An exploration of Parents/ Caregivers and Their Children's Experience of Undergoing Dental General Anaesthesia. A Multi-method Longitudinal Qualitative Study.

Short title: Parents/ Caregivers and Their Children's Experience of Dental General Anaesthesia

RESEARCH PROTOCOL
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ABBREVIATIONS

CI	Chief Investigator
CF	Consent Form
cPIS	Child participant information sheet
DGA	Dental General Anaesthesia
NI	Nicola Innes
NHS	National Health Service
PI	Principal Investigator
pPIS	Parent/ caregiver Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SB	Shannu Bhatia
TMF	Trial Master File
UDH	University Dental Hospital
UHW	University Hospital of Wales
WA	Waraf Al-yaseen

1. STUDY SUMMARY

Problem

Dental general anaesthetic (DGA) is used globally as a common treatment service to manage a wide range of oral diseases and problems, most often for children. It is often used to treat problems associated with the development of dental caries which affects an estimated 2 billion people for permanent teeth and 514 million children for primary teeth. population.[1] Although it is acknowledged that repairing or extracting teeth whilst children are asleep does not manage the problem of dental caries or prevent further problems, it is often the only way to provide dental care. This is especially for young children who cannot cope with the invasive nature of dental treatment when they are awake, especially if they have pain or infections associated with the teeth.

There is a large body of literature on its clinical safety. However, despite it being so common, there is little evidence of parents and children's experiences of either dental treatment provided under general anaesthetic (GA) or their experiences of GA itself. The minimal evidence available, suggests poor experiences for children. This presents a risk for parents and children with potentially minimal, or inappropriate information, communication and support needed, failing to meet their needs or being less effective in supporting recovery from this invasive and potentially traumatic event.

Aim

To explore children and their parents' or caregivers' expectations of, experience of, and reflections on, children's DGA in terms of the communication and support provided.

Project Plans

This is a descriptive longitudinal study using a multi-method data-collection, qualitative approach. The data will be collected from the parents/caregivers and their children (six years-old and above) who are undergoing a DGA experience. Data will be collected via in-depth interviews both pre, and post the DGA, complemented by audio diaries which the parents will self-record, around the operation time.

Discussion:

This study will bring in-depth, contemporaneous, directly reported insights into the DGA experiences of children and their parents/caregivers around the most common procedure for hospitalisation of children in the United Kingdom (UK). The findings of this project will provide information to form a building block for wider cross-nation research efforts to improve the DGA experience for children and their parents and inform future work using audio diaries to capture information from patients.

PROTOCOL CONTRIBUTIONS

This protocol has been developed, written, reviewed, and approved by the Chief Investigator (Waraf Al-yaseen), in association with the co-investigators (Nicola Innes, Daniela Raggio and Shannu Bhatia), and Study Manager (Alun Meggy). No conflicts of interest have been declared by the authors of this protocol.

2. BACKGROUND AND RATIONALE

General anaesthesia is a commonly used method to facilitate dental treatment provision for children when the planned care cannot be provided with local anaesthesia or behaviour management techniques alone. This type of anaesthesia, referred to as Dental General Anaesthesia (DGA), is typically conducted by a multi-disciplinary medical and dental team led by specialists or consultants in paediatric dentistry within children's hospitals or dedicated dental hospital theatres. In the UK, DGA services usually provide a range of dental procedures, mainly extractions and restorations, with local anaesthesia and sedation also given. After the DGA course of treatment, children are usually discharged to their general dental practitioner for continuing preventive care.

DGA is the most common reason for UK children to be hospitalized, with around 1-2 children out of every 100 undergoing DGA in England in 2020-2021 (n=22,459 DGA procedures). It is mainly used to manage dental caries, a preventable yet common disease in children. Although DGA is necessary, it is an invasive procedure and can have long-term adverse consequences, such as nightmares and negative memories. Studies of children undergoing GA for other medical conditions have shown that 35% experience separation anxiety for months post-operatively. To mitigate these negative effects, children should be prepared and cared for through well-planned protocols that include providing the right information, effective communication, and adequate follow-up. However, this is not always the case in practice. One study showed that some children undergoing DGA did not know much about the procedure, the venue, or whether their parents would accompany them to the operating theatre. Another English study revealed negative feelings and wide variations in service, environment, and communication across six hospitals from the perspectives of child patients and their parents. There is therefore a need for more research on the communication and support provided to children and their families during DGA, as most existing research focuses on clinical outcomes and quality of life.

DATA COLLECTION METHOD FOR THIS PROJECT:

Exploring the issue of DGA requires data collection methods that reflect the complexity of the process, as DGA involves multiple stakeholders and settings and can take months to complete. Interviews were chosen to provide rich data on the experiences and perceptions of the participants, capturing the influence of context, expectations, and social background on DGA. Interviews were combined with longitudinal audio diaries (LADs) for added insights. LADs provide opportunities for participants to verbalize and share their experiences, thoughts, and interactions with various stakeholders. They are also perceived as a convenient and easy-to-use tool, as participants can record their reflections at any time and place. However, LADs have limitations, such as a lack of control over the data collected and the need for constant reminders and prompts from the research team. As LADs are not a common data collection method in dental research, it is important to capture participants' perceptions of their usability.

IMPACT

This project aims to provide information for the formation of a building block for UK-wide research efforts to improve the Dental General Anaesthesia (DGA) experience for children and their parents or carers. It will achieve this by initially providing in-depth and current insights into the journey of children and their parents/carers through audio-recordings of their contemporaneous experiences.

The study will also assess the suitability of audio diaries as a method of capturing the experiences of patients.

3. AIMS, OBJECTIVES AND OUTCOMES

AIMS AND OBJECTIVES:

PRIMARY AIM:

To explore the expectations, experiences, and reflections of children and their parents/carers on the verbal and verbal communication and support provided during DGA.

SECONDARY AIMS:

To contribute to wider cross-nation research efforts aimed at improving the DGA treatment pathway in terms of communication and support provided to children and their parents/carers; and

To evaluate the suitability of audio diaries as a data collection method for capturing participants' experiences.

STUDY OBJECTIVES:

To gather views from children and their parents/carers on the process leading up to DGA and their expectations of the procedure through interviews prior to DGA;

- To gather data on parents' current perceptions of their child's DGA through longitudinal audio diaries (LADs) during the procedure;
- To gather reflections from children and parents/carers on their DGA experience through interviews following the procedure;
- To gather suggestions from parents/carers and children on how to improve communication and support provided during DGA;
- To identify further gaps in evidence to improve dental care and DGA experience for parents and children; and
- To assess the feasibility of using audio diaries as a means of capturing the lived experiences of parents/carers during the procedure.by these stakeholders. The study will also provide information on how best to capture contemporaneous experience of patients and whether audio diaries can adequately fulfil this need.

STUDY POPULATION

We will identify and recruit children and their parents/ caregivers who are attending Cardiff Dental Hospital, Paediatric Dentistry Department and where the child has treatment planned to be carried out under a DGA as part of their care plan.

- Inclusion criteria - children
  - between 6-16 years old;
  - referred by their dentist for DGA assessment and attending for routine or urgent care;
  - no restriction on their American Society of Anesthesiologists (ASA) score
  - parent considers that the child can understand enough to communicate verbally (should they choose to) for the interview;
  - can understand in English or Arabic;

- can provide permission for their parents to participate; and
- can sign an age-appropriate assent form.

- Exclusion criteria - children
  - Inability to understand English or Arabic;
  - Inability or unwillingness to provide permission to parent to take part in the study

- Inclusion criteria - parents/ caregivers
  - can be either the biological, step or adoptive parents, and must live with the child and have legal guardianship;
  - can read and communicate English or Arabic; and
  - can give an informed written consent to participate.
  - Have any type of mobile phones with recorder function
- Exclusion criteria – parents/caregivers
  - Inability to provide valid informed consent.
  - do not have any type of mobile phones with recorder function or any mean of voice recording (potential participant will be excluded from stage 2- longitudinal diary recoding during the operation)
  - Unable to sign the age-appropriate assent form

RECRUITMENT METHOD:

SAMPLING:

- A purposive recruitment strategy will be adopted to capture child and parent/ caregivers with a broad range of characteristics. Purposive sampling has been chosen as its aim is not to statistically 'reproduce' the characteristics of the total population, but rather to recruit a group of patients who may reveal important insights into the subject area.
- Recruitment will take a place at the Paediatric Dentistry Department of the Dental Hospital (DH) at University Hospital of Wales (UHW), Heath Park, Cardiff, Wales. We will aim for maximum variation through a sample of 10 to 12 parent/caregiver and child dyad participants whose characteristics include a variety of factors including clinical, social, and personal circumstances. We will achieve this by initially inviting all eligible patients to take part, and as cases accumulate, we will actively seek out participants whose demographics are different to those already recruited.
- A sample size of 10-12 parent/caregiver and child dyads is estimated. This estimate is based on qualitative studies with similar contexts and in the same area of research.

4. STUDY FLOW AND SCHEDULE

Study Activity	Dec. 2022 -Feb 2023	March 2023	April 2023	May 2023	June 2023	July 2023	Aug. 2023	Sep. 2023	Oct. 2023	Nov. 2023	Dec. 2023	Jan. 2024
Regulations & approvals												
Recruitment												
Stage 1: T1 data collection												
Stage2: LAD data collection												
Stage 3: T2 data collection												
Transcription												
Data synthesis												
Draft report to funders (submit 30/11/23)												
Manuscript write up												
											End of study	

IDENTIFICATION, SCREENING, AND RECRUITMENT PROCESS

Potential participants who are planned to have DGA will be identified through their clinical notes. At the beginning of each day, a member of research team who have an honorary contract with Cardiff and Vale University Health Board, or the research dental nurses will screen the clinical notes of the children who plan to have an appointment during the day. The notes of potentially eligible patients will have a reminder about the study placed in them for the clinician to remember to bring them to the attention of the researcher if they are having a GA planned. The clinicians will notify a member of the research team (WA, NI or SB) if a DGA is confirmed, and the operation consent has been signed while attending a dental appointment at the hospital. Potential participants will be screened against the eligibility criteria by a member of the research team who is also part of the clinical team in the clinic (including the research dental nurses) who will introduce the research project to the parent/ caregiver, along with explaining the risks and benefits of participating in the study. A copy of the Parent/caregiver Information Sheet (pPIS)(Appendix 2), and a consent form (CF)(Appendix 6) will be given to parent/ caregivers who are interested in participating to take home and read. A copy of the Child Participant Information Sheet (cPIS) (Appendix 3, 4, 5) will also be given for the parent/caregiver to read with the child and discuss the study at home. Three version of the cPIS have been developed to suit the various levels of cognitive abilities of the children. The age specification was deliberately removed from the main text of the cPIS age group for our Patient Information Sheet (PIS). This decision was made in recognition that cognitive abilities can vary among children, regardless of their chronological age. Therefore, we have left it to the discretion of the parent or caregiver to decide which version would suit their child understanding best. An estimation of the age groups was suggested at the footer section as follows:

- Young people: 11–16-year-old
- Young Children: 8–10-year-old
- Younger children 6–7-year-old

At the beginning of the recruitment process, all eligible parent/caregiver and child dyads will be recruited. Then, when a few pre-procedures semi-structured interviews (T1) have taken a place, a purposive recruitment approach will be conducted in which particular dyads will be invited to assure the diversity of the sample and provide a broad range of the participants views of the issue of interest. Contact details will be collected at this stage to make a follow-up contact to:

- answer any questions from parents/caregivers;
- confirm participation; and
- make further arrangements in terms of interview dates and venue.

INFORMED CONSENT

Preparation: A dedicated consent and assent forms in English, Arabic, and Welsh were developed to clearly explain the purpose, procedures, and potential risks and benefits of the study, as well as the participants' rights and obligations.

Obtaining Written Consent: During the T1 interview, the interviewer will introduce the study to the parents/caregivers and ask them to provide written consent using the dedicated consent forms. For children who participate in the interview, an assent form will also be sought to be signed by them.

Online Interviews: For participants who take part in an online interview, a consent form will be sent to

their preferred address along with a free return envelope and contact details for the research team. Participants will be able to ask questions or raise concerns about the study before providing their consent.

Verbal Verification: Before the participants sign the consent form, the interviewer will verify their understanding of the study and their willingness to participate. The interviewer will ask the participants to confirm their consent verbally and will record their response as part of the T1 interview recording.

Signing of Consent Forms: Once the participants have confirmed their consent verbally, they will be asked to sign three copies of the consent form. One copy will be kept within the child's clinical notes, one copy will be given to the participant to keep, and one copy will be securely stored in the project's. project's Trial Master File (TMF) at a locked cupboard within UDH.

Follow-Up: The research team will keep in touch with the participants throughout the T1 interview and beyond, to ensure that they are fully informed about the study and that their rights and welfare are protected. Participants will be able to withdraw from the study at any time without giving a reason.

DATA COLLECTION:

Clinical Variables: Clinical variables will be collected about participants in this study. These details will be collected from the patient and medical records where appropriate or necessary, and where appropriate consent has been obtained to do so. These will include the following (Appendix 1):

- parent and child names
- child NHS number,
- contact details.
- Demographics including ethnicity.
- Dental treatment plan details related to DGA
- Relevant medical history
- Previous DGA experience

QUALITATIVE DATA

collection will take place in three stages using two qualitative methodologies:

- Stage 1: Pre-procedure semi-structured interviews (T1): This stage will be initiated once the DGA (the informed consent form) has been signed and confirmed. A member of the research team will contact the parent or caregiver to schedule an interview. Interviews will be conducted either in-person in a quiet room within the UDH (University Dental Hospital) premises or virtually via a secure connection using Microsoft Teams software, as preferred by the participants. The interview will involve the parents/caregivers and the child if they are happy to join the interview (optional).

  In case of online interviews, a consent form will be sent to the participant's preferred address, along with a free return envelope. Open-ended questions will be used during the interview, guided by an interview protocol (found in the appendix 9). Interviews will be audio recorded using a Dictaphone voice recorder for in-person interviews and the software's built-in recording function for online interviews. These recordings will be saved on the university's secure cloud.

- Stage 2: Longitudinal audio diaries (LADs): Participants who have a phone with a recording function or another means of voice recording will be asked to record their thoughts and reflections up to one week before, during, and up to one week after the operation (T2). Participants will use their mobile phone for recording and then securely send the recordings to the WA (principal investigator's) Cardiff University email address.
  A member of the research team will guide participants through the process of recording and sending their diaries. If participants encounter IT difficulties, they will be instructed to contact the research team. If needed, the principal investigator will consult with the university's IT support team for assistance. If participants are unable to send their recordings, the principal investigator will provide a secure link to a OneDrive folder where they can upload their recordings directly to the university's secure cloud. If none of these solutions work, data transfer will take place manually using a cable that connects the phone or recorder to a Cardiff University computer, either during an exit interview or when the participant visits the dental hospital. Participants will be compensated with a £30 voucher for their time.

  Prompts will be sent, and reminders will be sent if no response is received after 14 days. If no response is received after 30 days, the LAD will be considered complete.

- Stage 3: Exit interviews (T2): Follow-up interviews will be conducted either in-person or online with individual parent/caregiver and child dyads, up to three months post-operatively. The date will depend on the hospital's follow-up appointment. The same data collection strategy used in T1 interviews will be followed. Participants will be asked to confirm their consent to participate verbally and it will be recorded as part of the interview recording and documented by the interviewer. The interview will involve the parents/caregivers and the child if they are happy to join the interview (optional).

Discontinuation/ Withdrawal of Participants

Participants have the right to withdraw from the study at any time and the investigator may discontinue a participant from the study at any time if the investigator considers it necessary or in the participants' best interest for any reason including: Ineligibility (either arising during the study or retrospectively having been overlooked at screening). If a participant withdraws, or is withdrawn, neither their medical treatment nor legal rights will be affected. Furthermore, participants will have the option to provide written consent for being contacted to take part in future other research projects if they would like. A participant may withdraw consent at any time in writing, verbally, or by failure to participate further. Data already collected with consent will be retained and used in the study. But no further data will be collected, or any other research procedures carried out on or in relation to the participant. The reason for withdrawal will be recorded if provided.

Definition of End of Study

Participant's involvement in the study will end upon completion of stage 3 (T2 interviews). The study will end once the data synthesis is completed, and funder's report is submitted.

Data Management and sharing

Access to Data

Only the immediate research team will have access to the study data. Direct access will also be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

DATA SHARING

This data will be shared anonymously with other researchers, including those outside the European Economic Area, for use as part of the international definition work. No personal identifiable information will be shared with external researchers and consent to share data will be sought from participants. Sharing data with other bona-fide researcher(s) will be subject to appropriate contractual agreement.

DATA STORAGE

Patient identifiable data will be always kept to a minimum and only used where necessary, with data being managed by, and accessible to, the research team only. The site file containing CF, screening and recruitment log, a copy of the transcription, and any other related documents will be securely stored in TMF in a locked cupboard within the DH. Participants identifiable (except CFs) data will be destroyed at the end of the study and funders reported is submitted.

Participant's anonymised research data and CFs will be stored for a period of 15 years following the end of this study, for use in future research. Data will be stored, curated, and managed in-line with the Sponsor data management policies and procedures.

Study data will be stored by the Chief Investigator on the Cardiff University IT environment database (e.g. Cardiff University OneDrive). Anonymised data will only be accessible by investigators at the Sponsor site. The TMF, containing essential documents and data logs will be kept in a locked cabinet within the UDH premises. Electronic copies of the transcripts will be stored on a password protected file on the Cardiff University IT secure environment database.

PARTICIPANT CONFIDENTIALITY

Data collected during the research will be kept strictly confidential and accessed only by members of the research team. Participants' personal details (name, address) will be stored by the site under the guidelines of GDPR[8]. Participants will be allocated an individual specific code number which will be used to identify their data. The code will be given by the interviewer who will write the unique code on the CFs. Audio recordings from the interviews will be kept until the end of the study and funder report is submitted to ensure research integrity. They will be transcribed by a suitably trained and experienced member of the research team who will pseudonymising the transcript from any personal details or indicatives of participants identity. Where necessary and appropriate, appropriate contractual arrangements that include confidentiality agreement will be in place with any external transcription service provider, ensuring the safety, dignity and rights of participants and their data is maintained.

ARCHIVING

The Trial Master File (TMF) containing essential documents will be archived at a locked cabinet within the Principal Investigator office room at UDH for 15 years after end of study. The principal Investigator will be responsible for archiving the documents. Study data must not be destroyed without written permission from the principal Investigator and Sponsor.

DATA ANALYSIS AND DISSEMINATION

QUANTITATIVE DATA

Descriptive analysis will be conducted the following data for each participant:

- Demographics including ethnicity;
- Relevant treatment plan details related to DGA;
- Relevant medical history;
- Previous DGA or experience.

QUALITATIVE DATA

Transcriptions will be imported to NVivo10™ software, coded by the chief researcher and checked. Theme development and data syntheses will be over two phases:

1. Deductive, framework thematic analysis, with areas of focus;
   - children and parents/caregiver's expectations
   - children and parents/caregiver's post-encounter perceptions;
   - gaps between both; and

differences between children and parents/caregiver's expectations and their experiences.

2. Inductive thematic analysis following Ritchie & Spencer's (1994)[10] five stages: 1) familiarisation: the researcher(s) familiarise themselves with the data through reading transcripts concurrently listening to audio recordings; 2) identifying key cross-sectional and longitudinal themes to develop a coding framework; (3) indexing: the coding framework will be used to code the data; (4) charting: with direct quotations according to themes/ subthemes; and (5) mapping and interpretation: data from different sources will be mapped together for synthesis cross-sectionally and longitudinally.

DATA PRESENTATION:

Themes will be presented cross-sectionally. A narrative longitudinal presentation via two longitudinal stories of the DGA journey will be based on participants' perceptions.

Trustworthiness of data findings:

A self-reflective approach will be employed with the researcher(s) keeping a reflective journal to discuss their position on participants' inputs, and explicitly recognise any personal bias that may influence data interpretations and synthesis. The interviews will be recorded and then transcribed verbatim, and all potentially identifiable participant data will be removed by the principal investigator as described above. On a question-by-question basis, key themes relating to the wording and structure of items will be identified, recorded, and used to develop a final questionnaire item set. Should more complex thematic analysis be required across multiple interviews then transcripts may be imported and coded using Nvivo software (used under license for its intended purpose by developer QSR International).

DISSEMINATION PLAN

The results of this study will be sent to the funders and published in peer-reviewed scientific and medical journals. The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.
Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion). A lay summary of the study will be available after study completion for the participants upon their request. For such cases, participant email address will be used for sending the lay summary.

Publication Policy

Ownership of the data arising from this study resides with the Chief Investigator and the Sponsor. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared. Authors will acknowledge any funding, and other contributors will be acknowledged.

Safety Reporting

This is a non-interventional study; therefore, no adverse events will be recorded.

5. Ethical and Regulatory Considerations

The study will be conducted in compliance with the principles of the Declaration of Helsinki (2013) and the principles of Good Clinical Practice and in accordance with all applicable regulatory guidance. This protocol and related documents (and any subsequent amendments) will be submitted for review to a recognised NHS Research Ethics Committee (REC).The study will respect the rights of participating patients and ensure confidentiality of patient information. Should participants have additional questions about the study, contact details of a member of a research team will be clearly available in the pPIS for the participant to contact and seek advice. Specific ethical considerations that are considered for this project:

Facilitating informed decision-making for the participant:

Parents/caregiver and their child dyad will be provided with details on the study at recruitment process. Patient information pack will be handed or sent via mail. The pack will include an information sheet for adults (pPIS), an age-appropriate version for the child, (cPIS) and the consent and assent forms. All interested potential participants will have an opportunity to discuss the study with the researcher.

Data handle and store:

Data will be handled and stored according to General Data Protection Regulation (GDPR) guidance (2018).[11] Participants will record their diary and send it via a secure server to a Cardiff University secure IT environment managed drive. Qualitive data and transcripts will be manually anonymised using CU managed computer, and any personal information will be censored. Identifiable data including patient personal details, recording and transcripts will be stored in a secure cloud space which only the research team will have access to.

Voluntary participation:

Participants will have the right to withdraw from the study at any stage.

CONSENT PROCESS:

Capacity to consent to take part in the semi-structured interviews for six years-old and above children and their parent/ caregiver(s). Age-appropriate information sheets and consent forms were developed, following review by children and adult lay persons, to ensure the readability and acceptability of these documents. Written consent will be obtained from parent/caregivers, after assessing capacity to consent, prior to undertaking the interview. Children will also have the opportunity to sign an Assent Form.

SAFEGUARDING CONCERNS:

Due to the inclusion of children, any safeguarding concerns that are raised or identified shall be managed in line with the Safeguarding Policy and Procedures as set out by Cardiff and Vale University Health Board. Wherever possible, a second opinion on safeguarding concerns will be raised with a clinician involved in a patient's care, or the two members of the research team who are Consultants and have extensive experience working with vulnerable children and managing safeguarding concerns (NI&SB).

6. REVIEW, APPROVALS AND AMENDMENTS

ETHICAL REVIEW

- Before the start of the study, approval will be sought from REC for the protocol, informed consent forms and other relevant documents.
- Amendments that require review by REC will not be implemented until approval is granted. The Chief Investigator (or delegate) should submit any amendments.
- The Chief Investigator (or delegate) also needs to notify the Research and Development (R&D) Office and local research team about the amendment(s). The R&D Office(s) will have 35 days from receipt of the amendment to confirm capacity and capability.
- All correspondence with the REC will be retained in the Trial Master File/Investigator Site File
- A progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief I; investigator will submit a final sponsor report with the results, including any publications/abstracts, to the REC.

GOVERNANCE REVIEW:

The study will be assessed for governance and legal compliance by the sponsor. The sponsor for the research will be Cardiff University. The principal Investigator will oversee the day to day running of the project. Governance of the study will be through the research team who will meet monthly for the study duration. Meetings will be in person where possible and virtually if necessary. The meetings are aimed at overseeing the progress of the study and adherence to timescales and the project plan. The

Chief investigator (WA) will be responsible for organising the meetings and populate the meetings minutes to the research team. As this is a non-intervention study, we consider the study to be low risk and do not require oversight of a Data Monitoring and Ethics Committee.

AMENDMENTS

It is the Sponsor's responsibility to classify amendments as being substantial or non-substantial. The Chief Investigator will seek advice from the Study manager (AM) prior to submission to the relevant bodies. The research team will not implement any amendments until relevant regulatory requirements are satisfied, and that NHS R&D office confirms capacity and capability. Amendments will be documented and securely stored within TMF (Appendix 10).

Commented [NR1]: Which appendix? Please Specify.

Commented [WAY2R1]: Addressed thank you

7. QUALITY ASSURANCE PROCEDURES

It is the responsibility of the Chief Investigator to ensure that this study is conducted in accordance with the relevant regulatory requirements. A self-reflective approach will be employed with the researcher(s) keeping a reflective journal to discuss their position on participants' inputs, and explicitly recognise any personal bias that may influence data interpretations and synthesis.

MONITORING

The study will be monitored by the Study Manager (AM) and may be audited by the sponsor (Cardiff University) or other regulatory bodies to ensure adherence with the protocol, any standard operating procedures including Data Protection Act (2018) and UK Policy Framework for Health and Social Care Research 2017.

REPORTING

By the end of the study, an End of Study notification and final report will be submitted to the REC, host organisation and Sponsor.

REGISTRATIONS

This study will be registered on ISRCTN registry.

DECLARATION OF CONFLICTING OR COMPETING INTERESTS

The authors of this protocol do not declare any competing or conflicting interests, financial or otherwise.

8. PATIENT AND PUBLIC INVOLVEMENT (PPI)

Incorporating the perspectives of patients and the public is crucial for ensuring the relevance, responsiveness, and generalizability of our research. As the Patient and Public Involvement (PPI) Group is still in the process of being established at the School of Dentistry, and there is no other forum to gather views from patients and children, we took a more informal approach to evaluate the suitability of our documents. We conducted casual interviews with two parents and two children from the public, presenting them with draft versions of the pPIS, cPIS, Consent Forms (CFs) for adults, and Assent Forms for children of various age groups.

During these informal discussions, we asked questions about the language used in the documents, the overall readability, and the layout and structure. The parents generally had a positive impression of the forms, but one parent suggested using a larger font size for the forms intended for younger children, with fewer words and more illustrations. The parents also pointed out some typos and provided suggestions for improving the English readability. Their feedback and suggestions were recorded on the documents and were incorporated into the following versions.

The priority of the research topic has been identified based on the clinical encounters of the research team on a routine basis. To further involve patients and the public, efforts will be made to include them in subsequent stages of the study, including the development of an appropriate method of dissemination.

9. FINANCE AND INDEMNITY

EXPENSES AND FINANCIAL BENEFITS

Children and parents/caregivers participating in the study will receive financial compensation for their time/ transportation a total of up to £100 if they have completed all the 3 stages of the study. A breakdown, each participant will receive £30 for each of stage 1 and 3 interviews. Participants will receive an additional £40 after completing the stage 2 diary part of the study. Participants may also be reimbursed for their time and travel expenses (up to the value of £30) if they have unresolved technical issue with sending the audio recording and they needed to visit the dental hospital to transfer the data manually using a cable. Payments will be handed person or will be sent via post in the form of vouchers. The vouchers be purchased by the Finance Office of the dental school and in line with organisational policy on financial reimbursement for study participation.

FINANCIAL AND OTHER COMPETING INTERESTS

No competing or financial interests have been declared by the authors of this protocol.

ROLE OF FUNDER

This study is funded by Oral and Dental Research Trust (Appendix 11). The finance department of Cardiff School of Dentistry is managing the financial and expenses matters of the project.
Neither the sponsor or funder(s) will play a role in the study design, conduct, data analysis and interpretation, manuscript writing, or the dissemination of results; this will be the responsibility of the Chief Investigator, who is an employee of the sponsor organisation.

Commented [NR3]: Which appendix? Please specify.

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INDEMNITY

Non-negligent harm: This study is an academic, investigator-led and designed study. The Chief Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a clinical study and they cannot offer any indemnity.

Negligent harm: Where studies are carried out in a hospital, the hospital continues to have a duty of care to a participant being treated within the hospital, whether or not the participant is participating in this study. Cardiff University does not accept liability for any breach in the other hospital's duty of

care, or any negligence on the part of employees of hospitals. This applies whether the hospital is an NHS Trust or not. The Sponsor shall indemnify the site against claims arising from the negligent acts and/or omissions of the Sponsor or its employees in connection with the Study (including design of the Protocol to the extent that the Protocol was designed solely by the Sponsor and the Site has adhered to the approved version of the Protocol) save to the extent that any such claim is the result of negligence on the part of the Site or its employees.

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