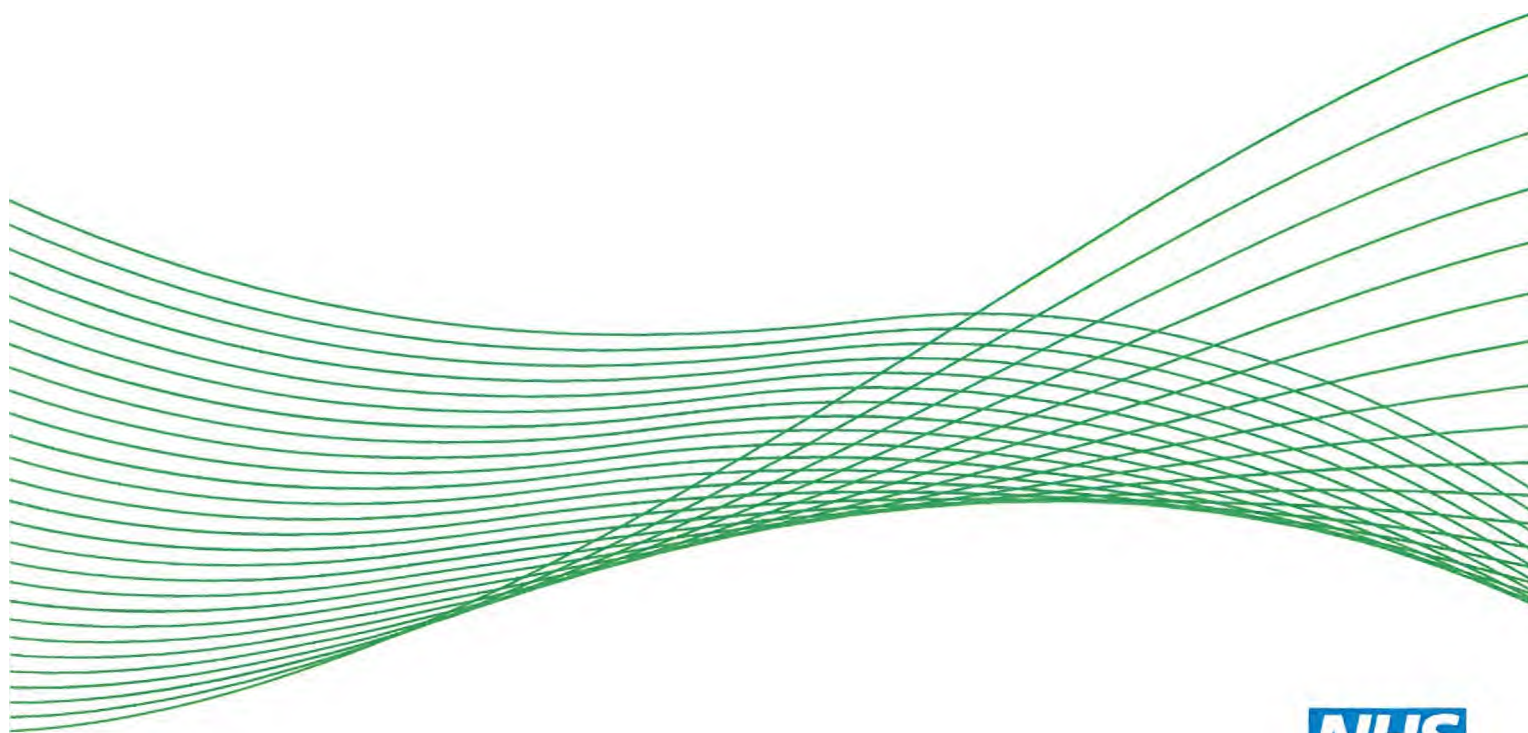


## **A randomised controlled trial to measure the effects and costs of a dental caries prevention regime for young children attending primary care dental services: the Northern Ireland Caries Prevention In Practice (NIC-PIP) trial**

*Martin Tickle, Ciaran O'Neill, Michael Donaldson, Stephen Birch, Solveig Noble, Seamus Killough, Lynn Murphy, Margaret Greer, Julie Brodison, Rejina Verghis and Helen V Worthington*



**National Institute for  
Health Research**

**TABLE 4** Advice for prevention of caries in children aged 0-6 years (summarised from *Delivering Better Oral Health: An Evidence-Based Toolkit for Prevention*)**Advice to be given****Children aged up to 3 years**

Breastfeeding provides the best nutrition for babies **I**

From 6 months of age infants should be introduced to drinking from a free-flow cup, and from age 1 year feeding from a bottle should be discouraged **III**

Sugar should not be added to weaning foods or drinks **V**

Parents/carers should brush or supervise toothbrushing **I**

As soon as teeth erupt in the mouth, brush them twice daily with a fluoridated toothpaste **I**

Brush last thing at night and on one other occasion **III**

Use fluoridated toothpaste containing no less than 1000 p.p.m. fluoride **I**

It is good practice to use only a smear of toothpaste

The frequency and amount of sugary food and drinks should be reduced **III, I**

Sugar-free medicines should be recommended **III**

**All children aged 3-6 years**

Brush at least twice daily, with a fluoridated toothpaste **I**

Apply a fluoride-containing varnish to teeth two times a year **I** (2.2% NaF<sup>-</sup>) **(I)**

Brush last thing at night and at least on one other occasion **III**

Brushing should be supervised by a parent/carer **I**

Use fluoridated toothpaste containing more than 1000 p.p.m. of fluoride **I**

Use only a pea-size amount (good practice)

Spit out after brushing and do not rinse, to maintain fluoride concentration levels **III**

The frequency and amount of sugary food and drinks should be reduced **(III, I)**

Sugar-free medicines should be recommended **III**

**Children aged 0-6 years giving concern (e.g. those likely to develop caries, those with special needs). All advice as above plus**

Use fluoridated toothpaste containing 1350-1500 p.p.m. fluoride **I**

Apply fluoride varnish to teeth two or more times a year (2.2% NaF<sup>-</sup>) **I**

Use only a smear or pea-size amount (good practice)

Reduce recall interval **V**

Investigate diet and assist adoption of good dietary practice in line with the Eatwell Plate **I**

When medication is given frequently or long-term request that it is sugar free, or used to minimise cariogenic effects (good practice)

(It is good practice) when medication is given frequently or long term, liaise with medical practitioner to request that it is sugar free or used to minimise cariogenic effects

Children aged up to 3 years (strength of evidence grades in bold font).

Adapted under the Open Government Licence from DBOH."

## Study settings

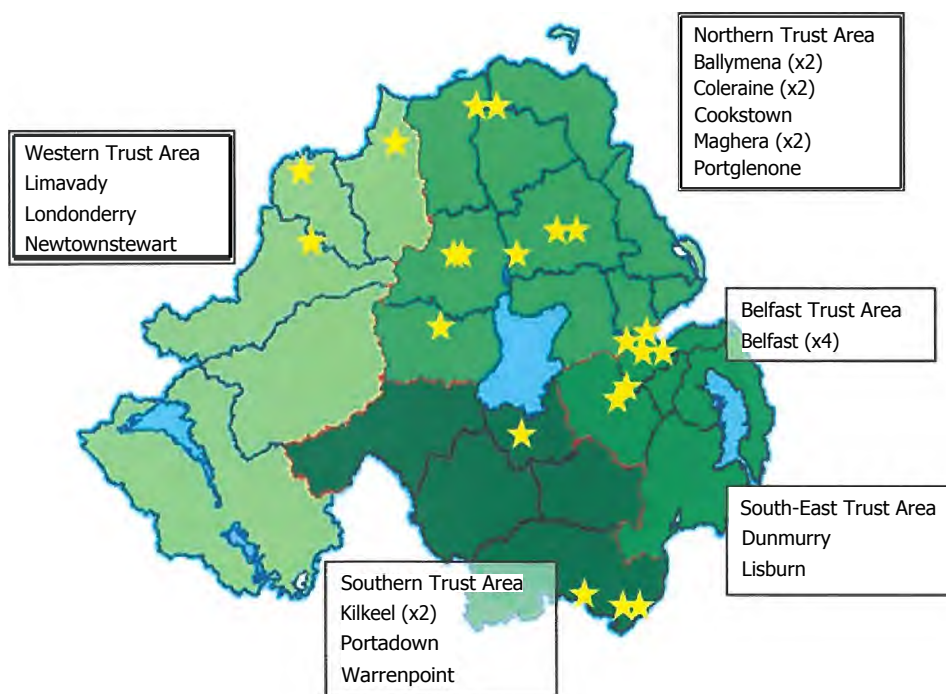
The study took place in 22 NHS general dental practices across Northern Ireland, UK. A map of the province (Figure 3) identifies the location of each practice participating in the study.

## Interventions

### Intervention group

The intervention was a composite fluoride intervention comprising two elements:

1. A fluoride-containing varnish (at a fluoride concentration of 22,600 p.p.m.) in the form of Duraphat® (Colgate-Palmolive Ltd, Guildford, UK), provided in its normal commercial packaging. Duraphat (used off label) is classed by the Medicines and Healthcare products Regulatory Agency as an investigative medicinal product and, therefore, its use in this CTIMP had to comply with relevant UK regulations.' A participating dentist applied the fluoride-containing varnish to all of the dried primary teeth of the children at two visits to the dental surgery each year, at approximately 6-monthly intervals ( $\pm$  4 weeks). One drop of varnish was applied to the primary teeth in each arch (two drops in total) using a standardised brush applicator. After application, parents were advised not to brush their children's teeth for 24 hours.
2. Participating dentists and their staff were trained to apply the varnish in accordance with the product brochure and practices were provided with an illustrated fluoride-containing varnish application guide describing the process of application. The UK summary of product characteristics" was also made available to the dentists. The varnish was dispensed by the pharmacy department at the Belfast Health and Social Care (HSC) Trust. The temperature of the varnish was monitored during distribution and storage using maximum and minimum thermometers to ensure the varnish used in the trial complied with the guidance in the product brochure.



**FIGURE 3** Location of the 22 general dental practices that participated in the Northern Ireland Caries Prevention In Practice trial. Reproduced from Land and Property Services data with the permission of the Controller of Her Majesty's Stationery Office, Crown copyright and database rights. Departmental Memorandum of Understanding 2015.

- The second element of the fluoride intervention comprised a free toothbrush and a free 50-m1 tube of toothpaste containing 1450 p.p.m. fluoride. This element was provided to intervention group children twice a year along with the fluoride-containing varnish. The toothpaste was Colgate® Cavity Protection (Colgate-Palmolive Ltd, Guildford, UK), which was provided in its normal commercial packaging. Parents of participating children under 3 years of age were advised to use a smear of toothpaste, and those whose children were over 3 years were advised to use a pea-sized blob of toothpaste when brushing their teeth. Photographs of a smear and a pea-size blob were included in a standardised dental health education sheet (see *Appendix 1*). It was stressed to parents that an adult must supervise the child when they brushed their teeth.

### **Control group**

Parents of children allocated to the control group were invited to bring their children for a dental check-up at 6-monthly intervals. At these visits the children received the same standardised dental health education as the children in the intervention group. The control group children did not receive any professionally applied or NHS service-provided fluoride interventions.

The trial visits were integrated into the usual 6-monthly dental check-up appointment of all children in both intervention and control groups over the 3-year follow-up period of the trial.

The date of visits for both intervention and control groups, and the date of each application of fluoride varnish, were recorded for each participant in the intervention group by the dentist (local investigator) on the CRF. The CRF identified the batch number of fluoride varnish used for each application. Empty or expired tubes of varnish were collected and retained. Participants who did not attend for their check-up appointments were sent out reminder letters.

### **Randomisation and blinding (sequence generation, type, allocation concealment mechanism, randomisation implementation and blinding)**

The practices identified potentially eligible children from their practice databases, based on their age and treatment history. For those practices without a computer, the Business Services Organisation provided the practice with a list of registered children between the ages of 2 and 3 years.

An invitation letter was sent to parents of identified children asking if they would like their child to participate in the trial. The invitation included a trial information sheet, which explained the study to parents. An appointment to attend a dedicated assessment session in the child's practice was included in the invitation pack. The child's dentist or the external CDS dentists (who completed the baseline clinical examinations) obtained parental consent for the child to take part in the trial. Baseline assessment was undertaken after consent had been obtained for each child but prior to randomisation. A specific randomisation schedule was prepared by the clinical trials unit (CTU) for each practice, using randomised permuted blocks. The block lengths varied to ensure that the CDS examiners undertaking baseline assessments were blind to patient allocation. Children who met the eligibility criteria and for whom written, informed consent had been provided by a person with parental responsibility were enrolled onto the trial. Randomisation was undertaken centrally by the CTU on a dedicated trial telephone line. The CTU verified the child's eligibility criteria and provided the local investigator with confirmation of the treatment allocation via fax (to provide a paper record of the allocation) and assigned a unique participant information number to each child.

### **Outcomes (primary and secondary outcomes how and when they were assessed)**

Clinical examinations for caries at baseline and outcome at 3 years were performed by trained and calibrated examiners, who were dentists employed by the CDS. Calibration took place on at least 15 4- to 6-year-old

# Appendix 1 Evidence-based, standardised parental advice sheet



## Oral Health for Children aged 2-7 Years Old

### Toothbrushing

1. Supervise and help your child to brush their teeth until they are 7 years old.
2. Brush teeth twice daily — once just before bedtime and on one other occasion.
3. Use a small headed toothbrush
4. Clean all tooth surfaces
5. Use toothpaste containing no less than 1000 parts per million (ppm) fluoride. (This information should appear on the packaging)



6. For children aged 0-3 years apply a SMEAR of toothpaste

7. For children aged 3-7 years apply a PEA-SIZED amount of toothpaste
8. After brushing don't rinse - encourage your child to spit out excess toothpaste. (Try to avoid swallowing)
9. Don't allow children to lick or eat toothpaste from the tube (keep out of reach)



### Dietary Advice

1. Limit the eating of sugary foods and drinks to mealtimes and no more than 4 x per day.
2. Avoid eating sugary foods and drinks before bedtime
3. Always ask for sugar free medicines

### Dental Visits

1. Children should visit the dentist approximately every 6 months or as often as their dentist advises.

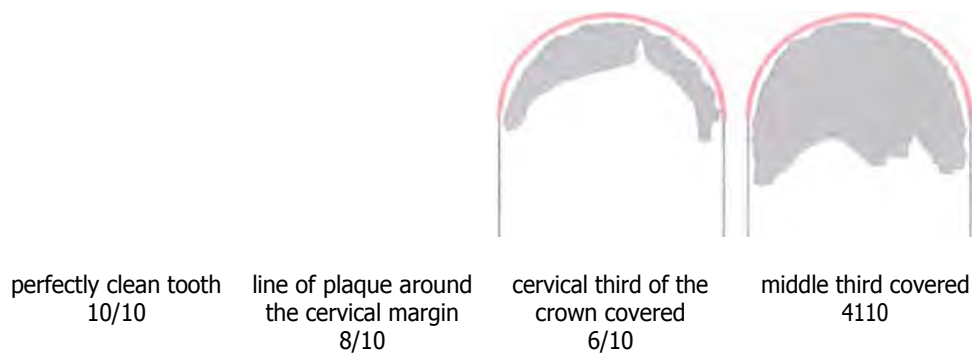
**Prevention and Management  
of Dental Caries in Children**  
Dental Clinical Guidance



## 3 Assessing the Child

### 3.4.6 Assessing Plaque Levels

Assessing and recording levels of visible plaque at each examination, and sharing this information with the child and their parent/carer, will help reinforce the importance of effective toothbrushing. An example of a quick method of recording plaque levels, and presenting the information in terms the child will understand, is to give marks out of 10 as follows:



Record the worst score in each sextant, for example:

8/10	6/10	8/10
8/10	6/10	8/10

It is also important to assess the surface of open carious lesions for plaque that is visible or evident when an instrument is gently drawn across the surface of the lesion, particularly if considering managing the lesion with a prevention-alone approach (Section 8.4).

- 11 Consider recording plaque scores at each examination, particularly if the child is assessed as at increased caries risk.

Record the presence of plaque on the surface of open carious lesions at recall visits for lesions where the prevention-alone management strategy has previously been selected (see Section 8.4).

## 3 Assessing the Child

### 3.5 Caries Risk Assessment

The caries risk assessment is an important part of the assessment of the child and enables the development of an appropriate individualised personal care plan based on the child's susceptibility to disease. The SDCEP *'Guidance on Comprehensive Oral Health Assessment'* provides further information on risk assessment. All children are at risk of developing dental caries and, therefore, require some preventive intervention. Some children are at increased risk of developing caries. Identifying these children enables additional prevention to be delivered to them.

The three main evidence-based indicators<sup>6,7</sup> of a child being at increased risk of developing caries within the next three years that are important to consider in the dental surgery are:

- **Previous caries experience** — any decayed, missing or filled teeth
- **Resident in an area of deprivation** — the home postcode can be used to identify whether a child lives in a deprived area (SIMD Quintile 1 is the most deprived 20% of the population; see Appendix 3)
- **Healthcare worker's opinion** — referral from a Health Visitor, Public Health Nurse or Dental Health Support Worker who has identified the need for additional preventive care

**Op** Based on the above indicators, your knowledge of the child and the history taken (including, caries incidence in siblings, toothbrushing and dietary habits; see Section 3.3), use your subjective clinical judgement to assess whether a child is at increased risk of developing caries.

**Op** Use the caries risk assessment to inform the frequency of review radiographs (see Section 3.4.2), provision of preventive interventions (see Section 6) and frequency of recall (see Section 12).





# Programme Manual for Childsmile Staff

July 2016



# Fluoride varnish application procedure

## Pre-application instructions:

These instructions could be written and/or verbal.

- advise patient on the purpose, benefits, process, possible side effects and answer any queries
- recommend the patient eats and drinks normally before attending
- advise that fluoride supplements should not be taken for two days after the fluoride application. After that, continue as directed
- advise that the patients' teeth may appear discoloured temporarily after fluoride varnish application and not to brush until the following morning.

## Duraphat<sup>®</sup> fluoride varnish application can be undertaken:

**In Practice:** by a dentist or under the prescription of a dentist by a dental therapist, hygienist or Childsmile trained **EDDN**, currently registered with the General Dental Council.

**In nursery/school:** by a Childsmile-trained EDDN in participating establishments, without an individualised prescription, as long as they are working under a Childsmile protocol for supply and application of treatment.

The dose of fluoride varnish for children is:

0.25 ml per child in Nursery and Primary 1

0.4 ml per child in Primary 2 and above

## Consent and medical history:

- **EDDNs should ensure they are familiar with the 'Childsmile protocol for the supply and application of Duraphat<sup>e</sup> varnish to children aged 2 years and over', and have signed it**
- **check that you have valid consent for the application.**

- **In the Practice setting** — check that you have a valid prescription for the fluoride varnish application. Check medical history with the parent, specifically check for allergy to sticking plaster or severe allergy or asthma that has required hospitalisation.

- if there are changes to the medical history or concern regarding consent refer back to dentist.

## Preparation:

- place your equipment so that it is accessible for yourself but away from the child

- dispense 0.25ml or 0.4ml Duraphat<sup>e</sup> of and ensure that the remaining varnish remains inaccessible to the child
- welcome each child and explain the procedure in simple terms
- ensure you and the child are comfortable and the child is wearing safety glasses and bib
- apply your own safety glasses, and follow local hand hygiene policies.

### **Risk assessment**

The Extra-Oral Assessment:

- check the skin of the face and around the mouth for abnormalities (spots, inflammation, swelling etc)
- check the lips for lesions/infections.

The Intra-Oral Assessment:

- check the inner cheeks and the insides of the lips
- check the upper and lower surfaces of the tongue.

Children showing obvious signs of systemic illness (e.g. colds, flu) or any abnormality of the face, lips or soft tissues of the mouth should be excluded on the day from fluoride varnish application.

- check the teeth and gums in a systematic order for signs of decay and/or infection.

If everything appears normal the fluoride varnish may be applied. If the child has signs of decay the fluoride varnish may be applied as it may help protect from further decay and it will acclimatise the child to dental treatment. However, fluoride varnish should not be applied to exposed pulps, in case it is uncomfortable.

**In the nursery/school setting** - If the child has any abnormality of the lips or mouth, or has dental caries identified in the risk assessment, send appropriate letter to parents advising that their child should be seen by a dentist. If the child is in pain follow local procedures to ensure the child is seen as soon as possible.

### **The application procedure:**

A systematic approach is more important than adopting a specific order or technique. However, the following represents one method, which could be followed. If a child gets upset or protests during any part of the procedure, then the procedure should be abandoned.

- gently retract the right cheek with your finger or mirror and dry the upper right canine and molars with a cotton roll
- place the cotton roll in the upper right buccal sulcus

- holding the roll in place, apply a small amount of fluoride varnish to the buccal, palatal, approximal and occlusal surfaces of the molars
- remove the cotton roll
- retract the upper lip with a finger. Dry the incisor teeth with a cotton roll
- apply varnish to the buccal, approximal and palatal surfaces of the canines and incisors
- repeat for upper left.
- repeat process for whole lower arch
- if there is insufficient varnish for full lower arch give priority to buccal, approximal and occlusal surfaces of molars on both sides of the mouth
- ensure all equipment is removed from the mouth. Count four cotton rolls, one brush, gloves, and one mirror and place all disposable equipment in the clinical waste bag
- complete patient record (on paper or electronically). In dental practice ensure relevant code is included on GP17 claim form or electronic equivalent. In nursery/school ensure the visit record is completed on the HIC system
- if any immediate allergic reaction, remove product by toothbrushing and rinsing and follow local protocol. Complete and submit a BNF yellow card as per local procedure.

**Post application instructions:**

- advise the patient not to eat or drink for 30 minutes following the procedure
- advise to eat soft food for the rest of the day
- advise that teeth should not be brushed that day but toothbrushing with fluoride toothpaste should resume the following morning
- fluoride supplements should not be taken for two days after the fluoride application. After that, continue as directed
- advise that the patients' teeth may appear discoloured temporarily.

- |   |
|---|
| <ul style="list-style-type: none"> <li>• <b>In the nursery/school setting</b> - provide the 'Fluoride varnish aftercare instructions' leaflet.</li> </ul> |
|---|

The beanbag or chair must be wiped with a detergent wipe after each child. At the end of the session leave the application area clean and tidy.

## The collapsed child protocol

Duraphat<sup>®</sup> when applied at the correct dose, is not normally associated with any adverse reactions. Every child in the Programme will have had a question asked regarding asthma and history of allergies.

In addition, children in Childsmile Practice will have had their medical history taken and updated at each appointment. Children who have severe asthma or allergies, categorised by a previous hospital admission for either asthma, allergies, or certain allergies such as colophony, will initially be excluded from Duraphat<sup>®</sup> application in the Nursery and School Programme and be referred to dental practice for a full assessment.

DHSWs and EDDNs are required to undertake Basic Life Support Training in their local area. Paediatric life support training should also be considered.

In the unlikely event of an adverse reaction, the protocol for dealing with a child who collapses whilst undergoing treatment is:

- stop the procedure immediately and summon help from the rest of the dental team and/or class teacher
- send someone to call 999 and note the time
  - remove all equipment from the vicinity of the child
  - put the child in the recovery position, ensuring that the chin is elevated
- make sure a member of the team keeps all the other children safe and away from the incident.

### In nurseries and schools

It is possible that a child may, for reasons not associated with the fluoride varnish, collapse while the dental teams are in the nursery or school. It is hoped that children with a medical history consistent with collapse are flagged up through the medical history form in Childsmile Practice or by the nursery or school teacher.

As the dental teams are visitors in nurseries and schools, it is reasonable to expect that the nursery or school will have their own protocols for dealing with such a situation. It is important that, in the extremely unlikely event of a collapse, the teachers in the classroom and the dental team work together.

### In dental practices

Each dental practice will have its own protocol for collapse and all employees working in the dental practice should be trained to follow this.

### **When a trained assistant is not available**

In October 2009, the GDC published "Principles of Dental Team Working" (GDC 2006) which states in paragraphs 3.7 and 3.8 "When treating patients, make sure there is someone else – preferably a registered team member – present in the room, who is trained to deal with medical emergencies. There may be circumstances in which it is not possible for a trained person to be present - for example, if you are treating a patient in an out-of-hours emergency or on a home visit. If this is the case, you are responsible for assessing the possible risk to the patient of continuing with treatment in the absence of a trained person."

In a dental practice, while it is important that this GDC standard is followed for EDDNs, it is accepted that there is not always an assistant available. On the occasions when an assistant is not available, the EDDN is responsible for assessing the possible risk to the patient of continuing with the Childsmile session in the absence of a trained person. They should also ensure that the GDC principles are met, namely that:

- at least two people are always available to deal with medical emergencies when treatment is planned to take place
- all members of staff (not just the registered team members) know their role if a patient collapses or there is another kind of dental emergency
- all members of staff who might be involved in dealing with a medical emergency are trained and prepared to deal with such an emergency at any time, and practice together regularly in a simulated emergency so that they know exactly what to do.

If the decision is to proceed, an "open door" policy should be adopted. This should be carried out as follows:

- the EDDN should inform the receptionist that they are seeing a patient and family member, and let them know which room will be used. This room should be within calling distance of another staff member **AT ALL TIMES**
- the door should be kept open at all times when the family is with the **EDDN**.

## Reporting adverse reactions protocol

If there are any adverse reactions to the fluoride varnish (e.g. mucositis, allergy etc.) remove product by toothbrushing and rinsing and follow local protocol. Complete and submit a BNF yellow card as per local procedure. The yellow card system is described below. This is the system used for any adverse reaction to any medicine in the British National Formulary (BNF). The web address is <http://yellowcard.mhra.gov.uk/>

NHS Education for Scotland (NES) in conjunction with the Yellow Card Centre Scotland has developed six e-learning modules to support healthcare professionals in identifying and reporting Adverse Drug Reactions (ADRs). These modules are available on learnPro.

The adverse reaction may be noticed immediately by the dental team or later by the parents. The parents may ring the dental practice, the nursery or school, depending on where the fluoride varnish was applied. In either case, it is unlikely that the dentist will be informed in the first instance but the EDDN in dental practice or the DHSW in nursery or school are more likely to be informed. It is good practice for the EDDN to inform the dentist who prescribed fluoride varnish in the dental practice. EDDNs /DHSWs should inform a dentist who is responsible for validating in Nursery and School Programmes.

Details required for reporting through the Yellow Card system are described in **Figure 7**.

# Appendix 7: Childsmile Toothbrushing Programme guidelines for staff training

## CHWDSMILE

### Briefing Sheet



## Childsmile Toothbrushing Programme: guidelines for staff training

The purpose of the training for the Toothbrushing Programme is to enable staff in participating establishments to be able to understand and apply the 'National Standards for Nursery and School Toothbrushing Programmes' version 3, 2015. in their establishment.

Staff members should be trained before the toothbrushing programme starts in their establishment. Any new members of staff require to be trained before carrying out the programme. All existing staff should receive yearly updates.

Every establishment will be monitored at least twice per school year by NHS staff who will update individual class brushing standards visit screen& after each visit on the Health Informatics Centre (HIC) data system.

Childsmile staff contact details should be available to every establishment.

**The following has been agreed as the minimum information that should be included in training sessions.**

### ORGANISATION

#### Explain background - Why are we doing the Toothbrushing Programme?

- Childsmile Programme developed from the Dental Action Plan 2005;
- Childsmile elements;
- National figure show a reduction in tooth decay since the introduction of the toothbrushing programme (local NDIP slats);
- Documents to support programme include: Nationals Standards for TB programme. abbreviated standards and DVD;
- Promote dental registration;
- Promote behaviour change;
- Emphasise links for education e.g. curriculum for excellence.

www.childsmile.org

NHS  
5t Oland





## Briefing Sheet

### **Discuss consent**

- Negative consent is in place for supervised, daily toothbrushing. It is assumed children will participate unless their parent or guardian refuses participation
- Ensure staff members are aware of the local procedures for recording and storing responses from parents withdrawing a child from the supervised toothbrushing programme.

### **Advice on infection control**

- Using the 'National Standards for Nursery and School Toothbrushing Programmes', cover topics including — storage; hand washing; infection control; cross contamination

### **Explain toothbrushing procedure and effective practice**

- Practicalities and demonstration. Practical demonstration should take place explaining Model A or Model B.

### **Resources available to support training**

- Presentation (<http://www.child-smile.org.uk/documents/26876.aspx> )
- National Standards for Toothbrushing. version 3 (<http://www.child-smile.org.uk/documents/5040.aspx> )

July 2016



**Appendix 8: Protocol for the supply and application of Duraphat® varnish to children aged 2 years and upwards in the Childsmile nursery and school programme.**



**NHS Board**

<b>Signatory</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>Clinical Dental Director</b>			
<b>Consultant in Dental Public Health</b>			

**Contact details for Clinical Dental Director or other responsible person**

**Management of Protocol**

This protocol must be read, agreed to and signed by all dental healthcare staff involved in its use. The protocol must be easily accessible to all healthcare staff in the clinical setting.

**LOCAL AUTHORISATION**

**(eg Childsmile Coordinator/Oral Health Improvement Manager/Team Leader)**

Authorised by .....

On behalf of .....

Signed .....

Date of implementation

I have read and understood the protocol and agree to use it.

Healthcare professional:

Name .....Name .....

Signature .....Signature .....

Profession .....Profession .....

Date .....Date .....

Name .....Name .....

Signature .....Signature .....

Profession .....Profession .....

Date .....Date .....

Name .....Name .....

Signature .....Signature .....

Profession .....Profession .....

Date .....Date .....

Name .....Name .....

Signature .....Signature .....

Profession .....Profession .....

Date .....Date .....

This protocol covers the supply and application of Duraphat for caries prophylaxis to children aged 2 years and over, who meet the selection and treatment criteria.

## 1. Patient selection

Criteria for inclusion	<ul style="list-style-type: none"> <li>• Child is at least 2 years old and attends a target Childsmile nursery or school</li> <li>• A Childsmile consent form has been completed and signed by a parent or legal guardian</li> <li>• In the case of a repeat procedure — a letter has been sent to the parent or legal guardian informing them of the planned Childsmile visit at least a week in advance. The letter will also have asked for any updates to the relevant medical history or personal details</li> </ul>
Criteria for exclusion	<ul style="list-style-type: none"> <li>• History of allergy to colophony (pink sticking plaster)</li> <li>• Previous admission to hospital for severe allergies or asthma <b>Action:</b> Refer patient for assessment by a dentist or dental therapist (local pathway)</li> <li>• Parent or legal guardian refuses on consent form <b>Action:</b> Record refusal but continue to offer fluoride varnish at subsequent visits.</li> <li>• Parent or legal guardian refuses further participation <b>Action:</b> Record refusal, complete procedure for permanent opting-out then record permanent refusal</li> </ul>

## 2. Patient Treatment

Name, form and strength of medicine	Duraphat® Varnish 50 mg/ml Dental Suspension 2.26% (22,600 ppm) Sodium Fluoride
Legal status	POM
Doses	0.25 ml per child in Nursery and Primary 1 0.4 ml per child in Primary 2 and above
Criteria for exclusion	<p>Children should be excluded from Duraphat® application if, on examination, they have:</p> <ul style="list-style-type: none"> <li>• Obvious signs of systemic illness (eg colds, flu)</li> <li>• Any abnormality of the face, lips or soft tissues of the mouth</li> </ul>

Adverse reactions/side effects	<p>In subjects with a tendency to allergic reactions, oedematous swelling of the oral mucosa has been observed in exceptional cases, especially after extensive application. If necessary the Duraphat<sup>®</sup> layer can be easily removed from the mouth by brushing and rinsing. Ulcerative gingivitis and stomatitis have been reported by sensitive individuals.</p> <p>In rare cases, asthma attacks may occur in patients who have bronchial asthma. In patients with gastric sensitivity, retching may exceptionally occur after a high dosage and extensive application.</p>
Overdose	<p>The toxic dose of fluoride ingestion is estimated at 5mg/kg child body weight. (The dose of 0.25 ml Duraphat<sup>®</sup> contains 5.6 mg fluoride.)</p> <p>Acute fluoride toxicity in small amounts causes stomach irritation, nausea and vomiting. In very high amounts/quantities, fluoride can cause serious systemic toxic signs and symptoms including the possibility of death.</p> <p>Fluoride is very quickly absorbed from the stomach; a child suspected of swallowing excessive levels of Duraphat<sup>®</sup> should be given a glass of milk to drink and then quickly transferred to the local A&amp;E department for further assessment.</p>
Follow up	<p>Ensure that all patient details have been recorded. Each child should be given a Childsmile Aftercare Instruction leaflet.</p>

### 3. Staff

Qualifications required	<p>Extended Duties Dental Nurses (patient selection and treatment)</p> <p>Dental Hygienists (patient selection and treatment)</p> <p>Dental Therapists (patient selection and treatment; reviewing patients referred for assessment)</p> <p>Dental Health Support Workers (patient selection only)</p> <p>Dentists (reviewing patients referred for assessment)</p>
Training requirements	<p>All staff to have undertaken NHS Education for Scotland Childsmile training (Dentists, Dental Hygienists and Therapists excluded) and CPD as appropriate.</p>

# Appendix 9: Information on Duraphat® Safety

## Duraphat® - Safety Issues

### Introduction

Fluoride varnishes are generally considered safe and well accepted. A Cochrane review<sup>5</sup> identified no evidence of adverse effects and recommended that future studies should actively record adverse effects. The safety information provided by Colgate (see Panel) indicates that their use is contraindicated in patients with ulcerative gingivitis or known sensitivity to colophony. However concerns have been raised regarding their use in allergic individuals<sup>2</sup>. This short paper summarises the available published literature on adverse effects related to fluoride varnishes.

### Safety information provided on Colgate professional website at:

<http://www.colgateprofessional.co.uk/products/Colgate-Duraphat-Varnish-50mgml-Dental-Suspension/specifics>

### Contraindications:

DURAPHAT is contraindicated in patients with ulcerative gingivitis or stomatitis or known sensitivity to colophony (kolophonium) or other ingredients. Not for ingestion during application (not for systemic treatment).

### Interactions with other substances:

On the day of DURAPHAT application, other fluoride preparations, such as fluoride gels, should not be administered. Routine regimens of fluoride tablets should be suspended for several days after treatment.

### Adverse Reactions:

In case of disposition to allergic reactions, edematous swellings have been reported only in rare instances, especially after application to extensive surfaces. In extremely rare instances, attacks of dyspnea have occurred in asthmatic children. Patients known for sensitive stomach may occasionally experience nausea with extensive applications. In any case of intolerance, the varnish layer can easily be removed by brushing and rinsing.

### Method

Searches of the Medline, Embase, Cochrane Library and TRIP database were undertaken using the following search terms:

Fluoride varnish  
Fluorides, Topical  
Duraphat®  
Allergy

## Hypersensitivity Asthma

Only four directly relevant articles were identified<sup>3-6</sup> none of which involved children. The most recent paper<sup>3</sup> involved in a 29-year old male being treated for hypersensitive teeth who suffered from swelling and redness of the tongue and lip within 24 hours of treatment, requiring treatment with antihistamines. Subsequent testing confirmed an allergy to colophony.

Colophony is a known contact sensitiser being a complex mixture of over 100 compounds derived from pine trees and has countless applications e.g.

- Cosmetics (e.g. mascaras, lipsticks, eye shadows, concealer creams, nail varnish)
- Adhesives (e.g. sticking plasters and tapes, glues)
- Medicines (e.g. wart removers, cold sore creams, ostomy products, nappy creams, haemorrhoid creams, sprays)
- Toiletries (e.g. transparent soaps, hair removing wax, dental floss, sunscreens, blister creams and first-aid ointments)
- Household items (e.g. grease removers for clothes, shoe wax, polish for floors, cars and furniture, laundry soaps, fly strips)
- Recreational (e.g. sport racket handles, athletic grip aids, golf club grips, bows for stringed instruments, fireworks, ski wax)
- Chewing gum
- Firewood and pine trees in the garden
- Paper products: one of the largest single uses of colophony is in the manufacture of paper and paperboard\*\*

A review by Downs and Sanson<sup>7</sup> found prevalence rates for colophony allergy to range from 1-7% with a paper by Husain<sup>8</sup> indicating a rate of 6.3% in the West of Scotland. The Scottish study was conducted in the 1970s and a recent paper from Sweden<sup>9</sup> has shown falls in the prevalence of colophony allergy which may be linked to decreased exposure.

To date there have been no published reports linking the use of fluoride varnishes to asthma episodes. Weintraub in a 2-years study<sup>10</sup> of fluoride varnish applications involving 376 children which specifically recorded adverse events only noted one (a cheek ulcer) with no adverse events being recorded in known asthmatic children.

A recent adverse event was recorded within the Childsmile programme<sup>11</sup> during which a child (with a reported elastoplast allergy) was inadvertently provided with a Duraphat<sup>®</sup> varnish application and suffered an allergic contact dermatitis type response.

### Conclusions

There is clear evidence of allergic reactions to Duraphat<sup>®</sup> in patients with known colophony allergy so it is important to follow the manufacturers' recommendations regarding this.

As there are no published reports linking the use of fluoride varnishes with asthma attacks there is no obvious reason to avoid using fluoride varnishes in this group of

patients. However, in view of the number of ingredients in Duraphat varnish and the fact that colophony is a complex mixture of over 100 compounds derived from pine trees, the current advice not to apply fluoride varnishes to those patients who have been hospitalised with an asthma attack seems justified as these are potentially the most atopic children.

It is also worth noting that the most common allergic response reported in the literature is the allergic contact dermatitis type response and that dentists assessing children's medical histories should take this into account when making recommendations for Duraphat® use.

Following that recent adverse event recorded within the Childsmile programme it is recommended that formal recording of all adverse events should be maintained.

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**\*\* Further information on colophony containing products can be found on the New Zealand Dermatological Society Incorporated website <http://www.dermnetnz.org/dermatitis/rosin-allergy.html>**

# Appendix 10: HIC Flow Chart

The flow chart below provides guidance on the procedures for consent forms and update letters.

## Childsmile HIC School I Nursery Consent Process 18/09/2012

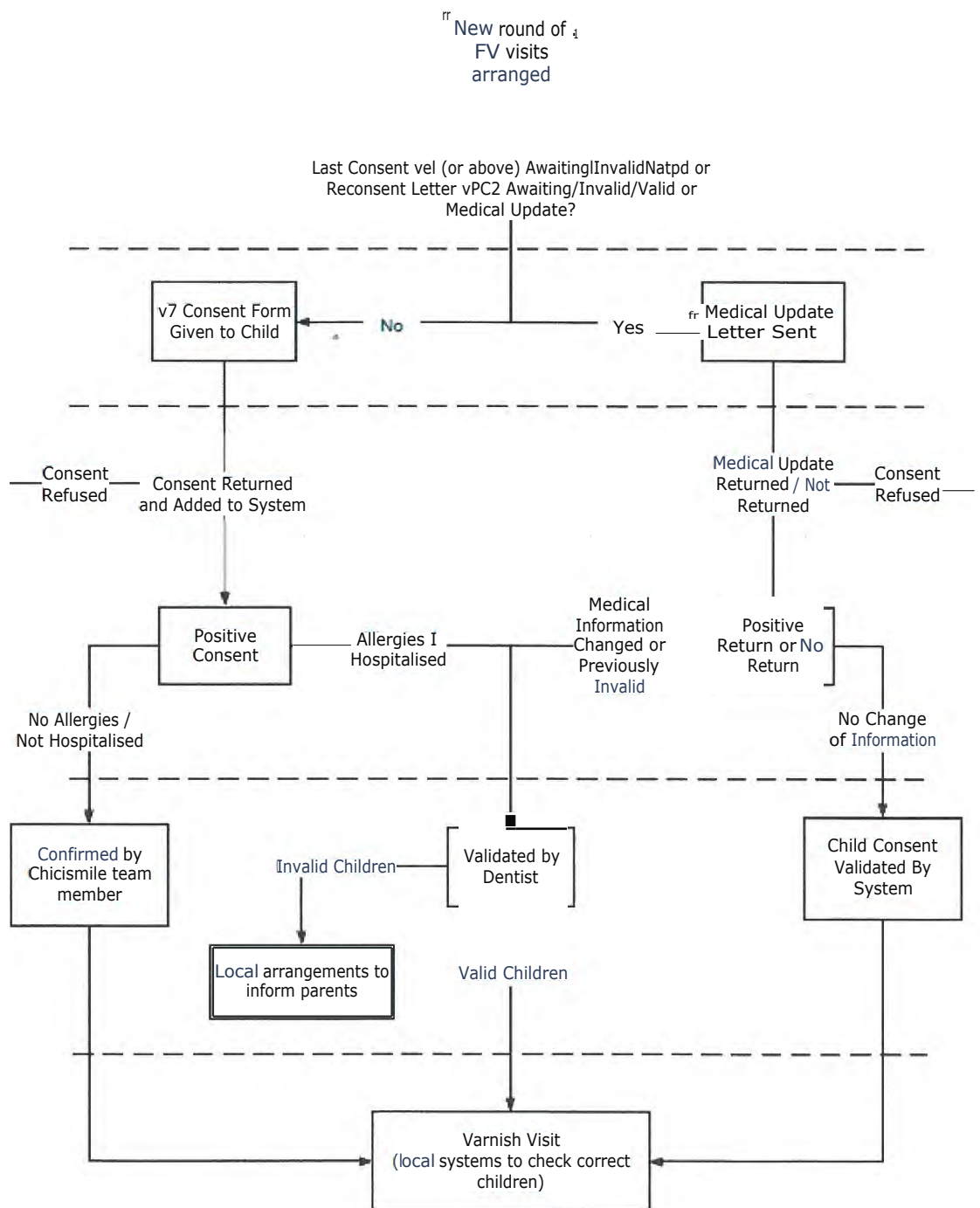


Figure 8: HIC Flow Chart

## Appendix 11: Childsmile Early Years Pathway

### Childsmile and the Universal Health Visiting Pathway — 6-8 week assessment

#### Procedure

##### The Dental Health Support Worker (DHSW) role:

A DHSW provides face-to-face, tailored home support to families that require oral health support in addition to that described in the Universal Health Visiting Pathway. Additional support from a DHSW includes toothbrushing demonstration/Instruction and the provision of dietary advice. The DHSW will work with the family to facilitate registration and regular, ongoing attendance at a dentist.

##### Why request Dental Health Support Worker (DHSW) assistance?

- ✓ The parent states that the family is not registered with a dentist.
- ✓ The parent states that the family do not attend a dentist.
- ✓ The parent and child's siblings have a history of symptomatic dental care and attendance at services prompted by dental problems or pain.
- ✓ Dental anxiety.
- ✓ Professional judgement (based on health and/or social factors) leads you to believe that provision of oral health support would be beneficial.

##### How to complete the Pre-5 Child Health Programme 6-8 week assessment:

Where face-to-face support from a DHSW is required:

- ✓ R = Record 'R' (request assistance from) in the Childsmile field in the 'future actions' box on the 6-8 week assessment form.
- ✓ W = In cases where a child is identified as needing additional support but the parent refuses, record 'W' (refused) in the Childsmile field in the future actions box on the 6-8 week assessment form.
- ✓ If additional DHSW support is not required, leave the Childsmile future action field blank and provide key oral health messages as per Universal Pathway.

##### When DHSW assistance is requested (R recorded in the Childsmile field)

- ✓ A health visitor referral to the DHSW is made using a locally agreed referral process. If unsure of this process, contact your local Childsmile Coordinator.
- ✓ On receiving this request for assistance, the DHSW will then have the responsibility of contacting the HV (if not already instigated by the HV) before visiting the family, to ensure any further appropriate background information is obtained.

## **Information - What Happens After a Referral Decision is Made?**

### **DHSW and HV work together to support a child's dental needs**

The amount of additional support required is tailored to a family's needs and all agreed activity will be recorded by the DHSW on the Childsmile HIC system.

The DHSW will deliver the agreed oral health support actions through home visits or at community venues.

In the majority of cases, DHSW activity will be ongoing from 3 months of age at the appropriate level and duration to promote oral health improvement/dental health and facilitate the child's registration with Primary Care Dental Services within the first year of life.

It is important the DHSW informs the child's HV (as the *Named Person*) of any challenges or concerns. Where a child is referred to a DHSW from a source other than a HV, the DHSW should liaise with HV colleagues to make them aware and provide opportunity for sharing of relevant information.

### **No identified need for additional face-to-face DHSW support**

The Health Visitor reinforces the key oral health improvement/prevention messages as described in the Universal Health Visiting Pathway.

Should circumstances change and the HV subsequently feels that additional support provided by the Dental Health Support Worker would be beneficial a referral can be made at any point. This can be recorded by the HV on an unscheduled CHSP form.

### **Primary care dental services provide oral health improvement/preventive care for registered children.**

- Primary Care Dental Services provide appropriate oral health improvement/preventive care in accordance with Scottish Dental Clinical Effectiveness Programme (SDCEP) guidance.
- Where a child fails to attend a practice appointment on more than one occasion the practice should contact the DHSW as per local 'failed to attend' policies.
- Where the practice team identify a concern for a child's wellbeing (e.g. repeated non-attendance, emergency pain relief on more than one occasion) they should contact the child's *Named Person* as per section 13 of the SDCEP Guidance: Prevention and Management of Dental Caries in Children [www.sdcep.org.uk/wp-content/uploads/2013/03/SDCEP\\_PM\\_Dental\\_Caries\\_Full\\_Guidance.pdf](http://www.sdcep.org.uk/wp-content/uploads/2013/03/SDCEP_PM_Dental_Caries_Full_Guidance.pdf)

## Appendix 12: 27-30 Month Review

### Childsmile and the Universal Health Visiting Pathway 27-30 month review

#### Procedure

##### Understanding pre-populated Childsmile field completion options:

1. record of outcome of previous Childsmile referral decision — (R) request assistance from, (W) refused, or blank if unknown
2. record of dental registration status — Yes (Y) or blank if unknown
3. record of 'participation' — this will show whether a child has attended for an appointment in the previous 12 months — Yes (Y), No (N) or blank if unknown

**Where a field is blank it is important to note there is no need to complete it. Reviewers need not gather any information in these fields. They are pre-populated to provide information to inform the review.**

##### Toothbrushing field

Are you confident the parent is brushing the child's teeth twice a day with at least 1000ppm fluoride toothpaste?

Enter 'Y' for yes and 'N' for no.

##### Childsmile Future Action field — refer to a DHSW

- ✓ The child is not registered with a dentist and/or does not attend a dentist regularly.
- ✓ A family history of attendance prompted by dental problems or pain.
- ✓ Dental anxiety.
- ✓ Professional judgement (based on health and/or social factors) leads you to believe that provision of additional oral health support would be beneficial.

##### Where face-to-face support from a DHSW is required:

- ✓ R = Record 'R' (request assistance from) in the Childsmile field in the 'future actions' box on the 27-30 month review form.
- ✓ W = In cases where a child is identified as needing additional support but the parent refuses, record 'W' (refused) in the Childsmile field in the future actions box.
- ✓ If additional DHSW support is not required, leave the Childsmile future action field blank and provide key oral health messages as per Universal Pathway.

## **Information**

### **Pre-populated data limitations**

There is a time lag between extraction of the data to pre-populate the registration and participation fields, and a child's actual review date. This means there is a possibility that a child may be registered with a dentist and/or attended in the intervening period.

It is important this information is used to explore dental registration status and involvement with dental services and is not seen as a definitive position.

### **Was the child referred to a DHSW at a previous review?**

The purpose of this field is to inform the HV carrying out the review of any previous decisions to refer for additional support. This can be used to gauge change in status over time.

### **Dental Registration Status at 24 Months**

The pre-populated entry in the dental registration field will give an indication of whether a child is registered with a dentist.

If the child is registered the field entry will be (Y) for yes. Otherwise the field entry will be (blank) for unknown. Regardless of whether the entry is 'Y' or blank this is an opportunity to discuss dental registration status.

### **Dental attendance between 12 and 24 Months**

This field tells the reviewer whether or not the child being reviewed has been taken by their parents/carers to their dental practice in the 12 months prior to the population of the review form.

This field will be pre-populated with Yes (Y) or No (N) for children who are registered. For children with unknown registration status, the field will be blank.

### **Support for family provided by routine universal services (e.g. Universal HV Pathway, PCDS)**

Where a child is registered with a dental practice and has attended for routine treatment there is no further current requirement to take action unless in response to a specific issue raised by the parent. In this scenario the family is engaging with services and the child is supported as required.