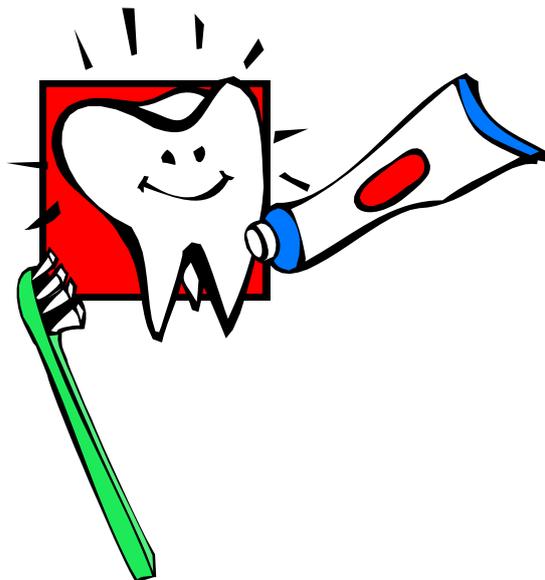




# ***"Use of Fluoride in the Promotion of Oral Health in the Republic of Ireland"***

Report of a Consultancy Project undertaken on behalf of the Department of Health & Children and the Regional Health Boards by the Oral Health Services Research Centre, University College Cork, Ireland



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# **SUMMARY**

## **Introduction**

In 1999 the Oral Health Services Research Centre (OHSRC) undertook a consultancy research project on behalf of the Department of Health and Children in collaboration with the Health Boards to investigate the current use of fluorides in the promotion of health and in particular oral health in the Republic of Ireland and to make recommendations on their use in the future. This contract was Lot 2 of a series of ten consultancy contracts in the Oral Health area which were awarded at the time.

## **Background to use of fluoride in Ireland for the control of dental caries**

Following the enactment of the Health (Fluoridation of Water Supplies) Act 1960 water fluoridation was introduced in Dublin in 1964 and in Cork in 1965. Over the next 10 years or so fluoride was added to the domestic water supplies of the main urban areas in the Republic of Ireland. At present 73% of the population resides in communities served with fluoridated water supplies. During the late 60s and early 70s a number of fluoride tablet programmes were initiated in a number of non fluoridated communities with a view to providing the benefits of systemic fluoride to those children residing in mostly rural communities where fluoridation of water supplies was not feasible. However, with increasing knowledge of the methods of action of fluoride in the control of dental caries and also due to concerns about the appropriate dosage to be used by children of different ages as well as problems with compliance of participants, use of fluoride tablets declined during the 90s and their use has been largely discontinued at this time. In 1969 fluoride toothpastes were first introduced in the Republic of Ireland and over the subsequent 10/15 years they represented an increasing proportion of the toothpaste market in the Republic of Ireland. It is now estimated that over 95% of toothpastes sold over the counter contain fluoride. In 1968 the first fluoride mouthrinsing programme was introduced in the Republic of Ireland and currently approximately 30,000 Primary School children participate in fluoride mouthrinsing programmes. Following the discovery of the relationship between fluoride in domestic water supplies and the incidence of dental caries in the 1940s, efforts were made by researchers to develop products which could be applied by dentists and auxiliary dental workers to individual patients in dental clinics. These products, such as gels, varnishes and filling materials, containing high levels of fluoride, were first introduced to Ireland in the mid 1960s. They continue to be used by clinicians in Ireland. Many studies have shown that certain food products contain high levels of fluoride, these include tea and fish.

When the decision was taken to introduce water fluoridation in Ireland, the evidence at the time showed that the benefit (i.e. reduction in dental caries) would be accompanied by a slight increase in the questionable and very mild grades of fluorosis. At the time it was considered that this risk of fluorosis was acceptable taking into account the benefit to be derived in the form of a reduction in the incidence of dental caries likely to lead to an overall improvement in oral health.

In the late 70s and continuing throughout the 80s however, the dental research community and dental public health workers began to raise concerns about the increased exposure of the population to fluoride from different sources as outlined above.

### **Forum on Water Fluoridation**

During the course of the work undertaken under Lot 2 the Forum on Water Fluoridation was established by the Minister for Health & Children in September 2001. A number of the aims of Lot 2 overlapped those of the Forum on Water Fluoridation hence, the reader of this report will be frequently referred to the Report of the Forum on Water Fluoridation ([www.fluoridationforum.ie](http://www.fluoridationforum.ie))

### **EU Project “Fluoride Ingestion from Toothpaste” FLINT**

When bidding for the Lot 2 Consultancy contract the Oral Health Services Research Centre (OHSRC) highlighted the fact that it had recently been successful in obtaining funding under the EU BIOMED 2 Research & Technical Programme to investigate methods of measuring fluoride ingestion from toothpaste and of measuring enamel fluorosis. The aims and objectives of this project are very closely linked with those of the Lot 2 consultancy project and also with the aims of the Forum on Water Fluoridation. The reader of this report should be aware of this interlinking of the activities of the OHSRC. In April 2004 the results of the FLINT multicentered project were published in a special supplement of Community Dentistry and Oral Epidemiology. (Ketley, O’Mullane and Holbrook, 32, Supplement 1, 1-76, April 2004).

### **Approach Adopted to Completion of Lot 2 Project**

The Project was divided into 3 main tasks:

#### **Task 1**

The first task was to establish the extent to which the fluoride programmes mentioned in the consultancy contract were in place in Ireland. In addition, the quality control measures currently in place for each programme were assessed. The main project undertaken under this first task was to conduct a detailed situation analysis. It should be noted that the engineering and other aspects of fluoridation plants in Ireland were the subject of another contract awarded to University Dental School & Hospital, Trinity College, Dublin.

#### **Task 2**

The second task was concerned with the various matters relating to the intake of fluoride amongst the Irish population. It was designed to develop internationally accepted methods for measuring intake of fluoride from various sources. Specifically in this task, measurement issues relating to fluoride intake, fluoride absorption, fluoride excretion and fluoride accumulation in body tissues were considered. In the conduct of this second task the OHSRC collaborated with a

number of internationally recognized fluoride research expert laboratories (Ketley et al, 2002).

### Task 3

The final task was to prepare proposals for development of methods for the measurement of fluoride accumulation in bone in the Irish population.

The project commenced 3<sup>rd</sup> January 2000.

### **Main Achievements**

The situation analysis undertaken under Task 1 revealed extensive and complex legislation governing oral health care products both at national and European level. In Ireland as well as the Department of Health, the Irish Medicines Board has a major role to play. In Europe the main legal document governing oral health care products is contained in “Cosmetics Legislation 1999 edition” (Enterprise Directorate-General Pharmaceuticals and Cosmetics). This is implemented in Ireland by the European Communities (Cosmetics Products) Regulations 1997 (as amended). The situation analysis undertaken also included a detailed questionnaire to all Principal Dental Surgeons in Ireland. As a result of the detailed analysis of the legislation (structures) this section of the Lot 2 consultancy is completed by a series of recommendations based on the findings to date. In the case of Task 2 the project team successfully developed a series of internationally accepted methods for the measurement of fluoride intake from the diet and oral health care products. Similarly when developing methods for the measurement of fluoride absorption, fluoride excretion and fluoride accumulation an international collaborative approach was adopted. Details of these methods are included in the report which follows with more detailed descriptions contained in accompanying Appendices and in articles published by members of the OHSRC team in the international dental research literature. In the case of Task 3 i.e. the development of methods for measuring fluoride accumulation in bone a detailed protocol has been agreed in collaboration with experts in the field of this subject.

### **Expert Body**

The Forum on Water Fluoridation recommended “an Expert Body should be established to implement the recommendations of the Forum and to advise the Minister for Health and Children on an ongoing basis on all aspects of fluoride and its delivery methods as an established health technology”. The Expert Body had its first meeting in April 2004. Throughout this report of the Lot 2 consultancy contract, the need for more information on various aspects concerning the use of fluoride in the control of dental caries are described. It is envisaged that an important task of the Expert Body is that it will prioritise the various projects required to address the current gaps in our information on fluoride use in the promotion of oral health in Ireland.

# Chapter 1 The Consultancy Research Programme

## 1.0 Introduction

Over the past 4 years a series of interim reports have been forwarded to the Department of Health and Children outlining the progress of the Lot 2 consultancy contract. In this Final Report the main activities undertaken in order to achieve the aims of Lot 2 are described. To begin with, the background to the consultancy contract is outlined.

The programmes included in this Lot were as follows:

1. Fluoridation of public water supplies (to include optimizing dosing and monitoring)
2. Fluoride mouth rinsing
3. Fluoride toothpaste
4. Other forms of systemic fluoride supplementation
5. Combinations of the above (including matters relating to intake)

It should be noted that during the course of the contract work undertaken under Lot 2, the Forum on Water Fluoridation was established by the Minister for Health & Children in September 2001. A considerable proportion of the work planned to be undertaken under Lot 2 was in fact also part of the remit on the Forum on Water Fluoridation (e.g. guidelines on use of fluoride toothpastes). The consequences of this overlap were two fold. Firstly this Final Report of Lot 2 has been delayed because of the fact that the principal investigator of Lot 2, Professor O'Mullane, and his colleagues in the OHSRC devoted a considerable amount of time in addressing the issues raised during the course of the Forum on Water Fluoridation. Secondly, some of the issues and conclusions contained in the Final Report of the Forum on Water Fluoridation ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)) are also relevant to the aims and objectives of the Lot 2 consultancy contract.

## **1.1 Water Fluoridation**

Following enactment of the Health (Fluoridation of Water Supplies) Act 1960 and the subsequent constitutional challenge, fluoridation commenced in Dublin City in 1964 and in Cork City in 1965. Over the following years fluoride was added to the water supplies in different urban areas; at present 73 per cent of the population reside in communities which are served with fluoridated water supplies. Under the Act there is an obligation on the authorities to monitor the health (Section 6) and dental health (Section 7) whenever and how often it is deemed as necessary. Periodic dental epidemiological surveys conducted over the last 25 years have shown that water fluoridation has been effective in controlling dental caries amongst Irish children and adults. There is no evidence that water fluoridation has caused negative effects on the general health of those residing in communities served with fluoridated water. Adjusting the level of fluoride in public piped water supplies is a major logistical task involving extensive collaboration between different bodies and agencies to ensure that those water supplies which are designated to be fluoridated contain a “satisfactory” level of fluoride at all times. Suppliers of fluosilicic acid, Principal Dental Officers, Directors of Public Health, Environmental Health Officers, Engineers, Caretakers in Waterworks all have crucial roles to play in ensuring that water supplies are efficiently fluoridated and that the fluoridation programme leads to lower levels of dental decay with no side effects or no detrimental effects on general health. For further information, see Final Report of the Forum on Water Fluoridation ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)).

In relation to Water Fluoridation, a separate contract was awarded to Dublin Dental School and Hospital designed to assess the quality of the monitoring procedures currently in place for ensuring that the level of fluoride in fluoridated domestic water supplies was within the range as set out in the regulations developed under the Health (Fluoridation of Water Supplies) Act. This project was undertaken under the direction of Professor John Clarkston and his colleagues and is the subject of a separate report.

## **1.2 Fluoride mouth rinsing**

Fluoride mouth rinsing is widely used as an alternative method of bringing the benefits of fluoride to communities. The first school fluoride mouth rinsing scheme in the Republic of Ireland started in 1968 in non fluoridated areas of west Co. Waterford. This scheme has been running continuously since then and is now one of the longest running fluoride mouth rinsing schemes in the world. In the Waterford scheme children in national school in 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> classes rinse every two weeks for 2 minutes under supervision in school with 10ml of a 0.2% solution of Sodium Fluoride. Other similar schemes, for example in counties Cork and Limerick, have been put in place over the years. School fluoride mouth rinsing programmes have been shown to be effective in controlling dental caries, though their cost effectiveness and long-term effect have been questioned. Fluoride mouth rinsing programmes require extensive collaboration between the school authorities, the health board dental service and parents.

Mouth rinses containing fluoride are also available in supermarkets and pharmacies. Sales of mouth rinses generally have increased over the last 10 years and it is likely that fluoride containing rinses are included in these increased sales. Many different brands of rinses containing fluoride are available for OTC sales; most contain 0.05% Sodium Fluoride for daily use. Such rinses are known to be highly effective and many dentists recommend them to patients who are at special risk of developing dental caries such as patients wearing orthodontic bands who may have difficulty in maintaining their usual standard of oral hygiene ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)).

### **1.3 Fluoride toothpaste**

Fluoride toothpaste first came on the market in the Republic of Ireland in 1971 and now over 95% of toothpastes sold contain fluoride. Whilst water fluoridation has been shown to have played a major role in the improvement in dental health of Irish children and adults, there is now clear evidence that fluoride toothpastes also have made an important contribution. The development, manufacture and sale of fluoridated toothpaste is an example of positive collaboration between industry, researchers and academics and dental public health workers. Expanding the use of effective fluoride toothpaste is a major objective of oral health promotion. In recent years however, there is increasing debate on the extent to which infants and young children ingest fluoride toothpastes and there is concern that as a result there may be an increase in unsightly fluorosis on anterior permanent incisors. One consequence of this is that some companies have begun marketing low fluoride toothpastes which are known to be less effective in caries prevention. Also, in 1989 most of the major toothpaste manufacturers agreed that labeling on toothpaste tubes should include a statement that for children under 7 brushing should be supervised and only a pea-sized amount should be used ([www.fluoridationforum.ie](http://www.fluoridationforum.ie))

### **1.4 Other Forms of Systemic Fluoride Supplementation**

In Europe, other forms of systemic fluoride supplementation used include fluoridated salt (e.g. France and Germany) and fluoridated milk (e.g. St. Helens UK) and fluoride drops/tablets. Up to recently in the Republic of Ireland, fluoride tablets were often prescribed by dentists for patients likely to develop high levels of caries. This practice is now less common and currently sales at pharmacies are negligible. For the last 20 years there has been an ongoing debate on the appropriate dosage required for fluoride drops and tablets for children of different ages. During that time there has been a gradual reduction in fluoride levels recommended for use in tablets and also an increase in the age at which infants and children should start using fluoride tablets.

Fluoride containing filling materials which slowly release fluoride over time may be considered systemic since the fluoride is ingested. They are being increasingly used in dental practice and there is growing evidence of their effectiveness in controlling caries. Fluoride gels and varnishes are products which contain high levels of fluoride and are applied by dentists and hygienists to

the surfaces of teeth at intervals of approximately 6 months, generally for patients deemed to be at high risk of developing caries. Fluoride varnishes are being increasingly used in dental practices to control both coronal and root caries. Gels and varnishes are applied topically with precautions taken to avoid ingestion, and they are also subjected to quality evaluation in Lot 2 ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)).

## **1.5 Combinations of the above including matters relating to intake**

Since the introduction of water fluoridation in the early '60s there has been an increase in the number of sources of fluoride in the community. In particular many of those who reside in communities served with fluoridated water also use fluoride toothpaste regularly. There is sound evidence that in these cases fluoride toothpaste bestows a worthwhile added benefit. However, as mentioned above, there is concern that some toothpaste may be ingested and absorbed by some people, especially infants and young children and they may be absorbing excessive fluoride, resulting in unsightly fluorosis of their permanent incisors. Some people also use other combinations such as fluoride mouth rinsing and fluoride toothpaste, the effectiveness of which is not fully established. Hence the question of total fluoride exposure in different communities in the Republic of Ireland is relevant at this time and levels of fluoride in water and toothpastes needed to be assessed in the light of these new circumstances. The amount of fluoride ingested and absorbed and the trends in the incidence of enamel fluorosis are parameters which will be relevant in deciding policy on these matters ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)).

## **1.6 Research Plan**

At the first meeting of the User Group of Lot 2 an outline of the approach to be adopted was presented by the OHSRC team. It was decided that the project would be divided into three main tasks. During the course of the project and the parallel work being undertaken on the Forum on Water Fluoridation, the tasks to be undertaken under Lot 2 were further refined as follows:

## Task 1

The primary purpose of this task was to establish the extent to which the programmes outlined above in 1.0 (apart from water fluoridation which was the subject of the Forum already mentioned) were in place in the Republic of Ireland. It was envisaged that this section would include:

Full details of the programmes themselves (structure, process, outcome)  
Full details of quality control measures for each programme

It was envisaged that this task would also include proposals prepared by the OHSRC in collaboration with the Health Boards on the future monitoring and promotion of the 4 different programmes by the Health Board Staff (Appendix 1).

**IMPORTANT NOTE:** The situation analysis (Task 1) was completed in October 2001 and thus does not take into account any changes in the availability or use of fluoride containing products or materials after this date. In this context, it should be noted that fluoridated salt is now on sale in some retail outlets in Ireland and the fluoride concentration is not stated on the packaging. Given the extensive water fluoridation programme in Ireland, other forms of systemic fluoride supplementation, such as fluoridated salt should not be used by consumers.

The following information is provided on the label of the packages of fluoridated salt sold over the counter in a well-known retail outlet in Ireland

*“Iodine salt with fluoride is well-suited for improving the supply of fluoride and iodine. The fluoride which it contains helps harden the tooth enamel. Additional preparations containing fluoride should only be taken if recommended by a doctor.*

*Ingredients: Table salt, Sodium fluoride 0.042% - 0.055%, Potassium iodate minimum 0.0025%, Anti-caking agents E500 and E535”*

It is recommended that the health authorities in Ireland to immediately communicate with the retail outlet which is currently selling fluoridated salt and highlight the fact that use of fluoridated salt in an area which already has fluoridated water is likely to increase the incidences of fluorosis in the permanent dentition.

## Task 2

The main objectives of this task were:

To develop internationally accepted methods for measuring the intake of fluoride from the diet and also from oral healthcare products

To develop internationally accepted methods for measuring the amount of fluoride ingested and absorbed.

A more diagrammatic representation of the approach adopted for Task 2 is presented in Appendix 2.

### **Task 3**

To prepare proposals for the development of methods for the measurement total fluoride accumulation in bones.

## Chapter 2 Fluoride Intake in Ireland: A Situation Analysis

### 2.0 Introduction

Dr Paul Beirne was the main researcher deployed to undertake the situation analysis. In the interim report submitted to the Department of Health in October 2001, the main findings of the Situation Analysis were presented. This report is attached as Appendix 1. A brief summary of the main findings are as follows:

The main aim of the situation analysis was to establish full details of the various fluoride programmes outlined in the introduction using a framework of structure, process and outcome for each programme. A further aim was to identify the quality control procedures in place for each measure.

### 2.1 Structure

As outlined in the Technical proposal (submitted by the OHSRC) for Lot 2, *'structure refers to the inputs into the services and the way the services are set up. For example, structure in the case of water fluoridation would include the number and the location of fluoridation plants and the facilities and equipment (including equipment for monitoring fluoride levels) in each plant. Structure in the case of fluoride toothpastes needs a different approach and includes current methods of licensing fluoride toothpastes, the degree of control of formulations, sales and advertising procedures, etc'*

With regard to the structure it was decided firstly to arrange a lengthy meeting was arranged with Mr Tom McGuinn, Chief Pharmacist, Department of Health and Children, in order to ascertain the various rules, regulations and practices associated with the use of various fluoride programmes in the Republic of Ireland. Following this meeting, a comprehensive review of the EU Regulations and Directives which are relevant to the use of various fluoride programmes was conducted. The following are the chief clauses regarding fluoride containing products:

If a manufacturer does not make any 'medical claim' (i.e. a claim for a health effect) for their product, then that product (by default) is regarded as a cosmetic product. The nature of the controls that are applicable therefore depend on the classification of the product – whether as a cosmetic product or as a medicinal product.

A company cannot put a cosmetic product on the market unless it is 'safe'. The company must have documentation attesting to the safety of their product but do not have to make this available automatically to the Department of Health. This documentation must, however, be made available if requested.

Legislation governing cosmetic products in the European Union is contained in the "Cosmetics Legislation 1999 edition" (Enterprise Directorate-General

Pharmaceuticals and Cosmetics). This is implemented in Ireland by the European Communities (Cosmetics Products) Regulations 1997 (as amended)

The concept of safety is defined in Article 2 of the above document as not causing “damage to human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular of the products presentation, its labeling, any instructions for use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.”

“Notes of guidance for testing of cosmetic ingredients for their safety evaluation” have been published by the European Commission and are contained in Volume 3 of “The Rules governing cosmetic products in the European Union” (Cosmetlex)

It must state on the label that a product contains fluoride. This required statement takes the following form (e.g.) “contains sodium monofluorophosphate”. The maximum authorised concentration of fluoride in oral hygiene products is 0.15% F (1500ppm).

If there were concerns about adverse health effects of fluoride containing ‘cosmetic’ products, then these should be directed to a ‘competent authority’ (i.e. Department of Health and Children in Ireland) who would refer the matter to the Scientific Committee on Cosmetics and Non-Food Products in Brussels (SCCNFP) via the European Commission.

The available ‘structure’ would appear to be of little assistance in, for example, any attempts to get companies to reduce the size of the nozzles on tubes of toothpaste nor in standardising the information available on labels (e.g. presenting fluoride concentrations in ppm as opposed to percentage). The national competent authority would be obliged to address its concerns with these matters to the European Commission where a harmonised approach would be decided upon with the advice of the SCCNFP.

For every fluoride-containing product available OTC the ‘obligation to notify’ rests in the Member State where the commodity is first put on sale. Once a product has been put on the market in any EU country, it can be made available in any other EU country without the ‘obligation to notify’. A cosmetic product lawful in one member state is regarded as lawful in any other member state.

Shelf life must only be stated on the label if the shelf life is < 3 years. As most manufacturers claim the shelf life for oral health products containing fluoride is greater than 3 years there is no obligation to place a ‘sell by’ date.

Advertising must be consistent with EU directives on advertising and in addition the advertising of cosmetic products must not imply that they have characteristics that they do not in fact have. The Advertising Standards Authority in Ireland (ASAI) updates its own rules periodically.

The same principles govern OTC sales of mouthwashes.

The fluoride mouthrinses (0.2% NaF) used in school programmes in Ireland, because of their intended function, would be regarded as medicinal products and as such would be subject to the authorisations granted by the Irish Medicines Board. Mouthrinses containing not more than 0.2% NaF are not subject to prescription-only control under the Medicinal Products (Prescription and Control of Supply) Regulations, 1996 (S.I. No. 256 of 1996) (as amended). However, mouthrinses for daily use containing more than 0.05% NaF, are subject to prescription-only control under these Regulations.

Fluoride gels and varnishes are classified as medicinal products and as such are also subject to authorisation control by the Irish Medicines Board. They are also subject to prescription-only control. They are sold direct to dentists by the dental wholesalers. These wholesalers are also subject to control by the Irish Medicines Board.

Sodium fluoride tablets are medicinal products subject to authorisation by the Irish Medicines Board. Under the Medicinal Products (Prescription and Control of Supply) Regulations, 1996, they are not subject to prescription-only control except where the recommended maximum daily dose exceeds 2.2mg i.e. 1mgF.

The classification of slow release fluoride restorative materials is somewhat ambiguous. These products could be regarded as having a primary function as a filling material and a secondary function as releasing fluoride. They could be regarded as functional medical devices and fall under the EU (medical devices regulations) 1994.

If a fluoride containing oral hygiene cosmetic product is being imported from outside the EU, it is up to the first member state of importation to ensure that it complies with the relevant directive

There is a prohibition on mail order selling of fluoride products that are medicinal products (which includes the Internet) governing individual companies in Ireland. However, there is no regulation governing individual purchasers *i.e.* a consumer is free to buy via mail order from a company outside Ireland

Further salient points were obtained from the review of the relevant legislation as follows:

1) 'Products for the care of the teeth and the mouth' (Directive 76/768/EEC. Annex I) are regarded as cosmetic rather than medicinal products. If a manufacturer does not make any 'medical claim' (i.e. a claim for a health effect) for their product, then that product is regarded as a cosmetic product. Although it could be argued that a claim that a fluoride toothpaste 'fights tooth decay' is a medical claim, such a claim is not apparently regarded as sufficient to classify a fluoride toothpaste as a medicinal product.

The operational definition in the EU of a 'cosmetic product' is '*any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view*

*exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.'* (Article 1 Cosmetics Directive 76/768/EEC).

2) A manufacturer cannot put a cosmetic product on the market unless it is 'safe'. The concept of safety is further defined as not causing '*...damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the products presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.'*

3) The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market must keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the product label:

The qualitative and quantitative composition of the product

The physicochemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product

The method of manufacture

Assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and level of exposure. Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned.

The name and address of the qualified person or persons responsible for the assessment of the safety of the product for human health. That person must hold a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline.

Existing data on undesirable effects on human health resulting from use of the cosmetic product

Proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product (Directive 76/768/EEC Article 7a)

For further information on legislation please see Appendix 1.

## **2.2 Process and Outcome**

In relation to process and outcome which are closely linked, the main approaches adopted were as follows:

A questionnaire was sent to all principal dental surgeons in the Health Board Dental Service in order to ascertain the pattern of use and monitoring procedures currently in place for the various fluoride programmes in each Health Board.

In order to assess the effectiveness of the various fluoride programmes, a literature search was undertaken with particular emphasis placed on studies conducted in Ireland. Of particular relevance in this regard is the recent series of systematic reviews on “the evidence base for topical fluoride applications” Marinho et al 2003 (Appendix 3). The evidence for use of topical fluorides was summarized in a recent editorial in Community Dental Health (Worthington & Clarkson, 2003).

## **2.2.1 Situation Analysis Questionnaire**

### **Mouthrinsing Programmes**

School based mouthrinsing programmes were introduced in rural parts of Ireland in order to bring the caries preventive benefits of fluoride to areas where it would not be possible to fluoridate water supplies (Holland *et al.*, 2001). School based fortnightly fluoride mouthrinsing programmes are currently in operation in non-fluoridated areas in six health boards: the Eastern Regional Health Authority (Wicklow and Kildare only), the Midland Health Board, the Mid-Western Health Board, the South-Eastern Health Board, the Southern Health Board (Kerry only) and the Western Health Board.

#### *Current Procedures adopted for obtaining consent*

As part of the process evaluation of mouthrinsing programmes, the situation analysis questionnaire requested information on the procedure adopted in each area for obtaining consent for participation in the mouthrinsing programme.

Written consent was obtained in all areas, with consent forms generally distributed through the schools to the pupils whose parents or guardians were then asked to sign and return to the schools for collection. Copies of the consent forms used were obtained from a number of respondents. These forms differed both within and between health boards in terms of the information given on the effectiveness and safety of the mouthrinsing programme. In addition some consent forms asked whether the child’s home received water from piped water mains. Other consent forms posed questions regarding whether the child was currently taking fluoride tablets or using a fluoride mouthrinse at home.

#### *Preparation of the rinse in health board areas*

All respondents to the situation analysis questionnaire reported using a 0.2% NaF (900ppm F) solution in the rinsing programmes. The dilution procedure adopted in each health board area typically involved dissolving 10g of sodium fluoride (2 x 5g sachets) in 5 litres of water or 4g sodium fluoride (1 x 4g sachet) in 2 litres of water. Two respondents to the situation analysis questionnaire reported using purified water purchased through a wholesale pharmacy supplier for the dilution procedure.

### *Supervision of the mouthrinsing programmes*

The situation analysis indicated that a variety of personnel were involved in the delivery and supervision of the mouthrinsing programmes and included health board dental surgeons, dental and general nurses and appropriately trained lay personnel. All supervisors were reported as monitoring the volume of the returned rinse to ensure that children were not swallowing the rinse. All reported excluding children who persisted in swallowing the rinse from the programme.

### *Amount of rinse dispensed*

Thirteen respondents to the situation analysis questionnaire reported using 10mls for the rinsing procedure; one reported using 8mls.

### *Duration of rinsing procedure*

9 respondents reported that children were requested to rinse for 2 minutes; 5 reported using a 1 minute rinse.

### *Current procedures adopted for disposing of the used mouthrinse*

11 respondents reported disposing of the rinse down the toilet or sink at the school. 3 reported treating the used rinse as clinical waste and double wrapping it in clinical waste disposal bags before returning it to the nearest health centre for disposal.

### *Withdrawals of children from programmes*

The situation analysis revealed that a small number (approximately 130) children had withdrawn from mouthrinsing programmes in the previous 12 months. The most common reason given was adverse media coverage of the fluoridation debate. Other reasons given included concerns over the safety of fluoride and the child not liking the taste of the rinse.

## **Literature review**

Two regimes have been adopted as standard for individual programmes of patient care or for school based programmes. Respectively, these are a 0.05 percent NaF rinse (230ppmF) used daily and a 0.2 percent NaF rinse (900ppmF) used weekly or fortnightly.

## **Effectiveness**

There is convincing evidence that fluoride mouthrinsing and fluoride toothpastes are effective in controlling dental caries. The evidence to support this observation is reviewed in Appendix 1. The reader is also referred to the systematic reviews undertaken by Mariho et al 2003 (Appendix 3). Appendix 1 also addresses the effectiveness of fluoride tablets and fluoride gels and varnishes. Fluoride drops and tablets are currently rarely used in Ireland. Fluoride varnishes are used more frequently particularly among adults. The evidence recording their effectiveness is increasing.

## **2.3 Recommendations**

### **Mouthrinsing Programmes**

#### *Consent Procedure*

It is recommended that all written consent forms should, as far as is practicable, incorporate the various component elements of informed consent. Consent forms should give an explanation of the purpose of the mouthrinsing programme including a description of the benefits of the programme that may reasonably be expected and the expected duration of the child's participation in the mouthrinsing programme. The consent form should be written in non-technical, easy to understand, primary school language, and should include a statement as to whom to contact for answers to pertinent questions involving the programme. It is also recommended that consent forms should include some statement to the effect that participation is voluntary, or that 'you may choose not to participate'. It is recommended that a standard consent form should be designed for use in all health board areas.

#### *Exclusion of children from programmes*

It is recommended that children should not commence rinsing programmes before the age of 6 years. Any children observed to have a tendency to swallow the rinse should be excluded from the rinsing programme.

#### *Reconstitution of Mouthrinse*

Based on the information obtained from the situation analysis questionnaire, there would appear to be no need to recommend any changes in the procedures used for reconstituting the rinse in all health board areas. The tap water used in the dilution procedure should be in accordance with the 1998 EU Drinking Water Directive (Council Directive 98/83/EC). There is no evidence to suggest that there is any benefit from using distilled or otherwise purified water routinely when reconstituting the rinse.

### *Duration of rinse*

From the situation analysis, it was evident that health board areas are using either a one or two minute fortnightly mouthrinsing procedure. It has been reported (Fejerskov *et al.*, 1996) that it is standard in the United States to use a 1 minute rinse in school based programmes, however, it should be noted that some of these programmes are carried out weekly rather than fortnightly. We are not aware of any studies comparing the relative effectiveness of 2 minute or 1 minute fortnightly school based mouthrinsing programmes.

Studies conducted in Ireland have demonstrated the effectiveness of a two minute rinsing procedure. We recommend, however, that studies should be carried out to determine the relative effectiveness of 2 and 1 minute rinsing procedures. If a one minute rinse is shown to be equally as effective as a 2 minute rinse, then the 1 minute rinse should obviously be adopted as the standard.

### *Disposal of used rinse*

It is recommended that the used rinse should be treated as 'clinical waste' and disposed of accordingly. In this regard, the procedure adopted in some health board areas of double wrapping the used rinse in clinical waste disposal bags and returning these to the nearest health centre for disposal, appears prudent.

### *Use of 0.05% daily rinses*

Health board dental surgeons and hygienists should consider recommending daily use (at home) of a 0.05% NaF rinse for individuals at increased risk for dental caries. This category includes individuals with active coronal and/or root surface caries; individuals with impaired ability to maintain oral hygiene; individuals wearing orthodontic appliances (banded, bonded and removable appliances) and patients with exposed root surfaces. In addition such rinses can be recommended for use by individuals with reduced salivary flow from disease, salivary glands and side effects of medication, chemotherapy and/or radiation treatment (Adair 1998). Fluoride mouthrinses should be used at a time during the day that is different to toothbrushing, in order to have an additive effect to fluoride toothpaste (Oulis *et al.*, 2000).

### *Fluoride Tablets*

We do not consider that fluoride drops or tablets have any application as a public health measure as long as community water supplies continue to be fluoridated in Ireland. Furthermore, given the problems with compliance and the increased risk of fluorosis associated with the use of these products we do not consider it appropriate to prescribe fluoride tablets on an individual basis, even to patients considered at high risk of dental caries. We recommend that other fluoride modalities, such as professionally applied topical fluoride varnishes, should be considered for use in high risk patients.

### *Fluoride Gels*

Professionally applied fluoride gels should only be considered for use on individuals regarded as high caries risk who are over the age of 4 years (Oulis *et al.* 2000). It is recommended that gels should be applied using the direct technique with appropriate care and attention to minimize the amount of fluoride ingested and in accordance with the following guidelines:

#### Direct Technique:

Keep gel out of reach of the patient

Never leave the patient unattended throughout the procedure

Isolate the teeth one quadrant at a time using cotton wool rolls.

Dry isolated teeth with compressed air and apply gel with a small brush or cotton wool pledget held in tweezers.

Apply gel to all tooth surfaces, especially into the inter-dental spaces from buccal and lingual sides.

Apply gel for 4 minutes and use a saliva ejector throughout the procedure.

After 4 minutes remove gel from accessible tooth surfaces using a cotton wool roll or gauze. Do not attempt to remove it from approximal tooth surfaces

Instruct the child to expectorate (spit out) thoroughly but not to rinse. Alternatively use a saliva ejector for 30 seconds after the gel application

Advise the patient not to eat or drink for half an hour

At present there is no reliable evidence to alter the recommendation that gels should be applied twice a year in caries susceptible individuals. The latter recommendation may need to be altered in the light of a systematic review of the effectiveness of fluoride gels currently being carried out by Marinho *et al.*, (2001).

### *Fluoride Varnishes*

High concentration fluoride varnishes can play an important role in preventing and controlling dental caries among groups and persons at high risk. Fluoride varnishes should be considered for use on patients with initial carious lesions, the medically and physically disabled, for early childhood caries and root caries, and for the treatment of hypersensitivity occurring as a consequence of gingival recession and exposed root surfaces. Given their reported effectiveness, ease of application, and safety, fluoride varnishes have definite advantages over other types of topical fluoride treatment. As fluoride varnish is reported to be as effective as APF gel and is free of the important disadvantages of gel applications it should be considered a preferable form of topical fluoride application.

We also recommend that fluoride varnishes should be considered for use in treating specific sites of caries activity, for example early enamel demineralisation at the cervical margins of teeth in older children and adults (Andlaw and Rock 1996; Fejerskov *et al.*, 1996). Fluoride varnishes should also be considered for use as a preventive adjunct to reduce enamel demineralization adjacent to orthodontic brackets, particularly in patients who exhibit poor compliance with oral hygiene and home fluoride use.

If varnishes are being used on pre-school children the amount applied should be the minimum necessary to cover the sites at risk. The best available evidence would suggest that fluoride varnishes should be applied bi-annually using the following technique:

The varnish should be applied *in a thin layer to clean, dry teeth* using a disposable brush or applicator until the teeth are completely covered. Once the varnish is applied, contamination with saliva is not a concern because the varnish sets quickly, even when exposed to moisture. An application takes one minute in the usual child patient. Patients (and parents) are instructed to maintain a soft (nonabrasive) diet for the remainder of the day and not to brush or floss the teeth until the following morning. Under these conditions the varnish remains on the teeth for a number of hours, especially in the pits and fissures, the interproximal and the cervical areas, where it is most needed, releasing fluoride into the immediate environment. If the appearance of the varnish is a problem, coating the facial surfaces of the maxillary anterior teeth can be avoided unless those surfaces have active caries or are at risk for caries.

## **CHAPTER 3 – Fluoride Intake and Absorption**

### **3.0 Introduction**

In the technical proposal submitted by the OHSRC to meet the research questions raised under Lot 2, it was stated that the main issues to be addressed in relation to intake (and ingestion/absorption) were methodological in nature. A review of the literature revealed that prior to setting out to measure the intake and ingestion/absorption of fluoride, there was a series of measurement issues to be addressed. This observation was shared by many researchers in the field at the time (International Collaborative Research on Fluoride, *J Dent Res*, 79(4): 893-904,2000). Hence it was decided that the main objectives of this part of the project were as follows:

To develop internationally accepted methods for measuring the intake of fluoride from the diet and also from oral healthcare products

To develop internationally accepted methods for measuring the amount of fluoride ingested and absorbed.

The structure of this part of the Final Report is that for each topic there is a brief summary of the work undertaken under the terms of the contract and relevant published reports are attached. It should be noted that as stated earlier the Forum on Water Fluoridation was in progress at the same time as the Lot 2 project. During the course of the Forum a number of extra tasks needed to be conducted immediately in order to inform the Forum. Some of these projects were funded under Lot 10 of the consultancy research programme. This Lot 10 was designed to provide funds for such contingencies. Also it should be noted that the OHSRC was conducting funded research in a number of areas which were relevant to Lot 2 e.g. the EU funded Flint Project (*Comm. Dent & Oral Epidemiol. Vol. 32; Suppl. 1, April 2004*). It is necessary then to refer to these projects in this Final Report.

In relation to the approach adopted for Task 2, the first issue that needed to be addressed was the development of methods for the collection of dietary samples (3.1.1) and secondly the development of standardized methods for analyzing the samples collected (3.2.2) Following this a number of projects were undertaken or are in progress in order to illustrate the nature of the issues when considering fluoride intake (3.2.3 to 3.2.8). In relation to absorption, examples of work undertaken in the measurement of fluoride in plasma, saliva, urine and fingernails are presented. In addition it is well recognized that the level of enamel fluorosis is a reliable biomarker of fluoride ingestion. A detailed diagrammatic outline of the approach taken in Task 2 is attached as Appendix 2.

### **3.1 Fluoride Intake**

There are two main sources of fluoride intake in Ireland. Firstly, in the diet various foods and drinks have different levels of fluoride. Secondly, even though oral health care products such as mouthrinses, toothpastes and fluoride

containing restorative materials are designed to have a topical effect inevitably some of the fluoride is swallowed.

### **3.1.1 Diet**

#### **3.1.1.1 Development of methods for monitoring the diet of 2 to 3 year old children**

An important issue to consider when measuring fluoride ingestion from diet is the method to be used when collecting dietary samples. Under the Lot 2 consultancy agreement, the OHSRC undertook to develop internationally accepted methods for monitoring the dietary patterns of children aged 2 to 3 years. In order to proceed with this project a protocol was prepared by the OHSRC in collaboration with the Department of Food Science, Food Technology and Nutrition in UCC. It was decided that the deployment of a Masters Degree student in Nutrition was the most efficient way to progress this project. Ms Cait Fitzgerald was recruited and she was supervised by Professor Kevin Cashman of the Department of Food Science, Food Technology and Nutrition and Professor Denis O'Mullane. A summary of this project is attached (Appendix 4). Ms Fitzgerald was conferred with a Masters Degree in UCC in December 2003. A copy of her thesis is available in the library of University College Cork. She is currently preparing a paper for publication in the international literature.

There are two internationally recognized methods used to record the diets of young children:

##### *3-day Diary*

Parents complete a 3-day diary of all foods, drinks and snacks consumed. Full details, including the amount consumed, the brand name of the food/drink item consumed is recorded. The researchers then purchase each individual food item recorded in the 3-day diary and measure the fluoride content of each individual weighed food item.

##### *Duplicate Portion*

Parents are asked to purchase sufficient food to allow them to put aside and store the exact amount of the food item consumed at each intake. All the items are stored together and the diet as a whole is analysed for fluoride content.

The conclusion reached was that for the purposes of monitoring fluoride ingestion in Ireland, the duplicate portion method was the most feasible at this stage. If however there was evidence that the diets contained excessive fluoride then the 3-day diary method could be used in order to ascertain which food item was the major source of the excessive fluoride.

The main aim of this project was to make a recommendation regarding the choice of the two methods for recording the diets of young children. In the course of this pilot study, food samples were collected from a number of families. These food

samples are currently stored in the OHSRC. It is planned to analyse these samples using the internationally agreed methods (see. 3.1.2) when funding is available.

The methods assessed in this project are clearly defined. It would be appropriate for Health Board staff to be trained in these methods when the planned projects for measuring total fluoride intake in Ireland are in progress.

### **3.1.1.2 Development of Standard Fluoride Analytical Methods**

In 2001 following discussions with Professor George Stookey, Indiana Dental School, USA, the OHSRC joined an international group set up to develop standard fluoride analytical methods, funded by the National Institute of Dental and Craniofacial Research (NIH) in the US. Eight collaborating laboratories analysed 25 samples of standard fluoride solution, beverage samples, biological samples and plasma samples. Probably the most revealing outcome from this particular project is that accurate measurement of fluoride in samples requires rigorous attention to detail. The results of this work were presented recently at the ORCA meeting in Konstanz, Germany (Appendix 5). It can be seen that further work is required, particularly for samples with low fluoride concentrations (< 0.2ppm) and for certain types of samples, especially saliva, urine and beverages. However it should be noted that there is sufficient agreement at this stage to measure fluoride levels in most samples. Phase 1 of the study has now been completed in which 110 samples have been analysed by all collaborators. Standard protocols can now be developed. Phase 2 of the study involved analysis of a further 110 samples in accordance with these protocols in place and this is currently in progress. The Final Report will be due in late 2004.

### **3.1.1.3 Fluoride levels in Powdered Infant Formula**

An issue which received considerable attention during the discussions of the Forum on Water Fluoridation was the question of fluoride ingestion by infants fed with powdered infant formula reconstituted with fluoridated water. This issue is fully addressed in the Forum Report ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)). For convenience however, the main recommendations regarding the use of infant formula in the Report are summarized here:

Infant formula should continue to be reconstituted with boiled tap water in accordance with manufacturers' instructions. Alternatively, ready-to-feed formula can be used.

The use of bottled water to reconstitute infant formula is not recommended unless the labeling indicates its suitability for such use.

One observation that was raised when the Forum was considering this matter was the fact that bio-availability of fluoride from infant formulae reconstituted with fluoridated water may vary depending upon the mineral and other content of the different formulae. (Spak, CJ et al , Caries Res. 1982: 16, 249-256). This was an important question to answer in order to allow the Food Safety Authority (FSA) to

proceed with the risk assessment it was conducting on the relationship between infant formula use and the development of fluorosis. The report of the FSA is included in the Final Report on the Forum on Water Fluoridation as appendix 18 ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)). It is also been accepted for publication in Caries Research (get Ref. From Wayne Anderson). At the time when this matter arose the laboratory procedures developed by the OHSRC in collaboration with its international partners was sufficiently advanced in the case of beverages such as infant formula diluted with fluoridated water.

The project undertaken by the OHSRC was designed to measure the level of “ionic” free fluoride in powdered infant formulas prepared with fluoridated water. The results of this work were presented at the meeting of the International Association for Dental Research (IADR). The results showed that there was indeed substantial reduction in the amount of ‘free’ fluoride relative to fluoridated water levels in infant formula. It is not known however, the extent to which the bound fluoride is subsequently debound in the acidic environment of the stomach. Further research is required to address this important issue (put in ref from Villa, get from Colette). The results of this project are summarized in Appendix 6.

#### **3.1.1.4 Infant Feeding Practices**

The Food Safety Authority in its risk assessment report to the Forum on Water Fluoridation highlighted the fact that there was a major lack of information on feeding practices amongst infants in Ireland. As a result a project proposal was prepared by the OHSRC in UCC in collaboration with the Food Science, Food Technology and Nutrition Department, UCC. The main objective of this project is to investigate formula feeding practices in infants aged 8-16 weeks in order to provide a basis for estimating fluoride intake from tap water. This study to be jointly funded by the Department of Health and Children and the Food Safety Authority. A summary of this study and its progress to date is attached (Appendix 7). The laboratory methods to be used will be based upon those developed through OHSRC and its international partners.

#### **3.1.1.5 Fluoride Content of Beverages**

In order to further develop standardized methods for measuring fluoride intake and ingestion/absorption, it was decided that since a large proportion of dietary intake in Ireland is in the form of beverages a project would be undertaken designed to assess properties of common beverages relevant to dental health. The project was undertaken by Mr Abdul Hakeem AlMasroori in the form of a student Summer Project funded by the Health Research Board. The factors investigated were pH and fluoride content. Samples of drinks were collected in Ireland and since the undergraduate was from Oman, samples were also collected from Oman. The fluoride content of the selected beverage samples was measured using the ion-specific electrode. There was a wide variation in the levels of fluoride in the beverages collected. For example in the case of bottled still water samples, the fluoride content ranged from 0.07 ppm in Ballygowan still water to 0.58 ppm in Supervalu still water. In the case of carbonated soft

drinks, again a wide range of fluoride levels were recorded. For example in the case of Coca-Cola, the fluoride level was found to be 0.04 ppm whereas in TK white lemonade it was 0.80 ppm. Fruit drink samples were also analysed. A widely promoted beverage, Ribena Toothkind contained 0.05 ppm fluoride whereas Supervalu apple juice contained 0.87 ppm fluoride. A summary of this project is attached (Appendix 8).

### **3.1.2 Oral Health Care Products**

#### **3.1.2.1 Mouthrinses**

It was found in the situation analysis conducted as part of Task 1, Lot 2, that fortnightly fluoride mouthrinsing programmes were in place in various locations in Ireland and involved approximately 30,000 primary school children. As well as these programmes, over the counter (OTC) sales mouthrinses designed for daily use are widely used. In order to further develop methods for measuring the sources of fluoride in Ireland, it was decided to conduct an investigation of the properties of these mouthrinses. The project was conducted by Ms Elizabeth Moloney, undergraduate dental student, Cork Dental School in the summer of 2001 and was funded under the Health Research Board summer student scholarship scheme.

The aim of the project was to measure fluoride levels, pH values and alcohol content of OTC mouthrinses in the Republic of Ireland. All available OTC mouthrinses on sale over the counter in the Republic of Ireland were purchased. The analysis was conducted in the OHSRC laboratory. Fluoride content was measured using the techniques developed as part of the international collaboration (3.2.2).

Thirty-nine mouthrinses were found to be available OTC in the Irish Republic. Twenty-six of these had a stated and verified fluoride concentration of, on average, 226ppmF. Thirteen samples had no stated fluoride level and when analyzed, contained <2ppmF. All of the fluoridated samples had pH values of above 5.6. Nine of the thirteen non-fluoridated samples had pH values below 5.6, rendering them potentially erosive. Labeling information regarding alcohol content of the samples, while conforming to EU regulations, was ambiguous in the majority of cases.

A more detailed account of this project is attached (Appendix 9).

#### **3.1.2.2 Toothpastes**

As stated in the introduction to this report, the tasks undertaken under Lot 2 overlapped in many instances with the work being undertaken to inform the Forum on Water Fluoridation by the Principal Investigator of this project, Professor Denis O'Mullane and the staff in the OHSRC. This was particularly true in relation to fluoride toothpaste and the reader is referred to the findings and

recommendations of the Forum on Water Fluoridation on fluoride toothpastes ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)). During the period when both of these projects were progressing, the OHSRC was also a lead partner in a major EU project (FLINT) designed to conduct research on two issues:

Development of methods for the measurement of fluoride ingestion from toothpastes by infants and young children.  
Development of objective methods for the measurement of enamel fluorosis.

Whilst this project was not directly funded by Lot 2, nevertheless when the OHSRC was competing for Lot 2 it was indicated that this project would be part of the work designed to achieve the aims of Lot 2. That project was funded by the European Union under the Research and Technological Development Programme, 1994 to 1998. It was entitled “Oral Health, Fluoride Toothpaste and Fluorosis: Information Based Planning for Europe”. The results of this project comprising 11 refereed papers have been published in a special edition of Community Dentistry and Oral Epidemiology (Comm. Dent. & Oral Epidemiol. Vol. 32, Suppl. 1, April 2004) (Appendix 10). These results were particularly useful to members of the Forum on Water Fluoridation and formed the basis of the recommendation on this topic (recommendation 3 – [www.fluoridationforum.ie](http://www.fluoridationforum.ie)) as follows:

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.

A more detailed description of the background to the project is the main subject of paper 1 of the 11 paper series (Appendix 10).

### **3.1.2.3 Fluoride Containing Dental Materials.**

Other sources of fluoride in oral healthcare products are restorative materials. Under this heading it was decided to employ a dentist with an interest in this area to carry out a detailed literature review on this topic. Ms Fiona MacSweeney’s review is attached (Appendix 11). There are three main fluoride releasing

restorative materials currently being used by practicing dentists in the Republic of Ireland:

Glass ionomers  
Compomers  
Fissure sealants

In general it can be concluded that the contribution of these materials to the total amount of fluoride ingested by the Irish population is likely to be low. Nevertheless there is good evidence to show that they can have an important role to play in controlling future caries activity.

## **3.2 Fluoride Absorption**

Over the years it has been well established that not all fluoride ingested is subsequently absorbed. For this reason, it is essential that techniques be developed to monitor the amount of fluoride absorbed. In this section the work undertaken by the OHSRC in relation to fluoride ingestion is described. It will be noted that the methods developed conform to international accepted standards.

### **3.2.1 Saliva**

Fluoride in saliva is derived from two sources. Firstly it is derived from fluoride in the diet and from fluoride in oral health care products such as mouthrinses and toothpastes. The other source of fluoride is from the fluoride which is absorbed, circulates in the plasma and is excreted in salivary glands and through the gingival fluid. It is now firmly established that the level of fluoride in saliva is an important factor in the development of caries. Maintenance of the ambient level of fluoride in saliva whether from an external source such as fluoridated water, fluoride toothpastes or systemically from the saliva or gingival fluid helps to control dental caries. The OHSRC has participated in the development of internationally accepted methods for the measurement of fluoride in saliva:

As part of the international collaboration described in 3.1.2, saliva was one of the samples which was analyzed by the OHSRC. It was found that the techniques developed by OHSRC compared well with those developed in the Gold Standard laboratory in the University Dental School, Indiana, USA.

As part of the Flint Project described in 3.2.7, the salivary expectorate used in the process of estimating the amount of fluoride toothpaste ingested was analyzed (see Appendix 10).

A member of the OHSRC, Ms Rose Kingston, is currently working on a project entitled "A Study of the Relationship among Oral Hygiene habits, Salivary fluoride levels and Dental Caries". This project which was funded initially by the oral health care industry and the follow-up work is currently being funded by a project grant from the Health Research Board. As part of this project, saliva samples have been collected at baseline from children in fluoridated and non-fluoridated areas in County Limerick and in non-fluoridated Derry City in Northern Ireland. The saliva samples have been analyzed in the OHSRC laboratory in Cork using

internationally accepted standard methods. In September 2003, the Limerick children were followed up and again salivary samples will be included in fieldwork in this part of the study. A more detailed account of this study is attached (Appendix 12). This project is part of the work being undertaken by Ms Rose Kingston in partial fulfilment of her requirements for her PhD degree under the supervision of Dr Helen Whelton.

### **3.2.2 Plasma**

Fluoride levels in plasma are considered to be an accurate measure of the fluoride absorbed within an immediate past (hours). However its usefulness in monitoring fluoride ingestion and absorption in a public health setting is limited because of the necessity to obtain blood samples. At this stage the OHSRC has not participated in a project requiring analysis of plasma fluoride levels. However, the OHSRC has developed internationally acceptable standard methods for such analysis through its participation in the international collaborative project outlined in 3.1.1.2.

### **3.2.3 Urine**

As part of the EU funded FLINT Project, urinary excretion by pre-school children in six European countries was measured (Appendix 10, Paper 9). Twenty-four hour urinary samples were collected from 3 year old children in Cork, Ireland (n=18) where the water is fluoridated through concentration of 0.8 to 1.0 ppm and from five sites with a water fluoride concentration <0.15ppm: Knowsley, England (n=18); Oulu, Finland (n=18), Reykjavik, Iceland (n=4); Haarlem, Netherlands (n=6); Almada/Setubal, Portugal (n=21). The volume of the samples was measured, they were analysed for fluoride concentration and the 24-hour urinary fluoride excretion was calculated. From this an estimate of the daily fluoride intake was made. It was found that the mean fluoride excretion in response to usual conditions of fluoride intake in the children in the non-fluoridated areas ranged from 0.16 mg ( $\pm 0.08$ ) in Oulu to 0.33 mg ( $\pm 0.27$ ) in Almada/Setubal with an overall mean of 0.23 mg ( $\pm 0.19$ ). The mean 24-hour fluoride excretion in fluoridated Cork was 0.37 mg ( $\pm 0.11$ ). There was a significant difference between the fluoride excretion in the non-fluoridated areas and that in the fluoridated areas, and the data were broadly in agreement with WHO standards. All the analysis for this project were conducted in the OHSRC laboratory using internationally developed standards as described in 3.2.2.

It is interesting to note that a study undertaken to measure urinary fluoride excretion of young children exposed to different fluoride regimes, it was found that the daily fluoride excretion in these children, corrected for age and fluoride ingested from toothpaste, appeared to indicate that the fluoride intake in the children drinking fluoridated school milk was somewhere between those living in an optimally fluoridated area and those in a low fluoride area (Ketley CE et al, 2002).

### 3.2.4 Tooth Enamel/Fluorosis

Over the last 20 years, the OHSRC has been the leading research group in the development of methods for measuring enamel fluorosis in populations. This work has been published widely in the international literature and has been referred to in detail in the Report of the Forum on Water Fluoridation ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)). It is important however to point out that relevant to the aims of the Task 2, Lot 2 (matters relating to absorption), enamel fluorosis is a reliable and measurable marker of the amount fluoride ingested during tooth development especially during the maturation phase of amelogenesis. During the period when the Lot 2 consultancy project was taking place two relevant projects in the further development of methods for measuring fluorosis were undertaken.

As part of the FLINT Project (Appendix 10) (Comm. Dent. & Oral Epidemiol. 2004) a standardized photographic method was developed for the objective measurement of enamel fluorosis. This method is now accepted internationally and is described fully in Paper 3 of Appendix 10.

During the course of the work of the Forum on Water Fluoridation, the question of the prevalence of enamel fluorosis in primary teeth was raised. It was noted that whilst much data had been collected on the prevalence of fluorosis in permanent teeth, little was reported on the prevalence of the condition in primary teeth. In order to begin to address this lack of information, a study was conducted by the OHSRC designed to measure the prevalence of dental fluorosis in primary teeth of 5 year olds in Ireland. This project was funded by a special grant from the Department of Health under Lot 10 of the consultancy contract. An important aspect of this project was the decision to train and calibrate the researcher employed to carry out the field work, Ms Mairead Harding, in the methods developed in the US for measuring fluorosis in primary teeth. Ms Harding was trained and calibrated by Dr John Warren of the University of Iowa, USA, in the techniques developed by the Iowa Dental Research Group. This work was presented at the American Association of Dental Research (AADR) in San Antonio, USA, in March 2003 ([http://iadr.confex.com/iadr/2003SanAnton/techprogram/abstract\\_27397.htm](http://iadr.confex.com/iadr/2003SanAnton/techprogram/abstract_27397.htm)). It was found that the severity of dental fluorosis in the primary dentition of children living in fluoridated and non-fluoridated communities in Ireland is low. There was no association between infant feeding practices and prevalence and severity of dental fluorosis. A summary of this project is attached (Appendix 13).

### 3.2.5 Fingernails

The development of a reliable and accessible biomarker for monitoring the amount of fluoride ingested and absorbed is now regarded as a priority (see Clarkson, International Fluoride Collaboration). In 1999, Whitford (Caries Res. 1999; 33:462-467) suggested that fluoride levels in fingernail clippings could provide a reliable, inert and non-invasive marker of the amount of fluoride ingested prior to clipping. His findings indicated that fluoride entered the fingernail at the germinal matrix only and not during its growth through the nail bed. Hence it was suggested that the amount of fluoride in the fingernail clipping could provide a

measure of the amount of fluoride being ingested some 2-3 months previously, that is the length of time it takes a nail to grow from the germinal matrix to the clipping stage.

The OHSRC has collaborated with Dr Whitford and his team in further developing this idea. To begin with the method of analysis of fingernail clippings used by Dr Whitford's group in Augusta, Georgia, USA and Ms Eileen MacSweeney, Head of the OHSRC Laboratory in Cork was agreed. This required much effort and involved the exchange of fingernail clippings over a one year period before the technique was finalized. A member of staff of the Department of Oral Health and Development in the Cork Dental School, Ms Sinead McDonnell, worked with the OHSRC in conducting a study which was funded by the HRB. The aim of the project was to ascertain if the technique developed was able to discriminate between fingernail clipping collected in a fluoridated area (Cork City) and a non-fluoridated area (Bangor, Co Down). The results were very encouraging and the level of fluoride in fingernail clippings are beginning to be accepted worldwide as a reliable marker of fluoride levels ingested some months prior to clipping. A brief summary of the project is attached (Appendix 14). (McDonnell ST et al, 2004) This project has been funded by the Health Research Board with supplementary funding from the Department of Health and Children.

### **3.3 Other Related Projects**

As a result of the development of internationally agreed standards for the collection and storage and analysis of different samples, the OHSRC is involved or is planning to be involved in a number of projects which are linked with the Lot 2 project. The following are two examples:

Fluoride ingestion from tea amongst adults in Ireland. There is increasing evidence that an important source of fluoride ingestion in Ireland is tea. Marketing data suggests that people in Ireland are enthusiastic tea drinkers; it is estimated that Ireland has the highest per capita consumption of tea in the world with an average consumption per person of four cups per day. Recent food consumption data from Irish adults indicate that 91% of adults aged 18-64 years are regular tea drinkers with a mean daily intake of tea of 619 mls per day.

One of the undergraduate prizes at the annual scientific meeting of the Irish Division of IADR requires a student to present a protocol of a study deemed to be relevant at this time. Working under the direction of Dr Helen Whelton, Director of the OHSRC, Mr Patrick O'Beirne developed a protocol designed to measure fluoride ingestion from tea amongst adults in Ireland. This protocol was developed in collaboration with the Department of Food Science, Technology and Nutrition. It is proposed to conduct a study using the collection and laboratory techniques under Lot 2. It is planned to apply for funding for this project in the Autumn of 2004.

A more detailed account of this protocol is attached (Appendix 15).

Toothpaste use evaluation. A key element of most oral health promotion projects is the recommendation that fluoride toothpaste be used at least twice a day. To date when attempting to measure compliance with this advice, the usual approach is to ask the participants or their parents how often they brush their teeth each day. A more accurate approach to compliance measure is to measure the level of fluoride in saliva. Salivary fluoride levels are positively linked with frequency of tooth brushing.

This is a collaborative project funded by the Health Promotion Unit, Department of Health and Children, in the Republic and the R&D office in N. Ireland. The study will be conducted over a 1-year period. Salivary fluoride levels will be measured at the base line and at the end of the study to measure the effectiveness of the intervention. The impact of the intervention on quality of life will also be measured (give details here of when this project is likely to be completed).

## **Chapter 4 – Fluoride Accumulation in Bone**

### **4.0 Introduction**

Under the Task 3, the OHSRC undertook to develop a protocol for measuring total fluoride accumulation in bone samples in subjects aged 50 – 60 years. The following proposals have been submitted to the Health Research Board as part of a larger proposal for measuring the risks and benefits of water fluoridation. The dental sections of this proposal were awarded funding. It is proposed to resubmit the attached bone health projects following the establishment of the Expert Group as recommended in the Forum Report ([www.fluoridationforum.ie](http://www.fluoridationforum.ie)). As can be seen, the OHSRC consulted widely with international experts in analysis of bone for fluoride.

There has been some speculation that the incidence of fracture neck of femurs is greater in the RoI, a fluoridated region, than in NI, a non-fluoridated region. To date, no studies have been conducted in Ireland to measure the association between fluoridation of water supplies and fracture neck of femur, nor to estimate the total amount of fluoride accumulated in bone of long-term residents of fluoridated communities. It is desirable that research be carried out in this area in order to ascertain if, and to what extent the above is the case. Proposed research in this area would involve the fieldwork and analysis outlined overleaf in a synopsis of two proposed studies.

#### **4.1 ‘Association between fluoridation of water supplies and the incidence of fracture neck of femur’**

**Aim:** To measure the incidence of fracture of the neck of femur amongst adults aged 50 years and older in NI and RoI.

Data on traumatic fracture neck of femurs sustained by patients aged 50 years or older will be collected in the Southern, Mid Western and South Eastern Health Boards in RoI and in the whole of NI in collaboration with hospital orthopaedic units.

During the first year of the Research Programme retrospective data on fracture neck of femurs occurring during the previous 5 years will be obtained from hospital records. Based on the findings of the retrospective study a three years prospective study will be planned during the second year of the project. This prospective study will record extra data so that potential confounding factors, not included in the PAS system in NI and the HIPE system in RoI (see below) will be taken into account.

The Directorate of Information Systems (DIS) of the Department of Health and Social Services and Public Safety in Northern Ireland (DHSSPSNI) annually collates computerised hospital admission data [Patient Administration System (PAS)]. There are only three hospitals in NI providing inpatient fracture services. For the largest of these (the Royal Victoria Hospital in Belfast) it has been possible to check the completeness of fracture neck of femur admission data from PAS against a large clinical audit database operated by the surgeons themselves. The resulting analysis has shown that PAS data captures over 99% of fracture neck of femur cases.

The HIPE database in RoI is a computer-based information system designed to record episodes of care in acute hospitals in Ireland. The HIPE database comprises demographic, administrative and clinical data on inpatients and day cases in acute hospitals. It is estimated that 98% of acute hospital activity data is now reported to the national HIPE database annually. However, the limitations of this database are that there are no data from other facilities, e.g. convalescent or nursing homes. A further limitation is that entries are based on episodes of care rather than individual patients; thus a patient who has been admitted repeatedly will be represented several times in the database. It is proposed that during the longitudinal phase of this part of the project an estimate of the proportion of fracture neck of femurs treated privately will be obtained and also the effect of patients with repeat fracture neck of femurs or repeated admissions for the same fractures on the overall incidence rates will be estimated.

The incidences of fracture neck of femur in NI and RoI will be compared using logistic regression techniques. Available data on confounding factors will be included in these analyses.

#### **4.2 'Femoral bone fluoride and risk of fracture neck of femur: a case-control study'**

Aim: To address the following hypotheses: 1) that the concentration of fluoride in bone will be higher in the Republic of Ireland, a fluoridated region, than in the North of Ireland, a non-fluoridated region, and 2) that the relative risk of fractured neck of femur increases with increasing concentration of bone fluoride.

A total of 500 subjects will be recruited from consecutive patients aged between 60 and 75 years inclusive admitted with first fractures of neck of femur to the Royal Victoria Hospital in NI and the relevant hospitals in the three health board regions in the south of Ireland.

All patients, aged between 60 and 75 years, with first presentation of fractured neck of femur will be potentially eligible for inclusion in the case group (n=250). Patients with a previous medical history of fracture neck of femur will be excluded. Controls (n=250) will be recruited from patients presenting for hip arthroplasty and will be stratum matched with cases for age, gender and hospital i.e. for each case one control of the same sex and in the same 5 year age stratum will be recruited from patients admitted to the same hospital for hip arthroplasty. Femoral bone samples will be obtained from cases and controls as part of their standard surgical interventions.

For the purpose of training and quality control a standard operating procedures manual will be developed for the study. A pilot study will be carried out to assess the feasibility, effectiveness and acceptability of the recruitment and patient assessment procedures.

The protocol has been seen and approved by the relevant senior consultant orthopaedic surgeons in the Northern Ireland and the Republic of Ireland centres. Data will also be collected on lifestyle variables of potential relevance to the risk of fracture neck of femur.

Analysis of bone samples will be carried out in the laboratory attached to the OHSRC in collaboration with the Department of Biochemistry, UCC, under the guidance of the Skeletal Tissue Research Group, University of Leeds. The rate of bone formation and bone re-absorption, the balance of which ultimately determines bone mass, may be assessed by measurement of biochemical markers. A blood sample will be obtained from all subjects, and an overnight urine sample will also be obtained for measurement of urinary markers of bone turnover.

Biochemical markers to be tested for: serum osteocalcin and serum bone specific alkaline phosphatase (biochemical markers of bone formation) and urinary pyridinoline and deoxypyridinoline (biochemical markers of bone resorption). This analysis will be carried out at the Department of Food Science, Technology and Nutrition, UCC.

The statistical analyses will be carried out jointly between OHSRC, UCC, the Department of Epidemiology and Public Health, Queens University Belfast, and the Department of Epidemiology and Public Health, UCC, under the supervision of a senior epidemiologist/biostatistician.

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# Appendix 1

## Task 1

## Situation Analysis

The overarching aim of the situation analysis was to establish full details of the aforementioned fluoride programmes using a framework of structure, process and outcome for each programme. It was also our aim to identify the quality control measures in place for each measure.

As outlined in the Technical proposal for Lot 2, *‘structure refers to the inputs into the services and the way the services are set up. For example, structure in the case of water fluoridation would include the number and the location of fluoridation plants and the facilities and equipment (including equipment for monitoring fluoride levels) in each plant. Structures in the case of fluoride toothpastes needs a different approach and includes current methods of licensing fluoride toothpastes, the degree of control of formulations, sales and advertising procedures, etc’*

With regard to determining the latter a meeting was arranged with the Chief Pharmacist of the Department of Health, Mr. Tom Mc Guinn, to discuss all aspects of ‘structure’ in relation to fluoride containing products in Ireland and to identify relevant National and European legislation and directives. The following points outline the key issues identified during this meeting and present the most pertinent clauses regarding fluoride containing products from the relevant EU Directives.

If a manufacturer does not make any ‘medical claim’(i.e a claim for a health effect) for their product, then that product (by default) is regarded as a cosmetic product. The nature of the controls that are applicable therefore depend on the classification of the product – whether as a cosmetic product or as a medicinal product.

A company cannot put a cosmetic product on the market unless it is ‘safe’. The company must have documentation attesting to the safety of their product but do not have to make this available automatically to the Department of Health. This documentation must, however, be made available if requested.

Legislation governing cosmetic products in the European Union is contained in the “Cosmetics Legislation 1999 edition” (Enterprise Directorate-General Pharmaceuticals and Cosmetics). This is implemented in Ireland by the European Communities (Cosmetics Products) Regulations 1997 (as amended)

The concept of safety is defined in Article 2 of the above document as not causing “damage to human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular of the products presentation, its labelling, any instructions for use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.”

“Notes of guidance for testing of cosmetic ingredients for their safety evaluation” have been published by the European Commission and are contained in Volume 3 of “The Rules governing cosmetic products in the European Union” (Cosmetlex)

It must state on the label that a product contains fluoride. The maximum authorised concentration of fluoride in oral hygiene products is 0.15% F (1500ppm). This required statement takes the following form (e.g) “contains sodium monofluorophosphate”.

If there were concerns about adverse health effects of fluoride containing ‘cosmetic’ products, then these should be directed to a ‘competent authority’ (i.e Department of Health) who would refer the matter to the Scientific Committee on Cosmetics and Non-Food Products in Brussels (SCCNFP) via the European Commission.

The available ‘structure’ would appear to be of little assistance in, for example, any attempts to get companies to reduce the size of the nozzles on tubes of toothpaste nor in standardising the information available on labels (eg presenting fluoride concentrations in ppm as opposed to percentage). The national competent authority would be obliged to address its concerns with these matters to the European Commission where a harmonised approach would be decided upon with the advice of the SCCNFP.

For every fluoride containing product available OTC the ‘obligation to notify’ rests in the Member State where the commodity is first put on sale. Once a product has been put on the market in any EU country, it can be made available in any other EU country without the ‘obligation to notify’. A cosmetic product lawful in one member state is regarded as lawful in any other member state.

Shelf life must only be stated on the label if the shelf life is < 3years. As most manufacturers claim the shelf life is > 3 years there is no obligation to place a ‘sell by’ date (this could pose difficulties for chalk based as opposed to silica based toothpastes)

Advertising must be consistent with EU directives on advertising and in addition the advertising of cosmetic products must not imply that they have characteristics that they do not in fact have. The ASA updates its own rules periodically.

The same principles govern OTC sales of mouthwashes

The fluoride mouthrinses (0.2% NaF) used in schools, because of their intended function, would be regarded as medicinal products and as such would be subject to the authorisations granted by the Irish Medicines Board. Mouthrinses containing not more than 0.2% NaF are not subject to prescription-only control under the Medicinal Products (Prescription and Control of Supply) Regulations, 1996 (S.I. No. 256 of 1996) (as amended). However, mouthrinses for daily use containing more than 0.05% NaF, are subject to prescription-only control under these Regulations.

Fluoride gels and varnishes are classified as medicinal products and as such are also subject to authorisation control by the Irish Medicines Board. They are also subject to prescription-only control. They are sold direct to dentists by the dental wholesalers. These wholesalers are also subject to control by the Irish Medicines Board.

Sodium Fluoride Tablets are medicinal products subject to authorisation by the Irish Medicines Board. Under the Medicinal Products (Prescription and Control of Supply) Regulations, 1996, they are not subject to prescription-only control except where the recommended maximum daily dose (MDD) exceeds 2.2mg i.e. 1mgF)

The classification of slow release Fluoride restorative materials is somewhat ambiguous. These products could be regarded as having a primary function as a filling material and a secondary function as releasing fluoride. They could be regarded as functional medical devices and fall under the EU (medical devices regulations) 1994.

If a fluoride containing oral hygiene cosmetic product is being imported from outside the EU, it is up to the first member state of importation to ensure that it complies with the relevant directive

There is a prohibition on mail order selling of fluoride products that are medicinal products(which includes the Internet) governing individual companies in Ireland. However, there is no regulation governing individual purchasers *i.e* a consumer is free to buy via mail order from a company outside Ireland

Following this meeting with the Chief Pharmacist, a literature review of relevant legislation was carried out. The following paragraphs elaborate on some of the issues raised above and summarise the most salient points from the relevant EU directives.

1) 'Products for the care of the teeth and the mouth' (Directive 76/768/EEC. Annex I ) are regarded as cosmetic rather than medicinal products. If a manufacturer does not make any 'medical claim' (i.e a claim for a health effect) for their product, then that product is regarded as a cosmetic product. Although it could be argued that a claim that a fluoride toothpaste 'fights tooth decay' is a medical claim, such a claim is not apparently regarded as sufficient to classify a fluoride toothpaste as a medicinal product.

The operational definition in the EU of a 'cosmetic product' is '*..any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.*' (Article 1 Cosmetics Directive 76/768/EEC).

2) A manufacturer cannot put a cosmetic product on the market unless it is 'safe'. The concept of safety is further defined as not causing '*...damage to human health when applied under normal or reasonably foreseeable conditions of use,*

*taking account, in particular, of the products presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.'*

3) The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market must keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the product label:

The qualitative and quantitative composition of the product

The physicochemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product

The method of manufacture

Assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and level of exposure. Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned.

The name and address of the qualified person or persons responsible for the assessment of the safety of the product for human health. That person must hold a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline.

Existing data on undesirable effects on human health resulting from use of the cosmetic product

Proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product (Directive 76/768/EEC Article 7a)

4) In Ireland the Department of Health is regarded as the 'competent authority

The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community Market. (Directive 76/768/EEC Article 7a. 4). Once a cosmetic product has been put on the market in any EU country and has fulfilled the 'obligation to notify' clause, then it can be made available in any other EU country without the 'obligation to notify' in that Member State. Essentially, therefore, if a cosmetic product is lawful in one Member State, it is lawful in any other Member State.

5) Member States must ensure that cosmetic products are marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering:

The name and address of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Member States may require that the country of origin be specified for goods manufactured outside the Community;

The nominal content at the time of packaging, given by weight or by volume

The 'date of minimum durability' (shelf life). The date of minimum durability of a cosmetic product is the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2 (*ie* the definition of safety). Indication of the date of durability is not mandatory for cosmetic products whose shelf life exceeds 30 months. Most toothpastes claim to have a shelf life over and above 30 months and are, therefore not obliged to include a sell-by date on their product.

Particular precautions to be observed in use. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or by a symbol which must appear on the packaging

The batch number of manufacture or the reference for identifying the goods.

A list of ingredients in descending order of weight at the time they are added

6) In accordance with Directive 76/768/EEC manufacturers of fluoride toothpastes are obliged to state that the product contains fluoride and the finished cosmetic product must not contain more than 0.15%F (1500ppm).

7) If there are concerns about adverse health effects of fluoride containing 'cosmetic products', they should be directed by a 'competent authority' to the Scientific Committee on Cosmetics and Non-Food Products in Brussels.

8) If a Member State notes, on the basis of substantiated justification, that a cosmetic product, although complying with the requirements of Directive 76/768/EEC, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision. The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in article 10 of Directive 76/768/EEC. In that event the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

9) The adequacy of the available 'structure' with regard to encouraging manufacturers to reduce the size of nozzles on tubes of toothpastes or to standardise the information on labels (e.g presenting fluoride concentrations in ppm as opposed to a percentage) needs to be examined.

10) The advertising of medical preparations and cosmetic products in Ireland is governed by Regulations made by the Minister for Health as follows:

Medical Preparations (Licensing, Advertisement and Sales) Regulations, 1984-1994

Medical Preparations (Advertising) Regulations, 1993

Medical Preparations (Labelling and Package Leaflets) Regulations 1993.

Medical Preparations (Prescription and Control of Supply) Regulations, 1993.

European Communities (Cosmetic Products) Regulations, 1990-1994

(taken from Advertising Standards Authority of Ireland Code – 3. Health and Beauty)

Article 6 of Directive 76/768/EEC states in relation to advertising of cosmetic products that *'Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have'*.

11) The classification of slow release Fluoride restorative materials (e.g glass ionmer cements) is somewhat ambiguous. These products could be regarded as having a primary function as a filling material and a secondary function as releasing fluoride. They could be regarded as functional medical devices and fall under EU (medical devices regulations) 1994.

12) There is a prohibition on mail order selling by companies in Ireland of fluoride containing products (this includes Internet sales). However, there is no regulation governing the individual purchaser *i.e* a consumer is free to buy by mail order (or Internet) from a company outside Ireland.

#### Legislation governing the sale of fluoride containing restorative materials

The complexity of the legislation governing fluoride containing restorative materials necessitated a very detailed and separate analysis in addition to that presented above.

The Medical Device Amendments of 1976 in the U.S. were the first laws, which emphasised the biological standardisation and testing of dental materials. They also required that all dental and medical materials intended for human use be classified as Classes I, II, or III depending on the complexity of the testing required.

According to the European Union Medical Devices Directive (MDD) 1994 and European Commission MEDDEV 2.4/1 Working document 1998, glass ionomer, compomer and fissure sealant restorative materials are classified as Class IIa invasive medical devices for long term use in the oral cavity. Classification is based on the most common intended use of the mentioned devices. When another intended use is specified or added, the indicated classification must be reconsidered. *"Classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices: whereas the conformity assessment procedures for Class I devices can be carried out as a general rule under the sole responsibility of the manufacturer in view of the low level of vulnerability associated with these products; whereas for Class IIa devices the intervention of a notified body should be compulsory at the production stage whereas for Class IIb, Class III which constitute a high risk potential, inspection by a notified body is required with regard to design and manufacture of the devices; whereas Class III*

*is set aside for the most critical devices for which explicit prior authorisation with regard to conformity is required for them to be placed on the market.”* Medical Devices Directive 93/42/EEC. Devices are classified Class I, IIa, IIb and III in accordance with Annex IX of the Medical Devices Directive. The classification system of the MDD is such that the level of control; applied to a medical device is proportional to the degree of risk inherent in its use.

#### Class IIa

A manufacturer of this class of product who wishes to affix the CE marking must apply to a Notified Body to carry out the conformity assessment procedures. These procedures give manufacturers a choice of routes to obtain CE marking authorisation.

The strictest controls will therefore only apply to the limited number of high risk products-----

Class I low risk

Class IIa and IIb medium risk

Class III high risk

The determination of the Class of a device is the primary responsibility of the manufacturer but the Department of Health may arbitrate if there is confusion or dispute.

The motivation behind the introduction of the Medical Devices Directive is the removal of trade barriers between the various EU member states by establishing harmonised standards in the manufacturing of medical devices. The directive has a defined scope and lays down the essential requirements for medical devices and the procedures for checking that all products comply with them. The CE mark is affixed to the product to indicate that it complies with the Directive (and all other directives that affect it). A product carrying the CE marking may be placed on the community market without further restrictions. Each member state has a notified body set up to carry out certain monitoring and remedial action in the case of a misapplication of the Directive.

CE originally stood for EC, European Community. Nowadays the European Commission claims that the two letters “C” and “E” are just intended to be a symbol without any literal meaning, indicating the free marketability of industrial goods within the European Economic Area. The first harmonising Directives that led to the development of the CE mark were introduced in 1985. These directives have specific Essential Requirements (ERs) that must be proven by the performance of conformity assessment procedures that are audited and certified by private third parties before CE mark is applied. With the introduction of the EC medical devices directive the ERs for industrial goods to be placed on the EC market changed significantly. Previously goods other than medical devices could be CE marked as soon as their safety was established. However the medical device directives introduced a new ER that asked for proof of the device’s performance, as declared in the manufacturer’s labeling. Thus, the performance of a medical device became a legal pre-condition for application of the CE mark. This led to quite a clear distinction between the value of the CE mark applied to medical devices and CE marks applied to other industrial goods. Essentially where non-medical devices only have to be safe and do not actually have to work, medical devices bearing a CE mark need to be both safe and effective. The legal ERs for medical devices have nothing in common with minimum requirements. Instead ERs ask for the compliance of the device with a continuously changing state of the art, forcing manufacturers to improve their devices in instances of medical progress. The CE mark implies a legal claim of

quality and additional private quality or safety marks that overlap with the meaning of the CE mark are unnecessary. Article 17 paragraph 3 of EC MDD (93/42/EEC) reads “ It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning ...of the CE marking.” To date there are 15-20 national and EC safety, quality and certification marks offered to the medical devices industry.

Prior to the transposition of the Medical Devices Directive into Irish law there were no statutory controls governing the manufacture or marketing of medical devices in Ireland, although manufacturers could conform to European, International and Irish manufacturing standards as set up by the National Standards Authority of Ireland. The directive was transposed into Irish law by the Minister for Health on 3<sup>rd</sup> August 1994 and titled “European Communities (Medical Devices) Regulations, 1994”

The Medical Devices Directive describes a medical device as *“any instrument, apparatus, appliance material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:*

*Diagnosis, prevention, monitoring treatment or alleviation of disease*

*Diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap*

*Investigation, replacement or modification of the anatomy or of a physiological process*

*Control of conception*

*And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.*

The regulations are concerned with the actual manufacturing process with the production of finished medical devices to accepted standards in safety, quality and design. Explicit obligations are placed on manufacturers who intend to place their products on the market in Ireland or elsewhere in the Community. All general medical devices that were placed on the market after June 13<sup>th</sup> 1998 have to carry the CE marking. The CE marking on a medical device indicates that the device is safe but it must not be viewed as a guarantee of safety; rather as a statement by the manufacturer that the product meets all the essential requirements of the directive that apply to it.

The Medical Devices Directive defines the term manufacturer as *“the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third person.*

*The obligations to be met by the manufacturers also apply to*

*The natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose with a view to their being placed on the market under his own name.”*

Clinical investigations for the purposes of the Directives (CE marking)

Clinical investigations of all medical devices may be carried out by the manufacturers for the purpose of obtaining clinical data, which helps establish conformity with the essential requirements of the Directives. In this regard the prior approval of the Minister for Health must be sought by the manufacturer before such investigations can be carried out in Ireland, in addition to having obtained approval from the local ethics committee. The necessary requirements for carrying out such investigations are prescribed in the regulations and must be adhered to

### Vigilance System

Under the terms of both Directives, the Department of Health is obliged to institute and coordinate a reporting system for adverse incidents associated with the use of medical devices, thereby helping to improve the protection of health and safety of patients, users and others. Under the regulations, manufacturers are required to immediately report certain types of product related adverse incidents occurring in Ireland to the Competent Authority at the Department of Health. This forms part of the overall vigilance system that Competent Authorities are obliged to set up under the Directives. The objective of the system is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated and to correct product problems.

The sequence of events that would generally take place once a manufacturer has reported an adverse incident in Ireland to the Department of Health are:

DOH receives and acknowledges and evaluates report.

Manufacturer carries out investigation within reasonable time limit DOH monitors progress.

Manufacturer consults with DOH regarding interim action ie. What needs to be done pending final report. DOH may take any further action it deems appropriate.

Final report from manufacturer to DOH in form of written statement

DOH may, usually following consultation with manufacturer take action on similar devices on the market here if necessary.

Dissemination of information by DOH normally following consultation with manufacturer eg. Public health notices if appropriate or contact with other Competent Authorities and the Commission.

The Minister for Health is the Competent Authority with the responsibility for the implementation of the Directives by the making of the appropriate regulations and also by taking on the following specific tasks:

Designation of Notified Body within the State.

Establishing a medical device vigilance system

Monitoring of clinical trials of medical devices for the purposes of CE marking in Ireland.

Liaison with EC in relation to both directives

Dealing with Classification problems

Notified Bodies are part of the regulatory system established by the medical devices Directives. They are usually certification bodies with relevant expertise and are responsible for carrying out correctly the conformity assessment procedures and establishing that devices conform to the relevant essential requirements and also to established standards in design and production. Such bodies may be privately or State owned and must be notified formally to the

European Commission for the purposes of the Directives by their relevant Competent Authority. The National Standards Authority of Ireland, (NSAI), has been assigned as a notifying body by the Minister for Health.

#### Standards

The adherence to standards has always been voluntary and continues to be the case despite the advent of the Directives. In endeavouring to satisfy a Notified Body that his devices meet the essential requirements it is not necessary for a manufacturer to call up any standard. Standards play an important part in the conformity assessment procedures and as a result of the decision of the EU to use standards in the new approach legislation; substantial activity is underway in the development of new, harmonised standards for the increasing range and sophistication of medical devices that are becoming available in the Community. The European Standards Bodies (CEN, CENELEC) have been mandated by the European Commission to produce the relevant standards to support the Directives. Member states are obliged to adopt these harmonised standards once they are issued and national standards will cease to apply.

#### Sources:

Medical Devices Regulations Introductory notes for manufacturers Department of Health March 1995.

Dentistry- Medical Devices used in Dentistry Guidance and assessment and approval CEN/TC 55N 157

European Commission MEDDEV 2.4/1 Working Document November 1998

Council Directive 93/42/EEC June 1993

Dental Materials : Biological Properties and Clinical Evaluations

Ivar A. Mjor CRC Press 1985.

The CE mark vs. additional safety marks the regulatory affairs journal (devices) by Rainer Hill.

#### Situation Analysis Questionnaire

At a meeting of the Oral Health Services Research team on 30<sup>th</sup> May 2000, it was agreed that in order to collect information for the situation analysis relating to Task 1 Lot 2, a questionnaire would be developed to be distributed to all Principal Dental Surgeons for completion. The following areas were highlighted as being relevant to the situation analysis and related quality control measures in each health board area.

#### Mouthrinsing Programmes

What programmes are in place in each health board and comprehensive details of these programmes.

The length of time these programmes have been running.

The number of schools and pupils involved in each area

Personnel involved in supervising the programmes

Procedures for consent, safety precautions during preparation and delivery of the rinse

Numbers of pupils who have withdrawn from programmes and reasons for withdrawal

Details of the concentration of the rinse used in the programmes, how the rinse is constituted, volume of rinse used, duration of rinse, frequency of administration of rinse

Precautions taken to ensure that participants use the mouthrinse and do not swallow the rinse

Over the counter sales of fluoride mouthrinses locally.

Targeting of special needs groups

Details of any plans to initiate new rinsing programmes

Details of any local studies that have been carried out on the effectiveness of mouthrinsing programmes.

#### Fluoride Tablets

Details of any fluoride tablet programmes currently in operation and details of any historical programmes run over the last ten years.

Details of any health board guidelines governing the prescription of fluoride tablets by Health Board Dental Surgeons in each health board area.

Prescribing patterns of Health Board Dental Surgeons

Availability of tablets in local pharmacies

#### Fluoride Gels and Varnishes

Details of any health board guidelines governing the application of topical fluoride gels by health board dental surgeons and hygienists

Reasons for usage (sensitivity/caries/other)

Which products are used

Fluoride content of gels and varnishes used.

Targeting of special needs / medically compromised patients

Quantities purchased annually

#### Fluoride Toothpastes

Any oral health promotion programmes in operation which involve the active promotion of the use of fluoride toothpaste

Details of any distribution of fluoride toothpaste (including free samples) by hygienists or health board dental surgeons

Any health board guidelines governing the recommendations given by dental personnel to parents regarding the use of fluoride toothpaste by children

Advice given to parents by dental personnel regarding the use of paediatric versus standard fluoride toothpaste (full strength).

Fluoride containing restorative materials

Brand names and fluoride content of materials used

Quantities of materials purchased annually

Annual expenditure on products

A questionnaire was subsequently designed to take account of all these points and was piloted initially amongst three Principal Dental Surgeons for comment before general distribution. The questionnaire, and the detailed responses to the

questionnaire by health board area are presented separately in an accompanying booklet.

Following an analysis of the responses to the questionnaire, a number of recommendations and suggested guidelines on the appropriate use of fluoride modalities in caries preventive programmes in the health boards were drawn up. These are to be discussed and modified as appropriate following consultation with the health boards. The proposed recommendations are presented in the following section.

## Appropriate use of fluoride modalities in the health boards: Recommendations and Suggested Guidelines

### Terminology: Special Needs Groups & High Risk Groups

As used in the recommendations section of this report, the terms 'special needs groups' and 'high risk groups' refer specifically to the following:

#### Special Needs Groups:

- Medical Card Holders
- Persons with disabilities
- The Traveller Community
- Refugees
- The homeless

The terms 'high risk' or 'considered to be at high risk for dental caries' refer throughout this section to circumstances which are indicative of increased risks of the disease or its consequences. Both general and local factors are relevant in this context:

#### General factors<sup>1</sup>

- Low socio economic groups
- Medically compromised patients at risk from dental caries and its sequelae
- Children with special needs, including learning difficulties.
- Children on long term medication containing sugar.

#### Local factors

- Evidence of past caries experience (dmft or DMFT >5, >10 initial lesions, caries in first permanent molars at 6-8 years of age, 3 years caries increment >3).
- Greater than 3 sugary intakes a day – greater than 10% of energy from non-milk extrinsic sugar consumption.
- Poor oral hygiene
- Non-fluoridated area
- Low salivary flow
- Orthodontic appliance therapy

Although we have identified these special needs and high risk groups, we recommend that, when deciding on appropriate preventive regimes in individuals,

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<sup>1</sup> General and Local Factors as defined in the document "Clinical guidelines in paediatric dentistry: preventive dentistry for children" British Society for Paediatric dentistry H/CG/95

health board dentists and hygienists should consider the risk status, age and use of other fluoride containing products by each individual patient.

#### Introductory remarks

Much of the work on the efficacy and effectiveness of individual fluoride modalities in preventing and controlling dental caries was conducted before 1980. At this time dental caries was more common and severe and different fluoride modalities were typically tested separately and with the assumption that the method would provide the main source of fluoride. Thus, various modes of fluoride use have evolved, each with its own recommended concentration, frequency of use and dosage schedule (CDC 2001). Recommendations regarding the use of fluoride modalities have not been standardized within or between different countries. This is not to suggest that such standardization is either necessary or desirable. Recommendations on the appropriate use of fluorides in a public health setting should be population specific and tailored to meet the needs of the population under consideration. In Ireland, for example, where 70% of the population reside in areas served with a fluoridated water supply and where there is a halo effect operating in non-fluoridated areas, we do not consider it appropriate to recommend the use of another systemic source of fluoride in the form of fluoride tablets, even for 'high risk' patients.

In making our recommendations, whilst acknowledging the international literature on the benefits and risks of the various fluoride modalities, we have emphasized, where available, evidence from Irish studies (particularly in relation to fluoride mouthrinsing programmes). This is in recognition of the difficulty in extrapolating to the Irish context, the results of studies conducted in different populations, settings, and using different treatment variables and measurement variables.

The recommendations are preceded in the first instance by a short précis of results of the situation analysis questionnaire, followed by a brief review of the literature pertaining to the fluoride modality under discussion. This review is narrative in nature and emphasis has been placed on the results of those studies considered to have been conducted with the greatest methodological rigor, in particular randomized trials and meta-analyses where available. The conduct of a systematic review of the effectiveness of the various fluoride modalities was beyond the remit of Lot 2.

A Cochrane review (systematic review), whose primary objective is to determine the effect of topical fluoride therapy in the form of toothpastes, mouthrinses, gels and varnishes in the prevention of dental caries in children and adolescents is currently in progress (Marinho *et al.*, 2001). The specific questions that will be addressed in this review are:

Is topical fluoride therapy effective for children and adolescents?

Is one of these forms of topical fluoride therapy more effective than another?

Are combinations of these topical fluoride therapies more effective than one form used alone? (Marinho *et al.*, 2001)

This systematic review will likely provide the best available and most reliable evidence on the effectiveness of fluoride modalities used in isolation or in combination, and as such, will be of particular relevance to recommendations made under Lot 2. The results and conclusions of this review will be incorporated in the Final Lot 2 Report.

We emphasise, therefore, that all the recommendations that follow may be subject to review in the light of new scientific evidence and if current policy on the

fluoridation of public water supplies in Ireland should change. Furthermore we wish to emphasise that these are proposed recommendations only and will be discussed and reviewed as appropriate in consultation with the Lot 2 user group and the health boards.

## Fluoride Programmes

### Mouthrinsing Programmes

School based mouthrinsing programmes were introduced in rural parts of Ireland in order to bring the caries preventive benefits of fluoride to areas where it would not be possible to fluoridate water supplies (Holland *et al.*, 2001). School based fortnightly fluoride mouthrinsing programmes are currently in operation in non-fluoridated areas in six health boards: the Eastern Regional Health Authority (Wicklow and Kildare only), the Midland Health Board, the Mid-Western Health Board, the South-Eastern Health Board, the Southern Health Board (Kerry only) and the Western Health Board.

### Current Procedures adopted for obtaining consent

As part of the process evaluation of mouthrinsing programmes, the situation analysis questionnaire requested information on the procedure adopted in each area for obtaining consent for participation in the mouthrinsing programme.

Written consent was obtained in all areas, with consent forms generally distributed through the schools to the pupils whose parents or guardians were then asked to sign and return to the schools for collection. Copies of the consent forms used were obtained from a number of respondents. These forms differed both within and between health boards in terms of the information given on the effectiveness and safety of the mouthrinsing programme. In addition some consent forms asked whether the child's home received water from piped water mains. Other consent forms posed questions regarding whether the child was currently taking fluoride tablets or using a fluoride mouthrinse at home.

### Preparation of the rinse in health board areas

All respondents to the situation analysis questionnaire reported using a 0.2% NaF (900ppm F) solution in the rinsing programmes. The dilution procedure adopted in each health board area typically involved dissolving 10g of sodium fluoride (2 x 5g sachets) in 5 litres of water or 4g sodium fluoride (1 x 4g sachet) in 2 litres of water. Two respondents to the situation analysis questionnaire reported using purified water purchased through a wholesale pharmacy supplier for the dilution procedure.

### Supervision of the mouthrinsing programmes

The situation analysis indicated that a variety of personnel were involved in the delivery and supervision of the mouthrinsing programmes and included health board dental surgeons, dental and general nurses and appropriately trained lay personnel. All supervisors were reported as monitoring the volume of the returned rinse to ensure that children were not swallowing the rinse. All reported excluding children who persisted in swallowing the rinse from the programme.

#### Amount of rinse dispensed

Thirteen respondents to the situation analysis questionnaire reported using 10mls for the rinsing procedure; one reported using 8mls.

#### Duration of rinsing procedure

9 respondents reported that children were requested to rinse for 2 minutes; 5 reported using a 1 minute rinse.

#### Current procedures adopted for disposing of the used mouthrinse

11 respondents reported disposing of the rinse down the toilet or sink at the school. 3 reported treating the used rinse as clinical waste and double wrapping it in clinical waste disposal bags before returning it to the nearest health centre for disposal.

#### Withdrawals of children from programmes

The situation analysis revealed that a small number (approximately 130) children had withdrawn from mouthrinsing programmes in the previous 12 months. The most common reason given was adverse media coverage of the fluoridation debate. Other reasons given included concerns over the safety of fluoride and the child not liking the taste of the rinse.

#### Literature review

Two regimes have been adopted as standard for individual programmes of patient care of for school based programmes. Respectively, these are a 0.05 percent NaF rinse (230ppmF) used daily and a 0.2 percent NaF rinse (900ppmF) used weekly or fortnightly.

#### Benefits

Most studies on the effectiveness of school based mouthrinsing programmes have been carried out in North America in the 1970s and 1980s. Many of the early studies were flawed in that it was common practice to base treatment effectiveness figures on historical, non-current comparisons rather than on concurrent, longitudinal control groups. Given the well documented secular decline of dental caries in the United States since the early 1970s the results of studies reported in preventive programs since that time cannot be interpreted if based on historical comparisons rather than concurrent controls (Disney *et al.*, 1990).

The discussion of the benefits of school based mouthrinsing programmes that follows concentrates on the results of studies conducted in Ireland.

In November 1968 a mouthrinsing programme commenced in the Portlaw area (non-fluoridated) of North Waterford and had continued without interruption for eight and a half years at which time a study was carried out.

Only those children who had taken part in the rinse since starting school were examined (582) as part of the study. For comparison, 513 children attending 5 schools in the same part of the county were examined. The results are presented in the table presented on the following page:

Age	Rinse Group		No Rinse		P	Diff between means
	N	DMFT	N	DMFT		
6	58	0.16	61	0.25	NS	0.09
7	71	0.56	55	1.38	<0.01	0.82
8	67	1.21	57	2.65	<0.01	1.44
9	70	2.11	46	3.15	<0.01	1.04
10	76	2.72	54	4.28	<0.01	1.56
11	65	3.11	53	4.70	<0.01	1.59
12	77	4.35	79	6.85	<0.01	2.5

The results as presented, suggested that the differences in the prevalences of dental decay in the two groups were not significant at 6 year olds, but the difference at age 7 was already sufficiently large to reach statistical significance. At age twelve the difference between the two groups was of the order of 2.5 decayed, missing and filled teeth (Holland et al., 1978)

In 1984 (Holland et al., 1987) the effectiveness of the mouthrinsing programme in the Portlaw area in the prevention of dental caries in non fluoridated communities was examined in the light of the general decline in the prevalence of dental caries.

As part of this study 325 children in four different schools who were participating in the mouthrinse programme were examined. A control group of 265 attended six nearby schools and received no special preventive programmes. All examinations were carried out at a neutral venue, so the examiner was unaware of whether a child was in the rinse or control group. The results are presented in the table below:

Age	Rinse Group		Control		
	N	DMFT	N	DMFT	P
8	56	1.2	57	1.2	NS
9	70	1.5	52	1.3	NS
10	64	1.9	52	2.3	NS
11	60	2.3	53	3.2	<0.05
12	75	2.5	51	4.5	<0.001
Total	325		265		

A further study (Holland et al 1995) of the same mouthrinsing programme sought to investigate the effectiveness of a school based fortnightly 0.2% sodium fluoride mouthrinse programme after children ceased to participate. The programme, which commenced at age 6 and ceased at age 12 was investigated 4 years following its cessation. Three groups of 12 year olds and three groups of 16 year olds were examined. The three groups were:

1. Children who had participated in the mouthrinse (mouthrinse group)
2. Those attending non-participating nearby schools (no mouthrinse group)
3. Lifetime residents of a fluoridated community (fluoridated group)

For both the 'mouthrinse' and 'no mouthrinse' group, neither schools nor the children's homes were connected to fluoridated water supplies. In the study, the school was taken as the sampling unit and random samples of children were chosen from each of the three categories in the 12- and 16- yr old group.

It was found that 12 year old children who had participated in the mouthrinse programme from age 6 (mouthrinse group) and those who had been lifetime residents of a fluoridated community had significantly lower DMFT scores at 1.2

compared with 12 year olds who attended 'no mouthrinse' schools, who had a mean DMFT of 1.9. In the 16 year old group, differences in mean DMFT scores for children in the 'mouthrinse group' (*i.e* those who rinsed up to age 12) and those who had attended 'no mouthrinse' schools, were not significant. In this group (16 years), those in the 'mouthrinse' and 'no mouthrinse' group had significantly higher mean DMFT scores (at 4.0 and 4.7 respectively), compared with 16 year old lifetime residents of a fluoridated community (mean DMFT 2.7). No significant differences in mean DMFS were found between the 'mouthrinse' group and the other two groups in those aged 12 or 16 years. However, significant differences in mean DMFS were found at both ages between the 'no mouthrinse' group and the fluoridated community (3.0 and 1.8 at age 12; 8.7 and 5.5 at age 16).

These studies would suggest that the school based fluoride mouthrinses are effective in reducing caries levels in children, but that the beneficial effects tend to fade following termination of the programme.

#### Cost effectiveness of mouthrinsing programmes

The cost benefit ratio and cost-effectiveness of mouthrinsing programmes have recently been questioned, especially in view of the continuing decline in dental caries in most industrialised countries. Petersson (1993) has noted that '*information on the total costs of prevention programmes is unavailable and the difficulty in finding relevant values for benefits to teeth is obvious.*'

The National Preventive Dentistry Demonstration Program (NPDDP) was a large project conducted in 10 U.S cities during 1976-1981 to compare the cost and effectiveness of combinations of preventive procedures. The Program reported that fluoride mouthrinse had little effect among schoolchildren, either among first-grade students with high and low caries experience or among all second and fifth grade students. In addition the NPDDP documented only a limited reduction in dental caries attributable to fluoride mouthrinse, especially when children were also exposed to fluoridated water (CDC 2001). On these grounds the Program questioned the cost-effectiveness of school based mouthrinsing particularly in fluoridated areas.

In a recent study Holland *et al* 2001 established the population size where the cost effectiveness of community water fluoridation and a school-based mouthrinsing programme coincided. In this case study, based in Waterford, Ireland, the cost of securing similar caries reductions at age 12 were lower for the mouthrinse programme if the population size of 12 year old children was below 3,168 and lower for water fluoridation if the population size was above this figure. The results of the dental caries survey component of this study demonstrated almost equal effectiveness for water fluoridation and mouthrinse in caries reduction for this community at age 12.

#### Risks

Following any fluoride mouthrinsing procedure, some of the rinse will be retained and, presumably, swallowed. Although there is large inter and intra individual variation in the amount of solution retained, four factors that influence retention are: age (the younger the rinsers, the more solution tends to be retained); rinsing time (longer periods produce more retention); volume (the more solution used for rinsing, the more retained) and previous experience with the rinsing procedure (the less experienced rinsers retain more). Several studies have documented the

inability of young children to rinse without ingesting some or all of the fluoride introduced into the oral cavity. Wei and Kanellis found that with a 0.05% NaF rinse, children aged 3-5 years might retain 0.25-0.41 mgF. The 'probably toxic dose' of fluoride has been estimated to be 5 mg/kg body weight. 22ml of a 0.05% solution would be required to deliver 5mgF. A 12 month old female weighing 7.8 to 11.2kg (the 5<sup>th</sup> and 95<sup>th</sup> percentiles) would have to consume 172-247 ml of a 0.05% NaF rinse to receive a probably toxic dose. This is 1-1.5 times the amount contained in a small bottle (180ml) of mouthrinse, or 18 times the amount typically dispensed in rinsing programmes. For children old enough to use over the counter products (about age 6) considerably more mouthrinse would have to be ingested to approach a toxic fluoride dose (Adair 1998). As children aged < 6 years are typically excluded from mouthrinsing programmes, there is an extensive margin of safety in supervised mouthrinsing programmes. In addition, the use of fluoride mouthrinses by children aged > 6 years does not place them at risk for cosmetically objectionable enamel fluorosis (CDC 2001)

### Fluoride Tablets

The results of the situation analysis indicated that fluoride tablets are rarely, if at all, prescribed by health board dental surgeons in Ireland. The last dietary fluoride supplement programme in the health boards ceased in the North Western area in 1996. 26 respondents to the situation analysis questionnaire stated that the prescription of fluoride tablets was at the discretion and clinical judgment of each individual dental surgeon or hygienist and that there were no guidelines specific to each health board area. Of the remaining 4 respondents, 2 stated that the guidelines were "*fluoride tablets not recommended*". The remaining 2 reported using as guidelines the dietary fluoride supplement schedule approved by the American Dental Association, the American Academy of Paediatrics and the American Academy of Paediatric Dentistry (1994/95) [see below]

### Benefits and Risks

There is only weak evidence for a pre-eruptive benefit from the use of fluoride supplements. However, there is evidence from randomised, blind, placebo controlled studies that supplements can have a beneficial post-eruptive effect in reducing caries in children when chewed, swished (to maximize the topical effect) and swallowed under supervision. Some studies have reported caries reductions using this regime of 20% to 28% over 3 to 6 years (De Paola et al., 1968; Driscoll et al., 1978). However, whilst fluoride supplements can prevent dental caries, poor compliance with the daily regimen can reduce their effectiveness. In addition there is now strong evidence that fluoride supplements, when ingested before tooth eruption, are a risk factor for dental fluorosis (Burt 1999).

### Fluoride Supplement Dosage Schedules

A number of changes in the dosage schedule for fluoride supplements have been recommended in recent years. During the autumn of 1991 a meeting was convened in Brussels entitled "European view of fluoride supplementation" (Clarkson 1992). It was acknowledged at this meeting that some special risk infants could benefit from starting fluoride supplements before the age of 3 years but this should be upon the advice of a dental practitioner. In this case, the dose

should be reduced to 0.25 mg/day. Unanimous agreement was reached to issue the following recommendations for the use of fluoride supplements in Europe: fluoride supplements have no application as a public health measure.

A dose of 0.5mg/day should be prescribed for at risk individuals from the age of 3 years.

Labelling should advise that fluoride supplements should not be used before three years of age unless prescribed by a dentist

#### Canadian Workshop (1992)

Further recommendations regarding the use of fluoride supplements arose out of a 1992 Canadian workshop, where it was suggested that:

Fluoride supplements:

Should not be recommended for children less than 3 years old

Should be targeted only for individuals or groups at high risk of dental caries

Should be sold in a chewable or lozenge form only and as a behind the counter product

Should not be recommended in fluoridated areas

Should be packaged with a written dosage regime

The use of fluoride supplements may be appropriate for targeted individuals and groups for children 3 years and older in areas with less than 0.3 ppm fluoride in the water. Evaluation of all fluoride intake from ingested fluids should be considered prior to their use.

Table 1: Proposed Prescribing Schedule

Age of child	Fluoride in water supply less than 0.3ppm
3, 4 and 5 yr	0.25 mg *
6 yr or more	1.00 mg
* If there is not regular use of fluoride toothpaste, then 0.5 mg is recommended	

The estimation of the mean fluoride ingested from all fluid sources should include all home and child care water sources, and the possible impact of water filtration devices within the home.

Commercial interests should be formally requested to formulate proper dosage regimes both for chewable fluoride and multivitamin supplements

At another conference in 1997, the Canadian schedule was replaced by one that was virtually the same as the schedule approved by the American Dental Association in 1994 which has now been jointly recommended by the American Academy of Paediatric Dentistry (AAPD), and the American Academy of Paediatrics (AAP) and is presented below:

Table 2: Recommended dietary fluoride supplement \* schedule

Fluoride Concentration in community drinking water†			
AGE	<0.3 ppm	0.3-0.6 ppm	>0.6ppm
0-6 months	None	None	None
6 months – 3 years	0.25mg/day	None	None
3 – 6 years	0.50mg/day	0.25mg/day	None
6 – 16 years	1.0mg/day	0.50mg/day	None

\* Sodium fluoride(2.2 mg sodium fluoride contains 1 mg fluoride ion)

† 1.0 parts per million (ppm) = 1mg/L

The supplement schedule outlined in Table 2 above is virtually identical to that recommended by the British Dental Association, the British Society of Paediatric Dentistry and the British Association for the Study of Community Dentistry with the exception that in the British schedule the recommendations are based on fluoride concentrations in the drinking water of < 0.3ppmF, 0.3-0.7ppmF and > 0.7ppmF.

Recommendations of the Center for Disease Control

The latest recommendations of the Center for Disease Control (CDC 2001) state that fluoride supplements should be prescribed judiciously:

*“fluoride supplements can be prescribed for children at high risk for dental caries and whose primary drinking water has a low fluoride concentration. For children aged < 6 years, the dentist, physician, or other health-care provider should weigh the risk for caries without fluoride supplements, the caries prevention offered by supplements, and the potential for enamel fluorosis. Consideration of the child’s other sources of fluoride, especially drinking water, is essential in determining this balance. Parent and caregivers should be informed of both the benefit of protection against dental caries and the possibility of enamel fluorosis. The prescription dosage of fluoride supplements should be consistent with the schedule established by ASA, AAPD, and AAP. Supplements can be prescribed for persons as appropriate or used in school-based programs. When practical supplements should be prescribed as chewable tablets or lozenges to maximize the topical effect of fluoride.”*

Products Available in Pharmacies:

En-De-Kay® (Manx)

Fluotabs 3-6 years, orange-flavoured, scored, sodium fluoride 1.1mgF (500 micrograms F).

Fluotabs 6+ years, orange-flavoured, scored, sodium fluoride 2.2mg (1mgF)

FluoriGard® (Colgate-Palmolive)

Tablets 0.5, purple, grape flavoured, scored, sodium fluoride 1.1mg (500 micrograms F)

Tablets 1.0, orange, orange-flavoured, scored sodium fluoride 2.2mg (1mgF).

Fluor-a-day® (Dental Health)

Tablets, buff, sodium fluoride 1.1mg (500 micrograms fluoride)

Tablets 2.2mg (1mgF).

## Fluoride gels and Fluoride Varnishes

Both fluoride gels and fluoride varnishes are topically applied fluorides which, by definition, are delivery systems which provide fluoride to the exposed surfaces of the dentition, at elevated concentrations, for a local protective effect, and are therefore not intended for ingestion (Marinho *et al.*, 2001).

### Fluoride Gels

The results of the situation analysis questionnaire suggested that fluoride gels are used for caries prevention in many health board areas, albeit infrequently, and are usually targeted towards those patients considered to be at high risk of dental caries. The majority of respondents to the situation analysis stated that the use of fluoride gels was at the discretion and clinical judgment of each individual health board dental surgeon or hygienist and that there were no guidelines governing the use of these products specific to the health boards. Of two respondents who stated that there were guidelines, one stated that fluoride gels should not be used; the other respondent stated that fluoride gels should be used according to manufacturers instructions, for early carious lesions only and should not be used in children < 7 years of age.

The products currently in use in the health boards are Oral B stop, Thixogel, NuproAPF Gel and ProFluoride gel. All of these products are either 1.23% APF gel or 0.4% stannous fluoride.

The commentary and recommendations that follow are concerned solely with operator (dentist or hygienist) applied fluoride gels.

### Products used and mode of action

When applied, fluoride gels tend to form a calcium fluoride precipitate on the enamel surface which acts as a reservoir of fluoride that becomes available for remineralisation when there is a fall in pH.

Various modes, concentrations and frequencies of gel applications have been tested over the years, with or without prior prophylaxis, and a number of different fluoride compounds have been used (Marinho *et al.*, 2001). Since the 1960s acidulated phosphate fluoride (APF) gel has become the most widely used professionally applied fluoride gel. It has been tested in various concentrations, the most common being 1.23% F, usually as sodium fluoride in orthophosphoric acid which is typically applied twice a year. APF gels have a low pH (about 3.0). 0.4% Stannous fluoride gel (containing 968ppmF) is also commonly used.

### Benefits

The best available evidence to date on the effectiveness of fluoride gels is provided in a meta-analysis carried out by Rijkom *et al.*, (1998). This review sought randomised studies on fluoride gels applied to permanent teeth of children aged six to fifteen years. Only English and German studies published between 1965 and 1995 were used, and only MEDLINE was searched. Twenty four studies were found with a wide variation in the number of decayed, missing and filled surfaces (DMFS) at baseline (mean 0.8 to 10.1) and application frequency (1 to 360 times per year). Follow up periods were 1.5 to 3 years (median 3 years). The overall caries inhibiting effect was 22% (95% CI 18-25%). This was a consistent effect at all levels of incidence of DMFS. There was no effect of type of

gel, or number of applications. This paper also calculated the numbers needed to treat at various levels of background prevalence, using the consistent 22% effect (Bandolier 1998).

Background caries incidence (DMFS/year)	NNT for one year treatment (95% CI)
0.25	18 (16 to 22)
0.50	9/1 (7.8 to 11)
1.00	4.5 (3.9 to 5.4)
1.50	3.0 (2.6 to 3.6)

No significant differences were found between applications either performed by tray or by brush. Although Ripa (1989) concluded that professional tray applications performed twice a year were more effective than performed once a year, the meta-analysis by van Rijkom *et al.*, (1998) demonstrated no significant influence of the variable 'application frequency' for the tray application studies. It was suggested that fluoride gel application provided an additional caries reduction in subjects using a general fluoride regimen, but that this should be interpreted cautiously. From the standpoint of cost effectiveness the authors suggested that fluoride gel treatment in current low and even moderate caries incidence child populations was questionable.

Ripa (1984) recommended that a prophylaxis prior to fluoride gel application was not necessary for full benefits to be obtained. Wei and Yiu (1993) reported that four independent clinical trials where APF gels were applied with or without prior cleaning, had failed to show a significant difference between the groups.

#### Risks

Topical fluoride gels contain high concentrations of fluoride (APF gel contains 12.3 mg/ml). Hence even a small bottle (200ml) of APF gel contains a potentially lethal dose for a young child. Furthermore, ingestion of smaller quantities (e.g 1.6 ml by a 5 year old child) may cause gastrointestinal symptoms. Topical fluoride gels should therefore be applied in accordance with strict guidelines to minimize the amount of gel that may be swallowed. Very careful application of a gel can reduce the amount of fluoride ingested to 10mg, however it is difficult to achieve this low level of ingestion especially in young children. The dose from a gel application is swallowed in a short period of time and can cause significant increases in plasma fluoride concentration (Bawden 1998).

#### Techniques of Application

Fluoride gels can be applied by either direct or indirect techniques

##### Direct Technique

Using this technique, the teeth are isolated one quadrant at a time using cotton wool rolls. The isolated teeth are dried with compressed air and the solution applied with a small brush or cotton wool pledget held in tweezers. The gel is then applied to all tooth surfaces, especially into the inter-dental spaces from buccal and lingual sides. The gel is applied for 4 minutes. A saliva ejector should be used throughout this procedure. After this time the gel is removed from accessible tooth surfaces and the child instructed to expectorate thoroughly but not to rinse. At the end of treatment the patient is advised not to eat or drink for half an hour to prolong contact of fluoride with approximal surfaces of teeth.

### Indirect Technique

Using the indirect technique gels are applied in foam lined mouth-trays and left in contact with the teeth for 4 minutes. Only one arch should be treated at a time. Topical fluoride gels should be applied indirectly in accordance with the following guidelines designed to minimize the amount that may be swallowed:

limit the amount of gel placed in each commercially available disposable mouth tray to no more than 2ml or 40% of the trays capacity.

Sit the patient in an upright position with the head inclined forward

Use suction throughout the 4 minute gel application procedure

At the end of the 4 minutes remove the tray and remove excess gel from accessible surfaces with a cotton wool roll or gauze

Instruct the patient to expectorate (spit out) or use a saliva ejector for 30 seconds after the gel application

Keep the gel out of the reach of the patient

Never leave the patient unattended. (WHO 1994) (Andlaw and Rock 1996)

### Fluoride Varnishes

The situation analysis questionnaire indicated that fluoride varnishes are used in many health board areas and are typically used in a targeted approach on individuals and groups considered to be at high risk of dental caries and in the treatment of dentinal hypersensitivity. In the majority of health board areas Duraphat® was the fluoride varnish of choice. The majority of respondents to the situation analysis questionnaire indicated that there were no guidelines for the application of fluoride varnishes specific to the health boards; rather, the decision to apply fluoride varnishes was left to the discretion and clinical judgment of each individual dental surgeon or hygienist.

### Mode of action and clinical features

Clinical studies have shown that fluoride varnishes are effective in increasing the fluoride content in the enamel and preventing caries (Fejerskov et al., 1996; Seppa 1999). The use of a fluoride varnish increases the fluoride concentration in saliva which remains significantly higher 2 hours after its application than after the use of other fluoride agents (Fejerskov *et al.*, 1996).

Fluoride varnishes are painted directly onto the teeth and are intended to be used as a vehicle for holding fluoride in close contact with the tooth surface for a period of time (CDC 2001). A theoretical advantage of varnishes over other methods of professional fluoride application is that varnishes are adhesive and hence should maximize contact with the tooth surface (Burt 1999).

Varnishes typically contain 5% wt. sodium fluoride (Duraphat® 2.26% fluoride) in a resin carrier or 0.7% fluorsilane (Fluor Protector® 0.1% fluoride as difluorsilane) in a polyurethane based lacquer (Bawden 1998)

Fluoride varnishes have favourable clinical features. They are quick and easy to apply, and patient acceptance is reported as good. Bawden (1998: 267) has noted that '*often it can be applied in young children, handicapped patients and otherwise difficult patients for whom a conventional gel application cannot be accomplished.*' As the varnish sets in contact with saliva, it is particularly useful when treating young children under the age of 6 years of age. Bawden (1998: 267) further notes that fluoride varnish offers important advantages in the public health setting:

“This is especially so in the context of increasing concerns about the devastating effects of early childhood caries and the difficulties many children affected by the disease have gaining access to care. APF gel treatments are difficult, if not impossible to do on many young children and there is considerable risk of overingestion of fluoride. Fluoride varnish can be successfully applied in most young children and there is no risk of overingestion of fluoride. These advantages make it possible to apply fluoride varnish safely to the newly erupting teeth of high-risk infants and young children in an effort to control bottle caries or generalised early childhood caries”

### Benefits

The majority of studies of Duraphat® have reported caries reductions in the permanent dentition of between 30% and 40%. In the primary dentition, Duraphat has a reported efficacy ranging between 7% and 44% (Fejerskov *et al* 1996). Although clinical studies have produced some contradictory results, it has been reported (Skold 1994) that this could be due to different study designs.

An early study by Holm (1979) demonstrated the caries-preventive effect of fluoride varnish on primary teeth. In this study, 225 3-year-old children received a semiannual application of fluoride varnish (Duraphat®). After two years the caries reduction achieved was 44% compared to a control group.

A Canadian study by Clark *et al.*, (1985) further demonstrated the effectiveness of semiannual applications of fluoride varnish to primary teeth. After 32 months, children who received fluoride varnish (Durafluor®) had 27.2 percent fewer carious primary molars compared to a control group.

In a randomized study (Autio-Gold *et al.*, 2001) to evaluate the effect of fluoride varnish on enamel caries progression in the primary dentition 140 children were randomized into varnish and control groups. Children in the varnish group received Duraphat at baseline and after four months, and children in the control group received no professional fluoride applications. It was found (after nine months) that in the varnish group 81.2 percent of active enamel lesions on occlusal, buccal and lingual surfaces became inactive, 2.4 percent progressed and 8.2 percent did not change compared with 37.8 percent, 3.6 percent and 36.9 percent respectively in the control group. It was concluded that fluoride varnish applications could be an effective measure in reversing active pit and fissure enamel lesions in the primary dentition and that fluoride varnish may offer an efficient, non-surgical alternative for the treatment of decay in children.

In a three year study (Modeer *et al.*, 1984) of the effect of Duraphat application on proximal caries progression in teenagers it was demonstrated that topical application of fluoride varnish every third month significantly reduced the progression of proximal carious lesions in premolars and molars. However, in those children with the highest caries activity (greater than nine new proximal lesions) Duraphat treatments did not significantly reduce proximal caries progression in premolars and molars.

In a study (Zimmer *et al* 1999) to evaluate the effectiveness of a preventive programme involving the application of Duraphat for children with high caries risk, 269 children in six primary schools in a district in Hanover, Germany were allocated to a test or control group. The test group received the fluoride varnish for 4 years whereas the control group received no professional fluoride application. At the end of the study, children who had received a minimum of two fluoride applications per year showed a significantly lower caries increment in

comparison with the control group (0.88 DMFT vs 1.39 DMFT,  $P < 0.05$ ). The authors concluded that a minimum of two applications of Duraphat per year may be an effective measure in preventing caries in socially deprived children with high caries activity.

More recently Zimmer (2001) has reported that in children aged 9-15 years, the biannual application of Duraphat varnish in school-based programmes provided a caries inhibition of 38%.

Using a meta-analysis, Helfenstein and Steiner (1994) analysed studies designed to detect the caries preventive effect of Duraphat. 8 studies (1851 patients) met the inclusion criteria for the review. The authors reported:

An overall reduction in caries in treatment groups of 38% (95% Confidence interval 19-57%) compared with patients in control groups.

The Duraphat effect was not likely to be due to publication bias

Because the effects of treatment diminished with time, a study duration-adjusted effect size was calculated. For the median time of study duration (2.5 years), this was calculated to be 44.9% (95% CI: 34.5%, 55.3%).

A more recent systematic review sought to assess the efficacy of preventive methods among individuals who have experienced or are expected to experience elevated incidence of carious lesions (Bader et al., 2001). The authors reported that although the evidence for the efficacy of many other methods of topical fluoride application was incomplete "*the strength of the evidence for the efficacy of fluoride varnish for the prevention of dental caries in high-risk subjects was fair*".

#### Use in patients undergoing orthodontic treatment

The presence of clinically detectable areas of decalcification following the removal of orthodontic appliances is well recognised (O' Reilly and Featherstone 1987). Several studies have reported a significant increase in the prevalence and severity of demineralisation after orthodontic therapy compared with controls and the overall prevalence amongst orthodontic patients ranges from 2 to 96%. The teeth most commonly affected are molars, maxillary lateral incisors, mandibular canines and premolars (Chang et al 1997).

European studies have reported that fluoride varnish prevents decalcification beneath orthodontic brackets and slows the progression of existing enamel lesions (CDC 2001). An ex vivo single blind study (Gillgrass *et al.*, 2001) has demonstrated the efficacy of Duraphat application in preventing demineralisation. In an in vitro study (Todd *et al.*, 1999) evaluating the ability of a fluoride varnish (Durafluor) to inhibit demineralisation of enamel surrounding orthodontic brackets, teeth treated with Durafluor exhibited 50% less demineralisation than the control teeth and an even greater difference when compared to the placebo group.

#### Treatment of hypersensitivity

Fluoride varnishes have also been used in reducing dentinal hypersensitivity occurring as a consequence of gingival recession and exposed root surfaces. Dentinal hypersensitivity results when stimulation causes the fluoride in open dentinal tubules to undergo pressure changes, which activates mechanoreceptor nerves and results in pain. Treatment with fluoride varnish forms a protective layer of calcium fluoride that prevents this fluid flow, thereby reducing dentinal hypersensitivity (Gaffar 1999).

### Frequency of Application

Seppa and Tolonen (1990) reported on a 2 year randomised clinical trial (254 children aged 9-13 years) comparing the efficacy of Duraphat® varnish applications performed either two or four times a year. The results suggested that fluoride varnish applications performed more frequently than twice a year may not provide additional caries protection in a population with relatively low caries activity.

An intensive regime involving application of fluoride varnish 3 times in one week, once per year has also been advocated (Skold *et al.*, 1994) and it has been reported that this regime might be more effective than the more conventional semi-annual regimen but that further research is required (CDC 2001). The caries preventive effect of intensive application of fluoride varnish once a year, even in children with low or moderate caries incidence is not clearly explainable. Three applications within a week might give a sufficiently high fluoride deposit on the enamel surface and in superficial and microscopical cavities to end all carious processes. This deposit will then be probably be maintained by daily supply of fluoride via toothpaste well enough to maintain a long term effect. In vitro studies support this proposal. There is the remote possibility that the treatment inhibits the metabolism and growth of the oral bacteria in such a way that further acid production is reduced for a long time. Inhibition of acid production is documented but no effect on the numbers of mutans streptococci in plaque or saliva (Skold *et al.*, 1994).

Further studies to ascertain the optimum application frequency for topical fluoride varnishes are continuing and at present the evidence of benefits from more than two applications per year or any other regime, remains inconclusive.

### Toxicology and Safety

Although Duraphat has a very high fluoride concentration (5% NaF) its safety is reported as acceptable (Petersson 1993). Fluoride ingestion following a fluoride varnish has barely detectable effects of plasma fluoride concentration (Bawden 1998). Ekstrand *et al.* (1980) found no toxic effects with respect to fluoride plasma levels or renal function in pre-school children and schoolchildren treated with Duraphat. This is attributable to the fast-setting varnish base, the slow release of fluoride over time, and the comparatively small amounts of varnish required for the whole dentition. Fejerskov *et al.*, (1996) have stated that fluoride varnishes are safe because of the amount of varnish usually used is 0.3-0.5ml. Petersson (1993) has reported that in the resin varnishes, the concentration of fluoride is about twice as high as in APF gel, but the amount of fluoride in the mouth of a child as a result of a varnish application is less than 7mg compared with 30mg or more with an APF application. Petersson (1993) has concluded that fluoride varnishes are toxicologically safe and can be recommended for caries prevention even in the primary dentition.

There is no published evidence indicating that professionally applied fluoride varnish is a risk factor for enamel fluorosis, even among children aged < 6 years. Proper application technique reduces the possibility that a patient will swallow varnish during its application and limits the total amount of fluoride swallowed as the varnish wears off the teeth over several hours (CDC 2001).

Application Technique for Fluoride Varnish (As described by Bawden 1998: 267)

In a typical child, no more than a small drop of varnish for each arch is required. The varnish should be applied *in a thin layer to clean, dry teeth* using a disposable brush or applicator until the teeth are completely covered. Once the varnish is applied, contamination with saliva is not a concern because the varnish sets quickly, even when exposed to moisture. An application takes one minute in the usual child patient. Patients (and parents) are instructed to maintain a soft (nonabrasive) diet for the remainder of the day and not to brush or floss the teeth until the following morning. Under these conditions the varnish remains on the teeth for a number of hours, especially in the pits and fissures, the interproximal and the cervical areas, where it is most needed, releasing fluoride into the immediate environment. If the appearance of the varnish is a problem, coating the facial surfaces of the maxillary anterior teeth can be avoided unless those surfaces have active caries or are at risk for caries. The varnish should be applied once every six months.

## Recommendations:

### Mouthrinsing Programmes

#### Consent Procedure

It is recommended that all written consent forms should, as far as is practicable, incorporate the various component elements of informed consent. Consent forms should give an explanation of the purpose of the mouthrinsing programme including a description of the benefits of the programme that may reasonably be expected and the expected duration of the child's participation in the mouthrinsing programme. The consent form should be written in non-technical, easy to understand, primary school language, and should include a statement as to whom to contact for answers to pertinent questions involving the programme. It is also recommended that consent forms should include some statement to the effect that participation is voluntary, or that 'you may choose not to participate'. A provision may be made for parents or guardians to be given a copy of the consent form. We would recommend that a standard consent form should be designed for use in all health board areas.

#### Exclusion of children from programmes

It is recommended that children should not commence rinsing programmes before the age of 6 years. Any children observed to have a tendency to swallow the rinse should be excluded from the rinsing programme.

#### Reconstitution of Mouthrinse

Based on the information obtained from the situation analysis questionnaire, there would appear to be no need to recommend any changes in the procedures used for reconstituting the rinse in all health board areas. The tap water used in the dilution procedure should be in accordance with the 1998 EU Drinking Water Directive (Council Directive 98/83/EC). There is no evidence to suggest that there is any benefit from using distilled or otherwise purified water routinely when reconstituting the rinse.

#### Duration of rinse

From the situation analysis, it was evident that health board areas are using either a one or two minute fortnightly mouthrinsing procedure. It has been

reported (Fejerskov *et al.*, 1996) that it is standard in the United States to use a 1 minute rinse in school based programmes, however, it should be noted that some of these programmes are carried out weekly rather than fortnightly. We are not aware of any studies comparing the relative effectiveness of 2 minute or 1 minute fortnightly school based mouthrinsing programmes.

However, as studies conducted in Ireland have demonstrated the effectiveness of a two minute rinsing procedure. We recommend, however, that studies should be carried out to determine the relative effectiveness of 2 and 1 minute rinsing procedures. If a one minute rinse is shown to be equally as effective as a 2 minute rinse, then the 1 minute rinse should obviously be adopted as the standard.

#### Disposal of used rinse

It is recommended that the used rinse should be treated as 'clinical waste' and disposed of accordingly. In this regard, the procedure adopted in some health board areas of double wrapping the used rinse in clinical waste disposal bags and returning these to the nearest health centre for disposal, appears prudent.

#### Use of 0.05% daily rinses

Health board dental surgeons and hygienists should consider recommending daily use (at home) of a 0.05% NaF rinse for individuals at increased risk for dental caries. This category includes individuals with active coronal and/or root surface caries; individuals with impaired ability to maintain oral hygiene; individuals wearing orthodontic appliances (banded, bonded and removable appliances) and patients with exposed root surfaces. In addition such rinses can be recommended for use by individuals with reduced salivary flow from disease, medications, chemotherapy and/or radiation treatment (Adair 1998). Fluoride mouthrinses should be used at a time during the day that is different to toothbrushing, in order to have an additive effect to fluoride toothpaste (Oulis *et al.*, 2000).

#### Fluoride Tablets

We do not consider that fluoride supplements have any application as a public health measure as long as community water supplies continue to be fluoridated in Ireland. Furthermore, given the problems with compliance and the increased risk of fluorosis associated with the use of these products we do not consider it appropriate to prescribe fluoride tablets on an individual basis, even to patients considered at high risk of dental caries. We recommend that other fluoride modalities, such as professionally applied topical fluoride varnishes, should be considered for use in high risk patients.

#### Fluoride Gels

Professionally applied fluoride gels should only be considered for use on individuals regarded as high caries risk who are over the age of 4 years (Oulis *et al.* 2000). It is recommended that gels should be applied using the direct technique with appropriate care and attention to minimize the amount of fluoride ingested and in accordance with the following guidelines:

#### Direct Technique:

Keep gel out of reach of the patient

Never leave the patient unattended throughout the procedure

Isolate the teeth one quadrant at a time using cotton wool rolls.

Dry isolated teeth with compressed air and apply gel with a small brush or cotton wool pledget held in tweezers.

Apply gel to all tooth surfaces, especially into the inter-dental spaces from buccal and lingual sides.

Apply gel for 4 minutes and use a saliva ejector throughout the procedure.

After 4 minutes remove gel from accessible tooth surfaces using a cotton wool roll or gauze. Do not attempt to remove it from approximal tooth surfaces

Instruct the child to expectorate (spit out) thoroughly but not to rinse. Alternatively use a saliva ejector for 30 seconds after the gel application

Advise the patient not to eat or drink for half an hour

At present there is no reliable evidence to alter the recommendation that gels should be applied twice a year in caries susceptible individuals. The latter recommendation may need to be altered in the light of a systematic review of the effectiveness of fluoride gels currently being carried out by Marinho *et al.*, (2001).

#### Fluoride Varnishes

High concentration fluoride varnishes can play an important role in preventing and controlling dental caries among groups and persons at high risk. Fluoride varnishes should be considered for use on patients with initial carious lesions, the medically and physically disabled, for early childhood caries and root caries, and for the treatment of hypersensitivity occurring as a consequence of gingival recession and exposed root surfaces. Given their reported effectiveness, ease of application, and safety, fluoride varnishes have definite advantages over other types of topical fluoride treatment. As fluoride varnish is reported to be as effective as APF gel and is free of the important disadvantages of gel applications it should be considered a preferable form of topical fluoride application.

We also recommend that fluoride varnishes should be considered for use in treating specific sites of caries activity, for example early enamel demineralisation at the cervical margins of teeth in older children and adults (Andlaw and Rock 1996; Fejerskov *et al.*, 1996). Fluoride varnishes should also be considered for use as a preventive adjunct to reduce enamel demineralization adjacent to orthodontic brackets, particularly in patients who exhibit poor compliance with oral hygiene and home fluoride use.

If varnishes are being used on pre-school children the amount applied should be the minimum necessary to cover the sites at risk. The best available evidence would suggest that fluoride varnishes should be applied bi-annually using the following technique:

The varnish should be applied *in a thin layer to clean, dry teeth* using a disposable brush or applicator until the teeth are completely covered. Once the varnish is applied, contamination with saliva is not a concern because the varnish sets quickly, even when exposed to moisture. An application takes one minute in the usual child patient. Patients (and parents) are instructed to maintain a soft (nonabrasive) diet for the remainder of the day and not to brush or floss the teeth until the following morning. Under these conditions the varnish remains on the

teeth for a number of hours, especially in the pits and fissures, the interproximal and the cervical areas, where it is most needed, releasing fluoride into the immediate environment. If the appearance of the varnish is a problem, coating the facial surfaces of the maxillary anterior teeth can be avoided unless those surfaces have active caries or are at risk for caries. The varnish should be applied once every six months.

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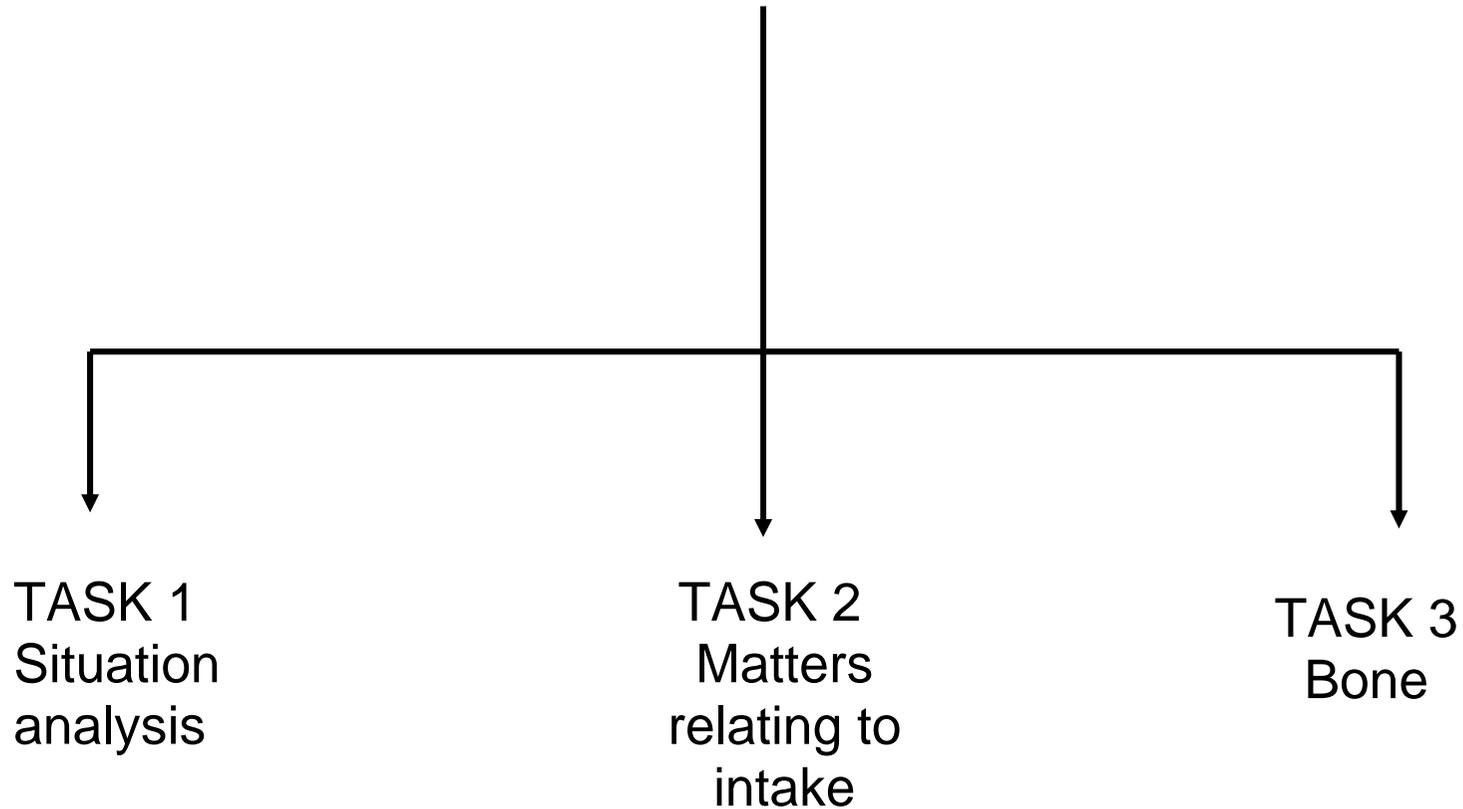
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# Appendix 2



OHSRC

# LOT 2 - FLUORIDES





OHSRC

In TASK 2, the OHSRC undertook to:

- Develop methods measuring total dietary intake by 2-3 year old children
- Train Health Board staff in taking appropriate samples (dietary, saliva, urine, fingernails)

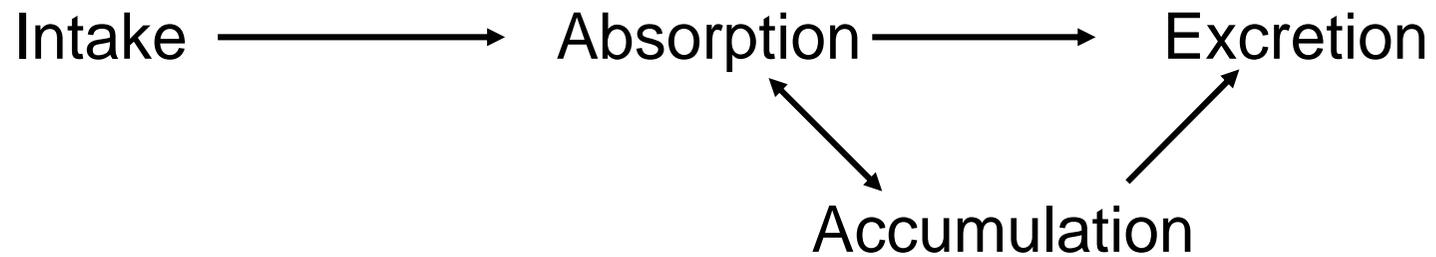




## TASK 2 –

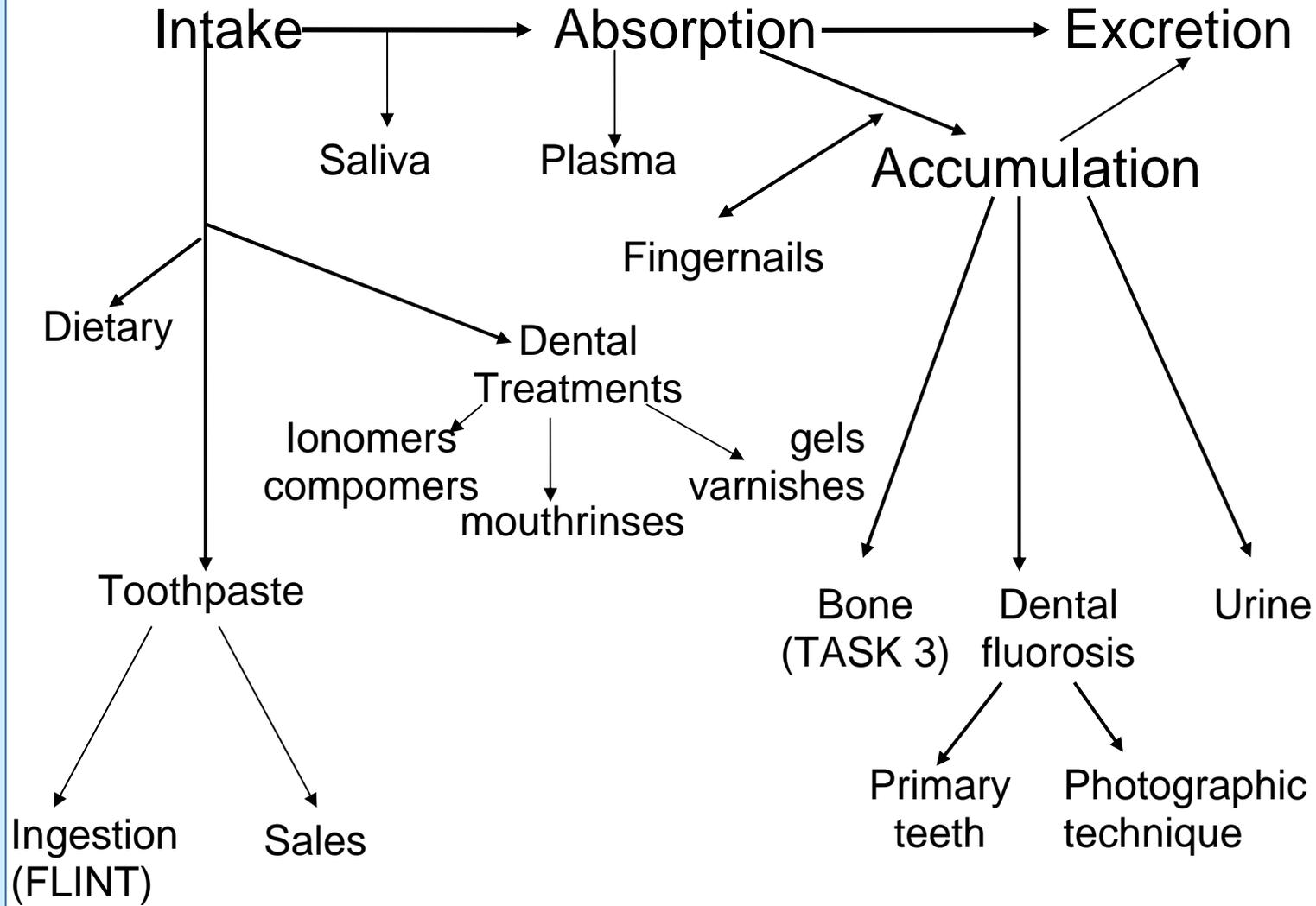
OHSRC

### Matters relating to intake





# TASK 2 – Matters relating to intake

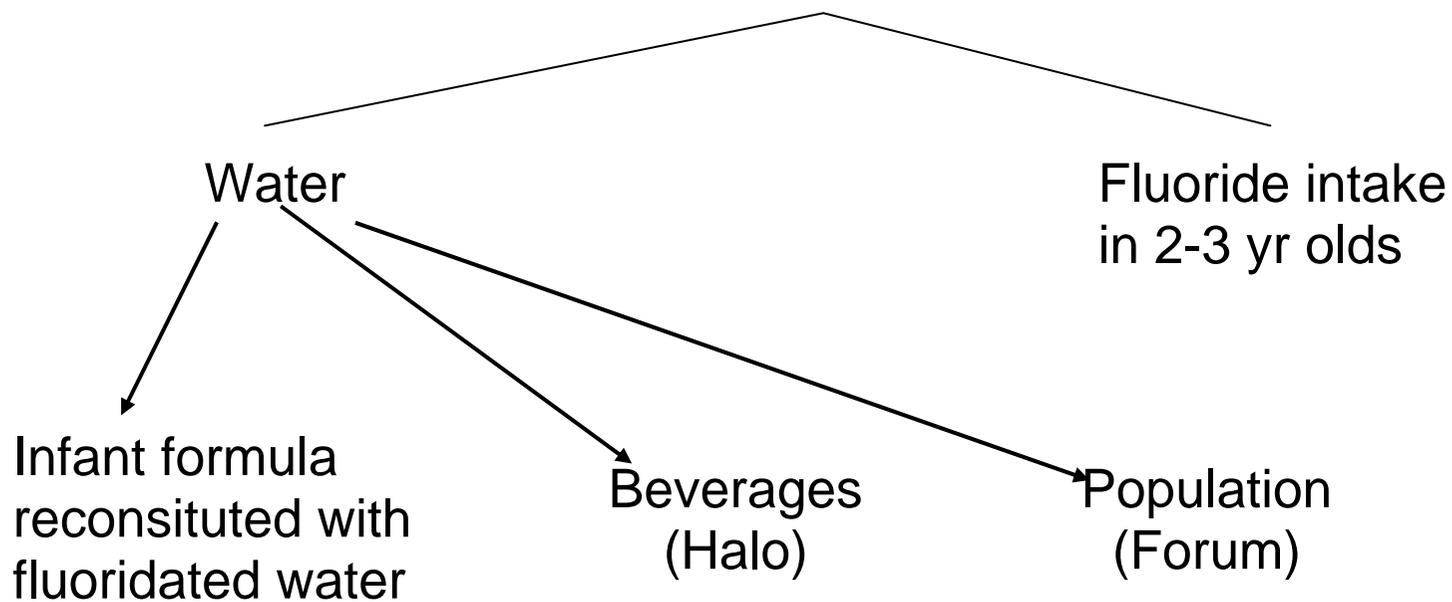




# TASK 2 (A) –

OHSRC

## DIETARY FLUORIDE INTAKE





**OHSRC**

# Rationale

Development of dental  
fluorosis  
in maxillary central incisors  
occurs between the ages of  
2 and 3 years





OHSRC

## PILOT STUDY

### **Aims:**

- Which method of dietary assessment (Three day diary or Duplicate Portion), is the most practical & convenient for parents
- Develop methods of fluoride analysis of resultant dietary samples (international collaboration)





OHSRC

Method	Advantages	Disadvantages
<b>DUPLICATE PORTION</b>	<ul style="list-style-type: none"><li>•User friendly</li><li>•Less analysis</li><li>•Cost</li><li>•Record book</li></ul>	<ul style="list-style-type: none"><li>•Validation</li><li>•More fieldwork</li><li>•Accuracy</li></ul>
<b>THREE-DAY DIARY</b>	<ul style="list-style-type: none"><li>•Individual items F conc</li><li>•WISP</li><li>&gt;&gt; validation</li><li>&gt;&gt; incentive</li></ul>	<ul style="list-style-type: none"><li>•Less user friendly</li><li>•More sample preparation and analysis</li><li>•Cost</li></ul>





OHSRC

# Outcomes of pilot study

Protocols and SOP's:

- Three-day diary
- Duplicate portion
- Fluoride analysis of dietary samples





OHSRC

# Recommendations

- Duplicate Portion with record book
  - Contributors isolated
  - Time (analysis)
  - Cost
  - Future needs of Health Boards?

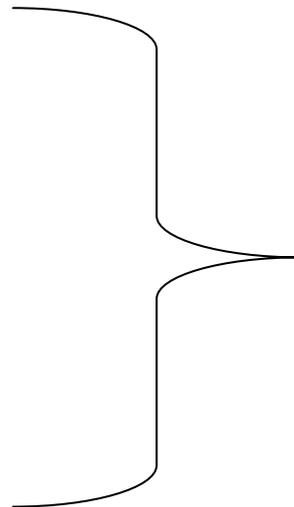




**OHSRC**

## Methodologies relevant to TASK 2:

- Diet
- Saliva
- Fingernails
- Urine



Fieldwork  
&  
Analysis (plasma)



## **NARRATION OF ATTACHED SLIDES**

**(Presented to the Lot 2 user group at the OHSRC in July 2003)**

SLIDE 1 : Reiterates the breakdown of Lot 2 into its component Tasks.

SLIDE 2: Outlines the Oral Health Services Research Centre's undertakings in Task 2 – "Matters relating to Intake". The methods of dietary assessment investigated were the three-day diary (weighed intake) and the duplicate portion technique. These methods of dietary assessment are explained in Appendix 4. With regard to training of Health Board staff in taking appropriate samples relevant to "Matters relating to intake", it is advisable that training exercises would not be undertaken by the Health Boards until it is decided what samples are to be collected and by whom.

SLIDE 3 : Flow diagram of the approach taken to Task 2 – "Matters relating to Intake". These matters revolve around the aspects of INTAKE, ABSORPTION, EXCRETION and ACCUMULATION of fluoride in the body.

SLIDE 4 : INTAKE of fluoride can occur in different forms – dietary, dental treatments (Filling / restorative materials, gels, varnishes), and through toothpaste ingestion. The OHSRC has worked extensively on the matter of fluoride intake from toothpaste in the 2-3 year old age group in a number of European countries (BIOMED 2). The issue of toothpaste sales was investigated, however, sufficient data was not available for this project. The user group has received a comprehensive report on fluoride containing restorative materials and OTC mouth rinses in the May 2002 progress report. The use of gels and varnishes is dealt with in Task 1 of the project.

Research undertaken in relation to dietary intake is outlined in a later slide. Between INTAKE and ABSORPTION, salivary fluoride branches off. This is due to the fact that it bears a relationship to both functions (research is continuing in this area under another project).

ABSORPTION of fluoride; biomarkers of fluoride intake include fingernail and plasma fluoride levels. Fingernail fluoride can be a useful indicator of fluoride accumulation in the body and work carried out in this area is also included in the report.

ACCUMULATION; Fluoride, which accumulates in the body associates with calcified tissue, i.e. teeth and bone. A photographic technique for measuring dental fluorosis has been previously developed by the Research Centre, and an investigation into detection of fluorosis by the TSIF index in primary teeth is also in progress. The issue of fluoride accumulation in bone is dealt with under Task 3 of the project.

EXCRETION: 90 – 95% of fluoride excreted is via the urine. The OHSRC is and has been involved in an international collaborative exercise involving 7 laboratories, to standardize methods of analysis for fluoride in foodstuffs, plasma, bone and urine.

- SLIDE 5 : TASK 2(A); Dietary fluoride intake in relation to Lot 2 involved piloting two methods of dietary assessment of 2-3 year old children to ascertain which was more practical and convenient for parents in the home situation. Other dietary intake matters investigated at the Research Centre include levels of free fluoride in infant formula reconstituted with fluoridated water (Appendix 6). Lot 10 will also investigate fluoride intake in infants (Appendix 7). A report on the fluoride content of a number of beverages was enclosed in the May 2002 progress report, as well as work pending in relation to fluoride levels in tea.
- SLIDE 6 : Outlines of rationale behind investigating dietary fluoride intake in this age group.
- SLIDE 7 : Aims of the pilot study.
- SLIDE 8 : Tabulated qualitative results of the pilot study, as outlined in Appendix 4.
- SLIDE 9 : Outcomes of the pilot study.
- SLIDE 10 : Recommendations based on the results of the pilot study, as outlined in Appendix 4.
- SLIDE 11 : Fieldwork and analytical methodologies relevant to Task 2 – “Matters relating to intake”.

# Appendix 3

## Editorial

### The evidence base for topical fluorides

Despite reductions in the prevalence and severity of dental caries in children, adolescents and young adults, significant numbers of individuals and communities are considered to be at high caries risk or indeed caries active. Faced with such individuals and communities dental professionals have a variety of methods that can potentially alleviate the problem primarily by delivering fluoride to the surfaces of teeth once they have erupted. Whilst the effectiveness of topical fluorides in preventing caries has been widely recognised for some time, perhaps they are not being used to their best advantage. Are you confident that you have access to robust evidence? What about evidence concerning factors that might influence the potential benefit of topical fluorides such as initial caries severity, background fluoride use, duration and frequency of use and concentration of fluoride? Also is the information presented in a consistent way using similar measures so that you are able to make sensible comparisons between the different topical fluorides? The Cochrane Oral Health Review Group has had the pleasure of editing and publishing an excellent series of systematic reviews on topical fluorides conducted by a single review team comprising; Valeria Marinho, Julian Higgins, Stuart Logan and Aubrey Sheiham. The protocols for this series of seven reviews were published between 1998 and 2000 on the Cochrane Library (Marinho *et al.*, 2003a,b,c,d,e,f,g). The first four reviews comparing fluoride gels, varnishes, rinses, toothpastes with placebo, or no treatment have now been completed and are published by the Cochrane Oral Health Group on the Cochrane Library (Issue 2, 2003) (Marinho *et al.*, 2003a,b,c,d). The remaining three systematic reviews are expected later this year. The review team have undertaken a monumental task in conducting these reviews that so far include 140 trials and over 67,000 children. It is a condition attached to undertaking a Cochrane review that reviews are updated usually every two years. Hence the review team have provided the dental community with a very valuable resource, an up-to-date evidence-base for the use of topical fluorides to prevent caries in children and adolescents. The reviews have all been conducted according to the Cochrane handbook using strict methodological principals (Clarke and Oxman, 2003). These methods draw on the experience of various Cochrane methods working groups. Methodologists within these methods working groups promote and support relevant empirical methodological research and help to improve the validity and precision of the Cochrane reviews. As part of the Cochrane Oral Health Group editorial process all protocols and reviews are carefully peer reviewed by members of the editorial team and by several international referees prior to publication on the Cochrane Library. A contact editor is appointed for each review and he/she ensures that all the referees' comments have been adequately addressed. One of the advantages of the publication of a series of reviews in this manner is that they can be compared with each other as similar methodology and outcome measures have been used. Cochrane reviews are conducted to maximise the effort and minimise the duplication of people conducting reviews. This series of reviews were based on the same comprehensive search strategy, which was applied to over ten electronic databases including the Cochrane Oral Health Group Trials Register. Decisions about whether trials were included, the quality assessment and the data extraction were duplicated in a random sample of one third of the studies. The selection of a topical fluoride procedure should be based on three general

considerations. First, the procedure should be effective in preventing dental caries. Second, it should be safe and, lastly, it should be easy to use and acceptable to the patient. The main question addressed by all these reviews is how effective is the use of each topical fluoride for the prevention of caries in children when compared to placebo or no treatment. All four topical fluorides were found to be effective. The outcomes used were preventive fraction and absolute reduction in DMFS. The preventive fraction (PF) is the difference between the mean control and test group increments, as a percentage of the control group increment, and is more commonly referred to as 'percentage caries reduction'. The preventive fractions ranged from 24% for fluoride toothpaste to 46% for fluoride varnish (rinses 26%, gel 28%). In terms of absolute reduction per year in D(M)FS increment, these ranged from 0.46 for gel to 0.74 for varnish (rinses 0.56, toothpaste 0.62). The reviews were generally not capable to look at safety as the trials rarely provided information on fluorosis and other side effects. In the toothpaste review the reviewers concluded that the lack of data on enamel fluorosis is likely, in part, to reflect the type of studies considered, the age ranges of the participants in such trials (five year olds and above), and the usual duration of two to three years. The reviewers concluded that although fluoride varnishes are generally considered safe and well accepted there is a lack of evidence on safety. This lack of direct evidence from clinical trials on relevant outcomes other than caries increments in all the reviews makes it more difficult for clinicians and policy makers to weigh the relative benefits of topical fluorides in preventing caries against potential negative effects. The ease of use and patient acceptance of the different topical fluorides were also not assessed in the trials underpinning these reviews so the reviewers are unable to comment on this aspect. Apart from confirming the relative effectiveness of 2 topical fluorides, these reviews address several other issues of interest. In the fluoride gel review the PF for the nine studies which compared the gel with a no treatment control group was 38% which was significantly greater than the 21% for the 14 studies comparing the gel to a placebo. The reason for this is unclear although the reviewers postulate that the double blind studies using the placebo gel are possibly of higher quality. However, a recent study comparing trials using placebo interventions with those using no treatment interventions concluded that there was no evidence that the placebo interventions in general have clinically important effects (Hróbjartsson and Gøtzsche, 2003). No difference between these two groups of studies was apparent in either the fluoride varnish or fluoride rinse reviews. Another important question for dental health professionals is whether the effect is associated with the initial caries severity of the children. Only the fluoride toothpaste review found that higher preventive fractions were statistically significantly associated with higher levels of caries. None of the reviews found a significant association between the size of the effect and different background levels of fluoride from water fluoridation, toothpaste and other sources. There were also no statistically significant associations between the PF and the duration of the study in any of the reviews. However, there was some evidence that frequency of use and fluoride concentration were associated with a greater PF with the gel, toothpaste and to a lesser extent, fluoride rinse. Supervised brushing was significantly associated with a higher PF in the toothpaste review. It is interesting to compare the results of these reviews to those of the systematic review on water fluoridation conducted by the NHS Centre for Review and Dissemination at York, in terms of reducing caries (NHS Centre for Reviews and Dissemination, 2000). The York review included studies in which a baseline examination had been conducted prior to the implementation of water fluoridation using a before and after study design. In other words caries examinations were

conducted in two areas, one of which was to be fluoridated the other serving as the control. Several years after fluoridation had been implemented different children living in the same areas were examined. The measure of effect used in the main analysis in this review was the difference of the change in caries from the baseline to the final examination in the fluoridated compared with the control area. For example, the change in DMFT in the fluoridated area (final survey minus baseline survey values) minus the change in DMFT in the control (non-fluoridated) area (final minus baseline survey values) is the *difference* in the change in DMFT for that study. The two main outcomes investigated by studies estimating the effect of water fluoridation on caries were DMFT (and dmft) scores and the percentage of caries free children. The main finding was a mean change of 2.25 teeth and a median change of 15% caries free. A comparison with the Cochrane topical fluoride reviews is difficult as the outcomes in these reviews were PF and absolute reduction in DMFS. It is important to emphasise that a change of 15% in caries free is a huge reduction in caries. In 1994 the Department of Health set the following target for caries in five year olds in England for 2003; namely that 70% of 5-year old children should have no caries experience (DoH, 1994). In the 2001/2002 BASCD survey 61% of 5-year old children in England were caries free; in the North of England this figure fell to 51% (Pitts *et al.*, 2003). The implementation of water fluoridation would improve these figures to 76% and 66% respectively thus meeting the 2003 target in England overall and reducing caries substantially in areas with higher levels of disease. A similar measure to the PF may be calculated for the comparisons in the York review, where the change in DMFT in the fluoridated group (usually a reduction) can be divided by the final mean score in the control group (rather than the change in the control group mean which will generally be around zero). This intuitively makes sense, as the children in the fluoridated water group will generally have been exposed to the intervention for several years and often from birth. This can be thought of as a sort of 'preventive fraction'. If this is calculated for the 19 comparisons for permanent teeth with data available for both DMFT and percent caries free then the median 'preventive fraction' is 40%, which corresponds to a median percent change in caries free of 13%. So for the same level of effect, percent change in caries free is substantially smaller than the equivalent 'preventive fraction'. This concept is further illustrated in a recently published randomised controlled trial in which toothpaste was provided to children from birth. In this study the 16% preventive fraction (as defined in both the topical fluoride reviews and above) was equivalent to a change of 8% caries free (Davies *et al.*, 2001). It is hoped that the results of the York review are not being wrongly interpreted since a 15% change in caries free is not equivalent to a 15% preventive fraction but probably to a 'preventive fraction' in the order of 40%. This is in line with the more effective topical fluoride agents and is further evidence of the effectiveness of water fluoridation. The three remaining topical fluoride Cochrane reviews from the series are eagerly anticipated. Two of these reviews compare different topical fluorides either singly or in combination with each other, and the third review brings the findings of the six reviews together in a comprehensive summary. The results of this series of reviews will enable clinicians and policy makers to make informed decisions about the use of topical fluorides. The abstracts for the Cochrane reviews can be freely accessed on <http://www.cochrane.org>. However the full reviews and protocols can only be accessed by reviewers who have individual subscriptions or who live in countries which have negotiated free Cochrane library access (for example England, Wales and Denmark, among others). The water fluoridation review may be accessed on <http://www.york.ac.uk/inst/crd/fluorid.htm>

In using the Cochrane reviews you can be confident in having access to robust evidence that will be updated as new trials are published. The important questions for today's practice need to be considered and if the evidence is lacking in any area as may be demonstrated in these reviews, this will be the best indicator for future research.

*Helen Worthington*

*Co-ordinating Editor, Cochrane Oral Health Group*

*Jan Clarkson*

*Editor, Cochrane Oral Health Group*

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# Appendix 4

# DIETARY FLUORIDE INTAKE IN 2 – 3 YEAR OLD CHILDREN

## **Background**

As described. Task 2 involves drawing up protocols for different components parts of measuring total body burden of Fluoride in 2-3 year old children. This involved a pilot study to determine which of two methods dietary assessment of 2-3 year old children is the most practical and convenient for parents in the home situation. The methods investigated were:

1. Three-Day Diary
2. Duplicate Portion

This was a qualitative study that aimed to develop the methodology of a larger scale study. The methods investigated have also been used in a similar pilot study in the US directed by George Stookey and colleagues at the University of Indianapolis, Indiana. The Three Day Diary has been used in this context by Andrew Rugg-Gunn and colleagues at the University of Newcastle upon Tyne, UK. We have collaborated with both Universities in this study.

## **Pilot Study**

### *Design*

Design of the study was Cross over. Each participant partook in both methods. Both methods were conducted over three consecutive days each, to include one day of the weekend in order to allow for variability in dietary habits at weekends.

## **Three-Day Diary**

In this method of dietary assessment the participant was asked to weigh and record, at the time of consumption, all foods and beverages over a three day period.

The amount of food and beverage served to the child was weighed using a digital balance. Detailed descriptions of the foods and beverages were required, such as brand names, types (low fat, regular, etc), and method of cooking. Follow-up interview of the forth day allowed the investigator to clarify methods of cooking and brands of food / drink consumed, or any other vague entries in the diary. The interview also allowed the investigator to receive feedback on the manageability and accuracy of the method. Foods and drinks consumed were purchased by the investigators and taken for laboratorial analysis.

The foods listed in the diary must be quantified, coded individually, sourced and purchased before any laboratory analysis could take place. Then each individual food is homogenized and tested in triplicate for total fluoride content. Given that a food diary for this age group contains anything up to 50 different consumable items over three days, this means a lot of coding, analyzing etc. The method was also found to be more cumbersome to three out of four of the parents in this pilot study than the duplicate portion and these three participants also felt that parents would find it easier to comply with the duplicate portion method of dietary assessment.

## **Duplicate Portion**

This method involved the duplication, by the participant, of all foods and beverages consumed over three days. Since there is no official data on the fluoride content of specific foodstuffs, we were naturally very interested in isolating foods or drinks which may be contributing to high dietary fluoride intake. The duplicate portion method did not suit our needs in this regard since what we were collecting was a mix of duplicated foods and a mix of duplicated drinks consumed by a child on a given day, and no data on what was actually in the mixes. In order to address this downfall with the technique, it was decided to introduce a record book with the method, whereby parents would also record what it was they were placing in the container. This allowed the investigators to see, where intakes of fluoride were elevated, what may be contributing to the high fluoride level. The food/drink could then be tested for fluoride to confirm this. The duplicate portions were stored in containers provided by the investigators in a refrigerator until collection the following day. Participants were provided with a liquids container and a solids container for each day of the study, the investigators also conducted a follow up interview with the participants the day following completion of the method. Again, feedback from the participants on how manageable and practical they felt the technique would be for parents was gathered. The food for one day was homogenized and analyzed for total fluoride, as was also the case with liquids. The advantage with this method is that the actual diet of the participant is analyzed directly without the use of food consumption tables, which may not include food items actually consumed, moreover, in this instance, fluoride values are not widely available in food consumption tables. It is therefore considered to be the most accurate way of sampling the diet.

The biggest problem with the duplicate portion was the fact that the contributors to suspiciously high dietary intakes of fluoride would not be isolated. The record book, which we introduced in conjunction with this method, addresses this problem in a very satisfactory way. It served the investigators in this study in three ways – first of all at the home of the participants, in that the investigators could see what was actually in the container and written in the record book, i.e., that the parents weren't putting leftovers into the containers. It is also very useful in isolating contributors to elevated fluoride intake as described earlier. All four parents who participated in this pilot study did, however, feel that the three-day diary was a more accurate way of assessing their child's diet.

## **Conclusion**

In terms of the needs of the Health Board in attempting to assess and evaluate the dietary intake of 2-3 year old children, it is our contention as the researchers of this project, that the duplicate portion method of dietary assessment is most practical specifically for this age group. The laboratory facilities available to the Health Board through the OHSRC would be best utilized in this regard by employing the duplicate portion method of dietary assessment. This is true also in terms of monetary cost to the Health Board with respect to labour, equipment, materials and consumables. Results of the duplicate portion method of assessment compare satisfactorily with previous investigators – results overleaf.

**RESULTS OF DUPLICATE PORTION METHOD OF DIETARY ASSESSMENT FOR FLUORIDE INTAKE**

<b>SUBJECT</b>				
<b>IDENTITY</b>				
		<b>MEAN</b>	<b>STANDARD DEVIATION</b>	<b>RANGE</b>
202	<b>AVERAGE DAILY FLUORIDE INTAKE FROM SOLIDS (mg)</b>	0.04	0.01	0.03 -0.05
	<b>AVERAGE DAILY FLUORIDE INTAKE FROM LIQUIDS (mg)</b>	1.27	0.40	0.87 - 1.67
	<b>AVERAGE DAILY DIETARY FLUORIDE INTAKE (mg)</b>	1.31	0.40	0.91 - 1.71
	<b>WEIGHT OF SUBJECT (Kg) (see individual file)</b>	15.00		
	<b>AVERAGE FLUORIDE INTAKE (mg/Kg/day)</b>	0.09	0.03	0.06 - 1.2
204	<b>AVERAGE DAILY FLUORIDE INTAKE FROM SOLIDS (mg)</b>	0.014	0.00	0.009 - 0.011
	<b>AVERAGE DAILY FLUORIDE INTAKE FROM LIQUIDS (mg)</b>	0.014	0.00	0
	<b>AVERAGE DAILY DIETARY FLUORIDE INTAKE (mg)</b>	0.029	0.00	0.028 - 0.030
	<b>WEIGHT OF SUBJECT (Kg) (see individual file)</b>	12.500		
	<b>AVERAGE FLUORIDE INTAKE (mg/Kg/day)</b>	0.002	0.000	0
103	<b>AVERAGE DAILY FLUORIDE INTAKE FROM SOLIDS (mg)</b>	0.09	0.01	0.08 - 0.1
	<b>AVERAGE DAILY FLUORIDE INTAKE FROM LIQUIDS (mg)</b>	0.20	0.04	0.16 - 0.24
	<b>AVERAGE DAILY DIETARY FLUORIDE INTAKE (mg)</b>	0.29	0.05	0.24 - 0.34
	<b>WEIGHT OF SUBJECT (Kg) (see individual file)</b>	13.50		
	<b>AVERAGE FLUORIDE INTAKE (mg/Kg/day)</b>	0.02	0.00	0.016 - 0.024
105	<b>AVERAGE DAILY FLUORIDE INTAKE FROM SOLIDS (mg)</b>	0.09	0.02	0.07 - 0.11
	<b>AVERAGE DAILY FLUORIDE INTAKE FROM LIQUIDS (mg)</b>	0.22	0.03	0.19 - 0.25
	<b>AVERAGE DAILY DIETARY FLUORIDE INTAKE (mg)</b>	0.31	0.05	0.26 - 0.36
	<b>WEIGHT OF SUBJECT (Kg) (see individual file)</b>	16.00		
	<b>AVERAGE FLUORIDE INTAKE (mg/Kg/day)</b>	0.02	0.00	0.017 - 0.0230

# Appendix 5

## Development of Standard Fluoride Analytical Methods: Pilot Study

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Currently available fluoride measurement techniques are not standardized and a universal standard for fluoride determination has not been established. The current study aimed at obtaining a preliminary measure of agreement among different laboratories. Eight collaborating laboratories analysed a common series of samples, and inter-laboratory correlation coefficients (ICC) were calculated for this exercise. The 25-sample set included standard fluoride solutions, beverage samples and biological samples: urine, mineralised, and plasma samples. Each laboratory analysed the set of samples, in duplicate, using their own methods. Standard fluoride solutions were analysed using the direct method; plasma samples were analysed using the diffusion method; while urine, saliva, mineralised and beverage samples were analysed using either the direct or the diffusion method. Statistical analyses found that for standard fluoride solutions ICC among the eight participating laboratories was almost perfect (0.99). The results that showed the largest differences from the target value, as well as the largest standard deviations, were mostly found for the lower concentration standards. The greatest coefficients of variation, which in this case are a measurement of agreement, were found for saliva samples. For beverage and urine samples the ICC value among laboratories were fair (0.71) to good (0.96), respectively, indicating less agreement among laboratories for beverage samples. Results for this pilot demonstrated that there is no consensus regarding the choice of techniques for different types of samples. Statistically significant differences among the results submitted by the different laboratories occurred for samples with low fluoride concentrations (<0.2 ppm) and for certain types of samples, especially saliva, urine and beverages.

# Appendix 6

Fluoride levels in powdered infant formula diluted with fluoridated water  
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**Objective:** To measure the level of ionic ('free') fluoride in powdered infant formulas prepared with fluoridated water. **Background:** The bio-availability of fluoride from infant formulae reconstituted with fluoridated water may vary depending upon the mineral and other content of the different formulae. (Spak, CJ et al. *Caries Res* 1982; 16: 249-256). **Methods:** Six commercially available infant formulae were purchased OTC, 4 for use from birth onwards and 2 for use by infants aged 6 months and older. The latter contained higher levels of minerals including calcium and magnesium. The six formulae were reconstituted with fluoridated water (0.8ppmF); manufacturer's instructions were followed when mixing powder and water. The ionic fluoride content of the reconstituted feeds was measured using the fluoride ion-specific electrode (Orion model 94-09) and reference electrode (Orion Model 90-01) immediately after mixing and after 1, 2, 3, 4, 5, 6, and 24 hours. The experiment was repeated at least twice for all six formulae. **Results:** In the case of the 2 formulae recommended for use from age 6 months onwards, the mean reduction in 'free' fluoride were 14% and 36% respectively. For all 6 formulae there was no difference between the level of 'free' fluoride recorded immediately after mixing and that recorded at each of the six measurements taken over the subsequent 24 hours. **Conclusion:** There is a wide variation in the level of ionic ('free') fluoride in the different powdered infant formulae reconstituted with fluoridated water.

# Appendix 7

## **FLUORIDE INTAKE IN INFANTS STUDY SUMMARY**

### **Objectives**

The main objective is to investigate formula feeding practices in infants aged 8-16 weeks in order to provide a basis for estimating fluoride intake from tap water.

### **Rationale**

The principal determinants of fluoride intake in formula fed infants residing in fluoridated regions are the fluoride concentration in drinking water and the volume of water consumed. Reconstituted formula is likely to be the major source of intake of tap water, although there may also be some contribution from drinks and solid foods mixed with tap water.

### **Study Design**

Eighty infants aged 8-16 weeks, with equal numbers of boys and girls, will be selected randomly from the child health registers of 4 public health nurses (PHN) in 4 separate areas of Cork city and environs. Twenty infants will be selected from each of the 4 areas. The residents of 2 of the areas will be predominantly medical card holders and the other 2 areas will have a mixed population of medical card holders and non-holders, to give an even socio-demographic spread to the sample.

Permission to contact the parents of each infant will be obtained on behalf of the researchers by the PHN during the primary (3 week) and developmental (12 week) visits of the infant to the PHN clinic. The research nurse will subsequently contact parents to make an appointment to visit them at their home. Infants who are fed on infant formula (and not currently breastfed), and who satisfy all other inclusion criteria, will be eligible for entry into the study and informed written consent will be obtained during the first appointment.

Consumption of formula at each feed, consumption of other fluids, and consumption of solid foods over a period of 4 days will be recorded by the parent(s) using a food diary. Samples of infant formula will be collected and analysed for fluoride concentration. Compliance of parent(s) with manufacturer's instructions for reconstitution of the formula will be evaluated by analysing the formula samples for moisture content.

Data will be entered into an electronic database and analysed using SAS.

The main outcome measures will be:

- Daily volume of tap water consumed from formula, other drinks and solid foods
- Degree of compliance with manufacturer's instructions for reconstitution of the formula

### **Progress to Date**

21 infants have been enrolled into the study. Formula samples, tap-water samples and feeding diaries have been collected. Samples have been frozen and will be analysed for fluoride content (formula and tap-water) and moisture content (formula) when a sufficient number have been collected.

The Research Nurse will continue to recruit infants of the appropriate age.

# Appendix 8

## Properties of Common Beverages relevant to Dental Health

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### Abstract

The consumption of soft drinks has increased recently. Levels of consumption are over 50% greater than in 1988. Children under five years of age consume, on average two litres a week. Fruit-flavoured drinks with some added pure fruit juice are particularly popular with young children. They are often seen as a healthier alternative to fizzy drinks, due to their fruit and vitamin content, however studies show that they contain similar sugar levels to Coca-Cola and most are highly acidic which may be detrimental to dental health. The aim of this study is to investigate factors associated with common beverages, which may affect oral health. The factors investigated were; pH and fluoride content. The pH of the drinks is of interest because of its potential to cause erosion. Fluoride content is important because on one hand it may help to resist erosion and on the other hand if it is too high it may contribute to the development of dental fluorosis. Samples of drinks were collected from Ireland and Oman. The pH was analysed directly using a pH meter. Fluoride content of the selected samples was measured using the fluoride ion-specific electrode (Orion Model 94-09) and reference electrode (Orion Model 90-01). Results: The pH of all the carbonated soft drinks and most of the fruit drink samples from the two cities were found to be lower than 5.5 which renders them potentially erosive. There was little difference between the pH of carbonated soft drinks (in Cork, average pH = 3.19) and the pH of 'fruit' type drinks (in Cork City average pH = 3.31). It was found that all of the samples of leading drinks from Cork City had lower levels of fluoride (0.02 ppm – 0.87 ppm) than the public fluoridated water (1ppm). In conclusion the pH of soft drinks and most of the 'fruit drinks' are below the "critical" level that renders them potentially erosive. The frequent consumption of low fluoride containing beverages is a cause for concern. Further research in this area is recommended.

### Introduction

The sales of soft drinks have increased in the last 20 years. Levels of consumption are over 50% greater than in 1988 (WHICH, 2000). One soft drinks company reported an increase in sales of 17.3% in 1999 alone (CCBI).

It has been reported that children under five years of age consume on average two litres of soft drinks a week (WHICH 2000). Fruit-flavoured drinks with added pure fruit are particularly popular with young children. Parents often see them as a healthier alternative to fizzy drinks. However, studies show that many of these drinks contain similar sugar levels to Coca Cola and are highly acidic (WHICH, 2000). The pH of the drinks is of interest because of the potential to cause erosion. Therefore frequent and increased

consumption of these drinks by the population may increase dental erosion levels (Larsen MJ and Nyvad B, 1999).

The change in pattern of liquid consumption by children with displacement of milk and water from the diet is likely to influence the effectiveness of water fluoridation in preventing dental caries if the fluoride content of these drinks is lower than in the natural drinking water (Turner et al, 1998). For example, in Cork City, Ireland fewer people are directly consuming the optimally fluoridated (1ppm) water. In other regions where there is natural water fluoridation, for example in Jalaan City, Oman (Middle East) similar problems are arising with a reported increase in the consumption of soft drinks.

On the other hand, if the fluoride content of these popular drinks is higher than the level in the drinking water, increased consumption of these drinks may contribute to the development of dental fluorosis (Turner et al, 1998).

The aim of this study was to measure the pH and fluoride content of the top selling soft drinks/fruit juices/carbonated water from Cork City, Ireland and Jalaan City, Oman. The subsidiary aims of the study were a) to compile an information database on the pH of regularly consumed drinks, b) to compare the fluoride content in common beverages consumed in Cork City with that of fluoridated water in Cork City (1ppm) and c) to compare fluoride levels in soft drinks/bottle water/tap water in two communities – Cork City, Ireland and Jalaan City, Oman – with widely divergent mean annual daily temperatures.

## Materials and Methods

Information regarding the top selling soft drinks/fruit drinks/bottled water in both cities was obtained by contacting a leading supermarket in each city. Leading brands were then purchased from these supermarkets.

## Samples

### Samples: Cork City, Ireland

Forty one of the top selling soft drinks/fruit juices/carbonated water from Cork City Ireland were obtained.

The forty one samples were divided into the following categories.

- 4 still bottled water samples
- 2 carbonated water samples
- 14 soft drink samples
- 21 fruit drink samples

### Samples: Jalaan City, Oman:

Twenty-four of the top selling soft drinks/fruit juices/carbonated water were obtained from Jalaan City, Oman. In addition, three samples of natural drinking water from different sources were collected for analysis.

The twenty-seven samples were divided into the following categories.

- 3 natural drinking water samples
- 4 bottled water samples
- 11 soft drink samples
- 9 fruit drink samples

### Measurement of pH level

The pH level of each sample was analysed directly using a pH meter.

### Measurement of fluoride content

Fluoride content of the selected samples was measured using the fluoride ion-specific electrode (Orion Model 94-09) and reference electrode (Orion Model 90-01). An appropriate range of sodium fluoride standards was used. All water samples and carbonated soft drinks were measured directly. The fruit drinks were prepared for analysis using the modified 'Taves' method (diffusion). All measurements were repeated three times and the average of the second two readings was recorded.

## Results

### Samples from Cork City, Ireland

#### 1. Still bottled water samples

Water samples	Fluoride (ppm)	pH
Ballygowan still water	0.07	6.6
Volvic still water	0.2	6.14
Riverrock still water	0.08	6.03
Supervalu still water	0.58	6.68

#### 2. Carbonated bottled water samples

Water samples	Fluoride (ppm)	pH
Ballygowan sparkling	0.067	4.88
Supervalu sparkling	0.56	4.66

#### 3. Carbonated soft drinks

Carbonated soft Drinks	Fluoride (ppm)	pH
Coca Cola	0.04	2.37
Diet Coca Cola	0.04	2.82
7up	0.04	3.05
Lucozade	0.02	3.24
Club Orange	0.02	4.8
TK White Lemonade	0.80	3.37
TK Tangerine	0.80	2.91

Schweppes Ginger Ale	0.75	2.7
Supervalu Orange	0.06	3.66
Supervalu Lemon and Lime	0.06	3.02
C&C Club Soda	0.78	4.8
Schweppes Tonic	0.71	2.3
Fanta Orange	0.04	2.71
Tanora	0.84	2.96

#### 4. Fruit drink samples

Fruit drink samples	Fluoride (ppm)	pH
Capri-Sun	0.21	3
Ribena Toothkind blackcurrant	0.05	3.68
Squeez concentrated orange juice	0.35	3.46
Ocean Spray cranberry classic juice	0.04	2.43
Ocean Spray cranberry and raspberry juice	0.05	2.55
Squeez apple juice	0.83	3.25
Squeez orange juice	0.71	3.72
Fruice apple juice	0.91	5.82
Fruice slimline orange	0.71	3.21
Britvic Juice	0.66	3.63
CMP dairy pure juice	0.71	3.63
Kulana orange juice	0.71	3.62
Tropicana orange juice	0.06	2.96
Super valu orange juice	0.48	3.66
Super valu apple juice	0.87	3.32
Valu saver orange juice	0.82	3.83
Drink 10	0.11	3.26
Mi-wadi	0.03	2.53
Sunny Delight California style juice	0.02	2.63
Sunny Delight Florida style juice	0.02	2.73
Ribena	0.06	2.73

Samples from Jalaan City, Oman

#### Natural water supplies

Drink	Fluoride (ppm)	pH
Falag Almahyool (1)	0.37	8.24
Falag Almunjarid (2)	0.37	8.20
Water (Drinking)	0.28	7.84

## 2. Bottled water samples

Water sample	Fluoride (ppm)	pH
Oasis sparkling water	0.009	5.46
Gulfa natural spring water	0.69	5.91
Masafi mineral water	0.009	5.6
Zulal water	0.39	5.6

## Carbonated soft drinks

Carbonated soft drinks	Fluoride (ppm)	pH
Everves Club Soda	0.38	4.97
Royal Strawberry	0.49	3.36
Sprite	0.01	2.85
Kaliber	0.37	4.20
Miranda Apple	0.22	2.98
RC Cola	0.32	2.61
7 up	0.20	3.10
Fanta Orange	0.01	3.29
Miranda Orange	0.44	2.90
Coca Cola	0.01	2.77
Mountain Dew	0.27	2.55

## Fruit drinks samples

Fruit drink samples	Fluoride (ppm)	pH
Unikai Mango	0.01	3
Nakhal Mango	0.05	3.38
Al marouj Mango	0.04	3.63
Sun Top Red Fruit	0.43	2.73
Sun Top Mango	0.32	3.42
Sun Top Pineapple	0.55	3.05
Sun Top Orange	0.38	3
Mango Milk	0.11	6.25
Zain Mango Drink	0.22	3.07

Comparison of results for Cork City, Ireland and Jalaan City, Oman

pH

Type of drink	Cork City	Average	Jalaan City	Average
Bottled water	4.66 - 6.6	5.8	5.46-5.91	5.6
Carbonated soft drinks	2.37 - 4.8	3.19	2.55 - 4.97	3.23
Fruit drinks	2.43-5.82	3.31	2.73-6.25	3.5

## The fluoride content

Type of drink	Cork city	Average	Jalaan City	Average
Bottled water	0.067-0.58	0.26	0.009-0.69	0.27
Carbonated soft drinks	0.02-0.84	0.36	0.01-0.49	0.25
Fruit drinks	0.02-0.87	0.4	0.01-0.55	0.24

## Discussion of the results

The pH of all of the carbonated soft drinks and fruit drinks samples (except only one fruit drink) from the two cities was found to be lower than the “critical” level (5.5), which renders them potentially erosive. Therefore, the increased consumption of these drinks may potentially increase the incidence of dental erosion in the population.

There was little difference between the pH of carbonated soft drinks (in Cork City, average pH = 3.19) and the pH of ‘fruit’ drinks (in Cork City average pH = 3.31). Therefore ‘fruit’ type drinks may have similar potential to carbonated soft drinks to cause dental erosion and should not be considered a safer alternative to carbonated soft drinks in relation to dental health.

The pH of the still bottled water samples of the two cities was found to be higher than the “critical” level that renders them potentially erosive and therefore can be considered safe for teeth. However, consideration should be given to the lower fluoride levels that were found in the Cork samples compared to the levels found in public drinking water of the city (1ppm). It was found that the average bottled water sample, carbonated soft drink and ‘fruit’ drink in Cork had a fluoride content of 0.26 ppm, 0.36 ppm and 0.4 ppm respectively. While in Jalaan City in Oman where the drinking water is sub-optimally fluoridated (average 0.34 ppm) near similar levels of fluoride were found in bottled water (0.27ppm), soft carbonated drinks (0.25 ppm) and ‘fruit drinks’ (0.25 ppm). Increased consumption of these low fluoride drinks will influence both the effectiveness of water fluoridation in preventing dental caries in the population and the validity of findings in studies examining the effectiveness of optimally fluoridated water in preventing dental caries.

## Conclusion

Commonly consumed beverages because of their low pH have an erosive potential. Both carbonated soft drinks and ‘fruit’ drinks have similar potential to cause dental erosion. Still bottled water is considered safer for teeth in terms of the potential to cause dental erosion but may contain less fluoride than fluoridated water supplies. All of the samples of leading soft drinks/fruit drinks/bottled water in Cork City had lower levels of fluoride than the optimally fluoridated water (1ppm) and similar levels of fluoride from drinks consumed

in a sub-optimally fluoridated city. The results of this study should influence the advice given by dental professionals to the public regarding the erosive potential of common beverages. Further studies of fluoride content of commonly consumed drinks are required to inform policy on appropriate use of fluorides in countries.

References:

Larsen MJ., Nyvad B (1999) *Enamel erosion by some soft drinks and orange juices relative to their pH, buffering effect and contents of calcium phosphate.*, Caries Res. 33(1): 81-7

Turner SD, Chan JT, Li E (1998) *Impact of imported beverages on fluoridated and non-fluoridated communities.*, Gen Dent 46(2): 190-3

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Oral Health Services Research Centre

# Appendix 9

## Abstract

For an increasing proportion of the Irish population, mouthrinsing has become a routine concept in their oral care regime. The Irish market for over-the-counter mouthrinse sales is an impressive IR 4.5m and 1.9m litres in volume. Mouthrinse usage has a rational basis since many people experience difficulty in maintaining adequate levels of plaque control, gingival health and breath-freshness.

There has been some debate about certain mouthrinses ingredients due to possible health implications arising from their presence. Foaming agents, alcohol content and fluoride & pH levels have come under scrutiny in several scientific studies.

The aim of this project was to identify the properties of over-the-counter mouthrinses on sale in the Irish Republic. All available OTC mouthrinses were purchased and analysed in a laboratory setting. Factors investigated were: the range of OTC mouthrinses on sale, active agents present, fluoride levels, pH values and alcohol content.

By studying mouthrinses labels, information regarding active agents and alcohol content was collected. Fluoride levels of each sample were measured using the fluoride ion-specific electrode (Orion Model 94-09) and reference electrode (Orion Model 90-01). The pH levels were measured directly using a pH meter.

Results: Thirty-nine mouthrinses were found to be available OTC in the Irish Republic. Twenty-six of these had a stated and verified fluoride concentration of, on average, 226ppmF. Thirteen samples had no stated fluoride level and when analyzed, contained < 2ppmF. All of the fluoridated samples had pH values of above 5.6. Nine of the thirteen non-fluoridated samples had pH values below 5.6, rendering them potentially erosive. Labelling information regarding alcohol content of the samples, while conforming to EU regulations, was ambiguous in the majority of cases.

As mouthrinse properties are constantly being modified, continuing research should be carried out in this important area of oral healthcare.

## General Introduction

The Department of Health through the Eastern Health Board, sponsored a number of research consultancy projects. One such project, entitled Lot 2, is concerned with the quality of preventative fluoride programmes in the control of dental caries in the Republic of Ireland.

The programmes included in this Lot are:

Fluoridation of public water supplies ( to include optimising dosing and monitoring )

Fluoride mouthrinsing

Fluoride toothpaste

Other forms of systemic fluoride supplementation

Combinations of the above ( including matters relating to intake )

The background and relevant issues to the programmes in relation to my project are described below:

### Fluoride mouthrinsing

Fluoride mouthrinsing is widely used as an alternative method of bringing the benefits of fluoride to communities. The first school fluoride mouthrinsing scheme in the Republic of Ireland started in 1968 in non-fluoridated areas of west Co. Waterford. This scheme ran continuously since then and, when it concluded recently, had been one of the longest running fluoride mouthrinsing schemes in the world. In the Waterford scheme, children in national school in 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, and 6<sup>th</sup> classes rinsed every 2 weeks for 2 minutes under supervision in school with 10ml of a 0.2% solution of Sodium Fluoride. Other similar schemes, for example in Cork and Limerick, have been shown to be effective in controlling dental caries, though their cost effectiveness and long-term effect have been questioned. Fluoride mouthrinsing programmes require extensive collaboration between the school authorities, the health board dental service and parents.

### Specific Introduction

The Health Research Board sponsors a Summer Student Scholarship Scheme. This scheme is open to undergraduate medical, dental and science students. It gives students an invaluable opportunity to undertake a research project of relevance to the university department in which the student wishes to work. For a period of 8 weeks, the student is advised and guided in his/her research and compiles a report on his/her findings.

From June 4<sup>th</sup> to July 27<sup>th</sup> 2001, I was privileged to work under the guidance of Professor Denis O' Mullane and Dr. Helen Whelton in the Oral Health Services Research Centre, Wilton, Cork. My project of interest was concerned with fluoride mouthrinsing. All information arising from the project contributed to the central fluoridation project of the Oral Research Centre

### Project Introduction

For an increasing proportion of the Irish population, mouthrinsing has become a routine concept in their oral care regime. The Irish market for mouthrinse sales is an impressive IR4.5m and 1.9m litres in volume (Feb/Mar 01 MAT from AC Neilson data). This adds to the overall oral care market, valued at IR 30m (Checkout Ireland Mar 2001), which is growing annually by 15% ( GSK, personal communication). Mouthrinse usage has a rational basis, since many people experience difficulty in maintaining adequate levels of plaque control and gingival health.

The Oral Health Services Research Centre in UCC is currently conducting a major review of fluoride usage in Ireland, including the use of fluoride-containing oral health products. There are many formulations of mouthrinse available. Some claim to prevent dental caries, others to remove dental plaque or to prevent plaque accumulation. Many of the rinses are targeted at halitosis, others claim a multiple effect.

The principal aims of this project were:

- To ascertain the range of mouthrinses on sale over the counter in Ireland
- To identify the active agents present
- To validate the fluoride content stated on the label
- To ascertain a value in the absence of label information
- To determine the pH level of each sample
- To analyze the alcohol content of the samples with regard to label information

Subsidiary aims were to establish a pattern of usage of mouthrinses and to identify ingredients such as surfactants and sweeteners.

Many articles have been published on active agents present in mouthrinses, but active agents differ in relation to specific function. To collectively analyze these differences was the purpose of this project aim.

To determine a product pattern of usage, it was necessary to establish the product range available as no definitive list existed.

Fluoride mouthrinses are proven cariostatic agents (1-9). Studies of fluoride mouthrinsing have given consistently positive results, with few reporting caries reductions of < 20% (10). It was of interest to compare actual fluoride values as opposed to stated values and to note if any major discrepancy existed. This information also benefited the debate on the possible contribution of high fluoride levels in oral care products to dental fluorosis.

The adverse effects of acidic drinks on dental enamel have been documented (Smith and Shaw, 1987; Duggal and Curzon, 1989) and it is possible that acidic mouthrinses may have a similar effect. (Bhatti et al, 1994). *In vitro* experiments have shown that mouthrinses are capable of eroding blocks of bovine enamel (Ryt et al, 1989). Therefore, it was with great interest that the pH levels of all available over the counter mouthrinses were analyzed, as it was an issue that concerned both dental professionals and the general public.

Alcohol levels in mouthrinses have been a cause for concern, as there is a possibility that acute ethanol toxicity could occur following ingestion of large quantities of mouthrinse (11). This danger is greatest among young children and physically and mentally challenged individuals.

Surfactants have come under scrutiny following reports of adverse reactions to some compounds. Sodium lauryl sulfate, a surfactant used in toothpastes and mouthrinses, has been implicated in an increased incidence of oral irritation in subjects predisposed to Recurrent Aphthous Stomatitis (RAS) (12).

By achieving the multiple aims of this project, it was hoped to present a comprehensive and informative report on the properties of over the counter mouthrinses on sale in Ireland.

## Results

As the primary aims of my project were of a scientific nature, all experimental work took place in the Oral Health Services Research Centre laboratory. Appropriate laboratory procedures and precautions were adhered to, under the guidance of the resident laboratory technician, Ms. Eileen MacSweeney, to ensure validity and consistency in the findings.

Five sets of diluted and buffered mouthrinse samples were tested, to measure fluoride content, with an additional rerun of the first samples.

pH levels were measured directly, immediately on opening the mouthrinse bottles. A random sample was again tested at a later date. This was done in order to establish a pH range for the samples and to note any possible change in values over a time lapse.

Information regarding alcohol content, active agents and foaming agents was collected solely from mouthrinse labels and journal and other relevant articles.

## Method

In assessing the range of mouthrinses available, visits were made to all major supermarkets & pharmacies in Cork City and in the town of Tralee, Co. Kerry. This was to ensure a true representation of product availability. Staff in each premise confirmed the extent of the range on sale. All mouthrinses on sale over the counter were then bought in these premises.

Further confirmation and information was sought by accessing the websites of the relevant pharmaceutical companies, including Glaxo-Smithkline, Warner-Lambert and Colgate-Palmolive. Product information was available on all websites accessed.

To establish a product pattern of usage, questionnaires were distributed to a random sample of 6 dental surgeries in Tralee, Co. Kerry and to the University Dental Hospital, Wilton, Cork City. Patients were asked to list their favoured mouthrinse and frequency of usage.

## Samples

After investigation, it was found that thirty-nine mouthrinses were available for sale over the counter in Ireland. All thirty-nine were analyzed in the laboratory.

## Identifying Active Agents & Alcohol Content

Active agents and alcohol content were identified by product information displayed on the label of each mouthrinse bottle.

## Measurement of pH level

The pH of each sample was measured directly using a pH meter, immediately on breaking the seal of the sample bottle. A random group was again measured at a later date, to compare any change in value that may have occurred.

## Measurement of fluoride content

Fluoride content of the samples was measured on an Orion Model 720A, using the fluoride ion-specific electrode (Orion Model 94-09) and reference electrode (Orion Model 90-01). All samples were diluted by 1/100 with double-deionised water (182 ) and buffered with TISAB ( Total Ionic Strength Adjustment Buffer ). An appropriate range of sodium fluoride standards was used. All measurements were repeated five times, on each occasion using new dilutions and buffer. An additional rerun of the first set of samples was also measured.

## History & Properties of mouthrinses

The earliest publication describing the use of a fluoride mouthrinse was by Bibby et al in 1946. The study, on a NaF rinse, failed to have a significant effect on caries. The subject received little additional study time until the 1960s, when mouthrinses were studied in depth in Scandanavia.

Torrell & Ericcson (1965) in Sweden indicated that fluoride mouthrinsing was likely to be among the most effective methods of topical fluoride treatment.

In 1975, the Council on Dental Therapeutics of the ADA accepted neutral NaF and acidulated phosphate fluoride rinses as effective caries preventive agents. Stannous fluoride was accepted later.

In 1978, Hirschfield concluded that regular use of fluoride mouthrinsing appeared to be effective at reducing decalcification of teeth undergoing orthodontic treatment.

Since then, most aspects of mouthrinse functioning have been analyzed, broadening our knowledge of the subject and improving the products available over the counter to the general public.

The breakdown of what constitutes a mouthrinse is described by Kimberly Loos (D.D.S) as being:

75% Humectant & H2O  
 20% Abrasive  
 1-2% Foaming & Flavoring Agent  
 Colourings  
 Opacifiers  
 Fluoride

Most over the counter rinses contain standard components: an active bacteria-fighting ingredient such as quaternary ammonium compounds, boric acid and benzoic acid, and phenolic compounds; a flavoring agent such as saccharin or glycerin; astringents like zinc chloride to provide a pleasant tasting sensation; ethyl alcohol, ranging from 18 to 26%; and water. Rinses can also contain buffers to reduce acidity, dissolve mucous films and alleviate soft tissue pain. Anticavity rinses usually contain 0.05% sodium fluoride, or 0.1% stannous fluoride, as approved by the FDA. Active ingredients in antiplaque rinses vary. Certain rinses contain Chlorhexidine (the most effective plaque-fighting drug yet tested). Commonly used rinses are:

Therapeutic Antiseptics Phenol Products: Listerine

Chlorhexidine Products: Corsodyl

Cosmetic Antiplaque Rinses: Plax, Oral-B Antibacterial

Therapeutic Anticavity Fluoride Rinses: Listermint with fluoride, Oral-B Anticavity Rinse

Cosmetic Breath Freshening Mouthrinses: Rembrandt, Breath Remedy  
 (Compiled by the Academy of General Dentistry)

[Table 1a:](#)List of fluoridated mouthrinses on sale over the counter in Ireland & fluoride concentration values in ppmF

Total ppmF in samples analyzed							
	1 <sup>st</sup> run	2 <sup>nd</sup> run	3 <sup>rd</sup> run	1 <sup>st</sup> rerun	4 <sup>th</sup> run	5 <sup>th</sup> run	Label
Mouthrinse							Label
Plax Softmint	108	109	108	109	111		113
Plax Coolmint	94	108	131	105	109		113
Plax Classic	108	111	109	111	111		113
Colgate Fluoride Daily Defense Rinse	197	234	230	279	217	231	226
Tesco Coolmint	199	234	221	210	209		225
Tesco Totalcare Coolmint	221	217	230	211	210		225
Tesco Freshmint	223	225	227	160	213		225
Tesco Extra Strength	222	220	221	214	208		225
Tesco Value	205	205	209	206	198		225
Reach Junior	218	211	227	273	215	223	226
Reach Freshmint	181	203	205	201	198	207	226

Reach Cinnamon	213	213	216	210	207		226
MacCleans Freshmint	229	242	129	230	220	235	225
MacCleans Coolmint	205	232	236	225	221		225
Boots Totalcare Freshmint	216	218	216	211	202		225
Boots Totalcare Coolmint	221	219	224	218	210		225
Boots Totalcare Original	220	233	229	236	219		225
Boots Sensitive Freshmint	199	114	215	230	214	228	225
Aquafresh	227	231	228	228	229		225
Dentyl pH Mint	215	218	221	238	212		225
Dentyl pH Clove	190	219	217	219	218		225
Oral B AntiPlaque	210	248	155	231	227	241	226
Dentimint	192	224	228	208	213		226
Listermint with Fluoride	204	235	228	224	217	226	226
Dunnes Extra Strength	208	240	239	226	225		226
Marks & Spencers Freshmint	215	226	227	223	217		226

Comment: From Table 1a, it is noted that all fluoridated samples have consistent fluoride values, averaging 226ppmF sodium fluoride. These values correspond to those provided on the label. The fluoride values for the samples averaged 226 ppmF sodium fluoride. This was within the limit of 0.15% sodium fluoride permitted in a finished cosmetic product, as stipulated by Council Directive 76/768/Eec on the approximation of the laws of the Member States relating to cosmetic products. The 1<sup>st</sup> run of samples was discounted as merely an estimate when analyzing the results.

Table 1b: List of non-fluoridated mouthrinses on sale over the counter in the Republic of Ireland & Fluoride Concentration in ppmF

Total ppmF in analyzed samples

	1 <sup>st</sup> run	2 <sup>nd</sup> run	3 <sup>rd</sup> run	1 <sup>st</sup> rerun	4 <sup>th</sup> run	5 <sup>th</sup> run	
Mouthrinse							Label
Listerine Original	3.2	1.3	.9	1.1	2	.8	Not stated
Listerine Coolmint	29	2.3	.8	2.5	.7	.8	Not stated
Listerine Freshburst	1	.9	.7	.8	.8	.6	Not stated
Listerine Tartar Control	1.2	.5	.9	4.5	.9		Not stated
Retardex	54	2	.9	.6	.8	.8	Not stated
Orasan Breath Remedy	2.3	.5	.9	.6	.5	.5	Not stated
Difflam	1.3	.5	.7	.9	.5	.5	Not stated
Oraldene	3	1.1	.8	1	.6	.6	Not stated
Rembrandt	7.3	.9	1.2	.8	1	1	Not stated
Corsodyl Aniseed	3.1	.8	.8	.9	.7	.7	Not stated
Corsodyl Mint	4.1	.8	.9	.6	.9	.9	Not stated

Listermint Green	3.4	.7	.7	.9	.6	.6	Not stated
Betadine	1.3	1	.7	1	.9	.9	Not stated

Comment: No label information was provided on any of the thirteen non-fluoridated samples regarding fluoride content. The trace values recorded by the fluoride probe were given a blanket value of < 2 ppmF. From the label information provided, these rinses tended to be manufactured with the purpose of treating a category of oral complaints including gingivitis, throat infections and halitosis. Fluoride protection was not advertised on the label of the samples.

Table 2: pH levels of mouthrinse samples

Mouthrinse	1 <sup>st</sup> pH reading	2 <sup>nd</sup> pH reading	3 <sup>rd</sup> pH reading
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Fluoridated Samples

Plax Softmint	7.2		
Plax Coolmint	7.3		
Plax Classic	7.2	7.2	
Colgate Fluoride Daily Defense Rinse	5.98		
Tesco Coolmint	6.5		
Tesco Totalcare Coolmint			
Tesco Freshmint	6.4		
Tesco Extra Strength	6.7		
Tesco Value	6.4		
Reach Junior	6.4		
Reach Freshmint	6.3		
Reach Cinnamon	6.3		
MacCleans Freshmint	6.5		
MacCleans Coolmint	6.5		
Boots Totalcare Freshmint	6.6		
Boots Totalcare Coolmint	6.6		
Boots Totalcare Original	6.6		
Boots Sensitive Freshmint	6.6		
Aquafresh	6.4		
Dentyl Ph Mint	5.9		
Dentyl Ph Clove	5.7		
Oral B	5.9		
Dentimint	6.5		
Listermint with fluoride	4.7	4.8	
Dunnes Extra Strength	7		
Marks & Spencers Freshmint	6.3		

Comment: The pH values of all fluoridated samples were above the critical level of 5.6, with many near a neutral pH of 7. With such values verging towards alkalinity, they should pose no erosive threat to enamel when used.

Mouthrinse reading	1 <sup>st</sup> pH	2 <sup>nd</sup> pH reading reading	3 <sup>rd</sup> pH
Listerine Original	4.1	4.2	
Listerine Coolmint	4.1	4.3	
Listerine Freshburst	4.2		
Listerine Tartar Control	4.1	4.2	
Retardex	6.7		
Orasan Breath Remedy	6.1		
Oraldene	3.9	4.1	
Rembrandt	6.4		
Corsodyl Aniseed	5.85		
Corsodyl Mint	5.7		
Listermint Green	3.4	3.5	3.4
Betadine	2.5	2.7	

Comment: Nine of the thirteen non-fluoridated samples had pH values below the critical level of 5.6. Mouthrinses are often promoted as adjuncts to oral hygiene or to reduce caries progression. With this aim some have added fluoride. However, the acidic nature of the mouthrinse could prevent remineralisation of enamel lesions or hasten any toothbrush abrasion/erosion already present (Meurman and Averil, 1990) and those that do not contain fluoride or an effective antimicrobial agent, could lead to the establishment of an aciduric bacterial population, which might promote caries (Marsh, 1991). The potential damage to dental tissues caused by aciduric mouthrinses may be influenced by how well buffered the agent is at that pH. It should be noted that no account could be taken of any buffering capacity in the mouthrinses, as their composition was unknown.

### Non-fluoridated Samples

**Table 3: Alcohol Content of Health Research Board Mouthrinses Fluoridated Samples**

Mouthrinse	Information on label
Plax Softmint	Alcohol
Plax Coolmint	Alcohol
Plax Classic	Alcohol
Colgate Fluoride Daily Defense Rinse	Alcohol
Tesco Totalcare Coolmint	8%
Tesco Coolmint	7.68%
Tesco Freshmint	8.64%
Tesco Extra Strength	21%
Tesco Value	5.76%
Reach Junior	Benzyl alcohol, ethanol free
Reach Freshmint	Alcohol
Reach Cinnamon	Alcohol
MacCleans Freshmint	Alcohol
MacCleans Coolmint	Alcohol
Boots Totalcare Freshmint	Alcohol
Boots Totalcare Coolmint	Alcohol
Boots Totalcare Original	Alcohol
Aquafresh	Alcohol
Dentyl Ph Mint	Alcohol Free
Dentyl Ph Clove	Alcohol Free
Oral B	Alcohol
Dentimint	Alcohol
Listermint with fluoride	Alcohol
Dunnes Extra Strength	Alcohol
Marks & Spencers Freshmint	Alcohol Free

Comment: Ethanol in various concentrations is used in most popular brands of mouthrinses sold in the United Kingdom (Bhatti et al, 1994). There is an overlap in the brands on sale in the Irish Republic and the United Kingdom so a comparison can be made. Its main functions are to act both as a preservative and solvent, to stabilize and solubilise the flavouring and active ingredients in the rinse. Only five of the fluoridated samples gave actual percentages of alcohol content. This lack of information is ambiguous but it is not in breach of labeling laws. According to Volume 1, Cosmetic Regulations of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, mouthrinse manufacturers have complied with regulations. Under Article 6, it states that; 'Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in the indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the

packaging alone.’ Point (g)(entire transcript not given her): ‘a list of ingredients in descending order of weight at the time they are added’. It is interesting to note that Tesco Extra Strength mouthrinse has 21% alcohol. This increased amount of alcohol is added to give the mouthrinse ‘bite’ and to potentiate the flavour (Johnson & Johnson, stated in Bhatti et al, 1994)>

Non-fluoridated Samples ( < 2ppmF )

Mouthrinse	Information on label
Listerine Original	Not stated
Listerine Coolmint	Not stated
Listerine Freshburst	Not stated
Listerine Tartar Control	Not stated
Retardex	Not stated
Breath Remedy	Not stated
Difflam	Not stated
Oraldene	Not stated
Rembrandt	Not stated
Corsodyl Aniseed	Not stated
Corsodyl Mint	Not stated
Listermint Green	Not stated
Betadine	Not stated

Comment: None of the non-fluoridated mouthrinses provided any information regarding alcohol content. Therefore, in the context of Volume 1, Article 6(g), Cosmetics Regulations of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, which was quoted above, it is concluded that the non-fluoridated rinses do not contain any alcohol.

## Discussion

### Range

Thirty-nine mouthrinses were found to be available for sale over the counter in the Irish Republic. In terms of availability, the Irish public is well served in the selection on offer to them. Every major supermarket chain and larger pharmacy has a considerable stock of mouthrinses on sale, making this form of oral care easily accessible to a dentally-aware population. All preferences of colour and flavour are catered for, enticing adults as well as children. Children are regarded some manufactures as a separate market, with special alcohol-free and sweet-tasting rinses produced for this target sector. Twenty-six mouthrinses were deemed fluoridated, with an average fluoride concentration of 225ppmF. Some claim antiplaque, others antibacterial properties. Thirteen of the rinses had an average value of <2ppmF. These rinses tended to be developed for complaints such as halitosis, gingivitis and mouth & throat infections.

As regards price range, fluoridated rinses tended to be priced similarly across all brands. Among the non-fluoridated rinses, prices tended to fluctuate to a greater degree and became more expensive in relation to the specificity of the problem to be treated.

### Active Agents

Active agents were listed on all mouthrinse labels. The most common agents occurred in fluoridated samples in combinations of .05% NaF & CPC and .03% Triclosan & .025% NaF. Non-fluoridated samples tended to have active agents particular to the mouthrinse function, for example, Retardex, a mouthrinse specifically targeted at halitosis, contains the CloSysII brand of stabilised chlorine dioxide.

### Fluoride Content

Fluoride mouthrinsing, at two different strengths and two different rinse frequencies, has proven a versatile method of caries control for individual home-based programmes and school-based community programmes. The regimes consist of a 0.05% NaF (230ppmF) used daily and a 0.2% (900ppmF) used fortnightly. This is known as low potency/high frequency and high potency/low frequency technique. The low potency/high frequency technique is the preferred method for fluoride mouthrinsing in the home (13). Over the counter mouthrinses are low potency rinses.

From Table 1a, it is evident that the experimental data validated the manufacturers labelling information. A consistent fluoride value was recorded for each fluoridated sample and that value correlated to the label information. Values were in the range of 226ppmF, except for Plax samples, which had values of 113ppmF, due to the fact that Plax is a pre-brush rinse, unlike the other samples, which are designed as post-brush rinses.

The importance of fluoride relates to its influence on the demineralisation/remineralisation process in enamel and dentine (FDI Statement, Fluoride and Dental Caries, June 2000). Under circumstances that favour demineralisation, cavitation occurs and under circumstances that favour remineralisation, the early carious lesion may be healed.

The presence of ionic fluoride at a site of demineralisation enhances remineralisation. Caries is prevented or arrested by an efficient delivery of ionic fluoride to the site in adequate concentration and duration.

Deutchman et al (1989) showed that a fluoride rinse increased the number of artificial lesions that showed remineralisation and reduced the average amount of demineralisation.

Currently, the most frequently used compound is neutral NaF, which has the advantages of chemical stability and tolerable taste. In Ireland there are two systems of delivery of the NaF in mouthrinses; a school-based programme which consists of circa 30,000 schoolchildren in the Republic and home-based rinsing. In a two year study, Torrell and Ericsson (1965), found a 50% caries reduction in a group of children who rinsed daily with a neutral NaF solution containing 225ppmF. Ripa et al (1988) found a 50% reduction in mesio-distal root surface caries in adults, aged 45-65 years, also using the low potency rinse. Holland et al (1987) found a mean DMFT reduction in a study on children in a mouthrinse programme aged 10-12 years, in comparison to a control group. In a later study, which assessed the oral health of 16 year olds living in fluoridated and non-fluoridated areas, four years after they ceased participating in a mouthrinsing programme, Holland et al (1995) noted caries level differences. Evidence from the study demonstrated that caries levels 4 years after cessation of the rinse, in those living in the non-fluoridated area was considerably higher than those living in a fluoridated area.

From Table 1b, it is clear that 13 of the samples provided no labelling information as regards fluoride content. When analyzed, these samples had average values of < 2ppmF. These rinses were not designed for fluoride delivery, but for oral complaints needing an antiseptic/antibacterial/halotosis remedy.

### pH values

The pH value of a rinse is usually a product of the total acid content and the buffering capacity of the other constituents. A pH value of less than 5.6 can be potentially erosive to enamel. All of the fluoridated samples, with the exception of Listermint with Fluoride, had >pH 5.6. One sample had a neutral Ph.

Seven of the thirteen non-fluoridated samples had a >pH 5.6. Indeed, all seven were inclined towards acidity, the most notable example being Betadine, with a low of Ph 2.6.

Mouthrinses are often promoted as adjuncts to oral hygiene or to reduce caries progression. With this aim some have added fluoride. However the acidic nature of the mouthrinse could prevent remineralisation of enamel

lesions or hasten any toothbrush abrasion/erosion already present (Meurman and Averil,1990) and those that do not contain fluoride or an effective antimicrobial agent, could lead to the establishment of an aciduric bacterial population, which might promote caries (Marsh,1991).

With such low pH values, the non-fluoridated rinses could potentially cause damage to dental tissues, if used for a prolonged period.

### Alcohol Content

When it came to ascertaining alcohol levels in the samples, labelling information was deficient. Only five samples gave a definitive percentage ethanol value. Sixteen fluoride samples merely stated 'alcohol' on the label. None of the non-fluoridated samples provided any information on alcohol type or content.

The main function of ethanol is to act as both a preservative and solvent, to stabilise and solubilise the flavouring and active ingredients in the rinse. The minimum concentration necessary to achieve these functions is approximately 5% w/v alcohol (Bhatti et al,1994). In 1984, the American Academy of Paediatrics, Committee on Drugs recommended that over the counter preparations of mouthrinses should be limited to 5% w/v alcohol. Of the five definitive ethanol values stated, all five were above the recommended level. Additional alcohol is often added to give the mouthrinses 'bite' or 'feel' (Johnson & Johnson (stated in Bhatti et al, 1994)). In a specific study on ethanol levels in mouthrinses, Bhatti et al (1994) presented data detailing ethanol levels of 27% in Listerine, 17% in MacCleans, 13% in Listermint, 10% in Oraldene and 8% in Plax.

There is a real danger that acute ethanol toxicity could occur following ingestion of large quantities of mouthrinse. The greater danger lies with ingestion by children, where only a low concentration is needed to produce morbidity and mortality. Ethanol poisoning from mouthrinses has been well documented (Weller-Fahy and Berger,1980) and over an eighteen month period in 1980 there were 422 cases of mouthrinse ingestion in children under the age of 6 reported to the US National Poison Centre (Bhatti et al,1994).The potential danger of such ingestion is due to the fact that mouthrinses aren't seen as hazardous, they are brightly coloured and often pleasant tasting. This combination is enticing to any inquisitive child. There is a guideline published by the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products regarding potentially hazardous cosmetic ingredients. Article 6(d) states that on a label; 'particular precautions to be observed in use, must appear on the container and packaging'. This guideline, it could be argued, should extend to alcohol content in mouthrinses, in respect to child safety. However, the Council of Directives also rules that: 'A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions'. Under normal conditions,

mouthrinsing is not hazardous to children, therefore the problem lies in the wording of the guidelines rather than the extent of the manufacturers labeling.

### Foaming Agents

Sodium Lauryl Sulfate is the detergent most commonly used in dentifrices and mouthrinses. It is used as an emulsifying and surface-cleaning agent. A study in the Journal of Clinical Peridontology (May 1997 Vol 24) implicated the agent in an increase incidence of oral irritation in subjects predisposed to recurrent aphthous stomatitis (RAU). Even though the amount of SLS retained in the oral cavity has been shown to be very small, a separate study showed that a strong enough reaction occurred to exhibit a denaturing property, increasing oral mucosal permeability and possibly causing oral desquamation (Journal of Clinical Peridontology 1996 Vol 23). Only four of the mouthrinses analyzed contained SLS: Plax Softmint, Coolmint, Classic and Rembrandt. Of these, all three Plax rinses contained Triclosan, an agent found to reduce the adverse side-effects of SLS (Scandanavian Journal of Dental Research 1993 Vol 101).

The low percentage of rinses containing SLS may signal an attempt by the manufacturers to find an alternative foaming agent, in mouthrinses at least.

### Sweetners

Sweetners are added to mouthrinses to make the solution more palatable. They tend to be added in combinations of Sodium Saccharin, Sorbitol and Xylitol. Xylitol is giving rise to much interest in the dental world. It is finding its way into many chewing gums, toothpastes and mouthrinses. It is a bulk sweetner (as opposed to an artificial sweetner) related to sugar and extracted from birch wood. Unlike most sugars, Xylitol cannot be converted to acid in the mouth by bacteria. It suppresses unfavourable mouth bacteria, especially Mutans streptococci, and inhibits plaque formation. Indeed, Dr. Ronnie Levine, author of the Scientific Basis of Dental Health Education for the Health Development Agency claims: "As an antiplaque and anti-caries agent, Xylitol is possibly the most promising development since the introduction of fluoride". (The Times, August 28 2001)

## Questionnaires

In order to establish a pattern of usage for the available mouthrinses, a questionnaire was distributed to a sample of seven dental surgeries in the Tralee area and to the University Dental Hospital, Wilton, Cork. Questionnaires were to be completed by patients. Of the 120 copies distributed, there was a 40% response rate.

The results gave a broad and general overview of consumer usage patterns. The cross-section of respondents encompassed patients aged ten to seventy.

The results would indicate a widespread use of mouthrinses, as the majority of respondents were regular users. Listerine products were the most popular brand and the most frequent reason given for this was the efficacy with which it freshened breath.

The respondents seemed more concerned with fresh breath than possible plaque and caries problems. This was borne out by the fact that a significant number used the mouthrinse alone in lieu of proper brushing.

The general pattern of usage seemed to range from infrequently to 2 to 3 times a day. Females tended to use mouthrinses more often than men. When parents with children under 7 years of age were questioned, no parent replied that their child used a mouthrinse. This is a welcome trend, diminishing the risk of fluorosis from a self-applied topical fluoride.

It is important to note that these results may be interpreted with caution because of the selected nature of respondents. However, the results indicate the need for further work, to establish a pattern of usage for over-the-counter mouthrinses amongst different population groups in Ireland.

## Conclusion

At the termination of the eight week research period, all aims of the project had been achieved. Standard laboratory guidelines had been followed to ensure valid and consistent results. Arising from these results, it is concluded that:

The range of mouthrinses on sale over-the-counter in the Irish Republic is extensive and is designed to alleviate the most common oral health problems of the general public

Ingredients regarding active agents, sweeteners and foaming agents are stated on the label of the mouthrinse container

The most common combinations of active agents are 0.05% NaF and CPC and 0.03% Triclosan and 0.025% NaF

The stated ppmF fluoride concentration corresponds to the actual value present in the mouthrinse

When ppmF fluoride concentration is not stated, values correspond to < 2ppmF

Ph values of all fluoridated mouthrinses on sale over-the-counter in the Republic are above the critical level of 5.6

Non-fluoridated mouthrinses tend to have a low pH level

There is a deficit of labelling information regarding alcohol levels in all types of over-the-counter mouthrinses. The problem lies in the wording of the European Commission Cosmetic Regulations Guidelines, rather than with the extend of the maufacturers labelling

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# Appendix 10

## **Project Flint: Fluoride Intake from Toothpaste**

### **Guest Editors:**

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University of Iceland

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- O'Mullane DM, Cochran JA, Whelton HP (2004). Fluoride ingestion from toothpaste: background to European Union-funded multicentre project. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 5-8.

In this paper the authors describe how there is increasing evidence to show that use of fluoride toothpaste has been a major factor in the reduction in the prevalence of dental caries throughout the EU during the last 30 years. There is also increasing evidence to suggest that inappropriate use of fluoride toothpastes particularly by infants and young children may be a factor in the increase in the prevalence of enamel fluorosis during the same period. Central to these concerns are two measurement issues namely the measurement of the amount of fluoride ingested by infants and young children when using fluoride toothpaste and secondly, the need to develop an objective method for measuring enamel fluorosis.

- Whelton, HP, Ketley CE, MacSweeney F, O'Mullane DM (2004). A review of fluorosis in the European Union: prevalence, risk factors and aesthetic issues. *Community Dent Oral Epidemiol*;32 (Suppl. 1): 9-18.

Following a detailed review of the prevalence of fluorosis throughout the EU and also an assessment of the risk factors and aesthetic issues associated with dental fluorosis. It was concluded that there is a need to co-ordinate studies measuring fluorosis throughout Europe and that development of a standardized photographic method would be useful. Furthermore, the aesthetic importance of fluorosis needs to be determined in more detail in each country in the light of each country's respective risk factors and dental health policies.

- Cochran JA, Ketley CE, Sanches L, Mamai-Homata E, Oila A-M, Arnadottir IB, Van Loveren C, Whelton HP, O'Mullane DM (2004). A standardized photographic method for evaluating enamel opacities including fluorosis. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 19-27.

In this study the authors demonstrated that a standardized photographic technique for recording fluorosis which they had developed was robust and reproducible when used by epidemiologists from seven European study sites.

- Cochran JA, Ketley CE, Arnadottir IB, Fernandes B, Koletsi-Kounari H, Oila A-M, Van Loveren C, Whelton HP, O'Mullane DM (2004). A comparison of the prevalence of fluorosis in 8-year-old children from seven European study sites using a standardized methodology. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 28-33.

Using the standardized methods developed which were described in the previous paper, the prevalence of enamel opacities including dental fluorosis was measured amongst samples of 8 year old children in the

participating countries. The prevalence of fluorosis was found to be highest in Cork City where the domestic water supplies are fluoridated. The prolonged use of fluoride supplements was found to be a risk indicator associated with fluorosis.

- Sigurjons H, Cochran JA, Ketley CE, Holbrook WP, Lennon MA, O'Mullane DM (2004). Parental perception of fluorosis among 8-year-old children living in three communities in Iceland, Ireland and England. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 34-38.

The impact of various grades of dental fluorosis was measured in Reykjavik (Iceland), Cork (Ireland), Knowsley (England) amongst the parents of groups of 8 year old children who had previously had their teeth photographed and graded for fluorosis. There was a trend towards more parents being unhappy with the appearance of their child's teeth with increasing fluorosis grade. However, the main reasons given by parents for being unhappy with the appearance of their child's teeth was tooth alignment (orthodontic reasons). It was only with a TF grade of 3 was any appreciable concern expressed about fluorosis. Further research is required into the aesthetic impact of fluorosis.

- Cochran JA, Ketley CE, Duckworth RM, van Loveren C, Holbrook WP, Seppa L, Sanches L, Polychronopoulou A, O'Mullane DM (2004). Development of a standardized method for comparing fluoride ingested from toothpaste by 1.5-3.5 year old children in seven European countries. Part 1: Field work. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 39-46.

In this paper the authors describe the fieldwork for the development of a standardized method for measuring fluoride ingestion from toothpastes in young children aged between 1.5 and 3.5 years. There was some difficulty in getting adherence to an agreed protocol at all sites. Despite this, there was clear evidence of considerable variation in the practice of oral hygiene including the use of fluoride toothpaste throughout Europe.

- Cochran JA, Ketley CE, Duckworth RM, van Loveren C, Holbrook WP, Seppa L, Sanches L, Polychronopoulou A, O'Mullane DM (2004). Development of a standardized method for comparing fluoride ingested from toothpaste by 1.5-3.5 year old children in seven European countries. Part 2: Ingestion results. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 47-53.

The standardised methods developed in the previous paper were used to measure the amount of fluoride ingested from toothpaste in 7 European sites by children aged 1.5 and 3.5 years. There was considerable variation between countries between the types of toothpastes used (including the level of fluoride) and in the amounts of toothpaste applied and ingested. The average percentage of the

toothpaste placed on the brush which was ingested was 64%. A high percentage of the younger children appeared to ingest over 80% of the toothpaste placed on the brush. The authors concluded that there is a need for clearer messages to be communicated to the parents regarding the use of fluoride toothpaste by young children.

- Van Loveren C, Ketley CE, Cochran JA, Duckworth RM, O'Mullane DM (2004). Fluoride ingestion from toothpaste: fluoride recovered from the toothbrush, the expectorate and the after-brush rinses. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 54-61.

The aim of this study was to determine the effects of rinsing and spitting on the amount of fluoride ingested amongst samples of children aged between 1.5 and 3.5 years in the Dutch and Irish sites. It was found that fluoride ingested from toothpaste is reduced by rinsing and/or spitting during toothbrushing.

- Ketley CE, Cochran JA, Holbrook WP, Sanches L, van Loveren C, Oila A-M, O'Mullane DM (2004). Urinary fluoride excretion by preschool children in six European countries. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 62-68.

In this paper, a study was designed to measure and compare 24-h urinary fluoride excretion in children aged 1.5-3.5 years from six European study sites and these data were used to estimate the 24-h fluoride intake. It was found that the mean fluoride excretion in response to the usual conditions of fluoride intake in the children in the nonfluoridated areas ranged from 0.16 mg ( $\pm 0.08$ ) in Oulu, Finland, to 0.33mg ( $\pm 0.27$ ) in Almada/Setubal, Portugal, with an overall mean of 0.23mg ( $\pm 0.19$ ). The mean 24-h fluoride excretion in fluoridated Cork was 0.37mg ( $\pm 0.11$ ). There was a significant difference between the fluoride excretion in the nonfluoridated areas and that in the fluoridated areas, and the data was broadly in agreement with WHO standards. It was concluded that daily urinary fluoride excretion and estimated fluoride intake in these children appeared to be within acceptable limits.

- Arnadottir IB, Ketley CE, van Loveren C, Seppa L, Cochran JA, Polido M, Athanassouli T, Holbrook WP, O'Mullane DM (2004). A European perspective on fluoride use in seven countries. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 69-73.

The study described in this paper set out to collate data on national policies for use of fluoride in the seven European countries participating in the Flint Project. It was found that considerable variation existed between European countries in their policies for fluoride use. There is even lack of coherent thought and planning within the different countries, let alone between them.

- O'Mullane DM, Ketley CE, Cochran JA, Whelton HP, Holbrook WP, van Loveren C, Fernandes B, Seppa L, Athanassouli T (2004). Fluoride ingestion from toothpaste: conclusions of European Union-funded multicentre project. *Community Dent Oral Epidemiol*; 32 (Suppl. 1): 74-76.

The conclusions of the Flint Project are summarised briefly in this paper. Firstly the logistical challenges involved in coordinating a research project involving participants from different cultures and different languages are described. The data however showed that it was possible to train and calibrate examiners from different backgrounds in the use of standardised photographic method for recording dental fluorosis. It is clear that this method has a number of important advantages for the objective monitoring of enamel dental fluorosis over time. Large differences were found between the 7 sites participating in the project in the toothpaste formulation used and in the pattern of use of toothpaste. The results indicated that it was possible to agree and adopt a standardised method measuring fluoride ingestion from toothpaste. The aesthetic impact of dental fluorosis seemed low in the populations included in this project. Further work is required on this issue however.

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# Appendix 11

## Fluoride containing Restorative Materials

Literature search assessing fluoride release from restorative materials.

Fluoride releasing restorative materials

Glass ionomers-conventional and resin modified

Compomers

Fissure sealants

Glass Ionomers:

A glass ionomer material consists of a basic glass and an acidic polymer which sets by an acid-based reaction between these components.

A resin modified glass ionomer is a hybrid material that retains a significant acid/base reaction as part of its overall curing process.

Resin, the main component of which is hydroxyethyl methacrylate (HEMA) is added to the liquid to the order of 18-20% resulting in a set cement with a 4.5-6% resin component (Mount, 1994a). Such materials are not a combination of glass ionomer and resin composite but are in fact true glass ionomers with small amounts of resin and will undergo the acid/base reaction essential to a true glass ionomer.

Originally unintended but now seen as an important feature of glass ionomer materials is their long-term release of fluoride

Fluoride is used as a flux in the manufacture of the glass such that up to 23% of the glass may be fluorine in various forms.

Fluoride increases the strength of the set material

Fluoride lowers the temperature of fusion

Fluoride improves the working characteristics of the material

Fluoride, in moderate amounts, improves translucency

Fluoride can both be released and taken up by the material

(Wilson and McLean, 1988).

Fluoride plays no part in the setting reaction of the material. The exact mechanism of fluoride release is unclear but the fluoride is capable of moving through the matrix and being released into the oral environment. Depending on the fluoride gradient the material can re-absorb fluoride, effectively acting as a fluoride reservoir. (Forsten 1991), (Hatibovic-Kofman and Koch, 1991), (Diaz-Arnold et al, 1995), (Creanor et al, 1994), (Takahashi et al, 1993).

The kinetics of the fluoride release is such to suggest that at least two reactions occur (Verbeck et al, 1993). The first process is the short-term initial elution (up to 4 days), which occurs rapidly but ceases after some time. As it occurs only during the first days equilibration it is probably associated with the setting and maturation reactions of the glass ionomer and occurs by the simple process of diffusion. The slower, more prolonged second process responsible for the long-term elution follows. The elution of fluoride from a glass ionomer is a complex process for which an adequate fundamental physiochemical model is not yet available. The fluoride is released from the aluminosilicate glass, which can contain up to 23% fluoride. The amount that is released is dependent upon the sodium content and to a lesser extent the

calcium content of the glass rather than on the total fluoride. The cement is not weakened by loss of fluoride, as fluoride is non-matrix forming.

Essentially, the availability of fluoride is determined by its chemical form and distribution in the cement. Initially all the fluoride is in the glass where it replaces oxygen anions in the main phase and also as phase separated fluorite. Following the process of cross-linking associated with the setting reaction diffusion becomes more difficult (Davies et al, 1993). The release process can be affected quantitatively by several experimental and intrinsic methods. The intrinsic variables are related to the chemical and physical formulations of the glass ionomer, which are determined by the manufacturer. Discrimination among different glass ionomer formulations on the basis of the long-term fluoride release process is not as pronounced as discrimination on the basis of short-term release (DeMoor et al, 1996).

Glass ionomer has been shown to release fluoride for the life of the restoration. Forsten (1994) has shown that the fluoride release of a glass ionomer is the same at 5 months as it is at 5 years. The fluoride released by the material is not of matricular importance and thus the continual release does not have any deleterious effects on the physical properties of the material (Mount, 1991a) (Walls, 1986). The initial fluoride released is from the surface of the material and subsequent to this the fluoride is released from the gel matrix by diffusion, the rate of release being linear to the square root of time (Mitra, 1991). The pattern of fluoride release is similar for all glass ionomers with an initial high burst of fluoride release within the first 24-48 hours. The fluoride release declines over the next 7-11 days with a further fall in the level of fluoride released over the following weeks until the rate of release levels off and the release is low and constant. (Swartz et al, 1984) (Muzynski et al, 1988), (Swift, 1989) (Castro et al, 1994). Several *in vitro* studies have shown that glass ionomer cements could be recharged due to uptake of fluoride from solutions (Forsten, 1991) (Hatibovic-Kofman and Koch, 1991).

The clinical significance of the quantitative long-term fluoride release is uncertain, as the exact minimal concentration of fluoride required to exert a cariostatic effect has not been determined, it is supposed that the material with the highest long-term release is to be preferred (de Araujo et al, 1996). It has been shown that there is a fluoride halo around a glass ionomer restoration up to 3mm in diameter, which will influence the surrounding tooth structure and the adjacent teeth (Kidd, 1978) (Tyaas, 1991).

The resin-modified glass ionomers appear to have at least the same fluoride-releasing properties of the conventional glass ionomers. They can similarly be recharged and they can also exert a remote caries effect (Tantbirojn et al, 1997).

There are no *in vivo* studies to date that have determined the minimal concentration of fluoride in saliva and plaque that would enhance remineralisation. Various *in vitro* studies show that a concentration of fluoride as low as 0.01-0.03ppm may favour remineralisation (Ingram and Morgan, 1988) (Featherstone et al, 1986). Until proved otherwise, it has been assumed that those restorative materials releasing the most fluoride over the longest period of time are the most beneficial.

Reviewing the literature, it is apparent that the majority of studies assessing the fluoride release of glass ionomers *in vitro* looked at fluoride release into

deionised water. However, the volume of water used, frequency of water change and preparation of specimen prior to storage of solution varied from one study to another. Those studies that looked at the fluoride release into artificial saliva did not use the same formulation or volume of artificial saliva. Different artificial saliva preparations lead to solutions of different pH, viscosity and chemistry and these factors will have an effect on the release profile of the specimen in storage.

Studies by Forsten(1990) and DeSchepper(1991) have reported that there may be large quantitative differences in the amounts of fluoride released by a given glass ionomer. Solubility, fluoride content, porosity of the material, nature of the storage medium (pH, osmolarity) and other unknown factors may play a role in fluoride release.

DeSchepper (1991) also noted that the differences of seconds in the interval between

mixing and immersion of specimens into solutions led to variability in fluoride release from the same material. This was also true for specimens from different batches of the same material.

Most studies to date have concentrated on studying the short and long-term release of fluoride into deionised water, which does not reflect the complex nature of the oral environment. A study by El Mallakh (1990) showed that fluoride release into a solution resembling saliva was considerably less than that into deionised water and this was explained in terms of the precipitation of calcium fluoride. It is thought that a salivary coating forms on the surface of the glass ionomer specimens and reduces the release of intrinsic fluoride (Damen et al, 1996). The presence of various cations in artificial saliva may also be responsible for the reduced release into artificial saliva. This is consistent with the view that glass ionomers are less soluble in artificial than they are in saliva (El Mallakh and Sarkar, 1990).

Forsten (1990) looked at the fluoride release from a variety of glass ionomer materials and his results showed that despite a large difference between materials initially, the differences between the materials diminished with time. The explanation for this is that with time the amount of fluoride being released by glass ionomers is so low that the difference between materials is negligible. The dynamics of the oral cavity are such that plaque films on the filling material, intra-oral pH fluctuations and lubrication will all have an effect on the rate of fluoride release.

The concept of measuring the fluoride uptake and release of glass ionomers is a simple one and with the continuing plethora of glass ionomers on the market it is a potentially clinically valid means of comparing materials. Ultimately, it is difficult to compare data between the numerous studies investigating fluoride release from restorative materials where experimental protocols differ. A recommendation is that an ISO standard be established for studies looking into the fluoride uptake/release profile of glass ionomer materials. For a given solution the range of variables that should be standardised include:

Procedure of specimen preparation

Dimension of specimens

Age of specimens at storage

Volume of storage medium

Formulation of a given storage medium

Frequency of change of solution  
Method of fluoride measurement  
Age of specimen on recharging  
Source of fluoride for recharging  
Time of exposure to recharging medium

Standardising these variables means that it would be possible to make objective judgements on the use of the materials based on the results from the different studies such that with the arrival of each new material on the market more realistic comparisons in terms of fluoride could be made.

Compomers ( polyacid-modified resin composites)

The compomer or polyacid-modified resin composite hybrid material is marketed as a multipurpose material. It contains the major ingredients of both composites (resin component) and glass ionomers (polyalkenoate acid and glass filler component) but not water. (McCabe, 1996). In contrast with the resin-modified glass-ionomers, they have a limited dual setting mechanism. The main setting reaction is the resinous photopolymerisation and no acid – base reaction can occur until later when the material can absorb water.

The name compomer is somewhat misleading, it implies that the material possesses a combination of the characteristics of both composites and glass ionomers but in fact it shows minimal glass ionomer qualities. The compomer materials are relatively new on the market and most of the information regarding the composition, physical properties and performance is based on short-term clinical reports, abstracts, laboratory studies or manufacturer's information leaflets. The results of long-term clinical trials have yet to become available.

Dyract was one of the earliest compomer restoratives available and it has been used in many clinical trials for comparison with the resin-modified glass ionomer cements. The release of fluoride from Dyract is well researched and documented (Suljak JP, 1996), (Nunez A, 1997), (Rasmussen, TE, 1997), (Friedl KH, 1997) and this material serves as a useful yardstick for discussion. The manufacturer, Dentsply, carried out laboratory investigations on the release of fluoride from Dyract over a 12month period. Their results indicated that after a year, Dyract continued to release fluoride ions and maintained the same rate of diffusion. The increase in concentration of fluoride in the adjacent tooth structure was equal to that of traditional glass ionomer with proven anticariogenic properties (Dentsply De Trey, 1994). More recent studies have found that the release of fluoride from Dyract was significantly less than resin-modified glass ionomer cement or other fluoride releasing resin composite (Forsten L, 1995), (Suljak JP, 1996), (Lavis JF, 1997), (Cardenas HL, 1995). Like glass ionomer it acted as a fluoride reservoir such that when it was exposed to fluoride sources such as fluoridated toothpaste fluoride would be absorbed and slowly released into the surroundings after the ion source was removed (Suljak JP, 1996), (Friedl KH, 1997). This may be an effective caries preventive measure for an adjacent tooth.

The cumulative fluoride release of the more recent compomers was found to be higher than the first generation products (Hse KMY 1999). One newer compomer, Compoglass F has as much as 50% more fluoride release than its original Compoglass (Vivadent, 1998). The increase in fluoride is partially due to the finer particle size of the fluoride glass contained in the newer

compomers and the incorporation of additional fluoride in some of the primer/adhesive systems. The caries inhibition effect of compomers was found to be higher than the conventional type of resin composite. (Erlenbaugh AM, 1995).

Variations in composition and chemistry among the materials marketed as compomers may directly affect their properties and clinical characteristics. They may or may not have the typical properties of true glass ionomers such as long-term fluoride release. Therefore they should be used carefully following manufacturers instructions as different handling methods may influence their clinical behaviour.

The fluoride release profile of conventional glass ionomers, resin modified glass ionomers and compomers are all similar. The rate of release of fluoride is dependent on the material type and brand formulation. Typically, the conventional glass ionomer gives off the greatest amount of fluoride initially (Nunez A, 1997), (Rasmussen TE, 1997).

### Fissure Sealants

The prevalence of caries has decreased in the past two decades in most industrialised countries particularly of smooth surfaces. Caries experience in the permanent dentition is confined primarily to occlusal surfaces of molar teeth. Caries is now pocketed with approximately 25% of children having 65% of the total caries (Manton DJ 1995). The use of fissure sealants is seen as a major cornerstone of modern preventive dentistry.

Early fissure sealant materials were water polymerised methyl-2-cyanoacrylate mixed with methyl methacrylate. Then bis-GMA (bisphenol-A-glycidyl methacrylate) which are either ultraviolet polymerised or autopolymerised by interaction of a benzoyl peroxide initiator with a tertiary amine activator. These are the most widely used present day fissure sealants (Williams B, 1996).

Glass ionomer cements are also used as sealants. These display poorer retention than the bis-GMA materials but have the advantage of leachable fluoride. The development of glass ionomers with improved retention properties might give them the potential to supersede bis-GMA resin sealants for the prevention of fissure caries.

The glass ionomer sealants have been shown to have a cariostatic effect on the fissures over which it was placed. The release profile of fluoride from the glass ionomer sealants will be similar to that discussed in the glass ionomer section with the release rate dependent on the type and formulation of the glass ionomer itself. Goody et al looked at the fluoride release from 5 commercially available fissure sealants and found that all released the greatest amount of fluoride within the first 24 hours after mixing with a sharp decrease on the second day and a slow decrease for the last days (Garcia-Godoy F, 1997).

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# Appendix 12

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**Project Title:**

A Study of the Relationship between Oral Hygiene habits, Salivary fluoride levels and Dental caries

**Background:**

There is considerable evidence showing that fluoride toothpastes are effective in the control of dental caries and that the more often they are used the greater the benefit. As a result oral health promotion programmes now include advice that people should brush their teeth at least twice a day. To date the method of monitoring compliance with this advice has been largely confined to data collected by means of questionnaires completed by those participating in the oral health promotion programme. However, it well known that these studies do not reflect actual toothpaste use patterns; respondents tend to overstate the frequency of use. Hence there is need for a more objective method of measuring the frequency of tooth brushing. The primary aim of this study is to develop an objective method for monitoring fluoride toothpaste usage. The method under investigation will make use of the fact that the level of fluoride in saliva is a marker for the frequency of use of fluoride toothpaste. This study will also investigate the relationship between levels of fluoride found in saliva and the number of new caries lesions, which develop over 1 and 4 years.

**Aims:**

- 1. To develop a laboratory based objective method of monitoring frequency of use of fluoride toothpaste in both fluoridated and non-fluoridated areas.*
- 2. To measure the substantivity of fluoride in saliva over time among thirteen year old teenagers according to concentration of fluoride in toothpaste and amount of toothpaste used.*
- 3. To measure the association between salivary fluoride levels and development of dental caries*

## **Methods:**

Some of the fieldwork required to meet the aims of this study has already been completed. As part of another research contract (Northern Study, funded by industry), a one-year prospective study in two sites Limerick and L'Derry has been completed in June 2001. The aim of the Northern Study was to measure the increment of caries in 11-13 year old children over a one-year period using a number of different examination methods. The baseline examinations of 440 children were completed, 150 of these children were from a fluoridated area (Limerick), 70 are from a non-fluoridated area with possible "halo" effect due to their proximity to fluoridated areas(Limerick county) and approx. 220 children are from a non-fluoridated area (L'Derry). Stimulated saliva samples of all participating children were taken and have been analysed for *s. mutans*, *lactobacillus* and salivary fluoride levels. A questionnaire on oral health habits and practices detailing frequency of brushing, amount of toothpaste used, method of rinsing, snacking habits was also completed by both parents and children. One -year follow up caries examinations were carried out in L'Derry only (220 children) where saliva samples and questionnaires were again collected. The variables were measured according to standard operating procedures and all measurement methods were valid and reliable.

In the next phase which is the subject of this HRB project grant, it is proposed to return to Limerick for follow up examinations, saliva sampling (both stimulated and unstimulated) and questionnaire distribution to all the children included in the baseline examinations (Sept 2003-Nov. 2003). Stimulated samples of all included adolescents (will be 15-16 year olds now) will be taken to ensure consistency of both conduct and results of this study with the fieldwork already completed. Unstimulated saliva samples are more representative of real life and will be taken of all the included adolescents on a separate date. For the unstimulated samples, participants will be asked to refrain from brushing after 9pm the previous evening. The relationship between reported toothpaste usage and salivary fluoride levels and the relationship between salivary fluoride levels and 1 year increment (L'Derry) and 4 year increment (Limerick) will be investigated.

Validation studies on the relationship between fluoride levels in saliva and toothpaste usage and properties will also be undertaken. It is planned to conduct a controlled validation study of substantivity of toothpaste among 13-year-old children under controlled conditions to examine the effect of varying brushing patterns on salivary fluoride levels amongst a group of known compliers with oral hygiene instruction. This separate validation study will be conducted in Cork.

Project funded by the Health Research Board, Dublin as part of a 3-year project grant

**Work to Date:**

*Follow up examinations have been completed in Limerick on adolescents. Both stimulated and unstimulated saliva samples were taken from each participant on separate days and each filled out an oral hygiene habits and practices questionnaire. The clinical data is at present being cleaned and entered. The saliva samples have been analysed for fluoride levels in the OHSRC laboratory*

# Appendix 13

## **0436 Dental Fluorosis in Primary Teeth of 5-year-olds in Ireland**

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**Objectives:** Little information is available on the patterns of dental fluorosis in the primary dentition. The aim of this study was to measure the prevalence of dental fluorosis amongst 5-year-old children resident in fluoridated and non-fluoridated communities in Cork, Ireland and to investigate the relationship between infant feeding practices and the prevalence of dental fluorosis. **Methods:** Lifetime residents of fluoridated (n=208) and non-fluoridated areas (n=86) were examined using a modification of the TSIF Index. The teeth were examined both wet and dry. The examiner (MH) was trained and calibrated by a gold standard examiner (JW). **Results:** In the fluoridated group dry TSIF scores were 0=67.8%, 1=29.3%, 2=2.4% and 5=0.5%. In the non-fluoridated group the dry TSIF scores were 0=98.8%, 1=1.2%. TSIF (wet) scores were very similar. The mothers of 130 (62.5%) (out) of the 208 subjects living in the fluoridated community claimed to have not breast fed their child. The remaining 78 (37.5%) claimed to have breast-fed and formulae fed for various periods over the first year of life. The prevalence of dental fluorosis was similar in these two groups. The majority of the fluorosis was largely confined to primary molars, mainly second molars. **Conclusions:** It is concluded that the severity of dental fluorosis in the primary dentition of children living in fluoridated and non-fluoridated communities in Ireland is low. There was no association between infant feeding practices and levels and severity of dental fluorosis.

[http://iadr.confex.com/iadr/2003SanAnton/techprogram/abstract\\_27397.htm](http://iadr.confex.com/iadr/2003SanAnton/techprogram/abstract_27397.htm)

# Appendix 14

## **Fluoride Levels in Fingernail Clippings from Fluoridated and Non-fluoridated Communities.**

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### **Introduction**

Over the last 20 years there is evidence that because of increased availability of fluoride, dental fluorosis is increasing in a number of countries including Ireland. A number of health agencies have recommended that the amount of fluoride ingested and absorbed should be regularly monitored using appropriate biomarkers in communities with varying exposure to fluoride (WHO 1994, Department of Health & Children Ireland 2002, Medical Research Council 1994). Whitford (1999) has suggested that fluoride levels in fingernail clippings could provide a reliable, inert and non-invasive marker of the amount of fluoride ingested prior to clipping. Their findings indicated that fluoride entered the fingernail at the germinal matrix only and not during its growth through the nail bed. Hence it was suggested that the amount of fluoride in the fingernail clipping could provide a measure of the amount of fluoride being ingested some 2-3 months previously, that is the length of time it takes a nail to grow from the germinal matrix to the clipping stage.

The aim of the project reported in this poster was to measure the amount of fluoride in fingernail clippings collected from children who had been lifetime residents of fluoridated and non-fluoridated communities. The project was undertaken as a first stage in determining the feasibility of using finger nail clippings to monitor fluoride ingestion over time.

### **Methods**

A convenience sample of 25 children in Bangor Co. Down, Northern Ireland (fluoride levels in drinking water <0.2ppm) and 25 children in Cork City Ireland (fluoride levels 0.9ppm) were included in the study. Children aged 2-3 were chosen because they are thought to be most at risk of developing enamel fluorosis in their maxillary permanent incisors at this age (Evans and Darvel 1995). A questionnaire was also completed by the parent in which details of the child's tooth brushing habits were recorded, including the amount of paste used frequency of brushing and rinsing/spitting habits after brushing. The amount of water drunk each day was also ascertained. A sample of the child's drinking water was taken and analysed for fluoride content (McDonnell et al, 2004).

Fingernail clippings were collected 10 weeks later (the time estimated for the nails to grow from the margin of the lunula where fluoride is incorporated to the point at which it could be cut). Following Hexamethyldisiloxane (HMDS) facilitated diffusion fingernail clippings were analysed for fluoride content using a fluoride ion specific electrode (Orion model 94-09) and a miniature calomel electrode (Beckman model 41239). Statistical analysis was carried out using multiple linear regression analysis of the natural log of fingernail fluoride concentration.



## Results

Table1		Fluoridation Status		
		Full	Non	Total
Male	n	11	11	22
Female	n	14	14	28
Total	n	25	25	50
Age	mean	30.2	29.3	29.7
(months)	SD	4.1	3.4	3.7
	Range	23-37	22-34	22-37
Fl Conc	mean	3.21	1.71	2.46
(ppm) in	SD	0.97	1.21	1.32
Fingernails	Range	1.56-5.14	0.83-6.65	0.83-6.65

The age and gender profile and the fingernail fluoride concentration of the sample is presented in table 1. The only significant factor associated with fluoride levels in fingernail clippings was fluoridation status. The mean fingernail fluoride concentration in the non-fluoridated areas was 1.71 (SD=1.21). In the full fluoridated group the mean fluoride concentration was 3.21 (SD=0.37). This difference between fluoridated and non-fluoridated groups was statistically significant ( $p < 0.0001$ ).

## Discussion

Biomarkers which measure the amount of fluoride absorbed in the previous 24 hours, such as plasma and urine provide the most reliable method of monitoring fluoride ingestion over time. However, collection of these body fluids is invasive and are not appropriate for monitoring fluoride ingestion over a long period. Probably the most widely used long term method of monitoring fluoride ingestion over time has been the measurement of dental fluorosis. However, this method lacks precision because many of the changes in the appearance of the enamel are due to factors other than fluoride ingestion. The advantages of fingernails are firstly their accessibility. Secondly, as pointed out by Whitford, finger nails appear to be inert in that the concentration of fluoride in fingernails does not alter even if they are exposed to fluoride solutions. Another advantage which came to light during this study

was that the accuracy of the method used to analyse fluoride levels in fingernails could be validated: as part of a pilot study before commencing the analysis finger nail clippings were halved; one half being analysed in Cork and the other being analysed in the gold standard laboratory directed by Dr Whitford in Georgia, USA.

### **Conclusion**

The level of fluoride in fingernails was higher in children resident in fluoridated communities than those resident in non-fluoridated communities having controlled for other possible factors. Further studies are required in order to establish the sensitivity of this method for monitoring fluoride ingestion in populations over time. This study was supported by the Health Research Board and the Department of Health & Children, Ireland.

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# Appendix 15

## Fluoride ingestion from tea amongst adults in Ireland

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### Abstract

**Introduction** Over the last five years a number of health agencies have reviewed the evidence on the benefits and risks of water fluoridation. All of these reviews have suggested that a deficiency in the evidence-base exists in relation to the total amount of fluoride ingested from all dietary sources by people of different ages in different communities. For example, given fluoride's affinity for calcified tissues, concern has been expressed about the relationship between the total amount of fluoride ingested and osteoporotic fractures. One significant dietary source of fluoride is tea. The tea plant (*Camellia Sinensis*) extracts fluoride from soil which then accumulates in its leaves. Dry tea leaves may contain between 4-400 ppm fluoride. Marketing data suggests that people in Ireland are enthusiastic tea drinkers. **Aim** The aim of this project is to estimate the amount of fluoride ingested from tea in a random sample of adults aged fifty years or older, resident in Cork city (fluoridated) and Cork county (non-fluoridated). **Method** Tea drinking patterns, including the type, amount and the strength of tea consumed per day will be ascertained by means of a structured questionnaire and a subsample will complete a 3-day diary. Initially, this questionnaire (n=40) and 3-day diary (n=10) will be piloted; this pilot will also be used to estimate sample size. The fluoride content of tea available on the Irish market, brewed to varying strengths, with fluoridated and non-fluoridated water and with varying amounts of milk added, will be measured in the Oral Research Laboratory in UCC using the Taves diffusion method. **Results** The results of this project will provide an important contribution to the estimation of the total amount of fluoride ingested by adults in Ireland.

### Introduction

Over the last five years a number of health agencies have reviewed the evidence on the benefits and risks of water fluoridation (Clarkson 2000, Mc Donagh et. al., 2000, CDC 2001, Medical Research Council 2002, Forum on Fluoridation in Ireland 2002). All of these reviews have suggested that a deficiency in the evidence base exists in relation to the total amount of fluoride ingested from all dietary sources by people of different ages in different communities. For example, given fluoride's affinity for calcified tissues, concern has been expressed about the relationship between the total amount of fluoride ingested and osteoporotic fractures in older adults. It is therefore important to ascertain precisely how much fluoride is being ingested by this subgroup of the population. One significant source of fluoride is tea. The tea plant (*Camellia Sinensis*) extracts fluoride from soil which then accumulates in its leaves. Dry tea leaves may contain between 4-400 ppm fluoride.

### Background and Literature Review

Marketing data suggests that people in Ireland are enthusiastic tea drinkers; it is estimated that Ireland has the highest per capita consumption of tea in the

world with an average consumption per person of four cups every day, i.e. a total of 5.2 billion cups per annum (Kavanagh and Renehan 1998). Recent food consumption data in Irish adults (IUNA, 2001) indicate that 91% of adults aged 18-64 years are tea consumers, with a mean daily intake of tea of 619ml/day and a 95<sup>th</sup> percentile intake of 1259ml/day.

Duckworth and Duckworth (1978) analysed fluoride levels in tea samples consumed by 213 subjects collected on three consecutive days from 50 households. It was found that the amount of tea consumed increased with age. Hence fluoride intake from this dietary source increased with age. It was also found that ingestion of fluoride by tea drinkers ranged from 0.04 to 2.7 mg per day. In this study the authors also examined the rate of release of fluoride from tea leaves. It was found that fluoride was rapidly released from tea leaves in an infusion and that a near equilibrium condition was reached after eight minutes. It is interesting to note that fluoride levels can vary widely between tea brands. In this study a fourfold variation in the fluoride content of tea was found between different brands. Regarding the addition of milk to tea, it was found that milk did not alter the fluoride ion content of tea.

Fluoride intake in heavy tea drinkers was examined in a study by Jenkins (1991). Heavy tea drinkers were defined as those who consumed greater than fifteen cups of tea per day. It was reported that such high levels of tea consumption led to an upper limit of intake by adults of 9.9mg fluoride per day.

Chan and Koh (1996) studied the fluoride content in caffeinated, decaffeinated and herbal teas available on the US market. In this study the fluoride content of infusions prepared from 44 different brands and types of tea was measured. It was found that fluoride levels ranged from 0.34 to 3.71 ppm (mean value 1.50 ppm) in caffeinated tea infusions, 0.02-0.14 ppm (mean value 0.05 ppm) in herbal tea infusions and 1.01-5.20 (mean value 3.19 ppm) in decaffeinated tea infusions. This study was the first to look at the fluoride levels in decaffeinated tea infusions and it was found that fluoride levels were significantly higher than the corresponding caffeinated tea.

A study by Pang et. al., (1992) looked at fluoride intake from beverage consumption in a sample of North Carolina children. The aim of this project was to investigate fluoride intake from beverages in a sample of children of ages susceptible to dental fluorosis. In this study a diary format was used and daily total fluid intake was recorded for a sample of children aged 2-10 years. Of all the beverages analysed, tea had the highest fluoride content. The majority of tea products had a fluoride content of 2.0-3.0 ppm and the highest level obtained was 6.7 ppm.

In a study conducted to investigate the tea drinking habits of the population of Iran, it was found that drinks made a greater contribution to the total dietary intake of fluoride compared with foods, and the percentage contribution of drinks to dietary fluoride increased with increasing water fluoride concentration: 72, 79, 87% of total dietary fluoride in low, medium and high fluoride areas, respectively, came from drinks (Zohouri and Rugg-Gunn 2000). The authors concluded that brewed tea was an important source of dietary fluoride, providing 31% to 38% of total dietary intake

## **Aim of Project**

The aim of this project is to estimate the amount of fluoride ingested from tea in a random sample of adults aged fifty years or older, resident in Cork city (fluoridated) and Cork county (non-fluoridated).

## **Methods**

### **The Sample**

Convenience samples of 20 adults aged 50 or older will be selected from urban /fluoridated and from rural/non-fluoridated areas of Cork. The questionnaire will be piloted on these groups. The results of this pilot will provide the estimates required to establish the sample size required for a full-scale study. Subsets of size 5 will be selected from the two groups to pilot the 3-day diary. For the full scale study a random sample of adults aged 50 or over will be selected from the electoral list by the Economic and Social Research Institute. The sample will be stratified according to age, gender and medical card status.

### **Fieldwork**

Tea drinking patterns will be ascertained by means of a structured questionnaire and a subsample will complete a 3-day diary. As a method of data collection, the 3-day diary has been found to be economical (Black 1982) and reasonably reliable (Hackett et. al., 1984).



### **The Questionnaire**

This will include questions on the following parameters:

- Type of tea consumed, brand name and blend.
- Amount of tea consumed per day (amount expressed in ml).
- Strength of tea consumed (time tea is allowed to brew).
- Brewing methods employed (is the tea left to stand, or is infusion encouraged using a spoon etc).
- Water used (fluoridated or non-fluoridated).
- Addition of milk and sweetener.

### **The 3-day Diary**

Participants will be given both verbal and written instructions on how to complete the 3-day diary. They will be encouraged not to change their tea consumption patterns over the study period and also to record all tea consumed including even sips. The following points will be emphasized:

- Participants will be given a demonstration on how to measure the amount consumed.
- Participants will be shown how to describe the procedure they follow when making a cup of tea.
- The type of water used (bottled, tap or filtered), the type of milk used (fresh, condensed) and the kind of sweetener used will be ascertained.
- The brand name and the infusion time will be recorded.

### **Laboratory Analysis**

The Modified Taves method/HMDS diffusion will be used to measure the fluoride concentrations in tea infusions. This hexamethyldisiloxane (HMDS) diffusion technique was developed by Taves in the late 1960s (Taves, 1968). The procedure essentially uses a standard set of fluoride solutions made up to known levels of fluoride e.g. 0.05 up to 10 ppm. These are then compared with the tea infusions made up according to the details recorded in the 3-day diaries. Each episode of tea drinking recorded by all the participants will be replicated and analysed by the Oral Health Services Research Centre (OHSRC) Laboratory. Each sample will be analysed twice to ensure reliability of the estimate.

The OHSRC at University College Cork, is currently collaborating with the University of Indianapolis and five other internationally recognised laboratories in standardising methods of fluoride analysis. The University of Indianapolis will also collaborate with OHSRC in the development of laboratory methods for this project.

### **Results**

The results of this research will be used to assess the confounding effect of fluoride levels in tea when estimating total fluoride ingestion and absorption in the population of Ireland. The results will add to the international pool of data concerning fluoride levels in tea. Estimation of the amount of fluoride ingested from all environmental and dietary sources is important so that rational and scientifically sound decisions can be made when guidelines for the use of fluorides are reviewed periodically and modified (Pang et al., 1992). The results will also be of use in studies investigating the role of fluoride in osteoporotic fracture incidence. Stemming from this project, the role which tea consumption may have in the development of fluorosis may be investigated, once tea consumption in children is investigated.

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