Report of the Working Group on the use of fluoride toothpaste in Children under Six Years of Age

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Executive Summary

As a result in an increase in the prevalence of dental fluorosis amongst Irish children between 1984 and 2002 the Forum on Fluoridation (FoF) recommended that the level of fluoride in the drinking water be reduced from 0.8 - 1 ppm to 0.6 – 0.8 ppm. The Regulation for this was implemented in 2007. The FoF also recommended that the use of fluoride toothpaste should not commence until age 2 years and that parents should supervise their children brushing their teeth between 2 and 7 years. In 2017 a working group was established in order to update the scientific evidence on the risks and benefits of use of fluoride toothpaste in children under the age of six years. The working group undertook a detailed search of the international and national literature relating to the relationship between the use of fluoride toothpaste in young children and the prevalence of dental caries in primary teeth and prevalence of dental fluorosis in permanent incisors, in order to determine if any new evidence had emerged since 2002. A review of guidelines on the use of fluoride toothpaste in young children in other countries was also carried out. Preliminary data from the Fluoride And Caring for Children’s Teeth (FACCT) study including the results for caries in 5-year-old children in Dublin and Cork/Kerry in 2013/14 and data on fluorosis in the same cohort of children at age 8 years in 2016/17 was made available to the Working Group. International evidence strongly supports the effectiveness of fluoride toothpaste in preventing caries in permanent teeth. The evidence of effectiveness in primary teeth is limited but is still positive. The evidence supports the view that the fluoride concentration of toothpaste and its early use are risk factors for fluorosis. All of the guidelines used in other countries include varying restrictions on the use of fluoride toothpaste in young children.

In Ireland, recent research shows that most parents claim to start brushing their child’s teeth with toothpaste before the age of 2 years, and this practice is associated with fluorosis in eight year olds. In addition the overall prevalence of fluorosis in eight year olds has not changed since 2002 despite the reduction of fluoride levels in the water supply. The working group recommends that the 2002 recommendations should remain but that comprehensive research be undertaken to monitor the implementation and effectiveness of the recommendations in controlling dental caries and dental fluorosis.
OVERALL REPORT

1. Introduction

Fluoride toothpaste has played a major role in reducing levels of dental caries worldwide. Their development and adoption as an effective oral health promotion technology is an example of positive collaboration between industry, researchers and public health over the last sixty years.

There is evidence that the use of fluoride toothpaste during the first 3-4 years of life is associated with fluorosis of the permanent front teeth, due to ingestion of toothpaste by children in this age range. In 2002, the Forum on Fluoridation, following extensive assessment of studies on caries and fluorosis, both in Ireland and worldwide, issued recommendations on the use of fluoride toothpaste for young children in Ireland (Department of Health and Children, 2002). The recommendations aimed to promote appropriate use of fluoride toothpaste that would minimise the risk of fluorosis while maintaining the caries-preventive benefit of fluoride toothpaste. A review of these recommendations was considered appropriate at this time in the light of ongoing research on the subject, on the introduction of different approaches in other countries with water fluoridation and also with the development of the new National Oral Health Policy in Ireland.

2. Background

Community water fluoridation has been a cornerstone of caries prevention in the Republic of Ireland (RoI) since the 1960s. A known side effect of community water fluoridation is that it increases the risk of developing dental fluorosis. Dental fluorosis is a condition that can affect the appearance of the enamel, and results from the ingestion of fluoride from all sources, not just water, at the time of enamel formation.

At the levels of fluoride used in community water fluoridation in Ireland, the change in the appearance of the enamel is predominantly in the categories of Questionable and Very Mild fluorosis (Dean’s Index), and manifests as the presence of fine opaque white lines or flecks, typically affecting between 10-25% of the tooth surface. These changes are not considered an aesthetic concern, and are deemed to be an acceptable trade-off for the benefit of caries prevention.

Oral health surveys conducted since the 1960s in the RoI and in other countries with community water fluoridation, demonstrate the continued effectiveness of water fluoridation at reducing caries levels in children and adults (Rugg-Gunn and Do, 2012, McDonagh et al., 2000, Griffin et al., 2007). However, from the 1980s onwards, a trend for increasing prevalence of dental fluorosis began to emerge, not only in the RoI but in other countries with and without water fluoridation (Whelton et al., 2004a, Kahn et al., 2005), which indicated that children may be ingesting too much fluoride at a young age. This trend coincided with the increase in use of fluoride toothpaste in developed countries. The ingestion of fluoride toothpaste by young children was identified as an important source of overall fluoride ingestion during the critical period of enamel formation, and consequently a potential risk factor for dental fluorosis (Buzalaf and Levy, 2011).
Forum on Fluoridation Recommendations in the Republic of Ireland

In 2002, in an effort to reduce levels of fluorosis in the RoI, the Forum on Fluoridation made the following recommendation regarding the use of fluoride toothpaste by young children.

- The Forum recommends the continued use of fluoride toothpaste in fluoridated and non-fluoridated areas because of the additive benefit from the combination of fluoridated water and fluoride toothpaste.
- 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.
- Paediatric toothpastes with low concentrations of fluoride require further research before the Forum can recommend their use.
- Guidelines for the use of oral health care products in childhood should be developed for use by all involved in advising members of the public on health care matters. The Expert Body will play a key role in the development of these guidelines.

Working Group Membership; Terms of Reference

As part of the development of the new National Oral Health Policy, and following communications with the former Expert Body on Fluorides & Health, the Chief Dental Officer of the Department of Health, Professor Dympna Kavanagh, asked the Chairman of the Oral Health Policy Academic Research Group, Prof Denis O'Mullane, to arrange an evidence update relating to the above recommendations on the use of fluoride toothpaste. A Working Group was established to undertake this task with a view to arriving at an objective decision on the current validity of these recommendations. The following Working Group was established:

- Prof. Denis O'Mullane — Member of the Forum on Fluoridation, member of the Irish Expert Body on Fluorides & Health 2004 ï 2017, Chairperson of the Oral Health Policy Academic Reference Group (OHPARG)
- Prof. John Clarkson — Member of the Forum on Fluoridation, member of the Irish Expert Body on Fluorides & Health 2004 ï 2017, with particular expertise in all aspects of dental fluorosis.
- Dr. Carmel Parnell — Co-opted member of the New and Emerging Issues subgroup of the Expert Body on Fluorides & Health 2010 ï 2017, with particular expertise in guideline development, including topical fluorides and caries prevention, and also an in-depth knowledge of systematic review methodology.
The terms of reference of the group were to update the scientific evidence on the risks and benefits of the use of fluoride toothpaste in young children.

A set of key questions and supplementary questions were developed by the Working Group which informed the search strategies for the evidence update. Preliminary data from the FACCT study (Fluoride and Caring for Children’s Teeth), including the results for caries in 5-year-old children in Dublin and Cork/Kerry in 2013/14, and data on fluorosis in the same cohort of children at age 8 years in 2016/17, were made available to the Working Group.

### 3. Findings of the Evidence Update

**Key Question 1 – Benefits of use of fluoride toothpaste in children under the age of 6 years**

In children under the age of 6 years*, does the use of fluoride toothpaste containing 1,000 ppm F or more provide a benefit in terms of caries prevention compared to the use of no toothpaste?

* Children under age 6 were chosen by the group as it was felt that it would broaden the number of studies that might be available to review, particularly in relation to the question on risk of fluorosis to both the upper permanent central and lateral incisors which are relevant when considering the aesthetic impact on fluorosis. The maturation and development of the crowns of central and lateral incisors is estimated to commence at age 3 months and extend up to 4 ï 5 years of age (Berowitz 1992) before erupting between 7 and 9 years. During this period excessive intake and absorption of fluoride could potentially give rise to enamel fluorosis of the permanent incisor teeth.

**Summary of Evidence Update**

The evidence for the effectiveness of fluoride toothpaste at preventing caries in permanent teeth is well established (Marinho et al., 2003, Walsh et al., 2010). However, the evidence regarding the effectiveness of fluoride toothpaste at preventing caries in primary teeth is limited in both quantity and quality.

A small body of studies of generally poor quality indicates that fluoride toothpaste containing 1,000- 1,500 ppm F is effective at reducing caries in the primary dentition of young children compared to placebo or no treatment (dos Santos et al., 2013, Wright et al., 2014). Based on the analysis of 5 studies involving 2,644
children, one review reported a reduction of 31% (95% CI 18-43%) in caries experience (dmfs) in children using toothpaste containing 1,000–1,500 ppm F (dos Santos et al., 2013). This is consistent with the finding that significant caries reductions in permanent teeth are only seen at fluoride concentrations of 1,000 ppm or more (Walsh et al., 2010).

The evidence for the effectiveness of low fluoride toothpaste (250–550 ppmF) compared to toothpaste containing 1,000–1,500 at preventing caries in primary teeth is limited in quantity and the findings are inconsistent. Based on the analysis of 4 studies comparing low F toothpastes with standard F toothpastes, a Cochrane review concluded that the results were equivocal and dependent upon the fluoride concentrations compared, the outcome measure (dmft, dmfs or percentage of children developing caries), or the caries activity of the participants (Walsh et al., 2010).

**Detailed evidence review of the effectiveness of fluoride toothpaste**

A Cochrane review published in 2003, was the first to apply systematic review methodology to investigate the effectiveness of fluoride toothpaste at preventing caries in children and adolescents (Marinho et al., 2003). This landmark review included 74 studies which compared fluoride toothpaste with placebo or no treatment. The overall finding of the review was that regular use of fluoride toothpaste reduced caries in the permanent dentition by 24% (95% CI 21-28%). There was evidence that the caries preventive effect of fluoride toothpaste increased with higher baseline levels of caries, increased fluoride concentration and increased frequency of use. The review also reported that fluoride toothpaste provided additional caries reduction in children from fluoridated areas.

Only one study in this review reported results for the primary dentition in children, which is the issue of particular interest to the Working Group. The average age of the participants in this study was 7 years at baseline, and the study reported a significant reduction in caries of 37% in the group using 1,500 ppm F toothpaste compared to placebo (Cahen et al., 1982).

The review authors suggested that future fluoride toothpaste trials should involve head-to-head comparisons with other toothpastes, other topical fluorides, or with non-fluoride caries preventive strategies. These trials should be carried out in pre-school children to measure the effect on caries incidence in deciduous teeth and on fluorosis in permanent incisor teeth, and should be of long duration (Marinho et al., 2003).

A subsequent Cochrane review examined the effect of different concentrations of fluoride toothpaste at preventing dental caries in children and adolescents (Walsh et al., 2010). This review found that fluoride toothpaste needed to contain at least 1,000 ppmF before a significant caries preventive effect was seen compared to placebo, and that the relative caries preventive effect of fluoride toothpastes of different concentrations increased with higher fluoride concentration. Only 6 of the 75 randomised controlled trials included in this review measured caries in primary teeth. The age of the children participating in these studies ranged from 12 months to 8 years. Two studies, one conducted in children with an average age of
7 at baseline (Cahen et al., 1982), and the other involving children with an average age of 4 years (Fan et al., 2008), compared 1,500 ppm F toothpaste with placebo. Both studies found significantly lower caries levels in the fluoride toothpaste group. In the remaining 4 studies, which compared low fluoride toothpastes containing 250, 440, 500 or 550 ppm F with standard fluoride toothpastes containing 1100, 1055, or 1450 ppm F, the results were equivocal, dependent upon the precise fluoride concentrations compared (Davies et al., 2002b, Winter et al., 1989) or the caries activity of the participants (Lima et al., 2008).

The review authors noted that "The lack of trials in the deciduous dentition, where the potential for harm as a result of caries or fluoride exposure compared to the mixed or permanent dentition is of particular concern." and they recommended more research into the effect of lower fluoride toothpastes using direct head-to-head comparisons and evaluating the effect on primary teeth (Walsh et al., 2010).

Four further reviews investigated the caries-preventive effect of fluoride toothpaste specifically in primary teeth of young children (under the age of 6 or 7). One of these reviews considered multiple therapies for preventing and treating Early Childhood Caries, but added little evidence on the effectiveness of fluoride toothpaste in children under the age of 6 and is not considered any further (Twetman and Dhar, 2015). The inclusion criteria for the remaining 3 reviews were less stringent than those of the Cochrane reviews, and consequently most of the included studies had methodological issues that put them at high risk of bias.

The first review included 8 studies and looked at the effectiveness of fluoride toothpaste compared to placebo or no treatment at preventing caries in the primary teeth of preschool children (dos Santos et al., 2013). This review found that fluoride toothpaste containing 1,000-1500ppmF significantly reduced caries experience (dmfs) in preschool children by 31% (95% CI 18-43%) (5 studies) and also reduced the risk of a preschool child developing caries by 14% compared to not using fluoride toothpaste (RR 0.86, 95% CI 0.81-0.93) (2 studies). This review also found a statistically significant caries-preventive effect for toothpaste containing ≤500 ppm F, based on the analysis of 2 heterogeneous studies which differed in their design and in the age of the participants at baseline (age 3 in one study and age 8 months in the other). This result differs from that of the 2010 Cochrane review, which found no significant difference in effect between toothpastes containing 400-550ppmF and placebo (Walsh et al., 2010).

The second review analysed 5 studies that compared the effect of toothpastes with different fluoride concentrations on caries prevention in primary teeth (Santos et al., 2013). The review found that low fluoride toothpaste (250-550ppm F) significantly increased the risk of caries in primary teeth by 13% (RR=1.13, 95% CI 1.07-1.20) compared to toothpaste containing 1,000-1450 ppm F.

The third review investigated the caries-preventive effect of fluoride toothpaste in primary teeth compared to with placebo or no treatment, and also compared low fluoride toothpastes with standard fluoride toothpastes (Wright et al., 2014). Nine of the 14 studies in this review were also included in the 2 reviews by Santos and co-authors described above. One of the additional studies in the Wright review (Ellwood et al., 2004) was a publication based on the same subjects of a study already included in the review (Davies et al., 2002a), and the inclusion of both papers in the analysis represents duplication and could affect the
outcome. Another of the additional studies had a control group in which it was unclear what intervention they received.

As in the other reviews, the Wright review analysed the effects of toothpastes containing > 1000 ppm F and <1000 ppm F and found similar results - toothpastes containing 1,000 ppmF or more were effective at reducing caries in primary teeth compared to placebo or no treatment and the head to head comparisons of low versus standard fluoride toothpaste varied depending on the concentrations compared. However, Wright found no significant difference in effect between toothpastes containing <500 ppm F and placebo or no treatment, whereas Santos found a statistically significant difference when analysing the same 2 studies. The 2 reviews used different measures for expressing the measure of effect (Standard mean difference in Wright and prevented fraction in Santos) which may explain the difference in the results.

Our update search identified only 1 toothpaste trial involving preschool published since the Wright review. This randomised controlled trial, which involved 315 children aged 2-4 years, was conducted in a fluoridated area of Brazil and tested the effect of a low-pH liquid toothpaste containing 550 ppm F on caries progression and net caries increment in children with active caries lesions and children without active caries lesions (de Almeida Baldini Cardoso et al., 2014). The control groups used liquid toothpastes with a neutral pH, containing 550 ppm F or 1,100 ppm F. In the caries inactive group, there was no significant difference in net caries increment between the 3 toothpastes. In the caries active group, caries progression and net caries increment were significantly lower in the low F/low pH toothpaste compared to low F/ neutral toothpaste. No difference was found between the low and high F neutral toothpaste. Thirty eight percent of the sample was lost to follow up during the 1 year study, which puts the study at high risk of attrition bias. A novel design feature of this study was that QLF was used on a sub-sample of the participants to assess the extent of demineralisation, and it could discriminate between the low and high F neutral pH toothpastes. Toenail clippings were also taken to measure total fluoride absorption at 6 months, and children who used the low F toothpastes had similar toenail F levels, which were significantly lower than those using standard F toothpaste.

Overall, the international evidence supports the caries-preventive benefit of toothpaste containing 1,000 - 1,500 ppm F in young children. The limited available international evidence indicates that fluoride toothpaste containing 1,000 - 1,500 ppm F is effective at reducing caries in the primary dentition of young children compared to placebo or no treatment. This is consistent with the larger body of evidence which supports the benefit of using fluoride toothpaste containing at least 1,000 ppm F for preventing caries in permanent teeth.

Based on the available evidence, and the lack of studies testing different fluoride concentrations under 1,000 ppm F, the Forum on Fluoridation statement that paediatric toothpastes with low concentration of fluoride require further research before their use can be recommended, remains as relevant today as it was in 2002. Further research is needed to evaluate the effectiveness of different formulations of lower fluoride toothpastes in young children.
Key Question 2 – Use of fluoride toothpaste in children under the age of 6 years and risk of dental fluorosis

In children under the age of 6 years, does the use of fluoride toothpaste containing 1,000 ppm F or more represent a risk in terms of increased fluorosis in permanent incisors, compared to the use of no toothpaste?

The first 3-4 years of life are accepted as the peak risk period of risk for fluorosis in the aesthetically important upper incisors (Ellwood and Cury, 2009, Buzalaf and Levy, 2011) and this also coincides with the peak period during which young children lack the ability to spit out toothpaste effectively after brushing. Consequently, there is evidence that fluoride toothpaste is a contributor to total fluoride ingestion in young children and is a recognised risk factor for dental fluorosis of the incisors (Buzalaf and Levy, 2011). A Cochrane review of topical fluorides as a cause of dental fluorosis in children analysed 25 studies of differing designs in an attempt to understand the relationship between fluoride toothpaste use and fluorosis risk (Wong et al., 2010). The key toothpaste factors explored in the review were:

- Age of commencing toothpaste use/tooth brushing (2 case control studies, 9 cross sectional studies)
- Frequency of tooth brushing (4 cross sectional studies)
- Fluoride concentration of toothpaste (2 RCTs, 3 cross sectional studies)
- Amount of toothpaste used (3 cross sectional studies)

The results for age of commencing toothpaste use/tooth brushing were inconsistent. Meta-analysis of 2 case-control studies found a significant reduction in the likelihood of a child having fluorosis if toothpaste use commenced after 24 months (OR 0.29 (95% CI 0.15, 0.53), whereas the analysis of 6 cross sectional studies looking at the same time comparison for commencing toothpaste use failed to find a significant difference (OR 0.92 (95% CI 0.71, 1.18). Five other cross sectional studies compared age of commencing toothpaste use after 12/14 months versus before 12/14 months, and the pooled analysis found a significant reduction in the likelihood of a child having fluorosis if tooth brushing commenced after 12/14 months (OR 0.7 (95% CI 0.57, 0.88). The review authors described this result as “weak and unreliable” evidence.

No significant association was found between fluorosis and frequency of tooth brushing (twice a day or more versus less than twice a day (4 cross sectional studies) or less than 7 times per week versus once or more a day (1 cross sectional study). The amount of toothpaste used (small vs medium or large) was also not significantly associated with fluorosis, based on the meta-analysis of 4 cross sectional studies.

The 2 RCTs which compared the effect of low fluoride (440 and 550ppm) and standard fluoride (1,000 and 1,450ppm) toothpaste both found that the risk of fluorosis was significantly lower with the use of low fluoride toothpaste. In one RCT (Tavener et al., 2006), toothpaste use commenced at age 1 and the study compared 440 ppm F toothpaste with 1,450ppm F paste whereas in the other study, the children were age 2 at baseline and the study compared 500ppm F toothpaste with 1,000ppm F. The analysis of 3 cross sectional studies
which compared 250/550 ppm F toothpaste with toothpaste containing 1,000 ppm or more found no statistically significant difference between the low and standard fluoride toothpaste in the likelihood of a child developing fluorosis.

It is important to note that the Cochrane review did not consider with the severity of fluorosis, but treated fluorosis as either present or absent. However, the authors noted that the available evidence in the review focused on mild fluorosis.

A subsequent review of the efficacy and safety of fluoride toothpaste in children younger than 6 years included 2 studies which were not included in the Cochrane review (Wright et al., 2014). Neither of the additional studies made any major difference to the overall findings of the Cochrane view. Two studies, published after this review, found significant associations between fluorosis and behaviours such as swallowing toothpaste after brushing or frequently eating or licking fluoride toothpaste at a young age (Bal et al., 2015, Celeste and Luz, 2016). A third study, which was conducted in a deprived area of Mexico, reported significant associations between fluorosis and frequent brushing (3 vs 1-2 times per day) and lack of parental supervision of brushing (Molina-Frechero et al., 2015).

Overall, there is some evidence that the fluoride concentration of toothpaste (1,000 ppm or more) and early age of commencing toothpaste use (under 12-14 months) are significant risk factors for fluorosis, while the impact of other factors such as frequency of brushing and amount of toothpaste used remains unclear. Optimising caries prevention while minimising the risk of fluorosis requires a judgement based not only on the scientific evidence but also on careful monitoring of the status of caries and fluorosis in the population. Minimising a child’s exposure to fluoride toothpaste during the key risk period for fluorosis is a prudent approach for controlling fluorosis, but further research is needed to identify the most effective control measures that achieve the desired balance between fluorosis minimisation and caries prevention.

In Ireland, a key finding of the FACCT study was that 4 out of 5 parents claimed to start brushing their child’s teeth with toothpaste before the age of 2 years, and this practice was associated with an increased risk of a child having fluorosis at age 8. This finding, coupled with the fact that the overall prevalence of fluorosis among 8 year olds had changed little since 2002, in spite of the reduction of the level of fluoride in the water, indicates that there is still a need to reduce the exposure of young children to fluoride toothpaste during the key risk period for fluorosis of the permanent incisors, which is the first 4 years of life.
Supplementary Question 1: International guidelines on fluoride toothpaste use

What are the guidelines on fluoride toothpaste use in young children in other countries with water fluoridation?

Guidelines or recommendations on the use of fluoride toothpaste in Australia (Fluoride Consensus Workshop, 2012), Canada (Canadian Dental Association, 2017), England (Public Health England, 2017), Hong Kong (Department of Health (Hong Kong), 2016), New Zealand (New Zealand Guidelines Group, 2009, New Zealand Medicines and Medical Devices Safety Authority (MedSafe), 2017) and the USA (American Academy of Pediatric Dentistry, 2017, American Dental Association Council on Scientific, 2014) were identified and are summarised in Table 1 for children aged under age 3 and Table 2 for children aged 3-6 and over. Guidelines from the Scottish Intercollegiate Guidelines Network (SIGN) were also included (Scottish Intercollegiate Guidelines Network (SIGN), 2014) for comparison with guidelines for a population which does not include a proportion served with fluoridated water.
Table 1: Selected guidelines on use of fluoride toothpaste for children under the age of 3 years

<table>
<thead>
<tr>
<th>Country</th>
<th>Authors</th>
<th>Date</th>
<th>Quality</th>
<th>Age Group 1</th>
<th>Age to start brushing with FTP</th>
<th>Frequency of brushing</th>
<th>Amount of FTP</th>
<th>F content of toothpaste (ppm)</th>
<th>Level of F in water (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia¹</td>
<td>Australian Dental Association</td>
<td>2017</td>
<td>Policy statement with guidelines on the use of fluoride</td>
<td>Up to 17mths</td>
<td>As soon as teeth erupt</td>
<td>NR</td>
<td>No toothpaste</td>
<td>NA</td>
<td>0.6-1.1</td>
</tr>
<tr>
<td>Canada²</td>
<td>Canadian Dental Association</td>
<td>2012</td>
<td>Position statement</td>
<td>under 3</td>
<td>Use of FTP based on risk</td>
<td>x2</td>
<td>Rice grain</td>
<td>NR</td>
<td>0.7</td>
</tr>
<tr>
<td>England &amp; Wales³,⁴</td>
<td>Public Health England</td>
<td>2017</td>
<td>Evidence-based</td>
<td>under 3</td>
<td>As soon as teeth erupt</td>
<td>x2</td>
<td>Smear</td>
<td>1,000</td>
<td>1</td>
</tr>
<tr>
<td>Hong Kong⁵</td>
<td>Various Agencies</td>
<td>2016</td>
<td>Unclear</td>
<td>Age 0-2</td>
<td>Introduce oral cleansing before the primary teeth erupt</td>
<td>x2</td>
<td>No toothpaste</td>
<td>NA</td>
<td>0.5</td>
</tr>
<tr>
<td>NZ⁶</td>
<td>Ministry of Health, New Zealand (revision 2017)</td>
<td>2009</td>
<td>Evidence-based</td>
<td>Age 5 &amp; under</td>
<td>As soon as teeth erupt</td>
<td>x2</td>
<td>Smear</td>
<td>1,000</td>
<td>0.7-1</td>
</tr>
<tr>
<td>USA³</td>
<td>American Academy of Pediatric Dentistry</td>
<td>2014</td>
<td>Policy document</td>
<td>under 3</td>
<td>NR</td>
<td>x2</td>
<td>Smear/rice grain</td>
<td>NR</td>
<td>Prior to 2015 – 0.7 to 1.2. From 2015, 0.7</td>
</tr>
<tr>
<td>USA</td>
<td>American Dental Association</td>
<td>2014</td>
<td>EB + opinion</td>
<td>under 3</td>
<td>As soon as teeth erupt</td>
<td>x2</td>
<td>Smear/rice grain</td>
<td>NR</td>
<td>1,000 -1,500 based on caries risk assessment</td>
</tr>
<tr>
<td>Scotland⁷</td>
<td>SIGN</td>
<td>2014</td>
<td>Evidence-based</td>
<td>under 3</td>
<td>As soon as teeth erupt</td>
<td>x2 at least</td>
<td>Smear (0.1ml)</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

All guidelines/position/policy statements recommend adult supervision of tooth brushing
## Table 2: Selected guidelines on use of fluoride toothpaste for children aged 3-6 years

<table>
<thead>
<tr>
<th>Country</th>
<th>Authors</th>
<th>Date</th>
<th>Quality</th>
<th>Age Group 2</th>
<th>Frequency of brushing</th>
<th>Amount of FTP</th>
<th>F content of toothpaste (ppm)</th>
<th>Level of F in water (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Dental Association</td>
<td>2017</td>
<td>Policy statement with guidelines on the use of fluoride toothpaste</td>
<td>18 mths to age 5</td>
<td>x2</td>
<td>small pea</td>
<td>500-550 unless high risk - use higher FTP if so</td>
<td>0.6-1.1</td>
</tr>
<tr>
<td>Canada</td>
<td>Canadian Dental Association</td>
<td>2012</td>
<td>Position statement</td>
<td>3 to 6</td>
<td>x2</td>
<td>green pea</td>
<td>NR</td>
<td>0.7</td>
</tr>
<tr>
<td>England &amp; Wales</td>
<td>Public Health England</td>
<td>2017</td>
<td>Evidence-based</td>
<td>3 to 6</td>
<td>x2</td>
<td>pea</td>
<td>&gt; 1000</td>
<td>1</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>Various Agencies</td>
<td>2016</td>
<td>Unclear</td>
<td>2 to 6</td>
<td>x2</td>
<td>pea</td>
<td>1,000</td>
<td>0.5</td>
</tr>
<tr>
<td>NZ</td>
<td>Ministry of Health, New Zealand</td>
<td>2009 (revision 2017)</td>
<td>Evidence-based</td>
<td>Age 6+</td>
<td>x2</td>
<td>pea</td>
<td>1,000</td>
<td>0.7-1</td>
</tr>
<tr>
<td>USA</td>
<td>American Academy of Pediatric Dentistry</td>
<td>2014</td>
<td>Policy document</td>
<td>3 to 6</td>
<td>x2</td>
<td>pea</td>
<td>NR</td>
<td>Prior to 2015 – 0.7 to 1.2. From 2015, 0.7</td>
</tr>
<tr>
<td>USA</td>
<td>American Dental Association</td>
<td>2014</td>
<td>EB + opinion</td>
<td>3 to 6</td>
<td>x2</td>
<td>pea</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td>Scotland</td>
<td>SIGN</td>
<td>2014</td>
<td>Evidence-based</td>
<td>over age 3</td>
<td>x2 at least</td>
<td>pea (0.25ml)</td>
<td>1,000 -1,500 based on caries risk assessment</td>
<td>0</td>
</tr>
</tbody>
</table>

All guidelines/position/policy statements recommend adult supervision of tooth brushing.

1. Australian guidelines are based on the recommendations of a Consensus workshop in 2012 attended by Australian and international experts (Fluoride Consensus Workshop, 2012).
2. Canada: "Parents should consult a health professional to determine whether a child up to 3 years of age is at risk of developing tooth decay" (Canadian Dental Association, 2017).
3. The English recommendation of a smear for under 3s is graded as a Good Practice Point – based on opinion of experts (Public Health England, 2017). The Scottish do not actually make a formal recommendation on the amount of toothpaste to use, but make a strong case for it in the text of the guideline, and include pictures of the amount to be used (Scottish Intercollegiate Guidelines Network (SIGN), 2014). The ADA notes that "It is especially critical that dentists provide counselling to caregivers that involves the use of oral description, visual aids and actual demonstration to help ensure that the appropriate amount of toothpaste is used" (American Dental Association Council on Scientific, 2014).
4. 1350-1500ppm FTP recommended for children aged 0-6 "giving concern" and amount used can be smear or pea.
5. Hong Kong: HK Reference Framework for Preventive Care for Children in Primary Care Settings, Revised Edition 2016 (Department of Health (Hong Kong), 2016).
6. NZ recommendations were updated in 2017 following the publication of the Cochrane review on different concentrations of fluoride toothpaste by Walsh et al 2010: Prior to the update, low F toothpaste could be considered for children aged under 6 years living in fluoridated areas who are at low risk of dental caries, but now the recommendation for all ages is at least 1,000ppm F (New Zealand Medicines and Medical Devices Safety Authority (MedSafe), 2017).
7. Scotland: Included in the list of guidelines because of the rigor of development of SIGN guidelines. F content depends on risk status of child rather than the age: 1,000 -1,500 for children and young people up to the age of 18 at standard risk of developing caries – Evidence level A. 1,500ppmF for children up to age 10 who are at increased risk of developing caries (Evidence Level GPP). No lower age distinction made. 2,800ppm F for children aged 10-16 at High risk of caries (Scottish Intercollegiate Guidelines Network (SIGN), 2014).
All countries recommended restricting exposure to fluoride toothpaste in children under the age of 3-5, by either delaying the introduction of toothpaste (unless indicated on the basis of caries-risk assessment), or minimising the amount used to a smear or the size of a rice grain. Only one guideline attributed a level of evidence to the recommendation to use a smear of toothpaste, which was a Good Practice Point i.e. based on expert opinion (Public Health England, 2017). Australia was the only country that recommended the use of low fluoride (500ppm F) toothpaste under the age 6, with all other countries recommending toothpaste containing at least 1,000 ppm F. Another consistent feature was the strong emphasis on parental supervision of tooth brushing for young children.

Supplementary Question 2: Prevalence and severity of fluorosis internationally

What is the prevalence of fluorosis in countries with community water fluoridation?

A search was conducted in PubMed and Google to identify recent studies or reports on the prevalence of fluorosis in countries with community water fluoridation and a broadly similar diet to that of Irish children. The countries considered were Australia, Canada, England, New Zealand and the United States. Large scale or national surveys were selected, when available. A secondary aim was to determine whether these countries considered fluorosis to be a public health issue.

The review of fluorosis levels in Australia (Bal et al., 2015, Do et al., 2014), Canada (Health Canada, 2010), England (Pretty et al., 2016), New Zealand (Ministry of Health (New Zealand), 2010) and the USA (Beltran-Aguilar et al., 2010) served to highlight the difficulty of comparing levels of fluorosis in different countries due variation in the indices and methods used to record fluorosis, and differences in the presentation of results e.g. amalgamating lower categories of fluorosis, and differences in the age range of participants. Similar variation in methodology was noted in a previous review of fluorosis prevalence in Europe, which prompted the author to call for standardised methodology for recording fluorosis, including the use of photographs (Whelton et al., 2004b).

A consistent finding across the studies included in the comparison undertaken by the Working Group was that the level of fluorosis that was considered to be of concern was at the more noticeable levels of fluorosis (Dean’s moderate or TF ≥3). The prevalence of this degree of fluorosis was very low in all countries. There is evidence from one longitudinal cohort study of fluorosis that milder forms of fluorosis (TF1 -3) tend to diminish with time, and consequently fluorosis at this level may not have a significant dental public health impact (Do et al., 2016).
**Table 3 Prevalence of fluorosis in selected countries with water fluoridation using TF index and Dean’s Index**

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Year of study</th>
<th>Sample size</th>
<th>Fluoridated water (Y/N)</th>
<th>Age examined</th>
<th>Index used</th>
<th>Teeth examined</th>
<th>Overall prevalence</th>
<th>TF1</th>
<th>TF2</th>
<th>TF3</th>
<th>&gt;TF3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (New South Wales)</td>
<td>2007</td>
<td>2611</td>
<td>Y</td>
<td>8 to 12</td>
<td>TF</td>
<td>2 Maxillary central</td>
<td>25%</td>
<td>15%</td>
<td>7%</td>
<td>2%</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>2003/4</td>
<td>264</td>
<td>NR</td>
<td>8-13 in 2003/4</td>
<td>TF</td>
<td>Maxillary central</td>
<td>20%</td>
<td>13%</td>
<td>8%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Australia (South Australia)</td>
<td>2011/2012</td>
<td>264</td>
<td>NR</td>
<td>16-22 in 2011/12</td>
<td>TF</td>
<td>Maxillary central</td>
<td>25%</td>
<td>20%</td>
<td>5%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>England (F) Newcastle &amp; Birmingham</td>
<td>2014/15</td>
<td>960</td>
<td>Y</td>
<td>11 to 14</td>
<td>TF</td>
<td>4 maxillary incisors</td>
<td>62%</td>
<td>40%</td>
<td>11%</td>
<td>8%</td>
<td>2%</td>
</tr>
<tr>
<td>England (NF) Manchester &amp; Liverpool</td>
<td>2014/15</td>
<td>939</td>
<td>N</td>
<td>11 to 14</td>
<td>TF</td>
<td>4 maxillary incisors</td>
<td>37%</td>
<td>32%</td>
<td>3%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Canada</td>
<td>2007-2009</td>
<td>1,070</td>
<td>NR</td>
<td>6 to 12</td>
<td>Dean's</td>
<td>Full mouth</td>
<td>40%</td>
<td>24%</td>
<td>12%</td>
<td>4%</td>
<td>Moderate too low to be reported</td>
</tr>
<tr>
<td>Ireland (Dublin &amp; Cork/Kerry)</td>
<td>2016/17</td>
<td>2,304</td>
<td>Both</td>
<td>8</td>
<td>Dean's</td>
<td>Full mouth</td>
<td>11%</td>
<td></td>
<td></td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>Full F (Dublin &amp; Cork/Kerry)</td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Questionable</td>
</tr>
<tr>
<td>Non F (Dublin &amp; Cork/Kerry)</td>
<td></td>
<td></td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Mild</td>
</tr>
<tr>
<td>England (F) Newcastle &amp; Birmingham</td>
<td>2014/15</td>
<td>960</td>
<td>Y</td>
<td>11 to 14</td>
<td>Dean's</td>
<td>4 maxillary incisors</td>
<td>64%</td>
<td>46%</td>
<td>10%</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td>England (NF) Manchester &amp; Liverpool</td>
<td>2014/15</td>
<td>939</td>
<td>N</td>
<td>11 to 14</td>
<td>Dean's</td>
<td>4 maxillary incisors</td>
<td>35%</td>
<td>29%</td>
<td>4%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>2009</td>
<td>3,196</td>
<td>Both</td>
<td>8 to 30</td>
<td>Dean's</td>
<td>UR4 - UL4</td>
<td>45%</td>
<td></td>
<td></td>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>USA</td>
<td>1999-2004</td>
<td>NR - but national survey</td>
<td>6 to 11</td>
<td>Dean's</td>
<td>NR</td>
<td></td>
<td>33%</td>
<td></td>
<td></td>
<td></td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>1999-2004</td>
<td>Probably both</td>
<td>12 to 15</td>
<td>Dean's</td>
<td>NR</td>
<td></td>
<td>41%</td>
<td></td>
<td></td>
<td></td>
<td>NR</td>
</tr>
</tbody>
</table>

1. Fluoride was taken at 3.1 mg F/l.
2. Water fluoridation was taken at 1 mg F/l.
3. Regular water sampling.
4. Water fluoridation was taken at 0.6 mg F/l.
5. Water fluoridation was taken at 1 mg F/l. Only Dean's index was used.
6. Water fluoridation was taken at 2 mg F/l. Only Dean's index was used.
Footnotes to Table

1. Prospective Cohort study
2. TF recorded from digital images of the maxillary anterior teeth. Maximum of 4 maxillary incisor teeth scored, and highest score affecting 2 or more teeth was recorded for each subject.
3. All F status categories combined (i.e. Full, Part, None, Unknown). Fluorosis scores presented for Very Mild upwards
4. Deans scored from digital images of dry teeth, so fluorosis scores in this study will be higher because Dean's is normally recorded clinically on wet teeth
5. Overall Fluorosis score presented for Very Mild upwards
4. Implications for the Forum on Fluoridation recommendations

The Working Group agreed that the key elements of Recommendation 3 of the Report of the Forum on Fluoridation 2002 should be retained. Comments and suggestions on each component of Recommendation 3 are outlined below:

Forum Recommendations

- **The Forum recommends the continued use of fluoride toothpaste in fluoridated and non-fluoridated areas because of the additive benefit from the combination of fluoridated water and fluoride toothpaste.**

  The evidence indicates the benefit of fluoride toothpaste for preventing and controlling dental caries across all age groups, with and without background exposure to fluoridated water.

  **The Working Group recommends that no change is required to this Recommendation**

- **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.**

  The FACCT study indicates that the tooth brushing practices of parents with their young children do not comply with this recommendation; 80% of parents of 5 year old children reported brushing their child’s teeth with toothpaste before the age of two years, and this practice was associated with an increased risk of a child having fluorosis at age 8. The FACCT Study also shows that fluorosis levels among 8-year-olds in Ireland have changed little since 2002, in spite of the reduction of the level of fluoride in water.

  It is important that measures are in place to minimise the risk of fluorosis from inappropriate use of fluoride toothpaste at a young age, and to ensure that caries and fluorosis levels in the population are monitored on an ongoing basis so that an optimum balance is maintained between the benefits and risks of fluoride toothpaste. This is particularly important in a country like Ireland that relies so heavily on fluoridation for caries prevention. The findings from the evidence update indicate that there is still a need to minimise the ingestion of fluoride toothpaste among children under the age of 2 years.

  Although some countries recommend using a smear amount of fluoride toothpaste for children under 2/3 years of age, there is no evidence showing the risk or benefits of a smear versus a pea-sized or no toothpaste or how well parents would comply with this.

  **The Working Group recommends retaining this recommendation until further research can be carried out to determine the effectiveness of the strategy**
• 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.  

The Working Group recommends a change in the wording of this recommendation, to read;  

‘Professional advice on the use of fluoride toothpaste should be sought where a child or particular groups of children below 2 years of age are considered to be at risk of developing dental decay’ 

This recommendation will also need to be reviewed as services are developed for children at risk.  

• 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 Working Group recommends no change to this recommendation – but better dissemination of the recommendation is required, including detailed instructions on the amount of toothpaste to be dispensed 

• Paediatric toothpastes with low concentrations of fluoride require further research before the Forum can recommend their use. 

The Working Group recommends no change to this recommendation  

• Guidelines for the use of oral health care products in childhood should be developed for use by all involved in advising members of the public on health care matters. The Expert Body will play a key role in the development of these guidelines.  

This recommendation should be reviewed by relevant agencies, including the Expert Body, and in the light of the evidence and recommendations in this Report.
5. Implementation and Monitoring

Processes and procedures should be put in place to ensure implementation of the recommendations. These processes should allow monitoring and evaluation of compliance with the recommendations.

Clear guidelines should be developed to ensure that the recommendations on age of commencement of toothpaste use and the amount to be used are understood and are acceptable to the public and professional interests.

Longitudinal monitoring of compliance with the recommendations on toothpaste use in a cohort of young children, with ongoing evaluation of the impact of compliance/non-compliance on caries and fluoride ingestion and absorption will address some of the current gaps in our knowledge outlined below. It will also serve to inform future reviews of the recommendations on toothpaste use among young children in Ireland.

6. Implications for Research

The evidence update identified the following key gaps in our knowledge:

- Timing of eruption of tooth groups in the primary dentition of Irish children.
- Age of caries initiation and rate of progression in children aged 2-5 in Ireland
- Effectiveness of using a "smear" of fluoride toothpaste at preventing caries compared to no toothpaste or a pea-size amount
- Reason for 81% non-compliance with the "no toothpaste under 2" recommendation but 84% compliance with use of a pea-size/small amount of toothpaste

An over-arching longitudinal cohort study, commencing before age 2 years, is needed to address these questions, while also monitoring implementation of the recommendations on toothpaste use and evaluating the outcomes of implementation on caries and fluorosis.

Challenges to interpreting and comparing fluorosis data from published papers were also noted, including:

- Variation in the indices used to measure fluorosis and terminology used to describe fluorosis e.g. mild used as a narrative description may differ from Mild used as part the Dean’s index
- Different methods for recording fluorosis (e.g. teeth wet or dry), visual or photographic
- Variation in methods of presenting results e.g. amalgamation of fluorosis grades.

There is a need to standardise the recording of fluorosis, including the use of photographs, to allow meaningful comparison of data between countries, and also to facilitate longitudinal monitoring of fluorosis levels in permanent incisor teeth.
Addendum 1

Search Strategy for Key Question 1 - caries

Database searched: PubMed

Date: 22/11/2017

Search strategy:

6. (((toothpaste OR dentifrice)) OR (fluor* OR "ppm F" OR AMF OR SNF2 OR amin*F OR AMF OR stannous* F OR acidulat* F, OR fluorophospat* OR phosphat* F OR monofluor OR NaF OR APF OR SMFP OR MFP)))
7. ("Dental Caries"[Mesh] OR caries OR "dental caries" OR "tooth decay" OR "cavities")
8. (child* OR preschool* OR kindergarten OR infant OR infancy OR "age 3" OR "age 4" OR "age 5" OR "age 6"
9. 1 AND 2 AND 3

Filters: published in the last 5 years; Humans

The cut off of 5 years was selected because the evidence search for the most recent systematic review addressing this key question was conducted in 2012 (Wright et al, 2014).

The search generated 221 "hits" which were scanned for relevance and then filtered using the Clinical Queries in PubMed to identify RCTs and systematic reviews. The search was also run with the terms "ECC" and "Early Childhood Caries" added to the search and this more than doubled the number of hits, but only added 1 potentially relevant study.

| Total hits | 221 |
| Potential relevant | 45 |
| Excluded | 39 |
| Included/potentially included | 7 |

4 systematic reviews: (dos Santos et al., 2013,(Wright, 2014 #2410), (Twetman and Dhar, 2015),(Santos et al., 2013)

3 RCTs: 2 excluded - ineligible study design (Jiang et al., 2014, Pieper et al., 2016)

1 relevant - (de Almeida Baldini Cardoso et al., 2014)
Addendum 2

Search Strategy for Key Question 2 - fluorosis

Database searched: PubMed

Date: 23/11/2017

Search strategy:

1. Toothpaste OR dentifrice
2. Dental fluorosis[MeSH Terms]) OR (((fluorosis OR fluorose* OR florotic OR florosis OR florose* OR florotic)))) OR ((enamel AND (opacit* OR hypomineral* OR hypoplasit* OR defect* OR porosit* OR white* OR motl*))))
3. (child* OR preschool* OR kindergarten OR infant OR infancy))
4. 1 AND 2 AND 3

Filters: published in the last 5 years; Humans

This search generated 43 "hits".

The search was re-run, this time using only (toothpaste OR dentifrice) AND fluorosis, just in case the child terms were limiting the yield. This search generated 49 hits, but no new relevant "hits".

There was some overlap between the caries and fluorosis searches — for example, the Wright and dos Santos reviews appeared in both searches.

Total hits 49
Excluded 44
Potentially relevant 2

2 systematic reviews: Santos, 2013, Wright 2014,

The following studies, which were included in the search but did not directly address the key question, were studied for background information on fluorosis.


References


