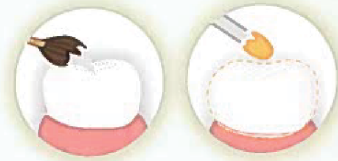




Information booklet for parents



Dear Parent/Guardian,

The Cardiff and Vale Community Dental Service would like to invite you and your child to help us evaluate two dental treatments to find out which one works best.

Before you decide if you want you and your child to take part or not, you need to know why the evaluation (study) is being done and what it will involve.

Please take the time to read the following information carefully. If you have any questions or want to know more, please call this number:

02920 687624



Bwrdd Iechyd Prifysgol
Caerdydd a'r Fro
Cardiff and Vale
University Health Board



SEAL OR
VARNISH

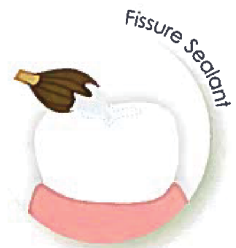
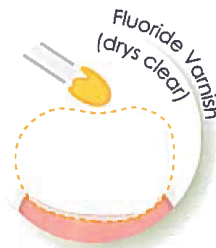
Q & A

Information for parents



What is this study about?

Dentists use two treatments to help prevent tooth decay in children's adult molar (back) teeth. One is a fluoride 'varnish' which is painted on to the tooth (like fluoride toothpaste only stronger) that helps strengthen the tooth against decay. The second is a plastic coating (or 'sealant') to prevent the harmful bacteria that cause tooth decay collecting on the tooth surface.



- Both treatments have been shown to work, and have been used for many years. We would like to find out if one treatment is better than the other, because no one currently knows.
- We also want to know what children, parents and the school think about the two treatments.
- We need the help of 920 Year 2 primary children (and their parents) to successfully complete the evaluation, which will last 3 years.

Why have my child and I been invited?

Because your child's school has been chosen and agreed to take part in this study.



Do my child and I have to take part?

No. It is totally up to you. If you choose for your child not to take part in the study, your child will still be able to take part in the existing Community Dental Service programme for prevention of tooth decay (See 2 & 7 on the CONSENT FORM).



What are the possible disadvantages and risks of taking part?

There are no significant disadvantages or risks for you or your child if you take part in the study.

What are the possible advantages about taking part?

There are unlikely to be any direct benefits for you or your child from taking part in the study, over and above the benefits of taking part in the current 'Designed to Smile' Fissure Sealant Programme. However both you and your child will be contributing to our understanding of which of the two treatments (fluoride varnish or plastic sealant) works best.

Will my taking part be kept confidential?

If you and your child choose to participate we would like to tell your child's dentist, but only with your permission (See 3 on the CONSENT FORM).

All information collected about you and your child during the course of the study will be kept strictly confidential (see 4 & 5 on the CONSENT FORM).

What if I do not want my child or I to carry on being part of the study?

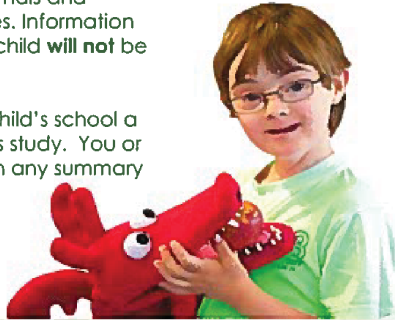
You can decide for you and your child to stop taking part at any time during the study, without giving a reason, by phoning **02920 687624**. If you decide to stop taking part, your child's dental care and the legal rights of either you or your child will not be affected in any way.

In order for us to understand the reasons why parents withdraw their children from the study, if you withdraw your child for any reason, with your permission (See 8 on the CONSENT FORM) we would like to contact you to find out why.



What will happen to the results of the research study?

- At the end of the study the results will be published in medical/dental journals and presented at dental conferences. Information that relates directly you or your child **will not** be presented.
- We will also give you and your child's school a summary of the findings from this study. You or your child **will not** be identified in any summary or report.



Who has funded and approved the study?

- This study has been funded by the Department of Health, and is being managed by Cardiff University in collaboration with the Community Dental Service.
- It has been looked at and approved by the independent Research Ethics Committee for Wales. Their job is to protect your safety, rights, wellbeing and dignity. The study has also been reviewed and approved by the UK medicines regulatory authorities.
- We have also received help and advice from the Forest Parents Group at the Forest Children's Centre, Dulfryn, Newport (<http://www.forestchildrenscentre.org.php>), to present the information provided to you in an understandable and jargon-free way.



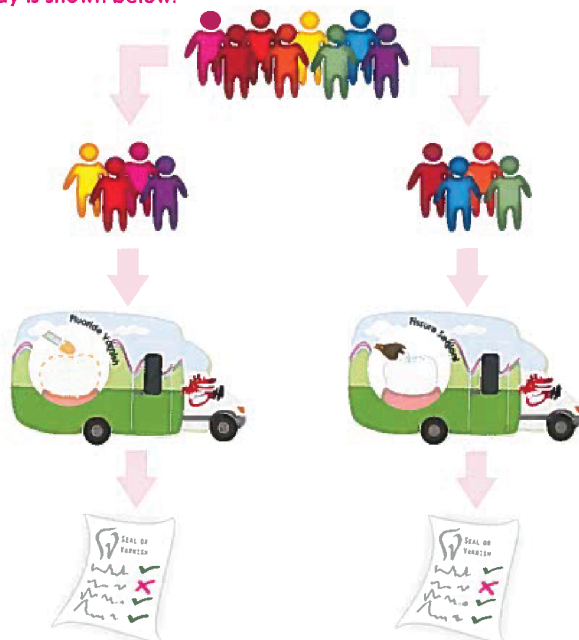
What if there is a problem?

- If at any point you are unhappy with any aspect of you or your child's involvement in the study, please advise the Dental Team (**02920 336414** or **07974 372002**). If you remain unhappy and wish to formally complain, you can do this through the normal NHS complaints procedure.
- In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff & Vale University Health Board Cardiff University Health Board and/or Cardiff University but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to my child and I if we take part?

- The Mobile Dental Clinic will visit your child's school early in the school year to look at your child's teeth to see if they are suitable for the study. The dentist will let you know if there are any problems with your child's teeth that need treatment.
- If your child is suitable for the study, he/she will receive either fluoride varnish or plastic sealant. Which treatment your child receives will be chosen randomly (by chance) using a computer. Your child will have a 50/50 chance of receiving either treatment.
- Your child will then be seen by the dental team and receive treatment (when required) every 6 months for the next 3 years through the Mobile Dental Clinic.

A summary of the study is shown below:



- After being seen by the dental team your child will be asked some questions about how they felt about the treatment.
- At the start and then each year we will be asking you to complete a short questionnaire relating to your child's dental health.
- At the beginning and end of the study a small number of children (in pairs) will be invited to speak with a member of the study team at the school to help us understand in more detail how children felt about the treatment they received. These sessions may be recorded (audio only), but only if you give your permission.
- We would also like to contact a number of parents by telephone at the beginning and at end of the study to hear their thoughts and feedback about the treatment their children received and on taking part in the study (the telephone call may also be recorded, but only if you give your permission).

What do I need to do now?

- We would like you to talk about the study with your child to help decide if you would both like to take part.
- If you decide you would both like to take part, please complete the following, and give to your child to hand in at school using the enclosed envelope:

1) MEDICAL HISTORY FORM

The Medical History Form is a document with a header featuring the 'Cynlun Gwên' dragon logo and the 'SEAL OR VARNISH' logo. It contains various sections for patient information, medical history, and consent, with checkboxes and text boxes for completion.

2) CONSENT FORM

(please remember to sign and date)

The Informed Consent Form is a document with a header featuring the 'Cynlun Gwên' dragon logo and the 'SEAL OR VARNISH' logo. It contains detailed information about the study, including its purpose, risks, and benefits, with checkboxes for consent and a section for the parent's signature and date.

- If your child normally sees your family dentist (for check-up etc) they should continue to do so during the study.
- During the study if you need to speak to a member of the dental team please call **02920 336414** or **07974 372002**.

Thank you for considering taking part in this study



South East Wales
Teulu Lloidi
Lloidi Ffynhoned
Deddfyrdd Cymru



Cynlun Gwên
Designed to smile



SEAL OR
VARNISH



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Caerdydd a'r Fro
Cardiff and Vale
University Health Board

