reMOte DEntal tReatment planniNg study- MODERN study

An exploration of remote treatment planning for a dental general anaesthetic by specialists in paediatric dentistry a mixed methods study.

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Research Reference Numbers

IRAS Number:	334702
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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: **Date:**

……/……/……

……

Name (please print):

Mrs Karen Jennings-Wilding

Position:

Senior Clinical Research Governance Manager

Chief Investigator:

Signature: **Date:**

…… ……/……/……

Name: (please print):

Sarah McKernon

Key Study Contacts

Insert full details of the key study contacts including the following;

Chief Investigator	Professor Sondos Albadri Sondos@liverpool.ac.uk
Study Co-ordinator	Sarah McKernon 07791474556 mckernon@liverpool.ac.uk
Contact for Clinical Queries (if not CI)	As above for Study Co-ordinator
Sponsor	The University of Liverpool is the research Sponsor for this Study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter. For further information regarding the sponsorship conditions,

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Committees	N/A

Study Summary

Study Design	This is a mixed methods study that aims to investigate the ability of specialists in paediatric dentistry (SPD) to remotely treatment plan a child for a dental general anaesthetic (DGA). The first part of the study will recruit children who are attending a paediatric new patient appointment and who require DGA. Two forms of clinical imaging will be collected from each participant: 1)

	five intraoral clinical photographs will be taken specifically for the purposes of the study and 2) a digital copy of routine radiographic images taken during new patient appointments will be made (no additional radiographs are required). A record of the treatment plan made by the SPD at the appointment will be made. Images and radiographs are then uploaded onto a custom-built password protected online platform to enable SPDs to create a treatment plan for a child, based upon the clinical photographs and radiographs only. A comparison will be made between the chairside treatment plan and those completed remotely to measure the sensitivity and specificity. The second part of the study will be one-to-one interviews with parents of children planned for a DGA. The interviews will use a semi-structured approach facilitated by open ended questions. The third part of this study will be intervention evaluation.
Study Participants	Participants will include: • children attending a New Patient Consultation (NPC) clinic in paediatric dentistry. • parental guardians (adults over the age of 18) who attend with a child for an NPC • specialists in paediatric dentistry (adults over the age of 18)
Planned Size of Sample (if applicable)	Clinical data from twenty children attending a NPC 10-15 interviews with parental guardians, ceasing once sufficient

	richness of data Five interviews with specialists in paediatric dentistry.
Follow up duration (if applicable)	N/A
Planned Study Period	Anticipated recruitment of children, parental guardians and specialists in paediatric dentistry October 2025
Research Question/Aim(s)	To what extent is an online treatment planning platform comparable to face to face assessment of children prior to DGA to identify need for treatment, proposed treatment type and performing the treatment planning process, and how acceptable is the intervention to parents and specialists?

Funding and Support in Kind

FUNDER(S)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
Royal College of Surgeons of England	**Doctoral funding for 12 months**

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study Steering Groups

The study steering group with include the study co-ordinator and all academic supervisors. The steering group will meet monthly to discuss progress.

Patient & Public Involvement Group

Formal PPI was undertaken with the kind support of Alder Hey Children's Hospitals dedicated Patient and Public Engagement Team who host a Young Person's Advisory Group (YPAG). Their feedback has been incorporated into the protocol. Their invaluable input was instrumental in developing part 2 and a suitable topic guide for part 2. Further engagement is planned at suitable stages during the study.

Protocol Contributors

The study team are multi-disciplinary and multi-institutional with a strong research background. The study co-ordinator will be meeting with protocol contributors monthly.

Professor Manu Mathur is Professor of Dental Public Health at Queen Mary University of London. His background is more than 20 years of global experience of working in different health systems.

Dr Girvan is a Reader in Biostatistics Health Data Science at the University of Liverpool. He has over 20 years' experience working in medical and dental research, primarily in clinical trials.

Dr Janine Yazdi-Doughty is a NIHR Clinical Lecturer in Primary Dental Care. Her background is oral health-related stigma and screening for chronic diseases in dental practice.

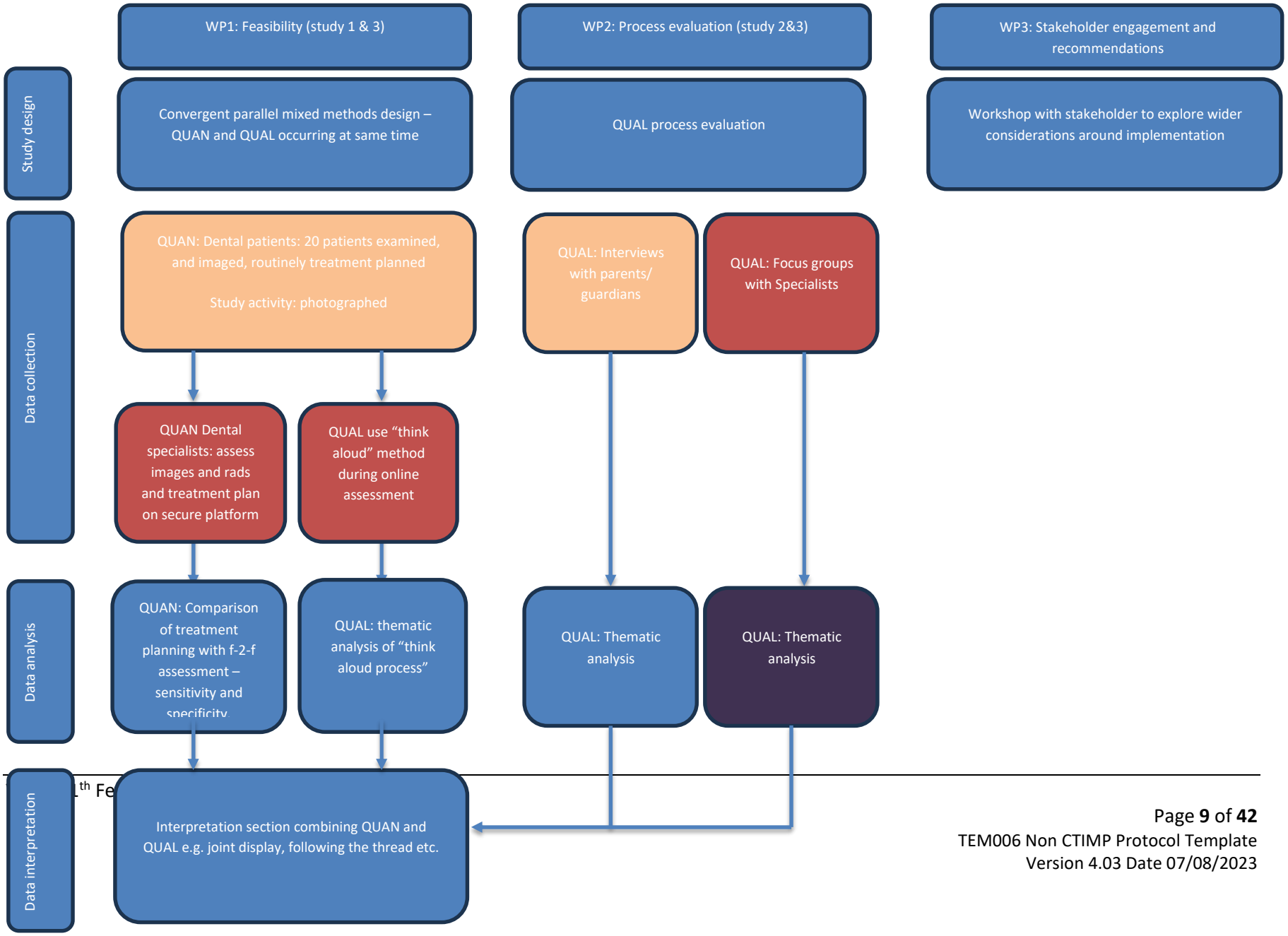
Key Words: General Anaesthetic

Dentistry

Pragmatism

Dental public health

Study Flow Chart



Glossary of Abbreviations

HRA	Health Research Authority
REC	Research Ethics Committee
DGA	Dental General Anaesthetic
LUDH	Liverpool University Dental Hospital
SPD	Specialist in Paediatric Dentistry

Contents

1. INTRODUCTION

This protocol describes the feasibility of remote treatment planning for a dental paediatric general anaesthesia and provides information about the study and provides information about procedures for entering participants, study procedures, safety reporting and governance requirements.

Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study. Problems relating to this Study should be referred, in the first instance, to the Principle Investigator (PhD Student) mckernon@liverpool.ac.uk , if unresolved, referred to Primary Supervisor sondos@liverpool.ac.uk

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy as well as any other regulatory requirements as appropriate.

2. LAY BACKGROUND

The problem

There were 30,966 hospital admissions due to tooth decay in 2023, with approximately 15,000 of them in children. Usually, hospital admission for tooth decay involves a child having a general anaesthetic (going to sleep) to remove teeth. It is important that the correct plan of treatment is made for each child so that the procedure goes well and to avoid the need for the procedure to be repeated due to omissions in planning. Unfortunately, large areas of the UK have no access to a specialist in children's dentistry – making treatment planning a 'postcode lottery'. This means that children are having plans made by dentists who have no specialist knowledge. Previous research has shown that if a treatment plan is made by a dentist who isn't a specialist in children's dentistry, the child is three times more likely to need more than one episode of general anaesthetic. Failing to complete the treatment under one anaesthetic is bad for the child, as they experience pain, and often have difficulty eating, drinking, schooling, and sleeping, for longer. It is also bad for the NHS as dentistry services

in hospitals are busy and expensive. It would be much better for the child, and more efficient for the NHS, for all presenting problems to be treated under one general anaesthetic.

What do we plan to do in this study?

We can't produce more specialists in children's dentistry without significant government intervention, and even then, training to become a specialist takes many years to complete. We wish to investigate whether we can use existing UK-based specialists in children's dentistry more effectively. Rather than the child or specialist travelling long distances, or the plan being written by a non-specialist, we aim to test whether planning can be done remotely by specialists using a specially designed platform on the internet.

This study will invite the participation of children (<16 years old) who have attended Liverpool University Dental Hospital to see a specialist in children's dentistry to plan their treatment under general anaesthetic. These children are attending as part of their routine dental care. Taking part will involve having photographs taken of the child's teeth. A password protected platform will be used to display these photographs, alongside routinely taken x-rays of the child's teeth. Each set of images will be given a code, and all names will be removed to make the records anonymous. Specialists in children's dentistry will be invited to participate and will be provided with access to the online platform. They will view each anonymised child patient's photos and x-rays and based on what they see, they will write a treatment plan for completion under general anaesthetic. We will then compare the accuracy of this online plan with the one made when the child attended the hospital in-person. In theory, if the plans are the same, we will have found a way to improve dental treatment planning and reduce the postcode lottery that currently exists. We also want to explore how parental guardians view the concept of remote treatment planning. We will do this using semi-structured interviews. As part of future planning, we want to also explore how specialists in paediatric dentistry use the platform, how acceptable they find using it and how we might be able to improve it for future research.

Impact

If this research proves that specialists in children's dentistry can plan remotely, the next steps will involve testing this in many different regions to strengthen our evidence. In future, this has the potential to improve oral health outcomes for children, reduce inequalities and improve the sustainability of dentistry. Moreover, this initiative will bolster the current infrastructure for managing paediatric oral diseases, thereby enhancing the quality and

accessibility of care for children

3. BACKGROUND

Dental caries, although an entirely preventable disease, remains the number one reason for children aged 6-10 years in the United Kingdom to be admitted to hospital (NHS Digital, 2020; Disparities, 2023). The most recent figures from the Oral Health Survey of 5-year-olds, demonstrate that 29.3% of children in England had experience of dental decay with nearly a half of 15-year-olds and a third of 12-year olds having obvious decay experience in their permanent teeth, and it follows social gradients with the most deprived being more affected (Public Health England, 2020; Vernazza *et al.*, 2016; England, 2023). This is a similar finding to the previous Oral Health Survey completed in 2017 (23.3%)(Vernazza *et al.*, 2016).

Children living in poverty are already disadvantaged and more likely to attend a hospital for caries management under DGA (Mills, 2020; Broomhead *et al.*, 2021). Tooth extraction due to dental caries in children and young people living in the most deprived communities is nearly 3.5 times that of those living in the most affluent communities (Disparities, 2023). In a report published by the UK's four chief medical officers it was stated that tooth decay was an entrenched inequality which needs to be addressed (Care, 2021). It was reported in 2019, that 6% of children aged under 16 in England had time off nursery or school in the last 6 months because of problems with their teeth, mouth or gums (Digital, 2021)

From 2019 to 2020, 35,190 children aged 0 to19 years in England were admitted to hospital for the extraction of carious. In the same year, the cost of hospital admissions for tooth extractions among those aged 0 to 19 years in England was estimated to be £54.6 million, with most due to preventable tooth decay. (England, 2019).

A dental general anaesthetic (DGA) enables a child to have all active disease managed one procedure (Kandiah *et al.*, 2010). Dental extractions, however, have the potential to be a negative experience for a child, and potentially lead to underlying dental phobia in future especially if completed under general anaesthetic, one reason why a repeat DGA should be avoided (Association of Paediatric Anaesthetists of Great Britain and Ireland, 2011; Davies C, 2008). GA is not a risk-free procedure and there are reports of significant complications

during a DGA (Roberts *et al.*, 2020). Therefore, all preventable measures to prevent a repeat DGA should be taken. Repeat DGA's are problematic for the child, their family and the healthcare service delivering the DGA. Repeat DGA rates vary from as low as 3.1% to as high as 59%. Repeat DGA have a financially burden to the healthcare system. (Siddik, Al Jaddir and Barnard, 2011; Goodwin, Pretty and Sanders, 2015; Friend and Allen, 2016).

Previous literature has sought to identify characteristics of children who are at risk of a repeat DGA. Children with dental caries effecting maxillary incisors and those who are not brought to future clinical assessments are more likely to require a repeat DGA (Sheller *et al.*, 2003). Furthermore, evidence demonstrates that children with medical co-morbidities are four times more likely to require a repeat DGA compare to healthy controls (Guidry *et al.*, 2017).

To avoid repeat DGA, guidance advises that the comprehensive assessment of children undergoing a DGA for extraction of teeth should be completed by a specialist in paediatric dentistry (Association of Paediatric Anaesthetists of Great Britain and Ireland, 2011; Davies C, 2008; NHS, 2022). Inappropriate assessment could potentially lead to the child having a repeat dental general anaesthetic.

This mixed methods study with three distinct objectives, aims to explore remote dental treatment planning. The overarching aim of the study is to explore to what extent an online treatment planning platform is comparable to face to face assessment of children prior to DGA to identify need for treatment, proposed treatment type and performing the treatment planning process, and how acceptable the intervention is to parents and specialists.

Study 1 MODERN study - reMOte DEntal tReatment planniNg study.

RQ1 To what extent is online treatment planning comparable to face to face treatment planning (QUAN)

The first part of this study utilises a custom-built online platform to compare a treatment plan undertaken chairside in clinic as part of routine care with a treatment plan completed remotely using only clinical images and radiographs. The sample size for the first part of the study is twenty children.

Study 2

RQ2 What is the acceptability of the intervention and recruitment process to the parent/guardians of the child participants in the study? (QUAL)

The second part of this study involves conducting one-to-one interviews with parents or guardians of children undergoing dental general anaesthesia, to explore their views and opinions on remote dental treatment planning.

Study 3

RQ3 What are the experiences and perceptions of specialist users regarding the effectiveness and implementation of the intervention? (QUAL)

The overarching study aim

To what extent is an online treatment planning platform comparable to face to face assessment of children prior to DGA to identify need for treatment, proposed treatment type and performing the treatment planning process, and how acceptable is the intervention to parents and specialists? (Mixed-methods)

4. RATIONALE FOR CURRENT STUDY

Treatment planning by non-specialists in paediatric dentistry leads to an increased rate of a child requiring a repeat DGA. Increased access to treatment planning by specialists in paediatric dentistry could prevent repeat DGAs. This could either be achieved by increasing the number of specialists which is both costly and time-consuming or by increasing the availability of specialists to provide treatment plans remotely. Therefore, in this study we are exploring the feasibility of remote specialist treatment planning using an online platform.

5. THEORECTICAL FRAMEWORK

We have used the Medical Research Council (MRC) framework for complex interventions which provides a theoretical underpinning for understanding and evaluating interventions that have multiple interacting components and dynamic relationships with their context (Skivington et al., 2021). This framework, commonly applied in health research, highlights the need to understand how interventions function, their effectiveness across various settings, and their interactions within larger systems. Although there is currently limited use in oral health research (Harris et al., 2023), it has extensively been used in medical research (Campbell et al., 2007; McMullen et al., 2015).

A summary of the framework:

Phases:

1. **Development**
    - Identify existing evidence and theoretical foundations.
    - Define the intervention's components and mechanisms.
2. **Feasibility/Piloting**
    - Test procedures and acceptability.
    - Assess recruitment, retention, and adherence strategies
3. **Evaluation**
    - Determine effectiveness and cost-effectiveness.
    - Understand how and why the intervention works.
4. **Implementation**
    - Facilitate adoption in real-world settings.
    - Ensure sustainability and scalability.

Core Elements (to consider at each phase):

- **Context Interaction**: Examine how the intervention interacts with its setting.
- **Programme Theory**: Develop a clear logic model outlining expected outcomes.
- **Stakeholder Involvement**: Engage diverse perspectives throughout the process.
- **Addressing Uncertainties**: Identify and plan for potential challenges.
- **Refinement**: Continuously improve the intervention based on feedback.
- **Cost-Effectiveness**: Evaluate whether the benefits justify the resources used.

6. RESEARCH QUESTION/AIM(S)

The overarching aim of this research is to explore to what extent is an online treatment planning platform comparable to face to face assessment of children prior to DGA

5.1. Objectives

1. To explore the specificity and sensitivity of remote treatment planning by specialists in paediatric dentistry in a sample of 20 children and 5 specialists in paediatric dentistry.

2.To understand the acceptability of remote treatment planning to parents/guardians of children requiring a dental general anaesthetic through one-to-one interviews.

3. To evaluate the intervention among specialists in paediatric dentistry

5.2. Outcome

The outcomes of this study include the following:

Quantitative:

1. The sensitivity and specificity of remote treatment planning compared to chairside treatment planning by specialists in paediatric dentistry (Study 1).

Qualitative:

2. An understanding of acceptability of the intervention to stakeholders, namely parents/guardians (Study 2)
3. An understanding of Specialist user evaluation using the think aloud method (Study 4) and acceptability of the intervention (Study 3).

7. STUDY DESIGN AND METHODS OF DATA COLLECTION

This three-part study utilises a mixed-methods explanatory sequential approach (Figure 1, page 9). We will be seeking NHS Health Research Authority approval for the conduct of the study. We anticipate commencing participate recruitment (children for intra-oral photographs, parents/guardians for one-to-one interviews and specialist in paediatric dentistry) October 2025 and ceasing in January 2026. We anticipate conducting interviews between January and March 2026. We anticipate conducting focus groups between January and March 2026.

Part 1: Quantitative data collection.

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The first part of the study utilises a custom-built platform. Specialists in paediatric dentistry will use the platform to complete a treatment plan for a child requiring a DGA. The child will have attended a New Patient Consultation appointment (as part of their routine care) and had a treatment plan completed chairside by a specialist in paediatric dentistry. The platform will enable specialists to view the image and routine radiographs taken at this appointment, then document their treatment plan.

For each tooth, SPDs can select one of five options:

- No treatment required
- Extract
- Restore
- Extract if deemed unrestorable following further examination under GA
- Restore prior to GA if feasible

Platform Development

The custom-built platform has gone through feasibility testing with SPDs and the wider research team. It is secured by an SSL/TLS certificate, which encrypts the connection between the user and the platform. It complies with GDPR requirements.

Sample Size

The sample size for children attending a NPC will be twenty.

The sample size for specialists in paediatric dentistry is five, this is primarily based upon convenience sampling. It will enable both inter-rater and intra-rater reliability to be calculated.

Sampling Strategy

Convenience sampling has been chosen based upon the availability of specialists locally. We anticipate that

participants will be self-selecting based upon previous engagement with feasibility testing.

Inclusion Criteria:

Specialists in paediatric dentistry who:

- Work within Liverpool University Dental Hospital, and
- Provide informed consent to participate.

Exclusion Criteria:

- Specialists who do not work within Liverpool University Dental Hospital.
- Specialists who decline to provide informed consent.

Recruitment

Specialists will be contacted via their work email address and invited to participate.

Data collection and analysis

The data collection will be completed in two forms. Once children have agreed to participate, a record of their treatment plan will be made on a Microsoft Word Document together with their radiographs. All personal data will be removed from clinical notes and images thereby anonymising the patients.

Once anonymised cases have been uploaded to the secure customised platform, SPDs will be given individual log in details, asked to view five cases and formulate a treatment plan for each. The data will be collected on the platform via an Excel Sheet.

For each anonymised case, both chairside and remote treatment plans will be compared. Both descriptive and inferential statistics will be calculated via SPSS.

Part 2a: Qualitative data collection (Study 2)

The next part of the study will involve qualitative research methodology. Initially, parents/guardians of children who consent to take part, will be invited to participate in one-to-one interviews. The interviews will be conducted by SMK online. The interviews will be semi-structured, using open ended questions. A topic guide will be developed, based upon PPI feedback on the research question and The Theoretical Framework of Acceptability (TFA) constructs.

Sample Size

We anticipate conducting 10 interviews with parents/guardians of children – ceasing at the point at which no new themes, insights, or patterns emerge from the data collection.

Sampling Strategy

Purposive sampling will be used to identify and select participants who have experience of a child receiving a dental general anesthetic. Participants will be recruited at the time of recruiting children for intra-oral

photographs. Formal consent for one-to-one interview will be achieved.

Inclusion Criteria:

Parental guardians of children who attend an NPC and are planned for a DGA and who's children agree to take part

Exclusion Criteria:

Parents or guardians of children who either:

- Do not attend a New Patient Clinic (NPC),
- Are not planned for a DGA, or
- Do not provide informed consent or whose children do not agree to participate.

Data collection and analysis

SMK will conduct all the interviews online using Microsoft Teams. Participants will be asked to provide consent to interviews being recorded for the purpose of interpretation. Data will be stored on the M Drive. Each interview will be transcribed by SMK. Analysis will be undertaken using Thematic Analysis and the six phase approach by Braun and Clarke. Microsoft Word, NViVo and Excel software will be used to manage the data and the analysis processes. The data will be presented as overarching themes and subthemes.

Part 2b: Qualitative data collection (Study 3)

The next stage of the study will be exploring the acceptability of the intervention to specialists in paediatric dentistry. This will be undertaken as a focus group. The topic guide will be developed using previous feasibility study feedback, The Theoretical Framework of Acceptability (TFA) constructs and NoMAD tool (based on Normalization Process Theory NPT).

Sample Size

The sample size for specialists in paediatric dentistry is five, this is primarily based upon those using the platform for the quantitative study.

Recruitment

Specialists will be contacted via their work email address and invited to participate as part of the entire research study.

Data collection and analysis

The focus group will be conducted in a seminar room within School of Dentistry. Participants will be asked to provide consent to audio recording for the purpose of interpretation. Data will be stored on the M Drive. Each interview will be transcribed by SMK. Analysis will be undertaken using Grounded Theory and the six phase approach by Braun and Clarke. Microsoft Word, NViVo and Excel software will be used to manage the data and the analysis processes. The data will be presented as overarching themes and subthemes.

Part 2c: Qualitative data collection (Study 3)

The final stage will be exploring user evaluation of the online platform using Think Aloud Test.

Sample Size

The sample size for specialists in paediatric dentistry is five, this is primarily based upon those using the platform for the quantitative study.

Recruitment

Specialists will be contacted via their work email address and invited to participate as part of the entire research study. Consent will be obtained as part of the study to enable audio recording during completion of remote treatment planning.

Data collection and analysis

Participants will be informed of audio recording during completion of remote treatment planning. Participants will be asked to provide consent to audio recording for the purpose of interpretation. Data will be stored on the M Drive. Every participates audio recording will be transcribed by SMK. Analysis will be undertaken using a Framework Approach. Microsoft Word, NViVo and Excel software will be used to manage the data and the analysis processes. The data will be presented as overarching themes and subthemes.

8. STUDY SETTING

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Participants will be recruited at University of Liverpool Paediatric Dentistry Department. Participants will be recruited using purposive sampling from children who attend the paediatric department in Liverpool University Dental Hospital's Paediatric Department for and are subsequently listed for dental treatment under a general anaesthetic. This is routine care. SPD will be recruited from the available population within Liverpool University Dental Hospital.

9. SAMPLE AND RECRUITMENT PARTICIPANT ENTRY

8.1 Eligibility Criteria

8.1.1 Inclusion Criteria

- Children/ young person aged 4-16 who are treatment planned for a DGA with radiographs taken at the time of consultation

- The child/young person lives with a parent/guardian who can consent, this adult needs to be present at the time of child recruitment
- The participant can communicate in spoken English or via a translator using Language Line
- Parent/guardian of a child undergoing a dental general anaesthetic
- Specialist in paediatric dentistry willing to undertake remote treatment planning and take part in process evaluation

8.1.2 Exclusion Criteria

- Children who are not able to tolerate intra-oral photographs
- Children in care who do not live with someone who can consent for them
- Unable to gain translation services for participants spoken language

8.2 Recruitment and sample identification

Potential participants will be identified by clinical team. SMK or a research nurse named on the delegation log will attend DGA treatment planning clinics to recruit children and their parental guardians. Eligible participants (children and parental guardians) will be invited to participate following completion of their outpatient appointment for DGA treatment planning.

They will be provided with verbal information about the study by SMK or a research nurse named on the delegation log and if they are interested in participating, they will be handed a copy of the Participant Information Sheets for both parental guardian and child, a consent form and assent form. The time commitment (10mins for intra-oral photographs and up to 60mins for interview) will be explained to them. Participants will be offered reimbursement for their time at £25/hour for interview.

Cheek retractors and intra-oral mirrors for photography will be shown to both parents/ parental guardian and children together with a how their images will be displayed. A copy of children's treatment plan will be copied onto a Microsoft Word document together with a copy of their radiographs. This data will be anonymised into case numbers (1-20). No record of patient identifiable information will be made.

Specialists in paediatric dentistry will be invited to take part via e-mail. A digital copy of the Participant Information Sheet for SPD will be sent along with a digital consent form.

8.2.2 Informed Consent

Informed consent will be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study. Children must have a parent/guardian present at the time of recruitment. All participants will be required to demonstrate sufficient capacity to consent to participation and sufficient understanding of English language to participate in one-to-one interviews. Capacity to consent will be judged to include understanding., reasoning, alternatives to taking part, the ability to communicate and voluntarily.

All potential participants will be provided with written Participant Information Sheets describing the nature and objective of the research. All participants will be informed of the voluntary nature of participation and their participation will in no way impact any dental care. Written informed consent will be gained by all participants.

10.ADVERSE EVENTS

9.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject, including unfavourable and unintended signs, including abnormal laboratory results, symptoms or a disease associated with treatment.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**

- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

We do not anticipate any significant events in this study. The risk of the study for AEs is low.

9.2 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

9.2.1 Non-serious Adverse Events (AEs)

We do not anticipate any significant events in this study. The risk of the study for AEs is low.

9.2.2 Serious Adverse Events (SAEs)

Upon identification of an SAE the Principle Investigator should complete a study specific SAE form and sent to the Prof Albadri within 24 hours. Relapse and death and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

Contact details for reporting SAEs

Contact details for reporting SAEs to the sponsor:

Dr Neil French
Head of Clinical Operations
Clinical Directorate
4th Floor Thompson Yates Building
Faculty of Health and Life Sciences

University of Liverpool
Liverpool L69 3GB
T: +44 (0)151 794 5852

sponsor@liverpool.ac.uk

All SAEs should be reported to the <name of REC> where in the opinion of the Chief Investigator, the event was:

- **'related'**, i.e. resulted from the administration of any of the research procedures; and
- **'unexpected'**, i.e. an event that is not listed in the protocol as an expected occurrence

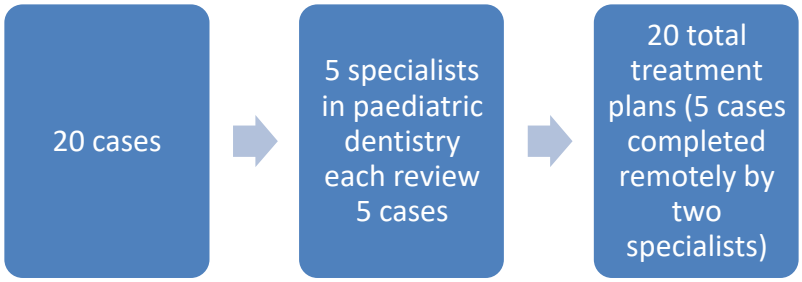
Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the HRA Non-CTIMP safety report to REC form. The Chief Investigator must also notify the Sponsor of all SAEs.

11.STATISTICS AND DATA ANALYSIS

10.1 Sampling

A sample size of twenty children has been designed to test this complex intervention based upon a feasibility

testing phase, therefore no formal sample size calculation has been calculated. Ten parents/guardians will be sufficient to reach data saturation from one-to-one interviews to answer the research question. Five specialists in paediatric dentistry is based upon the available local population of specialists, which currently is ten, with two on maternity leave, therefore five is an achievable number.



10.1.2 Sampling Technique

Participants will be recruited using purposive sampling from children who attend the paediatric department in Liverpool University Dental Hospital's Paediatric Department for New Patient Consultation appointment and are subsequently listed for dental treatment under a general anaesthetic. SPD will be recruited from the available population within Liverpool University Dental Hospital.

10.2 Data Analysis

Quantitative data analysis

- The data collection will be completed using the online platform at modernstudy.co.uk. It will be exported to an Excel Spreadsheet for analysis. Data will be analysed to evaluate the remote specialist's ability in accurately forming a treatment plan for a DGA, compared to that formed chairside. The primary

statistical measures used will be sensitivity and specificity. All analysis will be conducted using SPSS or STATA with significance set at $p<0.05$. The five potential outcomes per tooth are: 1) no treatment required; 2) extract; 3) restore; 4) extract if deemed unrestorable following further examination under GA; or 5) restore prior to GA if feasible. The sensitivity and specificity will be measured per tooth as outline below.

Qualitative data analysis

SMK will be conducting all interviews. Data will be recorded on a password protected device, securely transcribed and anonymised/de-identified using a University of Liverpool approved service such as Microsoft Teams. Anonymised data will be transcribed by SMK or an externally approved transcription service that complies with GDPR. All study researchers will have access to the anonymised transcriptions. SMK will have responsibility for anonymising the transcripts and archiving them at the completion of the study. Analysis of the qualitative data will be undertaken using Thematic Analysis, following the six step approach by Braun and Clarke. Microsoft Word, NViVo and Excel software will be used to manage the data and the analysis processes. The data will be presented as overarching themes and subthemes. All copies of data will be destroyed following transcription in compliance with University of Liverpool ethical and legal requirements.The treatment plan completed at NPC will be considered the reference test (gold standard), and the remote treatment plan will be considered the index test.

For each tooth:

- Gold standard (face-to-face specialist plan)

- Remote plan

- One of five treatment categories

Then, for each treatment category (e.g., extraction, pulp therapy, restoration, no treatment, etc.), treat that category as “positive” and all other categories as “negative”, and construct a 2×2 table.

For example, for “Extraction”:

True positive: gold standard = extraction AND virtual = extraction

False negative: gold standard = extraction BUT virtual ≠ extraction

False positive: gold standard ≠ extraction BUT virtual = extraction

True negative: gold standard ≠ extraction AND virtual ≠ extraction

Then:

Sensitivity = TP / (TP + FN)
Specificity = TN / (TN + FP)

Repeat that calculation for each of the five treatment categories

12. REGULATORY ISSUES

11.1 Ethics Approval

Before the start of the study, a favourable opinion will be sought from the UK NHS Health Departments Research Ethics Committee for the study protocol, informed consent forms and other relevant documents e.g. advertisements. Health Research Authority (HRA) approval will be obtained where required.

The study site file will be submitted to each proposed research site for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

11.2 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and

any other directly applicable regulation relating to data protection and privacy.

Each participants/parental guardian/SPD will be assigned a pseudonym name and the PI will retain the details of who the pseudonym is assigned to. The PI will share the pseudonym with the CI/primary supervisor only. The pseudonym will be used on any transcripts sent to supervisors to discuss analysis and would be used in all coding, themes and quotes in the final thesis/papers.

No personal information will be collected for the purpose of this research. The recordings and transcripts will be stored on the password protected drive (M Drive) of the postgraduate researcher. The postgraduate researcher and primary supervisor will have password access to the data. At the end of the postgraduate's studies the data will be stored by the research support officer on the secure university drive (M Drive). Data will be stored on the hard drive for up to 10 years and then destroyed.

11.3 Indemnity

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

11.4 Audits

The study may be subject to inspection and audit by the University of Liverpool under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

13. END OF STUDY

The end of study will be when all data has been collected, analysed and interpreted. End of the study will cumulate with submission of thesis.

DISSEMINIATION POLICY

13.1 Dissemination policy

The data arising from the study will be owned by the University of Liverpool. The results of this study will be presented at national and international conferences, and an abridged version published in a peer-reviewed scientific journal. Participants can request a copy of their survey responses or interview transcript from the study CI at any time during or after the study. The study will also contribute to a thesis in partial fulfilment of the PhD programme at the University of Liverpool.

13.2 Authorship eligibility guidelines and any intended use of professional writers

Key study contributors Sarah McKernon, Manu Mathur, Girvan Burnside, Janine Yazdi-Doughty, and Sondos Albadri will be granted authorship on the final study report and any peer reviewed publications. Any investigators who contribute significantly to the conduct and write up on the study sufficient to warrant recognition as co-authors, will also be granted authorship.

The ICMJE criteria for individually named authors is as follows:

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

Drafting the work or reviewing it critically for important intellectual content; AND

Final approval of the version to be published; AND

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

14.ARCHIVING

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study.

15. REFERENCES

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16. APPENDICES

16.1 Appendix 1- Required documentation

- Copies of letter headed patient information sheets for children having intra-oral photographs, one to one interviews and recruitment of specialists in paediatric dentistry in paper and electronic format
- Informed consent document in paper and electronic format

16.2 Appendix 2 – Schedule of Research Procedures (Example)

Stages	***Intra-oral photographs***	***One-to-one interviews***	***Specialists in paediatric dentistry***
Informed consent	*x*	*x*	*x*
Demographics	*x*	*x*	
Medical history	*x*		
Observation of treatment			
Focus Group			*x*
Interview		*x*	

16.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made