PROTOCOL

PANDA STUDY - AN EVALUATION OF AN ALTERNATIVE DENTAL PATHWAY

PROTOCOL COVER SHEET

STUDY TITLE:	An evaluation of an alternative Child Friendly Dental Pathway for Paediatric patients
INVESTIGATOR:	Dr Michaela Goodwin University of Manchester Dental Health Unit Williams House M15 6SE
STUDY PHASE:	Health service evaluation - effectiveness and impact
AIMS:	The aim of this research is to determine the performance of CFDP pathway compared to a traditional Specialist Paediatric Dental pathway on the longer term oral health and treatment outcomes for children referred to specialist care due to severe decay and the associated health economic costs.
PARTICIPANTS:	Children referred through a dental pathway in Greater Manchester who meet eligibility criteria to be seen within a Child Friendly Dental Practice
STRUCTURE:	Prospective, comparative, cohort study
NUMBER OF CENTRES:	20 Across Greater Manchester
PRIMARY OUTCOME:	Proportion of individuals who experience a dental general anaesthetic in each study group during the study period
SAMPLE:	All children referred through a dental pathway in Greater Manchester who meet the eligibility criteria to be seen in a Child Friendly Dental Practice
ESTIMATED TOTAL SAMPLE SIZE:	The minimum sample size at the end of the study required is 708 (354 in each area)
ADVERSE REACTIONS:	N/A none anticipated within the duration of the study – we are following treatment pathways which are already in place
STUDY ORIGINATORS:	Dr Michaela Goodwin
TRIAL REGISTRATION:	ISRCTN (16214896)

CONTENTS

An evaluation of a water fluoridation scheme in Cumbria.

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Trial Registration

Data category	Information
Primary registry and trial identifying number	ISRCTN - 16214896 https://www.isrctn.com/ISRCTN16214896
Date of registration in primary registry	27/04/2023
Source(s) of monetary or material support	NIHR, HSDR
Primary sponsor	University of Manchester
Contact for queries	Dr Michaela Goodwin, Michaela.goodwin@manchester.ac.uk

Title	PANDA study - An evaluation of an alternative child friendly dental pathway
Countries of recruitment	England
Health condition(s) or problem(s) studied	Services for children referred due to dental decay
Key inclusion and exclusion criteria	Inclusion criteria: Paediatric patients (aged 0 to 16 years old) referred through the Greater Manchester dental referral system and who have been triaged as appropriate for treatment at a CFDP. Patients with parents/guardians who have the capacity to consent. Exclusion criteria: Patients referred for orthodontic treatment
Study type	Observational, cohort
Date of first enrolment	TBC
Recruitment status	Study Set up

Protocol Amendment

V1.1
Author Michaela Goodwin
V1.2
Author Michaela Goodwin
V1.3
Author Michaela Goodwin
V1.4
Author Michaela Goodwin

Revision Chronology

Funding

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This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

I. INTRODUCTION

BACKGROUND

England and particularly the Northwest have a significant problem in relation to dental decay in young children (1). Extraction of teeth under general anaesthesia is the most common reason that children aged 5-9 are admitted to hospital. Since 2015 over 25,000 hospital admissions for tooth extractions have occurred every year, more than double the number of admissions for the next most common reason of tonsillitis (2,3). Waiting times for dental general anaesthetics

and specialist paediatric dental care in general are widely acknowledged to be unacceptably long (4–6).

Cases of tooth decay become more complex, and children are more likely to be referred into this system when the decay is severe or affects multiple teeth, the child suffers from dental anxiety, or the child is very young. Currently, General Dental Practitioners (GDPs, which we will refer to as High Street Dentists when describing a dentist who refers from their practice into the referral system) who feel unable to treat such complex cases may refer them on to a Specialist Paediatric Dentistry pathway, where they may be treated within one of two specialist settings: (Setting 1) to hospital (secondary care) or (Setting 2) to dentists with enhanced skills and specialist equipment and facilities (Community Dental Service) (7).

One solution to this crisis of children waiting, often in pain, for treatment is to increase capacity, however there are limits on being able to increase capacity within the existing specialised pathways, both within the hospital services and within the Community Dental Services. Hospital services have downward pressure from other paediatric specialties who also require specialised space and staff, and the Community Dental Service is intended to provide complex care for adults and children with additional needs, but is currently overwhelmed by otherwise healthy young children with extensive decay.

In late 2020, as a response to the increased pressure caused by Covid-19, a new model of enhanced primary care was piloted in Greater Manchester (GM), the Child Friendly Dental Practice (CFDP) Scheme. The aim was to provide timely access to dentists who have an interest in treating young children and who have received some additional training, access to a specialist-led peer support network and additional funding. The CFDPs have been developed around a prevention focused and evidence-based model of care with the aim of improving oral health outcomes. These include clinical techniques for treatment which are not typically used by High Street Dentists such as applying Silver Diamine Fluoride and placing preformed metal crowns using the ‘Hall Technique’ (8).

In 2021 the GM pilot scheme was evaluated within the resources available and the initial findings indicated that a large proportion (50%) of children referred could be treated within these CFDP settings. Following the pilot, the GM local dental network and commissioning team approached our research team with a request for research support to carry out an evaluation before the scheme is adopted more widely. This request demonstrates a research need that has been jointly identified by both dentists and commissioners within this area and further, is one of the top dental research priorities identified by the James Lind Alliance(9) including access to dental services and reducing oral health inequalities. Several studies have indicated that the majority of children initially referred by their own dentist for extractions under GA can be successfully treated under local anaesthesia by the Community Dental Service (10). The CFDP pilot scheme in Greater Manchester has now provided preliminary evidence that general dentists can be supported to treat a significant proportion of children referred through the same pathway. While the pilot work showed promising results, our proposed robust evaluation (building on this previous work) is required to determine the longer-term and broader impacts of implementing an alternative care pathway on children and NHS services. This need for a comprehensive evaluation is reiterated in our letter of support from Lindsey Bowes, the Primary Care Commissioning Manager.

In addition to being a local priority, the CFDP work also aligns with national strategic priorities for dental services. The current General Dental Services contract was implemented in 2006 and has been criticised as being target driven, with inadequate incentivisation for the provision of preventative care, and a lack of ability to account for the additional time and resources required

to deliver care for vulnerable and higher-need groups (11). Following the recommendations of an independent review of dental services in 2009, a range of alternative dental contracts have been piloted as part of a national dental contract reform programme initiated in 2011(12). However, in September 2021 The Department for Health and Social Care decided to end the pilots and not to implement the most recent iteration of the new prototype contract, because of a lack of evidence that it would maintain access for patients and reduce inequalities within the existing resources available for NHS dentistry (13).

The Department for Health and Social Care has now asked NHS England to lead the next stage of contract reform, with a focus on implementable proposals that will improve oral health, increase incentives for prevention-focused and evidence-based care and reduce inequalities in access to NHS dental care, particularly in relation to deprivation and ethnicity(14). NHS England has recently issued guidance to regional NHS commissioning teams to support 'flexible commissioning' as a way to achieve these aims within the current 2006 GDS contractual arrangements. Flexible commissioning uses the 'additional services' element of the current GDS contract to reallocate existing funding and activity to local commissioning priorities, based on need (15). The CFDP scheme acknowledges that additional time, training and resources are required when treating young patients with high levels of dental disease and provides for this through variations to existing GDS contracts. The national policy drivers in relation to reducing inequalities and improving the oral health of young children through the flexible use of existing contracts and resources is an important factor in considering how CFDPs could work in the national context.

Previous health services research in other areas of dentistry have already shown the benefit of utilising alternative pathways and upskilling primary care practitioners (16). The research outlined in this proposal could build on this area of research by exploring referrals within primary care practitioners and within specialist care. Reviews within the area have stated the need for further research acknowledging everyone's role within referral and treatment decisions (17)

To inform this proposal several data sources were searched, including Medline, EMBASE and the Cochrane Database for Systematic Reviews as well as grey literature, clinical guidelines and data collected from the audit of the pilot project.

Risks and benefits

As a direct result of the project the CFDP within Greater Manchester will either continue, expand or cease, this will be a short term impact as a decision on this could take place as soon as the results are released. If the CFDPs continue this could have long term impacts by reducing pressure on services such as the CDS allowing them to concentrate on more complex cases, individuals with more complex needs, the vulnerable, elderly, etc.

Patients will benefit if wait times are reduced and appropriate care is provided in a timely manner.

Several other areas of the country have already approached GM for further information on this new pathway of care and have begun to implement their own pilot (see information on Dr Devalia work in the South of England). If successful, the evidence produced in GM along with the pilot work conducted in the South of England could lead to adoption of this model nationally.

Furthermore, this work aligns with strategic intent to implement 'Primary Care Networks' across health and social care i.e. networks of practitioners within a neighbourhood who are able to lead on specific services to meet local population needs.

Rationale for current study:

Before Covid-19 children in Greater Manchester were already experiencing waiting times of up to 12 months for dental treatment under GA, often leading to episodes of pain, time off school and repeat courses of antibiotics. According to the Commissioners within GM as of December 2021, there were 1779 children on the waiting list, 716 of whom have been waiting over 52 weeks. These figures show the continued pressure on the system with children waiting an unacceptably long time for treatment. These numbers are now decreasing with the implementation of CFDP, where this pathway is able to take new patients entering the referral system. The CFDPs have shown promising preliminary results with 50% of children seen within a CFDP. The dental commissioning team in GM are committed to increasing the number of CFDPs by reallocating existing funding. There is considerable interest in this type of scheme from other areas of the country in view of the national policy drivers supporting flexible commissioning; following the work in GM further regional pilots have been established this year (for a minimum of 6 months) in the South East of England lead by Dr Devalia (who has agreed to join our steering committee if the study if funded – further information is available in the letter of support from Dr Devalia). There has also been interest in our research proposal from Northern Ireland and Wales.

While the pilot indicated promising results, with 50% of children being able to be seen within a CFDP, the long term impacts and health outcomes of the use of CFDP are unknown. There have also been concerns raised from some within the field that children treated within a CFDP may still require future intervention in a more specialist service, within a short period of time. If so, there would not be a reduction on the pressure seen on these services and the overall costs of this scheme would be higher than usual care. The proposed research is required to provide a robust, longitudinal evaluation of the CFDP pathway, building on the initial work from the pilots, which can strengthen the case for nationwide adoption if shown to be successful. Following a realist evaluation approach will also mean the research will provide evidence of what works, for whom and when. The project will provide evidence of long term outcomes (treatment required, pain, use of antibiotics) and a health economic evaluation which can be utilised by commissioners for future schemes. If a high proportion of children referred to specialist services can be treated at CFDPs, this model has the potential to improve access to care across the system. In particular, increased used of CFDPs could allow hospital/specialist services to focus on those in greater need. The implementation of an alternative pathway could allow those urgent cases, and cases for which a dental GA is unavoidable, such as medically compromised children and those with additional needs, to be seen sooner. It may also reduce the need for GA for some children if they are seen sooner than they would otherwise been seen along a traditional pathway.

Research objectives.

The aim of this research is to determine the performance of CFDP pathway compared to a traditional Specialist Paediatric Dental pathway on the longer term oral health and treatment outcomes for children referred to specialist care due to severe decay and the associated health economic costs.

Our primary and secondary research questions (and subsequent objectives/methods) are as follows:

Primary

- *Does treatment through a CFDP reduce treatment under General Anaesthetic when compared to the traditional pathway over a period of 2 years?*
    - Using GA data gained from Hospital Episode Statistics (HES)/Community Dental Service (CDS) records the team will assess the number of GAs carried out along each pathway for dental extraction.
- *What are the health economic impacts of using CFDP?*
    - The study will identify and compare healthcare resource utilisation, and associated costs, of both pathways using data collected from HES, NHS BSA, and local clinical records.

Secondary

- *What are the long-term impacts of treatment in terms of antibiotic use, pain experienced, anxiety, further treatment required by CFDP compared to treatment through a traditional pathway?*
    - Using a text message questionnaire, data will be collected from parents/guardians regarding antibiotic use, pain experienced and anxiety of the patient.
- *What are dental teams' beliefs and views on CFDPs/* traditional pathways*?*
    - Using a qualitative methodology dental team views will be recorded and analysed.
- *Are patients satisfied with their experience in using CFDPs and traditional services?*
    - Patient experience will be recorded using an adapted version of the NHS Friends and Family Test recorded through a text message questionnaire.
- *Looking only at the CFDPs - what proportion require an onward referral and what characteristics necessitate an onward referral?*
    - The project will assess the characteristics of patients who do and do not require onward referral.
- *Does the scheme work differently across different localities, for different patients?*
    - The project will determine similarities and differences in how CFDP sites operate for the patients they see and treat.

II. INVESTIGATORS

Key Contacts

The Principal Investigator for this study will be:

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Other individuals involved in this study include:

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Emily Lam
(Lay co-applicant / PPI advisor)

III. APPROVAL OF THE PROTOCOL

The protocol has been reviewed and approved in writing by NHS ethics (IRAS ID: 323977 REC Reference: 23/EM/0093), and The University of Manchester as sponsor.

The Principal Investigator will ensure all relevant staff participating in the study have appropriate training prior to study commencement.

IV. DURATION OF STUDY

3 Years (see timeline).

End of the study will occur when data is collected from NHS parties and there is no longer a requirement for CAG Support (section 251 support is closed down) for the legal basis of processing collected data.

V. PARTICIPANTS

Study population
Children with dental decay referred and triaged through the paediatric referral system who all meet eligibility criteria to be seen by a CFDP.

And

Individuals who work or are connected to the paediatric referral system (dentist, dental team , triages and stakeholders)

Inclusion and exclusion criteria
Inclusion criteria:

- Paediatric patients (aged 4 to 16 years old) referred through the Greater Manchester dental referral system and who have been triaged as appropriate for treatment at a CFDP.
- Patients with parents/guardians who have the capacity to consent through the study sites or unconsented cohort from the dental referral management system subject to CAG Approval.

Exclusion criteria:

- Patients referred for orthodontic treatment
- unconsented cohort who opts out of having their confidential data used for research purposes through the national and study specific opt-out service

Setting and sampling

The study sites are located across Greater Manchester and therefore the study will encompass a diverse range of sites with equivalent Community Dental Service clinics recruiting patients from a similar geographic area. Given the diversity within Greater Manchester the study will be able to recruit from a diverse and representative cohort. Participants will be assessed for inclusion into the study by the specialist triage according to inclusion and exclusion criteria.

Screening, Selection and Recruitment of Subjects

Children who attend either CFDP or CDS if they meet the eligibility criteria (or have been triaged as appropriate to be seen within a CFDP) they can be recruited into the study via the CDS or CFDP (a member of staff at the CDS or CFDP). If patients have already been seen and treated within a CFDP or CDS but are still eligible to be recruited a letter will be sent from the dental team at the CDS or CFDP.

Pseudonymized data on all eligible patients from 1st January 2022 to 31st December 2024 will also be obtained from the dental referral management system which contains dental data of participants who were eligible to be sent to the CFDP within that period. The Dental Referral Management System will handle the pseudonymization of unconsented data by assigning ID numbers. The pseudonymization key will be securely stored within the RMS system, ensuring that only authorized personnel can access it. The data provided by the system will be pseudonymized and will pertain to unconsented participants.

The data will be collected using an excel based data collection tool which will be provided by the study team to the dental referral management team to obtained pseudonymized data which will be sent to the research data storage by authorized RMS team and can only be accessed by authorized research staff.

For the consenting cohort, all eligible parents/guardians will be provided with the participant information sheet when they attend the CDS/CFDP (or via post if they have already attended).

The referral process will identify those who could take part, or if seen through the CDS recruiters can also identify participants according to the defined eligibility criteria.

Sufficient time will be given for the parents/guardians to read the study information and have the opportunity to ask questions

When consent is obtained a parent/guardian will consent both for themselves and their child to take part. Child assent will be gained for children, verbal assent can be taken and recorded on the main consent form by circling ‘yes’ to assent if a child verbally agrees but does not wish or is unable to sign the assent form.

Additional advertising will be placed in appropriate areas around the practice sites with links to website and contact information.

For staff as research participants this will include staff who work within the CFDP or CDS who treat patients who could be recruited into the study. Stakeholders who are connected to CFDP, dentists who refer into a CFDP or triages who triage referrals within this system

Participants can withdraw consent without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. Once data is analysed participants cannot withdraw consent as the data will already be included and published.

Sample size

To determine the required sample size, the sample size calculation was based on a two-sample test for proportions. Results indicated that 354 participants per group, 708 participants in total, will allow a difference in proportions in the need for a GA from 25% to 15% to be detected with 90% power and a two-sided significance test at the 0.05 level. We anticipate that at least 10 clinics who are providing care under Child Friendly dental pathway and 10 clinics who are providing care under the usual Specialist Dental pathway will participate in the study.

The study sites are divided into two groups: Community Dental Services (CDS) and Child Friendly Dental Practices (CFDP) with an original planned sample size of 708 participants from both groups, or 354 per group at the end of the study. Due to low recruitment numbers from the CFDP group among the study sites, the remainder of the required sample size for the CFDP group will be supplemented with unconsented, anonymised data obtained from the dental referral management system, the data will be from a similar timeframe of the consented data collected in the CDS group obtained from the study sites.

In 2023, 230 patients were seen and treated within CFDP if the same number are seen and treated within 2024 this will provide data on 460 patients. As we would have a larger sample from the CFDP this would mean only 292 patients would need to be recruited from the CDS to reach a power of 90% to detect a difference in proportions in the need for a GA from 25% to 15%.

This approach will allow the study to meet its target sample size and effectively address the research questions and objectives. Recruitment and numbers seen through CFDP will be closely monitored so that recruitment can end as soon as the minimum sample size is reached.

Inclusion / exclusion characteristics

Child aged 4-15 years only (cut-off 16th birthday)
Child resident in Greater Manchester
Child referred by general dental professional based in Greater Manchester
Child contact information complete i.e., age, contact address, telephone number, carer
Extractions requested and radiograph provided
Child medical history complete
Reason why treatment cannot be provided by referring dentist provided
Dental charting complete
Child with no or mild medical complexities
Child with no or mild behavioural complexities
Child presents with symptomatic teeth in one or two quadrants only

A referring dentist should chart all teeth in a referral indicating all teeth that are carious and which are symptomatic. When deciding triage outcome, if one or two teeth only are symptomatic (i.e., causing pain) and this could be managed by extraction/restoration, then the child would be suitable for management within CFDP. The child should attend the referring dentist for completion of treatment (shared care model).

Not suitable for management in CFDP:

Child who has developmental defects of permanent teeth requiring treatment
Child with three or more symptomatic carious teeth
Child with unrestorable teeth in three or four quadrants e.g., extractions indicated in three or four quadrants
Child who needs root canal treatment (RCT) in permanent teeth
Child with moderate to severe medical complexities
Child with moderate to severe behavioural complexities

VII. STUDY DESIGN Prospective, comparative, observational cohort study

VI: Planned interventions:

The exposed cohort will receive care following triage and treatment through the alternative pathway (treatment through the new CFDP).

The control cohort (non-exposed) will receive care following triage and treatment through the traditional pathway (treatment through the Specialist Paediatric Dental pathway).

Time scale (see appendix for more detailed time line)

Year 1 – 2023

Months Feb-March -Study set up
Months Feb-March -Ethics application
Months March – PPI development,
Months May -December (2024) – Recruitment
Months May - December (2024) – Data collection (CRF)
Months May – September – Observational data collection
Months May – March (2024) -text message survey
Months Nov – Dec – Data coding
Months August to October – Qualitative interviews

Year 2 – 2024

Months Jan -Feb – NHS BSA application
Months May-July – Text message survey
Months May – September – Observational data collection
Months August to October – Qualitative interviews
Months November to December -Qualitative analysis

Year 3 – 2025

Months March – April finalise NHS application
Months May – August -text message survey
Month June – August – NHS data retrieval (NHS BSA, CDS, clinical records, NHS digital, HES)
Month September – November – Data analysis
Month November -Jan – report write up

Year 3 – 2026

Month Jan – March -Dissemination

Outcomes
Proposed outcome measures

Primary: The primary outcome, measures whether a child has had a dental extraction under General Anaesthetic two years after referral as indicated in electronic patient records (recorded through HES data or through CDS patient records).

Secondary: The secondary outcomes to be considered in this project include:

- Waiting time until first appointment
- Number of sessions of treatment
- Whether a child was successfully seen and treated. For this outcome success is defined as treatment completed by a dentist that results in a child being referred back to their own dentist or discharged, pain free.
- The number of extractions and restorations as reported in NHS BSA data
- The courses of antibiotics taken during wait and treatment
- Participants referred back into the specialist pathway within two years of referral.
- Dental pain experienced by a child
- Participants views of their treatment and engagement with the dental profession (follow up of dental appointment) as indicated by the responses to the text message. Questions will include an adapted version of the NHS Friends and Family Test, questions on satisfaction, possible negative/adverse experiences, possible positive experiences, and an option for free text comments at the end of the survey.

Qualitative work will focus on two groups: (a) dental professionals (incl. triage, in-practice dental teams, CDS teams and referring practices) and (b) patients (incl. parents and children) accessing and using CFDPs.

(a) Dental teams' attitudes and beliefs regarding CFDP will be examined to better understand what worked well, what created barriers and look at how best to support implementation for such initiatives if they become routine practice.

In a qualitative approach, we will explore dental team beliefs, attitudes, and opinions regarding CFDPs and traditional pathways. To allow for the realist evaluation to take place, a combination of focus groups and one-to-one interviews will take place with the triage team and staff at CFDPs.

Focus group(s) will be organised with some of the dental staff depending on their availability. We aim for at least 1 focus group (up to 8 people) to be conducted. For most dental staff, in-depth one-to-one interviews will explore personal and professional experiences. We aim for around 28 interviews 3 with the triage team, 10 for the CFDP pathway, 10 for the traditional pathway and 5 with referring practices. Data saturation will be monitored throughout and data collection will cease when saturation is reached across all necessary domains. Interviews will explore barriers and facilitators in incorporating and utilising the child friendly practices initiatives, level of acceptability and practicability and what needs to change (or be sustained) for the initiative to be successful and easily incorporated into routine practice. Semi-structured interviews based on the Theoretical Domains Framework (19) will be developed to allow for deductive analysis approach to explore barriers and facilitators within dental teams.

(b) Patients' attitudes and beliefs regarding their experiences accessing and using CFDPs as well as the traditional pathways will be explored through a qualitative, semi-structured approach. A similar approach as with dental teams will be followed where parents of children accessing/using CFDPs and the traditional pathway will be invited to an interview to understand what, in their experience, worked well with CFDPs, if there were any barriers and shortcomings in their experience with CFDPs and the traditional pathway, how can the service be improved in

the future and what access to CFDPs meant for them. We aim for 20 interviews to be completed with parents whose children accessed/used CFDPs and the traditional pathway.

For children accessing/using CFDPs, given their age, a different approach to understand their experiences and provide them with a chance to hear their voices and opinions will be utilised. Children who attended CFDPs will be asked to produce a picture of their experience when attending the service, how they felt before seeing a dental professional, how they felt afterwards and their key emotions throughout the process. Asking children of a certain age to populate and communicate their experiences using art is not new but it is rarely used within healthcare research (20). The benefits of this approach can be multiple from offering children a platform to share their experiences to helping with the dissemination of findings through visual and artistic approaches. In total, we aim for at least 5 children to engage in this process and share their experiences.

Further qualitative research will involve a qualitative researcher attending and observing sessions at the Child Friendly Dental Practices to record what happens during the sessions to detail how they work, the way they are organised, how patients are welcomed and looked after, etc. Service users will be asked consent for a researcher to remain within the room to observe the service being provided. Information collected will revolve around elements that make the service child friendly, what are the barriers and facilitators to patients using the service and what is provided by the service for example is the service located in an area easily accessible by public transport, does it have a car park, what is provided in the reception area (toys, child friendly environment) how are patients greeted and treated by staff. This information will be recorded in writing by the attending researcher. Observational data will be stored on the University of Manchester research storage drive (isilon)

Verbal consent will be obtained from participants through a verbal consent script prior to the commencement of any interview questions. Participants will be asked to clearly state their names in the audio recording following a comprehensive explanation of the study's objectives and the purpose of the interview, which would be read aloud individually by the research staff and provided to participants in a clear and concise language. Participants will be asked to confirm “Yes” or “No” to taking part in the interview with additional points will be clearly stated. Prior to soliciting consent, participants will undergo a confirmation of understanding to ensure comprehension of the study's aims and importance of their response. Only after this confirmation will verbal consent be sought for participation in the qualitative interview. Additionally, participants will be informed of their right to refuse participation or withdraw consent at any point during the interview process. The verbal consent process will be thoroughly documented, including the date of consent, and confirmation of the participant's agreement to participate. Alternatively, written consent can also be sought if requested by participants. Participants who consent to partake in the interview will be sent a hard copy of the consent form via email or post. Qualitative interviews will be recorded on a recording device. Information shared by consented participants will only be used for research purposes, Audio recordings will be pseudo anonymised with participant ID, and at a later stage in the study, the audio files will be renamed to “Parent 1” to destroy the link between the name and the participant ID. After data analysis is completed, data will be deleted and destroyed after two years Only approved transcriptions services will be used, audio recordings will be transferred from devices onto secure UoM storage as soon as possible following the interview and deleted from the audio recording device.

Cost effectiveness

Healthcare resource utilisation will be collected for those treated in both the Child Friendly Dental Practice and Specialist Paediatric Dental Service pathways.

- Dental resource use: treatments provided, prescriptions of antibiotics. Data collected from routine data NHS BSA and local clinical records

- Secondary care resource use: dental extractions under GA. Data collected from routine data: HES and CDS software
- Intervention resource use for CFDP pathway: additional costs paid to deliver the pathway (as outlined in the service level agreement) and additional costs in terms of setting up the pathways (providing training and resources/support for dentists. Data collected from CFDP providers and commissioners.

Unit costs will be attached to dental treatments via the dental treatment band and the associated Units of Dental Activity cost. Unit costs for prescribed antibiotics will be obtained from Prescriptive Cost Analysis data (21). Unit costs for secondary care resource use are sourced from the Healthcare Resource Group tariffs for tooth extractions(22).

Intervention costs will be attached data from CFDP providers and commissioners using salary costs from Unit Costs of Health and Social Care (23). The cost per patient for each pathway will be summarised and presented adjusted for inflation.

The health economics analysis will adopt a cost-consequences approach whereby the costs of each pathway will be presented separately but alongside relevant outcomes: 1) dental extractions under GA, 2) count of children who are successfully seen and treated in each pathway, 3) count of treatments performed (extractions, restorations), 4) mean wait time and 5) dental pain experienced by a child. Resource use and costs from the CFPD pathway will also be used in a budget impact analysis. Differences in outcomes will be generated from the quantitative analysis.

The analysis will take an NHS perspective with a 2 year time horizon. Longer term costs and outcomes will not be modelled due to the need for treatment being acute and focusing on child teeth. This approach will provide dental service commissioners with appropriate health economic data to inform future commissioning decisions related to CFDP.

VII. Monitoring of the study

A steering group, will monitor this study at periodic intervals. This group will include the Principal Investigator, University of Manchester staff, lay member of the community (Public and Patient Involvement (PPI) to ensure that the study is being conducted according to Good Clinical Practice Guidelines. An Oversight Committee (chaired by Zoe Marshman) will monitor and feedback to both the research group and NIHR. Further PPI - patient and public involvement - will be sought for various aspects of the study including visits to practices for recruitment opportunities and through organisations which work with parents and children (such as sure start) to gain relevant opinions on the study, for example both the questionnaire and leaflet will be given to parents to fill in to test before the study begins.

The research will be monitored by the Lead Investigator on a weekly basis and at key project milestones.

The study will be subject to the audit and monitoring regime of the University of Manchester.

VIII. Data handling

The data controller will be the University of Manchester. Data will be collected through

- Clinical examinations. Dentists at the CFDP or CDS will fill out a Case report form (CRF) including information on treatment, antibiotic use (see Appendix B) - pseudo anonymised
- Text message surveys. Participants will answer text message survey at baseline, 1 year and 2 years after consent (See Appendix B). Surveys through text message survey (Text messages will be sent to participants using SafeMessage. SafeMessage is operated by FDS Consultants who are an NHS Business Partner (ODS: 8J025) who have met the following regulatory and legislative requirements: Fully completed NHS

DSPT, CyberEssentials Plus, Data stored in HSCN servers within ISO27001 certified, UK only data centres, DCB0219 met, Clinical Safety Officer, Data Protection Officer and Calidcott Guardian. The system is regularly penetration tested and complies with all the requirements of NHS Digital for the safe storage of sensitive data under GDPR.) Answers from text message survey will be transferred to csv and pseudo anonymised

- Routinely collected data. Following participants consent, data will be linked and collected to be used within the study. This data will come from but not limited to NHS BSA, NHS England, HES, clinical records from the Community Dental Service, GDP and CFDP and referral forms (See appendix B) this data will be pseudo anonymised.
- Supplemental routinely collected pseudonymized dental data for all children who were eligible to be seen within a CFDP will be acquired from the dental referral management system and data collected by commissioners and sent to the University of Manchester to be stored in the research data storage. Additionally, identifiable data with assigned ID numbers for these same children will be provided by the dental referral management system to NHS England and NHS BSA following the approval of the Confidentiality Advisory Group (CAG). Pseudo anonymised data provided from NHS England, NHS BSA following linkage with the dental referral management system, will be sent to the University of Manchester Data Safe Haven.
- The Dental Referral Management System will assign unique ID numbers to the pseudonymized data. The RMS system will securely store the identification key, ensuring that only authorized personnel within the system can access it. It will be destroyed as soon as the pseudo anonymised data has been provided to UoM.
- Participants will be shared a copy of their consent via email or via post.
- Audio recordings will be transferred to UoM storage after interviews and deleted from the audio recording device.
- Audio recordings will be kept for as long as the hard copy consent would be.
- Consent will be kept separately to research data

Data will be securely stored securely at the University of Manchester. Where necessary this will be within system compliant for NHS data, all other data will be stored within Isilon storage which is normally used for research data. If NHS/clinical data need to be combined for analysis this will occur within the Data Safe Haven.

All data will be pseudo anonymised. The key will be stored on a separate system from clinical data provided by NHS. With participant consent identifiable information will be provided to third parties such as NHS BSA in order to link the data and for these parties to provide pseudo anonymised back to the study team as part of this research.

Two years after the completion of the study consent forms will be destroyed, the key detailing the connection between identifiable data and ID will be destroyed which will ensure all data is fully anonymised.

IX. Randomization

Not applicable. Prospective, comparative, population based study.

X. DATA ANALYSES

Summary descriptive data will be reported by study arm and overall using tables of frequencies or means and standard deviations as appropriate to characterise the population and identify any imbalance between groups. The comparison of outcomes from the traditional specialist dental service route (control) compared to the intervention treatment under the alternative Child-Friendly Dental Practice will be assessed to determine if there are clinically meaningful and statistically significant differences in key outcomes. The primary outcome is receipt of GA for tooth extraction within two years of initial referral. Referral along both pathways may still result in the need for a GA for some children but a key metric will be to determine whether there

is a meaningful difference in the number of GAs per referral pathway. The primary outcome will be analysed using a mixed effects logistic regression model, accounting for the traditional specialist dental service route or alternative Child-Friendly Dental Practice, with random effects for centre. An adjusted logistic regression analysis additionally accounting for the age, deprivation, ethnicity, sex of the child along with the number of teeth requiring treatment at initial examination (through the CFDP or CDS) will also be undertaken. The analysis dataset will include all participants for whom there is follow-up data from the NHS BSA and the baseline covariates.

Analysis of secondary outcomes will be undertaken in a similar manner using covariate adjusted linear or logistic regression models as appropriate, we will include the modifying effect of deprivation

The health economics analysis will adopt a cost-consequences approach whereby the costs of each pathway will be presented separately but alongside relevant outcomes: 1) dental extractions under GA, 2) count of children who are successfully seen and treated in each pathway, 3) count of treatments performed (extractions, restorations), 4) mean wait time and 5) dental pain experienced by a child. Resource use and costs from the CFPD pathway will also be used in a budget impact analysis. Differences in outcomes will be generated from the quantitative analysis.

The analysis will take an NHS perspective with a 2 year time horizon. Longer term costs and outcomes will not be modelled due to the need for treatment being acute and focusing on child (non-permanent) teeth. This approach will provide dental service commissioners with appropriate health economic data to inform future commissioning decisions related to CFDP. For qualitative data, deductive analysis will be used throughout to complement and enhance other data sources.

Overall the evaluation of Child Friendly Dental Practices will utilise a realist approach (24). This will not only allow the evaluation to determine the impact of the scheme on patients and access to services but will allow us to determine ‘what works, for whom, and in what circumstances’. A logic model has been developed based on the initial pilot data, this model will be tested using a mixed methods design using Context Mechanism Outcome configuration. The realist approach therefore will allow us to understand what the linkages are between these different components. The realist approach focuses on the mechanisms which operate in real time along the treatment and referral pathway. The mechanisms reveal the way things really happen, rather than what practitioners, researchers, funders, assume or think happens.
Given the complexity of the evaluation and range of perspectives the study aims to capture; a parallel mixed methods study will be undertaken.

XI: Patient and Public Involvement and Engagement (PPI/E)

From a purely practical perspective, ensuring that study recruitment and dissemination activities facilitate the inclusion of diverse groups is essential to ensure the generalisability of the results, ability to capture impacts on social inequalities, and maximise the impact of the research. More universal objectives of patient and public involvement and engagement activities include raising awareness and understanding of the research process, breaking down barriers and increasing trust in science, research, and healthcare, increasing the knowledge of participants about the subject matter, developing a shared understanding of the issues and empowering individuals and communities. These broader underpinning goals are implicit in the patient and public

involvement and engagement proposals, with more study specific aims and objectives detailed below.

Aim

The aim of the patient and public involvement in this research is to ensure that the study findings will be relevant to the users of this pathway

Objectives

1. To develop communication materials that are clear, understandable, and accessible
2. To design study procedures that promote equality, diversity, and inclusion in research
3. To capture outcomes that reflect the concerns of families going through this pathway
4. To bring patient and public perspectives to the interpretation of the study findings

PPI roles within the study:

PPI lead (DM)

The PPI/E lead is a budgeted member of the research team who has responsibility for the delivery of the study and access to the relevant institutional support, e.g., HR services, budgets, training. The PPI/ E lead will lead the development of the PPI/E strategy, planning and co-ordinating events and activities, recruiting PPI contributors and ensuring adequate training and support, be the main point of contact for PPI/E, will lead the writing up of the impact and outcomes of PPI/E in the study.

Lay co-applicant (EL)

The lay co-applicant is an experienced public contributor who will provide ongoing input into the conduct of the study, design of patient facing materials, interpretation of results and planning of dissemination activities through the quarterly operational management group meetings and associated communications.

In addition, the lay co-applicant may be involved in co-researcher activities. Any involvement will be agreed in advance and will take account of the skills and experience of the lay co-applicant, identified training needs, and areas that they would like to gain further skills and experience in. A University of Manchester honorary contract and training appropriate to any co-researcher activities will be arranged. Example co-researcher activities include:

a) Assisting with the running of any one-off PPI/E activities

b) Acting as a mentor / buddy for PPI panel members

c) Co-chairing PPI panel meetings

d) Contributing to the evaluation of PPI/E during the study

e) Contributing to the development of the qualitative interview topic guide

f) Contributing to the qualitative analysis

PPI panel

We plan to establish a PPI panel which may consist of the PPI co-applicant and three or four other public contributors who have experience of going through the CFDP pathway or the standard paediatric pathway. The PPI panel is intended to open up opportunities for

involvement in research to relatively inexperienced public contributors, with a view to increasing equality, diversity, and inclusion in research.

The PPI panel will meet around twice a year, or as required, to provide feedback on participant recruitment, patient facing materials, interpretation of study findings, dissemination materials, and dissemination channels. Once recruited, the panel could meet online or respond to requests for feedback via email if appropriate. However, it is recognised that to maximise inclusion, a more flexible approach may be required which may include one-off feedback activities hosted at a dental practice or other suitable venue. The exact format for PPI panel input will be agreed and developed with the panel members.

Funding

PPI contributors will be re-imbursed for their time as NIHR INVOLVE recommended rates.

NIHR guidance will be followed and contacts for further advice will be shared regarding the potential impact of any remuneration on welfare benefits.

Evaluation

Evaluation of the PPI/E elements within the study will include both and impact evaluation.

Process will be evaluated using an activity-specific evaluation tool, for example, the Public and Patient Engagement Evaluation Tool (PPET V2) developed by McMaster University: https://ppe.mcmaster.ca/resources/public-and-patient-engagement-evaluation-tool/

This type of evaluation is useful to capture PPI feedback on specific activities, for example, how well contributors felt they could communicate ideas, if they were listened to, and how easy it was to join the session etc.

Overall outcomes and impact of PPI/E on the study will be evaluated and reporting using the GRIPP2 tool: https://www.bmj.com/content/bmj/358/bmj.j3453.full.pdf

XII: Dissemination / knowledge transfer

A full stakeholder engagement plan outlining the range of stakeholders to be engaged with and the most appropriate methods to do so, will be developed iteratively by the Operational Management Groups.

Patient / public focused dissemination:

We will produce plain-language summaries, an infographic and a PPI-inspired animated video. The development of the non-academic dissemination products will be led by the PPI members of the study team. We will seek input and feedback on the products from key stakeholder representatives during their development.

Professional / academic stakeholder focused dissemination:

We will issue press releases coordinated with the CDO's office and the Office for Health Improvement and disparities (OHID) as well as holding webinars for the UK public health community, promoted via links with the Faculty of Public Health and NIHR. We will distribute the briefing materials, infographic and animated video through NHS England regional offices for distribution to their individual dental and medical contract holders via newsletters, meeting notes

or webpages. We will also share our dissemination products through social media channels that are context-sensitive and relevant for that particular target group, for example, the British Association for the Study of Community Dentistry (BASCD), or the popular members-only Facebook group “For Dentists, By Dentists”, which has 14,000 General Dental Council registered members.

The results will be published in a high-impact journal and will be presented nationally for example, at conferences held by the Faculty of Public Health and the British Association for the Study of Community Dentistry,

PEER REVIEW

This research study has been reviewed bas part of the funding process from NIHR HSDR

Risks

The burden on participants is incredibly low. They are being asked to consent to the study team to access their records in relation to their dental health/treatment and to complete short text message survey (which they will be compensated for - £10 voucher). The text message survey has been chosen to be easy and quick to respond to.

The potential risk is access to their dental records/data. This will be minimised by keeping the data in the UoM Data Safe Haven, developed to keep NHS data safe and according to NHS data requirements.

STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

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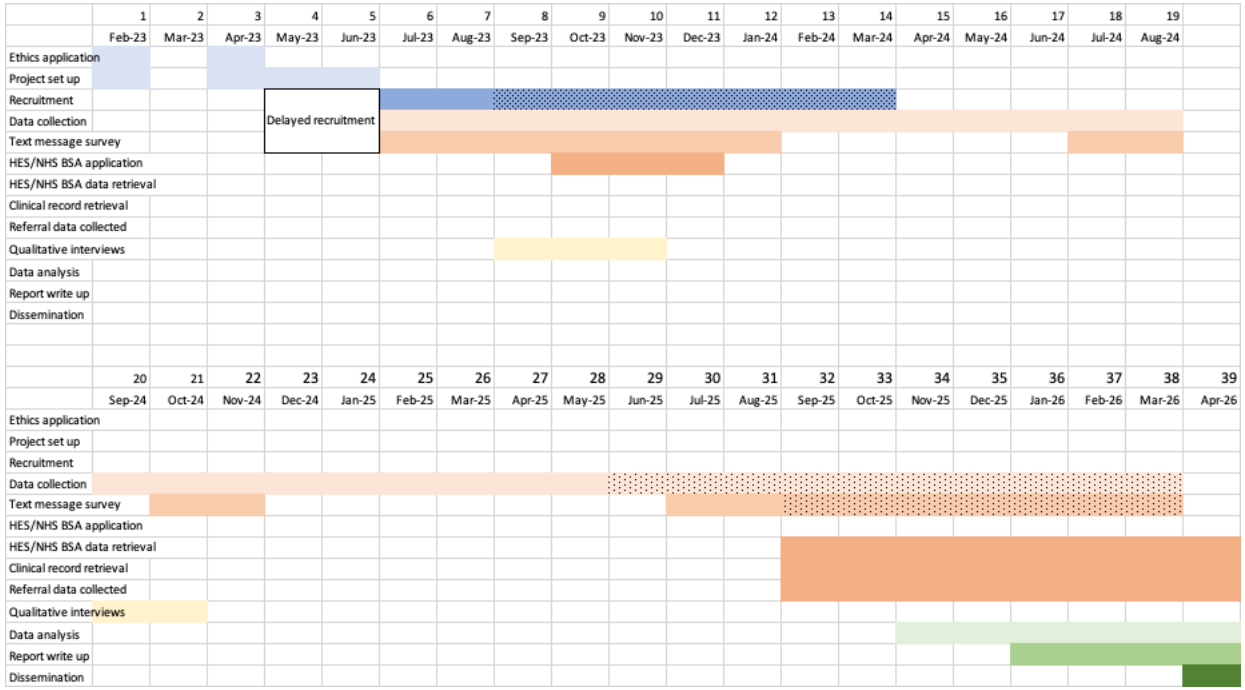
Appendix A – Gantt Chart



APPENDIX B – Data collection

Data collected through CDS

ID	Contract Number	Provider Name	Locality	Month of Submission to Dental Comm Team	Practice patient code	Pt Age (in years)	Patient Postcode	URN	Referring Practice Name	Referring GDP Name	Referring Practice Postcode	Number of courses of Antibiotics whilst waiting?

Date of Referral	Appt made? (Yes / No)	Reason no appt (Please select from the drop down)	Number of appts attended	Number of appts WNB	Bitewings taken?	Date of Initial Appointment	Number of decayed teeth needing treatment *at CDS	Outcome (please select from drop down)

Treatment Provided								Notes	Who carried out treatment	Previously seen at CFDP or other services after referral	GM central emergency system (Out of hours) Y/N
Number of Filling(s)	Number of Extraction(s)	Number of Stainless Steel Crowns (SSCs)	Number of Temp Fillings	Fluoride Varnish Application (Y/N)	Silver Diamine Fluoride (SDF) (Y/N)	Oral Health Improvement Advice Given (Y/N)	Antibiotics (Yes / No)				

Data collected through CFDP

ID	Contract Number	Provider Name	Locality	Month of Submission to Dental Comm Team	Practice patient code	Pt Age (in years)	Patient Postcode	URN	Referring Practice Name	Referring GDP Name	Referring Practice Postcode

Number of courses of Antibiotics whilst waiting?	Date of Referral	Appt made? (Yes / No)	Reason no appt (Please select from the drop down)	Date of Initial Appointment	Number of appts attended	Number of appts WNB	Bitewings taken?	Number of decayed teeth needing treatment
			Cannot contact					

Treatment Provided								Outcome (please select from drop down)	Notes	Who carried out treatment	GM central emergency system (Out of hours) Y/N	Patie
Number of Filling(s)	Number of Extraction(s)	Number of Stainless Steel Crowns (SSCs)	Number of Temp Fillings	Fluoride Varnish Application (Y/N)	Silver Diamine Fluoride (SDF) (Y/N)	Oral Health Improvement Advice Given (Y/N)	Antibiotics (Yes / No)					

NHS BSA data headings

Link	Flagged (linked or not linked data set 0 = not linked, 1 = linked)
PANDA_ID	PANDA ID (include if linked)
PATIENT_ID	Patient ID (random number generated by NHS BSA for each patient)
Age of Pt at every CoT	age of Pt at every CoT (will need to use DOB and treatment date)
GENDER	Gender
PT_LSOA	Lower Super Output Area of patient's home address at time of treatment

IMD	UoM will supply this as a post-code lookup. IMD against NEPU 2019 scores an
IMD rank	
Patient_charge_due	Patient charge due (££) for ever CoT
Patient_charge_ collected	Patient charge actually collected (i.e. if they did not complete the course of treatment - are there outstanding payments owed? = remittance)
TX_COMPLETE	Is the treatment complete or incomplete? NO=0, Y=1
TX_DAYS	Interval in days between date of acceptance and date of completion or last visit
YEAR_MONTH	Date of when the form was submitted
TREATMENT_DATE	date of treatment
TREATMENT_CHARGE_BAND	treatment charge band
CONTRACT_TYPE	Type of contract (we are requesting information on: GDS / GDS and / PDS - no ortho needed).
12_MONTH_LIST	ND looking into this = Number of unique patients seen in previous 12 months (contract level)
24_MONTH_LIST	ND looking into this - Number of unique patients seen in previous 24 months (contract level)
PRACTICE_LSOA	Lower super output area of dental practice address
PRACTICE_CCG	Clinical commissioning group of dental practice address
PRACTICE_CCG_POPULATION_PER_DENTIST	Population per dentist of practice Clinical Commissioning Group
CONTRACT_UDAs	Annual number of contracted UDAs
CONTRACT_UDA_VAL	UDA Value (price per UDA)
CONTRACT_RADS_PER_100	Radiographs rate per 100 FP17s for contract (unless this is available by performer?)
CONTRACT_REATTEND	Average Re-attendance interval (days) on contract. I.e. number of days between courses of treatment completion and start of new course of treatment
FORM_ID	Is this just each treatment line - if so keep in
FOUNDATION_DENTIST	foundation dentist
AGE_LAST_3103	Dentists age. Age at that CoT (Age at march of that year - preceding treatment)
PERFORMER_NUMBER	NHS BSA to TRANSFORM into another numeric value to allow us to still identify the same performers within the dataset but not linkable to any real-world information
PERFORMER_PROVIDER	Is the performer also a provider (i.e. contract holder)? N=0, Y=1
PERFORMER_DATE_REGISTERED	Date of performer entry to General Dental Council register

PERFORMER_BDS_PLACE	Place of performer BDS qualification (from GDC / NHS Performers list)
PERFORMER_GENDER	
ADV_MAN_SERV	
ADV_MAN_SERV_COUNT1	YES "referral for advanced mandatory service"
ANTIBIOTICS	
ANTIBIOTICS_COUNT	
BEST_PRACTICE_COUNT	
CROWNS	
CROWNS_COUNT	
DECAYED_PERM	This is part of the DMFT index number of decayed teeth.
DECAYED_PERM_COUNT	This is part of the DMFT index f they completed the Decayed component. 0=N and 1=Y
ENDODONTIC_TREATMENT	
ENDODONTIC_TREATMENT_COUNT	
EXEMINATION_COUNT	
EXTRACT_ORTHO_COUNT	
FILLED_PERM	Number of filled permanent teeth (in DMFT component). This is part of the DMFT index
FILLED_PERM_COUNT	If the Filled component was completed or not. N=0, 1=Y. This is part of the DMFT index
FISSURE_SEALMENTS	
FISSURE_SEALMENTS_COUNT	
FLOURIDE_VARNISH_COUNT	
INLAYS	
INLAYS_COUNT	
MISSING_PERM	Number of missing permanent teeth . This is part of the DMFT index
MISSING_PERM_COUNT	if the M component was completed or not (0=N, 1 =Y). This is part of the DMFT index
RADIOGRAPHS	Number of radiographs taken (will only be from 2015 as not in legacy data)
RADIOGRAPHS_COUNT	If rads were taken or not (N=0, Y=1)
SCALE_POLISH_COUNT	
EXTRACTIONS_COUNT	If extractions were carried out

EXTRACTIONS	How many extractions
PERM_FILL_COUNT	If fillings were carried out. 0=NO, 1-Y
PERM_FILL	Number of permanent fillings and / or sealant restorations provided
RECALL_COUNT	Was a recall interval completed? Y=1, N=0
RECALL_INTERVAL	What is the recall interval? (3,6,12,18,24 months)
LAST_TREATMENT_DATE	This is date of last CoT
NUM_PERFORMERS	Total number of unique performers that the patient has seen over the 10 years. (Will be the same number in each row)
NUM_PRACTICES	Total number of different practice addresses the patient has attended over th 10 years.
DECAYED_deciduous	Decayed deciduous. This is part of the dmft index number of decayed teeth.
DECAYED_deciduous_COUNT	This is part of the dmt index f they completed the Decayed (deciduous) compenent. 0=N and 1=Y
FILLED_deciduous	Number of filled deciduous teeth (in dmft component). Double check this isn't fillings carried out. This is part of the DMFT index
FILLED_deciduous_COUNT	If the Filled (deciduous) component was complet dmfted or not. N=0, 1=Y. This is part of the DMFT index
MISSING_deciduous	Number of missing deciduous teeth . This is part of the dmft index
MISSING_deciduous_COUNT	if the M (deciduous) component was completed or not (0=N, 1 =Y). This is part of the dmft index
Sedation	Sedation
Treatment on referral	Treatment on referral
Further treatment within 2 months –	Further treatment within 2 months –

HES NHS digital CDS data

Link using DOB Name, URN NHS number	PANDA ID	dental GA (yes no)	Date of referral for DGA	Date of dental GA (if occurred)

Referral form data

Patient complaint	free text

Reason for urgent care	free text
Indicate if following is requested (GA)	GA no GA
Previous dental history	free text
Main reason for referral	tick box
Teeth requested for treatment within referral	dental chart
Complexity score	tick box
Reason for referral	free text
Medical behaviour indicators	tick box
Patient anxiety question	5 questions on likert scale
radiograph included	yes no
Date of referral	date

Text message survey

	Text message Question	**Potential response**
1	Does your child have any pain in his/her mouth/teeth at the moment? Please reply: yes or no.	"Yes" / "No"
1a	If yes, how would he/she rate this pain from 1 (not too painful) to 10 (most painful pain ever)?	"1-10"
2	Has your child received any antibiotics for a dental problem recently for example, in the last year?	"Yes" / "No" / "Can't remember"
2a	If yes, do you remember how many days he/she was given and for how long did he/she take them? Just type your answer below.	Open text
3	In the last 3 months, has your child had any of the following problems: pain, difficult sleeping, problems eating/drinking?	"pain" / "sleeping" / "eating/drinking"
4	Overall, how was your experience of the service you attended for your child's dental treatment. Please reply: very good, good, neither good nor poor, poor, very poor?	"very good"/ "good"/ "neither"/ "poor"/ "very poor"
5	Did you feel the service your child attended for their dental treatment was appropriate for your child? Please reply: yes definitely, yes to some extent, no	"yes definitely"/ "yes" / "no"
6	Would you recommend the service to family and friends? Please reply: yes, no, not sure	"Yes" / "No" / "Not sure"