

A. Summary

This protocol describes the training and calibration of dental examiners who will undertake clinical assessments as part of the Seal or Varnish Clinical Trial. These examiners will be experienced Community Dental Officers, employed by Cardiff and Vale University Health Board with substantial clinical experience of the examination of young children. A Training and Calibration exercise will be undertaken on four occasions during the study at baseline before the baseline clinical assessment and at 12, 24 and 36 months ahead of the caries assessments.

B. Aim

To train two dentists involved in the caries assessment to use the ICDAS caries assessment.

C. Training of dental examiners

- The Training and Calibration will be based on British Association for the Study of Community Dentistry (BASCD) Training and Calibration Guidance⁽⁷⁴⁾ with substitution of the International Caries Detection & Assessment System (ICDAS).⁽⁷⁵⁾
- Training will involve an online International Caries Detection & Assessment System (ICDAS)⁽²⁶⁾ training package and a training day. Examiners and recorders will be given access to the training package ahead of the training day to give them the opportunity to familiarise themselves with all aspects of the criteria and conventions prior to the start of the training day. The training day will be lead by Professor Christopher Deery (University of Sheffield) an experienced ICDAS examiner. It will involve a seminar to review the criteria followed by caries assessments of twenty 6-7 year old primary school children from a Community First school in South Wales to practice use of the criteria. A formal Calibration carried out on ten different children will be undertaken after the practice examinations.

D. Recruitment of children for training purposes

- Recruitment of children for the training exercise will take place in a Community First school in South Wales once agreement has been obtained from the head

teacher. A letter to head teachers is included (Section M). The school used for the Training and Calibration exercise will not be used in the main study.

- Written consent will be obtained for the children to be examined as part of the training course. A letter will be sent (via the school) to the parents of children aged 6-7 years and positive consent obtained for them to take part. A letter / consent form for parents is attached (Section L).
- Sufficient children (30-35) will be recruited for the training session to ensure that they are not examined continuously. If any child does not wish to participate on the day or becomes tired, another will be substituted.

E. Conduct of Dental Examination

- Dental examinations will be conducted within the schools using conventional dental epidemiological survey techniques in line with British Association for the Study of Community Dentistry -co-ordinated surveys.⁽⁷⁴⁾
- The examiner will be seated behind the subject who will be in a supine position on a table or reclined sun-lounger.
- Children will be given a new, sterile toothbrush of appropriate size and asked to brush their teeth. No toothpaste will be used and the toothbrush will immediately be discarded and treated as clinical waste. This aspect of the examination is necessary to allow visualisation of the tooth surfaces to record dental caries in its earliest stages (enamel caries). In the event that plaque or food debris remains adherent, supragingival deposits will be removed by the dentist using either a toothbrush or probe.

F. The examination equipment

- A purpose built light yielding 4000 lux at 1 metre (e.g. Daray) or a similar protected light source will be used for illumination.
- Extension flex and plug adapter for use when necessary with the lamp.
- Disposable paper roll for laying out instruments.
- Materials to ensure cross-infection control including containers for clean instruments, containers for dirty instruments, disinfectant spray/wipes, clean latex-free gloves, eye protection for subjects, clinical waste bags together with sufficient cotton wool buds/rolls etc. for each child.

- Examiners will wear a fresh pair of gloves for each examination.
- Diagnoses will be visual using a plane mouth mirror. A blunt ball-ended probe (CIPTN) with an end diameter of 0.5mm will be used as described below.
- All necessary steps must be taken to prevent cross-infection. A fresh set of previously sterilised instruments will be used for each subject.

G. Examination procedure

- Data will be recorded onto a paper chart chairside.
- Teeth will be examined for caries in the following order:
 - (a) Upper Left to Upper Right
 - (b) Lower Right to Lower Left
- Surfaces will be examined in the following order:-
 - Distal, Occlusal, Mesial, Buccal, Lingual
- Each tooth will be identified and each surface recorded according to the diagnostic criteria for caries.
- Presence or absence of sepsis in the mouth will be noted and coded.
- If a primary tooth is missing, the state of the permanent successor will be recorded. In cases where both the primary tooth and its permanent successor are present further details will be recorded for the permanent tooth only.
- A tooth is deemed to be present if any part of it is visible.

H. Caries Criteria (ICDAS)

- The ICDAS detection codes for coronal caries range from 0 to 6 depending on the severity of the lesion. There are minor variations between the visual signs associated with each code depending on a number of factors including the surface characteristics (pits and fissures versus free smooth surfaces), whether there are adjacent teeth present (mesial and distal surfaces) and whether or not the caries is associated with a restoration or sealant. Therefore, a detailed description of each of the codes is given under the following headings to assist in the training of examiners in the use of ICDAS: Pits and fissures; smooth surface (mesial or distal); free smooth surfaces and caries associated with restorations and sealants (CARS). However, the basis of the codes is essentially the same throughout:

Code	Description
0	Sound
1	First Visual Change in Enamel (seen only after prolonged air drying or restricted to within the confines of a pit or fissure)
2	Distinct Visual Change in Enamel
3	Localized Enamel Breakdown (without clinical visual signs of dentinal involvement)
4	Underlying Dark Shadow from Dentin
5	Distinct Cavity with Visible Dentin
6	Extensive Distinct Cavity with Visible Dentin

- ICDAS two-digit coding method. A two-number coding system is suggested to identify restorations/sealants with the first digit, followed by the appropriate caries code, for example a tooth restored with amalgam which also exhibited an extensive distinct cavity with visible dentin would be coded 4 (for an amalgam restoration) 6 (distinct cavity), an unrestored tooth with a distinct cavity would be 06. The suggested restoration/sealant coding system is as follows:

0 = Sound: i.e. surface not restored or sealed (use with the codes for primary caries)

1 = Sealant, partial

2 = Sealant, full

3 = Tooth colored restoration

4 = Amalgam restoration

5 = Stainless steel crown

6 = Porcelain or gold or PFM crown or veneer

7 = Lost or broken restoration

8 = Temporary restoration

9 = Used for the following conditions

96 = Tooth surface cannot be examined: surface excluded

97 = Tooth missing because of caries (tooth surfaces will be coded 97)

98 = Tooth missing for reasons other than caries (all tooth surfaces will be coded 98)

99 = Unerupted (tooth surfaces coded 99)

I. Procedure in the event of serious pathology being suspected

- In the course of the training or calibration, an examining dentist may encounter suspected serious pathology (e.g. malignancy). This is very unlikely as the prevalence of such potentially serious pathology is extremely low in this age group. The examination is not a screening exercise and does not involve examination of the oral soft tissues. However, it is possible that such a lesion may be noticed and, as the implications are serious, a protocol to deal with this eventuality is in place.
- In the event that such a lesion is noted, the examiner is obliged to follow a set protocol, which is designed to make sure that the participant's parent or carer is informed, whilst not causing unnecessary worry or alarm.
- The examiner will note the child's name, date of birth and school and will contact one of the survey consultants by telephone, a Consultant in Paediatric Dentistry (Professor Barbara Chadwick). The Consultant will liaise with the examining clinician to obtain parental / carers contact details. Parents will then be contacted by telephone and arrangements made for the child to be seen by their general medical practitioner. A follow-up letter will be sent to the parents/carers and the child's medical practitioner.

J. Data analysis

- A master sheet will be completed for each training session to allow comparison between examiners at the tooth or surface level.
- The number of decayed missing and filled teeth or surfaces each examiner has recorded when examining the same child will be compared to and differences highlighted and discussed.
- For training, no formal statistical analyses will be undertaken and discussions use differences identified from the master sheets and individual charts for instant feedback.
- For calibration ten children will be examined and data entered onto a master sheet.
- Calculation of mean indices (DMFT,FT,dmft,dt) by examiner and the size and direction of the deviation from the benchmark examiner will be compared.
- Subsequently inter and extra examiner agreement will be determined using Kappa statistics.