Published in final edited form as:

Methods Mol Biol. 2019 ; 1922: 511–523. doi:10.1007/978-1-4939-9012-2_39.

Measurement of early childhood oral health for research purposes: dental caries experience and developmental defects of the enamel in the primary dentition

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Abstract

Epidemiological investigations of early childhood oral health rely upon the collection of high-quality clinical measures of health and disease. However, ascertainment of valid and accurate clinical measures presents unique challenges among young, preschool-age children. The paper

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4. Notes

¹Explaining all procedures to the participating children using the “tell-show-do” technique and actively involving them in the process, where they can even hold a hand mirror to watch and for example, ‘help the examiner count teeth’, are very helpful strategies—especially in cases of reluctant or anxious children.

²In cases of uncertainty about the diagnosis/classification of a condition prefer ‘under-calling’ it. For instance, if uncertain whether an early stage (incipient) caries lesion is present or not, prefer to record the lesser diagnosis, which -in this case- is health (e.g., surface-code 0). Apart from resulting in a more conservative estimation of disease burden, this rule is helpful in training and calibration, so that examiners have a uniform rule for resolving uncertainties.

³Multiple traits besides the ECC case status (binary) and the dmfs index (0–88) can be constructed using the diagnostic codes collected as part of the protocol. The construction of 10 example traits and two treatment indicator variables is presented in Table 5. For example, trait 3 is the “classic” ECC definition and trait 4 is the same case status definition not considering early-stage lesions.

⁴The custom modified air compressor referred to in §2.1 has proven to be an excellent solution for the provision of compressed air during the visual dental caries examinations in the field—it is lightweight, silent and produces sufficient airflow.

⁵Consider a tooth present if any part of it has penetrated the mucosa and record any condition that can be detected on its erupted portion.

⁶Overjet measurements can be performed if any pair of upper-lower primary central incisors is present (e.g., #F-O or #E-P).

⁷Placing multiple layers of plastic covering on dental chair and tray saves time when turning over the set up for the next participant.

presents a clinical research protocol for the conduct of oral epidemiological examinations among children, implemented in ZOE 2.0, a large-scale population-based genetic epidemiologic study of early childhood caries (ECC). The protocol has been developed for the collection of information on tooth surface-level dental caries experience and tooth-level developmental defects of the enamel in the primary dentition. Dental caries experience is recorded using visual criteria modified from the International Caries Detection and Assessment System (ICDAS), and measurement of developmental defects is based upon the modified Clarkson and O'Mullane Developmental Defects of the Enamel Index. After a dental prophylaxis (toothbrushing among all children and flossing as needed), children's teeth are examined by trained and calibrated examiners in community locations, using portable dental equipment, compressed air, and uniform artificial light and magnification conditions. Data are entered directly onto a computer using a custom Microsoft Access-based data entry application. The ZOE 2.0 clinical protocol has been implemented successfully for the conduct of over 6000 research examinations to date, contributing phenotype data to downstream genomics and other

Keywords

dental caries; children; clinical research; protocol; caries diagnosis; early childhood caries; developmental defects of the enamel

Introduction

Epidemiological investigation of early childhood oral health relies upon the collection of high-quality clinical measures of health and disease. This, in turn, requires a clinical research protocol to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results. In the research studies of oral health domain, ascertainment of valid and accurate clinical measures presents unique challenges among young, preschool-age children. This is due to the reduced ability (e.g., limited attention span, acute anxiety, etc.) of very young children to cope with and cooperate with clinical research procedures compared to older children and adults. Nevertheless, clinical dental research is not only feasible in this young age group but also necessary to answer important biological, clinical and public health research questions [1].

Understanding the entire spectrum of social, environmental, behavioral and biological determinants of early childhood caries (ECC) [2] remains a priority. ECC is an early-onset, severe form of dental caries, that confers substantial impacts to affected children, their families, the health system, and the society in general. It is a persistent clinical and dental public health problem that is known to be influenced by social determinants of health and mediated by oral hygiene, fluoride exposure and diet [3], but also has a substantial heritable component [4]. Developmental defects of the enamel (DDE) are non-carious enamel conditions, comprising a heterogeneous group of defects of various severity and diverse etiology (i.e., hypoplastic defects of the enamel versus fluorosis). Importantly, DDE occur during dental development (i.e., prior to tooth eruption and exposure to protective and harmful exposures) and because they can increase one's susceptibility to dental caries [5,6], their study within the context of ECC heritability can be informative.

Genetics studies of dental caries in the primary dentition caries have had mixed results [7,8] and a knowledge gap exists on the genomic basis of ECC [9]. To address this knowledge gap and add to the evidence base of social, behavioral and biological determinants of ECC, the investigators are undertaking the ZOE-G4S (Zero-out Early Childhood Caries- “Genes for Smiles”)—an NIH-funded genetic epidemiologic study conducted among a large population-based sample of preschool-age children enrolled in Head Start centers in North Carolina. The paper presents the study’s clinical protocol for the conduct of research examinations among children in the primary dentition (e.g., ages 2–5), designed to detect and record surface-level dental caries experience and tooth-level developmental defects of the enamel. The phenotype data collected using this protocol are then carried forward to genomics [15] and microbiome [16] studies, as well as other traditional clinical and epidemiologic dental investigations.

Clinical examiners (registered dental hygienists or dentists) are trained and calibrated for the dental caries examinations using a sequence of online International Caries Detection and Assessment System (ICDAS) modules, clinical photos, natural extracted teeth, and clinical examinations. Tooth-surface caries diagnoses are based on ICDAS criteria [10,11] made at the levels of health (ICDAS code: 0), early-stage (ICDAS codes: 1–2) and established/severe stage (ICDAS codes: 3–6). A dmfs (decayed, missing due to caries and filled/restored primary tooth surfaces; ranging between 0 and 88) index is created as a sum of surface-level conditions, with dmfs>0 indicating an ECC case [2], which is the primary study outcome. The presence of sealants, intra-coronal and full-coverage restorations is also recorded at the surface-level. Inter-examiner reliability in caries classification is determined by comparing un-calibrated examiners with a reference golden standard examiner. The calibration includes examination of ~25 children by all examiners, including un-calibrated ones and the gold standard, and re-examination of ~8. Examiner performance is evaluated by the weighted *kappa* statistic, indicating agreement with the gold standard examiner. Achieving a weighted *kappa* of at least 0.65, a rigorous level of inter-examiner reliability, is required for all examiners following their initial training and calibration and at annual re-evaluation sessions. The corresponding threshold for intra-examiner reliability is weighted *kappa* at least 0.75 [12].

Developmental defects of the enamel are measured at the tooth-level using Clarkson and O’Mullane’s modified DDE epidemiologic index [13]. Several other clinical measures are obtained as part of the research examination, including anthropometry (i.e., height, weight, BMI, BMI percentile for age and sex), extra-oral characteristics (i.e., profile, lip competence), intra-oral occlusal characteristics (i.e., molar/canine classification, overjet, overbite), dental trauma (using a modified Ellis’ index [14]) and a summary of treatment needs. With supervision and/or assistance from research staff, children’s teeth are cleaned using a toothbrush and no toothpaste; flossing is done when needed. The aim is to improve measurement and, in the process, provide instruction in dental hygiene while helping desensitize children who might be fearful of dental procedures. Before tooth cleaning, saliva and supragingival plaque samples are collected to enable downstream studies involving the human genome and oral microbiome, according to procedures detailed in [15] and [16].

2. Materials

2.1 Clinical examination equipment and instruments

- Foldable dental chair (Aseptico® ADC-01P-RED, Aseptico Inc., Woodinville, WA)
- Foldable hydraulic dentist stool (Aseptico® ADC-10, Aseptico Inc., Woodinville, WA)
- Dental instrument tray (Aseptico® ATC-03CF, Aseptico Inc., Woodinville, WA)
- Air compressor (Figure 1; custom modified TC-20 compressor, TCP Global, San Diego, CA) with air syringe and disposable tips
- Examiner magnifying loupes with headlight (Orasoptic XV1™ Loupe + Light, Orasoptic, Middleton, WI)
- Pediatric toothbrushes
- Flossers
- Disposable dental examination mirrors
- US/CPTIN round-ended plastic periodontal probes with markings at 2/3/4/5/7/9mm

2.2 Clinical examination supplies

- Disposable gowns
- Gloves
- Masks
- Bibs
- Hand held mirrors
- Disposable plastic tips and sleeves/covers for air syringe
- Barrier tape
- Plastic chair and tray covers
- Surface disinfecting wipes
- Hand sanitizer
- 2×2 gauze
- Paper towels
- Sterile pouches for used probes

2.3 Anthropometric measurement equipment and supplies

- Portable digital stadiometer (seca® 213 or seca® 264, seca GmbH & Co. KG, Hamburg Germany)

- Portable digital scale (DS6150, Doran® Remote Indicator Scale, Doran, Batavia, IL)
- Carrying case for portable digital stadiometer and scale (Seca® 414, seca GmbH & Co. KG, Hamburg Germany)
- iPad tablet with ‘ChildBMI’ app (Tactio Health Group) for pediatric BMI percentile calculation
- Printed “subject cards” for intermediate recording of height, weight, BMI and BMI percentile values prior to electronic data capture

2.4 Electronic data recording and other study source documents

- Laptop
- Microsoft Access-based, custom-written data entry application (DEA)
- Handheld barcode reader (for scanning of barcode labels with participant IDs)
- Printed screenshots of DEA data entry screen (as back-up)
- External monitor for examiner
- Power strips, extension cords, and adapters
- Blue masking (floor) tape
- Encrypted, portable USB storage device (e.g., IronKey™, Kingston Technology Company, Inc., Fountain Valley, CA)

2.5 Biospecimen collection

- Saliva collection for DNA extraction is detailed in [15]
- Supragingival plaque collection for microbiome analyses (i.e., metagenomics, metatranscriptomics and metabolomics) is detailed in [16]

3. Methods

Research examination teams use the mobile dental equipment, instruments, and supplies to set up clinical examination stations (Figure 2) where there is suitable space and a power outlet in community locations (e.g., classrooms). Each examiner has custom-fit magnifying loupes with headlights at their disposal (§2.1) and is trained to use basic child behavior guidance and management techniques routinely used in pediatric dentistry, including tell-show-do (TSD), positive reinforcement, negative reinforcement, voice control, modeling and labeling. Children whose legal guardians have provided informed consent are examined -at least 30, preferably 60 minutes- after they have had breakfast or snack. The families (and teachers, where applicable) are instructed not to brush the children’s teeth the morning before the examination--the examiner cleans the teeth with a toothbrush (no toothpaste) and floss (when needed) after biospecimen collection, and the teeth are dried before the examination. The examiner completes the exam and all data are directly recorded

electronically by a designated recorder using the DEA. The procedures are carried out as follows:

3.1 Pre-clinical procedures and assessments

1. Greet the child addressing them by their name and ideally kneeling down to their eye level
2. Explain the procedures that will follow in an age-appropriate manner
3. Offer stickers at each examination 'station' beginning at initial contact
4. Record height, weight, and compute BMI and BMI percentile for age and sex.
5. Collect saliva sample with OG-575 kit. This can be accomplished by the child sitting upright in any (regular, or dental chair).
6. Collect supragingival plaque samples using the sterile toothpicks in a semi-reclined position, ideally a dental chair. One sample (plaque sample A) from the upper right dentition (facial surfaces of #A, #B, #C, #D and #E according to the Universal nomenclature system; or #55, #54, #53, #52 and #51 according to the FDI system) and another sample (plaque sample B) from the upper left dentition (facial surfaces of #F, #G, #H, #I and #J, or #61, #61, #63, #64 and #61).
7. Store plaque A is stored in an RNA*later* tube and plaque B in a CryoVial to freeze immediately, until transfer to a lab and storage in -80°C .

3.2 Clinical procedures and assessments-dental caries and DDE

1. Clean teeth with a toothbrush and provide oral hygiene instruction for all children. Clean inter-proximal areas with dental floss as needed.
2. Record extra-oral characteristics as follows: profile (1=straight, 2= convex, 3=concave; 9=unable to assess); lip competence (1=competent: <3mm distance between upper and lower lip and no mentalis muscle strain; 2= incompetent: 3mm distance between upper and lower lip or mentalis muscle strain; 9=unable to assess).
3. Record intra-oral characteristics as follows: overjet (mm; 999=unable to assess); overbite (percent coverage of lower incisors from the upper incisors; 999=unable to assess); right/left molar anterior-posterior classification (1=flush, 2=mesial step, 3=distal step, 9=unable to assess); right/left canine anterior-posterior classification (1=class I, 2=class II, 3=class III, 9=unable to assess).
4. Dry each tooth to be examined for surface-level dental caries lesions or other conditions with compressed air (or alternatively with a 2×2 gauze) and visualize with artificial light, magnification and disposable mirror. Recording is based on a two-step system: first provide a tooth-level code (Table 1) and then, as indicated, 4 or 5 surface-level codes (Table 2). The purpose of this system is to a) expedite data collection in cases where all surfaces within a tooth receive the same diagnosis (i.e., healthy, crowned, extracted due to caries, missing due to trauma, permanent tooth is present, unable to assess) and b) allow the implementation of

logical checks, thus minimizing data entry errors. Five surfaces (occlusal, facial, lingual, mesial and distal) are assessed for molar teeth and four surfaces (facial, lingual, mesial and distal) for anterior teeth.

5. Examination for DDE is best done on non-desiccated teeth and for this reason the child is asked to close their mouth and swallow or lick their teeth after the dental caries examination. Examine only the facial/buccal surface of all teeth for non-carious enamel defects that are of 1mm diameter, using the type and extent codes listed in Table 3. If more than one condition is present (e.g. diffuse opacity and hypoplasia) record the extent of the largest one. If more than two-thirds of a tooth's facial/buccal surface is heavily restored, badly decayed or fractured, then do not assess it for DDE (i.e., 9=Unable to assess).

3.3 Measurement of other clinical characteristics: trauma, treatment needs, behavior, completion and examination notes

1. Examine the 4 primary maxillary incisors for evidence of dental trauma using the modified Ellis [14] classification criteria listed in Table 4.
2. Provide a behavior assessment score at the end of the examination to provide a global measure of the child's cooperation using the Frankl behavior scale [17], as follows: 4=completely cooperative, enjoys the process, 3=cooperative, somewhat reluctant/shy, 2=uncooperative, very reluctant/shy, 1=completely uncooperative. In cases where part or the entirety of the research examination was not done due to non-cooperation, a score of 1 is given.
3. Provide a 'treatment needs' score, according to the level and urgency of dental treatment that the child requires, as follows: 1=no obvious problems were found today; establish or maintain a dental home and continue routine dental visits, 2=possible problems were found today; please check at the next dental visit, 3=problems were found today that require treatment as soon as possible.
4. Provide a 'completion' code indicating whether all planned research procedures were completed at this visit: 1=completed; 2=not complete. A built-in check routine in the DEA will prevent entering '1' if a data field is incomplete.
5. Provide free-text comments in the appropriate comments box, if and as needed. In this section, general remarks protocol deviations (e.g., changes in procedures due to behavior/cooperation) and any extraordinary findings can be recorded. A comment is mandated if a partial exam (i.e., 'not complete' code) exam was conducted.

Acknowledgement

This work was supported by a grant from the National Institutes of Health, National Institute of Dental and Craniofacial Research, U01-DE025046.

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Figure 1.
Custom modified air compressor

Figure 2.
Example clinical research set up in a non-clinical setting

Table 1.

Tooth-level diagnostic and classification codes for recording of dental caries

Code	Explanation
1	Sound, no decay or restorations ²
2	Sealed ¹
3	Decayed or filled (restored) ¹
4	Crown (stainless steel or other) ²
5	Missing due to caries ²
6	Exfoliated ²
7	Missing due to trauma ²
8	Permanent tooth present ²
9	Unable to score ²

¹Tooth surface-level codes are entered by the examiner only for tooth-level codes 2 and 3. See Table 2.

²For the other tooth-level codes, tooth-surface codes are auto-filled by the DEA, as follows: Tooth-level code 1—Sound, auto-filled surface-level codes: 0; Tooth-level code 4—Crown, auto-filled surface-level codes: 44; Tooth-level code 5—Missing due to caries, auto-filled surface-level codes: 55; Tooth-level codes 6,7,8,9—Exfoliated, Missing due to trauma, permanent tooth present, unable to score, auto-filled surface-level codes: 99.

Table 2.

Surface-level diagnostic and classification codes for recording of dental caries

Code	Explanation
0	Sound , no caries lesion (ICDAS: 0)
50	Restored , no caries lesion
80	Sealed , no caries lesion ¹
Caries	
10	Arrested enamel lesion (enamel-only) ²
11	Early stage caries lesion (ICDAS: 1–2)
12	Established/severe caries lesion (ICDAS: 3–6)
Restored and separate caries lesion	
30	Restored and separate arrested enamel lesion (enamel-only) ²
31	Restored and separate early stage caries lesion (ICDAS: 1–2)
32	Restored and separate established/severe caries lesion (ICDAS: 3–6)
Restored and recurrent caries lesion	
40	Restored and recurrent arrested enamel lesion (enamel-only) ²
41	Restored and recurrent early stage caries lesion (ICDAS: 1–2)
42	Restored and recurrent established/severe caries lesion (ICDAS: 3–6)
Sealed and separate caries lesion	
60	Sealed and separate arrested enamel lesion (enamel-only) ²
61	Sealed and separate early stage caries lesion (ICDAS: 1–2)
62	Sealed and separate established/severe caries lesion (ICDAS: 3–6)
Sealed and recurrent caries lesion	
70	Sealed and recurrent arrested enamel lesion (enamel-only) ²
71	Sealed and recurrent early stage caries lesion (ICDAS: 1–2)
72	Sealed and recurrent established/severe caries lesion (ICDAS: 3–6)
Auto-filled codes	
44	Surface of tooth with a crown, i.e., if tooth code=4
55	Surface of tooth that has been extracted due to caries, i.e., if tooth code=5
99	Surface of tooth that has exfoliated, is missing due to trauma, a permanent tooth is present, or is unable to score for any other reason, i.e., if tooth code=6, 7, 8, or 9

¹ Any evidence of sealant material present (i.e., partially retained) is recorded as sealant

² Caries lesion activity is only considered for enamel-level non-cavitated (i.e., white spot) lesions

Table 3.

Diagnostic and classification codes for recording of type and extent of developmental defects of the enamel

Type	
Code	Explanation
0	Normal (no DDE)
1	Demarcated opacity
2	Diffused opacity
3	Hypoplasia
4	Demarcated opacity + diffused opacity
5	Demarcated opacity + hypoplasia
6	Diffused opacity + hypoplasia
7	Demarcated opacity + diffused opacity + hypoplasia
8	Other defect
9	Unable to score
Extent	
0	Normal (no DDE)
1	< 1/3 of facial/buccal tooth surface
2	At least 1/3 but less than 2/3 of facial/buccal tooth surface
3	At least 2/3 of facial/buccal tooth surface
9	Unable to score

Table 4.

Diagnostic and classification codes for recording of dental trauma

Code	Explanation
0	No evidence of trauma
1	Simple crown fracture, involving little or no dentin
2	Extensive crown fracture, involving considerable dentin surface, without pulp exposure
3	Extensive crown fracture, involving considerable dentin surface, with pulp exposure
4	Displacement of the tooth due to trauma
5	Necrotic/discolored tooth (due to trauma) w/wo crown fracture
6	Total tooth loss due to trauma
7	Unable to assess

Table 5.

Examples of 10 person-level caries traits (disease indices and definitions) that can be constructed using the surface-level caries diagnosis codes used in this protocol

Trait 1	Trait 2	Trait 3	Trait 4	Trait 5	Trait 6	Trait 7 ³	Trait 8 ³	Trait 9 ³	Trait 10 ³	surface codes ¹	description
composite index	two-level disease	ECC definition	established/severe disease	caries experience, two-level	caries experience, established/severe	"restored" disease	"unrestored" disease	"healthy", sealed	"healthy", non-sealed		
0	0	0	0	0	0	0	0	0	1	0	Sound
1	0	0	0	0	0	0	0	1	0	80	Sealant
2	1	1	0	1	0	0	0	0	1	10, 11 60, 61 70, 71	Caries: early stage (arrested or active)
2	1	1	0	2	1	1	0	0	0	30 ² , 31 ² 40 ² , 41 ²	Recurrent or Secondary Caries: early stage (arrested or active)
3	2	1	1	2	1	0	1	0	0	12, 32 ² , 42 ² , 62, 72	Caries: established/severe
4	2	1	1	2	1	1	0	0	0	50	Restored
5	2	1	1	2	1	1	0	0	0	44 [auto-filled]	Crowned
6	2	1	1	2	1	1	0	0	0	55 [auto-filled]	Missing due to caries

¹Surfaces with code: 99 (when tooth code is 6,7,8 or 9) are excluded

²These surfaces have been restored, and thus can be grouped with trait 4 if the interest is examining 'disease severity'; if the interest is in active disease, then these surfaces can be counted according to the lesion classification, i.e., as early stage (trait 2) or established/severe (trait 3)

³For traits 7–10 disease is considered at the established/severe level

Additional person-level indicator variable definitions: **restorativetx**=1 if one or more surfaces are in (30, 31, 32, 40, 41, 42, 50, 44, 55), else **restorativetx**=0; **sealantstx**=1 if one or more surfaces are in (80, 60, 61, 62, 70, 71, 72), else **sealantstx**=0