122 (18)	186 (26)	30 (9)	67 (18)	17 (7)	122 (16)
Missing	21 (3)	31 (4)	6 (2)	14 (4)	4 (2)	20 (3)
Frequency of toothbrushing (age 8)						
Once a day or less	286 (42)	195 (28)	128 (39)	97 (26)	103 (44)	204 (26)
Twice a day or more	387 (57)	498 (70)	202 (61)	271 (72)	127 (55)	561 (73)
Missing	6 (<1)	14 (2)	2 (<1)	8 (2)	3 (1)	7 (<1)
Amount of toothpaste (age 8)						
Pea-sized^ or less	289 (43)	600 (85)	161 (48)	305 (81)	92 (39)	642 (83)
> Pea-sized	381 (56)	88 (12)	170 (51)	60 (16)	138 (59)	114 (15)
Missing	9 (1)	19 (3)	1 (<1)	11 (3)	3 (1)	16 (2)
Rinse method after toothbrushing (age 8)						
Glass	181 (27)	147 (21)	99 (30)	84 (22)	91 (39)	209 (27)
Other[◊] or no rinse	483 (71)	547 (77)	232 (70)	284 (76)	137 (59)	555 (72)
Missing	15 (2)	13 (2)	1 (<1)	8 (2)	5 (2)	8 (1)
Sweet foods/drinks between meals (age 8)						
≥ 4 times per day	74 (11)	68 (10)	19 (6)	32 (9)	13 (6)	48 (6)
2-3 times per day	321 (47)	308 (44)	163 (49)	165 (44)	90 (39)	296 (38)
Once a day or less	275 (41)	312 (44)	148 (45)	164 (44)	127 (55)	411 (53)
Missing	9 (1)	19 (3)	2 (<1)	15 (4)	3 (1)	17 (2)

Data are for children who had a caries and/or fluorosis examination in 2002 (n=1244) or 2017 (n=1855). Sample size in Cork-Kerry No-CWF is larger in 2017 than 2002 because the FACCT study was powered to demonstrate differences (Full-CWF vs No-CWF) within Cork-Kerry, whereas the No-CWF sample in Cork-Kerry 2002 contributed to a national No-CWF sample. Percentages may not sum to 100 due to rounding.

*mean (SD), no missing data

[ǂ]Medical card ownership indicates socio-economic disadvantage. A medical card is a means-tested benefit provided by the Irish state to applicants who meet criteria based on income, expenses, marital status, dependants and other circumstances.

∞Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age of first using toothpaste in 2014 (collected at age 5)^Recommended from 2002 onwards [◊]Other = using toothbrush to rinse/cupping hands to rinse/rinsing directly from the tap

Table 2: Dental caries experience in primary teeth of 8-year-olds in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2002 and 2017

	Children with caries experience (d_{3vc}mft(cde) > 0)						Full sample (children with and without caries experience)			
	2002			2017			2002		2017	
	n	%	mean (SD)	n	%	mean (SD)	n	mean (SD)	n	mean (SD)
Dublin										
Full-CWF	368	54	3.3 (2.1)	388	55	3.4 (2.3)	679	1.8 (2.2)	704	1.9 (2.4)
Cork-Kerry										
Full-CWF	182	55	3.5 (2.2)	209	56	3.7 (2.4)	332	1.9 (2.4)	375	2.1 (2.6)
No-CWF	169	73	4.9 (2.6)	497	65	4.2 (2.5)	233	3.5 (3.1)	770	2.7 (2.8)

Table 3: Multivariable (adjusted) regression analyses of the association between year of examination, dental caries in primary teeth and dental fluorosis in permanent teeth of 8-year-olds in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF)

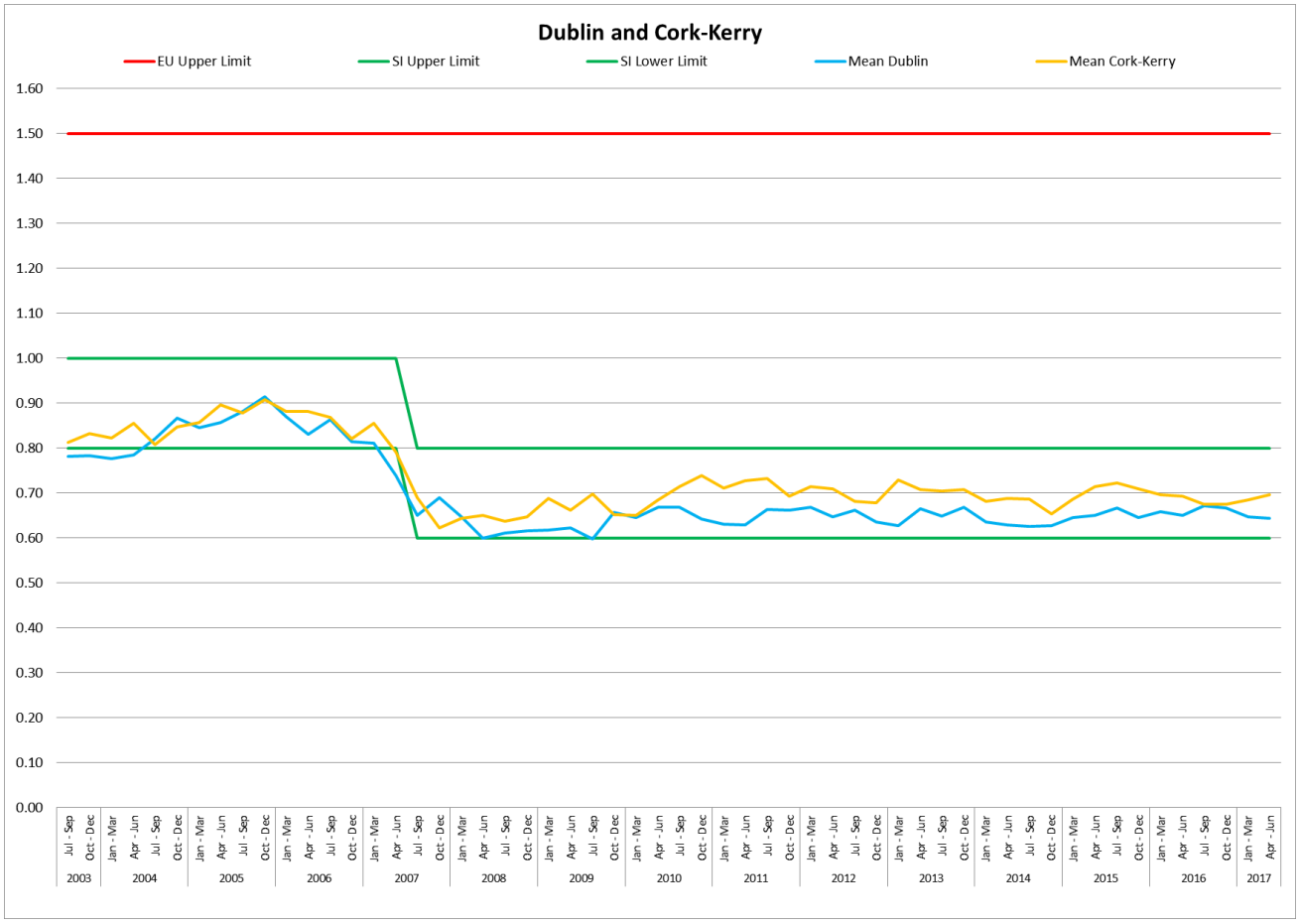
		Dublin Full-CWF			Cork-Kerry Full-CWF			Cork-Kerry No-CWF		
Outcome	Year	n	OR% (95%CI)	P value	n	OR% (95%CI)	P value	n	OR% (95%CI)	P value
Caries prevalence[a]	2017	1291	14 (-13, 49)	0.350	663	25 (-12, 78)	0.208	941	-23% (-48, 13)	0.179
	2002		Reference			Reference			Reference	
Caries severity[ab]	2017	699	5 (-9, 21)	0.487	369	7 (-9, 27)	0.424	622	-13 (-24, -1)	0.039
	2002		Reference			Reference			Reference	
Fluorosis prevalence[c]	2017	1338	16 (-13,56)	0.312	678	-7 (-41, 48)	0.771	979	97 (-18,373)	0.129
	2002		Reference			Reference			Reference	

Multivariable models are presented in full in Appendix Tables 4 - 7
OR% = odds ratio percent: the percentage increase/decrease in odds
CI = confidence interval, CWF = Community water fluoridation
[a]Negative binomial Hurdle Model analysis. Adjusted for medical card ownership, age, age first used toothpaste, age at first visit to the dentist, frequency of toothbrushing (age 8), amount of toothpaste (age 8), method of rinsing after toothbrushing (age 8), frequency of intake of sweet foods or drinks between meals (age 8).
[b] Percentage change in mean d_{3vc}mft(cde)
[c]Logistic regression analysis. Adjusted for age, gender, medical card ownership and age first used toothpaste.

Table 4: Prevalence of fluorosis and distribution of clinical Dean's Index scores among 8-year-olds in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF) in 2002 and 2017

	Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
	2002	2017	2002	2017	2002	2017
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fluorosis Prevalence						
Normal/Questionable	567 (85)	576 (82)	283 (87)	328 (88)	222 (97)	732 (95)
Very mild or greater	104 (15)	127 (18)	42 (13)	43 (12)	6 (3)	40 (5)
Total	**671 (100)**	**703 (100)**	**325 (100)**	**371 (100)**	**228 (100)**	**772 (100)**
Dean's Index score						
Normal	488 (73)	441 (63)	245 (75)	232 (63)	196 (86)	613 (79)
Questionable	79 (12)	135 (19)	38 (12)	96 (26)	26 (11)	119 (15)
Very mild	75 (11)	99 (14)	25 (8)	34 (9)	6 (3)	38 (5)
Mild	24 (4)	26 (4)	17 (5)	8 (2)	0 (0)	2 (<1)
Moderate	5 (<1)	2 (<1)	0 (0)	1 (<1)	0 (0)	0 (0)
Total	**671 (100)**	**703 (100)**	**325 (100)**	**371 (100)**	**228 (100)**	**772 (100)**

No cases of severe fluorosis were recorded

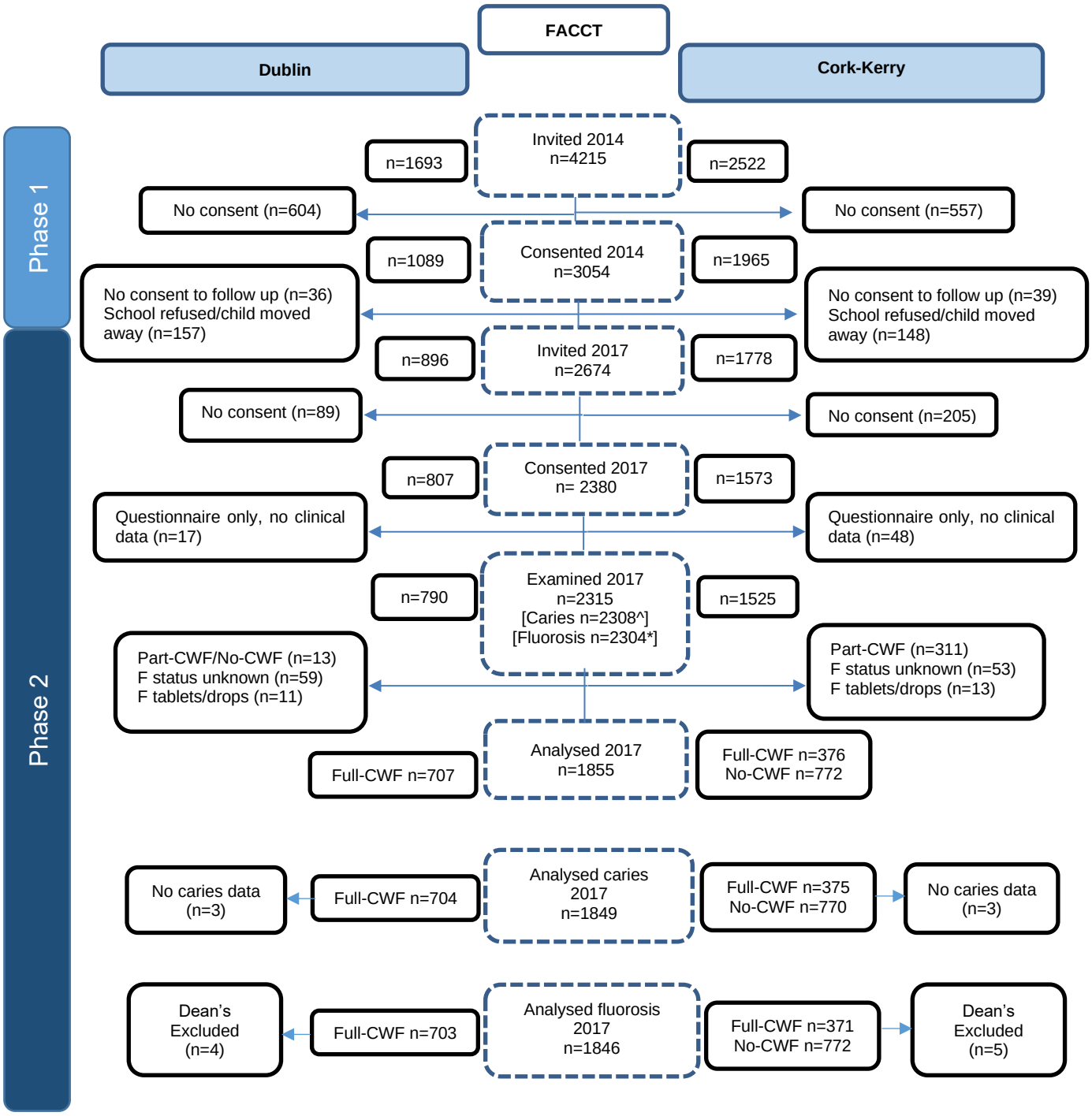


Appendix Figure 1: Quarterly mean water fluoride concentration (ppm F) for Dublin and Cork-Kerry from July 2003 to June 2017.

Appendix Table 1: Details of training and calibration 2002 and 2017

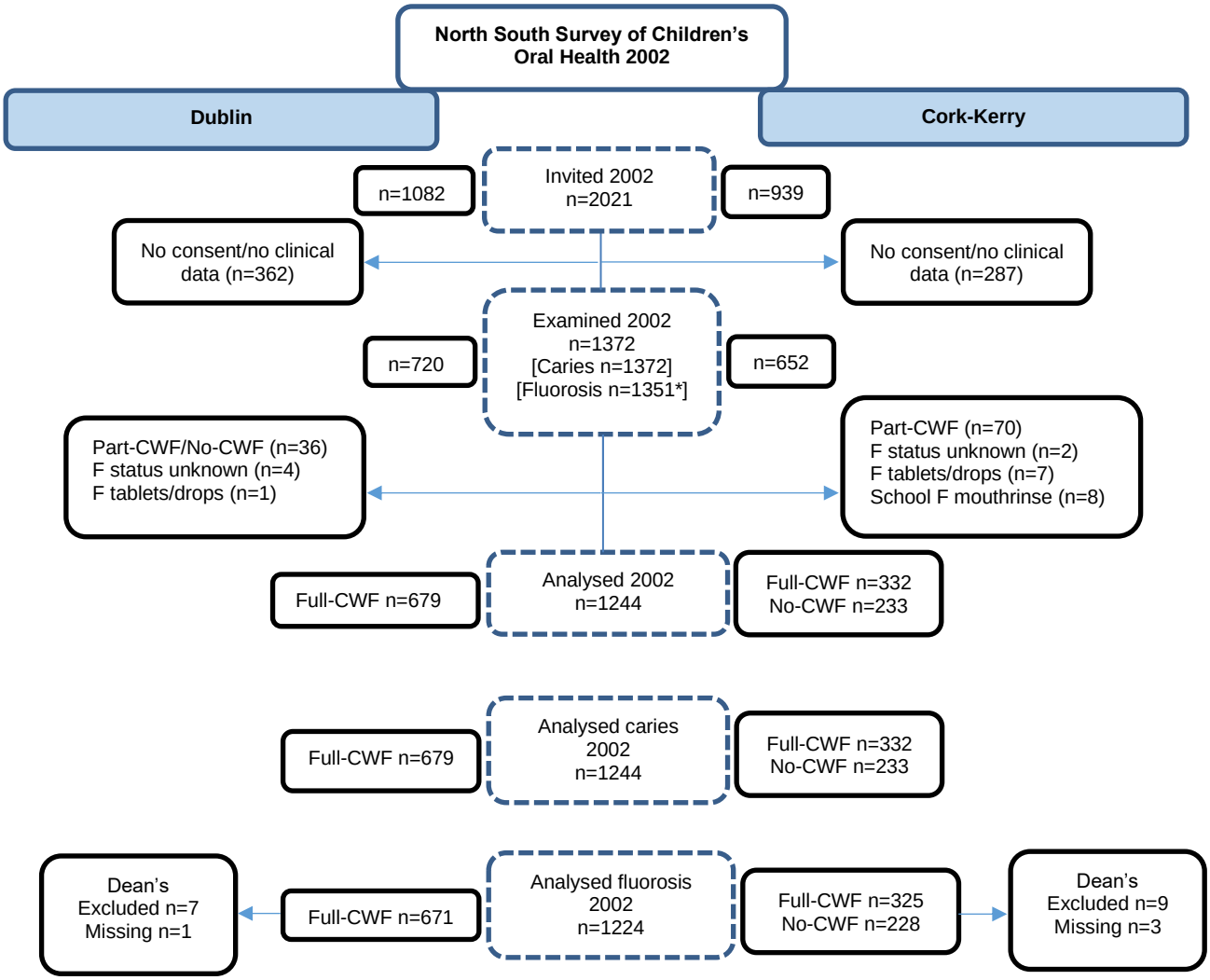
Training and calibration before commencement of fieldwork	2002	2017
Dental nurses trained to use direct data entry software on dedicated laptop computers	√	√
Video resource "Setting up for School Dental Examinations"	x	√
Small group interactive teaching sessions for dentists	√	√
Group discussion and individual scoring of photographic images of caries, dental fluorosis and other developmental defects of enamel by dentists.	√	√
Use of training and calibration components of the online fluorosis training tool ' e-training for Dean's Index' (Whelton et al. 2014)	x	√
School based clinical training	√	√
Final calibration based on clinical scores in school-based calibration exercise	√	√
Minimum acceptable level of agreement with gold standard examiners during calibration exercise	0.4 'moderate agreement*'	0.6 'substantial agreement*^'

* (Landis and Koch 1977)
^ Moderate agreement (McHugh 2012)



Appendix Figure 2: Flow of participants through the FACCT study

^ 7 children do not have a caries measurement in 2017: Dublin Full-CWF n=3, Cork-Kerry Full-CWF n= 1, Cork-Kerry No-CWF n=3 (one of whom reported taking F tablets/drops)**.** *11 children were examined in 2017 but not assigned a Dean's Index score: "Dean's Excluded". Dublin Full-CWF n=4, Cork-Kerry Full-CWF n=5, Cork-Kerry Part-CWF n=2



Appendix Figure 3: Flow of participants through the North South Survey 2002

*17 children were examined in 2002 but not assigned a Dean's Index score: "Dean's Excluded" (Dublin Full-CWF n=7, Dublin Part-CWF n=1, Cork-Kerry Full-CWF n=5, Cork-Kerry No-CWF n=4). Dean's index score was

Appendix Table 2: Sensitivity analysis of impact of re-classifying Part-CWF 2002

		Part-CWF 2002 assumed to be Full-CWF				Part-CWF 2002 assumed to be No-CWF	
		Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
Outcome	**Year**	**OR% (95%CI)**	**P value**	**OR% (95%CI)**	**P value**	**OR% (95%CI)**	**P value**
Caries prevalence[a]	2017	14%→14%	0.350→0.349	25%→24%	0.208→0.206	-23%→-29%	0.179→0.064
	2002	Ref		Ref		Ref	
Caries severity[a,b]	2017	5%→4%	0.487→0.548	7%→3%	0.424→0.704	-13%→-15%	0.039→0.010
	2002	Ref		Ref		Ref	
Fluorosis prevalence[c]	2017	16%→15%	0.312→0.356	-7%→ -4%	0.771→0.859	97%→8%	0.129→0.806
	2002	Ref		Ref		Ref	

OR% = odds ratio %: the percentage increase/decrease in odds

95%CI = 95% confidence interval

[a] Negative binomial Hurdle Model analysis. Adjusted for medical card ownership, age, age first used toothpaste, age at first visit to the dentist, frequency of toothbrushing (age 8), amount of toothpaste (age 8), rinse method after toothbrushing (age 8), frequency of intake of sweet foods or drinks between meals (age 8).

[b] Percentage change in mean $d_{3vc}mft(cde)$

[c] Logistic regression analysis. Adjusted for age, gender, medical card ownership and age first used toothpaste.

Appendix Table 3: Characteristics at baseline (2014) for all children who consented in phase 1 (Consented 2014), children who were followed-up and examined in phase 2 (Examined 2017) and children who consented in phase 1 but were not examined in phase 2 (Lost to follow-up 2017)

Characteristic	**Dublin**			**Cork-Kerry**		
	Consented 2014	**Examined 2017**	**Lost to follow-up 2017**	**Consented 2014**	**Examined 2017**	**Lost to follow-up 2017**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Gender						
Female	542 (50)	413 (52)	129 (43)	993 (51)	795 (52)	198 (45)
Male	546 (50)	376 (48)	170 (57)	969 (49)	731 (48)	238 (54)
Missing	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)	1 (<1)
Total	**1088 (100)**	**789 (100)**	**299 (100)**	**1963 (100)**	**1526 (100)**	**437 (100)**
Age* (phase 1)	5.2 (0.4)	5.2 (0.4)	5.2 (0.4)	5.3 (0.4)	5.4 (0.4)	5.3 (0.4)
Economic disadvantage						
MC/GP card	424 (39)	275 (35)	149 (50)	652 (33)	467 (31)	185 (42)
No MC/GP card	646 (59)	504 (64)	142 (47)	1273 (65)	1032 (68)	241 (55)
Missing	18 (2)	10 (1)	8 (3)	38 (2)	27 (2)	11 (3)
Total	**1088 (100)**	**789 (100)**	**299 (100)**	**1963 (100)**	**1526 (100)**	**437 (100)**

*mean (SD). Percentages may not sum to 100 due to rounding.

MC/GP card=Medical card or GP visit card

Total number 3051 rather than 3054 as reported in Appendix Figure 2 because parents/caregivers of three children consented and completed residential history only. No demographic information is available for these three children.

Numbers for phase 2 differ slightly from those reported in Appendix Figure 2 because by necessity, demographic variables and the county variable for phase 1 (age 5) rather than phase 2 (age 8) were used to generate this table.

Numbers examined 2017 include all children (all F status categories) who had a caries or fluorosis examination in phase 2 (total n=2315).

Appendix Table 4: Negative binomial hurdle model analyses of the association between year of examination and the prevalence and severity of dental caries among 8-year-olds in Dublin (Full-CWF)

		Dublin Full-CWF (d_{3vc}mft(cde))					
		Prevalence (n=1291)			Severity (n=699)		
Explanatory Variable		**OR (%)**	**95% CI**	**p-value**	**Mean (%)**	**95% CI**	**p-value**
Year	2017	14%	(-13%, 49%)	0.350	5%	(-9%, 21%)	0.487
	2002	Ref					
Medical card	Yes	71%	(29%, 127%)	<0.001	23%	(7%, 40%)	0.003
	No	Ref					
Age (in years)		15%	(-14%, 55%)	0.347	1%	(-13%, 18%)	0.877
Frequency of toothbrushing (age 8)	Once/day or less	51%	(17%, 94%)	0.001	16%	(2%, 33%)	0.021
	Twice/day or more	Ref					
Amount of toothpaste (age 8)	Pea-sized^ or less	-1%	(-25%, 31%)	0.956	7%	(-8%, 24%)	0.388
	> Pea-sized	Ref					
Rinse method after toothbrushing (age 8)	Glass	12%	(-15%, 47%)	0.421	6%	(-8%, 22%)	0.393
	Other◊	Ref					
Sweet food/drinks between meals (age 8)	≥ 4 times/ day	130%	(51%, 252%)	<0.001	34%	(10%, 63%)	0.004
	2-3 times/day	69%	(33%, 116%)	<0.001	13%	(-1%, 30%)	0.072
	Once/day or less	Ref					
Age at first visit to the dentist	≤ 4 years old	151%	(79%, 252%)	<0.001	76%	(44%, 114%)	<0.001
	5-6 years old	88%	(37%, 159%)	<0.001	46%	(20%, 77%)	<0.001
	≥ 7 years old	76%	(24%, 150%)	0.002	21%	(-2%, 49%)	0.082
	Never	Ref					
Age first used toothpaste*	≤ 24 months	-47%	(-61%, -27%)	< 0.001	-3%	(-16%, 12%)	0.675
	> 24 months^	Ref					

Ref = Reference group/category
OR% = odds ratio %: the percentage increase/decrease in odds
Mean % = the percentage change in mean d_{3vc}mft(cde)
95%CI = 95% confidence interval
^Recommended from 2002 onwards
◊Other = using toothbrush to rinse/cupping hands to rinse/rinsing directly from the tap
*Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2014 (collected at age 5)
Year of examination adjusted for the effect of the other explanatory variables is the main explanatory variable. The OR (%) and Mean (%) for the other explanatory variables represents the association between each explanatory variable and the prevalence and severity of dental caries controlled for the effect of the other explanatory variables.

Appendix Table 5: Negative binomial hurdle model analyses of the association between year of examination and the prevalence and severity of dental caries among 8-year-olds in Cork-Kerry (Full-CWF)

		Cork-Kerry Full-CWF (d_{3vc}mft(cde))					
		Prevalence (n=663)			Severity (n=369)		
Explanatory Variable		**OR (%)**	**95% CI**	**p-value**	**Mean (%)**	**95% CI**	**p-value**
Year	2017	25%	(-12%, 78%)	0.208	7%	(-9%, 27%)	0.424
	2002	Ref					
Medical card	Yes	45%	(-1%, 110%)	0.053	34%	(14%, 58%)	0.001
	No	Ref					
Age (in years)		58%	(7%, 132%)	0.021	-8%	(-24%, 11%)	0.376
Frequency of toothbrushing (age 8)	Once a day or less	47%	(3%, 110%)	0.033	13%	(-4%, 33%)	0.138
	Twice a day or more	Ref					
Amount of toothpaste (age 8)	Pea-sized^ or less	-9%	(-37%, 31%)	0.605	-1%	(-17%, 18%)	0.912
	> Pea-sized	Ref					
Rinse method after toothbrushing (age 8)	Glass	38%	(-5%, 99%)	0.090	14%	(-3%, 35%)	0.119
	Other◊	Ref					
Sweet food/drinks between meals (age 8)	≥ 4 times per day	73%	(-9%, 229%)	0.092	26%	(-4%, 66%)	0.094
	2-3 times per day	52%	(10%, 112%)	0.012	12%	(-5%, 31%)	0.168
	Once a day or less	Ref					
Age at first visit to the dentist	≤ 4 years old	82%	(7%, 210%)	0.027	87%	(40%, 150%)	< 0.001
	5-6 years old	77%	(6%, 193%)	0.028	79%	(35%, 136%)	< 0.001
	≥ 7 years old	9%	(-36%, 86%)	0.757	31%	(-4%, 78%)	0.087
	Never	Ref					
Age first used toothpaste*	≤ 24 months	-20%	(-49%, 25%)	0.332	-17%	(-31%, 1%)	0.061
	> 24 months^	Ref					

Ref = Reference group/category
OR% = odds ratio %: the percentage increase/decrease in odds
Mean % = the percentage change in mean d_{3vc}mft(cde)
95%CI= 95% confidence interval
^Recommended from 2002 onwards
◊Other=using toothbrush to rinse/cupping hands to rinse/rinsing directly from the tap
*Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2014 (collected at age 5)
Year of examination adjusted for the effect of the other explanatory variables is the main explanatory variable. The OR (%) and Mean (%) for the other explanatory variables represents the association between each explanatory variable and prevalence and severity of dental caries controlled for the effect of the other explanatory variables.

Appendix Table 6: Negative binomial hurdle model analyses of the association between year of examination and the prevalence and severity of dental caries among 8-year-olds in Cork-Kerry (No-CWF)

		Cork-Kerry No-CWF (d_{3vc}mft(cde))					
		Prevalence (n=941)			Severity (n=622)		
Explanatory Variable		**OR (%)**	**95% CI**	**p-value**	**Mean (%)**	**95% CI**	**p-value**
Year	2017	-23%	(-48%, 13%)	0.179	-13%	(-24%, -1%)	0.039
	2002	Ref					
Medical card	Yes	15%	(-21%, 67%)	0.467	17%	(3%, 32%)	0.012
	No	Ref					
Age (in years)		-15%	(-42%, 24%)	0.394	-3%	(-15%, 11%)	0.664
Frequency of toothbrushing (age 8)	Once a day or less	50%	(9%, 108%)	0.013	9%	(-2%, 21%)	0.111
	Twice a day or more	Ref					
Amount of toothpaste (age 8)	Pea-sized^ or less	27%	(-12%, 82%)	0.199	-6%	(-18%, 7%)	0.342
	> Pea-sized	Ref					
Rinse method after toothbrushing (age 8)	Glass	39%	(1%, 91%)	0.044	2%	(-9%, 13%)	0.771
	Other◊	Ref					
Sweet food/drinks between meals (age 8)	≥ 4 times per day	125%	(17%, 334%)	0.016	30%	(8%, 57%)	0.006
	2-3 times per day	83%	(35%, 148%)	<0.001	17%	(5%, 30%)	0.004
	Once a day or less	Ref					
Age at first visit to the dentist	≤ 4 years old	136%	(52%, 266%)	<0.001	87%	(50%, 132%)	<0.001
	5-6 years old	280%	(143%, 494%)	<0.001	76%	(42%, 118%)	<0.001
	≥ 7 years old	108%	(30%, 232%)	0.002	51%	(20%, 91%)	0.001
	Never	Ref					
Age first used toothpaste*	≤ 24 months	-10%	(-37%, 30%)	0.587	-6%	(-17%, 6%)	0.324
	> 24 months^	Ref					

Ref = Reference group/category
OR% = odds ratio %: the percentage increase/decrease in odds
Mean % = the percentage change in mean d_{3vc}mft(cde)
95%CI= 95% confidence interval
^Recommended from 2002 onwards
◊Other=using toothbrush to rinse/cupping hands to rinse/rinsing directly from the tap
* Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2014 (collected at age 5)
Year of examination adjusted for the effect of the other explanatory variables is the main explanatory variable. The OR (%) and Mean (%) for the other explanatory variables represents the association between each explanatory variable and prevalence and severity of dental caries controlled for the effect of the other explanatory variables.

Appendix Table 7: Multivariable logistic regression analyses of the association between year of examination and prevalence of dental fluorosis among 8-year-olds in Dublin (Full-CWF) and Cork-Kerry (Full-CWF and No-CWF)

		Fluorosis ('very mild' or greater)					
		Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
		n=1338		n=678		n=979	
Explanatory variable		**OR% (95%CI)**	**P-value**	**OR% (95%CI)**	**P-value**	**OR% (95%CI)**	**P-value**
Year	2017	16% (-13, 56)	0.312	-7% (-41, 48)	0.771	97% (-18, 373)	0.129
	2002	Ref		Ref		Ref	
Age (in years)		-16% (-42, 21)	0.337	45% (-14, 143)	0.164	-40% (-74, 36)	0.221
Gender	Female	55% (16, 108)	0.003	6% (-34, 70)	0.801	44% (-22, 166)	0.244
	Male	Ref		Ref		Ref	
Medical card	Yes	6% (-24, 48)	0.736	-5% (-44, 60)	0.845	62% (-17, 215)	0.157
	No	Ref		Ref		Ref	
Age first used toothpaste*	≤ 24 months	29% (-13, 91)	0.211	94% (-10, 315)	0.090	-6% (-55, 100)	0.882
	>24 months^	Ref		Ref		Ref	

OR% = odds ratio %: the percentage increase/decrease in odds
95%CI= 95% confidence interval
* Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2014 (collected at age 5)
^Recommended from 2002 onwards
Year of examination adjusted for the effect of the other explanatory variables is the main explanatory variable. The OR (%) for the other explanatory variables represents the association between each explanatory variable and prevalence of fluorosis controlled for the effect of the other explanatory variables.

References

Landis JR, Koch GG. 1977. The measurement of observer agreement for categorical data. Biometrics. 33(1):159-174.

McHugh ML. 2012. Interrater reliability: the kappa statistic. Biochem Med (Zagreb). 22(3):276-282.

Whelton H, Browne D, Felicia P, Whelton J. 2014. e-training for Dean's Index Version 2 [accessed 31 October 2020] http://www.fluorosisindex.com/.

Appendix B: Supplemental material for Chapter 3: Systematic Review

Search strategies for electronic databases

Table B 1: PubMed search strategy for systematic review: "Impact of downward adjustment of water fluoride concentration on dental caries and fluorosis"

Research Question: What is the impact of downward adjustment of the fluoride concentration of community water fluoridation programmes on dental caries and dental fluorosis in children and adults? **PICO** **Population:** Population (children or adults) receiving an artificially fluoridated water supply. **Intervention:** Downward adjustment of the fluoride concentration of the water supply. **Comparison:** Historical or concurrent control groups with exposure to the higher concentration of water. Control groups with no exposure to CWF. **Outcome:** Dental caries, or fluorosis	**PICO**		**Search Query (Up to date 4 Mar 2022)**		**# Records**
	Intervention	Community water fluoridation	#1	(Water Supply [Mesh] OR Drinking Water [Mesh] OR water)	1,130,727
			#2	(Fluoridation [Mesh] OR fluorid*)	67,248
			#3	#1 AND #2	12,320
		Downward adjustment	#4	(adjust* OR "downward adjustment" OR reduction OR reduce* OR decreas* OR change*)	8,039,490
			#5	#3 AND #5	4,132
	Outcome	Dental Fluorosis	#6	(Fluorosis, Dental [Mesh] OR fluorosis OR "dental fluorosis" OR "enamel fluorosis" OR "Thylstrup-Fejerskov" OR "Dean's Index" OR "developmental defects of enamel" OR "diffuse opacit*")	4,644
		Dental Caries	#7	(Dental Caries[Mesh] OR Tooth Demineralization [Mesh] OR DMF Index [Mesh] OR caries OR DMF OR "dental caries" OR "dental decay" OR "tooth decay" OR "caries increment")	77,157
			#8	#6 OR #7	80437
			#9	#5 AND #8	1484
			Limit Human		1056
			Limit Human & English		**961**

Table B 2: Web of Science search strategy for systematic review: "Impact of downward adjustment of water fluoride concentration on dental caries and fluorosis"

Research Question: What is the impact of downward adjustment of the fluoride concentration of community water fluoridation programmes on dental caries and dental fluorosis in children and adults? **PICO** **Population:** Population (children or adults) receiving an artificially fluoridated water supply. **Intervention:** Downward adjustment of the fluoride concentration of the water supply. **Comparison:** Historical or concurrent control groups with exposure to the higher concentration of water. Control groups with no exposure to CWF. **Outcome:** Dental caries, or fluorosis	**PICO**		**Search Query (Up to date 4 Mar 2022)** **All Fields**		**# Records**
	Intervention	Community water fluoridation	#1	Water	3,601,453
			#2	("Fluoridation" OR fluorid*)	136,568
			#3	#1 AND #2	26,040
		Downward adjustment	#4	(adjust* OR "downward adjustment" OR reduction OR reduce* OR decreas* OR change*)	13,834,431
			#5	#3 AND #5	8,994
	Outcome	Dental Fluorosis	#6	(fluorosis OR "Thylstrup-Fejerskov" OR "Dean's Index" OR "developmental defects of enamel" OR "diffuse opacit*")	5,209
		Dental Caries	#7	(caries OR DMF OR "dental caries" OR "dental decay" OR "tooth decay" OR "caries increment")	82,162
			#8	#6 OR #7	86,119
			#9	#5 AND #8	1735
			Limit English		**1694**

Table B 3: Scopus search strategy for systematic review: "Impact of downward adjustment of water fluoride concentration on dental caries and fluorosis"

Research Question: What is the impact of downward adjustment of the fluoride concentration of community water fluoridation programmes on dental caries and dental fluorosis in children and adults? **PICO** **Population:** Population (children or adults) receiving an artificially fluoridated water supply. **Intervention:** Downward adjustment of the fluoride concentration of the water supply. **Comparison:** Historical or concurrent control groups with exposure to the higher concentration of water. Control groups with no exposure to CWF. **Outcome:** Dental caries, or fluorosis	**PICO**		**Search Query (Up to date Mar 5th 2022)** TITLE-ABS-KEY		**# Records**
	Intervention	Community water fluoridation	#1	Water	4,313,828
			#2	("Fluoridation" OR fluorid*)	181,083
			#3	#1 AND #2	31,476
		Downward adjustment	#4	(adjust* OR "downward adjustment" OR reduction OR reduce* OR decreas* OR change*)	18,635,687
			#5	#3 AND #4	10,305
	Outcome	Dental Fluorosis	#6	(fluorosis OR "Thylstrup-Fejerskov" OR "Dean's Index" OR "developmental defects of enamel" OR "diffuse opacity" OR "diffuse opacities")	8,133
		Dental Caries	#7	(caries OR DMF OR "dental caries" OR "dental decay" OR "tooth decay" OR "caries increment")	120,208
			#8	#6 OR #7	126,589
			#9	#5 AND #8	2,180
			Limit English		**1887**

Excluded studies

Table B 4: Records excluded from the systematic review and reasons for exclusion

Record ID	Reference	Reason for exclusion
Angelillo 1999	Angelillo IF, Torre I, Nobile CGA, Villari P. 1999. Caries and fluorosis prevalence in communities with different concentrations of fluoride in the water. Caries Research. 33(2):114-122.	Comparison of groups with different concentration of fluoride in the water, no downward adjustment
Attwood 1988	Attwood D, Blinkhorn AS. 1988. Trends in dental health of ten-year-old school children in south-west Scotland after cessation of water fluoridation. Lancet. 2(8605):266-267.	CWF cessation study
Attwood 1989	Attwood D, Blinkhorn AS. 1989. A reassessment of the dental health of urban Scottish schoolchildren following the cessation of water fluoridation. Community Dent Health. 6(3):207-214.	CWF cessation study
Attwood 1992	Attwood D, 1992. Dental health of children before and after the cessation of water fluoridation. University of Glasgow	CWF cessation study (PhD Thesis)
Burt 2000	Burt BA, Keels MA, Heller KE. 2000. The effects of a break in water fluoridation on the development of dental caries and fluorosis. Journal of Dental Research. 79(2):761-769.	CWF cessation study
Clarke 2006	Clark DC, Shulman JD, Maupome G, Levy SM. 2006. Changes in dental fluorosis following the cessation of water fluoridation. Community Dentistry and Oral Epidemiology. 34(3):197-204.	CWF cessation study
Evans 1987	Evans RW, Lo EC, Lind OP. 1987. Changes in dental health in Hong Kong after 25 years of water fluoridation. Community Dent Health. 4(4):383-394.	Review
Hawew 1996	Hawew RM, Ellwood RP, Hawley GM, Worthington HV, Blinkhorn AS. 1996. Dental caries in children from two Libyan cities with different levels of fluoride in their drinking water. Community Dent Health. 13(3):175-177.	Comparison of groups with different concentration of fluoride in the water, no downward adjustment
Jackson 1999	Jackson RD, Kelly SA, Katz B, Brizendine E, Stookey GK. 1999. Dental fluorosis in children residing in communities with different water fluoride levels: 33-month follow-up. Pediatr Dent. 21(4):248-254.	Comparison of groups with different concentration of fluoride in the water, no downward adjustment
James 2021	James P, Harding M, Beecher T, Browne D, Cronin M, Guiney H, O'Mullane D, Whelton H. 2021. Impact of Reducing Water Fluoride on Dental Caries and Fluorosis. Journal of Dental Research. 100(5):507-514.	Subject of this thesis
Kalsbeek 1993	Kalsbeek H, Kwant GW, Groeneveld A, Dirks OB, Vaneck A, Theuns HM. 1993. Caries experience of 15-	CWF cessation study

	year-old children in The Netherlands after discontinuation of water fluoridation. Caries Research. 27(3):201-205.	
Karim 2021	Karim FA, Yusof ZYM, Nor NAM. 2021. Prevalence of dental fluorosis and its associated factors after cessation of water fluoridation. Malaysian Journal of Medicine and Health Sciences. 17(1):68-76.	CWF cessation study
Kunzel 1980	Kunzel W. 1980. Effect of an interruption in water fluoridation on the caries prevalence of the primary and secondary dentition. Caries Research. 14(5):304-310.	Effect of interruption to CWF
Kunzel 2000a	Kunzel W, Fischer T. 2000. Caries prevalence after cessation of water fluoridation in La Salud, Cuba. Caries Research. 34(1):20-25.	CWF cessation study
Kunzel 2000b	Kunzel W, Fischer T, Lorenz R, Bruhmann S. 2000. Decline of caries prevalence after the cessation of water fluoridation in the former East Germany. Community Dentistry and Oral Epidemiology. 28(5):382-389.	CWF cessation study
Leake 2002	Leake J, Goettler F, Stahl-Quinlan B, Stewart H. 2002. Has the level of dental fluorosis among Toronto children changed? J Can Dent Assoc. 68(1):21-25.	Review
Lee 2016	Lee GHM, Pang HN, McGrath C, Yiu CKY. 2016. Oral health of Hong Kong children: a historical and epidemiological perspective. Hong Kong Medical Journal. 22(4):372-381.	Review
Lo 1997	Lo GL, Bagramian RA. 1997. Declining prevalence of dental caries in school children in Singapore. Oral Dis. 3(2):121-125.	Review
Maupome 2001	Maupome G, Clark DC, Levy SM, Berkowitz J. 2001. Patterns of dental caries following the cessation of water fluoridation. Community Dentistry and Oral Epidemiology. 29(1):37-47.	CWF cessation study
McLaren 2016	McLaren L, Patterson S, Thawer S, Faris P, McNeil D, Potestio M, Shwart L. 2016. Measuring the short-term impact of fluoridation cessation on dental caries in Grade 2 children using tooth surface indices. Community Dentistry and Oral Epidemiology. 44(3):274-282.	CWF cessation study
McLaren 2017	McLaren L, Patterson S, Thawer S, Faris P, McNeil D, Potestio ML, Shwart L. 2017. Exploring the short-term impact of community water fluoridation cessation on children's dental caries: a natural experiment in Alberta, Canada. Public Health. 146:56-64.	CWF cessation study
McLaren 2021	McLaren L, Patterson SK, Faris P, Chen G, Thawer S, Figueiredo R, Weijs C, McNeil D, Waye A, Potestio M. 2021. Fluoridation cessation and children's dental caries: A 7-year follow-up evaluation of Grade 2 schoolchildren in Calgary and Edmonton, Canada. Community Dent Oral Epidemiol.	CWF cessation study
Meyer 2018	Meyer J, Margaritis V, Mendelsohn A. 2018. Consequences of community water fluoridation	CWF cessation study

	cessation for Medicaid-eligible children and adolescents in Juneau, Alaska. Bmc Oral Health. 18.	
Seppa 1998	Seppa L, Karkkainen S, Hausen H. 1998. Caries frequency in permanent teeth before and after discontinuation of water fluoridation in Kuopio, Finland. Community Dentistry and Oral Epidemiology. 26(4):256-262.	CWF cessation study
Seppa 2000	Seppa L, Karkkainen S, Hausen H. 2000. Caries in the primary dentition, after discontinuation of water fluoridation, among children receiving comprehensive dental care. Community Dentistry and Oral Epidemiology. 28(4):281-288.	CWF cessation study

References for included and linked studies

Table B 5: Details of included studies

Study ID	Included studies and linked publications
Evans 1991	Evans RW, Stamm JW. 1991. Dental fluorosis following downward adjustment of fluoride in drinking water. J Public Health Dent. 51(2):91-98. • Evans RW. 1989. Changes in dental fluorosis following an adjustment to the fluoride concentration of Hong Kong's water supplies. Adv Dent Res. 3(2):154-160.
Wong 2014	Wong HM, McGrath C, King NM. 2014. Diffuse opacities in 12-year-old Hong Kong children--four cross-sectional surveys. Community Dent Oral Epidemiol. 42(1):61-69. • Wong HM, McGrath C, Lo EC, King NM. 2006. Association between developmental defects of enamel and different concentrations of fluoride in the public water supply. Caries Res. 40(6):481-486.
Mohd Nor 2018	Mohd Nor NA, Chadwick BL, Farnell DJJ, Chestnutt IG. 2018. The impact of a reduction in fluoride concentration in the Malaysian water supply on the prevalence of fluorosis and dental caries. Community Dent Oral Epidemiol. 46(5):492-499. • Mohd Nor NA. 2017. The impact of the downward adjustment of fluoride concentration in the Malaysian public water supply on dental fluorosis and caries. PhD Thesis, Cardiff University https://orca.cardiff.ac.uk/id/eprint/107108/
	Other linked study not relevant to this review: • Mohd Nor NA, Chadwick BL, Farnell DJJ, Chestnutt IG. 2021. Factors associated with dental fluorosis among Malaysian children exposed to different fluoride concentrations in the public water supply. J Public Health Dent. 81(4):270-279.

Characteristics of included studies

Table B 6: Characteristics of Included Studies Table for Evans 1991

Evans 1991	
Date/year and change in concentration	June 1978, 1.0 ppm F to 0.7 ppm F
Study Characteristics	
Country	Hong Kong
Study location and setting	Primary school
Climate	Sub-tropical
Study Design	Cross-sectional study/Uncontrolled before and after study. Successive cohorts of children whose permanent incisors mineralised before (during) and after downward adjustment of CWF concentration.
Study Duration	Not applicable
Criteria for inclusion	Primary school children aged 7-12 years, continuous residents of Hong Kong schools with enrolment >80 children, schools for 'handicapped' [sic] excluded.
Sampling procedures	Sampling frame consisted of 98% of primary schoolchildren. Two-stage cluster sampling with probability of school election proportional to school size. Second stage of selection: systematic selection of children ensuring all major strata of the population were adequately represented.
Recruitment procedures	Letter sent to parent with consent form, demographics questionnaire, and residential history form. There was no substitution for refusals and no follow up of children absent on the day of the dental examinations. Of 1,680 children invited, 1,541 were examined (92% of those invited) and 1,062 were included in the analysis (63% of those invited).
Characteristics of participants	
Number of participants	Age 7 (Born 1978) n=122 Age 8 (Born 1977) n=184 Age 9 (Born 1976) n=190 Age 10 (Born 1975) n=202 Age 11 (Born 1974) n=227 Age 12 (Born 1973) n=137 Total n=1062
Demographic characteristics	None reported
Exposure to CWF	
Measurement of exposure to CWF	Lifetime residents of Hong Kong only. Actual mean fluoride concentration in the 48 months before adjustment 0.82 (rather than 1 ppm) and 0.63 ppm (rather than 0.7 ppm) in the 48 months after the adjustment.
Duration and timing of exposure	Successive cohorts of children born before during and after downward adjustment of CWF concentration Age 7 (Born 1978) 0.7 ppm Age 8 (Born 1977) Mixed 1.0 and 0.7 ppm Age 9 (Born 1976) Mixed 1.0 and 0.7 ppm Age 10 (Born 1975) Mixed 1.0 and 0.7 ppm Age 11 (Born 1974) 1.0 ppm Age 12 (Born 1973) 1.0 ppm
Other explanatory variables and confounders	
Other sources of fluoride	Bulk of toothpaste marketed in Hong Kong non-fluoridated until 1983, then fluoride toothpaste introduced. Study participants had

	no exposure to fluoride toothpaste during mineralisation of the maxillary central incisors.
Dietary behaviours	Not reported.
Utilisation of dental/preventive services	Not reported
Outcomes	
Dental caries outcome	N/A
Dental fluorosis outcome	Dean's Index, natural light, teeth were cleaned but not dried prior to scoring, all permanent teeth scored but analysis restricted to permanent right maxillary central incisor. Community Fluorosis Index also reported.
Training and calibration of examiners	One examiner (RWE).
Reproducibility	10% of children re-examined on same day (attempt at single blind) Kappa 0.92 on maxillary right central incisors. Sample in one school re-examined one month later (Kappa 0.68), and in another school four months later (Kappa 0.57).
Statistical analysis	
Identification of potential confounders	Gender identified as potential confounder.
Statistical analysis and management of confounders	CFI and fluorosis prevalence (Dean's 'very mild' or greater) reported separately for males and females. Multiple regression analysis of CFI on cohort and gender to obtain parameter estimate for cohort (whether fluorosis prevalence differed across cohorts).
Additional information	
Sample size calculation	With 90% power at a 5% level of significance to detect a reduction in CFI of 0.2 or more, at least 257 children in each of two subsamples (those exposed to the higher F level and those exposed to the lower) were required.
Funding	Supported by a grant from the Faculty of Dentistry Research Committee, University of Hong Kong.
Conflicts of interest	None reported

Table B 7: Characteristics of Included Studies Table for Wong 2014

Wong 2014	
Date/year and change in concentration	1978, 1.0 ppm F to 0.7 ppm F 1988, 0.7 ppm F to 0.5 ppm F
Study Characteristics	
Country	Hong Kong
Study location and setting	Primary school
Climate	Sub-tropical
Study Design	Repeated cross-sectional study/Uncontrolled before and after study
Study Duration	Not applicable
Criteria for inclusion	Not reported
Sampling procedures	Oral photographs were taken during previous epidemiological surveys in Hong Kong. A two-stage cluster sampling procedure was used for all the surveys to be representative of 12-year-old Hong Kong children.
Recruitment procedures	Not reported
Characteristics of participants	

Number of participants	n analysed: 1983 (n=700), 1991 (n=670), 2001 (n=620), 2010 (n=668)
Demographic characteristics	None reported
Exposure to CWF	
Measurement of exposure to CWF	It is not clear whether photographs for all children included in the epidemiological surveys were scored or just those for lifetime residents of Hong Kong. No information is provided in support of the accuracy of the reported water fluoride concentrations.
Duration and timing of exposure	Groups of 12-year-old children whose incisors mineralised before and after each downward adjustment of CWF concentration Born 1970: incisors mineralised at 1.0 ppm Born 1978: incisors mineralised at 0.7 ppm Born 1988: incisors mineralised at 0.5 ppm Born 1997: incisors mineralised at 0.5 ppm
Other explanatory variables and confounders	
Other sources of fluoride	Not reported. However, a separate paper (Evans 1991) indicated that fluoridated toothpaste was introduced in Hong Kong in 1983. Prior to 1983, toothpaste did not contain fluoride.
Dietary behaviours	Not reported.
Utilisation of dental/preventive services	Not reported.
Outcomes	
Dental caries outcome	N/A
Dental fluorosis outcome	Photographic slides taken using a standardised technique at each time point after cleaning with gauze but without drying the teeth. Slides were randomly viewed at x20 magnification at a distance of 5 metres in a darkened room. Labial surfaces of the four permanent maxillary incisors were scored using the modified DDE Index with diffuse opacities component used as a measure of fluorosis.
Training and calibration of examiners	One trained and calibrated examiner (HMW).
Reproducibility	A random selection of 10% of slides were re-examined one month later to assess intra-examiner agreement. Kappa 0.78 at subject level for diagnosis of prevalence of diffuse opacities.
Statistical analysis	
Identification of potential confounders	None identified.
Statistical analysis and management of confounders	Pearson's chi-square test and Fisher's exact tests were used to determine the overall statistical significance of the differences in the prevalence and severity of diffuse opacities among children examined in the different years. For pairwise comparisons among different years, tests with Bonferroni adjustment of *P*-values were performed. There was no adjustment for confounding in the analysis.
Additional information	
Sample size calculation	Not reported
Funding	Supported by a grant from Research Grants Council of the Hong Kong Special Administrative Region, China.
Conflicts of interest	None reported

Table B 8: Characteristics of Included Studies Table for Mohd Nor 2018

Mohd Nor 2018	
Date/year and change in concentration	December 2005: 0.7 ppm F to 0.5 ppm F
Study Characteristics	
Country	Malaysia
Study location and setting	Two states in peninsular Malaysia, Negeri Sembilan (fluoridated) and Kelantan (non-fluoridated)
Climate	Tropical
Study Design	Cross-sectional study/Controlled before and after study
Study Duration	Not applicable
Criteria for inclusion	9- and 12-year-old school children who were lifetime residents of the study areas
Sampling procedures	Two-stage stratified cluster sampling. The first stage (selection of schools, stratified by school size) was random, the second stage (selection of children within schools) was systematic (every second child selected) in large schools (>50 children). In small schools (≤50 children), all children were selected.
Recruitment procedures	Survey forms including consent form, patient information sheet, parental questionnaire about fluoride history, infant feeding, and oral hygiene practices were distributed to parents of selected children via schools. Of 1,600 children invited to participate, 1,298 (81%) returned documentation and 1,291 (81%) provided signed parental consent. 50 children were subsequently excluded as non-lifelong residents. A further 86 were excluded because they were absent on the day, or their incisors were unerupted, or for other reasons.
Characteristics of participants	
Number of participants	Total n analysed for caries= 1155 **Age 9:** Fluoridated n=313, non-fluoridated n=247, Total n=560 **Age 12:** Fluoridated n=294, non-fluoridated n=301, Total n= 595 Total n analysed for fluorosis = 1143 (12 photographs could not be scored).
Demographic characteristics	**Gender (% male):** **Age 9:** Fluoridated: male 42.8%, non-fluoridated: male 42.9% **Age 12:** Fluoridated: male 44.6%, non-fluoridated: male 41.5% **Ethnicity (% Malay):** **Age 9:** Fluoridated: Malay 96.8%, non-fluoridated: Malay 99.6% **Age 12:** Fluoridated: Malay 96.3%, non-fluoridated: Malay 99.0% Parents' education and monthly income also reported.
Exposure to CWF	
Measurement of exposure to CWF	Lifetime residents of study areas only.
Duration and timing of exposure	**Age 9:** Fluoridated area had lifetime exposure to 0.5 ppm **Age 12:** Fluoridated had exposure to 0.7 ppm to approx. age 2 (depending on DOB) and to 0.5 ppm thereafter.
Other explanatory variables and confounders	
Other sources of fluoride	Infant formula reconstituted with fluoridated water, fluoride toothpaste, exposure to fluoride varnish/gel before age 6.
Dietary behaviours	Only infant feeding reported (i.e., breastfeeding and use of infant formula)
Utilisation of dental/preventive services	Not reported

Outcomes	
Dental caries outcome	ICDAS-II examined supine in mobile dental chair with portable light, mouth mirror and WHO probe (if necessary). Teeth were cleaned and dried with gauze prior to examination.
Dental fluorosis outcome	Dean's Index, natural light, maxillary central incisors, without drying the teeth. Clinical Dean's Index scores were not reported. Digital oral photographs were taken according to a standard protocol without drying the teeth. Images were scored using Dean's index by three examiners (consensus score was used in analysis). Images were projected onto a screen for scoring. Examiners were blind to subject exposure to fluoride.
Training and calibration of examiners	Caries: One trained and calibrated examiner (NAMN). Fluorosis clinical: One trained and calibrated examiner (NAMN). Fluorosis from photographs: Three trained and calibrated examiners.
Reproducibility	A pilot study was conducted before the main study. 111 children were clinically examined for caries and fluorosis and 20 children were re-examined two weeks later. The kappa statistic for intra-examiner reliability for caries was 0.81 and for fluorosis was 0.89. During calibration, inter-examiner reliability (kappa) for caries based on 40 clinical slides was 0.61. Inter-examiner agreement for the photographic scoring (unweighted kappa) between the 3 examiners ranged from 0.72 to 0.85.
Statistical analysis	
Identification of potential confounders	**The following potential confounders were identified:** Gender Age Mothers' and fathers' education Mothers' and fathers' income Age started toothbrushing Age when toothbrushing with toothpaste started Use of infant formula (yes/no), Breastfeeding (yes/no) Age finished breastfeeding, Age started formula, Age finished formula, Type of water used to prepare formula, Duration of formula use, Feeding method (formula only, breast only, combination) Exposure to fluoride varnish/gel before age 6 **Oral hygiene habits at age < 6 years and at the time of the study (at age 9 and 12):** Frequency of toothbrushing Frequency of supervised toothbrushing After brushing routine Eating/licking toothpaste Amount of toothpaste Type of toothpaste No information about dietary behaviours and dental service utilisation of 9- and 12-year-old participants was collected.
Statistical analysis and management of confounders	**Fluorosis analysis:** 1) Difference in fluorosis prevalence between fluoridated and non-fluoridated areas:

	Association between all potential confounders (except for oral hygiene habits at the time of the study) and fluorosis (Dean's 'very mild' or higher) were assessed in bivariate analysis. Variables that were significant in bivariate analysis were included in multivariable analysis using the enter method (all variables entered in one block). The main explanatory variable was the fluoride level in the water classified as 0 lifetime (reference)/0.5 ppm lifetime/0.7 ppm F in the first two years of life, then 0.5 ppm F. 2) Difference in fluorosis prevalence between 9-year-olds and 12-year-olds (in both fluoridated and non-fluoridated areas) Chi-square tests were used to compare fluorosis prevalence in 9- and 12-year-olds with CWF and between 9- and 12-year-olds without CWF. The unadjusted % difference between the fluoridated and non-fluoridated groups before and after the downward adjustment were presented in answer to the main research question regarding the impact of the downward adjustment on dental fluorosis. **Dental caries analysis:** Dental caries levels in 9- and 12-year-olds could not be directly compared as they had different teeth present and because caries tends to increase with age. 1) The unadjusted difference in mean DMFT/S and dmft/s and caries prevalence between children in fluoridated and non-fluoridated areas at age 9 and age 12 was assessed using the Mann Whitney test. Note: the published study and the PhD thesis both report regression analyses of age and area of residence and the outcomes caries prevalence and mean caries experience. However, these analyses are not considered as part of this review because it not considered appropriate to analyse dental caries data for two different age groups in this manner.
Additional information	
Sample size calculation	90% power at a 5% level of significance to detect: • a 10% difference in fluorosis prevalence between children living in fluoridated and non-fluoridated areas (227 in each cell). • a 25% difference in mean DMFT between children living in fluoridated and non-fluoridated areas (116 in each cell). Inflated for 30% non-response, 15% non-consented and 15% mobility rate a total sample size of 1600 (400 per cell) was required.
Funding	Funded by the Ministry of Education, Malaysia
Conflicts of interest	None reported

Risk of bias of included studies assessed using ROBINS-I

Table B 9: Risk of Bias Table for Evans 1991

	Evans 1991	
Domain	**Assessment**	**Comment**
Bias due to confounding	Moderate	Data collected at one time point for cohorts of children (aged 7-12) whose permanent incisors mineralised before (during) and after downward adjustment of CWF concentration. Five to six-year difference in age from youngest to oldest child examined makes it unlikely that major extraneous events or changes in context affected the different groups of children. Analysis included multiple regression of CFI on cohort (age -group as proxy for exposure to the downward adjustment) adjusting for gender only. No controlling for non-water sources of fluoride, however, it is considered unlikely that confounding due to exposure to other sources of fluoride had an important impact on the study results (study conducted prior to the availability of fluoride toothpaste in Hong Kong).
Bias in selection of participants into the study	Moderate	Participants were selected into the study based on attending primary schools in Hong Kong several years after the downward adjustment. Some children who were exposed to the intervention when their permanent central incisors were mineralising were likely to have moved away before selection of participants into the study. Thus, some eligible children were not included in the study; however, the reasons children were not included are unlikely to be related to the intervention or the outcome.
Bias in classification of interventions	Low	The population was clearly defined. All children had exposure to CWF with the concentration under the control of the authorities. Exposure to the intervention was classified based on the date of the downward adjustment of CWF concentration (June 1978). Although the actual mean water fluoride concentrations did not exactly correspond with official concentrations in the 48 months before (0.82 rather than 1 ppm) and after the downward adjustment (0.63 ppm rather than 0.7 ppm), the mean fluoride concentration was on average lower by approximately 0.2 ppm in the 48 months following the adjustment compared with the 48 months prior to the adjustment.
Bias due to deviations from intended interventions	Low	All children were lifetime residents of Hong Kong with exposure to CWF at a concentration under the control of the authorities. There were no co-interventions reported or likely.
Bias due to missing data	Serious Direction of bias unpredictable	Of 1,680 children invited, 1,541 were examined (92% of those invited) and 1,062 were included in the analysis (63% of those invited). Children were excluded from the analysis if they were not lifetime residents (172, 10% of those invited, 11% of those examined) or if they did not have adequately erupted maxillary central incisors (n=307, 18%

		of those invited, 20% of those examined). These exclusions are likely to have involved the younger cohort, born after the adjustment (i.e., the intervention group). Although missing data are not reported by age cohort, reasons for missingness are likely to differ across the cohorts. However, the trend of decreasing fluorosis prevalence across the age cohorts provides some evidence that the findings were robust to the missing data for younger participants.
Bias in measurement of outcomes	Serious Away from the null	The examiner could not be blinded to exposure to the reduced CWF concentration due to an awareness of the age of the child. Lack of blinding puts the outcome data at risk of differential measurement error.
Bias in selection of the reported result	Moderate	There was no pre-registered protocol or statistical analysis plan but outcomes are clearly defined and there is no indication of selective reporting of results from among multiple analyses.
Overall	**Serious**	

Table B 10: Risk of Bias Table for Wong 2014

	Wong 2014	
Domain	**Assessment**	**Comment**
Bias due to confounding	Serious	Measurement of outcomes at one time point before and after each downward adjustment of CWF concentration (2 time points after the 1988 adjustment). Long time span of investigation introduces risk that extraneous events or changes in context could have had an impact on the outcome. Potential confounders were not identified and there is no control for confounding in the analysis.
Bias in selection of participants into the study	Moderate	Participants were selected into the study based on attending primary schools in Hong Kong several years after the downward adjustment. Some children who were exposed to the intervention when their permanent central incisors were mineralising were likely to have moved away before selection of participants into the study. Thus, some eligible children were not included in the study; however, the reasons children were not included are unlikely to be related to the intervention or the outcome.
Bias in classification of interventions	Moderate	It is not clear from the study report if all children had exposure to CWF while their permanent incisors were mineralising (i.e., if all included children were lifetime residents in Hong Kong). Exposure to the intervention was classified based on the dates of the two downward adjustments of CWF concentration (1978 and 1988). No supporting information regarding actual concentrations of water fluoride were reported. Information about the intervention comes from the health authorities and is unlikely to be affected by the outcome.
Bias due to deviations from intended interventions	No information	All children had exposure to CWF at a concentration under the control of the authorities. No information is reported regarding possible co-interventions.

Bias due to missing data	Low	Of 10,632 surfaces available for scoring, 425 (4%) were excluded for reasons not considered to be associated with the outcome. Losses and reasons for losses were not reported by group (year of examination) but the overall proportion of surfaces not scored was low.
Bias in measurement of outcomes	Moderate	Although fluorosis measurement is subjective, the one examiner was blind to the year the photograph was taken. The Developmental Defects of Enamel (DDE) Index measures diffuse enamel opacities rather than specifically measuring fluorosis. Therefore, there was a risk of misclassification of fluorosis.
Bias in selection of the reported result	Moderate	There was no pre-registered protocol or statistical analysis plan. However, outcomes are clearly defined and there is no indication of selective reporting of results from among multiple analyses.
Overall	**Serious**	

Table B 11: Risk of Bias Table for Mohd Nor 2018

	Mohd Nor 2018	
Domain	**Assessment**	**Comment**
Bias due to confounding	Fluorosis outcome: Serious	Potential confounders were identified but there was no control for confounding in the analyses of the difference in fluorosis prevalence between children with lifetime exposure to CWF at 0.5 ppm F and children with exposure to 0.7 ppm for the first two years of life and 0.5 ppm F thereafter.
	Caries outcome: Serious	Potential confounders were identified but there was no control for confounding in the analyses of the difference in dental caries between children with lifetime exposure to CWF (at 0.5 ppm F and at 0.7 ppm for the first two years of life and 0.5 ppm F thereafter) and children with No CWF.
Bias in selection of participants into the study	Moderate	Participants were selected into the study based on their age and the geographic areas where they lived. Some children who were exposed and not exposed to the intervention when their permanent central incisors were mineralising are likely to have moved away before selection of participants into the study. Some eligible children were not included in the study; however, the reasons children were not included are unlikely to be related to the intervention or the outcome.
Bias in classification of interventions	Overall	Exposure to the intervention was classified based on the date of the downward adjustments of CWF concentration (Dec. 2005). Information about the intervention comes from the health authorities and is unlikely to be affected by the outcome.
	Fluorosis outcome: Moderate	Because the pre-intervention group (age 12) had partial exposure to the reduced water fluoride concentration that varied depending on their date of birth and because there is variation in the period of mineralisation of the permanent maxillary central incisors, it is likely that the pre-intervention group had partial exposure to the reduced water fluoride concentration while the permanent maxillary central incisors were mineralising. Any misclassification of exposure to the adjustment would bias towards the null.
	Caries outcome: Serious	Whereas the 9-year-olds had lifetime exposure to 0.5 ppm F, the 12-year-olds had exposure to the higher concentration of fluoride only for the first two years of life; a small part of the time that the permanent teeth were mineralising. The 12-year-olds had exposure to 0.5 ppm F for most of their lives including topical exposure to the lower F concentration after the permanent teeth erupted. Any misclassification of exposure to the adjustment would bias towards the null.
Bias due to deviations from intended interventions	No information	No information is reported regarding possible co-interventions.
Bias due to missing data	Low	Of 1,600 children invited to participate, 1,291 (81%) returned documentation and provided signed parental consent. 50 children were subsequently excluded as non-lifelong residents. 57 children were absent on the day and a

		further 29 were excluded for other reasons. 1155 were clinically examined and photographed (72% of those invited). Quote: "The number of children excluded across age groups and in fluoridated and non-fluoridated areas was broadly similar".
Bias in measurement of outcomes	Fluorosis outcome: Moderate	Although fluorosis measurement is subjective, the three examiners were blind to fluoridation status. Based on the dental age of the children (age 9 and 12), blinding to water fluoride concentration (pre or post adjustment) may have been compromised (but examiners still would have been unaware of exposure to CWF).
	Caries outcome: Serious	Caries measurement is subjective, and the one examiner was not blind to exposure to CWF (one geographic area was non-fluoridated and the other was fluoridated) or exposure to the original or the adjusted concentration of water fluoride (children aged 9 were exposed to the lower concentration and children aged 12 to the higher concentration).
Bias in selection of the reported result	Fluorosis outcome: Serious	Dean's Index was measured clinically as well as photographically but the results for Dean's Index measured clinically were not reported in the published paper or the associated PhD thesis. The authors justified the decision to only report the photographic data on the basis that this blind measurement was at lower risk of bias than the clinical measurement and there was a high level of agreement between clinical and photographic scores for 111 selected participants. However, both outcome measures should have been reported in full.
	Caries outcome: Moderate	There was no pre-registered protocol or statistical analysis plan, but outcomes were clearly defined and there is no indication of selective reporting of results from among multiple analyses.
Overall	**Serious**	

Additional forest plot showing heterogeneity between the included studies

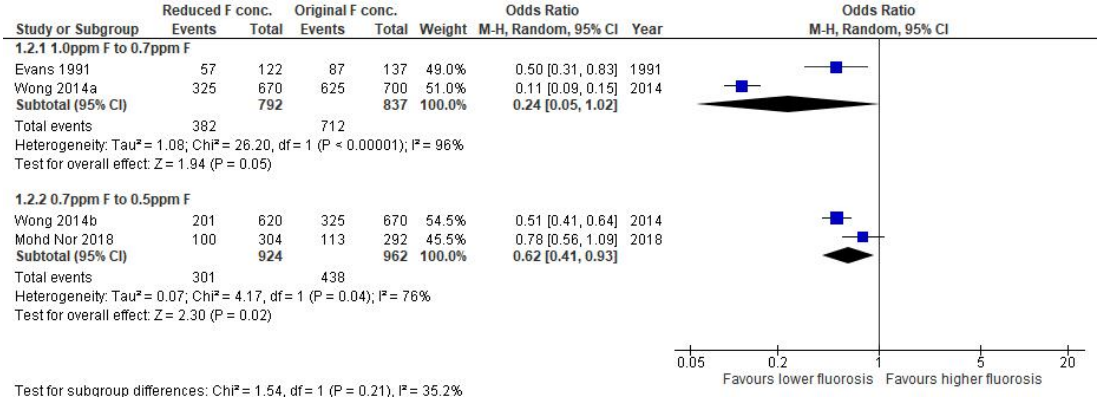


Figure B1: Forest plot showing heterogeneity between studies within subgroups evaluating downwards adjustments of different water fluoride concentrations

Note: Two subgroups were created (by concentration of the downward adjustment) to separate the results for Wong 2014 so that the results could be presented evaluating two different adjustments within the same study (Wong 2014a is adjustment from 1.0 to 0.7 ppm fluoride and Wong 2014b is 0.7 to 0.5 ppm fluoride) and no overall pooled measure of effect was calculated. This is because it would not have been appropriate for one group of participants from Wong 2014 (1991 with 0.7 ppm fluoride) to contribute data twice to a meta-analysis.

GRADE evidence profile

Table B 12: GRADE evidence profile for the impact of downward adjustment of water fluoride concentration on dental fluorosis

GRADE domain	Judgement	Concerns about certainty domains
Risk of bias	Lack of randomisation and no control for confounding in all three included studies.	Very serious
Indirectness	Two of the four comparisons involved populations who only had exposure to fluoride from water (no exposure to other sources of fluoride such as fluoride toothpaste). This reduces the applicability of the body of evidence to contemporary populations with exposure to fluoride from several sources including water.	Serious
Imprecision	For 2 studies, reductions in fluorosis were judged to be clinically meaningful at both the upper and lower boundaries of the 95% confidence intervals. In the remaining study the 95% confidence interval included an OR of 1, however the study is likely to have been underpowered to detect a difference between the two fluoridated groups (it was powered to detect a difference in fluorosis between the fluoridated and non-fluoridated groups) and an identified source of bias favoured a null finding.	Not serious
Inconsistency	Despite high clinical and statistical heterogeneity, results consistently showed a reduction in fluorosis. The only difference was in the size of the reduction.	Not serious
Publication bias	This is thought to be unlikely due to the small number of countries that have implemented the intervention (downward adjustment) and the comprehensive search for evidence relating to adjustments in these countries.	Not likely

Appendix C: Ethical approval and data protection

Ethical approval letters from the Clinical Research Ethics Committee of the Cork Teaching Hospitals

Approval Letter dated 8th May 2013 for FACCT Phase 1 protocol and study documents 2013-14

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

COPY

Our Ref ECM 5 (2) 07/05/13

ORAL HEALTH SERVICES
22 JUL 2013
RESEARCH CENTRE

8th May 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The Clinical Research Ethics Committee of the Cork Teaching Hospitals reviewed your correspondence at its recent meeting held on 7th May 2013.

Full approval is granted by the Committee to carry out the above study at:

- Oral Health Services Research Services Centre
- Schools.

The following documents were approved:

- Signed Application Form
- CV for Chief Investigator
- Draft Protocol Version 1.4 dated 23rd April 2013 (Please send final version of this document when available)
- Information Leaflet and Consent Form for Parents
- Assent Form
- Parent Survey for Parents of Junior Class Children
- Parent Survey for Parents of 2nd Class Children
- Parent Survey for Parents of 6th Class Children
- Parent Perceptions Questionnaire and Family Impact Scale
- Focus Group Consent and Draft Discussion Guide
- Letters to School Board of Management and School Principal
- Child Oral Health Related Quality of Life Questionnaire for 2nd Class
- Child Oral Health Related Quality of Life Questionnaire for 6th Class
- Oral Health Behaviours Questionnaire for 6th Class Children
- Measurement for Height and Weight
- Criteria and Codes for Clinical Indices
- Images for Index of Orthodontic Treatment Need
- Images for Self-Perception of Enamel Opacities
- Clinical Record Form, Paper Representation of Electronic Forms.

UCC
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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

The following Committee Members attended the above meeting.

Professor Michael Molloy – (Chairman)
Dr Mike O'Connor
Professor Brendan Buckley
Professor Colin Bradley
Matt Murphy
Frank Nyhan (lay-member)
Dr Michael Hyland

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 7th August 2013 for training and calibration of examiners prior to commencement of FACCT Phase 1 fieldwork 2013-14

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 5 (1) 06/08/13

7th August 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00113: A training and calibration exercise in preparation for a clinical study on dental caries and enamel fluorosis in children.

Dear Professor Whelton

Expedited approval is granted to carry out the above study at:

- Oral Health Services Research Centre, Cork Dental Hospital.

The following documents were approved:

- Original Signed Application Form
- CV for Chief Investigator
- Study Protocol Final Version dated 16th July 2013
- Letter to Parent/Guardian
- Information Leaflet
- Consent/Assent Form
- General Medical History Form
- Child Oral Health Questionnaire (8 to 10 years)
- Child Oral Health related Quality of Life Questionnaire for 6th Class
- Images for self-perception of enamel opacities
- Oral Health Behaviours Questionnaire for 6th Class Children
- Letters to School Board of Management and School Principal
- Measurement of Height and Weight
- Criteria and Codes for Clinical Indices
- Images for Index of Orthodontic Treatment Need
- FACCT Clinical Record Form.

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

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Approval Letter dated 6th September 2013 for training and calibration of gold standard examiners prior to commencement of FACCT Phase 1 fieldwork 2013-14

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University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (ww) 01/10/13

6th September 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00113: A training and calibration exercise in preparation for a clinical study on dental caries and enamel fluorosis in children.

Dear Professor Whelton

The Chairman approved the following:

- Amendment Application Form
- Amended Protocol Final Version dated 21st August 2013
- Parent Amended Cover Letter, Information Leaflet, Consent Form and Child Assent Form
- Letter to School Board of Management and School Principal.
- Letter to School Principal.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 6th September 2013 for amendments made to the FACCT Phase 1 2013-14 study protocol and study documents

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Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (vv) 01/10/13

6th September 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The Chairman approved the following:

- Signed Amendment Form
- Revised Study Protocol Draft Version 1.5 dated 20th August 2013
- Information Leaflet for Parents
- Consent Form for Parents
- Parent Survey for Junior Infants Version 1.2 dated 20th August 2013
- Parent Survey for 6th Class Children Version 1.2 dated 20th August 2013
- Parent Perceptions Questionnaire and Family Impact Scale Version 1.2 dated 20th August 2013
- Letters to School Board of Management and School Principal Version 1.2 dated 20th August 2013
- Child Oral Health Related Quality of Life Questionnaire for 6th Class Version 1.2 dated 20th August 2013
- Oral Health Behaviours Questionnaire for 6th Class Children Version 1.2 dated 20th August 2013
- Criteria and Codes for Clinical Indices
- FACCT Clinical Record Form
- Parent Letter – Child not Selected for FACCT Version 1.1 dated 20th August 2013
- Parent Letter Re Urgent Care
- Letter dated 2nd September 2013 – Clarifications regarding Section 2.1 Objectives.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 22nd October 2013 for further training and calibration of examiners prior to commencement of FACCT Phase 1 2013-14 fieldwork

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (kk) 05/11/13

22nd October 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00113: A training and calibration exercise in preparation for a clinical study on dental caries and enamel fluorosis in children.

Dear Professor Whelton

The Chairman approved the following:

- Study amendment detailed in letter dated 21st October 2013
- Cover Letter and Information and Consent/Assent Form re: training and calibration exercise for FACCT study
- Letter to School Board of Management and School Principal.

Yours sincerely

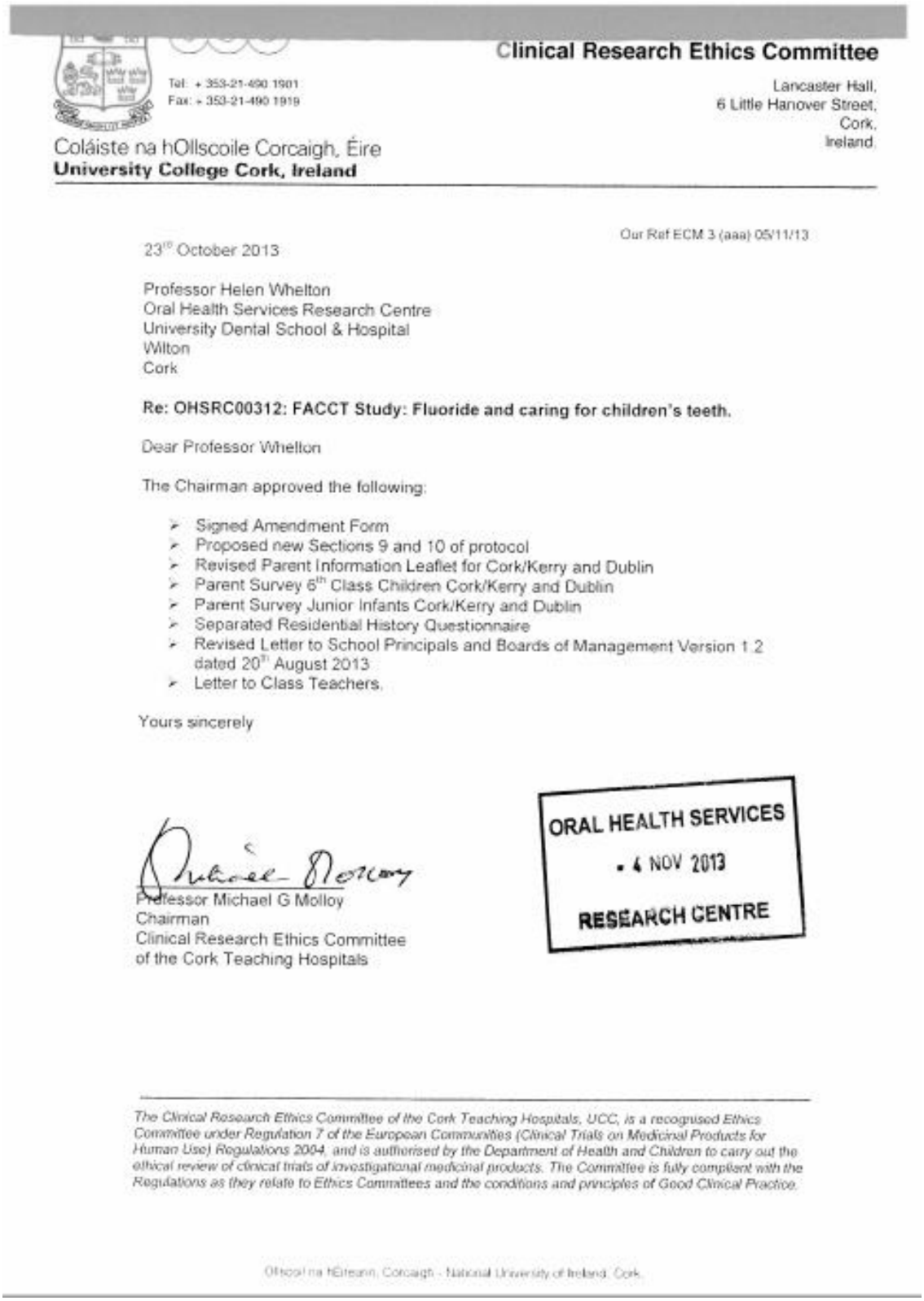
Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

ORAL HEALTH SERVICES
- 4 NOV 2013
RESEARCH CENTRE

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork

Approval Letter dated 23rd October 2013 approving further amendments to the FACCT Phase 1 2013-14 study protocol and study documents



Clinical Research Ethics Committee

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6 Little Hanover Street,
Cork,
Ireland.

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

Our Ref ECM 3 (aaa) 05/11/13

23rd October 2013

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The Chairman approved the following:

- Signed Amendment Form
- Proposed new Sections 9 and 10 of protocol
- Revised Parent Information Leaflet for Cork/Kerry and Dublin
- Parent Survey 6th Class Children Cork/Kerry and Dublin
- Parent Survey Junior Infants Cork/Kerry and Dublin
- Separated Residential History Questionnaire
- Revised Letter to School Principals and Boards of Management Version 1.2 dated 20th August 2013
- Letter to Class Teachers.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

ORAL HEALTH SERVICES
4 NOV 2013
RESEARCH CENTRE

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork

Approval Letter dated 27th June 2016 for amendments to the protocol and study documents for FACCT Phase 2 Fieldwork 2016-17

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (e) 05/07/16

27th June 2016

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The Chairman approved the following:

- Cover Letter dated 21st June 2016
- Amendment Application Form signed 21st June 2016
- Study Protocol Version 2 dated 21st June 2016
- Information Leaflet Revised for Cork, Kerry and Dublin
- Consent/Assent Form Revised
- Residential History Form Revised
- Parent Questionnaire Booklet for 2nd Class (Cork/Kerry and Dublin Versions)
- Child Oral Health related Quality of Life Questionnaire age 8-10 (entered electronically)
- Oral Health Behaviours Questionnaire for 2nd Class Pupils (entered electronically).

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 28th July 2016 for further amendments to the protocol and study documents for FACCT Phase 2 Fieldwork 2016-17

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Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (kk) 09/08/16

28th July 2016

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The Chairman approved the following:

- Cover Letter dated 19th July 2016
- Amendment Application Form signed 19th July 2016
- Study Protocol Version 3 dated 19th July 2016
- Parent Questionnaire Booklet for 2nd Class (Cork/Kerry and Dublin Versions)
- Oral Health Behaviours Questionnaire for 2nd Class Pupils (entered electronically).
- School Contact Letters 2016/17
- Urgent Care Letter 2016/17
- Letter of Explanation for Parents of Children not invited to Participate in 2016/17.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork.

Approval Letter dated 2nd August 2016 for training and calibration of examiners prior to commencement of FACCT Phase 2 fieldwork 2016-17

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 4 (e) 06/09/16

2nd August 2016

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00416: A training and calibration exercise in preparation for the second round of fieldwork in a clinical study on dental caries and enamel fluorosis in children.

Dear Professor Whelton

Full approval is granted to carry out the above study at:

- Oral Health Services Research Services Centre
- Schools.

The following documents were approved:

- Cover Letter dated 19th July 2016
- Application Form signed 22nd July 2016
- CV for Chief Investigator
- Study Protocol Final Version dated 19th July 2016
- Cover Letter for Parents
- Parent Information Sheet and Consent Form
- General Medical History Collection Sheet
- Child Oral Health Questionnaire 8-10 years
- Looking after your Teeth Questionnaire
- Letter to Schools
- Measurement of Height and Weight Instructions
- Criteria and Codes for Clinical Indices
- FACCT Clinical Record Form.

We note that the co-investigators involved in this study will be:

- Dr Mairead Harding, Deputy Director and Dr Michael Cronin, Statistician.

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

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Clinical Research Ethics Committee

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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

Yours sincerely,

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 9th November 2016 for further amendments to the FACCT Phase 2 2016-17 study documents

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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 3 (mmmm) 15/11/16

9th November 2016

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00312: FACCT Study: Fluoride and caring for children's teeth.

Dear Professor Whelton

The chairman approved the following:

- Cover letter dated 4th November 2016
- Amendment application form signed 4th November 2016
- Letters to School Board of Management, School Principal and Class Teacher: please put version two on this document prior to use.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Approval Letter dated 9th November 2016 for training and calibration of new examiners for FACCT Phase 2 2016-17 fieldwork

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref ECM 4 (e) 06/09/16 & ECM 3 (nnnn) 15/11/16

9th November 2016

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00416: A training and calibration exercise in preparation for the second round of fieldwork in a clinical study on dental caries and enamel fluorosis in children.

Dear Professor Whelton

The Chairman approved the following:

- Cover letter dated 4th November 2016
- Amendment application form signed 4th November 2016
- Cover letter for parents: Please put version 2 on this document prior to use
- Letters to School Board of Management and School Principal: Please put version 2 on this document prior to use.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork

Data protection

Health research regulations checklist

Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (As Amended):

Health Research Regulations Checklist

This checklist is for use by researchers who are carrying out health research to determine if their research meets the requirements of the **Health Research Regulations**. Please note that one of those requirements is to obtain explicit consent from research participants, therefore this checklist should be used in conjunction with the **Explicit Consent Checklist** to establish if the consent they have received is sufficient to meet the requirements of the Health Research Regulations.

Preliminary Notes:

- The above Regulation is available to view at: http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

- Health research is defined at Regulation 3(2) as:

9 (a) …"health research" means any of the following scientific research for the purpose of human health:
10 *(i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels;*
(ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
(iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
(iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
(v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status;
(b) Health research referred to in clause (i) to (v) of subparagraph (a) may include action taken to establish whether an individual may be suitable for inclusion in the research.

- Further information on the above Regulation is available at https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/

- Information about recent amendments and matters under consideration by the Department of Health are available at on the Health Research Consent Declaration Committee website. This includes important information with regard to retrospective clinical studies – see: https://hrcdc.ie/possible-amendments-to-health-research-regulations-matters-under-consideration-by-the-department-of-health/

Health Research Regulations Checklist

The Health Research Regulations require that the following measures are in place to safeguard the rights and freedoms of the data subject:

	Required Measure:		**Guidance Notes:**
1.	Arrangements are in place to ensure that personal data will be processed as is necessary: a) to achieve the objective of the health research and; b) to ensure that shall not be processed in such a way that damage or distress to the data subject	√	This can be ensured by having a patient-focused research questionnaire for your project. In most cases, you will already have this in place. Please ensure that your questionnaire has been reviewed/logged by UCC's Clinical Research Reporting Officer (Dr. Muiris Dowling). Also ensure compliance with Good Clinical Practice guidelines as far as is applicable: https://www.ich.org/home.html
2.	Appropriate governance structures for the carrying out of the health research are in place including:		
	(i). Ethical approval of the health research by a research ethics committee	√	(i). Self evident.
	(ii). Specification/identification of data controller;	√ PIL	(ii). Your Patient Information Leaflet/Informed Consent Form (PIL/ICF) must specify who the data controller is (i.e. the body who determines the purposes and means of the processing of personal data). In most cases, the data controller will be UCC. A

				historical consent form can be considered adequate to address this requirement if a research participant can readily determine from the PIL/ICFthat UCC and a named Principal Investigator(s) is the organisation / person(s) in charge of and managing their stored data. A PIL/ICF does not need to contain the words 'Data Controller' if a research participant can readily identify UCC and the contact point/PI from the PIL/ICF.
	(iii).	Specification/identification of joint data controllers (if any) and compliance with Article 26 of GDPR;	n/a	(iii). Article 26 of GDPR provides: *Where two or more controllers **jointly determine the purposes and means** of processing [personal data], they shall be joint controllers…..*[1]
	(iv).	Specification/identification of any data processors (if any) involved;	n/a	(iv). Please see Section 9 (Definitions) of UCC's Data Protection Policy for further information: https://www.ucc.ie/en/ocla/comp/data/dataprotection/.
	(v).	Specification/identification any person or organization (if any) who provides funding for, or otherwise supports, the project.	√ PIL	(v). This should be contained within the Patient Information Leaflet/Informed Consent Form given to the patient at the time of enrolment
	(vi).	Specification of any person (if any) other than the named data controller, joint controllers or processors with whom it is intended to share	n/a	(vi). The Patient Information Leaflet/Informed Consent Form needs to acknowledge that data may be shared with others if applicable (e.g. with other academic collaborators) and for what

[1] Article 26 further provides: *They [Joint Controllers] shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Articles 13 and 14, by means of an arrangement between them….The arrangement may designate a contact point for data subjects. 2 The arrangement referred to in paragraph 1 shall duly reflect the respective roles and relationships of the joint controllers vis-à-vis the data subjects. The essence of the arrangement shall be made available to the data subject. 3 Irrespective of the terms of the arrangement referred to in paragraph 1, the data subject may exercise his or her rights under this Regulation in respect of and against each of the controllers.*

	any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.		purpose but specific named individuals do not need to be identified. The Patient Information Leaflet/Informed Consent Form also needs to indicate if any data will be sent to a country outside of the European Union.
	(vii). Provision of training in data protection law and practice to those involved in carrying out the health research is a mandatory legal requirement.	√	(vii). Please note: ➢ UCC has online data protection training available at: https://www.ucc.ie/en/gdpr/trainingandresources/ ➢ The HRB has an online training resource in relation to the Regulations available at: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/
3.	The following processes and procedures relating to the management and conduct of the health research are in place:		
	(i). the carrying out of an assessment of the data protection implications of the health research;	√	(i). This should have been part of the original ethics application and would reflect adherence to the principles of Good Clinical Practice (GCP)
	(ii). where the assessment carried out under clause (i) indicates a high risk to the rights and freedoms of individuals, the carrying out of a data protection impact assessment;	n/a	(ii). Please see UCC's Data Protection Policy: https://www.ucc.ie/en/ocla/comp/data/dataprotection/
	(iii). measures that demonstrate compliance with the data minimisation principle in Article 5(1)(*c*);	√	(iii). Please see UCC's DPIA procedure at: https://www.ucc.ie/en/gdpr/procedures/dataprotectionimpactassessmentprocedure

			Note: In most cases, a DPIA will be required.
	(iv). controls to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data;	√	(iv). Consistent with Good Clinical Practice Guidelines
	(v). controls to log whether and by whom personal data have been consulted, altered, disclosed or erased;	√	
	(vi). measures to protect the security of the personal data concerned;	√	(vi). Consistent with Good Clinical Practice Guidelines
	(vii). arrangements to anonymise, archive or destroy personal data once the health research has been completed;	√	
	(viii). other technical and organisational measures designed to ensure that processing is carried out in accordance with the General Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.	√	(viii). Ensure that appropriate security measures are in place to protect personal data.
4.	Arrangements to ensure that personal data are processed in a transparent manner are identified and in place;	√	For guidance on the transparency requirements of GDPR, see Section 5.1 of UCC's Data Protection Policy: https://www.ucc.ie/en/ocla/comp/data/dataprotection/ See also UCC's Data Protection Notice Procedure and Template: https://www.ucc.ie/en/gdpr/procedures/dataprotectionnoticeprocedure/

			https://www.ucc.ie/en/media/support/gdpr/TemplateDataProtectionNotice.docx This information would typically be provided within your Patient Information Leaflet/Informed Consent Form.
5.	Explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof.	√	Please refer to the Explicit Consent Checklist – available at: https://www.ucc.ie/en/research/support/fuf/. In the event that explicit consent is *not* in place, you will need to follow the process for seeking a declaration from the Health Research Consent Declaration Committee if you are of the view that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject. More information is available at: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/consent/health-research-consent-declaration-committee/consent-declaration-decision-tree/

Explicit consent checklist for research

Data Protection Act 2018 (section 36(2)) Health Research Regulations 2018 (as amended))

Explicit Consent Checklist for Researchers

This checklist is for use by researchers who are carrying out **health research** to establish if the consent they have received from research participants is sufficient to meet the requirements of the Health Research Regulations.

The Health Research Regulations 2018, which came into operation on 8 August 2018, require that those who are processing personal data for the purposes of health research (see definition at Appendix 1 (Definition of Key Terms) below) shall ensure that a number of measures are taken to safeguard the fundamental rights and freedoms of the data subject (i.e. research participant). One such required measure is to obtain the **explicit consent** of the data subject for the processing of their personal data for the purpose of the specified health research either in relation to a particular area or more generally in that area or a related area of health research, or part thereof. The only limited exception to the requirement to obtain this explicit consent is if researchers have obtained a **"consent declaration"** from the Health Research Consent Declaration Committee.

For the avoidance of doubt, please note the Health Research Regulations apply to health research which commenced prior to the introduction of the Health Research Regulations 2018. Specifically, Regulation 6 provides that "a controller" who is carrying out health research that commenced prior to 8 August 2018 who processes or further processes personal data for the purposes of that health research after 8 August 2018 shall, as soon as practicable and no later than 7 August 2019, have explicit consent of the data subject for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof.

Therefore, if you are carrying out health research, please review your current "consents" for your health research project against the checklist below to ascertain if you have explicit consent in line with the Health Research Regulations and GDPR. In order to have valid explicit consent, you must be able to respond "yes" to all of the questions (save for questions 10 and 11 unless they are applicable). If you are not able to respond "yes" to each question, you will

need to follow the process for seeking a declaration from the Health Research Consent Declaration Committee if you are of the view that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject. The deadline for application is **on or before 7 July 2019**.

The HRB has developed a decision tree to help researchers assess whether they might be eligible to submit an application to the Health Research Consent Declaration Committee to obtain a declaration that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/consent/health-research-consent-declaration-committee/consent-declaration-decision-tree/

Explicit Consent Checklist

GDPR Consent Requirements	Insert Yes/No (or not applicable if required under Q10 and Q11)	Notes
1. Has the data subject (research participant) given an unambiguous indication of her/his wishes?	Yes	The GDPR is clear that consent requires a statement from the data subject or a clear affirmative act, which means that the data subject must have taken a deliberate action to consent to the particular processing. It must be obvious that the data subject has consented to the particular processing.
2. Has the consent been freely given?	Yes	"Freely given" implies real choice and control for data subjects. As a general rule, the GDPR prescribes that if the data subject has no real choice, feels compelled to consent or will endure negative consequences if they do not consent, then consent will not be valid.
3. Have you ensured that there is no imbalance of power when seeking consent?	Yes	Consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences (e.g. extra costs) if he/she does not consent.

4. Have you made the request for consent prominent and separate from your other terms and conditions?	n/a	Article 7(4) of the GDPR indicates that "bundling" consent with the acceptance of terms or conditions, or "tying" the provision of a contract or a service to a request for consent to process personal data that are not necessary for the performance of that contract or service, is considered highly undesirable. If consent is given in this situation, it is presumed to be not freely given (recital 43).
5. Have you given separate distinct ('granular') options to consent separately to different purposes and types of processing?	Yes	A research project may involve multiple processing operations for more than one purpose. In such cases, the data subjects should be free to choose which purpose they accept, rather than having to consent to a bundle of processing purposes. Please note the Health Research Regulations 2018 allow for the fact that it may be difficult to fully specify the purposes of the research at the outset. Regulation 3(1)(e) provides that explicit consent from the individual may be obtained "*for the purpose of the specified health research, **either in relation to a particular area or more generally in that area or a related area of health research, or part thereof***". For further information see: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/consent/broad-consent/
6. Can individuals refuse to consent without detriment?	Yes	You should be able to prove that the data subject had a free or genuine choice about whether to consent and that it was possible to withdraw consent without detriment.
7. Have you informed data subjects of the data controller's identity (or if there is more than one the	Yes	UCC is the Data Controller and should be readily identifiable on the Consent Form as the organisation managing the research

name of each data controller)?		participant's personal data. In a case where the consent sought is to be relied upon by multiple (joint) data controllers or if the data is to be transferred to other data controllers who wish to rely on the original consent, these organisations should all be named.
8. Have you included the purpose of each of the processing operations for which consent is sought?	Yes	Have you clearly explained why you are collecting the data and what it will be used for?
9. Have you clearly stated what (type of) personal data will be collected and used?	Yes	e.g. names, addresses, blood type, medical condition, etc.
10. If applicable: Have you included information about the use of the data for automated decision-making in accordance with Article 22 (2)(c)?	n/a	Processing is "automated" where it is carried out without human intervention, and where it produces legal effects or significantly affects you. Automated processing includes profiling. **Further Information:** https://gdpr-info.eu/art-22-gdpr/ UCC's Data Protection Policy Section 5.11: https://www.ucc.ie/en/ocla/comp/data/dataprotection/
11. If applicable: Have you included information on the possible risks of data transfers outside the EEA due to absence of an adequacy decision and of appropriate safeguards as described in Article 46? See: https://gdpr-info.eu/art-46-gdpr/	n/a	

12. Have you informed the data subject that they have the option to withdraw consent?	Yes	Article 7(3) of the GDPR prescribes that the controller must ensure that consent can be withdrawn by the data subject as easy as giving consent and at any given time.
13. **Have you used clear, plain language that is easy to understand?**	Yes	
14. Can you demonstrate that consent has been given?	Yes	Article 7(1) of the GDPR clearly outlines the explicit obligation of the controller to demonstrate a data subject's consent. The burden of proof will be on the controller.

Appendix 1 - Definition of Key Terms

The following terms used throughout this guide have specific legal meanings under the GDPR. In order to understand your rights fully, please read the following glossary of key terms:

Health research

Regulation 3.(2) of the Regulations defines 'health research' as follows:

(a) …"health research" means any of the following scientific research for the purpose of human health: (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels; (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; (iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals; (iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; (v) research with the goal of improving the

health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status;
(b) Health research referred to in clause (i) to (v) of subparagraph (a) may include action taken to establish whether an individual may be suitable for inclusion in the research.

Personal data

The term "personal data" means any information relating to a living person who is identified or identifiable (such a person is referred to as a "data subject"). If the information can be used on its own or in combination with other information to identify a specific person, then it counts as personal data.

The GDPR gives examples of identifiers, including names, identification numbers, and location data. A person may also be identifiable by reference to factors which are specific to their identity, such as physical, genetic or cultural factors.

Processing

The term "processing" refers to any operation or set of operations performed on personal data. Processing includes storing, collecting, retrieving, using, combining, erasing and destroying personal data, and can involve automated or manual operations.

Data Controller

"**Data controller"** means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data. UCC, for example, is a data controller in relation to personal data relating to its own staff and students.

Data Processor

A “data processor” refers to a person, company, or other body which processes personal data on behalf of a data controller. (Note: the term ‘Data Processor’ does not include an employee of a data controller who processes such data in the course of their employment. Examples of data processors include payroll companies, accountants and market research companies, all of which could hold or process personal information on behalf of someone else).

Consent

Some types of processing are carried out on the basis that you have given your consent. Under the GDPR, consent to processing must be freely given, specific, and informed. You cannot be forced to give your consent, you must be told what purpose(s) your data will be used for and you should show your consent through a ‘statement or as a clear affirmative action’ (e.g. ticking a box).

Profiling

Profiling is any kind of automated processing of personal data that involves analysing or predicting your behaviour, habits or interests.

Special categories of personal data

Certain types of sensitive personal data are subject to additional protection under the GDPR. These are listed under Article 9 of the GDPR as “special categories” of personal data. The special categories are:

1. personal data revealing racial or ethnic origin,
2. political opinions,
3. religious or philosophical beliefs,
4. trade union membership,
5. genetic data and biometric data processed for the purpose of uniquely identifying a natural person,
6. data concerning health,
7. data concerning a natural person’s sex life or sexual orientation.

Processing of these special categories is prohibited, except in limited circumstances set out in Article 9 of the GDPR.

Data Protection Officer (DPO)

The GDPR requires data controllers and data processors to appoint a Data Protection Officer (DPO) in certain circumstances. A data controller can also voluntarily decide to appoint a DPO. UCC's Data Protection Officer is:

Catriona O'Sullivan
Information Compliance Manager
Officer of Corporate & Legal Affairs, University College Cork
Tel: +353 (0)21 4903949 Email: gdpr@ucc.ie

Appendix D: Study documents

FACCT 2016-17 information leaflet and consent form

If I agree and if my child agrees, can they still say No on the day of examination?

Yes, certainly! If your child does not feel up to participating on the day, he/she is free to withdraw from the study.

Will this be a dental check-up for my child?

No. This is not a dental check-up and it will not be possible to give feedback on an individual child's dental health. You will be notified if your child needs **urgent** dental care.

Will my child be protected from infection?

Absolutely! The most rigorous infection control will be in place to protect your child and the dental team (more information on infection control is available on our website).

What do I have to do?

After reading this information leaflet, and if you agree for your child to participate, you will need to:

1. **Sign the Consent Form** and invite your child to sign the assent form.
2. **Complete the Residential History** form.
3. **Complete the Medical History** form
4. **Fill in the Survey** that comes with this pack.
5. **Supply a sample of tap water from your child's home** so that we can measure the amount of fluoride in it (please ensure that the container cap is securely fastened before returning the water sample).
6. **Return** the signed consent/assent form, completed residential and medical history forms and survey, along with the water sample in the Ziplock bag, to the class teacher in the envelope provided (sealed) without delay.

Where can I get more information about the FACCT study?

The coordinator of the study is: Dr Máiréad Harding, Oral Health Services Research Centre, University College Cork

Phone: (021) 490 1210 weekdays from 9am–5pm

Email: ohsrc@ucc.ie

Web: facct.ucc.ie

You can also like us on **facebook.com/ohsrc** or follow us on **twitter.com/ohsrc** for news and updates as the study progresses.

The FACCT study is designed and co-ordinated by the **Oral Health Services Research Centre,** University College Cork, and is supported by the Health Research Board, the HSE and the Department of Health.

Children's Oral Health Survey

Information for Parents

About FACCT

FACCT is an important research study about children's oral health. The FACCT study is a joint University College Cork/Health Services research project and is funded by the Health Research Board. FACCT stands for ***F**luoride **A**nd **C**aring for **C**hildren's **T**eeth.* The study will take place in primary schools in Dublin, Cork and Kerry.

Did you know … ?

Fluoride helps to strengthen our teeth and makes them more resistant to decay. Water contains some fluoride naturally and in Ireland water fluoride levels are adjusted so that it can help protect our teeth. Fluoride is also found in most toothpastes and mouthwashes.

Why is the FACCT study so important?

In 2007, the government reduced the level of fluoride in drinking water. The FACCT study will look at the impact that this reduction in fluoride has on the oral health of children living in Dublin, Cork and Kerry.

Your child kindly participated in the study in 2013/14 when they were in Junior Infants. Now that they are in 2nd class, we would like to invite them to take part in FACCT again so that we can check their adult teeth. This will give us a good understanding of how children's teeth develop over time.

Why should my child take part?

Healthy teeth are important for your child's general health and well-being. The FACCT study will provide up-to-date information on the oral health of children in Ireland. The results of the FACCT study can be used to inform national policy and planning of dental services. By taking part in FACCT, you and your child will contribute to this process.

What does my child have to do?

Open wide!

A dentist will visit your child's school and will look at your child's teeth. It will take less than 10 minutes and there is no treatment involved. There will be no risks or discomforts to your child.

Smile please!

Photographs will be taken of your child's front teeth to record marks on the teeth. The photographs will be a close-up of the teeth only, so it will not be possible to identify your child's face. These photographs may be used for education and teaching purposes.

Stand tall!

We will measure your child's height and weight as indicators of your child's well-being and development. Rest assured that we will do this in a sensitive and confidential manner. This information will be used for research purposes only, and again your child will not be identified.

Tell us about their teeth!

Children will be asked to complete a questionnaire about how they look after their teeth, how they feel about their teeth, and what effect their teeth have on their daily life. This questionnaire has been used with children of this age in other countries. It will be completed under supervision on a secure laptop computer that will only be used for the FACCT Study. The computer will not be connected to the internet.

What happens if the dentist discovers my child needs treatment?

You will be notified if your child needs **urgent** dental care.

How many times will my child be examined?

Your child will be examined once. However, to ensure accuracy, one child in 20 will be examined a second time—this is a normal procedure in studies like this one.

What other information will be collected for the FACCT study?

We may invite some parents and 2nd class children who take part in the main study to take part in a group discussion. The information from these meetings will help us understand how the public feels about policies to do with fluoride and about dental health.

We may also like to see the children again when they reach 6th class so that we can check all their adult teeth.

Finally, if your child has a HSE School Dental Record then the FACCT Study would like to collect relevant oral health information from that record to help us understand how school dental services are used and whether these records could be used in the future to provide reliable information about children's oral health. Not all children have a HSE School Dental Record.

Confidentiality

All the information you give will be private and treated confidentially. It will be stored on a secure computer in UCC. No personal information will be shared with any other organisation. The paper Survey that comes with this pack will be sent to a professional data entry company so that the information in it can be put on computer to be analysed. Only the barcode you see on the Survey document can be used to link the information with your child, and we will not be sharing the barcode key. Once entered on computer, the computer files and paper Surveys will be returned to UCC and eventually destroyed.

UCC is the Data Controller for all information collected as part of this study. Personal data will be erased / destroyed when no longer required for the purposes of the study. The information will be used only for research or teaching purposes. We will never identify either you or your child.

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

CONSENT FORM

1. Consent for your child to take part in the FACCT study

Please check that you understand each of the following points. If you are happy for your child to take part in the **FACCT** study, please fill in your child's details below and sign in the space provided to indicate your consent (permission). If you require any further information before signing, you may contact: Dr Máiréad Harding, FACCT Programme Coordinator, Oral Health Services Research Centre, on (021) 4901210.

- I have read and understand the information provided about the **FACCT** study.
- I understand that my child may:
  - Be examined by a dentist in the school;
  - Have his/her height and weight measured;
  - Have photographs taken of his/her front teeth, that the photographs will be a close-up of the teeth only, so it will not be possible to identify my child's face, and that these dental photographs may also be used for dental education and teaching purposes;
  - Be asked to complete a questionnaire under supervision, on a laptop computer that is not connected to the internet.
- I understand that my child may be invited to participate in a follow up to the **FACCT** study when he/she is in 6th class.
- I understand that the information collected for the **FACCT** study will be held on a secure computer and that it will be used for research purposes only.
- I understand that any information regarding my child will be treated confidentially.
- I understand that participation in the **FACCT** study is voluntary and that I may withdraw consent at any time.

PLEASE USE BLOCK CAPITALS

I consent to my child taking part in the FACCT study.

Child's Full Name: _____ Child's Date of Birth: ___|___|_____
DD MM YYYY

Parent's Signature: _____ Date: _____

Mobile 1:_____Mobile 2:_____ Landline phone: _____

Email: _____

2. Consent to follow up

I agree to be contacted in the future in relation to FACCT, and I give permission for my contact details (Address/ Mobile/Phone/Email) to be retained by the Study Team for the next four years, until my child finishes 6th class.

Parent's Signature: _____ Date: _____

3. Consent for access to relevant dental information from your child's HSE school dental record

I understand that the FACCT study would like to collect relevant oral health information (data) from my child's HSE school dental record (if one exists). This will help the study team to understand how school dental services are used and whether these records could be used in the future to provide reliable information about children's oral health.
I understand that any such information collected will be treated in the strictest confidence and will be used for research purposes only.

Parent's Signature: _____ Date: _____

PTO

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

ASSENT FORM

Your child's assent to take part in the FACCT Study

It is very important to us that each child who takes part in the study is happy to do so themselves. This is called the child's "assent" to participation.
Please explain the study to your child in whatever way you, as their parent/guardian, think is appropriate, bearing in mind their age and ability to understand.

If your child is happy to participate in the study, please ask them to sign below:

The study has been explained to me and I am happy to participate in the study.

Child's Signature: _____ Date: _____

FACCT 2016-17 Medical history form

MEDICAL HISTORY FORM

We would like to know about your child's medical history

Child's name: _____ **Date of birth:** _____

School: _____ **Class:** _____

MEDICAL HISTORY

	YES	NO	Please provide details (USE BLOCK CAPITALS)
Is your Child...			
Attending or receiving treatment from a doctor, hospital, clinic or specialist?	☐1	☐2	
Taking any medicines from his/her doctor? (tablets, inhalers, creams, ointments, injections, other)	☐1	☐2	*Please write the names of any medications*
Does your Child...			
Suffer from any allergies?	☐1	☐2	
Have fainting attacks, blackouts, seizures or epilepsy?	☐1	☐2	
Have diabetes?	☐1	☐2	
Are there any other important aspects of your child's health that the dentist should know about?	☐1	☐2	

PARENT SIGNATURE: _____ **DATE:** _____

FACCT 2016-17 Residential History Form

Residential History Questionnaire

It is **VERY** important to our research to know if your child has had fluoride in their drinking water and for how long. To do this we need to know **everywhere** your child has lived and the type of water supply (public mains, group scheme or private well) at each address.

Please tell us **everywhere** your child has lived **since starting primary school (Junior Infants)**.

Child's name: _____ Date of birth_____

School: _____ Class: _____

Current Address

House/Apartment no.: _____ Street/Estate: _____

Area/Town: _____ City/County: _____

Type of water supply at this address now: **Public mains** ☐1 **Group scheme** ☐2 **Own Well** ☐3

Are you aware of any change to the water supply at this address while your child has lived there? For example, changing from well water to a group water scheme or mains water; getting a well and stopping mains water; fitting a reverse osmosis system; a boil notice or other interruption to normal supply? If yes, please describe: _____

_____

_____

My child lived here from: _____ **to**: _____

Month and Year Month and Year

Has your child always lived at this address since starting primary school?

Yes ☐1 Please proceed to **Parent Survey**

No ☐2 Please continue overleaf

Previous Address 1

House/Apartment no.: _____ Street/Estate: _____

Area/Town: _____ City/County: _____

Type of water supply at this address: **Public mains** ☐1 **Group scheme** ☐2 **Own Well** ☐3

My child lived here from: _____ **to**: _____

Month and Year Month and Year

Previous Address 2

House/Apartment no.: _____ Street/Estate: _____

Area/Town: _____ City/County: _____

Type of water supply at this address: **Public mains** ☐1 **Group scheme** ☐2 **Own Well** ☐3

My child lived here from: _____ **to**: _____

Month and Year Month and Year

Previous Address 3

House/Apartment no.: _____ Street/Estate: _____

Area/Town: _____ City/County: _____

Type of water supply at this address: **Public mains** ☐1 **Group scheme** ☐2 **Own Well** ☐3

My child lived here from: _____ **to**: _____

Month and Year Month and Year

Previous Address 4

House/Apartment no.: _____ Street/Estate: _____

Area/Town: _____ City/County: _____

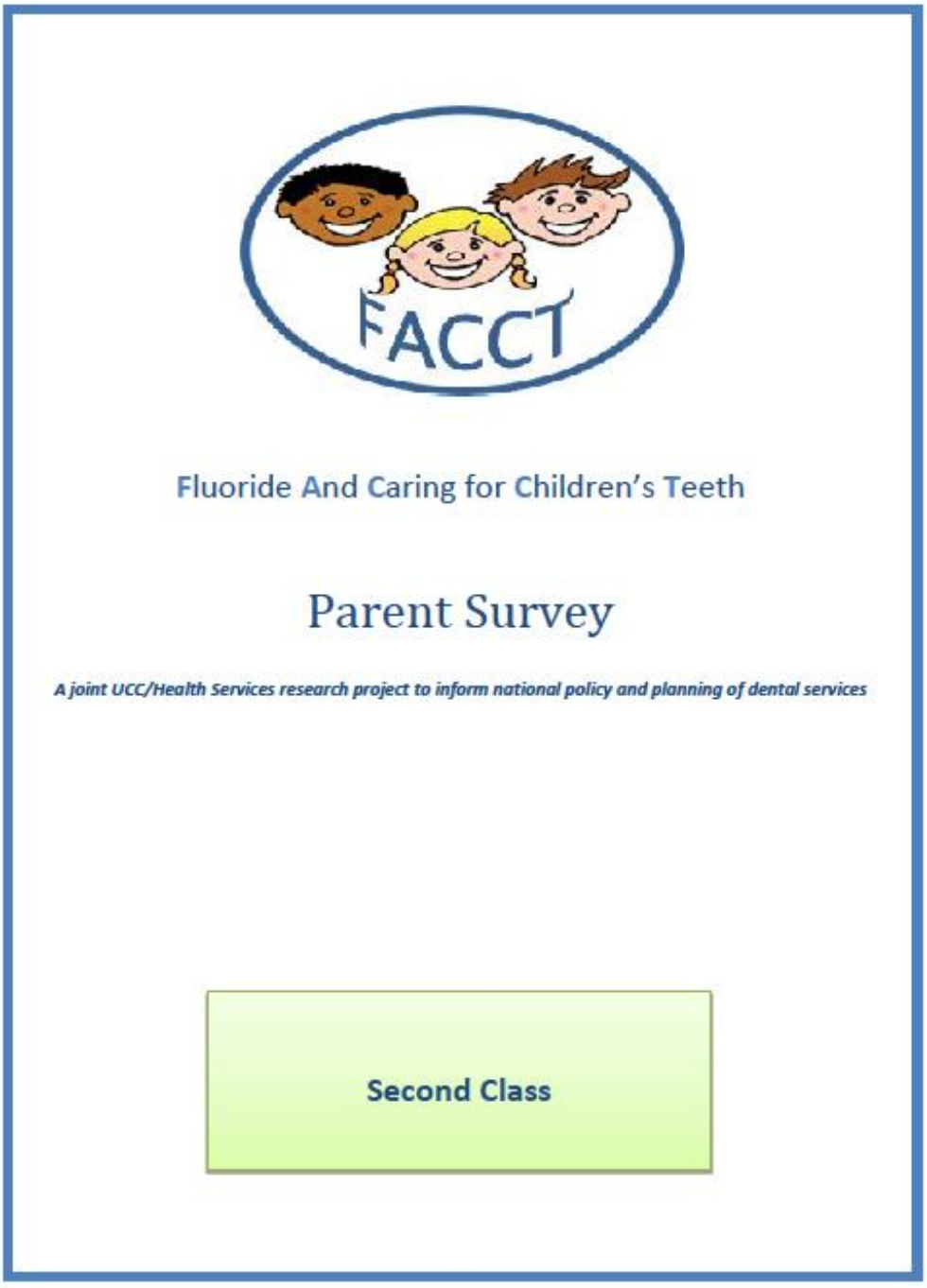
Type of water supply at this address: **Public mains** ☐1 **Group scheme** ☐2 **Own Well** ☐3

My child lived here from: _____ **to**: _____

Please use a separate page if your child has lived at more addresses since starting primary school (Junior Infants).

Thank you for completing this questionnaire! Now please proceed to the Parent Survey!

FACCT 2016-17 Parent survey second class



Thank you for agreeing to participate in this study.

This Survey Booklet has 6 parts. The information you are providing is very important to us; please complete all questions, right to the end of the booklet.

We ask questions about different factors that could affect your child's teeth e.g. going to the dentist, your child's toothpaste, and what they eat and drink. We also ask some questions about how you feel about your child's teeth, your child's physical activity and the family. Finally we ask questions about how your child's oral and dental health affects their wellbeing and everyday life, and how it affects the family.

Instructions

- Most questions can be answered simply by putting a tick ✓ in the box next to the answer that applies to you/your child.
- Please complete all 6 parts of the survey, right to the end of the booklet.
- When you have finished answering all of the questions, please put this booklet, the completed and signed medical history form, the completed residential history questionnaire and the signed consent form, along with the filled water bottle in the Ziplock bag, into the envelope provided and have your child return the sealed envelope to his/her teacher without delay.

Part 1

➢ Please answer the following questions about your child's attendance at the dentist

1. My child had his/her <u>first visit</u> to a dentist (including HSE/school dentist)

at the age of _____ *(Enter age in years)*

OR

My child has never been to a dentist ☐0 Go to **Q10**

2. What was the reason for this first visit? (Tick one box only)

Check up	☐1
I felt treatment was needed but my child had no pain	☐2
My child was in pain	☐3
I was sent an appointment by the HSE/school dentist	☐4
Other e.g. trauma to teeth *(please describe)*:	☐5

_____

3. My child <u>last</u> went to the dentist

at the age of _____ *(Enter age in years)*

OR

My child is currently undergoing treatment ☐0

4. When your child does go to the dentist (excluding orthodontic/braces), why does he/she normally go? (Tick one box only)

For a check-up every 6 months or at least once a year	☐1
For a check-up at least every two years	☐2
When I or my child feels he/she needs treatment	☐3
When my child is in pain or has a problem	☐4
When sent an appointment by the HSE/school dentist	☐5

5. **When your child goes to the dentist (excluding orthodontic/braces), what type of dental service does your child usually attend?** (Tick one box only)

HSE/school dentist	☐1
Private dentist (Republic of Ireland)	☐2
Private dentist (Northern Ireland)	☐3
Dental Hospital	☐4
Other *(please describe):*	☐5

_____

6. **Has your child ever received treatment (examination or other treatment) from the HSE/school dental service?**

Yes	☐1
No	☐2 Go to **Q10**

7. **When your child used the HSE/school dental service was it for** (Tick one box only)

Emergency treatment (relief of pain, trauma)	☐1
Routine treatment (e.g. exam, fissure sealants, fillings)	☐2
Both – emergency and routine treatment	☐3

8. **Were you satisfied with the service your child received from the HSE/school dental service?** (Tick one box only)

Very satisfied	☐1
Satisfied	☐2
No opinion/doesn't concern me	☐3
Dissatisfied	☐4
Very dissatisfied	☐5

9. **In the last 6 months, have you (or your partner) ever had to take time off work or away from other responsibilities to bring your child to a dentist because he/she had a toothache?** (Tick one box only)

Yes	☐1
No	☐2

10. **In the last 6 months, have you ever had a sleepless night because your child was awake with toothache (excluding teething/cutting teeth)?**

Yes	☐1
No	☐2

11. **In the last 6 months, has your child ever missed school because of toothache?**

Yes	☐1
No	☐2

12. At what age do you think a child should have his/her <u>first visit</u> to a dentist (HSE/school dentist or private) (Tick one box only)

Before his/her first baby (milk) tooth appears	☐1
When his/her first baby (milk) tooth appears	☐2
When he/she starts preschool	☐3
When he/she starts primary school	☐4
When he/she is sent an appointment by the HSE/school dentist	☐5
When he/she is in pain or has a problem	☐6

Part 2

- Kindly continue and answer the following questions on how you feel about your child's teeth

13. If your child had a painful <u>baby tooth</u> would you prefer if it was (Tick one box only)

Filled	☐1
Taken out	☐2
Don't know/No opinion	☐3

14. If your child had a painful <u>back</u> tooth and it was not a baby (milk) tooth but a permanent (adult) tooth would you prefer if it was (Tick one box only)

Filled	☐1
Taken out	☐2
Don't know/No opinion	☐3

15. If your child had a painful <u>front</u> tooth and it was not a baby (milk) tooth but a permanent (adult) tooth would you prefer if it was (Tick one box only)

Filled	☐1
Taken out	☐2
Don't know/No opinion	☐3

16. Are you happy with the <u>colour</u> of your child's permanent (adult) front teeth? (Tick one box only)

Yes	☐1
No	☐2
Don't know	☐3

17. Have you noticed any brown, creamy or white marks on your child's permanent (adult) front teeth that don't rub off? (Tick one box only)

Yes	☐1
No	☐2
Don't know	☐3

18. How do you feel about the position/alignment/straightness of your child's permanent (adult) front teeth? (Tick one box only)

Very satisfied	☐1
Satisfied	☐2
No opinion/indifferent	☐3
Dissatisfied	☐4
Very dissatisfied	☐5

19. We would like to know what parents value most about their child's teeth. There are no right or wrong answers to this question.

*Please rank the following options from 1 to 4 in the order that you believe is **most important** for your child. Use only **one number** for each box and **do not repeat any numbers.***

1=most important; 2=second most important; 3=third most important; 4=least important

Having white teeth	☐
Having healthy permanent teeth with no fillings	☐
Having healthy baby (milk) teeth with no fillings	☐
Having straight teeth	☐

Part 3

- We would like to know about your child's toothbrushing, and use of toothpaste and mouthwash

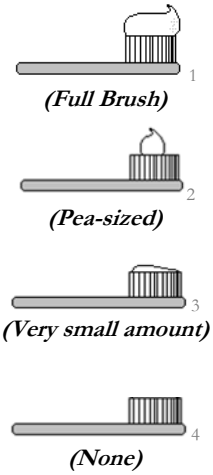
20. How often does your child use toothpaste when brushing his/her teeth? (Tick one box only)

Never	☐1
Most days but not every day	☐2
Once a day	☐3
Twice a day	☐4
More than twice a day	☐5
My child does not usually brush his/her teeth	☐6

21. What type of toothpaste does your child use? (Tick one box only)

Toothpaste with fluoride	☐1
Toothpaste without fluoride	☐2
None	☐3
I don't know	☐4

22. How much toothpaste does your child use on his/her toothbrush? (Please circle the image that matches your answer)



23. Fluoride is added to toothpaste to help prevent tooth decay. Which of the following do you think might be the recommended fluoride content for toothpaste for children in Ireland? (ppm = parts per million)

500 – 750 ppm ☐1
1,000 – 1,500 ppm ☐2
2,000 ppm or more ☐3
I don't know ☐4

24. These pictures show children rinsing their teeth after brushing. Which picture shows what your child usually does?

My child's teeth are not usually brushed ¨1



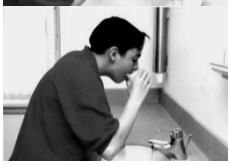
Picture 1
Using the toothbrush to rinse ¨2



Picture 2
Rinsing directly from the tap ¨3



Picture 3
Cupping hands to rinse ¨4



Picture 4
Using a glass to rinse ¨5

My child does not rinse ¨6
Other *(please specify)*: ¨7

_____

25. Does your child usually use mouthwash (Tick one box only)

Never ☐1 if **'Never'** Go to **Q28**

Infrequently ☐2
Once a week ☐3
A few times a week ☐4
Every day ☐5

26. When your child uses mouthwash, is it usually

Immediately or shortly after brushing ☐1
At a different time to brushing ☐2

27. Does your child's mouthwash contain fluoride? (Tick one box only)

Yes ¨1 No ¨2 Don't know ¨3

28. Has your child ever taken a course of fluoride tablets or drops? (Tick one box only)

Yes ¨1 No ¨2 Don't know ¨3

Thank you for your help so far!

Part 4

➢ We would now like to ask you about what your child normally eats and drinks and about their physical activity.

29. How many times does your child have sweet food or sweet drinks between meals? (for example, sweets, biscuits, cakes, juice, squash (diluted), fizzy drinks, fruit drinks etc.) (Tick one box only for each option below)

On a typical weekday (Monday, Tuesday, Wednesday, Thursday or Friday)		**On a typical day at the weekend (Saturday, or Sunday)**	
Never	☐1	Never	☐1
Once	☐2	Once	☐2
Twice	☐3	Twice	☐3
Three times	☐4	Three times	☐4
Four times	☐5	Four times	☐5
Five times	☐6	Five times	☐6
Six times or more	☐7	Six times or more	☐7
Don't know	☐8	Don't know	☐8

30. What type of water does your child usually drink? (Tick one box only)

Tap water mostly ☐1
Bottled water mostly ☐2
Both tap and bottled ☐3
My child does not drink water ☐4

31. If your child drinks tap water, is it (Tick one box only)

Unfiltered	☐1
Filtered using a cartridge filter in a water jug	☐2
Filtered under the sink (reverse osmosis)	☐3
Other *(please describe)*:	☐4

_____

32. Does your child ever have a drink by the bedside in case he/she gets thirsty during the night?

Yes ☐1 No ☐2

If you answered 'Yes' what type of drink does he/she usually take?

Tap water	☐1
Bottled water	☐2
Squash (diluted)/fruit drink	☐3
Milk	☐4
Other *(please describe)*:	☐5

_____

33. What type of water do you usually use for preparing and cooking food? (Tick one box only)

Tap water mostly	☐1
Bottled water mostly	☐2
Both tap and bottled	☐3

34. How many times in the <u>past 7 days</u> has your child done <u>at least 20 minutes of hard exercise</u>, hard enough to make him/her breath heavily and make his/her heart beat faster? (Hard exercise includes, for example, playing football, jogging, or fast cycling.) Include time in physical education (PE) class.

None	☐1
1 to 2 days	☐2
3 to 5 days	☐3
6 to 7 days	☐4

35. How many times in the <u>past 7 days</u> has your child done <u>at least 20 minutes of light exercise</u>, that was <u>not</u> hard enough to make him/her breath heavily and make his/her heart beat faster? (Light exercise includes, for example, walking or slow cycling.) Include time in physical education (PE) class.

None	☐1
1 to 2 days	☐2
3 to 5 days	☐3
6 to 7 days	☐4

Thank you for that information – nearly there!

Part 5

➢ Please tell us a little about your family

36. Are you the child's

Mother ☐1
Father ☐2
Other *(please specify)*: ☐3
_____

37. Who is the child's primary caregiver?

Mother ☐1
Father ☐2
Other *(please specify)*: ☐3
_____

38. What type of healthcare cover do you have? *Please tick ALL that apply*

Full medical card ☐1
GP visit card ☐2
Private health insurance e.g. VHI/Aviva ☐3
PRSI ☐4
No healthcare cover ☐5
Other *(please describe)*: ☐6
_____

39. In general, how would you describe your child's health in the past year?

Very healthy, no problems ☐1
Healthy, but with a few minor problems ☐2
Sometimes quite ill ☐3
Almost always unwell ☐4

40. What is the highest level of education both Parents/Caregivers have completed to date?

	Mother/Female caregiver	Father/Male caregiver
Primary or less	☐1	☐1
Intermediate/Junior/ Group Certificate or equivalent	☐2	☐2
Leaving Certificate or equivalent	☐3	☐3
Diploma/Certificate	☐4	☐4
Primary degree	☐5	☐5
Postgraduate/Higher degree	☐6	☐6

41. Food choices vary between different cultures and this can have an effect on dental health. We would be grateful if you could tell us if your ethnic or cultural background is

Irish ☐1 Other ☐2

(Please specify):_____

Thank you. Just one more part to complete.

Part 6

- This part asks about the effects of oral conditions on your child's wellbeing and everyday life: we are interested in any condition that involves teeth, lips, mouth or jaws

Please **do not discuss the questions with your child,** in this part of the survey we are interested in the parents' perspective.

42. How would you rate the health of your child's teeth, lips, jaws and mouth?

Excellent ☐1 Very Good ☐2 Good ☐3 Fair ☐4 Poor ☐5

43. How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaw or mouth?

Not at all ☐1 Very little ☐2 Some ☐3 A lot ☐4 Very much ☐5

44. How much is the daily life of your family affected by the condition of his/her teeth, lips, jaw or mouth?

Not at all ☐1 Very little ☐2 Some ☐3 A lot ☐4 Very much ☐5

In this section, each question is followed by the same set of options. Please give the response that **best describes your child's experience**. If the question does not apply to your child, please answer with "Never".

45. During the last 3 months, how often has your child had:

a. Pain in the teeth, lips, jaws or mouth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Food caught in or between the teeth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Food stuck in the roof of the mouth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Bad breath?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

46. During the last 3 months, how often has your child:

a. Had difficulty biting or chewing firm foods such as fresh apple, corn on the cob or firm meat because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Had difficulty drinking or eating hot or cold foods?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Taken longer than others to eat a meal because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Had trouble sleeping because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

47. In the last 3 months, has your child:

a. Been upset because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Been irritable or frustrated because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Been anxious or fearful because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Acted shy or embarrassed because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

48. In the last 3 months, has your child:

a. Missed school because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Not wanted to talk to other children because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Had a hard time paying attention in school because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Avoided smiling or laughing when around other children because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

Thank you for taking the time to complete this survey and support this important study!

CHECKLIST

Please check you have done all of the following:

Completed all parts of this Parent Survey	☐
Completed and signed the Medical History Form	☐
Completed the Residential History Questionnaire	☐
Signed the Consent Form	☐
Asked your child to sign the Assent Form	☐
Taken a sample of tap water and securely fastened its bottle cap	☐

Now, please put this booklet, the completed and signed Medical History Form, the completed Residential History Questionnaire, the signed Consent Form, along with the filled water bottle in the Ziploc bag, into the envelope provided and have your child return the sealed envelope to his/her teacher without delay.



Thank you.



Fluoride And Caring for Children's Teeth

Parent Survey

A joint UCC/Health Services research project to inform national policy and planning of dental services

Junior Infants

Child's name:

School:

Thank you for agreeing to participate in this study.

This Survey Booklet has 3 sections: Please complete all 3 sections.

In Section 1 we ask some short questions about your child's general health.

In Section 2 we ask questions about different factors that could affect your child's teeth, e.g. their diet, their toothpaste and going to the dentist. We also ask some short questions about the family.

In Section 3 we ask questions about how your child's oral health affects their wellbeing and everyday life, and how it affects the family.

Instructions

1. Most questions can be answered simply by putting a tick ✓ in the box next to the answer that applies to you.
2. Please complete all 3 sections.
3. When you have finished answering all of the questions, please put this booklet, the completed residential history questionnaire, the signed consent form, along with the filled water bottle in the Ziplock bag, into the envelope provided and have your child return the sealed envelope to his/her teacher without delay.

SECTION 1

- We would like to know about your child's medical history

Child's name: _____ **Date of birth:**_____

MEDICAL HISTORY

	YES	NO	Please provide details (USE BLOCK CAPITALS)
Is your Child...			
Attending or receiving treatment from a doctor, hospital, clinic or specialist?	☐1	☐2	
Taking any medicines from his/her doctor? (tablets, inhalers, creams, ointments, injections, other)	☐1	☐2	***Please write the names of any medications***
Does your Child...			
Suffer from any allergies?	☐1	☐2	
Have fainting attacks, blackouts, seizures or epilepsy?	☐1	☐2	
Have diabetes?	☐1	☐2	
Are there any other important aspects of your child's health that the dentist should know about?	☐1	☐2	

PARENT SIGNATURE: _____ **DATE**: _____

SECTION 2: Part 1

- In this section we would like to know about your child's toothbrushing, and use of toothpaste and mouthwash

1. At what age did you start cleaning/brushing your child's teeth?

Before 12 months of age	☐1
Between 12 and 18 months of age	☐2
Between 19 and 24 months of age	☐3
After 24 months of age	☐4
My child's teeth are not usually brushed	☐5

2. At what age did you first start using toothpaste with your child?

Before 12 months of age	☐1
Between 12 and 18 months of age	☐2
Between 19 and 24 months of age	☐3
After 24 months of age	☐4
My child does not use toothpaste	☐5

3. What type of toothpaste did you use when you first started using toothpaste with your child?

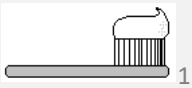
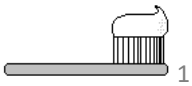
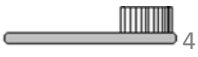
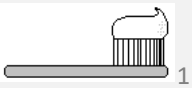
Children's toothpaste with fluoride	☐1
Children's toothpaste without fluoride	☐2
Regular/Family toothpaste with fluoride	☐3
Regular/Family toothpaste without fluoride	☐4
My child does not use toothpaste	☐5

4. What type of toothpaste does your child use now?

Children's toothpaste with fluoride	☐1
Children's toothpaste without fluoride	☐2
Regular/Family toothpaste with fluoride	☐3
Regular/Family toothpaste without fluoride	☐4
My child does not use toothpaste	☐5

5. Fluoride is added to toothpaste to help prevent tooth decay. Which of the following do you think might be the recommended fluoride content for toothpaste for children in Ireland? (ppm = parts per million)

500 – 750 ppm	☐1
1,000 – 1,500 ppm	☐2
2,000 ppm or more	☐3
I don't know	☐4

Please tick one box for each age period in your child's life			
	Under Age 2	**From 2 to 3 years**	**Now**
6. **How often did/does your child brush his/her teeth with toothpaste?**	Never ☐1 Most days but not every day ☐2 Once a day ☐3 Twice a day ☐4 More than twice a day ☐5	Never ☐1 Most days but not every day ☐2 Once a day ☐3 Twice a day ☐4 More than twice a day ☐5	Never ☐1 Most days but not every day ☐2 Once a day ☐3 Twice a day ☐4 More than twice a day ☐5
7. **Have you ever noticed your child eating or licking toothpaste?**	Often ☐1 Sometimes ☐2 Never ☐3	Often ☐1 Sometimes ☐2 Never ☐3	Often ☐1 Sometimes ☐2 Never ☐3
8. **How much toothpaste did/does your child (or do you) use on his/her toothbrush?** (please circle the image that matches your answer)	 1 ***(Full Brush)***  2 ***(Pea-sized)***  3 ***(Very small amount)***  4 ***(None)***	 1 ***(Full Brush)***  2 ***(Pea-sized)***  3 ***(Very small amount)***  4 ***(None)***	 1 ***(Full Brush)***  2 ***(Pea-sized)***  3 ***(Very small amount)***  4 ***(None)***

9. These pictures show children rinsing their teeth after brushing. Which picture shows what your child usually does?

My child's teeth are not usually brushed ☐1



Picture 1
Using the toothbrush to rinse ☐2



Picture 2
Rinsing directly from the tap ☐3



Picture 3
Cupping hands to rinse ☐4



Picture 4
Using a glass to rinse ☐5

My child does not rinse ☐6
Other *(please specify)*: ☐7
_____

10. Does your child usually use mouthwash (Tick one box only)

Every day ☐1
A few times a week ☐2
Once a week ☐3
Infrequently ☐4
Never ☐5 if **'Never'** Go to **Q13**

11. When your child uses mouthwash, is it usually

Immediately or shortly after brushing ☐1
At a different time to brushing ☐2

12. Does your child's mouthwash contain fluoride?

Yes ☐1 No ☐2 Don't know ☐3

13. Has your child ever taken a course of fluoride tablets or drops?

Yes ☐1 No ☐2 Don't know ☐3

Thank you for your help so far!

SECTION 2: Part 2

➢ We would now like to ask you about your child's diet

14. Was your child breast-fed as a baby?

Yes ☐1 No ☐2

***If you answered 'Yes'*, how long was your child breast-fed for?**

Less than 2 weeks	☐1
Less than 2 months	☐2
2–3 months	☐3
4–6 months	☐4
Longer than 6 months	☐5

15. If you used formula to feed your baby, did you mainly use

Powdered formula	☐1
Ready-made liquid formula	☐2

16. What source of water did you mostly use to make up the formula?

Unfiltered tap water	☐1
Filtered (using a cartridge filter in a water jug)	☐2
Filtered at tap or under sink	☐3
Bottled water	☐4
Other *(please specify)*:	☐5

_____

17. Which of the following liquids did your child regularly/frequently drink from a baby bottle?
(Tick all that apply please)

Milk	☐1	Tea	☐9
Milk with sugar/honey	☐2	Coffee	☐10
Flavoured milk	☐3	Tea/coffee with sugar/honey	☐11
Follow on formula milk	☐4	Hot chocolate	☐12
Tap water	☐5	Fruit juices	☐13
Bottled water	☐6	Squash (No added sugar)	☐14
Flavoured water	☐7	Squash	☐15
Water with sugar/honey	☐8	Carbonated (fizzy) drinks	☐16
		Other *(please specify)*:	☐17

_____

18. At what age was your child weaned from the breast or baby bottle to use a cup/mug?

Before 12 months of age	☐1
Between 1–2 years	☐2
Older than 2 years	☐3
I do not remember	☐4

19. Did your child regularly take a baby bottle into bed?

Yes ☐1 No ☐2 Don't remember ☐3

20. At what age did your child stop taking a baby bottle into bed?

Before 12 months of age ☐1
Between 1–2 years ☐2
Older than 2 years ☐3
My child still takes a bottle to bed ☐4
I do not remember ☐5

21. Now that your child is older, does he/she ever have a drink by the bedside in case he/she gets thirsty during the night?

Yes ☐1 No ☐2

If you answered 'Yes' what type of drink would he/she usually take?

Tap water ☐1
Bottled water ☐2
Squash (diluted)/fruit drink ☐3
Milk ☐4
Other *(please describe)*: ☐5

_____

22. What type of <u>water</u> does your child usually drink?

Tap water mostly ☐1
Bottled water mostly ☐2
Both tap and bottled ☐3
My child does not drink water ☐4

23. What type of water do you usually use for preparing and cooking food?

Tap water mostly ☐1
Bottled water mostly ☐2
Both tap and bottled ☐3

24. If your child drinks tap water, is it

Unfiltered ☐1
Filtered (using a cartridge filter in a water jug) ☐2
Filtered at tap or under sink ☐3

25. In the last 24 hours, how often has your child had the following drinks? (Please tick one box for all drinks that apply)

	Not at all	Once	More than once	Don't know
Tap water	☐1	☐2	☐3	☐4
Bottled water	☐1	☐2	☐3	☐4
Fruit Juice	☐1	☐2	☐3	☐4
Diet Soft drinks/minerals/cordial /squash	☐1	☐2	☐3	☐4
Non-diet Soft drinks/minerals/cordial /squash	☐1	☐2	☐3	☐4
Milk	☐1	☐2	☐3	☐4
Flavoured milk	☐1	☐2	☐3	☐4
Tea with sugar/honey	☐1	☐2	☐3	☐4
Tea without sugar/honey	☐1	☐2	☐3	☐4
Coffee with sugar/honey	☐1	☐2	☐3	☐4
Coffee without sugar/honey	☐1	☐2	☐3	☐4
Hot chocolate	☐1	☐2	☐3	☐4

26. On a typical weekday, how often does your child have sweet food or sweet drinks <u>between meals</u> (for example, sweets, biscuits, cakes, juice, squash (diluted), fizzy drinks, fruit drinks etc.)?(Tick one box only)

Never ☐1
Once ☐2
Twice ☐3
Three times ☐4
Four times ☐5
Five times ☐6
Six times or more ☐7
Don't know ☐8

Thank you for completing the section on your child's diet. You have almost completed this survey.

SECTION 2: Part 3

- Kindly continue and answer the following question on what you feel is important about your child's teeth

27. We would like to know what parents value most about their child's teeth. There are no right or wrong answers to this question. Please rank the following options from 1 to 4 in the order that you believe is most important for your child. Use only one number for each box and do not repeat any numbers.

1=most important; 2=second most important; 3=third most important; 4=least important

Having white teeth ☐
Having healthy permanent teeth with no fillings ☐
Having healthy baby (milk) teeth with no fillings ☐
Having straight teeth ☐

SECTION 2: Part 4

- Kindly continue with the following questions about your child's attendance at the dentist

28. My child had his/her first visit to a dentist (including HSE/school dentist)

at the age of _____ *(Enter age in years)*

OR

My child has never been to a dentist ☐0 Go to **Q30**

29. How long is it since your child was at the dentist?

Less than 12 months ☐1
More than 12 months ☐2

Thank you!

SECTION 2: Part 5

- Please tell us a little about your family

30. What type of healthcare cover do you have?

Full medical card/GP visit card ☐1
Private health insurance e.g. VHI/Aviva ☐2
No healthcare cover ☐3
PRSI ☐4
Other *(please describe)*: ☐5
_____

31. What is the highest level of education both Parents/Caregivers have completed to date?

	Mother/Female caregiver	**Father/Male caregiver**
Primary or less	☐1	☐1
Intermediate/Junior/ Group Certificate or equivalent	☐2	☐2
Leaving Certificate or equivalent	☐3	☐3
Diploma/Certificate	☐4	☐4
Primary degree	☐5	☐5
Postgraduate/Higher degree	☐6	☐6

32. Diet varies between different cultures and this can have an effect on dental health. We would be grateful if you could tell us if your ethnic or cultural background is

Irish ☐1 Other ☐2

(Please specify):_____

Thank you for that information – nearly there! Just one more section to complete.

SECTION 3

- This section asks about the effects of oral conditions on your child's wellbeing and everyday life: we are interested in any condition that involves teeth, lips, mouth or jaws

Please **do not discuss the questions with your child,** as we are interested only in the parents' perspective in this part of the survey.

33. How would you rate the health of your child's teeth, lips, jaws and mouth?

Excellent ☐1 Very Good ☐2 Good ☐3 Fair ☐4 Poor ☐5

34. How much is your child's overall well-being affected by the condition of his/her teeth, lips, jaw or mouth?

Not at all ☐1 Very little ☐2 Some ☐3 A lot ☐4 Very much ☐5

35. How much is the daily life of your family affected by the condition of his/her teeth, lips, jaw or mouth?

Not at all ☐1 Very little ☐2 Some ☐3 A lot ☐4 Very much ☐5

In this section, each question is followed by the same set of options. Please give the response that **best describes your child's experience**. If the question does not apply to your child, please answer with "Never".

36. During the last 3 months, how often has your child had:

a. Pain in the teeth, lips, jaws or mouth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Food caught in or between the teeth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Food stuck in the roof of the mouth?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Bad breath?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

37. During the last 3 months, how often has your child:

a. Had difficulty biting or chewing firm foods such as fresh apple, corn on the cob or firm meat because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Had difficulty drinking or eating hot or cold foods?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Taken longer than others to eat a meal because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Had trouble sleeping because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

38. In the last 3 months, has your child:

a. Been upset because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Been irritable or frustrated because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Been anxious or fearful because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Acted shy or embarrassed because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

39. In the last 3 months, has your child:

a. Missed school because of his/her teeth, lips, mouth or jaws**?**

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

b. Not wanted to talk to other children because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

c. Had a hard time paying attention in school because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

d. Avoided smiling or laughing when around other children because of his/her teeth, lips, mouth or jaws?

Never ☐1 Once or twice ☐2 Sometimes ☐3 Often ☐4 Everyday or Almost everyday ☐5 Don't know ☐6

Thank you for taking the time to complete this survey!

CHECKLIST

Please check you have done all of the following:

Completed and signed the Medical History section (page 2)	☐
Completed all sections of this Parent Survey	☐
Completed the Residential History Questionnaire	☐
Signed the Consent Form	☐
Taken a sample of tap water and securely fastened its bottle cap	☐

Now, please put this booklet, the completed Residential History Questionnaire, the signed Consent Form, along with the filled water bottle in the Ziploc bag, into the envelope provided and have your child return the sealed envelope to his/her teacher without delay.

Thank you


FACCT

Do not write in this space

Subject No. ☐ ☐☐ ☐☐ ☐☐☐

School No. ☐☐☐☐☐ ☐

National Survey of Children's Dental Health 2002

Questionnaire for Parents of Primary 4 Children

How to fill in this form

A. **Most questions can be answered simply by putting a tick (✓) in the box next to the answer that applies to you.**

Example:	**Yes**	☑
	No	☐

B. **Usually after answering each question you go on to the next one unless a box you have ticked has an arrow next to it with an instruction to go to another question.** *In this example: If you tick the **Yes** box, **go to question 4.** If you tick the **No** box, continue to question 5.*

Example:	**Yes**	☑→**Q4**
	No	☐→**Q5**

C. **If you cannot remember, do not know, or are unable to answer a particular question please write that in alongside the tick box.**

D. **If you have more than one child, please answer the questions in relation to the child to whom this form was given.**

E. **When you have finished answering the questionnaire, please enclose in the envelope provided and have your child return the envelope to his/her teacher tomorrow.**

We are most grateful for your help and co-operation.

Your Child's Name: _____

Your Child's Date of Birth: ____/____(Date) ____/____(Month) 19_____(Year)

Q1. **At what age did you or your child start brushing your child's teeth?**

		Tick one box
My child's teeth are not usually brushed	**1**	☐
Before 12 months of age	**2**	☐
Between 12 and 18 months of age	**3**	☐
Between 19 and 24 months of age	**4**	☐
After 24 months of age	**5**	☐

Q2. **How often does your child brush his/her teeth (or have them brushed for him/her)?**

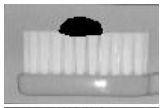
		Tick one box
My child's teeth are not usually brushed	**1**	☐
Less than once a day (e.g., every second day, once a week)	**2**	☐
Once a day	**3**	☐
Twice a day	**4**	☐
More than twice a day	**5**	☐

Q3a. These pictures show different amounts of toothpaste on a brush. Which picture shows the amount of toothpaste your child uses?

Tick one box

My child's teeth are not usually brushed **1** ☐

My child does not use toothpaste **2** ☐



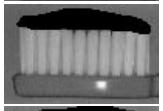
Picture 1

pea-sized amount of toothpaste **3** ☐



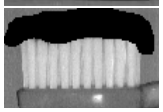
Picture 2

half brush of toothpaste **4** ☐



Picture 3

full brush of toothpaste **5** ☐



Picture 4

overflowing brush of toothpaste **6** ☐

Q3b. These pictures show children rinsing their teeth after brushing. Which picture shows what your child does?

Tick one box

My child's teeth are not usually brushed **1** ☐



Picture 1

using the toothbrush to rinse **2** ☐



Picture 2

rinsing directly from the tap **3** ☐



Picture 3

cupping hands to rinse **4** ☐



Picture 4

using glass to rinse **5** ☐

My child does not rinse **6** ☐

None of these **7** ☐

Q4. How often does your child eat sweet food or sweet drinks (such as biscuits, cakes, sweets, Coca-Cola, Pepsi-Cola, 7-Up, Ribena, fruit drinks, etc.) between normal meals?

Tick one box

Never **1** ☐

Less than once a day: (e.g., once a week, every second day) **2** ☐

Once a day **3** ☐

Twice a day **4** ☐

Three times a day **5** ☐

Four times a day **6** ☐

Five times a day **7** ☐

Six times or more a day **8** ☐

Don't know **9** ☐

Q5. When your son/daughter was a baby did he/she ever have baby or infant formula, or follow-on milk like Progress or Junior Milk (not liquid cow's milk)?

Tick one box

Yes **1** ☐ **Q6**

No/Never **2** ☐ **Q8**

Don't know **3** ☐ **Q8**

Q6. How old was your son/daughter when he/she started to drink baby or infant formula, or follow-on milk like Progress or Junior Milk (not liquid cow's milk)?

Tick one box

Under 1 month **1** ☐

1 month – under 2 months **2** ☐

2 months – under 4 months **3** ☐

4 months – under 6 months **4** ☐

6 months – under 9 months **5** ☐

9 months – under 1 year **6** ☐

1 year – under 1 1/2 years **7** ☐

1 1/2 years – under 2 years **8** ☐

2 years – under 2 1/2 years **9** ☐

2 1/2 years – under 3 years **10** ☐

3 years or older **11** ☐

Q7. How old was your son/daughter when he/she <u>stopped</u> having baby or infant formula, or follow-on milk like Progress or Junior Milk, even just at bedtime?

Tick one box

Under 1 month	**1**	☐
1 month – under 2 months	**2**	☐
2 months – under 4 months	**3**	☐
4 months – under 6 months	**4**	☐
6 months – under 9 months	**5**	☐
9 months – under 1 year	**6**	☐
1 year – under 1½ years	**7**	☐
1½ years – under 2 years	**8**	☐
2 years – under 2½ years	**9**	☐
2½ years – under 3 years	**10**	☐
3 years or older	**11**	☐

Q8. If your child had a painful <u>baby tooth</u> would you prefer if it was

Tick one box

Filled	**1**	☐
Taken out	**2**	☐
Don't know/No opinion	**3**	☐

Q9. If your child had a painful <u>back</u> tooth and it was not a baby (milk) tooth but a second (permanent) tooth, would you prefer if it was

Tick one box

Filled	**1**	☐
Taken out	**2**	☐
Don't know/No opinion	**3**	☐

Q10. If your child had a painful <u>front</u> tooth and it was not a baby (milk) tooth but a second (permanent) tooth, would you rather it was

Tick one box

Filled	**1**	☐
Taken out	**2**	☐
Don't know/No opinion	**3**	☐

Q11. Are you happy with the colour of your child's front teeth?

Tick one bo

Yes	**1**	☐
No	**2**	☐
Don't know/No opinion	**3**	☐

Q12. Have you noticed any brown, creamy or white mar on your child's front teeth which don't brush off?

Tick one box

Yes	**1**	☐
No	**2**	☐
Don't know	**3**	☐

Q13. *Please complete as applicable:*

Enter Age in Years

My child had his/her first visit to a dentist (including school dentist) at the age of **1** ☐

Or

Tick Box

My child has never been to a dentist **2** ☐

Q14. What was the reason for this first visit?

Tick one box

Check up	**1**	☐
I felt treatment was needed but my child had no pain	**2**	☐
My child was in pain	**3**	☐
Was sent an appointment by school dentist	**4**	☐
Other (e.g., trauma to teeth)	**5**	☐
My child has never been to the dentist	**6**	☐

Q15. How often does your child go to the dentist?

Tick one box

Occasionally	**1**	☐
Every six months or more often	**2**	☐
Every 6 – 12 months	**3**	☐
Every 12 – 24 months	**4**	☐
Every 2 years/more	**5**	☐
My child has never been to the dentist	**6**	☐

Q16. In the last 6 months, have you (or your partner) ever had to take time off work to bring your child to a dentist because he/she had toothache?

Tick one box

Yes	**1**	☐
No	**2**	☐
I (or my partner) have not been working (employed) in the last 6 months	**3**	☐

Q17. In the last 6 months, have you ever had a sleepless night because your child was awake with toothache (excluding teething/cutting teeth)?

Tick one box

Yes	**1**	☐
No	**2**	☐

Q18. In the last 6 months, has your child ever missed school because of toothache?

Tick one box

Yes	**1**	☐
No	**2**	☐

Q19. *Please complete as applicable:*

Enter Age in Years

My child <u>last</u> went to the dentist at the age of	**1**	☐

Or

Tick one box

My child is currently undergoing treatment	**2**	☐
My child has never been to the dentist	**3**	☐

Q20. When your child does go to the dentist, why does he/she normally go?

Tick one box

For a check-up every 6 months or at least once a year	**1**	☐
For a check-up at least every two years	**2**	☐
When I or my child feels he/she needs treatment	**3**	☐
When my child is in pain or has a problem	**4**	☐
When sent a letter by the school dentist	**5**	☐
My child has never been to the dentist	**6**	☐

Q21. Was your child's <u>last</u> visit to the dentist:

Tick one box

To a private dentist	**1**	☐
To the community dentist	**2**	☐
To the Dental Hospital	**3**	☐
My child has never visited a dentist	**4**	☐

Q22. Were you satisfied with the service your child received last?

Tick one box

Very satisfied	**1**	☐
Satisfied	**2**	☐
No opinion/Doesn't concern me	**3**	☐
Dissatisfied	**4**	☐
Very dissatisfied	**5**	☐
My child has never visited a dentist	**6**	☐

Q23. Not all parents sit in the room with their child when the child is receiving dental treatment. Would you prefer to be in the room with your child when he/she receives treatment?

Tick one box

Yes	**1**	☐
No	**2**	☐
Don't mind	**3**	☐
Depends on the advice of the dentist/dental hygienist/dental nurse	**4**	☐

Q24. If your child had a toothache today could you get emergency treatment locally?

Tick one box

Yes	**1**	☐
No	**2**	☐
Don't know	**3**	☐

Q25. Where would you get this emergency treatment?

		Tick one box
Private dentist	**1**	☐
Community dentist	**2**	☐
Dental hospital	**3**	☐
Don't know	**4**	☐

Q26. Which type of dental service does your child <u>normally</u> use?

		Tick one box
Private dentist	**1**	☐
Community dental clinic	**2**	☐
Dental hospital	**3**	☐
My child has never been to the dentist	**4**	☐

Q27. How many hours would your child sit in front of a TV, game console or computer

		Enter Hours
On an average week<u>day</u>	**1**	
On an average Saturday or Sunday	**2**	

Q28. How many children do you have?

	Enter No.
1	

Thank You For Your Help

FACCT Coding sheet for clinical examination

DDE: Type of defect	
Normal	0
Demarcated opacity	1
Diffuse opacity	2
Hypoplasia	3
Demarcated + diffuse	4
Demarcated + hypoplastic	5
Diffuse + hypoplastic	6
All 3	7
Other	8
Excluded	X

DDE: Extent	
Normal	0
< 1/3	1
at least 1/3 < 2/3	2
at least 2/3	3

Dean's	
Normal	0
Questionable	1
Very mild	2
Mild	3
Moderate	4
Severe	5

MIH	
Yes	Y
No	N

Photo Taken	
Yes	Y
No	N

Caries: Status	
Permanent tooth present	A
Deciduous tooth present	P
Permanent tooth unerupted or congenitally absent	U
Permanent tooth extracted due to caries	E
Deciduous tooth extracted due to caries	C
Permanent tooth extracted due to perio disease	G
Deciduous tooth extracted due to ortho	B
Permanent tooth missing due to other reasons	M
Permanent tooth extracted for reason unknown	K
Deciduous tooth present with a sinus tract	R

Caries: Condition	
No caries (sound)	S
Fissure sealant	R
Visual caries	V
Decayed, cavity	D
Filled – amalgam restoration	F
Filled – non-amalgam restoration	G
Filled – amalgam restoration and primary decay	K
Filled – non-amalgam restoration and primary decay	L
Filled – amalgam restoration and secondary decay	Y
Filled – non-amalgam restoration and secondary decay	Z
Crowned	C
Crowned and decayed	Q
Trauma	T
Excluded	X

Treatment Need			
None	0	Pulp treatment required due to coronal caries followed by crown	7
One surface restoration	1	Extraction due to coronal caries	8
Two surface restoration	2	Extraction due to other reasons	W
Three or more surface restoration	3	Replacement with removable prosthesis	R
Fissure sealant or preventive resin restoration	4	Replacement with bridge	F
Crown	5	Other treatment for crown caries	X
Pulp treatment required due to coronal caries followed by filling	6		

FACCT clinical record form (Paper back-up version)

FACCT Clinical Record Form

Recorder No. ☐ Examiner No. ☐

Stick barcode here
(write barcode number if unavailable)

Date of Exam. Day ☐☐ Month ☐☐ Year 201☐

Exam. Type ☐
N – New
D – Duplicate
G – Gold Standard

School name _____ School roll no. ☐☐☐☐☐☐

First name _____

Last name _____

Gender ☐
M – Male
F – Female

Date of birth Day ☐☐ Month ☐☐ Year 200☐ Age (ask child) ☐☐

Height ☐☐☐.☐ cm Weight ☐☐.☐ kg

Enamel Opacities

Developmental Defects of Enamel (DDE) (Labial/Buccal surface only)

Tooth	1.4	1.3	1.2	1.1	2.1	2.2	2.3	2.4	3.6	4.6
Defect										
Extent										

Dean's Index	Molar, Incisor Hypoplasia (MIH)	Photo Taken
☐	☐	☐

Caries

		UR							MAXILLA							UL
TOOTH		1.8	1.7	1.6	1.5	1.4	1.3	1.2	1.1	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8
PRESENCE		U	U													U	U
CROWN CONDITION	O																
	M																
	B																
	D																
	P																
TR CROWN		0	0													0	0

		LR							MANDIBLE							LL
TOOTH		4.8	4.7	4.6	4.5	4.4	4.3	4.2	4.1	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8
PRESENCE		U	U													U	U
CROWN CONDITION	O																
	M																
	B																
	D																
	L																
TR CROWN		0	0													0	0

Appendix E: Fluoridation status rules

FACCT Fluoridation status rules

Fluoridation Status	Description	Age	Rules
Full-Fl	Lifetime exposure to domestic water fluoridation	5/8	• Must be continuously fluoridated at > 0.4 ppm from at least 6 months old to date of examination o The 1st ≤ 6 months continuous without water fluoridation at > 0.4 ppm is acceptable
		12	• Must be continuously fluoridated at > 0.4 ppm from at least 6 months old to at least 6 months before the date of examination o The 1st ≤ 6 months continuous without water fluoridation at > 0.4 ppm is acceptable o The last ≤ 6 months continuous before date of examination without water fluoridation at > 0.4 ppm is also acceptable
Non-Fl	No exposure to domestic water fluoridation	5/8	• Must be continuously non-fluoridated at ≤ 0.4 ppm from at least 6 months old to date of examination o The 1st ≤ 6 months continuous with water fluoridation at > 0.4 ppm is acceptable
		12	• Must be continuously non-fluoridated at ≤ 0.4 ppm from at least 6 months old to at least 6 months before the date of examination o The 1st ≤ 6 months continuous with water fluoridation at > 0.4 ppm is acceptable o The last ≤ 6 months continuous before date of examination with water fluoridation at > 0.4 ppm is also acceptable
Part-Fl	Some exposure to domestic water fluoridation, but does not meet criteria for FULL or NON	All	• Does not meet the criteria for Full-Fl because > 6 months continuous without water fluoridation at > 0.4ppm at any age • Does not meet the criteria for Non-Fl because > 6 months continuous with water fluoridation at > 0.4ppm at any age • Participants with multiple shorter periods without fluoridation at > 0.4 ppm will be classified on an individual basis considering the timing and duration of the fluctuations of their exposure to domestic water fluoridation
Unknown	Unknown exposure to domestic water fluoridation	All	• Lived abroad (does not include *holidays* abroad unless > 6 months continuous duration) • Parents refused to complete residential history • The OHSRC team have been unable to obtain sufficient water data to confirm fluoridation status.

Cases not covered by these rules are reviewed and classified on an individual basis.

Appendix F: Supplemental tables

Table F 1: Multivariable HNB regression analysis of the prevalence and severity of dental caries (d_{3vc}mft(cde)) among 8-year-olds in Cork-Kerry (Full-CWF and No-CWF, 2002 and 2016-17 combined) with interaction between fluoridation status and year of examination.

	Cork-Kerry Full-CWF and No-CWF combined			
	Prevalence of caries (HNB model part 1) n=1604		Severity of caries (HNB model part 2) n=991	
Explanatory Variables	**OR (95% CI)**	***P* value**	**Mean (%) (95% CI)**	***P* value**
CWF (Full-CWF vs. No-CWF)	0.82 (0.57, 1.18)	0.282	-14 (-24, -2)	0.020
Year (2016-17 vs. 2002)	0.47 (0.32, 0.69)	<0.001	-33 (-42, -22)	<0.001
CWF * Year	**1.48 (0.93, 2.36)**	**0.098**	**26 (5, 52)**	**0.013**
Age	1.15 (0.88, 1.51)	0.295	-6 (-16, 5)	0.262
Medical card[a] (yes vs. no)	1.30 (1.00, 1.69)	0.053	23 (11, 35)	<0.001
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	0.89 (0.67, 1.17)	0.395	-10 (-19, 0)	0.050
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.52 (1.20, 1.93)	0.001	10 (1, 20)	0.030
Amount of toothpaste at age 8 (pea-sized or less vs. full brush)	1.06 (0.82, 1.37)	0.656	-4 (-14, 6)	0.400
Rinse method after toothbrushing at age 8 (glass vs. other[d] or no rinse)	1.37 (1.07, 1.74)	0.011	5 (-4, 15)	0.308
Sweet foods or drinks between meals at age 8				
≥ 4 times a day	2.02 (1.28, 3.18)	0.002	28 (10, 50)	0.002
2-3 times a day	1.70 (1.36, 2.11)	<0.001	15 (5, 25)	0.002
Once a day or less	Reference		Reference	
Age at first visit to the dentist				
≤ 4 years old	2.13 (1.52, 2.98)	<0.001	85 (56, 120)	<0.001
5-6 years old	2.73 (1.96, 3.81)	<0.001	75 (48, 108)	<0.001
≥ 7 years old	1.59 (1.12, 2.26)	0.010	42 (19, 71)	<0.001
Never	Reference		Reference	

The main explanatory variable was the interaction between CWF and year of examination (**CWF * Year**)
HNB = Hurdle negative binomial regression
OR = Odds ratio
Mean (%) = the percentage change in mean d_{3vc}mft(cde)
[a] Medical card ownership was used in this study as a measure of socioeconomic disadvantage
[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[c] Recommended from 2002 onwards
[d] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

Table F 2: Univariate HNB regression analysis of the association between each explanatory variable and the prevalence and severity of dental caries (d_{3vc}mft(cde)) among 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Cork-Kerry 2002 Full-CWF and No-CWF combined				Cork-Kerry 2016-17 Full-CWF and No-CWF combined			
	Prevalence of caries (HNB Model Part 1) n = 565		Severity of caries (HNB Model Part 2) n=351		Prevalence of caries (HNB Model Part 1) n=1145		Severity of caries (HNB Model Part 2) n=706	
Explanatory Variables	**OR (95% CI)**	***P* value**	**Mean (%)**	***P* value**	**OR (95% CI)**	***P* value**	**Mean (%)**	***P* value**
CWF (Full-CWF vs No-CWF)	0.46 (0.32, 0.66)	<0.001	-31 (-40, -20)	<0.001	0.69 (0.54, 0.89)	0.004	-13 (-23, -2)	0.027
Age	1.55 (1.07, 2.24)	0.021	2 (-13, 21)	0.780	0.95 (0.69, 1.31)	0.763	-3 (-17, 13)	0.719
Medical card[a] (yes vs. no)	1.00 (0.66, 1.52)	0.996	11 (-7, 33)	0.235	1.42 (1.06, 1.90)	0.018	18 (4, 33)	0.010
Mother's Education (LC[b] or less vs. Diploma/Cert or higher)	-	-	-	-	1.43 (1.07, 1.91)	0.015	22 (8, 38)	0.001
Age first used toothpaste[c] (≤ 24 months vs. >24 months[d])	0.65 (0.40, 1.04)	0.072	-22 (-34, -7)	0.005	0.95 (0.70, 1.30)	0.757	-3 (-15, 12)	0.718
Frequency of toothbrushing at age 8 (≤ once a day vs. ≥ twice a day)	1.18 (0.83, 1.67)	0.352	16 (1, 34)	0.041	1.98 (1.48, 2.65)	<0.001	9 (-4, 22)	0.180
Amount of toothpaste at age 8 (pea-sized vs. full brush)	0.82 (0.58, 1.16)	0.257	-14 (-26, -1)	0.040	1.07 (0.77, 1.48)	0.705	-7 (-20, 9)	0.389
Rinse method after toothbrushing at age 8 (glass vs. other[e]/no rinse)	1.11 (0.77, 1.59)	0.574	14 (-2, 32)	0.101	1.55 (1.17, 2.06)	0.002	6 (-6, 19)	0.367
Sweet foods/drinks between meals at age 8								
≥ 4 times a day	1.42 (0.65, 3.12)	0.379	9 (-19, 47)	0.563	2.51 (1.48, 4.26)	0.001	41 (16, 70)	<0.001
2-3 times a day	1.08 (0.76, 1.53)	0.684	-5 (-19, 10)	0.468	1.99 (1.52, 2.59)	<0.001	19 (6, 34)	0.004
Once a day or less	Reference	-	Reference	-	Reference	-	Reference	-
Type of water child usually drinks (tap vs tap and bottled or bottled)	-	-	-	-	1.28 (0.99, 1.65)	0.056	4 (-8, 17)	0.529
Regularly took baby bottle into bed (yes vs. no)	-	-	-	-	1.72 (1.33, 2.21)	<0.001	10 (-2, 23)	0.096
Age weaned to cup/mug: (after age 2 vs. before age 2)	-	-	-	-	1.67 (1.56, 2.42)	0.006	9 (-6, 27)	0.261
Age at first visit to the dentist								
≤ 4 years old	2.13 (1.10, 4.11)	0.025	46 (4, 107)	0.031	1.70 (1.18, 2.44)	0.004	86 (51, 128)	<0.001
5-6 years old	2.10 (1.11, 4.00)	0.023	55 (10, 118)	0.012	2.61 (1.81, 3.76)	<0.001	79 (47, 119)	<0.001
≥ 7 years old	1.15 (0.60, 2.22)	0.679	21 (-16, 74)	0.298	1.78 (1.21, 2.64)	0.004	45 (16, 80)	0.001
Never	Reference	-	Reference	-	Reference	-	Reference	-

HNB = Hurdle negative binomial regression; OR = Odds ratio; Mean (%) = the percentage change in mean d_{3vc}mft(cde)

[a] Medical card ownership is used in this study to indicate socio-economic disadvantage

[b] LC= Attainment of Leaving Certificate indicates completion of second level education

[c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[d] Recommended from 2002 onwards [e] Other = using toothbrush to rinse or cupping hands to rinse or rinsing directly from the tap

Table F 3: Multivariable logistic regression analysis of dental fluorosis prevalence in Cork-Kerry (Full-CWF and No-CWF, 2002 and 2016-17 combined) with interaction between fluoridation status and year of examination.

	Fluorosis (Dean's Index 'very mild' or greater)	
	Cork-Kerry Full-CWF and No-CWF combined n=1657	
Explanatory Variables	**OR (95% CI)**	***P* value**
CWF (Full-CWF vs No-CWF)	5.44 (2.26, 13.07)	<0.001
Year (2016-17 vs. 2002)	2.07 (0.86, 4.95)	0.103
CWF * Year	**0.43 (0.16, 1.16)**	**0.094**
Age	1.13 (0.73, 1.75)	0.582
Gender (female vs. male)	1.19 (0.82, 1.72)	0.362
Medical card[a] (yes vs. no)	1.14 (0.75, 1.72)	0.538
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	1.41 (0.83, 2.41)	0.202

The main explanatory variable was the interaction between CWF and Year of examination (**CWF * Year**)
OR = Odds ratio
[a] Medical card was used in this study as a measure of socio-economic disadvantage
[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)
[c] Recommended from 2002 onwards

Table F 4: Univariate logistic regression analysis of the association between each explanatory variable and the prevalence of dental fluorosis (Dean's Index 'very mild' or greater) among 8-year-olds in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Fluorosis (Dean's Index 'very mild' or greater)			
	Cork-Kerry 2002 n=553		Cork-Kerry 2016-17 n=1143	
Explanatory Variables	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
CWF (Full-CWF vs No-CWF)	5.49 (2.29, 13.15)	<0.001	2.40 (1.53, 3.76)	<0.001
Age	0.95 (0.51, 1.77)	0.870	0.93 (0.51, 1.71)	0.822
Gender (female vs. male)	1.05 (0.58, 1.91)	0.873	1.32 (0.84, 2.07)	0.234
Medical card[a] (yes vs. no)	1.00 (0.48, 2.07)	0.995	1.45 (0.89, 2.37)	0.137
Mother's Education at age 8 (LC or less[b] vs. Diploma/Cert or greater)	-	-	1.29 (0.78, 2.12)	0.316
Age first used toothpaste[c] (vs. >24 months[d])				
Before 12 months	1.95 (0.68, 5.61)	0.214	3.19 (1.57, 6.48)	0.001
Between 12 and 18 months	2.10 (0.77, 5.68)	0.146	1.21 (0.61, 2.40)	0.580
Between 19 and 24 months	1.49 (0.44, 5.08)	0.522	0.69 (0.29, 1.64)	0.402
Frequency of toothbrushing before age 2 (≥ twice/day vs. ≤once/day)	-	-	1.94 (1.22, 3.11)	0.005
Amount of toothpaste before age 2 (pea-sized[d] or less vs. >pea-sized)	-	-	0.89 (0.21, 3.87)	0.881
Eats/licks toothpaste before age 2 (often/sometimes vs. never[d])	-	-	1.15 (0.73, 1.81)	0.541
Breastfed (yes vs. no)	-	-	1.20 (0.77, 1.88)	0.428

OR = Odds ratio

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage

[b] LC=Leaving Certificate. Attainment of Leaving Certificate indicates completion of second level education

[c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[d] Recommended from 2002 onwards

Table F 5: Multivariable logistic regression analyses of dental fluorosis prevalence (TF 1 or greater, TF 2 or greater) in Cork-Kerry (2016-17 and 2002, Full-CWF and No-CWF, combined) testing interaction between fluoridation status and year of examination.

	Cork-Kerry Full-CWF and No-CWF combined n=1528			
	TF 1 or greater		TF 2 or greater	
Explanatory variable	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
CWF (Full-CWF vs. No-CWF)	2.03 (1.37, 3.00)	<0.001	4.20 (2.36, 7.50)	<0.001
Year (2016-17 vs. 2002)	0.11 (0.08, 0.16)	<0.001	0.44 (0.23, 0.85)	0.014
CWF * Year	**2.17 (1.32, 3.57)**	**0.002**	**1.13 (0.53, 2.42)**	**0.749**
Age	0.89 (0.66, 1.20)	0.455	0.90 (0.61, 1.34)	0.615
Gender (female vs. male)	1.33 (1.04, 1.69)	0.024	1.17 (0.83, 1.65)	0.366
Medical card[a] (yes vs. no)	0.80 (0.60, 1.07)	0.126	0.77 (0.51, 1.17)	0.224
Age first used toothpaste[b] (≤ 24 months vs. >24 months[c])	1.22 (0.89, 1.67)	0.226	1.32 (0.81, 2.15)	0.259

The main explanatory variable was the interaction between CWF and Year of examination (**CWF * Year**)
OR = Odds ratio

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage

[b] Grouped responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5)

[c] Recommended from 2002 onwards

Table F 6: Univariate logistic regression analysis of the association between each explanatory variable and dental fluorosis prevalence (TF 1 or greater, TF 2 or greater, scored from photographs) in maxillary central incisors of children in Cork-Kerry (Full-CWF and No-CWF combined) in 2002 and 2016-17

	Cork-Kerry Full-CWF and No-CWF combined							
	2002 n=499				2016-17 n=1066			
	TF 1 or greater		TF 2 or greater		TF 1 or greater		TF 2 or greater	
Explanatory Variables	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
CWF (Full-CWF vs. No-CWF)	2.10 (1.43, 3.09)	<0.001	4.27 (2.41, 7.56)	<0.001	4.32 (3.19, 5.86)	<0.001	4.74 (2.89, 7.77)	<0.001
Age	0.69 (0.46,1.03)	0.068	0.55 (0.34, 0.89)	0.016	0.78 (0.52, 1.16),	0.224	1.25 (0.66, 2.39)	0.492
Gender (female vs. male)	1.55 (1.06, 2.27)	0.023	1.20 (0.76, 1.89)	0.444	1.21 (0.91, 1.62),	0.196	1.11 (0.69, 1.78)	0.664
Medical card[a] (yes vs. no)	0.90 (0.57, 1.43)	0.660	1.15 (0.67, 1.97)	0.620	0.97 (0.69, 1.37),	0.877	0.80 (0.45, 1.44)	0.465
Mother's Education (LC[b] or less vs. Diploma/Cert or greater)	-		-		0.84 (0.59, 1.19),	0.322	1.11 (0.65, 1.90)	0.690
Age first used toothpaste[c] (vs. >24 months[d])								
Before 12 months	1.10 (0.61, 1.96)	0.753	1.51 (0.71, 3.18)	0.282	1.82 (1.11, 2.98),	0.018	2.11 (0.97, 4.60)	0.061
Between 12 m and 18 months	1.23 (0.72, 2.10)	0.454	1.67 (0.83, 3.34)	0.148	1.45 (0.95, 2.21),	0.082	1.51 (0.75, 3.02)	0.249
Between 19 and 24 months	0.99 (0.51, 1.93)	0.982	1.01 (0.41, 2.51)	0.976	1.04 (0.64, 1.70),	0.870	0.80 (0.33, 1.92)	0.613
Frequency of toothbrushing < age 2 (≥ twice/day vs. ≤once/day)	-		-		1.83 (1.33, 2.53),	<0.001	2.16 (1.32, 3.53)	0.002
Amount of toothpaste < age 2 (pea-sized[d] or less vs. >pea-sized)	-		-		0.71 (0.27, 1.86),	0.488	0.45 (0.13, 1.56)	0.207
Eats/licks toothpaste < age 2 (often/sometimes vs. never[d])	-		-		1.82 (1.34, 2.47),	<0.001	1.20 (0.74, 1.96)	0.458
Breastfed (yes vs. no)	-		-		1.09 (0.82, 1.46),	0.552	1.46 (0.91, 2.36)	0.119

OR = Odds ratio

[a] Medical card ownership was used in this study as a measure of socio-economic disadvantage [b] LC=Leaving Certificate. Attainment of Leaving Certificate indicates completion of second level education. [c] Responses for age at first toothbrushing in 2002 (prior to introduction of toothbrushing guidance, collected at age 8) and age first used toothpaste in 2013-14 (collected at age 5) [d] Recommended from 2002 onwards

Appendix G: Results of sensitivity analyses

Sensitivity analysis of impact of re-classifying Part-CWF 2002 on comparison of dental caries and fluorosis 2016-17 vs. 2002

		Part-CWF 2002 assumed to be Full-CWF				Part-CWF 2002 assumed to be No-CWF	
		Dublin Full-CWF		Cork-Kerry Full-CWF		Cork-Kerry No-CWF	
Outcome	**Year**	**OR**	***P* value**	**OR**	***P* value**	**OR**	***P* value**
Caries prevalence[a]	2017	1.14→1.14	0.350→0.349	1.25→1.24	0.208→0.206	0.77→0.71	0.179→0.064
	2002	Ref		Ref		Ref	
Caries severity[a,b]	2017	5%→4%	0.487→0.548	7%→3%	0.424→0.704	-13%→-15%	0.039→0.010
	2002	Ref		Ref		Ref	
Fluorosis prevalence Dean's Index[c]	2017	1.16→1.15	0.312→0.356	0.93→ 0.96	0.771→0.859	1.97→1.08	0.129→0.806
	2002	Ref		Ref		Ref	
Fluorosis prevalence TF Index: TF 1 or greater[c]	2017	-	-	0.24→0.25	<0.001→<0.001	0.11→0.10	<0.001→<0.001
	2002	-		Ref		Ref	
Fluorosis prevalence TF Index: TF 2 or greater[c]	2017	-	-	0.50→0.53	0.001→0.002	0.49→0.37	0.036→0.001
	2002	-		Ref		Ref	

OR = Odds ratio

[a] Hurdle negative binomial regression analysis. Controlled for medical card ownership, age, age first used toothpaste, age at first visit to the dentist, frequency of toothbrushing (age 8), amount of toothpaste (age 8), rinse method after toothbrushing (age 8), frequency of intake of sweet foods or drinks between meals (age 8).

[b] Percentage change in mean $d_{3vc}mft(cde)$

[c] Logistic regression analysis. Controlled for age, gender, medical card ownership and age first used toothpaste.

Appendix H: Conference presentations and other dissemination activities

Summary of conference presentations

Month/Year	Conference	Presentation Title	Mode of presentation
July 2021	International Association for Dental Research General Session, Virtual Experience	Fluorosis and risk factors among 8-year-olds with 0.6-0.8 ppm water fluoridation	Poster presented orally
January 2021	International Association for Dental Research, Irish Division Virtual meeting	Impact of water fluoridation, socio-demographic and behavioural factors on caries	Oral Presentation
October 2019	International Association for Dental Research, Irish Division meeting, Cork, Ireland	Impact of downward adjustment of water fluoride concentration on fluorosis	Oral Presentation

Conference Abstracts

Fluorosis and Risk Factors Among 8-year-olds with 0.6-0.8 ppm Water Fluoridation

Authors: Patrice James, Deirdre Browne, Mairead Harding, Tara Beecher, Denis O'Mullane, Michael Cronin, Helen Whelton

2021 IADR/AADR/CADR General Session (Virtual Experience): Poster presented orally.

One sentence summary: In a random sample of Irish 8-year-olds with lifetime exposure to community water fluoridation (CWF) at 0.6-0.8 ppm, fluorosis in maxillary central incisors was predominantly at the lowest levels (TF1/TF2); prevalence of scores ≥TF 3 was low (4%) and CWF along with early and inappropriate use of fluoride toothpaste were associated with fluorosis.

ABSTRACT

Objective: To determine prevalence and severity of fluorosis and factors associated with fluorosis in maxillary central incisors of 8-year-olds with and without community water fluoridation (CWF).

Methods: Following ethical approval, a random sample of 5-year-olds in Dublin (urban with CWF) and Cork-Kerry (urban/rural with and without CWF) recruited to the Fluoride and Caring for Children's Teeth study 2013-14 were followed up at age 8 (2016-17). Standardised digital oral photographs were taken (8s drying). Parents completed demographic and oral health behaviour questionnaires at ages 5 and 8. Children were categorised as having lifetime/no exposure to CWF at 0.6-0.8 ppm (Full-CWF/No-CWF). Fluorosis (Thylstrup-Fejerskov (TF) Index) on permanent maxillary central incisors was scored in duplicate by two trained and calibrated examiners, blind to fluoridation status, with disagreements resolved by consensus. Person-level TF score was the highest score on central incisors. Multi-variable logistic regression assessed the association between CWF (Cork-Kerry only), socio-demographic variables, fluoride toothpaste use and fluorosis (TF≥1).

Results: Of 707 children in Dublin with Full-CWF, 376 in Cork-Kerry with Full-CWF and 772 in Cork-Kerry with No-CWF, TF scores for 618 (87%), 355 (94%) and 753 (98%) respectively were analysed. Fluorosis prevalence was 41% in Dublin (Full-CWF), 40% in Cork-Kerry (Full-CWF) and 14% in Cork-Kerry (No-CWF). In Dublin (Full-CWF), Cork-Kerry (Full-CWF) and Cork-Kerry (No-CWF), scores were: TF1 24%, 25%, 10%; TF2 13%, 11%, 3% and TF≥3 4%, 4%, <1%, respectively. In Dublin, eating/licking toothpaste sometimes/often before age 2 (vs. never, P=0.012) was associated with fluorosis. In Cork-Kerry, having Full-CWF (vs. No-CWF, P<0.001), brushing with toothpaste twice/day or more before age 2 (vs. once/day or less, P=0.019) and eating/licking toothpaste sometimes/often before age 2 (vs. never, P=0.010) were associated with fluorosis.

Conclusion: Fluorosis in central incisors was predominantly of low severity. Lifetime exposure to CWF, early and inappropriate use of fluoride toothpaste were associated with fluorosis.

Impact of Water Fluoridation, Socio-demographic and Behavioural Factors on Caries
Authors: Patrice James, Mairead Harding, Tara Beecher, Denis O'Mullane, Michael Cronin, Helen Whelton

2021 International Association for Dental Research, Irish Division Virtual meeting: Oral Presentation

ABSTRACT

Objective: To assess the association between community water fluoridation (CWF) at 0.6 to 0.8 ppm, socio-demographic and behavioural factors and caries prevalence and severity in primary teeth of 8-year-old children in Cork-Kerry in 2016-17.

Methods: Following ethical approval, a random sample of 8-year-old children in Cork-Kerry were examined for dentinal caries in primary teeth (d_{3vc}mft(cde)). Parents completed demographic and oral health behaviour questionnaires. Children were categorised as having lifetime or no exposure to CWF (Full-CWF/No-CWF). Multi-variable regression (negative binomial Hurdle model) assessed the association between CWF, socio-demographic variables, dental visiting, infant feeding, dietary and toothbrushing behaviours and caries prevalence (proportion with d_{3vc}mft(cde) > 0) and severity (mean d_{3vc}mft(cde) among children with caries). Significance level was $P < 0.05$.

Results: Of 1521 8-year-olds examined for caries, 375 (25%) with Full-CWF and 770 (51%) with No-CWF were included in the analysis. Having Full-CWF (vs. No-CWF) was associated with lower caries prevalence (56% Full-CWF vs. 65% No-CWF, $P = 0.001$) and severity (mean d_{3vc}mft(cde) 3.7 Full-CWF vs. 4.2 No-CWF, $P = 0.002$). Brushing with toothpaste once/day or less (vs. twice/day or more), using a glass to rinse after toothbrushing (vs. other rinse method/no rinsing), having sweet foods/drinks more than once/day between meals (vs. once/day or less), having regularly taken a baby bottle into bed and having visited the dentist (vs. never) were associated with higher caries prevalence. Medical card ownership, having sweet foods/drinks more than once/day between meals (vs. once/day or less) and having visited the dentist (vs. never) were associated with higher severity of caries.

Conclusion: In primary teeth of 8-year-old children, CWF at 0.6 to 0.8 ppm was associated with lower prevalence and severity of dentinal caries. Socio-demographic and modifiable behavioural factors were associated with higher caries prevalence and severity.

Impact of downward adjustment of water fluoride concentration on fluorosis
Authors: Patrice James, Mairead Harding, Tara Beecher, Deirdre Browne, Denis O'Mullane, Michael Cronin, Helena Guiney, Helen Whelton.

2019 International Association for Dental Research, Irish Division meeting, Cork, Ireland: Oral Presentation.

Objective: To determine the impact of downward adjustment of water fluoride concentration (2007) from 0.8-1.0 ppm to 0.6-0.8 ppm on prevalence of fluorosis in 8-year-olds.

Methods: Ethical approval was obtained. A random sample of 8-year-olds in Cork/Kerry and Dublin were clinically examined for fluorosis in 2016-17. Parents/caregivers completed a demographics and oral health behaviours questionnaire. Based on complete residential history, children were categorised as having lifetime/no exposure to community water fluoridation (Full-F/Non-F). Prevalence of fluorosis (Dean's Index scores very mild/mild/moderate) in 2016-17 (9 years post-adjustment) was compared with prevalence of fluorosis in 1224 8-year-olds olds (Full-F: Dublin n=671, Cork/Kerry n=325 Non-F: Cork/Kerry n=228) in the same regions in 2002 (5 years pre-adjustment). Effect of examination year on prevalence of fluorosis was assessed using multivariable logistic regression analyses controlling for socio-demographic variables and tooth-brushing behaviours. Significance level was $p<0.05$.

Results: Of 2304 8-years-olds examined for fluorosis in 2016-17, 1846 were categorised Full-F (Dublin: n=703, Cork/Kerry: n=371) or Non-F (Cork/Kerry: n=772). In 2016-17 [vs 2002], prevalence of fluorosis was 18.1% [15.5%] in Dublin Full-F, 11.6% [12.9%] in Cork/Kerry Full-F, and 5.2% [2.6%] in Cork/Kerry Non-F. In 2016-17 [vs 2002] prevalence of very mild fluorosis was 14.1% [11.2%] in Dublin Full-F, 9.2% [7.7%] in Cork/Kerry Full-F and 4.9% [2.6%] in Cork/Kerry Non-F. In 2016-17 [vs 2002] prevalence of mild fluorosis was 3.7% [3.6%] in Dublin Full-F, 2.2% [5.2%] in Cork/Kerry Full-F and 0.3% [0.0%] in Cork/Kerry Non-F. At both time points, prevalence of moderate fluorosis was ≤1% in Dublin and Cork/Kerry Full-F, and zero in Cork/Kerry Non-F. In multivariable analyses, there was no statistically significant difference in prevalence of fluorosis in 2016-17 compared to 2002 in Dublin ($p=0.27$), Cork/Kerry Full-F ($p=0.91$) or Cork/Kerry Non-F ($p=0.18$) holding all other variables constant.

Conclusions: There is no difference in the prevalence of fluorosis in 2016-17 following downward adjustment of water fluoride concentration.

FACCT infographics (2019)

Fluoride And Caring for Children's Teeth (FACCT) study - Health Research Board (HRB) Knowledge Exchange and Dissemination Scheme (KEDS) 2017: **Supporting individuals and organisations involved in implementation of community water fluoridation**

James, P., Beecher, T., Whelton, H. and Harding, M. (2020, June 27). FACCT Infographics. Available from: https://www.ucc.ie/en/ohsrc/research/facct/infographics/

This was a mixed methods study to develop tailored dissemination materials for specified target groups based on the findings of the FACCT study.

The resulting infographics are available for printing in A4 leaflet, mobile-friendly scrollable and A2 poster formats.

This work was funded by HRB KEDS Award KEDS-2017-017

Online CPD training module for GDPs

Fluoride And Caring for Children's Teeth (FACCT) study - Health Research Board (HRB) Knowledge Exchange and Dissemination Scheme (KEDS) 2018: **What the Researcher and the Dentist want to share, supporting knowledge dissemination**.

James, P., Beecher, D., Whelton, H. and Harding, M. (2021, Mar 31). FACCT Educational Resources for Dental Professionals. Available from:

https://www.ucc.ie/en/ohsrc/research/facct/educationalresourcesfordentalprofessionals/

The aim of this project was to develop a set of online educational resources to disseminate the results of the FACCT study to General Dental Practitioners. The project was

completed in collaboration with the Irish Faculty of Primary Dental Care (IFPDC), whose input guided the structure and content of the materials.

This work was funded by the Health Research Board: HRB KEDS Award KEDS-2018-045.