University College Cork

FACCT (Fluoride And Caring for Children's Teeth)

Fieldwork Manual 2016-2017

Contents

1. Introduction

1.1 The FACCT study

FACCT stands for **F**luoride **A**nd **C**aring for **C**hildren's **T**eeth, and is a collaborative project between the Oral Health Services Research Centre (OHSRC), University College Cork and the HSE dental service, with funding from the Health Research Board under a competitive Collaborative Applied Research Grant in Population Health and Health Service Research.

1.2 Aim of the FACCT study

The aim of this study is to evaluate the impact and the outcome of the change in water fluoridation policy (2007) on dental caries and enamel fluorosis in Irish children, while also considering the change in policy on the use of fluoride toothpastes (2002).

In 2013-2014, 2378 6th class children (age 12) and 2894 junior infants (age 5) were examined based on whether their permanent incisors were formed prior to (age 12, born 2001) or after (age 5, born 2008) the reduction in fluoride levels in water. They were examined by ten HSE dentist and dental nurse teams in Cork, Kerry and Dublin. The evaluation also incorporated estimation of the impact of oral health on their quality of life. Now in 2016-2017 the children who consented to participate in 2013-2014 when they were in junior infants, whose parents consented to follow up, will be invited to participate in the study again.

The FACCT study also includes an economic evaluation of water fluoridation and will explore the potential of electronic health records to generate oral health data that can be used to monitor oral health. These aspects of the study are not covered in this manual.

1.3 Study location

The study is being conducted in primary schools in Dublin and in Cork/Kerry. Dublin has been selected because over one quarter (28%) of the population of Ireland resides in Dublin (Census 2011) and it is served by large water treatment plants with an excellent record of control of water fluoridation at the recommended levels. All of Dublin is fluoridated. Cork and Kerry have been selected to represent both fluoridated non-fluoridated areas.

1.4 Fieldwork 2016-2017

In 2016/17, our sample is made up of children who consented to participate in 2013-2014 when they were in Junior Infants and whose parents consented to follow up.

1.5 Examining teams

Examining teams of a dentist (examiner) and a dental nurse (recorder) will undertake the fieldwork for FACCT with additional HSE staff coordinating the fieldwork. Each examiner and each recorder will be assigned a number which will be used when logging onto the direct data entry system.

2. Study administration

2.1 FACCT consent packs

FACCT consent packs will be prepared and distributed to teams by the Oral Health Services Research Centre in advance of the commencement of fieldwork.

Please note that the manual was originally written for HSE dental fieldworkers. Non HSE fieldworkers will need to adapt the content of the manual to suit their particular situation.

Each pack contains

- A parent information leaflet
- Consent/assent form
- Medical history form
- Residential history form
- Parent survey
- A small labelled bottle for taking a sample of domestic tap water (Cork & Kerry only)

All documents except the information leaflet are barcoded with a 5-digit number – this is the child's unique subject ID. **Under no circumstances should you reallocate one child's subject ID to another child**, for example, by giving an absent child's pack to someone else or using documents from one pack to supplement another**.** You will be provided with a supply of complete non-barcoded FACCT packs to use if a child loses/wets/mislays their own.

During the fieldwork please **SCAN barcodes** using the barcode scanner provided wherever possible. If you must type the barcode, please double check what you have entered.

The FACCT consent packs are distributed to the children in unsealed envelopes. Parents are instructed to return the envelope to the class teacher sealed.

2.2 Initial contact with schools by OHSRC

Letters to the school Board of Management, school principal and class teacher/s will be issued by the Oral Health Services Research Centre (OHSRC) in late August and early September. Copies of the letters can be found in Appendix 1 for your information. The letters will be followed up by the OHSRC with a phone call to assess the school's willingness to participate in the study and to identify a key contact person in each school for future contact and administration of the study. In some situations the schools may agree to participate very quickly but often the Principal will want to discuss participation with the School Board of Management first which may mean that we do not know whether a school will participate for a number of weeks. The OHSRC will follow up with the schools as far as practicable until all of the schools have made a decision regarding participation in the study.

2.3 List of schools

Each team will be provided with a list of schools that have been contacted by the OHSRC. Schools which have agreed to participate, which have not yet made a decision and which have refused to participate will be indicated. Each team will be allocated particular schools depending on the team's location. The spreadsheet will contain the following information:

- the school name
- roll number (this is the unique identifier for the school and is very important to distinguish between schools with the same/similar names and to identify schools that have changed their names since 2013-2014)
- address
- phone number
- number of children in each school to be issued FACCT consent packs/examined

2.4 Contact with schools by examining teams

Each team is responsible for planning and organising the schedule for school visits in a way that maximises efficiency. We will provide you with the link to a google map showing the location of each school to assist you in planning your schedule. Please bear in mind that it may be best to plan to visit schools in rural or difficult to access areas first while the weather holds as in winter bad weather may affect the team's ability to access these schools.

If the school is located near to the examining team's location a site visit may be possible to speak to the school staff, deliver consent packs and view the facilities available for the fieldwork (but not on a Friday or day before a school break). If it is not possible to visit the school prior to conducting the fieldwork, the examining team will need to make arrangements with the school by phone.

A member of the examining team will make contact with each school to:

- Emphasise the importance of the study for providing up-to-date information on children's oral health that can be used to inform oral health policy.
- Confirm that the school is happy to participate or ascertain whether the school is happy to participate if this has not already been established.
- Arrange a date to visit the school to conduct the fieldwork. Please bear in mind that these children will be starting preparations for their first confession and first Holy Communion. It is imperative that the examining teams are cognisant of minimising any disruption to these preparations. Ideally the fieldwork would be completed well in advance of the later stages of preparation for these activities.
- Outline the requirements for the survey (natural light if possible, power sockets, and sufficient space to set up an examination area and separate area within the same room where children can complete the Quality of Life questionnaire, some tables and chairs).
- Arrange delivery of study documentation by post or in person (depending on how far the school is in relation to the team's location). Advise the school principal/secretary/other contact person that you will be delivering or posting the FACCT consent packs; ask that the packs be distributed to the named children early in the week and to request the return of the completed packs on the next day/by the end of the week. You may request that 'not selected' letters (Appendix 2) be distributed to the second class children who did not receive an envelope labelled with a name. The OHSRC will provide each team with copies of this letter.
- Ask the school if it is possible to send a reminder to parents to return completed consent forms using the school texting system, a paper note or email.
- Phone the school 2 or 3 days before the visit to check the number of FACCT consent packs returned. If the response rate is poor, please reinforce the importance of a good response rate for the study results and suggest that the school issue a reminder to the children/parents involved.
- Completed FACCT consent packs should be returned by the parent in the envelope provided (sealed). The sealed envelopes should be collected by the class teacher and then stored in a secure location such as in a locked filing cabinet or in the principal's office until the examining team arrive to start the fieldwork in the school.

- Ascertain the number of second classes in the school, the number of children in each class and the name of each class teacher (if this information has not already been provided to you by the OHSRC).

2.4.1 Site visit (if school is near to examining team location)
NOTE: not a Friday or day before a school break.

A visit to the school to deliver the FACCT consent packs offers the opportunity to meet the personnel in the school and to assess the proposed room/area for the examinations

- Speak to the Principal and highlight the importance of the survey for national policy. Stress that a good response rate is necessary.
- If possible, view the room/space that the school can provide for you. Check that appropriate sized tables and chairs, adequate lighting will be available and the location of power sockets in the examination room.
- If possible, speak to the second class teacher/s about the importance of the FACCT study and the importance of obtaining a good response rate to the survey. An explanatory letter for the class teacher has been prepared and will have been distributed in advance (a copy can found in Appendix 1 for your information).
- Speak to the class if possible about the importance of the survey. Hand out FACCT consent packs to those pupils who have been selected to participate. Children who were not selected may receive a letter to inform parents why their child was not invited to participate and to assure them that the FACCT study is separate from the HSE School Dental Service.
- Stress the importance of immediate return (next day if possible) of all consent forms to the teacher. Speak to the class teacher about collecting the forms. Suggest that once returned, the forms be stored in a secure location such as in a locked filing cabinet or in the principal's office.
- Arrange/confirm a date for conduct of the clinical examination. Arrange to phone the school contact a few days before the day of the survey to check the response rate/number of sealed envelopes returned.
- It would be very helpful if the school could help to encourage a good response rate by issuing a reminder to parents (paper note, global text message or email) to return the forms.

2.5 Special considerations

2.5.1 Gaelscoileanna and schools in gaeltacht areas
Our sample of schools includes a number of Gaelscoileanna and schools located in Gaeltacht areas. When we visited these schools in 2013-2014 a number of schools requested dual language FACCT consent packs and a small number of schools located in Gaeltacht areas requested the FACCT consent forms in Irish only. Each team will be provided with the type of pack (Irish only or dual language) that was provided the last time we visited these schools. In addition, should a school that received English only packs in 2013-2014 request dual language packs, these can be provided on request from the OHSRC.

An Irish version of the electronic Child Oral-Health-Related Quality of Life (COHRQoL) and oral health behaviours questionnaire will also be made available on paper.

2.5.2 Schools where a large proportion of children have English as a second language or where literacy among parents is low

In 2013-2014 we encountered schools where children have English as a second language and parents may not have any proficiency in speaking/reading English. There have also been cases of schools where literacy among parents is low. In these situations we will take a pragmatic approach. It is really important that these children are included in our sample so that we get an accurate picture of the oral health of children in modern Ireland. You could consider asking the principal if there is a home-school liaison officer available. They may be able to help the parents to complete the paperwork.

In this situation we will aim to obtain the **minimum information required to enable us to examine the children:**

- ✓ Completed signed Part 1 of consent form and
- ✓ Completed medical history (which may or may not be signed)

In addition (if possible) **we would like to obtain some information about the child's background**, namely:

- Residential history completed
- Part 5 of the parent survey only "Please tell us a little about your family".

3. Data protection

Before the FACCT study began, a significant body of work was completed to ensure the study procedures for fieldwork and data processing comply with all current Data Protection regulations. As part of the consent process, we assure participants' parents that we will store their child's data **securely**, keep all information regarding their child **private and confidential**, and **never identify** either the child or their parent.

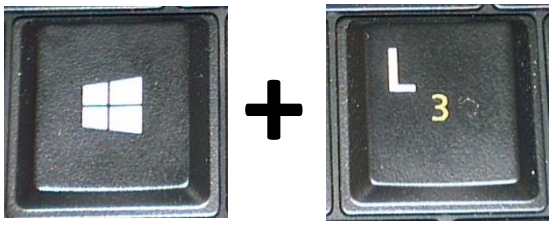
For the first round of fieldwork, FACCT packs were assembled and distributed anonymously, meaning data protection issues did not arise until completed packs were returned to schools. However, in this round of fieldwork we need to be able to link the previous data to the new data. This means we have to send out named consent packs which are individual to each child. Therefore there is a data protection concern from the very moment you receive your fieldwork equipment right through to when you finally return your records and equipment from your very last school.

To complete your role as a fieldworker, you are being entrusted with the full names, schools and subject numbers of approximately one tenth of all study participants. In keeping with our commitments to the data protection commission, please be mindful at all times of the need to store these records securely and to maintain privacy, confidentiality and anonymity.

Please make sure that consent packs are stored securely at all times. Pay particular attention to ensure consent packs are distributed to the correct children; otherwise you would be inadvertently telling another family the name of a participant! Use only the correct, anonymous barcodes when completing the photographic and urgent care logs books; if one is lost, at least the names of the children concerned will not be revealed. We understand that some note taking is necessary to organise your work; please use subject numbers rather than names wherever possible, and keep all notes in your FACCT notebook. Return absolutely every piece of paper to us at the OHSRC, including all lists, un-used consent packs and spare barcode stickers, all notebooks and notes, any scraps of paper, and anything else with a subject number or name on it.

With regard to the computers,

- The FACCT laptops are encrypted. Without the password the data cannot be read.
- You will be given an individual password card and USB drive. Keep these in a secure place – **NOT with the laptop**. Do not write passwords on the machine, on these notes, or leave the card or USB drive in the laptop bag.
- **Always lock the laptop by holding down the Windows key and pressing 'L'** if you are leaving it unattended, even for a brief period.



- The laptop should always be kept in a secure place. Do not leave it in the car overnight, or for other extended periods, for example.
- Keep it out of sight; i.e. lock it into the boot of the car rather than the passenger compartment.
- Once the survey has been completed, the laptop must be returned to the OHSRC for secure data removal.
- Do not connect the laptop to any unauthorised devices, e.g. non-FACCT USB drives, smart phones, etc. Connecting to other devices may change some of the settings within the computer and cause the process to send data to fail.
- Do not keep copies of the data on any other device; e.g. memory/USB sticks, CDs, etc.
- Do not change any of the passwords on the laptop.
- Do not change any of the display settings. The screen is set to lock automatically if the machine is not used for a few minutes. This was specifically included in our data protection application, so please do not change it.
- Use the laptops and associated equipment for study purposes only. These laptops, USB drives and internet dongles are not for personal, or other non-study related, use.

4. Survey visit

4.1 Health and Safety

- The examining team should adopt safe work practices and take reasonable care of their own safety, health and welfare and that of others in line with HSE Manual Handling and People handling policy when transporting equipment to and from the car to the examination room and in setting up the examination area.
- Consideration must be given to health and safety regarding the positioning of extension leads and cables to avoid slips, trips or falls. Cables of extension leads and lights must be taped down.
- Use tables and chairs of appropriate height to allow the examining team to work as ergonomically as possible to minimise strain and fatigue.
- The recorder should observe standard health and safety procedures when working with the direct data entry system.

4.2 Infection Control

Standard cross infection control measures will be observed. A log of waste delivery must be maintained by each team. A copy of this log will be distributed to each team by the OHSRC. (See Appendix 3 for further Information on setting up an exam station and handling, transporting and disposing of waste).

- Wash hands prior to commencing examinations in the school. If hand washing facilities are not available, apply an alcohol hand rub using the recommended technique. (http://www.hse.ie/eng/services/healthpromotion/handhygiene/).
- Change non-latex gloves before each examination.
- Change face masks once every hour, at least or sooner if moist.
- Place a disposable paper sheet under each set of instruments and change between subjects.
- Wipe light handles with disinfectant wipes between subjects.
- Place piece of tissue roll in the head area of the foam camping mat during the caries examination and change after each child.
- Wipe protective glasses with disinfectant wipes between subjects.
- Dispose of used mirrors and probes in the sharps container.
- Ensure the aperture of the sharps container is returned to the closed position after disposal and for transportation.
- Dispose of used gloves, cheek retractors, alcohol wipes, tissues, clinical sheets and headrest covers in a clinical disposal plastic bag (yellow bag).
- Return all waste to the dental clinic for disposal.
- Please keep a record of generation and disposal of yellow waste bags and sharp bins in accordance with current HSE standard operating procedures and guidance on the collection, transport and disposal of healthcare risk waste.

4.3 Equipment

See Appendix 4

4.4 Check completion of FACCT paperwork

- When the examining team arrive at the school, they retrieve the FACCT consent packs from the principal/ secretary's office.
- The examining team open the sealed envelopes for the first group of children they intend to call (suggest groups of 2 to 4 depending on the space available) and check that the parental consent, child assent and medical history are completed and signed. Ensure that only children with these forms completed are asked to come for the survey (see exclusion criteria 4.4.2).
- The examining team should decide on the most suitable way to organise the day. They can then call to the class (with the first 2 or 4 checked envelopes), and introduce themselves to the teacher. If the teacher agrees, the examining team should briefly introduce themselves to the class and explain the reason they are in the school. They can then ask the teacher to send out the first 2 to 4 named children.
- Confirm the child's name and age and check that it matches the completed FACCT consent pack documentation before the child's barcode is scanned into the questionnaire laptop.
- Thank the child for taking part in the study and explain briefly to the child the sequence of events: first they will complete the electronic survey; next you'll measure them, then have a look at their front teeth, take a photo and then ask them to lie on the table so that you can look at all their teeth.

Please Note

The names on the envelopes were generated from the names entered by teams in the field during the previous round of fieldwork. While every effort has been made to correct obvious mistakes, unfortunately not all names will be spelled correctly. If the child's name is spelt incorrectly, please apologise to the child for the error and ensure that the correct spelling of the child's name is entered into the correct fields of the clinical record on the computer to ensure any mistakes are corrected.

4.4.1 Inclusion criteria

- Completed parental consent Part 1, child assent and medical history.
- Pupil in second class and consented to participate in FACCT 2013-2014 and subsequent follow up.

4.4.2 Exclusion criteria

- Consent form not completed and signed by the parent/guardian.
- Medical history not completed (can proceed if completed but not signed)
- Children who are unable or unwilling to participate on the day
- Children with any medical condition that would mean their participation in the study would pose a risk to their health or wellbeing.

4.5 FACCT Tally Sheet

A tally sheet will be provided with the FACCT consent packs for each school. Please make a note of whether each pack was distributed, returned, how complete the returned paperwork is, and if the child concerned was examined. Please provide a brief note to explain why packs were not distributed, or why children with completed, signed consent and completed medical history were

not examined. The information in the tally sheet will be cross checked with the paper returns from each school and the direct data entry records to monitor progress and sample size.

Sequence of activities in the school

1. Child oral health-related quality of life (COHRQoL) and oral health behaviours questionnaire (laptop with the textured external surface)
2. Height and weight
3. Clinical examination (including photograph)

A diagram suggesting the optimal room set up and the flow of participants through the various activities can be found in Appendix 5.

5. Child oral health-related quality of life (COHRQoL) and oral health behaviours questionnaire

- **To be completed before the clinical exam.**
- **Check that the child's consent form is signed before they commence the COHRQoL/health behaviours questionnaire.**
- The child oral health-related quality of life and oral health behaviours questionnaire should be completed on the dedicated secure laptop, before the clinical examination
- Scan the child's barcode into the device
- A member of the examining team should be available to assist any child who needs help with completing the questionnaire.
- The laptop should at all times remain in view of the fieldworkers, or another responsible adult (e.g. teacher, SNA)
- If parents are unwilling to have their child complete the survey on computer, provide the child with a paper version of the questionnaire for completion prior to their clinical examination.
- Paper versions of the survey should be used should insurmountable issues arise in relation to the laptop on a particular day, or in the case of a power cut. Paper versions of the OHRQoL questionnaire will be provided to all teams at the outset and additional paper copies can be requested from the OHSRC.
- An Irish version of the electronic child oral health-related quality of life (COHRQoL) and oral health behaviours questionnaire will also be made available on paper.

Tip for maintaining the correct order of electronic questionnaire and clinical exam

Set up the questionnaire laptop (textured external surface) computer first thing in the morning and ask the first child to complete the electronic questionnaire while the team sets up for the clinical examination. The first child then progresses to the clinical examination while the next child commences the electronic questionnaire and this linear flow continues through the day.

6. Height and Weight:

The weighing scales will be calibrated prior to the commencement of the study.

- Place a paper tissue on the height and weight scales and change between subjects.
- Measurements of height and weight should be taken in a sensitive and confidential manner.
- Measurements (particularly weight) should not be read aloud. Note the readings on the back of the child's envelope (the side that doesn't have the child's name on it) for entry into the direct data entry system.
- Please ensure that the child's weight on the scales or on the back of the envelope are not seen by other students.

Height

1. Wipe head part of the measure with alcohol wipes between subjects.
2. Ask child to remove their shoes.
3. Hairstyles should allow height measure to fit comfortably on head. If necessary, ask the child to adjust their hairstyle to allow height measure to fit comfortably on head.
4. Stand with heels together against backstop.
5. The spine at pelvis and shoulder level should touch the upright.
6. Stand as tall as possible, unsupported and clear of any furniture.
7. Position head in Frankfurt Plane position (i.e. the lower border of the left orbit and the upper margin of the external auditory meatus are horizontal).
8. Place measure on head.
9. Ask child to take a deep breath in during the measurement.
10. Record height in centimetres (cm) to one decimal point.
11. **Repeat to check accuracy.**

Weight

1. Ask child to:
    a.) Remove any excess clothing e.g. coats, blazers etc.
    b.) Remove their shoes.
    c.) Empty pockets containing keys, money, coins etc.
    d.) Remove any heavy jewellery.
2. Scales viewfinder should read (0.0) kgs.
3. Instruct child to stand on scales free of any objects and walls etc.
4. Record weight to one decimal point in kgs.

7. Clinical examination

Non-latex gloves will be used to examine all children

The clinical examination will be conducted in the following order:

1. DDE (Developmental Defect of Enamel)
2. Dean's Index
3. Molar Incisor Hypomineralisation (MIH)
4. Photograph of anterior teeth (wet and dry)
5. Dental Caries

7.1 Developmental Defects of Enamel (DDE)

[Exclude children with fixed orthodontic appliances from this examination]

Introduction

The index tooth surfaces to be examined are the labial surfaces of the maxillary first pre-molar, canine and incisor teeth and the buccal surfaces of the lower first permanent molars.

Three basic defects are recorded, demarcated opacities, diffuse opacities and hypoplastic defects. If any defects do not fall into these categories they should be scored as 'other' defects.

The extent of a defect is measured in increments of thirds. Colour images will be used as part of the training material.

Opacity is defined as a qualitative defect of enamel identified visually as an abnormality in the translucency of enamel. It is characterised by a white or discoloured (cream, brown, yellow) area but in all cases the enamel surface is smooth and the thickness of enamel is normal, except in some instances when associated with hypoplasia.

Clinical examination DDE

- Teeth will not be cleaned prior to the examination except for the removal of food debris with a cotton wool roll if necessary.
- Natural light will be used to examine the upper index teeth (1.4 – 2.4) and artificial light will be used to examine the lower first permanent molars; 3.6 and 4.6.
- The subject should be examined in the upright position for 1.4 to 2.4, with the examiner facing the subject with the examiners back to the light (window). The subject should be examined lying down using artificial light for 3.6 and 4.6. The DDE examination is completed when the score for both 3.6 and 4.6 are recorded with the patient lying down, just before the caries examination is commenced.
- When inspecting the teeth, the examiner should move their line of vision around. This approach will help to overcome the variability in recording due to angle of inspection and specular reflection.

- The teeth will be examined wet at the time of examination. This approach allows recording of the usual appearance of the teeth. Ask the child to lick their teeth if you find that they are drying out.
- The recorder will initiate the examination by calling out the first tooth and the surface to be examined, i.e. “upper right maxillary first premolar labial”.
- The designated surface of the Index Tooth should be inspected visually for defects.
- If a hypoplastic area appears to be present it should be tactilely explored with a CPE probe to confirm the abnormality of enamel contour.
- Diagnosis will usually be readily evident where a defect is obvious. However, in other instances the most difficult decision will be whether or not an abnormality is present, i.e. the examiner may be unsure whether the enamel is defective or fully within the range of normal. When in doubt the tooth surface should be scored normal. Similarly where defects are obviously not developmental in origin, i.e. white spot caries, they should be scored normal. Where an abnormality is obviously present but cannot readily be classified into one of the listed categories of defects, it should be scored ‘other’ defect.
- **Disregard any single defect on a surface which is less than 1 mm at its greatest width.** However, record defects whose total greatest width is greater than 1 mm.
- Defects of the same type show considerable variations and it is essential they be classified with respect to the definition of the DDE Index.
- A surface is present and examined for defects provided any part of the surface has penetrated the oral mucosa. **In the case of a partially erupted tooth, score the surface present as normal unless there is a defect on the erupted portion**. If the patient is wearing a fixed orthodontic appliance exclude the patient from examination.
- If more than two defects occur on a surface, the two defects affecting the greatest area will be scored. For the “extent” section the total area affected by all types of defects will form the basis of the assessment.

The codes for the DDE can be found in Appendix 6

7.2 Dean’s Index

[Exclude children with fixed orthodontic appliances from this examination]

- **<u>Dean’s Index is a whole mouth score</u>**
- The subject should be examined in the upright position, with the examiner facing the subject with the examiner’s back to the light (window).
- Natural light is to be used.
- Note the distribution pattern of any defects and decide if they are typical of fluorosis, i.e. the defects in the questionable to mild scores (the most likely to occur) may consist of fine white lines or patches usually near the incisal edges or cusp tips. They are paper white or frosted in appearance and tend to fade into the surrounding enamel. They are of a generalised nature and there is usually a definite tendency to bilateral distribution. The premolars and second molars are most frequently affected followed by the upper incisors. The mandibular incisors are least affected.

- **If fluorosis is present then decide on the two most severely affected teeth. Dean's Index is scored on the condition of these two teeth. If the two teeth are not equally affected score on the *less* affected tooth of these two teeth.**
- When scoring, start at the higher end of the Index i.e. severe, and eliminate each score until you arrive at the condition present. If in any doubt the lowest score should be given.

Criteria for Dean's Classification System for Dental Fluorosis (Dean, 1934) can be found in Appendix 7.

7.3. Molar Incisor Hypomineralisation (MIH)

Introduction

Molar-Incisor hypomineralisation (MIH) is a developmental condition resulting in enamel defects in first permanent molars and permanent incisors. Enamel defects can range from mild opacities, white or yellow in colour, to severe enamel involvement, which breaks down rapidly shortly after eruption (Daly and Waldron, 2009). In addition to being of public health importance due to the symptoms associated with it and the complexity of treating the condition, MIH could potentially be confused with the moderate and severe Dean's Index scores, therefore examiners will be trained to recognise the condition and to note the presence or absence of MIH in the clinical record.

Any examination for MIH should be undertaken on clean wet teeth and the age of 8 years is optimum, as at this age all permanent first molars and most of the incisors are erupted. In addition, the permanent first molar teeth will be in a relatively good condition without excessive posteruptive breakdown (Weerheijm et al., 2003).

Differential Diagnosis

Teeth with developmental defects of enamel (DDE) may present similarly, regardless of aetiology, and the development defects of enamel hypoplasia may be confused with MIH. Enamel hypoplasia is a quantitative defect associated with reduced localised thickness of enamel whereas hypomineralisation is a qualitative defect affecting enamel translucency. Diagnostically, MIH and enamel hypoplasia (EH) can be difficult to differentiate when affected molars have post eruptive enamel breakdown (PEB) due to caries or masticatory trauma. In a child with high caries rate, MIH can be masked by extensive caries or restorations. PEB may lead to a clinical picture resembling hypoplasia. However, in hypoplasia, the borders of the deficient enamel are smooth, while in post eruptive enamel breakdown the borders to normal enamel are irregular. MIH can also be confused with fluorosis, however, the enamel opacities of fluorosis are diffuse, in contrast to the well-demarcated borders of hypomineralised enamel seen in MIH. In addition, fluorosed enamel is caries resistant; in comparison to the caries prone MIH-affected enamel. The difference between MIH and amelogenesis imperfect (AI) is one of definition. In AI, all teeth are affected and may be detected pre eruptively on radiograph. Generally, affected FPM's with MIH are asymmetrical. There is usually a positive family history in cases of AI (Fitzpatrick and O'Connell, 2007, Garg et al., 2012).

Clinical appearance

Clinical appearance, symptoms and signs associated with MIH:

- Large demarcated opacities, whitish-cream or yellow/brown in colour
- May or may not be associated with post eruption enamel breakdown (PEB)
- Hypersensitivity
- Difficult to anesthetise
- Rapid caries progression

Clinically, the lesions of MIH are fairly large demarcated opacities of altered enamel translucency. The defective enamel is white-cream or yellow-brown in color. The opacities are usually limited to the incisal or cuspal one third of the crown, rarely involving the cervical one third. The intact enamel surface is typically hard, smooth and often hypermineralised following posteruptive maturation; the subsurface enamel is soft and porous (Fitzpatrick and O'Connell, 2007, Garg et al., 2012).

Diagnosis of MIH

The identification of MIH is descriptive and dichotomous, it is either present or not. Opacities will first be identified using the Developmental Defects of Enamel index. A judgement of the presence or absence of MIH will be made **with the child lying down using artificial light (so that 1.6 and 2.6 can be assessed)** taking into consideration the following criteria of Weerheijm et al. 2003:

- absence or presence of demarcated opacities;
- posteruptive enamel breakdown;
- atypical restorations;
- extraction of molars due to MIH;
- failure of eruption of a molar or an incisor.

The following definitions (Weerheijm et al., 2003)will be helpful in discerning MIH:

Molar Incisor Hypomineralisation (MIH): definitions of the judgement criteria to be used in diagnosing MIH for prevalence studies	
Demarcated opacity	A demarcated defect involving an alteration in the translucency of the enamel, variable in degree. The defective enamel is of normal thickness with a smooth surface and can be white, yellow or brown in colour.
Posteruptive enamel breakdown (PEB)	A defect that indicates deficiency of the surface after eruption of the tooth. Loss of initially formed surface enamel after tooth eruption. The loss is often associated with a pre-existing demarcated opacity.
Atypical restoration	The size and shape of restorations are not conforming to the temporary caries picture. In most cases in molars there will be restorations extended to the buccal or palatal smooth surface. At the border of the restorations frequently an opacity can be noticed. In incisors a buccal restoration can be noticed not related to trauma.
Extracted molar due to MIH	Absence of a first permanent molar should be related to the other teeth of the dentition. Suspected for extraction due to MIH are: opacities or atypical restorations in the other first permanent molars combined with absence of a first permanent molar. Also the absence of first permanent molars in a sound dentition in combination with demarcated opacities on the incisors is suspected for MIH. It is not likely that incisors will be extracted due to MIH.
Unerupted	The first permanent molar or the incisor to be examined are not yet erupted.
Notes: in cases of a large caries lesion with demarcated opacities at the border of the cavity or on the non caries surfaces, these teeth should be judged as MIH. Other changes in dental enamel such amelogenesis imperfecta, hypoplasia, diffuse opacities, white spot lesions, tetracycline staining, erosion, fluorosis, white cuspal and marginal ridges should be excluded from the types of enamel defects outlined as above.	

7.4 Photograph of anterior teeth

7.4.1 Introduction

Two photographs of the incisors will be taken for each subject. The digital photograph provides a permanent record of the appearance of the teeth and will be scored for Dean's (anterior teeth only) and the TF Index of enamel fluorosis by a researcher blind to the child's fluoridation status. This will help to minimise subjectivity within the grading of fluorosis of the anterior teeth and will increase the quality of the data. The photographs will also assist us in validating the clinical DDE, Dean's and MIH scores if required. Two photographs should be taken for each child regardless of whether the upper permanent incisors have emerged.

The teeth will be photographed 'wet' to record the appearance of the teeth under normal conditions and 'dry' to allow detection of fluorosis at the very lowest levels of severity.

Photographs will be taken of the incisor teeth of all children, except where the following exclusion criteria apply:

- fixed orthodontic appliance present,
- severe ulceration of lips or oral mucosa,
- inability to comply with protocol,
- those showing anxiety or reluctance to comply with protocol.

If a photo cannot be taken for any of the reasons above, please stick the barcode into the photo log book and note the reason that no photo was taken.

7.4.2 The camera

The camera is a Canon EOS 1100D with a Sigma 105mm macro lens and Sigma EM140-DG macro ring flash for even lighting.

Always wear the camera strap around your neck when taking the photos to minimise the risk of dropping the camera, and keep your elbows tucked into your chest to support the weight of the camera and reduce shake. Hold the camera with one hand under the body of the camera and the other hand under the macro lens, taking care not to turn the lens focus ring.

Do not touch the glass lens as it may blur the photographs.

Camera settings have been fixed by the OHSRC as follows:

- Manual focus
- Shutter 1/125
- F 18

Please note that the manual was originally written for HSE der ed to adapt the content of the manual to suit their particular situation.

- Magnification Ratio 1:1.5 (0.35 m)

Do not adjust any of these settings and take care not to turn the focus ring on the lens. [Note: If the focus ring has inadvertently turned, realign the white bar with the yellow numbers 1:1.5 or white numbers 0.35].

To get the teeth in focus, lean your body towards and away from the subject until the incisor teeth appear sharp and in focus.

Both flash and camera will go into power save/standby mode if they are left idle for some time. If you activate the camera by half-pressing the button used to take photos, the flash should also be reactivated.

7.4.3 Assembling the Camera

1. Ensure the flash is turned off, slide the flash onto the body of the camera and tighten ("lock").

2. Remove the lens cap (put it safely into the camera bag).

2. Screw on the flash adapter ring to the lens

3. Press in two black buttons on the sides of the ring flash to attach it to the adapter ring on the lens (bright side out), keeping the Sigma label at the 12 o'clock position

4. Turn on flash, and then turn on camera

Ideally, ambient lighting should be even and without strong light sources such as windows and overhead lights (i.e. close blinds and turn off lights where appropriate). Strong sources of ambient lighting cause reflections in the photographs and makes grading of fluorosis more difficult.

7.4.4 Photographic procedure

- **Take a photo of the child's subject number.**
- Set the top LCD timer to count up to 8 seconds and the middle LCD timer screen to count up to 60 seconds in the second section. Do not start the timer.
- Seat the child and give them sunglasses to protect their eyes from the camera flash.

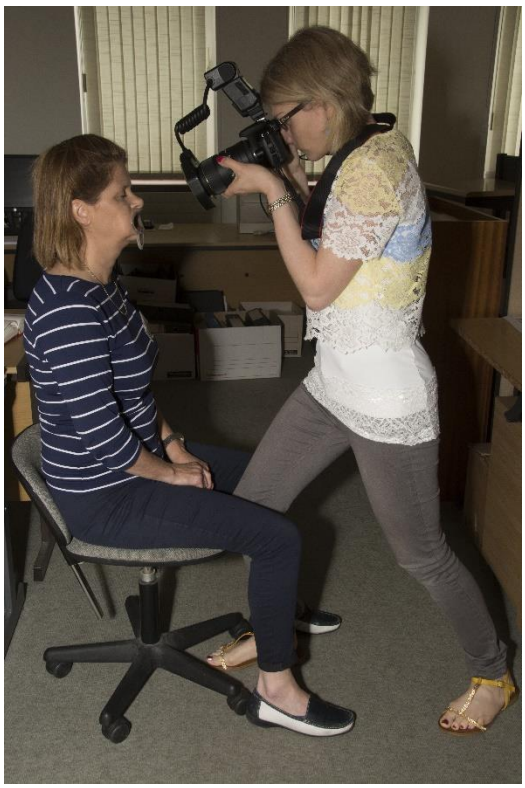
- If the child has a lot of plaque on their front teeth, this should be wiped off with a cotton wool roll prior to the photograph being taken.
- Position the child's head so that the labial surfaces of the central incisors are perpendicular to the floor.
- Check that the child can place their teeth edge to edge - or as close to the same vertical plane as far as possible. The child is also instructed to keep their tongue curled up or away from their front teeth while adopting this position.
- Apply Vaseline to the child's lips if they are very dry.
- Tell the child you are going to retract the lips and gently insert the lip and cheek retractor.
- Ask the child to adopt the edge-to-edge position.
- Keep the teeth moist by wiping them with damp cotton wool at approximately 5 second intervals for approximately 20 seconds. The damp cotton wool rolls should be placed in a small disposable plastic cup to avoid cross infection. The cup and cotton wool rolls are disposed of in the yellow clinical waste bag.
- The camera field should capture the area of the upper and lower incisors only. The child's face should <u>never</u> be included in the image.
- The photographs are taken at approximately 30^{o} above the incisal edge of the tooth to reduce lip shadow. In practice, this is a subjective assessment and where doubt occurs, the examiner should bear in mind that it is better to over-estimate the camera angle and be slightly steeper. The angle of the camera will be expected to fall between 30^{o} and 45^{o} above the incisal edge of the tooth.
- The plane that coincides with the interproximal surface between the two upper central incisors is the plane in which the camera is held. The examiner is aware that adopting a body position either to the left or right of this plane will affect the positioning of the camera. The point of focus should be within the incisal 1/3 of the anatomical crown.
- While the examiner focuses the camera, the teeth are kept moist with wet cotton wool rolls as described above. When the photographer is ready, he/she gives the signal and the recorder **<u>stops wetting the teeth,</u>** starts the timer and stands back to allow the examiner to prepare to take the photo while counting the seconds 1, 2 3, 4 etc.
- The first photograph should ideally be taken at 8 seconds from the ready signal (acceptable error plus or minus 2 seconds).
- When the flash goes off, the assistant records the time in seconds (6, 7, 8, 9, or 10) as displayed on the count up clock, in the photographic log book.
- If the photographer is not satisfied with the photograph taken they will need to re-wet the teeth again (i.e. moisten the teeth by wiping them with damp cotton wool at approximately 5 second intervals for approximately 20 seconds … and then take the repeat photograph ideally at 8 seconds from the ready signal (acceptable error plus or minus 2 seconds).
- The teeth are now dried with cotton wool roll, and the timer continues to count up to 60 seconds. The used cotton wool rolls should be placed in the small plastic cup and disposed of in the yellow clinical waste bag.
- The second photograph should be taken at 60 seconds from the ready signal (i.e. approx 52 seconds after the 'wet' photograph).
- When the flash goes off, the assistant records the time in seconds as displayed on the count up clock, in the photographic log book.

- If the photographer is not satisfied with the photograph they will need to retake the photograph again after drying the teeth for 60 seconds as above.
- Once the photographs have been taken **take another photo of the child's subject number.**
- The child's barcode, number of photographs taken at 8 and 60 seconds and any difficulties encountered in taking the photographs will be noted in the photographic log book. This will act as a failsafe for linking the clinical photos to the child.

If the examiner makes a mistake, e.g. by taking a photograph of the child's teeth without a prompt, this is logged in the photographic log book. Where such an error occurs, then there may be three or possibly four photographs for that subject. Do not delete the photos. If needs be, write on a separate piece of paper e.g. "error in previous photo" and photograph this statement before taking the subsequent photograph.

Any difficulties with child co-operation during the photographs and any difficulties relating to the camera or other equipment are noted in the photographic log book by the assistant.

Where the examiner is unsure about the exposure of the timed photographs, a repeat photograph is taken. When a repeat photograph is taken, the time of the repeat exposure is noted in the photographic log book.



7.4.5 Photographic log book

A photographic log book will be distributed to each team by the OHSRC.

7.4.6 To Disassemble the Camera

Reverse of 12.4.3 above, i.e.

1. Turn camera off, turn flash off.
2. Press the two black portions of the flash together to release ring flash.
3. Unscrew the flash from the body of the camera (un-“lock”).
4. Unscrew the flash adapter ring from the lens and reattach the lens cap onto the lens
5. Place camera and flash + adapter ring in their respective separate bags.

7.4.7 Quality control

- The image should ideally include upper and lower canine to canine teeth but at a minimum should include upper and lower incisors.
- Try to centre the image on the mid line, tuck your elbows into your body to steady the camera.
- Remember to ask the child to bite edge to edge.
- Too steep an angle may result in the child's nose being visible in the frame and foreshortening of the upper incisors-check the image and adjust your angle if necessary.
- To get the teeth in focus, lean your body towards and away from the subject until the incisor teeth appear sharp and in focus. Once you have the teeth in focus, hold your breath and take the photograph.

8. Clinical recording of dental caries

[For children undergoing fixed orthodontic treatment exclude surfaces that are banded/covered including surfaces with bonded orthodontic brackets]

The examination for caries is largely a visual one.

Each child is asked to lie on a table covered with a foam camping mat with a clean disposable head rest cover under their head. Remember that all children **must be examined for caries lying on a table**. We need to do this so that our data are standardised and are comparable. If a school/parent will not allow this, we will be unable to examine that child/children for caries. We will be unable to use caries data that are obtained from a child in seated position. If you wish you may suggest that children are asked to wear their school tracksuit the day the examining team visits.

The teeth are examined wet and a CPITN probe is used to remove food debris. The CPITN probe may also be used to confirm cavitation.

Dental caries is recorded for primary and permanent teeth at the dentine level (cavitated and non-cavitated); d_{3c}mft and d_{3vc}mft; D_{3c}MFT andD_{3vc}MFT.

Lighting is provided by a portable dental light source ('Daray' lamp). The light is clamped to the table in a position that will enable it to be angled towards the mouth. The teeth are be examined wet and a CPITN probe used to remove food debris.

The examiner should commence examinations on the upper right, upon the call of the upper right 6 by the recorder. He/she should call the status for each tooth or space following the recorder's call, from the upper right 6 (tooth number 1.6) continuing to the upper left (tooth number 2.6). The examiner should then call the status for each lower tooth or space beginning at the lower left 6 (3.6) and proceed to the lower right 6 (4.6). It should be noted that although the FDI international system of numbering teeth has been used the recorder may call 6 ,5 etc. to retain simplicity without causing confusion. The examiner may have to use clinical judgement regarding tooth morphology, and take into account the subject's previous dental history if doubt exists as to the correct notation for a particular tooth.

Tooth presence codes and crown condition status codes can be found in Appendix 8

8.1 Urgent need for care

Parents of children for whom the examiner, based on their own clinical judgement, deems to have an **urgent** need for dental treatment will be notified by the examining team. Decisions about what conditions are considered urgent will be left to the discretion of the examining dentist. A letter informing the parents of an urgent need for treatment will be given to the child in a sealed envelope. A copy of this letter can be found in Appendix 9 and paper copies of the letter will be provided to all teams. A log record must be kept of each child considered by the examining dentist to require urgent dental treatment. The child's barcode rather than their name is used as an identifier in the log book. A log book for recording details of children requiring urgent dental care will be distributed to each team by the OHSRC.

9. Ensuring examiner consistency during the study

9.1 Intra-Examiner agreement

Each examiner will re-examine approximately 5% of children during the fieldwork for weight and height and all relevant indices:

- DDE (Developmental Defect of Enamel)
- Dean's Index
- MIH
- Dental caries
- **A repeat photograph must also be taken**

Duplicate examinations:

1. **Please re-examine at least 1 in 20 children**
2. **Please allow maximum time between child's first exam and the re-exam to minimise recall.**
3. **When taking a repeat photograph, please write "duplicate" near the subject number and photograph both as a single shot. This will allow Tara to easily identify the duplicate photos.**
4. **When entering data for a duplicate exam, please remember to change exam type from N (new) to D (duplicate).**

Suggestions for arranging to do duplicate exams:

- Re-examine the first child that you see every day. If you examine twenty or more children in a day, then also re-examine the second child of the day.

9.2 Inter-Examiner agreement

Inter-examiner agreement will be measured during the fieldwork by arranging for examiners in each study area to visit at least one school together with the gold standard examining dentist and to examine all children for relevant clinical indices.

When entering data for a gold standard exam, please remember to change exam type from N (new) to G (gold standard) AND to change the name of the examiner for that particular examination to the GS on the day.

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APPENDIX 1: Copies of letters sent to school Boards of Management, Principals and Teachers

Date:

Re: FACCT Children's oral health survey

Dear Chairperson,

FACCT (**F**luoride **A**nd **C**aring for **C**hildren's **T**eeth) is a collaborative University College Cork/Health Service Executive programme, and is funded by the Health Research Board. In 2013/14 your school participated in this important new research study about children's oral health.

The FACCT study is being conducted in Dublin, Cork and Kerry. It aims to measure the effect that changes to oral health policies on water fluoridation and fluoride toothpaste are having on children's oral health and on their quality of life. The results of the FACCT study will help inform national policy and planning of dental services.

In 2013/14, you kindly facilitated our visit to your school where we conducted oral examinations for your Sixth Class and Junior Infant students. Now, during the 2016/17 school year, we hope to return to re-examine the children we saw as Junior Infants, who are now among your Second Class students.

An information leaflet about the study and a copy of the consent form are attached for your information. Children whose parents consent and who are happy to do so will have their teeth examined by a HSE dentist assisted by a dental nurse, and will have photographs taken of their front teeth. The photographs will show only the front teeth, so it will not be possible to identify an individual child. We will also measure children's height and weight as indicators of their general wellbeing and development. All procedures will be done in a sensitive and confidential manner. We do not anticipate that the children will experience any pain or discomfort. Any child who is identified as having an urgent need for dental care will be given a letter in a sealed envelope to bring home to their parent/guardian advising them to seek immediate treatment.

Children will also be asked to complete a child-friendly electronic questionnaire under the supervision of the examining team. There is also a paper-format survey for parents. All information collected will be confidential and will be used for statistical purposes only.

We are keenly aware that Second Class is a very busy year, and we will work with you to minimise any disruption to you and your students. We are beginning the work as early in the school year as practicable, though we ask for your patience as we work through more than 250 schools across Dublin, Cork and Kerry.

This research has the potential to affect the oral health of every child in this country now and for years to come. Your co-operation with the study would be very much appreciated. The study will have full ethical approval prior to commencement.

We have also written to your school's Principal, seeking permission to revisit the school this year. Should you require any further information regarding this project, you can speak to the coordinator of the study, Dr Máiréad Harding, and her team by phoning (021) 490 1210 weekdays from 9am–5pm.

Yours sincerely,

_____ _____

Dr Helen Whelton

Principal Investigator, FACCT study
Adjunct Professor, OHSRC

Dr Máiréad Harding

Co-Investigator, FACCT study,
Deputy Director, OHSRC

Date:

Re: FACCT Children's oral health survey

Dear Principal,

Good oral health is important for your students. It allows them to speak and smile with confidence, and to eat a healthy diet. Dental pain is associated with poorer school performance and increased absence.

FACCT (**F**luoride **A**nd **C**aring for **C**hildren's **T**eeth) is a collaborative University College Cork/Health Service Executive programme, and is funded by the Health Research Board. In 2013/14 your school participated in this important new research study about children's oral health.

The FACCT study is being conducted in Dublin, Cork and Kerry. It aims to measure the effect that changes to oral health policies on water fluoridation and fluoride toothpaste are having on children's oral health and on their quality of life. The results of the FACCT study will help inform national policy and planning of dental services.

In 2013/14, you kindly facilitated our visit to your school where we conducted oral examinations for your Sixth Class and Junior Infant students. Now, during the 2016/17 school year, we hope to return to re-examine the children we saw as Junior Infants, who are now among your Second Class students. We are now writing to seek your permission to visit your school once more in the coming months. We have also written to your Board of Management seeking its support for this study.

An information leaflet about the study and a copy of the consent form are attached for your information. Children whose parents consent and who are happy to do so will have their teeth examined by a HSE dentist assisted by a dental nurse, and will have photographs taken of their front teeth. The photographs will show only the front teeth, so it will not be possible to identify an individual child. We will also measure children's height and weight as indicators of their general wellbeing and development. All procedures will be done in a sensitive and confidential manner. We do not anticipate that the children will experience any pain or discomfort. Any child who is identified as having an urgent need for dental care will be given a letter in a sealed envelope to bring home to their parent/guardian advising them to seek immediate treatment.

Children will also be asked to complete a child-friendly electronic questionnaire under the supervision of the examining team. There is also a paper-format survey for parents. All information collected will be confidential and will be used for statistical purposes only.

We are keenly aware that Second Class is a very busy year, and we will work with you to minimise any disruption to you and your students. We are beginning the work as early in the school year as practicable, though we ask for your patience as we work through more than 250 schools across Dublin, Cork and Kerry.

We will liaise with you to schedule a suitable day(s) for the examinations. In this regard, it would be very helpful to have a nominated contact person in the school, both to liaise with us and to facilitate us on the day our team is in the school.

We will require the use of the school hall or a room with natural light and sufficient space to conduct dental examinations over 1 or 2 days, depending on the number of children who are participating. Our only requirements are a power socket and some tables and chairs.

This research has the potential to affect the oral health of every child in this country now and for years to come. Your co-operation with the study would be very much appreciated. The study will have full ethical approval prior to commencement.

Should you require any further information regarding this project, you can speak to the coordinator of the study, Dr Máiréad Harding, and her team by phoning (021) 490 1210 weekdays from 9am–5pm.

Yours sincerely,

Dr Helen Whelton	Dr Máiréad Harding
Principal Investigator, FACCT study Adjunct Professor, OHSRC	Co-Investigator, FACCT study, Deputy Director, OHSRC

Date:

Re: FACCT Children's oral health survey

Dear Teacher,

Good oral health is important for your students. It allows them to speak and smile with confidence, and to eat a healthy diet. Dental pain is associated with poorer school performance and increased absence.

FACCT (**F**luoride **A**nd **C**aring for **C**hildren's **T**eeth) is a collaborative University College Cork/Health Service Executive programme, and is funded by the Health Research Board. In 2013/14 your school participated in this important new research study about children's oral health.

The FACCT study is being conducted in Dublin, Cork and Kerry. It aims to measure the effect that changes to oral health policies on water fluoridation and fluoride toothpaste are having on children's oral health and on their quality of life. The results of the FACCT study will help inform national policy and planning of dental services.

In 2013/14, the staff in your school kindly facilitated our visit where we conducted oral examinations for your Sixth Class and Junior Infant students. Now, during the 2016/17 school year, we hope to return to re-examine the children we saw as Junior Infants, who are now among your Second Class students. We are now writing to seek your permission to visit your school once more in the coming months. We have also written to the school Board of Management and Principal seeking their support for this study.

We are keenly aware that Second Class is a very busy year, and we will work with you to minimise disruption to you and your students. We are beginning the work as early in the school year as practicable, though we ask for your patience as we work through more than 250 schools across Dublin, Cork and Kerry. We will liaise with you to schedule a suitable day(s) for the examinations.

We will send out forms to you in advance of the examinations and some suggestions regarding their distribution and return. Each child who was seen previously in Junior Infants will be invited to participate again. The other children in the class may be given a letter explaining why they are not being examined, and assured that this is not the HSE dental school screening. Those whose parents consent and who are happy to do so will have their teeth examined by a HSE dentist, will complete a child-friendly questionnaire regarding dental health on a laptop, and will have their height and

weight measured in a sensitive, confidential manner. We do not anticipate that the children will experience any pain or discomfort. Any child who is identified as having an urgent need for dental care will be given a letter in a sealed envelope to bring home to their parent/guardian advising them to seek immediate treatment.

This research has the potential to affect the dental health of every child in this country now and for years to come. Your co-operation with the study would be very much appreciated. Should you require any further information regarding this project, you can speak to the coordinator of the study, Dr Máiréad Harding, and her team by phoning (021) 490 1210 weekdays from 9am–5pm.

Yours sincerely,

_____ _____

Dr Helen Whelton

Principal Investigator, FACCT study
Adjunct Professor, OHSRC

Dr Máiréad Harding

Co-Investigator, FACCT study,
Deputy Director, OHSRC

APPENDIX 2: Not-selected letter

Dear Parent/Caregiver,

FACCT (**F**luoride **A**nd **C**aring for **C**hildren's **T**eeth) is a research study of Irish children's oral health. With funding from the Health Research Board and through partnership with the HSE dental service, we began the study during the 2013/14 school year and examined a random selection of junior infants in your child's class.

Now, during the 2016/17 school year, we are coming back to examine the adult teeth of these same children. We will be seeing only the children we already saw in 2013/14 whose parents/guardians consented to being contacted again in relation to FACCT. Your child was either not examined in 2013/14, or you did not consent to being contacted again in relation to FACCT so he/she will not be involved.

We are writing just to let you know what is happening in your child's class, in case you or your child have any questions about it. We also want to assure you that your child is not missing the HSE school dental screening programme; that is separate, and will include all children in 2nd class.

Should you require any further information regarding this project, you can speak to the coordinator of the study, Dr Máiréad Harding, and her team by phoning (021) 490 1210 weekdays from 9am–5pm.

Yours sincerely,

_____ _____

Dr Helen Whelton

Principal Investigator, FACCT study
Adjunct Professor, OHSRC

Dr Máiréad Harding

Co-Investigator, FACCT study
Deputy Director, OHSRC

APPENDIX 3: Infection Control

Protocol for setting up exam station

1. While working on the FACCT study, the examining team should adopt safe work practices and take reasonable care of their own safety, health and welfare and that of others in line with HSE Manual Handling and People handling policy and cross contamination policy when transporting equipment to and from the car to the examination room and in setting up the examination area.
2. Consideration must be given to health and safety when positioning **tables** and **chairs** so that students can get on and off tables safely.
3. Consideration should be given to health and safety when dealing with cables. Cables should be either taped down securely or covered with a large mat so that examining team, school staff or students cannot trip over them.
4. Examination light should be well secured onto examination table.
5. PPE should be worn.
6. Proper hand hygiene needs to be observed.
7. Sharps bins should be correctly assembled signed and dated.
8. They should be kept out of reach of students and ensure temporary closure at all times.
9. Sharps bins which are three quarters full should be locked immediately and not left open until the end of the day.
10. Teams should ensure that yellow bags are secured and not allowed fall over and spill.
11. Yellow bags that are three quarters full should be closed immediately and not left open until the end of the day.
12. At the end of the day all cables should be folded neatly to prevent members of the teams tripping over them when putting them away.
13. Log to be completed at end of day signed and dated and retained for future reference.

Handling, Transporting and disposing of waste

The examining team should adopt safe work practices and take reasonable care of their own safety, health and welfare and that of others in line with HSE Manual Handling and People handling policy when transporting sharp bins and yellow bags.

Sharps bins:

1. Ensure size of sharps bin is suitable for the number of children being examined.
2. Ensure extra sharps bins are at hand
3. Sharps bins should be correctly assembled, dated and signed.
4. Ensure temporary closure is on at all times
5. Ensure that access to bins is restricted to healthcare team only
6. Sharps bins should be fully locked when three quarters full
7. Partially filled sharps bins should be locked at the end of each day
8. Sharps bins should be signed and dated after locking

9. Sharps bins should be placed within a rigid lockable container before being removed from the school building.
10. Container must be labelled with a sticker saying contaminated
11. Container must be amenable to cleaning
12. Container must only be transported within the boot of a car
13. Sharps bins must be taken to the nearest HSE dental clinic at the end of each working day and under no circumstances stored in a car overnight.
14. Date, signatures, number of sharps bins and clinic where bins were disposed of should be recorded as well as the name of the person transporting them on the given day.

Yellow bags:

1. A new yellow bag should be used at the start of each day
2. Ensure extra yellow bags are available
3. Ensure that access to yellow bags is restricted to healthcare team only
4. Only clinical waste should be disposed in yellow bags
5. Yellow bags should be closed when three quarters full and secured with a labelled plastic tie
6. Partially filled yellow bags should be closed and secured at the end of each day and not reused the next day
7. Yellow bags should be placed within a rigid lockable container before being removed from the school building
8. Container must be amenable to cleaning
9. Container must be labelled with a sticker saying contaminated
10. Yellow bags must be taken to the nearest HSE dental clinic at the end of each working day and under no circumstance stored in a car overnight
11. Number of yellow bags, and location of clinic where they are being disposed as well as name of person transporting them, must be recorded.

Please read and sign that you agree to follow the appropriate steps outlined above:

Examiner Signature:_____

Date:_____

Recorder 1 Signature:_____

Date:_____

Recorder 2 Signature:_____

Date:_____

APPENDIX 4: FACCT survey equipment list

Transporting Equipment:

1. Solid storage boxes (supplied by HSE)
2. Two-wheel trolley (supplied by HSE)

Weight and Height:

1. **Height Measure**: Leicester Height Measure
2. **Digital Floor Weighing scales**: Tanaka Scale

Camera:

1. Camera body
2. Lens
3. Flash
4. Battery charger for camera body
5. Spare rechargeable camera battery
6. Battery charger for flash
7. Rechargeable batteries for flash
8. 4 X spare AA batteries for flash
9. Memory card (16 G) (Not to be substituted for any reason)
10. Camera bag for camera
11. Bag for ring flash
12. Laminated camera set up guide
13. Sunglasses for child (supplied by HSE)
14. Disposable cheek retractors
15. Countdown timer

Clinical examination:

1. Disposable exam kits (Mirror & CPITN probe) (supplied by HSE)
2. Daray lamp
    a) Clamp
    b) Spare bulb
    c) Screw driver
3. Cotton wool rolls (supplied by HSE)
4. Vaseline (supplied by HSE)
5. Tissue rolls/packs(supplied by HSE)
6. Alcohol wipes (supplied by HSE)
7. Non-latex gloves (supplied by HSE)
8. Face masks (supplied by HSE)
9. Alcohol handrub (supplied by HSE)
10. Liquid soap (supplied by HSE)
11. Laminated Coding sheet
12. Fieldworker's manual
13. Yellow clinical waste bags (supplied by HSE)

14. Domestic waste bags (supplied by HSE)
15. Sharps box (for CPI probe and mirror) (supplied by HSE)
16. Foam camping mat
17. Masking tape for taping down the mat

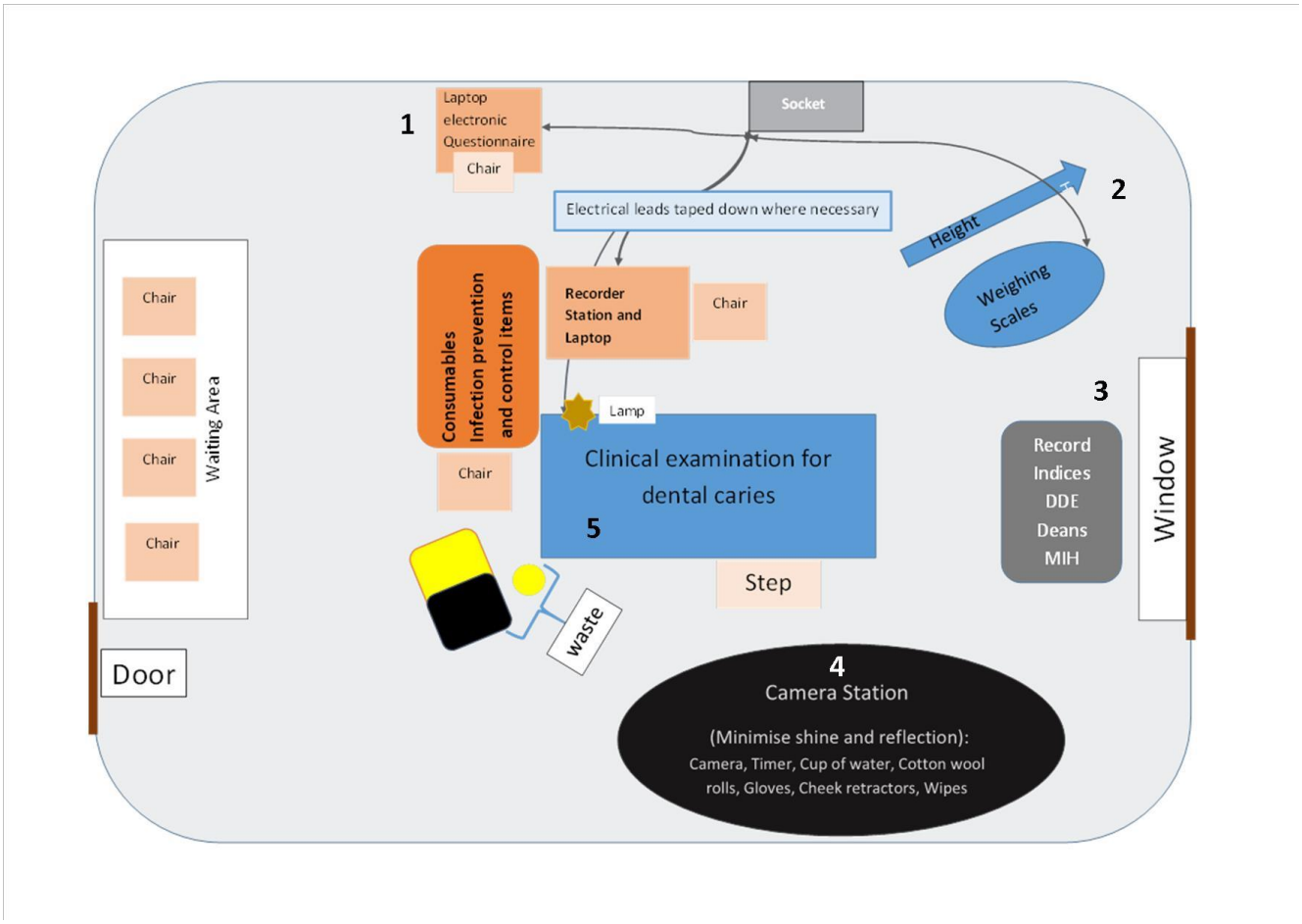
IT Hardware:

1. Laptop bag (One bag holds both laptops)
2. Clinical laptop (smooth external surface)
3. Power cable
4. Mouse
5. Barcode scanner
6. Questionnaire laptop (textured external surface)
7. Power cable
8. Mouse
9. Barcode scanner
10. Internet dongle (white)
11. USB drive (green) x 2
12. Password card x 2 (USB drives and password cards MUST be kept separately from the computers; the USB drive is the equivalent of a password for the Questionnaire laptop - not a standard USB drive)
13. Direct data entry manual

Administration:

1. Paper clinical recording forms
2. Paper OHRQoL/health behaviours questionnaires
3. Irish language paper OHRQoL/health behaviours questionnaires
4. School tally sheet
5. Photographic logbook
6. Logbook for children requiring urgent dental care
7. Log of waste disposal
8. Letter notifying the parent of need for urgent dental treatment (Appendix 9)
9. Mobile phone (FACCT related calls on personal mobiles will be refunded upon submission of appropriate records)
10. Multi-socket extension lead x 2
11. Pens, highlighter
12. Notebook
13. Some envelopes and paper (in case they are required)
14. Stamps, SAEs

APPENDIX 5: Room set up and participant flow through the various activities (numbered)



APPENDIX 6: Developmental Defects of Enamel (DDE) – Codes

Type of defect	Code	Definition
Normal	0	
Demarcated opacity	1	An opacity well demarcated from the adjacent normal enamel. It may be white, cream or yellow/brown in colour
Diffuse opacity	2	Diffuse opacity Irregular cloudy areas of opacity lacking well-defined margins or fine white distinct lines of opacity which follow the pattern of the perikymata. Confluence of adjacent lines may be observed.
Hypoplasia	3	Hypoplasia is defined as a quantitative defect of enamel visually and morphologically identified as involving the surface of the enamel (an external. defect) and associated with a reduced thickness of enamel. The defective enamel may occur as (a) shallow or deep pits or rows of pits arranged horizontally in a linear fashion across the tooth surface or generally distributed over the whole or part of the enamel surface; (b) the defective enamel may occur as small or large, wide or narrow grooves; (c) in enamel over small or considerable areas of dentine.
Demarcated + diffuse	4	
Demarcated + hypoplastic	5	Combinations of hypoplasia and opacities can occur on the same tooth surface (Codes 5, 6 and 7). They may be quite distinct from each other, that is, separated by normal enamel, or as a composite lesion composed of an adjacent opacity and hypoplasia.
Diffuse + hypoplastic	6	
All 3	7	
Other	8	Other defects may occur which do not fulfil the specific definitions of opacity or hypoplasia, e.g. staining: These are listed under “Other defects”
Excluded	X	Primary teeth occupying the tooth space, unerupted, missing, heavily restored, badly decayed or fractured teeth and teeth (or tooth surfaces) which for any other reason cannot be classified for defects. This implies that these teeth will be disregarded from statistical purposes.

Extent of defect	Code
Normal	0
< 1/3	1
at least 1/3 < 2/3	2
at least2/3	3

APPENDIX 7: Criteria for Dean's Classification System for Dental Fluorosis

Classification	Code	Extent of surface affected	Criteria
Normal	0		The enamel represents the usual translucent semivitriform type of structure. The surface is smooth, glossy and usually of pale creamy white colour
Questionable	1	<10%	The enamel discloses slight (<10% of surface) aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilised in those instances where a definite diagnosis is not warranted and a classification of 'normal' not justified
Very Mild	2	10-25%	Small, opaque, paper white areas scattered irregularly over the tooth but not involving as much as approximately 25 per cent of the tooth surface. Frequently included in this classification are teeth showing no more than about 1 – 2mm of white opacity at the tip of the summit of the cusps, of the bicuspids or second molars.
Mild	3	25-50%	The white opaque areas in the enamel of the teeth are more extensive but do involve as much as 50 percent of the tooth.
Moderate	4	100%	All enamel surfaces of the teeth are affected and surfaces subject to attrition show wear. Brown stain is frequently a disfiguring feature
Severe	5	100%	All enamel surfaces are affected and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is discrete or confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance

APPENDIX 8: Tooth presence codes and crown condition status codes

Tooth Presence Code

Existence of Teeth Code

A	Permanent tooth present
P	Primary tooth present
U	Permanent tooth unerupted or congenitally absent
E	Permanent tooth extracted due to caries
C	Primary tooth extracted due to caries
G	Permanent tooth extracted due to perio disease
B	Primary tooth extracted due to ortho
M	Permanent tooth missing due to other reasons i.e. lost due to trauma or orthodontic extractions
K	Permanent tooth extracted for reason unknown i.e. not caries or periodontal disease
R	Primary tooth present with a sinus tract

For subjects aged 5-years and younger when any of baab/baab are missing, use clinical judgement to decide status. If there is evidence that the tooth or teeth have been extracted due to caries, score status C.

For those aged 12-years and older where there is a space and the primary tooth is absent record U under Status.

Preface to Surface Conditions Coding

A condition code will be given to each surface of each tooth present. The crown has 4 surfaces; mesial, distal, buccal and lingual, in the case of incisors and canines. Premolars and molars have an extra surface (occlusal). It will be noted, some tooth codes exclude a need for surface condition coding, e.g. if a tooth has been extracted or is congenitally missing the surface condition code will be left blank.

In the case of a partially erupted tooth, score all surfaces present and sound unless there is caries on the erupted portion.

If the score is the same for each surface put the condition number in the first box and draw a line through the rest (if using a paper clinical record) No distinction need be made between a primary and permanent tooth in the surface condition.

Condition Status - CROWN

The teeth will be examined visually. The CPITN probe may be used to confirm a diagnosis of cavitation to check for sealants or to remove food debris.

Code R - Fissure sealant: A fissure sealant is recorded to be present when it is detectable on a surface and when there is no probeable caries on the same surface.

Code S - No Caries

A surface should be considered sound if it shows no evidence of treated or untreated caries, or if it is at the doubtful stage. These scores will also apply in the case of defects not to be counted as caries:

(a) white and/or chalky spots;
(b) discoloured or rough spots;
(c) stained pits or fissures in the enamel that catch the explorer but do not have a detectably softened floor, visibly undermined enamel or softening of the walls.
(d) Dark, shiny, hard pitted areas of enamel in a tooth showing signs of moderate to severe fluorosis.

Code V - Visual Caries

Visual caries is recorded when there is definite evidence of caries into dentine, but where there is no probable cavity through the enamel. The appearance may vary but will usually look like grey or creamy white shadowing under enamel. Where there is any doubt score sound.

Code D - Decayed, cavity

Caries will be considered to be present in a surface when any lesion has a detectably softened floor, undermined enamel, or softened wall. On an approximal surface, the lesion must be visible and the probe point must enter a lesion with certainty. Where any doubt exists, caries should not be diagnosed as being present. It must be emphasised that clinical caries is a stage in the process of dental caries. Dental caries proceeds from a microscopic lesion, which cannot be diagnosed positively by present clinical methods, to a cavity (or clinical caries) which can be diagnosed by clinical examination. The upper limit for this category is the complete destruction of the crown. Where only roots remain for primary teeth, decayed is recorded only when no permanent successor has erupted.

Dental caries affecting enamel only, such as white spot lesions and other conditions similar to the early stages of caries should be deliberately excluded because they cannot be diagnosed positively and reliably.

Decayed is recorded where a surface contains a temporary filling requiring further treatment, or where a complete filling is lost (See filled or defective filling). For a primary surface, decayed is recorded even though it is about to be exfoliated.

Code K - Filled ***Amalgam*** and Primary Decay

A surface should be classified filled and primary decay when a surface has been filled and another area is carious.

Code L – Filled (restoration non-amalgam) **and primary decay**

Code Y - Filled ***Amalgam*** and Secondary Decay

Surface should be classified filled and secondary decay when there is recurrent caries in contact with a filling.

Code Z – Filled (Restoration non-amalgam) **and secondary decay**

Code F – Filled ***Amalgam*** Restoration

Surfaces should be considered filled whenever a filling or any permanent material is present and there is no discrete or recurrent caries. A defective filling where there is no discrete or recurrent caries e.g. cracked or partly missing, is scored F with the appropriate treatment code indicating the replacement restoration required.

Code G – Filled – Non-amalgam Restoration

Code C - Crowned

All surfaces should be placed in this category if a tooth has full crown (intended total crown coverage) in a permanent material and including bridge abutments except where the reason for the crown is trauma.

Code Q - Crowned and Decayed

A surface should be scored as crowned and decayed when caries is contiguous with the crown.

Code T - Trauma

A permanent surface should be recorded 'trauma' if part of its substance is missing for reasons other than treated or untreated caries and the latter condition is not present. T is the score for all surfaces where a crown is present due to trauma.

Code X - Excluded

This category should be used for teeth, which cannot be properly examined (i.e. impacted teeth or teeth which have been banded for orthodontic reasons).

Treatment Need

Treatment need must be assessed and recorded - this is the last box for each tooth in the caries chart. *Codes are also displayed in the pane to the right of the caries chart in the direct date entry program for reference and to facilitate date entry by clicking.*

Code 0 – None (This code is used when it is considered that a tooth requires no treatment).

Code 1 - One surface restoration

Code 2 - Two surface restoration

Code 3 - Three surface restoration

Code 4 - Fissure sealant or preventive resin restoration

Depending on the surface coverage, these codes should be used to designate treatment required to remove caries lesions (primary or secondary) to repair trauma, or replace unsatisfactory fillings, in consideration of both function and appearance. Replacement of a filling is adjudged necessary, in the absence of untreated caries or after a condition score of 0, when there is one or more of:

(i) A deficient margin which, in the examiner's judgement on the evidence of insertion of an explorer, or deep staining, allows leakage at least to dentine.
(ii) An overhanging margin of a dimension at least equal to the thickness of a standard precast crown.
(iii) A deficient contact point between normally spaced teeth or a deficient marginal ridge allowing, or facilitating food impact.
(iv) A fracture or defect in a filling allowing leakage at least to dentine.
(v) A discolouration or disharmony of shape or colour of an existing filling
(vi) A clinical decision to fill in case of doubt, e.g. 'sticky fissure' or to restore tooth defects

Code 5 - Crown.

A decision to restore a tooth with a crown must be made by clinical judgement. Discolouration of a tooth due to trauma or a pulp condition may be a reason for restoration. Replacement of a crown is adjudged necessary in the absence of untreated caries after a condition score of 0, when there is one or more of:

(i) A deficient margin which, in the examiner's judgement on the evidence of insertion of an explorer, or deep staining, allows leakage at least to dentine.
(ii) An overhanging margin of a dimension at least equal to the thickness of a standard precast crown
(iii) A deficient contact point between normally spaced teeth or a deficient marginal ridge allowing, or facilitating food impact
(iv) A fracture of defect in a crown allowing leakage at least to dentine
(v) A discolouration or disharmony of shape colour of an existing crown

Code - 6 Pulp treatment required due to coronal caries followed by restoration by filling

Code - 7 Pulp treatment required due to coronal caries followed by restoration with crown

Code - 8 Extraction Due to Coronal Caries. These scores are used when there is obvious pulp involvement or when more than 2/3 of tooth structure has been lost and restoration with crown is deemed inappropriate. The examiner's clinical judgement must be relied upon to select which of these scores (5,6 or 7) apply in individual cases and it is noted that there may be a consistent difference between individual examiners in different regions.

Code - W Extraction due to other reasons e.g. impacted tooth

Code - R Replacement with removable prosthesis

Code - F Replacement with a conventional fixed bridge at a later date: removable prosthesis or other as interim treatment

Code - S Replacement with resin bonded bridge

Code - V Veneers

Code - X Other treatment of the crown not covered and specifically for recontouring and repairing restorations – other treatments of the crown but treatments like scale and polish and oral hygiene instructions should not be recorded.

Code - F Replacement with a conventional fixed bridge at a later date: removable prosthesis or other as interim treatment

Code - S Replacement with resin bonded bridge

Code - V Veneers

Code - X Other treatment of the crown not covered and specifically for recontouring and repairing restorations – other treatments of the crown but treatments like scale and polish and oral hygiene instructions should not be recorded.

APPENDIX 9: Copy of letter notifying parent of the need for urgent dental treatment.

Dear Parent,

Thank you for consenting to let your child take part in the FACCT study.

The FACCT team was in your child's school today and your child was seen by the study dentist.

Your child requires urgent dental treatment for

_____
_

_____
_

Please seek dental care for your child as soon as possible.

Your local HSE clinic provides a free service for eligible children. You can find your local HSE clinic by visiting the following webpage hse.ie/eng/services/list/1/LHO/ or by calling the HSE infoline on callsave **1850 24 1850** or **041 6850300**, from 8am to 8pm, Monday to Saturday.

Please note that the manual was originally written for HSE dental fieldworkers. Non HSE fieldworkers will need to adapt the content of the manual to suit their particular situation.