



MOH/K/GIG/1.2019 (GU)

MANUAL

FLUORIDE VARNISH PROGRAMME FOR TODDLERS

Oral Health Programme
Ministry of Health Malaysia
2019



**FOREWORD BY
THE PRINCIPAL DIRECTOR OF ORAL HEALTH
MINISTRY OF HEALTH MALAYSIA**

Early Childhood Caries is a major oral health problem among toddlers because of its high prevalence and impact on quality of life. Dental caries in young children can lead to unwanted pain, poor nutrition and medical complications.

In Malaysia, the successful implementation of water fluoridation programme since the 1970s has contributed to the marked improvement in the oral health of the population. However, disparity of oral health status persists both geographically and demographically. Among preschool children, there has been very slow improvement on oral health.

Fluoride varnish is recommended as a community-based caries preventive programme for toddlers. This fluoride varnish programme targets toddlers in high-risk communities to reduce the prevalence and severity of dental caries. It is hoped that this will further enhance the effectiveness of early childhood oral healthcare programme to address the disparity in oral health status of young children in Malaysia.

The purpose of this manual is to guide oral health personnel on the implementation, monitoring and evaluation of the fluoride varnish programme for toddlers.

I extend my warm appreciation to the committee members for their commendable effort and to all who have contributed directly or indirectly in the preparation of this manual.

A handwritten signature in black ink, appearing to be 'N. B. Taharim', written over a faint circular stamp.

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ACKNOWLEDGEMENTS

The Oral Health Programme, Ministry of Health Malaysia extends its heartfelt appreciation and gratitude to all who have contributed in one way or another in the preparation of this manual.

Special Thanks to

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1. INTRODUCTION

Fluoride varnish application is the only professionally-applied topical fluoride recommended for controlling and preventing dental caries in toddlers. Other topical fluoride modalities e.g. fluoride gels, fluoride mouth rinses are contraindicated for children aged below 6. Fluoride varnish is indicated for children and adults at high risk to developing caries. This manual aims to guide oral health personnel in the Ministry of Health on the implementation, monitoring and evaluation of the fluoride varnish (FV) programme for toddlers. This document is an additional guide to the 'Guidelines on Early Childhood Oral Healthcare: Never Too Early to Start'¹. Extensive literature review is also provided for reference (**ANNEX**).

The Ministry of Health Malaysia defines toddlers as children aged 4 and below.

2. OBJECTIVES OF THE MANUAL

2.1 General Objective

To establish a standardised, comprehensive and systematic fluoride varnish (FV) initiative as an integral part of the Early Childhood Oral Healthcare Programme

2.2 Specific Objectives

- To implement a community-based FV initiative as part of the Early Childhood Oral Healthcare Programme
- To monitor and evaluate the performance of the FV programme
- To increase the proportion/number of high-risk toddlers receiving FV application annually
- To determine the 2-year caries incident of toddlers receiving FV application as measured by change from baseline in the decayed, missing, filled and carious teeth to be extracted in all primary teeth at start and end of the programme.

3. TARGET POPULATION

For best use of resources in the Ministry of Health, the FV programme will focus on high-risk toddler populations/communities. The programme may be carried out at identified locations such as child care centres, health clinics and dental clinics.

4. TRAINING

All dental officers and dental therapist must be trained and updated periodically on relevant subjects which may include:

- Knowledge on professionally-applied topical fluoride (e.g. caries risk assessment, indications for FV application, application frequency and technique and safety of fluoride varnish use)
- High-risk individual/community identification
- Data collection and reporting
- Monitoring and evaluation

5. IMPLEMENTATION

5.1 Identification of High-Risk communities

The State Deputy Director of Health (Oral Health)/District Dental Officer and Officer-in-charge shall identify high-risk communities as priority for FV application.

Oral health status (caries prevalence and caries experience) of 6-year-old in the community is used as a proxy indicator for the oral health status of the toddlers in the community.

In the context of Malaysia (based on national caries prevalence and mean dfx of 6-year-old school children in Malaysia²) and for the purpose of this manual, a community is considered as high risk if:

- Mean dfx of 6-yr-olds is > 3, or
- Caries prevalence of primary dentition among 6-year-olds is more than 70%, or
- Located in non-fluoridated area

Communities with the highest caries prevalence and caries severity shall be prioritised.

5.2 Selection of Health Clinics/Child Care Centres/Dental Clinics

The District Dental Officer shall identify Health Clinics (HC)/Child Care Centres/Dental Clinics (DC) that serve the identified high-risk communities. The District Dental Officer shall brief all relevant personnel/institution to garner good cooperation in ensuring successful implementation of the programme.

5.3 Identification of High-Risk Children (Appendix 1)

Fluoride varnish is indicated for individuals with moderate to high risk of developing dental caries. Children with moderate to high risk for caries with/without lesions shall be selected for the programme. Guide for caries-risk assessment^{3,4} is provided in **Appendix 2**.

5.4 Fluoride Varnish Application (Appendix 1a)

5.4.1 Consent

Signed informed consent must be secured from the parent/guardian/caregiver of the child, refer to '*Pengurusan Kebenaran Rawatan Pergigian Kementerian Kesihatan Malaysia*⁵'. Parents/Guardians/Caregivers should receive explanation on the benefits and safety of FV application and the importance of compliance for the treatment.

5.4.2 Medical/Dental/Family/Social History (Appendix 3)

- a. A thorough medical history, including known allergies, shall be obtained from parents/guardians/caregivers of toddlers prior to FV application. Fluoride varnish application is **contra-indicated** in asthmatic children, children with ulcerative gingivitis or stomatitis or other known allergies.
- b. Dental and family social history shall be obtained from parents/guardians/caregivers of toddlers.

5.4.3 Instruments and materials (Appendix 6)

5.4.4 Pre-application instructions

- a. Explain the procedure to parents/guardians/caregivers
- b. Advise parent/guardian/caregiver
 - to give the child something to eat and drink before FV application
 - where possible, to brush the child's teeth before FV application

5.4.5 Position of Operator/Parent/Guardian/Caregiver/Toddler (Appendix 4)

- a. The operator may sit in a “knee to knee” position with parent/guardian/caregiver.
- b. Instruct the parent/guardian/caregiver to hold the child facing them with the child’s legs around their hips.
- c. Place paper towel/disposable bib on the operator’s lap and have the parent/guardian/caregiver gently lower the child onto the operator’s lap. Or, as you gain experience, do whatever works for you.

5.4.6 Application Technique (or according to manufacturer’s instructions) (Appendix 5)

- a. Clean teeth by wiping with cotton gauze. Where there is heavy plaque or debris, clean with a toothbrush. (Professional prophylaxis is not necessary before FV application).
- b. Lightly dry the teeth with cotton gauze. (Strict moisture control is not necessary as the varnish will adhere even if the teeth are moist).
- c. Isolate the teeth (e.g. with cotton rolls) to prevent recontamination with saliva
- d. Apply a **small amount of varnish (a thin layer)** using a small brush or applicator. (Avoid applying fluoride varnish on large open carious cavities or when there is intra-oral inflammation)
- e. Apply FV on upper teeth first starting from posterior teeth followed by anterior teeth. Then apply FV on lower teeth from posterior teeth to the other posterior ends.

Due to substantial growth rate between birth and age two, infants and toddlers absorb fluoride differently from older children⁶. Fluoride varnish should be applied in a thin layer and only on tooth surfaces where caries usually develops⁷. Caution must be taken to prevent children from swallowing the excess material during FV application.

5.4.7 Post-application Instructions (or according to manufacturer's instructions)

- a. The child should not rinse, eat or drink for at least 30 minutes after the procedure. Soft diet is recommended for the rest of the day.
- b. The child should not brush his/her teeth for the rest of the day. Normal oral hygiene procedures can recommence the next morning.
- c. Inform parents/guardians/caregivers of the temporary discolouration of the teeth that may occur.
- d. Inform parents/guardians/caregivers that FV may produce certain tastes due to flavouring.

5.4.8 Record of Treatment

Record FV application in the treatment card (LP8-2 Pin 7/97)

5.5 Establishment of Recall System

For effective caries prevention, there should be at least **four (4) FV applications at 6 monthly (± 1 month) intervals^{8,9}**. Follow up the child for at least 2 years from first application for purposes of FV reapplication and reassessment. Thus, it is recommended to start the first FV application on toddlers aged 1 - 2 years-old in order to complete the cycle of four FV applications at 6 monthly interval before the child goes to preschool. An effective call-recall mechanism should be in place to ensure patient compliance such as notifying parents/guardians/carers before the appointment for FV application.

6. MONITORING AND EVALUATION

6.1 Responsibilities

The respective State Deputy Director of Health (Oral Health) shall appoint a state coordinator to monitor and evaluate the outcome of the programme at state and district levels.

6.2 Data Collection

Data shall be collected manually at district level using the following formats:

-
- a. **FV 1:**
Listing of Schools by Oral Health Status of 6-year-olds (**Appendix 7**)
 - b. **FV 2:**
Pendaftaran Dan Pernyataan Sapuan Varnis Berfluorida Untuk Toddler (**Appendix 8**).
 - c. **FV 3:**
Pemantauan Bagi Sapuan Varnis Berfluorida Untuk Toddler (**Appendix 9**).
Monitoring shall be done by cohort
 - d. **PG 301:**
Create columns for topical fluoride varnish application (**Appendix 10**).
 - e. **PG 302:**
Create columns for topical fluoride varnish application (**Appendix 11**).
 - f. **PG 206:**
Create columns for topical fluoride varnish application. Create additional row for toddlers programme (**Appendix 12**).
 - g. **PG 207:**
Create columns for topical fluoride varnish application. Create additional row for toddlers programme (**Appendix 13**).
-

6.3 Data Flow

Data from districts shall be compiled at state level in January of the following year and submitted to national level by 31 of January using FV 3.

Each district/state shall be responsible for monitoring and evaluation of its individual programme.

6.4 Evaluation at State and National Levels

Evaluation of the FV programme shall be carried out yearly at state level and national level. Performance indicators to be used for evaluation include process indicators and outcome measure.

6.4.1 Process indicators

Shall be measured by COHORT using form FV 3. The following data are to be collected:

-
1. number of toddlers at identified facilities indicated for FV application
 2. number of toddlers rendered FV
 3. number of toddlers with one time (1x) FV application
 4. number of toddlers with two times (2x) FV application
 5. number of toddlers with three times (3x) FV application
 6. number of toddlers with four times (4x) FV application
 7. number of toddlers comply to six-monthly (± 1 month) FV application
-

The indicators to be used are as follows:	Formula/ equation[#]
Percentage of toddlers with FV need rendered FV	= $2/1 \times 100$
Percentage of toddlers with one times (1x) FV application	= $3/2 \times 100$
Percentage of toddlers with two times (2x) FV application	= $4/2 \times 100$
Percentage of toddlers with three times (3x) FV application	= $5/2 \times 100$
Percentage of toddlers with four times (4x) FV application	= $6/2 \times 100$
Percentage of toddlers comply to six-monthly (± 1 month) FV application	= $7/2 \times 100$

#: refer to the numbering as above

6.4.2 Evaluation of outcome measure

Shall be carried out using service/survey data. The outcome indicators to be used are:

- a. The 2-year caries increment of toddlers receiving FV application as measured by change from baseline in the decayed, missing, filled and to be extracted carious teeth in all primary teeth at start and end of the programme (evaluation by COHORT).
- b. Percentage of caries free mouth among 6 year-old schoolchildren (Standard 1).

7. RESEARCH

Research activities can be carried out during implementation of this programme at state and district levels. For example, an assessment of the effectiveness of community-based FV programme may be carried out based on different frequency of applications.

8. CONCLUSIONS

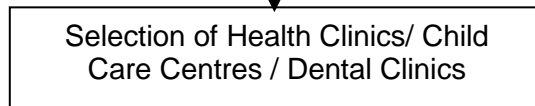
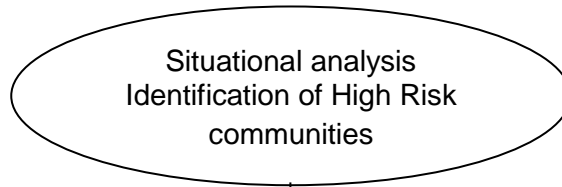
The oral health status of preschool children and toddlers in Malaysia will continue to be the main priority of the Oral Health Programme, MOH. This manual will facilitate the standardisation and systematic implementation of a FV application programme. It is an additional guide to the Guidelines on Early Childhood Oral Healthcare, towards the improvement of oral health of young children in Malaysia thereby enhancing their quality of life.

9. REFERENCES

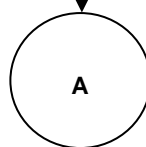
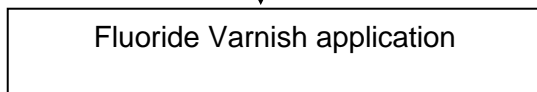
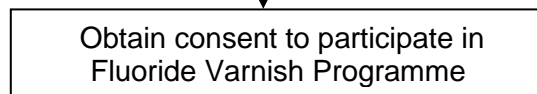
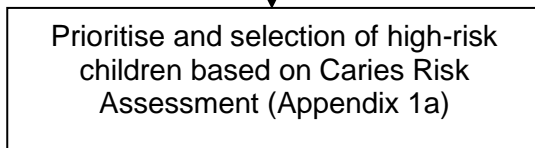
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Flow Chart for Identification of High Risk Children

1. Planning Phase (state/district level)

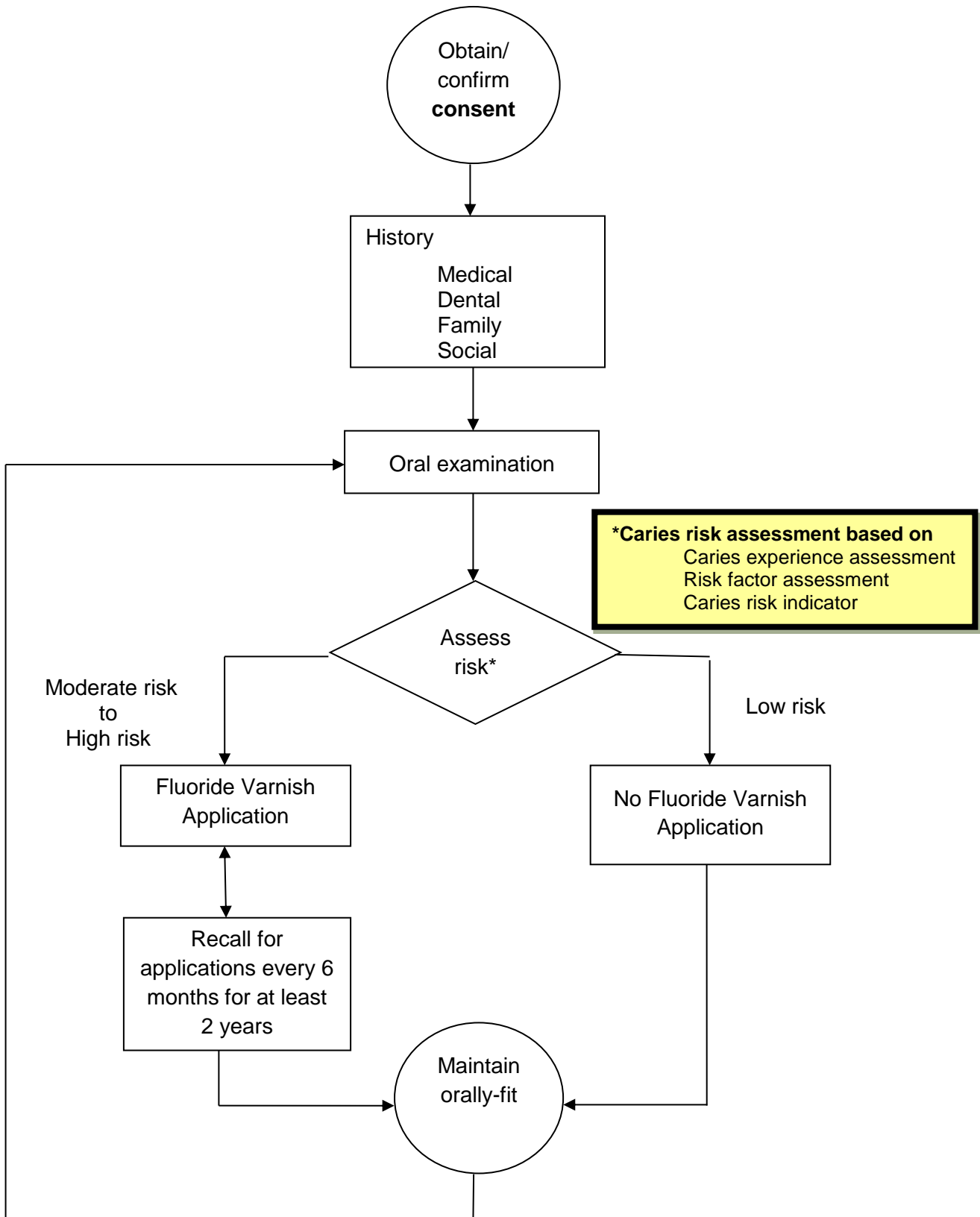


2. Implementation phase
(district/clinic level)



Appendix 1a

Flow Chart for Fluoride Varnish Application



Appendix 2

CARIES RISK ASSESSMENT

Step 1: Current Caries Experience Assessment

Visual Examination	Sound (Code 0)	Early Caries (Code E)	Caries (Code 7)
Tick *Highest Code Observed			

Step 2: Risk Factor Assessment

<input type="checkbox"/>	Visible Plaque
<input type="checkbox"/>	Crowding
<input type="checkbox"/>	Any dental appliances
<input type="checkbox"/>	No Fluoride Exposure
<input type="checkbox"/>	Sugar/Snacks Intake Between Meals
<input type="checkbox"/>	Medically Compromised
<input type="checkbox"/>	Mother/Sibling Caries Experience History
<input type="checkbox"/>	Dry Mouth

Step 3: Caries Risk Indicator (based on *Highest Code Observed and Number of Risk Factors)

Number of Risk Factors	Sound (Code 0)	Early Caries (Code E)	Caries (Code 7)
<input type="checkbox"/> 0	Low	Moderate	Moderate
<input type="checkbox"/> 1 - 2	Low	Moderate	High
<input type="checkbox"/> 3 or more	Moderate	High	High

Children with moderate to high risk for caries with/without lesions shall be selected for the programme.

Adapted from NB Pitts, Al Ismail, S Martignon, K Ekstrand, G.V.A Douglas and C Longbottom. International Caries Classification and Management system (ICCMS) Guide For Practitioners And Educators. London, King's College Dental Institute 2014 and American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. J Am Dent Assoc 2006;137(8):1151-9.

Appendix 3**Medical/Dental/Family/Social History****Medical History:**

A thorough medical history to determine known allergies, similar to that obtained prior to the administration of any therapeutic agent, is recommended prior to fluoride varnish use.

- Is the child quite fit and well at present?
- Has the child been treated for a general illness during the last 6 months?
- Is the child taking any medicines or tablets?
- Others

Dental History:

- Developmental history (history during pregnancy)
- Eruption of teeth – tooth eruption dates, any associated problems
- Toddler feeding techniques/ weaning
- Home dental hygiene care
- Diet history
- Fluoride use including toothpaste, fluoridated water supply (determined by address)
- Soft tissue problems

Family history:

- Family diet
- Siblings with caries

Social history:

- Parents occupation/income

Appendix 4

Position of Operator/Parent/Guardian/Caregiver/Toddler

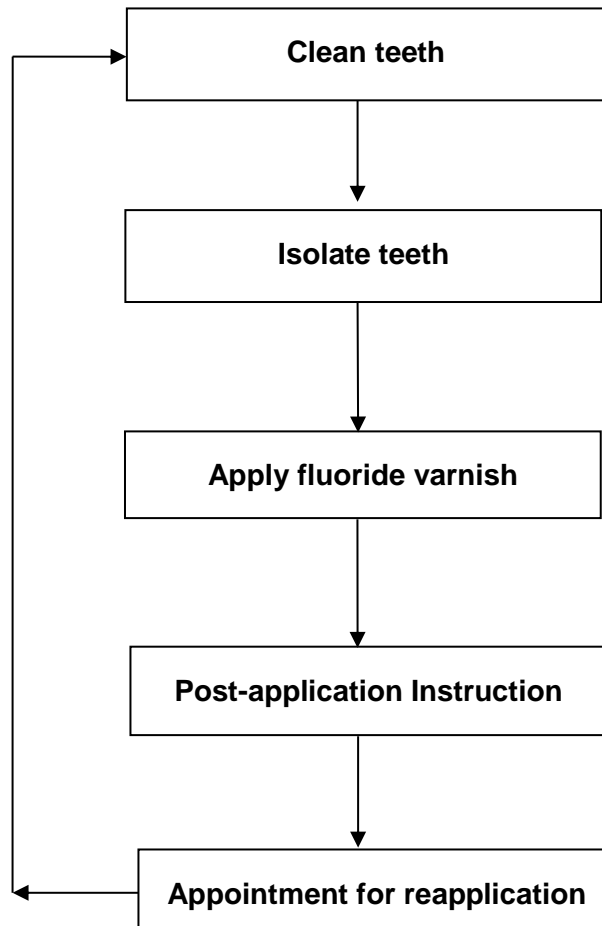


Knee-to-knee position



Side-by-side position

Flow Chart for Application Technique



Appendix 6

Instruments and Materials

Basic requirement for FV application:

- Disposable gloves
- Disposable face masks
- Instrument tray
- Mouth mirror
- Tweezers
- Cotton gauze
- Cotton roll
- Fluoride varnish containing **22,600 ppm fluoride**
- Container (e.g. Dappen glass) to hold fluoride varnish
- Small disposable fluoride applicator
- Lap barrier - Paper towels or disposable bibs to place under the child's head (optional)

Fluoride Varnish Programme for Toddlers
LISTING OF SCHOOLS BY ORAL HEALTH STATUS OF 6-YEAR-OLDS

FV 1

Dental Clinic/District:.....

Year:

No	Name of Primary School	6-year-olds (Information to be obtained from PG201)				Caries prevalence > 70%		Mean dfx > 3		Fluoridation status		High-risk Status (if fulfil any of the criteria g,i,l)		Name of <i>Taska</i> Near the School	Name of Health Clinic Serving the School
		No of Patients (New Attendance)	Caries Free Mouth (CFM) %	Caries Prevalence = (100% - %CFM)	Mean dfx	Yes	No	Yes	No	Yes	No	Yes	No		
						g	h	i	j	k	l	m	n		
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p
TOTAL															

Number of schools with high risk status (total m):.....

Number of high-risk *taska* selected (total o):.....

LITERATURE REVIEW ON USE OF FLUORIDE VARNISH

1 Introduction

The aim of professional topical fluoride application is to treat the tooth surface so that dental caries lesions are controlled and progression is retarded, arrested, or even reversed efficiently.¹ Professionally-applied topical fluoride (PATF) should not be applied on a routine basis in dental practices,² it should be based on caries-risk assessment.^{3,4,5} Several professional topical fluoride applications are available, for example, fluoride varnishes, gels, and foams.

Fluoride varnishes were introduced in 1960s and have become the most widely used professionally applied topical fluoride in Europe since 1980s.^{2,4} It has been proven to be effective in preventing dental caries in both primary and permanent dentition.^{6,7} The use of fluoride varnishes is considered appropriate for at-risk tooth-surfaces in caries susceptible individuals and for moderate and high caries prevalence child populations in community-based preventive programs.^{6,8} Several fluoride varnishes are available, however, there are two main fluoride agents for fluoride varnish products, i.e. 5% sodium fluoride (equivalent to 22600 ppm fluoride ions) and 0.9% difluorsilane (1000 ppm F).⁹

The advantage of varnish is its ability to adhere to tooth surfaces, which prolongs contact time between fluoride and enamel and improves fluoride uptake into surface layers of enamel, acting as slow-releasing reservoirs of fluoride.^{2,10} Thin coating of fluoride varnish is painted to the tooth surface, this technique holds a high concentration of fluoride in a small amount of material in close contact with the teeth for many hours.³ Fluoride varnish has practical advantages, e.g. ease of application, a non-offensive taste, and use of smaller amount of fluoride than required for gel applications.³ It reduces the risk of inadvertent ingestion in children younger than 6 years.⁵ Children with a gag reflex tolerate varnishes better than the gel-trays technique.¹¹

Adair⁴ noted that when a choice of professionally applied fluoride is available, it appear that fluoride varnish may be superior to fluoride gels and foams in caries reductions. Miller and Vann¹² took a stand that when clinicians have made a decision to use topical fluoride therapy, fluoride varnish should be the only consideration for children ages 0 to 6 and children of all ages who have special healthcare needs that limit their attention span and/or cooperation. Fluoride varnish should be the topical fluoride of choice for children ages six to twelve.

2 Effectiveness

A number of systematic reviews showed strong evidence of effectiveness of fluoride varnishes in preventing dental caries. Azarpazhooh and Main¹³ stated that there is clear evidence of the efficacy of fluoride varnish in preventing dental caries in children and adolescents (Evidence Level I, Grade A Recommendation). A Cochrane review⁶ suggests a substantial caries-inhibiting effect of fluoride varnish in both permanent and the deciduous dentitions. The prevented fraction for permanent teeth was 46% (95% CI, 30% to 63%; $p < 0.0001$), whereas the prevented fraction for primary teeth was 33% (95% CI, 19% to 48%; $p < 0.0001$). A meta-analysis concluded that fluoride varnish provided a 38% overall reduction of caries in permanent dentition compared to patients in control groups.¹⁴ Petersson et al¹ concluded from their systematic reviews on fluoride varnishes that the mean prevented fraction provided by fluoride varnish was 30%, compared to untreated control groups, They found inconclusive evidence for a caries-reduction effect by varnish in the primary dentition. United States National Institute of Health¹⁵ has noted that the evidence for the benefit of applying fluoride varnish to *permanent* teeth is generally positive. In contrast, the evidence for effectiveness of fluoride varnish applied to *primary* teeth is incomplete and inconsistent.^{4, 15} However, the Association of State and Territorial Dental Directors Fluoride Committee¹⁶ noted that fluoride varnish also has recently been shown to prevent or reduce caries in the primary teeth of young children. The recently updated Cochrane Review⁷ showed the prevented fraction for permanent teeth was 43% (95% CI, 30% to 57%; $p < 0.0001$), whereas the prevented fraction for primary teeth was 37% (95% CI, 24% to 51%; $p < 0.0001$). A total of 22 trials were included in this review. The fluoride concentration in 18 trials was 22,600 ppm, the others were 7000 to 56,300 ppm. An American review panel “found evidence of no benefit from use of 0.1 percent fluoride varnish in children”.¹⁷

3 Target population

Fluoride varnishes are recommended for patients (children) with a high and moderate risk of developing dental caries.^{8,9} especially in children with inadequate exposure to fluoride (e.g. children residing in non-fluoridated communities, children with low socioeconomic status). Hawkins and co-authors² stated that from the cost effectiveness perspective, professionally applied topical fluorides is not recommended for patients with low caries risk who reside in communities with water fluoridation.

4 Indications

It has been recommended that any protocol on the application of fluoride varnish should be based on risk assessment.¹³ The best indicator of risk for caries is previous or current caries experience. The Scottish Intercollegiate Guidelines Network¹⁸ suggested that the following factors should be considered when assessing caries risk, i.e. clinical evidence of previous disease, dietary habits, frequency of sugary food and drink consumption, social history, socio-economic status, use of fluoride, plaque control, saliva, and medical history.

Clinical criteria for application of fluoride varnish include presence of carious lesion, incipient caries (white spot lesions) and history of dental caries.¹⁹ New Zealand School Dental Service Guidelines²⁰ stated that fluoride varnish is used in the school dental services principally for spot applications of fluoride on enamel caries diagnosed visually or by radiograph, rather than for whole mouth applications. Other indicators for fluoride varnish include: the occlusal surfaces of partly erupted permanent molars and hypoplastic areas of teeth.

Fluoride varnish has been regarded as a safe and easy alternative for caries control in patients with special needs, such as those receiving head and neck radiation, orthodontic treatment, and those using medications that result in reduced salivary flow.^{9,21} Furthermore, as suction devices and trays are not needed for fluoride varnish application, varnish can be applied even for very young children and in field situations, such as the classroom.^{9,22}

5 Contraindications

Fluoride varnish application is contraindicated in patients with ulcerative gingivitis or stomatitis or known sensitivity to colophony [kolophonium] or other product ingredients which include: Ethyl Alcohol Anhydrous USP 38.58%, Shellac powder 16.92%, Rosin USP 29.61%, Copal, Sodium Fluoride 4.23%, Sodium Saccharin USP 0.04%, Flavourings, Cetostearyl Alcohol.^{23,24} It has been suggested that as a precaution, fluoride varnish is contra-indicated in asthmatic patients due to possible allergic reaction.² Fluoride varnish should not be applied on large open carious lesions and patient with intra-oral inflammation.²³ On the day of varnish application, other fluoride preparations, such as fluoride gels, should not be administered.²⁴

6 Frequency of application

Cochrane reviews^{6,7} suggested that fluoride varnishes can be applied professionally at a frequency from two to four times a year. Azarpazhooh and Main¹² noted there is clear evidence of efficacy with 2 applications in a year (Evidence Level I, Grade A Recommendation) and there is insufficient evidence to support 3 applications within a short interval such as 1 or 2 weeks (Evidence Level I, Grade E Recommendation).

Programs using fluoride varnish will be more likely to demonstrate benefits and reduce dental caries in at-risk populations when applications are offered at least at six-month intervals over at least two years in duration in combination with counselling.¹⁶

Clinically, varnish can be applied to fissures, proximal surfaces, or smooth surfaces of primary or permanent teeth. It can also be targeted only to specific tooth surfaces, and applications can be done according to individual needs.⁹

7 Professional cleaning before applications

Autio-Gold⁹ stated that varnish should be applied to dry, clean teeth. However, professional prophylaxis of the teeth is not essential before application. It has been shown that fluoride ions can migrate through plaque, and tooth brushing performed by the patients themselves is sufficient prior to varnish application.^{25, 26}

8 Adverse Event Protocol²³

A. Oedematous swellings have been reported in rare instances, especially after application to extensive surfaces. Dyspnoea, although extremely rare, has occurred in asthmatic people. Nausea has been reported when extensive applications have been made to patients with sensitive stomachs.

B. If required, varnish is easily removed with thorough tooth brushing and rinsing.

9 Safety

The concentration of fluoride in varnishes is much higher than that of APF gels or other topical fluorides. However, due to the sticky form of the varnish and the small amount used per application, risk of ingestion and toxicity is very low. Less than 0.5 ml of varnish is usually required to coat the teeth of a young child¹⁹. The recommended dose for children under 6-years is 0.25ml (primary dentition) while the dose for children over 6-years (mixed-dentition) is 0.40ml.^{27,28}

Seppa²⁶ highlighted that fluoride varnish should be applied in a thin layer and only on tooth surfaces where caries usually develops. With this precaution, accidental swallowing of large amounts of fluoride varnish can be avoided. In addition, fluoride varnishes need to be stored/placed at safe location, out of reach of children.

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