FiCTION 07/44/03: HEAP (and associated documents)

COURSE OF TREATMENT DEFINITION (see *Section 4.2.2)*

A course of treatment as defined Standard General Dental Services Contract (2013) states:

(a) "subject to paragraph (c), an examination of a patient, an assessment of his oral health, and the planning of any treatment to be provided to that patient as a result of that examination and assessment,
(b) the provision of any planned treatment (including any treatment planned at a time other than the time of the initial examination) to that patient, and
(c) but where the course of treatment is an interim care course of treatment provided under a Capitation and Quality Scheme 2 Agreement in the context of regulation 13A of the NHS Charges Regulations, it does not include the treatment mentioned in paragraph (a).

provided by, except where expressly provided otherwise, one or more providers of primary dental services, but it does not include the provision of any *orthodontic services* or *dental public health services.*"[1]

So if a child has a number of visits for one treatment, e.g. 3 fillings for dental decay were identified at an initial examination but were provided at subsequent visit(s), additional UDAs were not provided for the additional visits. Thus, the reimbursement mechanism for England and Wales provides a potential incentive for under treatment.

Initially, we assumed, based on clinical advice and current regulations that a new course of treatment would be defined as:

a) Any visit after 90 days[a] (supported by the Dental Assurance Framework)[2]

While this assumption would be sensible when treating adults for the management of children the following issues were considered for the economic analysis;

a) Children could come back for a completely new course of treatment (potentially due to a newly apparent problem), or
b) The same treatment/pain that would be classified as one course of treatment but the practice may have "closed" their course of treatment even if it was not complete as they were not back within a specific timeframe or for other reasons and start their treatment as a new course of treatment.

As a result, this led to the following assumptions for defining a course of treatment:

a) All visits after 60 days[b] were defined as a new course of treatment. This is supported by the guidance in the Dental Contract Management Handbook [3] where practices are discouraged from making potentially inappropriate new Band 1/2/3 claims within 2 months of a previous claim.
b) Visits between 1 and 28 days were still be regarded as 1 course of treatment regardless of pain, treatment etc. as we could assume it is was related to the original problem. The 28 Day Re-attendance Review strongly discouraged new Band 1/2/3 claims within 28 days.[4]
c) Visits between 29 days and 60 days would be a new course of treatment if the child had an emergency visit.
d) Visits between 29 days and 60 days were a new course of treatment if the child had experienced pain and had operative treatment. This is based upon the assumption that most of these cases were probably not delivering care within an open treatment plan, despite the research paperwork completed by the dentist.

[a] 30 days = 1 month
[b] 30 days = 1 month

Assumption (d) at present leads to a slight overestimate of UDAs, but removing this assumption would lead to an underestimate. The assumptions were explored in sensitivity analyses to see what affect, if any, they had on overall results. Figure A is an illustrative presentation of the course of treatment pathway.

References

1. Standard General Dental Services Contract. 2013, Department of Health: https://www.gov.uk/government/publications/standard-general-dental-services-contract-and-personal-dental-services-agreement.
2. NHS England. Dental Assurance Framework. Policy & Corporate Procedures. 2014: https://www.england.nhs.uk/wp-content/uploads/2014/05/dental-assurance-frmwrk-may.pdf.
3. Department of Health. Dental Contract Management Handbook. 2010: https://www.pcc-cic.org.uk/sites/default/files/articles/attachments/dental_handbook_2010_version_1_01.pdf.
4. NHS Business Service Authority. Dental Activity Reviews. 28 Day Re-attendance. 2016: http://www.nhsbsa.nhs.uk/DentalServices/5143.aspx.

DEFINING A FILLING (see *Section 4.2.2)*

We had information on the restoration material used but could not determine whether this was done as part of a filling or a sealant (e.g. glass ionomer). We had established that different resources were needed for fillings hence we need to distinguish between the two. The following conservative assumptions were applied to create a dummy variable to indicate whether or not a tooth had been filled.

A filling had been provided if:

- the number of surfaces used > 1 & filling material was used
- complete caries removal was undertaken & filling material was used
- partial caries removal was undertaken & filling material was used
- local anaesthetic was attempted & filling material was used
- if sealant was not provided & filling material was used

While these assumptions were applicable clinically they were insufficient to account for all of the operative treatments recorded as part of FiCTION. As a result we adopted additional assumptions to distinguish between fillings and sealants.

A filling had <u>not</u> been provided if:

- if sealant was indicated on the CRF (note: this assumption over-rides previous assumptions)
- if a crown (conventional/halls) was provided

For those cases that could not be defined with the rules above (<20%) we adopted the following assumptions

- A filling had been undertaken if sealant over restoration was indicated on the CRF
- A filling had not been undertaken if the tooth was extracted
- A filling had not been undertaken if a lesion was opened
- A filling had not been undertaken if all operative treatment information was missing
- A filling had not been undertaken if pulpotomy was undertaken
- A filling had been undertaken if caries removal (partial/complete) was undertaken, local anaesthetic was attempted and the number of surfaces > 1 even if there no information on restoration material – assumed they would dress the tooth with glass ionomer in these instances
- A filling had been undertaken if caries removal (partial/complete) was undertaken and local anaesthetic was attempted but number of surfaces and information on restoration material was missing (n=2) – again we assumed they would dress the tooth with glass ionomer
- A filling was not undertaken if no caries removal was undertaken and no local anaesthetic was attempted

Finally, there were some outliers that still couldn't be defined with the above rules (<1%) that required additional assumptions the data to distinguish between fillings and sealants:

- A filling was not undertaken if no local anaesthetic was attempted
- A filling was no undertaken if there was not caries removal attempted and no filling material was indicated

MICRO-COSTING UNIT COSTS

RESOURCES USED AT EVERY VISIT			
Consumables	**Cost/item**	Source	Date
Disposable gloves	£0.13	https://www.dentalsky.com/medibase-blue-nitrile-powder-freeglovesx100-m-medibase.html	26/04/2017
Disposable mask	£0.08	https://www.dentalsky.com/medibase-masks-earloop-blue-50-medibase.html	26/04/2017
Disposable bibs	£0.11	https://www.dentalsky.com/medibase-disposable-bibs-light-blue-500-medibase.html	26/04/2017
Tissues	£0.01	https://www.dentalsky.com/p-facial-tissues-20x10-cm-72x100-sheets-perfection-plus.html	26/04/2017
Disposable cup	£0.01	https://www.dentalsky.com/medibase-plastic-cups-light-blue-3000-medibase.html	26/04/2017
Mouthwash Tablet	£0.01	https://www.dentalsky.com/pegasus-mouthwash-tablets-green-1000-pegasus.html	26/04/2017
3 in 1 tip	£0.21	https://www.dentalsky.com/sanitip-pack-of-200-std-76mm-no-sanishield-dentsply.html	26/04/2017
Sheath	£0.06	https://www.dentalsky.com/pegasus-surgi-safe-tubing-sleeve-small-pegasus.html	26/04/2017
PREVENTATIVE CARE			
Consumables	**Cost/item**	Source	Date
Disclosing tablets	£0.09	https://www.dentalsky.com/plaqsearch-tablets-20-tepe.html	26/04/2017
Dental floss	£0.02	https://www.dentalsky.com/oral-b-essential-floss-50m.html	26/04/2017
Dental wand	£0.04	https://www.dentalsky.com/wisdom-clean-between-flossers-p-shape-mint-30.html	26/04/2017
Page with instructions	£0.54	http://www.ncl.ac.uk/library/services/print-bind-copy/print-services/printing/#5	05/05/2017
LOCAL ANAESTHESIC			
Consumables	**Cost/item**	Source	Date
Topical anaesthetic gel (e.g Xylonor)	£0.05	https://www.dentalsky.com/xylonorgel-15g-paste-septodont.html	26/04/2017
Disposable Cartridge	£0.48	https://www.medicinescomplete.com/mc/bnf/current/DMD21313511000001103.htm?q=Lignospan%20Special%202%25%20injection%202.2ml%20cartridges%20%28Kent%20Pharmaceuticals%20Ltd%29&t=search&ss=text&tot=1&p=1#DMD21313511000001103	26/04/2017
Cotton wool roll	£0.01	https://www.dentalsky.com/medibase-cotton-rolls-no2-300g-medibase.html	26/04/2017
Needle	£0.08	https://www.dentalsky.com/pegasus-hdent-needles-27g-long-100-pegasus.html	26/04/2017
FLUORIDE VARNISH			
Consumables	**Cost/item**	Source	Date
Micro-brush	£0.06	https://www.dentalsky.com/medibase-applicator-brushes-regular-blue-100-medibase.html	26/04/2017
Varnish	£0.17	https://www.dentalsky.com/duraphat-varnish-colgate.html	26/04/2017
Dappen's dish	£0.03	https://www.dentalsky.com/disposable-dappen-dishes.html	26/04/2017

FISSURE SEALANTS			
Consumables	**Cost/item**	Source	Date
Etch	£0.30	https://www.dentalsky.com/clinixgel-etch-12g-syringe-tips-20-clinix.html	26/04/2017
Aspirator tips	£0.02	https://www.dentalsky.com/orsing-aspirator-tips-white-135cm-100-jh-orsing-ab.html	26/04/2017
Dry tips	£0.43	https://www.dentalsky.com/dry-tips-child-50-molnlycke.html	26/04/2017
Resin	£1.91	https://www.dentalsky.com/clinpro-sealant-sealant-bottle-6ml-3m-espe.html	26/04/2017
Glass ionomer cement capsule	£4.08	https://www.dentalsky.com/ketac-cem-maxicap-50-capsules-3m-espe.html	26/04/2017
Glass ionomer cement powder sachet	£0.17	https://www.dentalsky.com/carboxylate-cement-powder-90g-heraeus-kulzer.html	26/04/2017
Disposable paper mixing pad	£0.02	https://www.dentalsky.com/medibase-mixing-pads-7x8cm-3x100-sheets-medibase.html	26/04/2017
Saliva Ejector	£0.04	https://www.dentalsky.com/medibase-saliva-ejectors-blue-100-medibase.html	26/04/207
FILLINGS			
Consumables	**Cost/item**	Source	Date
Bur	£1.50	https://www.dentalsky.com/rs-steel-burs-round-4-iso-014-6-r-s.html	26/04/2017
Wedge	£0.12	https://www.dentalsky.com/hawe-wedges-assorted-100-kerr.html	26/04/2017
Matrix strip	£0.56	https://www.dentalsky.com/polydentia-matrix-strip-5mm-polydentia.html	26/04/2017
Matrix band	£0.16	https://www.dentalsky.com/eco-matrix-band-narrow-siqveland-12-perfection-plus.html	26/04/2017
Articulating paper	£0.05	https://www.dentalsky.com/bausch-articulating-paper-blue-200-300-bausch.html	26/04/2017
Local anaesthesia cartridge	£0.48	https://www.medicinescomplete.com/mc/bnf/current/DMD21313511000001103.htm?q=Lignospan%20Special%202%25%20injection%202.2ml%20cartridges%20%28Kent%20Pharmaceuticals%20Ltd%29&t=search&ss=text&tot=1&p=1#DMD213135110000001103	26/04/2017
Amalgam capsule	£3.23	https://www.dentalsky.com/grandioso-set-caps-80x025g-voco.html	26/04/2017
Vaseline	£0.00	https://www.amazon.co.uk/Vaseline-Original-Petroleum-Jelly-250ml/dp/B0042280CM/ref=pd_sbs_121_1?_encoding=UTF8&psc=1&refRID=06QSTDFZZMYCJC4289DE	26/04/2017
Bond	£0.60	https://www.dentalsky.com/optibond-solo-plus-refill-5ml-kerr.html	26/04/2017
White filling material (compules)	£2.43	https://www.dentalsky.com/esthetx-hd-compule-refill-20-a1-dentsply.html	26/04/2017
PREFORMED METAL CROWN			
Consumables	**Cost/item**	Source	Date
Spacers	£0.02	https://www.dentalsky.com/loose-radiopaque-separators-dentsply-gac.html	26/04/2017
Preformed crown	£5.67		04/08/2017

Gauze	£0.02	https://www.dentalsky.com/gauze-napkins-15x15cm-500-perfection-plus.html	26/04/2017
PULPOTOMY			
Consumables	**Cost/item**	Source	Date
Saline	£5.60	https://www.dentalsky.com/sterile-saline-water-pouches-hygitech.html	26/04/2017
Ferric Sulfate	£0.08	http://www.ebay.co.uk/itm/Dental-Astringedent-Hemostatic-15-5-Ferric-Sulfate-Ultradent-Hemostasis-30-ml-/330981429046	07/08/2017
Cotton wool wedget	£0.03	https://www.dentalsky.com/steriblue-cotton-pellets-size-1-1000-steriblue.html	26/04/2017
AUTOCLAVING			
Consumables	**Cost/item**	Source	Date
Washing detergent	£0.12	https://www.dentalsky.com/thermodent-alka-clean-5-litres-schulke.html	26/04/2017
Storage bags	£0.04	https://www.dentalsky.com/medibase-sterilisation-pouches-90x130mm-200-medibase.html	17/07/2017
Bags used in the autoclave	£0.38	https://www.fishersci.co.uk/shop/products/polypropylene-clear-autoclave-bags/p-8000601	17/07/2017
SALARIES			
Job Description	**cost/min**	Source	Date
GDP - NHS dentist (provider only)	£0.68	PSSRU - 2016: provider only dentist	17/07/2017
Dental Therapist	£0.28	Band 5 point 20 - used starting band midpoint	05/05/2017
Dental Hygienist	£0.28	Band 5 point 20	05/05/2017
Oral Health Educator	£0.28	Band 5 point 20	05/05/2017
Childsmile/Extended duty dental nurse	£0.23	Band 4 point 14	05/05/2017
Vocational Therapist	£0.23	**assume band 4** midpoint	05/05/2017
Dental nurse	£0.21	Band 4 point 1	06/05/2017
CT1	£0.35	Band 6 point 6/ Band 7 point 1	07/08/2017
Dental nurse trainee	£0.16	75% of Band 4 point 1	07/08/2017

RESOURCES FOR OPERATIVE TREATMENTS

Materials and instruments – used for fillings
Standard Kit (common to every filling material)
Conservation (Cons) kit (reusable)
Cotton wool rolls (single use)
high speed drill (reusable)
slow speed drill (reusable)
aspirator (reusable)
aspirator tip (single use)
2 x burs (single use)
If 2 or more surfaces involved
wedge (single use)
matrix band (single use)
matrix strip
If occlusal surface implicated
articulating paper (single use)
amalgam
Amalgam capsule (single use)
Dappen's dish (single use)
Amalgam carrier (reusable)
Amalgam Capsule Mixing Machine Tool Mixer (reusable)
glass ionomer
glass ionomer cement (single use product but multiple mixes from one bottle)
Composite
Bond (single use material but many X ml amounts from one bottle)
Dappen's dish (single use)
Microbrush (x2)
Composite gun (reusable)
Curing light (reusable)
white filling material (compules) (single use)
Compomer
same as composite
Resin modified GI
same as glass ionomer
curing light (assume included)

ASSUMED RESOURCES FOR EACH TREATMENT

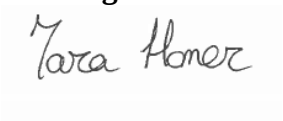
Resources used at every visits
Gloves (GDP & nurse)
Masks (GDP, nurse, & child)
Bib (child)
Tissues
Disposable cup (water)
Tablet (water)
3 in 1 tip
Sheath
Mirror
Probe

FiCTION
Fillings in Children's Teeth; Indicated Or Not

FiCTION Health Economics Analysis Plan

August 2017

Version 2.0

Author	Signature	Date
Tara Homer Health Economist		04/08/2017
Reviewed by:	**Signature**	**Date**
Professor Luke Vale Health Economist		04/08/2017
Professor Jan Clarkson Chief Investigator		25/08/2017

Newcastle University

Table of Contents

1. Brief summary of the study - protocol

Filling **C**hildren's **T**eeth: **I**ndicated **O**r **N**ot? (FiCTION) is a NIHR HTA programme funded multi-centre three-arm parallel group patient-randomised controlled trial (RCT). The aim of FiCTION is to determine the clinical and cost-effectiveness of three treatment strategies for the management of dental decay in primary teeth. In the first instance the clinical and cost-effectiveness of a conventional filling-based strategy will be compared to best practice prevention alone. In addition, an intermediate treatment strategy based on the biological management of dental decay will be compared with best practice prevention. Both conventional and biological management strategies will also include, as part of the trial protocol, best practice prevention but will be referred to as "conventional" and "biological" throughout the HEAP.

At present, teaching in UK dental schools is based on guidance from the British Society of Paediatric Dentistry (BSPD) which includes the recommendation that the optimum treatment of decay in primary teeth should be the removal of decay, followed by the placement of a conventional filling to replace lost tooth tissue.[1, 2] However, these recommendations are largely based on evidence obtained from studies on the effectiveness of fillings conducted in either a secondary care or specialist paediatric dental practice setting. It is the generalisability of this evidence to a primary care setting that is in question and, in particular, the barriers (e.g. time) to providing fillings of sufficient quality to prevent pain and sepsis. In addition, this lack of evidence for the effective management of dental decay in children's primary teeth causes considerable uncertainty for the dental profession and participants. A Cochrane review [3] found that emerging biologically-orientated strategies for managing decay are effective. In addition, a "biological" method of managing primary teeth by sealing in the decay with preformed metal crowns has been found to be both effective at preventing pain and sepsis, and acceptable to children, parents and general dental practitioners.[4] The primary clinical objective of FiCTION is to compare three treatment strategies, conventional management with best practice prevention, biological management with best practice prevention and best practice prevention alone in children aged 3-7 years (at inception) with decay in primary teeth. Originally it was anticipated that all children would be followed up for three years however due to an extension in the recruitment phase those recruited after May 2014 now have a variable follow-up. The co-primary outcomes are:

- the proportion of children with at least one episode of pain due to caries and/or dental sepsis during the follow up period (incidence), and
- the total number of episodes of pain due to caries and/or dental sepsis for each child during the follow-up period (as defined in the SAP (V1.0) Section 9.1.1

As defined in the SAP (V1.0) Section 9.1.2 the primary outcome measure is a binary indicator of pain due to caries and/or dental sepsis at each treatment visit during the follow-up period (minimum of 23 months to a maximum of 36 months). Treatment visits are scheduled appointments and unscheduled/emergency appointments.

- Pain due to caries is defined on the CRF by a yes to question 7 and yes to question 7a (caries)
- Dental sepsis is defined as confirmed infection on the CRF by yes to question 8

For the final report we will consider reporting the primary outcome differently, such as dental pain and/or dental sepsis, to be consistent with the statistical team. However, for the purpose of the HEAP we are reporting the primary outcome as it is reported in the SAP (V1.0) to ensure consistency between the two documents.

The primary economic objective of FiCTION is to determine the relative cost-effectiveness of these three management strategies for treating dental decay in primary teeth over the follow-up period (minimum of 23 months to a maximum of 36 months) with respect to the clinical outcomes of pain due to caries and/or dental sepsis.

Recruitment began on 1st October 2012 and was anticipated to continue until 30th June 2013, with follow-up finishing on 30th June 2016. An extension was granted to the trial, which extended recruitment until June 2015 but reduced the duration of follow-up for participants recruited during the later stages of trial recruitment. The target recruitment was 1113 randomised children, which was exceeded as 1124 children were randomised to FiCTION. The contract variation request submitted to HTA is described in further detail in the SAP (V1.0) Section 1.3.2. It is anticipated that approximately 153[3] participants[4] will therefore have their outcome data censored before the completion of the pre-planned three year follow-up. The issues relating to differential follow-up period for some participants and subsequent missing data will be addressed later in the analysis plan.

2. Outline of the economic analysis

The key objective of the health economic analysis plan is to outline the economic evaluation that will be performed as part of the FiCTION trial. This economic evaluation will include a within trial cost-effectiveness analysis and a number of sub-group analyses. All analyses will estimate the incremental cost per incidence of pain due to caries and/or dental sepsis avoided and the incremental cost per episode of pain due to caries and/or dental sepsis avoided in an

[3] Figures taken from Trial Manager Update 7.2.17

[4] Recruitment continued until June ‘15 but because of a data lock on May 31st 2017 to allow for data cleaning and analysis only those recruited by May ’14 will have a three year follow-up. All participants recruited after this time will have a variable follow-up in our analyses.

analysis that order the management strategies in terms of incremental cost and then compare a more costly strategy with a less costly strategy in terms of incremental cost-effectiveness.
To allow a full understanding of cost-effectiveness and add value to the analysis, two different ways of measuring incremental costs will be compared; time/material-based costs (micro-costing) and the current charges to the NHS for treating children with dental decay in primary teeth in Scotland, England and Wales. This is because the payment systems differ for these areas with fee-for-service (FFS) arrangement used in Scotland and the agreed unit of dental activity (UDA) used in England/Wales. Both costing measures are explained in further detail later in the analysis plan (Sections 3.3 and 3.4). The primary analysis will use costs estimated using micro-costing. Costs based on UDA and FFS will be used in sensitivity analyses.
The perspective of the trial is that of the UK National Health Service (NHS) and in further analysis, a wider societal perspective accounting for parents' time and out-of-pocket expenses incorporated. The primary costs are dental service utilisation costs, i.e. the total average cost to the NHS for treating a child with dental decay in primary teeth. Scenario analysis will take a broader perspective, in which individual child/parent costs are also considered. These include direct (e.g. childcare, pain medication) and indirect (e.g. time off paid work) costs.
For the cost-effectiveness analysis the following outcomes will be reported:

- NHS costs of treating dental decay
- Costs to parents with children who have dental decay
- Incidence of pain due to caries and/or dental sepsis avoided (defined in the SAP (V1.0) Section 9.1.1)
- Episodes of pain due to caries and/or dental sepsis avoided (defined in the SAP (1.0) Section 9.1.3)

3. Within trial analysis

Using the effectiveness and cost data derived from the trial allows us to estimate the cost-effectiveness of different treatments for dental decay in primary teeth over the follow-up period (minimum of 23 months to a maximum of 36 months). It is important to note that the economic analysis will be an intention-to-treat (ITT) analysis. The ITT analysis will adopt the same assumptions as the statistical ITT analysis as defined in the SAP (V1.0) Section 1.4.

Table 3.0 Analysis sets (as per statistical analysis)

Analysis set	n	Definition:
All randomised		All randomised children, retaining participants in their randomised treatment groups.
Intention-to-treat (ITT)		All randomised children with at least one CRF in MACRO [i.e. at least one clinical assessment of the primary outcome], retaining participants in their randomised treatment groups. Primary outcome data is from completed CRFs
Imputed ITT		The same participants as in the ITT analysis set, but with the addition of an imputed measure of pain for participants where there is an 18m or final visit adult non-attendance questionnaire. Primary outcome data is from completed CRFs and completed adult non-attendance questionnaires. This analysis will only be carried out if ≥ 80% of non-attendance questionnaires are completed and returned.
Per protocol (PP)		The per protocol analysis set will exclude participants from the ITT analysis set who were: • deemed likely to have had dental pain and/or dental sepsis at consent • 'non-compliant' with the operative treatment protocol of their randomised treatment arm (i.e. defined as having a TDF involving a 'major' deviation from the randomised treatment arm operative treatment protocol at every study visit).

*taken from the SAP (V1.0) Section 1.4 Table 1.

3.1 Structure of the within trial analysis

As described briefly above and in more detail elsewhere [5] three treatments options are being analysed within FiCTION:

C = Conventional management of decay with best practice prevention (Usual dental care)

The conventional management of decay is commonly known as the "drill and fill" method. In this method teeth are numbed with local anaesthetic, dental decay is then mechanically removed using rotary instruments or by hand excavation and a restoration is placed in the

tooth to fill the cavity. Best practice prevention is carried out in line with current guidelines [6-8].

B = Biological management of decay with best practice prevention

The biological management involves sealing the decay from the oral cavity by application of an adhesive filling material, or by covering with a metal crown. Decay may, on occasion, be partially removed prior to the tooth being sealed. Best practice prevention is carried out in line with current guidelines.[6-8]

P = Best practice prevention alone

In the best practice prevention alone arm, no drilling, no filling or sealing of primary teeth occurs. With good oral hygiene it is possible to slow down the rate of tooth decay.[6-8] Dentists and other members of the dental team will base treatment plans for participants on best practice prevention care for teeth and oral health. Best practice prevention will include treatments such as; tooth brushing, dietary investigation, fissure sealants of permanent teeth and fluoride varnish.

A three-arm individually randomised RCT design has been adopted to analyse these three management options. Table 3.1 is an illustrative example of how costs, effects and the incremental cost-effectiveness ratio (ICER) will be presented in our economic evaluation. In the first instance we will estimate the incremental cost per incidence of pain due to caries and/or dental sepsis avoided and the incremental cost per episode of pain due to caries and/or dental sepsis avoided with usual dental care (conventional) as the basecase, as specified in the trial protocol (V5.0).

Table 3.1 Basecase incremental cost-effectiveness results (Biological vs Conventional and Preventative vs Conventional)

Treatment Arm	**Costs**	**Effects**	**ICER**
C. Conventional	C	C	-
B. Biological	B	B	B vs. C
P. Prevention	P	P	P vs. C

*ICER = Incremental cost-effectiveness ratio

In addition we will perform a full incremental analysis comparing all three treatment arms against each other. Mean costs and effects will be calculated for each treatment arm. The mean costs will be ordered in terms of size of costs (Table 3.2) and the difference in costs between a more costly and the next costly option will be calculated. The difference in effects for this comparison will also be calculated if a more costly management strategy is more

effective and an ICER will be calculated. If a more costly intervention is as effective/less effective then the less costly intervention will be judged as being dominant i.e. cost-effective. Dominance occurs when an intervention, or in this instance management strategy, is less costly and at least as effective as its comparators (ideally, one of which is the status quo). In this situation the management strategy would be judged, unequivocally, to be a better use of health care resources. We will identify any potential differences in costs and outcomes between the randomised arms from the presentation of these results and determine the most cost-effective management strategy for treating dental decay in primary teeth.

Table 3.2 Full incremental cost-effectiveness results (three arm comparison)

Treatment Arm	**Costs (£)**	**Effects (episodes)**	**ICER**
i. Most costly treatment arm			iii vs. ii
ii. Second most costly treatment arm			ii vs. i
iii. Least costly treatment arm			

*ICER = Incremental cost-effectiveness ratio

3.2 Costs and frequency of use of services

The question being addressed by the economic evaluation is:

"For children aged 3-7 years diagnosed with dental decay into dentine in one or more primary teeth what is the cost-effectiveness of best practice prevention alone and biological management of decay compared to conventional management of decay?"

The costs collected as part of the cost-effectiveness analyses are based on the use of dental services over the follow-up period (minimum of 23 months to a maximum of 36 months); the use of dental services is recorded in the case report forms (CRFs) for scheduled and unscheduled visits to a general dental practitioner (GDP) and patient referrals[5].

Once participants agree to participate in the study they are randomly allocated into one of three treatment arms. A clinical protocol has been provided for treatment guidance dependent on the randomised arm however as this is a pragmatic trial treatment received may not be consistent with the treatment a participant was randomised to. Nevertheless, each dental treatment received will be costed, all of which are associated with different unit costs. All treatment arms will incur a cost for best practice prevention.

[5] A patient referral is classified as a child referred to a dental hospital/clinic for a consultation and/or operative treatment by their GDP. The team will be notified of patient referrals by a referral letter and the CRF (Q18 and Q19).

The CRF provides information such as the length of the visit, what type of treatment was provided and who provided the treatment. The frequency of dental services resource use at each schedule and unscheduled visit will be calculated for each participant to generate the total average resource use for each treatment arm.

For any participant who is referred from their FiCTION practice for consultation or treatment elsewhere (e.g. to a referral centre or dental hospital) during the follow-up period a Patient Referral Form collects information on the additional treatments received (more detail is provided in Section 3.2.2).

The parent questionnaire completed at baseline, scheduled, and unscheduled appointments will provide information on absence from school, time off paid work to care for a child, any additional paid childcare, non-prescribed (over the counter) pain-killing medication, and any time spent away from usual activities (for the child and parent) due to pain arising from tooth decay. Pain arising from tooth decay will be assumed to be equivalent to dental pain and/or sepsis.

To summarise, data collection on resource use and cost can be split into 3 areas:

- Treatment costs (baseline, scheduled and unscheduled visits) collected via the CRF completed at every visit.
- Patient Referrals collected via the "Patient Referral" form completed on an ad hoc basis.
- Child/Parent costs collected via "About your child's teeth" questionnaire completed at scheduled and unscheduled visits.

3.2.1 Treatment costs

The cost of each treatment is based on information provided in the CRF and will be estimated on an individual-participant level (micro-costing) and in sub-group analyses on an aggregate level using UDAs and FFS values.

The CRF will be used to capture any information on treatments which occur during the follow-up period as visits to the practice. The CRF is collecting detailed information on preventative treatments and operative treatments that were performed at each visit and who they were performed by, whether scheduled or unscheduled; the CRF also includes any treatment deviations from the child's allocated treatment. The CRF includes information on the appointment start time and end time; this will allow us to estimate the length of time of each visit for every participant. The length of time estimated for each visit for every participant will be used to estimate the cost of dental personnel who provided treatments at the visit. For each visit a binary question will determine if a radiograph had been taken and this will be costed from routine sources and included in the treatment cost at that visit.

Source of unit cost data

In the basecase analysis unit costs will be based on costs estimated from micro-costing. Micro-costing will involve collating all the unit costs for each consumable item used in providing the dental treatment (see Section 3.3). All information on the resource use for treatments will be collected via the CRF.

In sensitivity analyses standard unit costs will collected from UDAs for England/Wales and FFS in Scotland. UDAs are a generic cost for a package of treatment; the value of the UDA is the same regardless of the number of visits and treatments (e.g. 3 UDAs is the standard reimbursement for a filling – regardless of whether a participant had 1 or 10 fillings). FFS is itemised costing for reimbursement for all dental treatments provided.

3.2.2 Patient Referral costs

Participants who need additional consultations and/or dental treatment[6] could be referred by their GDP for this treatment to a dental hospital/clinic. Data on the dental treatments received will be captured from the information outlined on a referral letters sent to and from the GDP, the CRF and via communication between clinical lead secretaries and practices. The data on treatments received following referral to a dental hospital/clinic will be obtained by a clinical researcher who will use this data to populate a patient referral form. This form will collect information on the type of referral (e.g. consultation only, management of traumatised teeth etc.), type of treatment (e.g. fissure sealants, preventive care etc.) and pain relief (e.g. general anaesthetic). What will not be captured is the number of treatments, length of treatments or who provided the treatment. Therefore, to estimate costs we will generate "packages of care". These "packages of care" will define where the treatment took place, who provided the treatment and how many visits were required for the treatment identified on the patient referral form. The content of these packages will be based on clinical advice. The "packages of care" will be costed using routine sources [9] and the total cost of each treatment package will be estimated based on advice from staff at Newcastle Dental Hospital. It was originally anticipated that we would source this information from a site in Newcastle and Scotland, however, after preliminary research it was agreed that no additional information would be provided from the extra site.

In order to correctly assign the "packages of care", the patient referral form will be reviewed by two dental clinicians to determine what "package of care" is associated with the treatment recorded on the patient referral form. A third dental clinician will then review this decision and provide further input if necessary.

[6] Dental treatment refers to consultations and/or operative treatment including radiographs

3.2.3 Child and Parent costs

Child and parent time and out-of-pocket expenses will be included as a scenario analysis. Out-of-pocket expenses include non-prescribed medications and additional childcare. Time costs include time off school due to a toothache, time off paid work to care for a child with a toothache and time off paid work to attend dental appointments. In our scenario analysis including time costs only parent costs will be considered as children are not economically active. However, children's time has an opportunity cost so we will cost their time as leisure time in a subsequent analysis to determine what effect, if any, this has on overall results.

Source of data

Information on child and parent costs will be collected via the Parent Questionnaire administered at baseline and at all scheduled and unscheduled appointments. The unit costs for time will be based on the Department of Transport and Office of National Statistics (ONS).[10, 11] All medication costs will be sourced from the British National Formulary (BNF).[12] Childcare costs will be sourced from recent UK online reports of current childcare costs.

3.3 Micro-costing

A time-and materials-based costing will be used to estimate the initial treatment costs for each individual participant. Capital costs will not be included in our analysis.

We anticipate using existing data sources, where possible, to estimate the costs for micro-costing. If these costs are not readily available we will contact a selection of practices to source this information.

A spreadsheet has been developed using information collected in the CRF (see sections 3.3.1 and 3.3.2) and clinical advice to determine what consumable and reusable resources would be used to perform each dental treatment. The resources on this spreadsheet will be assigned a unit cost based on available data. For the data we cannot source we will collate the information required and use this to design an itemised data collection tool. This itemised data collection tool will be sent to the selected practices to provide unit cost information for dental treatment. The precise mode of administration is being explored.

3.3.1 Conventional Management of decay and Biological Management of decay

Operative treatment refers to conventional management and biological management of decay. This information is captured by Questions 11, 12, 17, 18, 19, 20 and 21 on the CRF. The information collected includes who provided the treatment (GDP, dental therapist, dental hygienist, oral health educator or childsmile/extended duty dental nurse) as different dental practitioners have different unit costs. A number of consumable and reusable items used in operative treatments are recorded in the CRF, some are applicable to both conventional

management and biological management whereas others are just applicable to one treatment. The CRF provides additional information on the number of surfaces involved; if more than one surface of a tooth is treated this will incur additional costs such as a matrix band.

3.3.2 Best Practice Prevention

Information on the preventive treatment performed is provided in Q10 of the CRF. This includes who provided the treatment, what preventive activities were performed and how much time was spent on those activities. Data collection via the CRF distinguishes between who provided the treatment; a GDP or dental therapist as their unit costs differ. Best practice prevention should be provided at every treatment regardless of randomised allocation as it is a component of each treatment arm.

3.4 Costs to the NHS

Costs to the NHS will be explored as sensitivity analyses. As previously described there are two different payment structures for reimbursing dentists in the UK, UDAs in England and Wales and FFS in Scotland. Costs to the NHS for treating dental decay in primary teeth will be collected from both sources and combined to estimate the total cost to the NHS for treating dental decay in primary teeth. That is care delivered in Scotland will be costed using FFS data and care delivered in England and Wales will be costed using UDA data. The primary objective of FiCTION is *"to compare these three treatment strategies, when applied over a period of three years to 3-7 year old children with caries in primary teeth, with respect to the clinical outcomes of incidence of pain and sepsis*". The focus of the primary outcome and economic analysis is primary teeth hence treated permanent teeth were excluded from the analysis. Sensitivity analysis will look at UDAs and FFS individually and the impact the different fee structures have on the cost-effectiveness of the dental management strategies being explored.

3.4.1 Units of Dental Activity

In England a reimbursement similar to FFS was in play until 2006 when UDAs were introduced. UDAs are a fixed reimbursement GDPs receive for dental work which varies between practices (between £16 and £40 per UDA).[13] We will collect the UDA value from each practice in the study, where possible, and apply their UDA value to the participants they are treating. Imputation methods will be used for practices with no UDA values using the UDA values from similar practices and national UDA values. Sensitivity analyses will address any uncertainty from these assumptions. Under the UDA system dental procedures can be classified into three bands.[14] The main bands are:

Band 1 (1 UDA) This refers to diagnosis, treatment planning and maintenance. This includes examination, x-rays, scale and polish and preventative care.

Band 2 (3 UDAs) This refers to treatment. This includes simple treatments such as fillings, extractions and periodontal treatment.

Band 3 (12 UDAs) This refers to complex treatment that includes a laboratory element. Examples include bridges, crowns and dentures.

It is important to note that the UDA is only reimbursed for one course of treatment. A course of treatment as defined by the Standard General Dental Services Contract (2013) states:

(d) "subject to paragraph (c), an examination of a patient, an assessment of his oral health, and the planning of any treatment to be provided to that patient as a result of that examination and assessment,

(e) the provision of any planned treatment (including any treatment planned at a time other than the time of the initial examination) to that patient, and

(f) but where the course of treatment is an interim care course of treatment provided under a Capitation and Quality Scheme 2 Agreement in the context of regulation 13A of the NHS Charges Regulations, it does not include the treatment mentioned in paragraph (a).

provided by, except where expressly provided otherwise, one or more providers of primary dental services, but it does not include the provision of any *orthodontic services* or *dental public health services.*"[15]

So if a participant has a number of visits for one treatment, e.g. 3 fillings for dental decay were identified at an initial examination but will be provided at subsequent visit(s), additional UDAs are not provided. Thus the reimbursement mechanism for England and Wales provides a potential incentive for under treatment.

Initially, we assumed, based on clinical advice and current regulations that a new course of treatment would be defined as:

b) Any visit after 90 days[7] (supported by the Dental Assurance Framework)[16]

While this assumption would be sensible when treating adults for the management of children the following issues are being considered for the analysis;

c) Children could come back for a completely new course of treatment (potentially due to a newly apparent problem), or

d) The same treatment/pain that would be classified as one course of treatment but the practice may have "closed" their course of treatment even if it was not complete as they were not back within a specific timeframe or for other reasons and start their treatment as a new course of treatment.

[7] 30 days = 1 month

As a result, this has led to the following assumptions for defining a course of treatment:

e) All visits after 60 days[8] will be a new course of treatment. This is supported by the guidance in the Dental Contract Management Handbook [17] where practices are discouraged from making potentially inappropriate new Band 1/2/3 claims within 2 months of a previous claim.

f) Visits between 1 and 28 days would still be regarded as 1 course of treatment regardless of pain, treatment etc. as we could assume it is still related to the original problem. The 28 Day Re-attendance Review strongly discouraged new Band 1/2/3 claims within 28 days.[18]

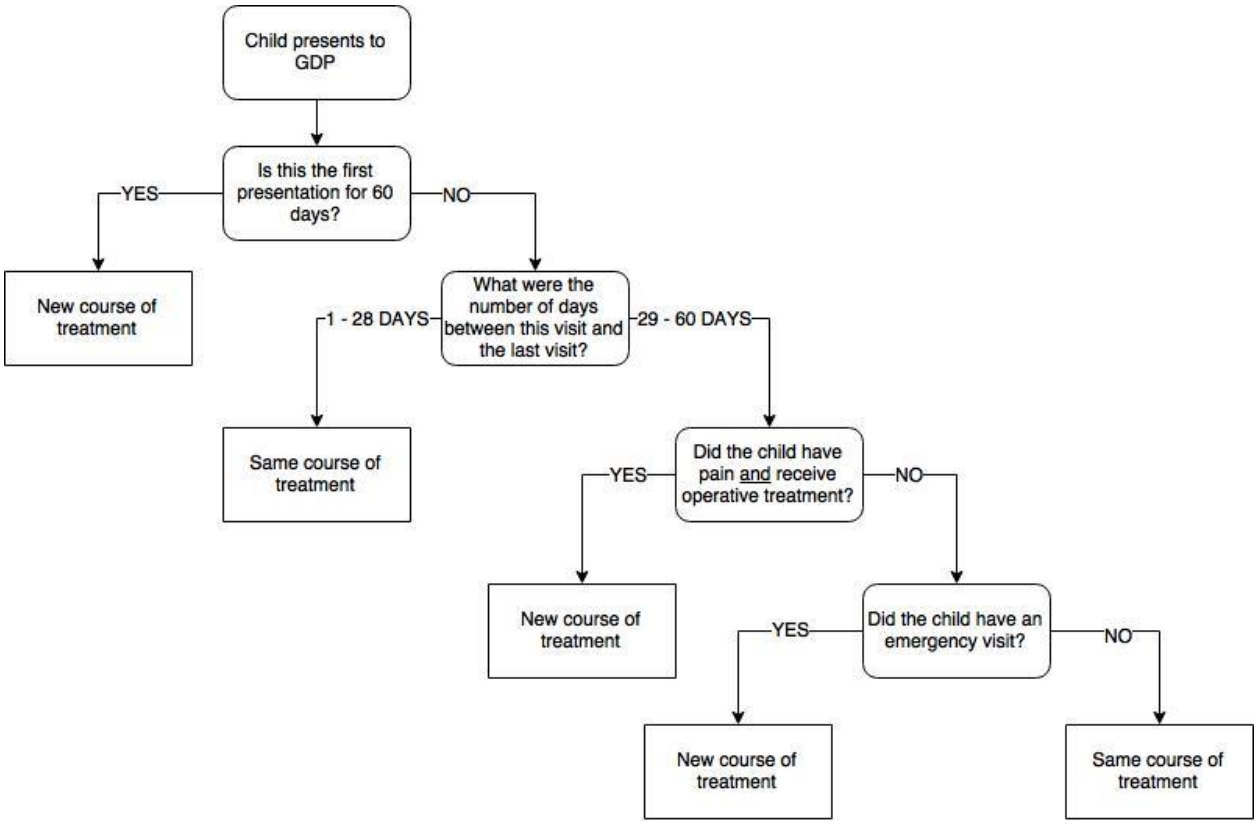
g) Visits between 29 days and 60 days would be a new course of treatment if the child has an emergency visit.

h) Visits between 29 days and 60 days would be a new course of treatment if the child has experienced pain and had operative treatment. This is based upon the assumption that most of these cases were probably not delivering care within an open treatment plan, despite the research paperwork completed by the dentist.

Assumption (d) at present leads to a slight overestimate of UDAs, but deleting them will lead to an underestimate. These assumptions will be removed in a sensitivity analysis to see what affect, if any, they have on overall results. Figure 3.0 is an illustrative presentation of the course of treatment pathway.

[8] 30 days = 1 month

Figure 3.0 Course of Treatment Pathway



With regards to preventative treatment there are other considerations to made when defining a course of treatment because if the GDP is not providing the treatment technically it is not a new course of treatment (this is the guidance but does not always happen in practice) and all FiCTION participants meet the GDP at their visits.

a) Technically there is no time limit for preventative treatment, and this would apply until a dentist next sees the patient but for the purposes of this analysis we are assuming that the 60 day timeframe would apply for preventative treatment and a new course of treatment would only begin if the child has an emergency visits (option d above). We would assume option (e) would not be applicable for preventative treatment as they are randomised not to receive operative treatment.

b) In practice some practices still claim preventative treatment as separate courses of treatment and in the future, depending on the results from the prototype practices that are currently piloting different reimbursement methods in England, these could be claimable as separate courses of treatment. Therefore sensitivity analysis will look at the number of preventative treatments provided, who provided the treatment, and how frequent were these treatments

The UDAs for each course of treatment will be combined into a total number of UDAs delivered for each participant over their follow-up period (minimum of 23 months to a

maximum of 36 months). These costs will be combined to produce a total cost per participant and then will be divided by the number of participants in England and Wales to estimate the average total England/Wales NHS cost for treating dental decay in primary teeth according to treatment arm.

3.4.2 Fee-For-Service

In Scotland, GDPs are reimbursed for every unit of activity they perform; this could create an incentive to over treat participants in relation to funding mechanisms that are not fee for each service provided. This will be explored in sensitivity analysis comparing both funding mechanisms FFS and UDA. Unit costs will be collected from the Statement of Dental Remuneration, Scotland.[19] The costs for treating each participant for each scheduled and unscheduled visit will be used to estimate the average total Scottish NHS cost for treating dental decay in primary teeth.

3.5 Effectiveness Measure

For the economic evaluation a cost-effectiveness analysis will be performed with the number of incidences/episodes of pain due to caries and/or dental sepsis avoided as the primary outcome measure. The analysis will focus on the incremental difference between the three treatment arms and be used to estimate the cost per incidence/episode of pain due to caries and/or dental sepsis avoided. Further details on the methods for deriving this outcome are described in detail in the SAP (V1.0) Section 9.1.

3.6 Discounting

Participants are being followed up for up to three years depending on when they were randomised into FiCTION. As a result, costs and effects will be estimated beyond a one year time horizon and will be discounted at the UK recommended rate of 3.5%.[20]

3.7 Cost-Effectiveness Analysis

An adjusted analyses will be performed to estimate cost-effectiveness. All results will be presented as point estimates of the mean incremental costs, effect and cost per incidence/episode of pain due to caries and/or dental sepsis avoided.

3.7.1 Adjusted Analysis – seemingly unrelated regression (SUR)

An adjusted analysis will be used to estimate the point estimates of the mean incremental costs, effects and cost-effectiveness using seemingly unrelated regression (SUR).[21] SUR permits the simultaneous estimation of costs and effects, calculated at individual level, while accounting for unobserved individual characteristics that could affect both costs and effects and lead to potential correlation between these two variables.[22] In addition the SUR allows us to control for the same covariates as the statistical analysis as reported in the SAP v1.0

(section 9.2.1) (e.g. differences between dental practices, length of follow-up (yrs), age (yrs) and randomised arm). Additional statistical analyses will control for number of decayed teeth, ethnicity, fluoride level, and index of deprivation as defined in the SAP (V1.0) Section 9.2.1.2.) Any additional covariates that may affect costs or effects or both will also be considered for our analysis. The SUR allows us to control for the effect of the truncated follow-up on our outcome measures and estimate the impact this has on our overall cost-effectiveness results.

4. Sensitivity Analysis

Sensitivity analyses will be conducted to assess the robustness of the results to realistic variations in the levels of underlying data. Deterministic sensitivity analysis will be used to address any uncertainty in the assumptions used in our basecase analysis. These analyses will include:

- Costs estimated from UDA and FFS (As described in Sections 3.4.1 and 3.4.2)
- Costs estimated using UDA only (As described in Section 3.4.1)
- Costs estimated using FFS only (As described in Section 3.4.2)

A stochastic sensitivity analysis, using the bootstrapping technique,[23] will explore the impact of the statistical imprecision surrounding estimates of costs, effects and cost-effectiveness. The bootstrapping results will also be used to estimate confidence intervals for both costs and effects. The bootstrapped results from the three-arm comparison will be presented as a cost-effectiveness frontier. The cost-effectiveness frontier allows us to determine the treatment option that maximised net benefits over a range of values for society's willingness-to-pay value for an additional unit of health effect (i.e. a reduction in the number of incidence/episodes of pain due to caries and/or dental sepsis).

4.1. Complete Case Analysis

Given the potential issues with the data due to the truncated follow-up and no routine scheduled follow-up visits a complete case analysis will be performed. The duration of follow-up for the complete case analysis will be decided once we receive the final dataset and will be consistent with the statistical analysis. All participants had the opportunity to have at least 23 months follow-up so the duration of the complete case analysis will be at least 23 months. A longer duration of follow-up will be considered if it is still considered clinically meaningful and the dataset is suitable (i.e. number of participants, distribution of costs and effects across treatment arms etc.). The inclusion of a complete case analysis will allow us to overcome some of the issues regarding missing data described in Section 5.2. It is important to note that this analysis will be underpowered.

5. Issues with the data

When dealing with trial data there are a number of potential issues that will need to be dealt with.

5.1 Ineligible Participants

The economics analysis will mirror the statistical analysis in that any participants excluded from the statistical analysis will be excluded from the economics analysis. There were 1149 randomisations on the randomisation log but only 1124 included in the final dataset due to administration errors where no child was involved (n=5)[9] or those randomised in error (n=20) [10]. Currently, we anticipate, given that it is an ITT analysis, all randomised participants with at least one study visit will be included. There has to be a completed CRF to be considered a study visit as it contains information on the primary outcome. Those participants with no completed CRFs (n=88) will be excluded. Final figures on ineligible participants will be confirmed during the final analysis and will be consistent with the final CONSORT diagram,

5. 2 Potential issues and dealing with missing data

The focus of the missing data analysis will be of data that is missing because the CRF and/or follow-up questionnaires were not fully completed.

There are 3 reasons for variable follow-up in this study:

1. Randomised after 31st May 2014 and hence did not have the opportunity for 3 years follow-up
2. Withdrawals
3. Lost to follow-up (i.e. they didn't attend any further visits)

Currently the statistical analysis is accounting for all three types of variable follow-up in the same way which is appropriate for their co-primary outcome measures; the proportion of children with at least one episode of pain due to caries and/or dental sepsis during the follow-up period (incidence), and the total number of episodes of pain due to caries and/or dental sepsis for each child during the follow-up period. However, this is not an appropriate assumption for estimating costs as each type of variable follow-up has implications for costs. The method of imputation will depend upon the nature and pattern of missingness. As a result we can make the following assumptions to deal with variable follow-up but the imputations cannot be decided upon until we receive our final dataset for analysis:

1. For participants who were recruited after 31st May 2014 they are considered to be missing completely at random as they did not have the opportunity to attend any

[9] Figures taken from Data Monitoring Committee Report May 2016
[10] Figures taken from Data Monitoring Committee Report May 2016

further dental appointments if they experienced dental caries or dental sepsis for the duration of the follow-up period. Hence we will control for their length of time in the study as part of the SUR analysis to estimate the effect of reduced follow-up on our outcomes costs and effects. .

2. For those who have formally withdrawn we will look at why they withdrew to determine whether there is something atypical about these participants compared to those who remained in the study and make assumptions accordingly.
3. Since it is a pragmatic trial with no scheduled follow-up visits we could assume those who had the opportunity to complete their 3 year follow-up but had no further contact (i.e. did not attend their final visit or was not seen for >240days) did not experience dental pain or dental sepsis and hence had no reason to visit the dentist. Therefore we will assume that they incurred no further costs. This could lead to an underestimation of costs/effects but we are assuming that participants are only attending when they have to and that this will be balanced across the three randomised arms. In an extreme sensitivity analysis we will assume these participants' experience severe dental pain/sepsis and had a high resource use as a result. If the number of patients 'lost to follow-up' is balanced across the three arms this should just result in an increase in the total average cost of each arm and not affect the overall cost-effectiveness results.

We will need to know the pattern of missing data before methods of imputation can be chosen. Participants could potentially be matched based on their baseline characteristics and number of episodes of pain at the end of treatment phase. Briggs *et al* [24] have argued that statistical imputations are accurate methods of imputation as they generate more robust standard deviations. An alternative approach for our primary analysis could be to conduct a complete case analysis (see Section 4.1) on all participants. Decisions on dealing with missing data will be made when we have the final dataset.

7. Dummy Tables

Table 1 – Unit costs – Treatments – Micro-costing

Resource	Unit	Cost (£)	Source
Treatment Provider			
GDP	Cost per minute		CRF (Q10a/11a)
Dental Therapist	Cost per minute		CRF (Q10a/11a)
Dental Hygienist	Cost per minute		CRF (Q10a)
Oral health educator	Cost per minute		CRF (Q10a)
Childsmile/Extended duty dental nurse	Cost per minute		CRF (Q10a)
Someone else	Cost per minute		CRF (Q10a)
Prevention care			
Fissure Sealants of permanent teeth*	Cost per tooth		CRF (Q10a)
Fluoride Varnish*	Cost per tooth		CRF (Q10a)
Biological/Conventional treatment			
Caries removal – complete*	Cost per tooth		CRF (Q12)
Caries removal - partial *	Cost per tooth		CRF (Q12)
Restoration – Amalgam*	Cost per tooth		CRF (Q12)
Restoration – Glass ionomer*	Cost per tooth		CRF (Q12)
Restoration – Composite	Cost per tooth		CRF (Q12)
Restoration – Preformed metal crown (conventional) *	Cost per tooth		CRF (Q12)
Restoration – Preformed metal crown (hall technique) *	Cost per tooth		CRF (Q12)
Restoration – Compomer*	Cost per tooth		CRF (Q12)
Restoration – Resin modified GI*	Cost per tooth		CRF (Q12)
Restoration – Sealant only*	Cost per tooth		CRF (Q12)
Restoration – Sealant over restoration*	Cost per tooth		CRF (Q12)
Restoration – Pulpotomy*	Cost per tooth		CRF (Q12)
Local anaesthetic – Topical anaesthetic*	Cost per tooth		CRF (Q12)
Extraction*	Cost per tooth		CRF (Q12)
Lesion opened *	Cost per tooth		CRF (Q12)
Surfaces managed – matrix banding*	Cost per tooth		CRF (Q12)
Miscellaneous			
Radiographs	Cost per image		CRF (Q9)
Inhalation Sedation	Cost per tx		CRF (Q17)

Relative analgesia	Cost per tx		CRF (Q17)
Medications/Antibiotics			
Med 1	Cost per script		CRF (Q20)/BNF.org
Med 2	Cost per script		CRF (Q20)/BNF.org
Med 3	Cost per script		CRF (Q20)/BNF.org
Antibiotics 1	Cost per script		CRF (Q20)/BNF.org
Patient Referrals			
Grouping A	Cost per referral		Patient referral form/Routine sources
Grouping B	Cost per referral		Patient referral form/Routine sources
Grouping C	Cost per referral		Patient referral form/Routine sources
Grouping D	Cost per referral		Patient referral form/Routine sources
Grouping E	Cost per referral		Patient referral form/Routine sources
Grouping F	Cost per referral		Patient referral form/Routine sources
Parent/Child costs			
Time off paid work	Cost per min		Parent questionnaire/Dept. of transport
Time off leisure activities	Cost per min		Parent questionnaire/Dept. of transport
Time off school	Cost per min		Parent questionnaire/Dept. of transport
Additional childcare	Cost per day		Parent questionnaire/
Pain medication (over the counter)	Cost per day		Parent questionnaire/BNF.org

*Cost of equipment and consumables needs to be collected.

Table 2 – Unit costs – Treatments – UDA/FFS

Resource	**Cost (£) mean (SD)**	**Cost (£) median (IQR)**	**Source**
UDA			
Band 1 (I UDA)			GDP survey/PCT
Band 2 (3 UDAs)			GDP survey/PCT
Band 3 (12 UDAs)			GDP survey/PCT
Fee-for-service			
Resource	**Unit**	**Cost (£)**	**Source**
FFS 1			ISD
FFS 2			ISD
FFS…n			ISD

*SD = standard deviation; IQR = interquartile range

Table 3 – Resource Use by Treatment Arm

Resource Use	Conventional (Mean/SD)	n	Biological (Mean/SD)	n	Prevention (Mean/SD)	n
Intervention						
Mean appointment duration						
Number of fillings						
Number of caries removals						
Number of restorations**						
Number of preventative tx**						
Number of extractions						
Number of sedations						
Number of LAs						
Number of radiographs						
Number of antibiotics/medication						
Follow-up visits						
Number of scheduled visits						
Mean scheduled visit duration						
Number of unscheduled visits						
Mean unscheduled visit duration						
Number of patient referrals						
Number of fillings						
Number of caries removal						
Number of restorations**						
Number of preventative tx**						
Number of extractions						
Number of sedations						
Number of Las						
Number of radiographs						
Number of antibiotics/medication						
Parent/Child						
Number of days off school						
Number of days off paid work						
Number of additional child-minding days						
Number of non-prescribed main medications						

*SD = standard deviation; ** Can be broken down into each type of restoration/preventive treatment

Table 4 – Average total cost per treatment arm

Resource Use	**Conventional (Mean/SD)**	**Biological (Mean/SD)**	**Prevention (Mean/SD)**
Cost of initial treatment provided			
Cost of scheduled follow-up visits			
Cost of unscheduled follow-up visits			
Total average NHS treatment cost **			
Child time costs			
Parent time costs			
Parent out-of-pocket expenses			
Total average parent/child costs			
Total average costs (Total NHS costs + total parent/child costs)			

*SD = standard deviation; ** table will be replicated for NHS costs

Table 5 – Average incidence/episodes of pain due to caries and/or dental sepsis per treatment arm

Resource Use	**Conventional (Mean/SD)**	**Biological (Mean/SD)**	**Prevention (Mean/SD)**
Incidence of pain due to caries and/or dental sepsis			
Episodes of pain due to caries and/or dental sepsis			

*SD = standard deviation

Table 6 – Cost-effectiveness analysis

Treatment Arm	**Costs**	**Pain/Sepsis**	**ICER**	**Probability of C/E at £10k/£20k/£30k**
C. Conventional			C vs. P	
B. Biological			B vs. C	
P. Prevention			P vs. B	

*ICER = Incremental cost-effectiveness ratio; C/E = cost-effective

8. References

1. Fayle S.A., Welbury R.R., Roberts J.F. British Society of Paediatric Dentistry: a policy document on management of caries in the primary dentition. Int J Paediatr Dent, 2001: **11**: pp. 153 - 157.

2. Fayle S.A. UK National Clinical Guidelines in Paediatric Dentistry*. International Journal of Paediatric Dentistry, 1999: **9**(4): pp. 311-314.

3. Ricketts D., Kidd E., Innes N., Clarkson J. Complete or ultraconservative removal of decayed tissue in unfilled teeth. Cochrane Database of Systematic Reviews 2006: (3).

4. Innes N.P., Evans D.J.P., Stirrups D.R. The Hall Technique; a randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcomes at 23 months. BMC Oral Health, 2007: **7**: pp. 18.

5. Innes N., Clarkson J., Speed C., et al. The FiCTION dental trial protocol - filling children's teeth: indicated or not? BMC Oral Health, 2013: **13**(1): pp. 25.

6. Scottish Intercollegiate Guidance Network (SIGN). Prevention and management of dental decay in pre-school children - a national clinical guideline 2005: Edinburgh: SIGN.

7. UK Department of Health and British Association for the Study of Community Dentistry (BASCD). Delivering better oral health. An evidence-based toolkit for prevention. 2009. (2 ed): 2 London; Department of Health.

8. Scottish Dental Clinical Effectiveness Programme (SDCEP). Prevention and management of dental caries in children. Dental clinical guidance. 2010, (SDCEP): Dundee.

9. NHS reference costs. Series "NHS reference costs" 2013-14 [cited August 2014]; Available from: https://www.gov.uk/government/publications/nhs-reference-costs-2013-to-2014.

10. TAG Unit A1.3 User and Provider Impacts. 2014, Department of Transport: https://www.gov.uk/government/publications/webtag-tag-data-book

11. Annual Survey of Hours and Earnings, 2014 Provisional Results. 2014, Office of National Statistics http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2014-provisional-results/stb-ashe-statistical-bulletin-2014.html.

12. British National Formulary. Series "British National Formulary" [cited August 2014]; Available from: https://www.medicinescomplete.com/mc/bnf/current/.

13. Department of Health. Dental Contract Reform: Prototypes. Overview document. 2015: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/395384/Reform_Document.pdf.

14. Health and Social Care Information Centre. A Guide to NHS Dental Publications. 2013.

15. Standard General Dental Services Contract. 2013, Department of Health: https://www.gov.uk/government/publications/standard-general-dental-services-contract-and-personal-dental-services-agreement.

16. NHS England. Dental Assurance Framework. Policy & Corporate Procedures. 2014: https://www.england.nhs.uk/wp-content/uploads/2014/05/dental-assurance-frmwrk-may.pdf.

17. Department of Health. Dental Contract Management Handbook. 2010: https://www.pcc-cic.org.uk/sites/default/files/articles/attachments/dental_handbook_2010_version_1_01.pdf.

18. NHS Business Service Authority. Dental Activity Reviews. 28 Day Re-attendance. 2016: http://www.nhsbsa.nhs.uk/DentalServices/5143.aspx.

19. National Health Service (General Dental Services) Scotland. Statement of Dental Remuneration. 2016: http://www.scottishdental.org/professionals/statement-of-dental-remuneration/.

20. National Institute for Health and Care Excellence (NICE). Guide to the methods of technology appraisal 2013. 2013, National Institute for Health and Care Excellence London, UK.

21. Fiebig D.G. Seemingly Unrelated Regression, in *A companion to theoretical econometrics*. 2003, Blackwell Publishing Ltd.: Malden, MA, USA: pp. 101-121.

22. Willan A.R., Briggs A.H., Hoch J.S. Regression methods for covariate adjustment and subgroup analysis for non-censored cost-effectiveness data. Health Economics, 2004: **13**(5): pp. 461-475.

23. Barber J.A. and Thompson S.G. Analysis of cost data in randomized trials: an application of the non-parametric bootstrap. Statistics in Medicine, 2000: **19**(23): pp. 3219-3236.

24. Briggs A., Clark T., Wolstenholme J., Clarke P. Missing.... presumed at random: cost-analysis of incomplete data. Health Economics, 2003: **12**(5): pp. 377-392.

CHEERS checklist

Section/item	Item No	Recommendation	Reported on page No/line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	n/a
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	Page vii Lines 28-29 Page viii Lines 3-4 and 21-24
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	Page 6 Lines 40-45 Page 7 Lines 10-17
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	Page 34 Lines 10-25 & 33-37 Page 35 Table 4 Page 51 Lines 11-12 Page 51 Lines 9-12 & 18-24
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Page 14 Lines 13-16
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Page 51 Lines 20-21 & 23-26

Section/item	Item No	Recommendation	Reported on page No/line No
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Page 1 Lines 22-32 Page 12 Lines 21-45 Page 13 Lines 1-12
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Page 51 Lines 22-24
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Page 57 Lines 13-15
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Page 55 Lines 11-18
Measurement of effectiveness	11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	n/a
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
Estimating costs and resources	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	n/a
Currency, price date and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Appendix 5 Tables 70, 71 & 72 Tables 1-3 Appendix 5 Tables 74 & 75

Section/item	Item No	Recommendation	Reported on page No/line No
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	n/a
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	n/a
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	Page 56 Lines 1-39 Page 57 Lines 1-24 Appendix 5 Table 73
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	n/a
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Page 59 Table 13 Page 61 Table 15 Page 62 Table 16 Page 64 Table 17
Characterising uncertainty	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	n/a

Section/item	Item No	Recommendation	Reported on page No/line No
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	Page 65 Lines 2-9 Page 66 Lines 1-19 & 34-44
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	Page 93 Lines 38-40 Page 94 Lines 1-37 Page 100 Lines 31-37 Page 104 Lines 14-25
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	Page xxxii Lines 16-17
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	Title page lines 24-30 ICMJE forms were submitted for all authors with the final report