Protocol

"The effect of dental and salivary gland radiation dose on the occurrence of post-radiotherapy dental disease in patients with head and neck cancer."

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<u>Clinical hypothesis</u>
The primary hypothesis is that increased mean radiation dose to the teeth and to the 'spared' parotid gland is associated with an increase in the mean number of carious teeth and in the proportion with periodontal disease 2 years post-radiotherapy.

<u>Study design:</u> **Prospective cohort study.**
-Pre-radiotherapy assessment at baseline and patients rendered dentally fit (i.e. free of dental disease).
-Post-radiotherapy follow-up assessments at 6 months, 12 months, and 24 months.

<u>Selection criteria:</u> Adult dentate patients (i.e. patients with natural teeth) diagnosed with a primary or secondary malignant tumour of the oral cavity, nasal cavity, sinuses, salivary glands, pharynx, or larynx* requiring radiation treatment within Northern Ireland. *International Classification of Diseases (ICD-10) codes C00.0-C14.8 and C30.0-32.9.[1]

<u>Exclusion criteria:</u>
-Patients deemed to have poor prognosis, or patients to receive palliative treatment only (as advised by the Clinical Oncology team).
-Patients with less than 6 teeth before the radiotherapy start date.
-Patients with recurrent head and neck cancer, or patients receiving a repeat course of head and neck radiotherapy.
-Patients with diseases affecting tooth development (e.g. amelogenesis or dentinogenesis imperfecta) or salivary gland function (e.g. Sjogren's Syndrome).
-Patients with pre-existing trismus (mouth opening less than 35mm).

Protocol for pre-radiotherapy dental assessment

In line with current practice, the Multidisciplinary Head and Neck Cancer Team (Royal Victoria Hospital, Belfast) will continue to refer head and neck cancer patients for pre-radiotherapy dental assessment to the School of Dentistry, Belfast. Referred patients will be assessed in the existing 'Head and Neck Clinic' on a Wednesday morning or afternoon in the Prosthetics Department of the School of Dentistry, Belfast, as per current clinical practice.

All potentially eligible patients will be informed of the research study and invited to participate. Willing participants will be asked to sign a written consent form. A member of the direct care team – a dentist – will complete all of this process.

Each recruited patient will be assessed by a trained and calibrated dentist (examiner). Examiners will undergo pre-study training and calibration to ensure consistent clinical measurements.[2] Inter-examiner consistency will be calculated using the Kappa statistic.[3,4] The same examiner(s) will also interpret and record data from all prescribed radiographs.

<u>Clinical assessment</u>

-**Dental caries**: The presence or absence of dental caries on each tooth will be determined using the World Health Organization's criteria and coding system, and ICDAS, and recorded in a modified version of the Oral Health Assessment Form for Adults, 2013.[2,5] All surfaces of the crown and root of each tooth will be assessed by: visualisation using a mouth mirror, dental probe, adequate lighting, and compressed air from a 3-in-1 tip.

Presence or absence of dental caries on each surface will be recorded as follows (Figures 1 and 2):

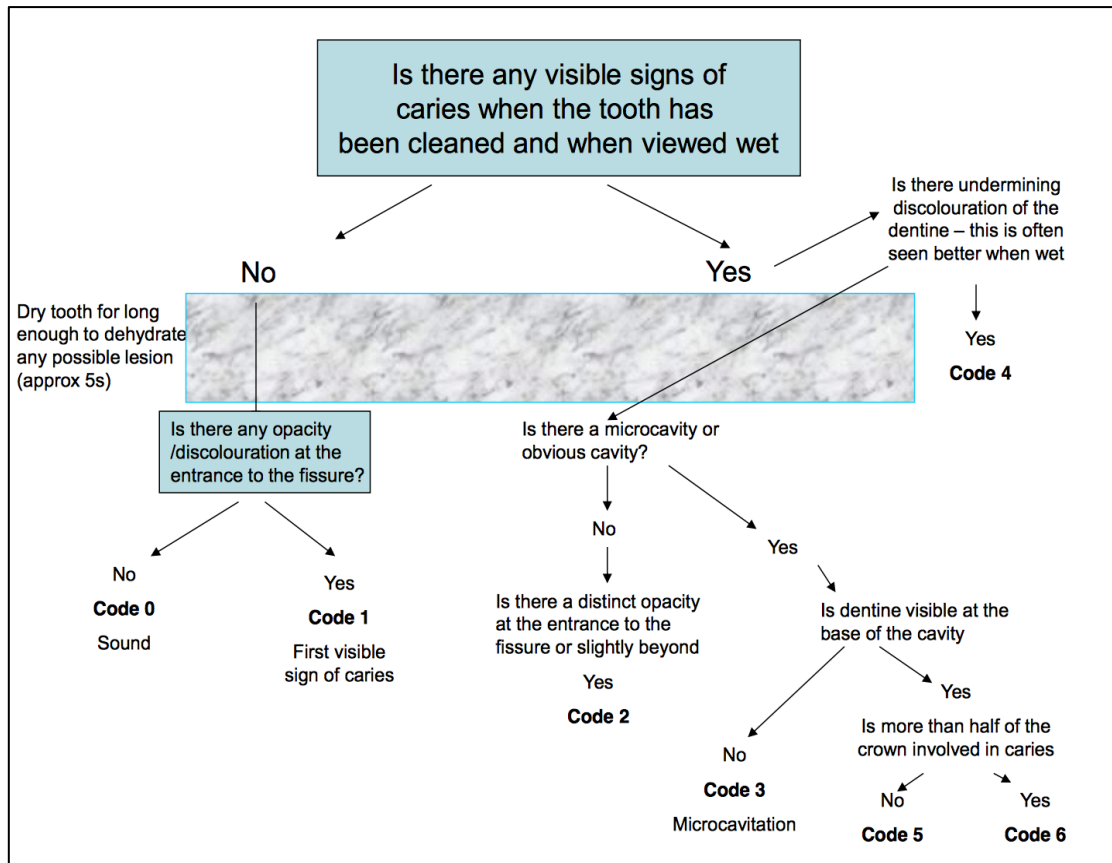| Code			Condition/status
Primary teeth	**Permanent teeth**		
Crown	**Crown**	**Root**	
A	0	0	Sound
B	1	1	Caries
C	2	2	Filled, with caries
D	3	3	Filled, no caries
E	4	–	Missing due to caries
–	5	–	Missing for any other reason
F	6	–	Fissure sealant
G	7	7	Fixed dental prosthesis abutment, special crown or veneer/implant
–	8	8	Unerupted tooth (crown)/unexposed root
–	9	9	Not recorded

Figure 1: WHO criteria and coding system

Figure 2: ICDAS coronal caries decision tree

-**Periodontal disease**: A six-point periodontal charting will be performed for all patients. Clinical attachment loss and probing pocket depths will be measured using a Williams Periodontal Probe and recorded for six sites on each tooth using the Oral Health Assessment Form. The 'Centers for Disease Control and Prevention (CDC)', in partnership with the 'American Academy of Periodontology (AAP)' workgroup definition of periodontitis will be used to identify those with active periodontal disease: 2 or more interproximal sites with attachment loss ≥3 mm, and 2 or more interproximal sites with pocket depths ≥4 mm (not on same tooth) or one site with pocket depth ≥5 mm.[6,7]

-**Stimulated salivary flow rate** using paraffin pellets.[8] Patients will chew an unflavoured paraffin pellet for 5 minutes whilst expectorating into a pre-weighed disposable specimen pot. This will be undertaken in one of the private units in the Prosthetics Department of the School of Dentistry, Belfast. Following collection, the specimen pot will be transported to the Institute of Pathology, Royal Victoria Hospital, Belfast. The mass of collected saliva will be determined using a calibrated precision weighing balance. After the calculation of salivary flow rate, each patient's saliva sample will be disposed of as clinical waste and destroyed by incineration in line with the Human Tissue Act 2004.

Patients will be asked to refrain from smoking, eating and drinking, and other forms of oral stimulation (e.g. oral hygiene) 90 minutes prior to the collection of saliva. It is anticipated that the length of each patient's pre-radiotherapy dental assessment will be at least 90 minutes (based on current clinical practice). Patients will therefore be instructed not to engage in oral stimulation for 90 minutes after they have signed the written consent form at the start of the appointment.

-Ruler measurement of **mouth opening**.[9] Maximum interincisal distance will be measured when the upper and lower central incisors are present (natural or prosthetic). Alternatively, the alveolar ridge(s) will be used as a reference point for measurement where no natural or prosthetic central incisors are present.

All of the above data, including the Oral Health Assessment Forms, will be recorded and stored in patients' clinical records (dental notes).

-**Oral hygiene practice** and **dietary assessments** will be performed using the World Health Organization's Oral Health Questionnaire for Adults.[2]

-**Quality of life** and experience of **xerostomia** will be assessed using questionnaire booklets containing the European Organization for Research and Treatment of Cancer (EORTC) QLQC30 quality-of-life instrument, the associated head and neck specific module HN35, the Oral Health Impact Profile, and the modified Xerostomia Questionnaire.[10-14]

-**Micro-costings study**. Patients will also be asked to complete a short questionnaire enquiring of their gross annual income, the mode of transport they used for attending their dental appointment, and whether another person accompanied them to their dental appointment. The micro-costings study questionnaire will be attached to the oral hygiene/diet/quality of life/xerostomia questionnaire booklet outlined above.

The questionnaire booklets will be completed anonymously. Upon acceptance into the study, a random number generator will assign each recruited patient a 6-digit anonymous code. Each patient will be informed of his or her anonymous code. This will be the only identifier recorded on completed questionnaire booklets.

Patients will be asked to complete the questionnaire booklet in one of the dental units in the main clinic of the School of Dentistry, Belfast. The questionnaire booklets will be given to, and collected by, the dentist performing the clinical assessments. They will be stored securely in a locked cupboard in a locked room in the School of Dentistry, Belfast.

A password-protected spreadsheet will be created with a list of patients' anonymous codes and their corresponding Dental Health and H&C numbers. This will be stored on a password-protected Belfast Health and Social Care Trust computer.

Radiographs
The decision to prescribe, take, and interpret dental radiographs for the purposes of diagnosis and treatment-planning should be made on a case-by-case basis and follow current clinical practice. There should be clear justification for the medical exposure of patients in line with the Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.[15] The following criteria, adapted from the FGDP's Selection Criteria for Dental Radiography[16], is intended to guide the decision-making process:

Dental pantomogram (DPT) **– mandatory**

IOPAs – symptomatic teeth, clinical signs (sinus, swelling), caries with suspected pulpal involvement, toothwear with suspected pulpal involvement, previous root canal treatment (RCT), crowned teeth, heavily restored teeth with restoration in close proximity to pulp, clinical attachment loss >6mm, furcation disease.

Bitewings – lack of clarity regarding the presence of interproximal caries on DPT.

Radiographic evidence of secondary caries or caries into dentine will be recorded on each patient's Oral Health Assessment Form.

Other special investigations
Electric pulp test – caries with suspected pulpal involvement, toothwear with suspected pulpal involvement, heavily restored teeth with restoration in close proximity to pulp.

Prevention and treatment planning

All patients will receive standardised oral hygiene and dietary advice:

Diet advice

- Sugary and acidic food/drink to be consumed at mealtimes only
- Rinse mouth with 0.05% fluoride mouthwash after each sugar attack
- Advice on the use of sugar-free medications

Oral hygiene instructions

- Powered or manual medium toothbrush to be used (Bass technique)
- 5,000ppm Duraphat fluoride toothpaste to be used twice daily
- 0.05% fluoride mouthwash to be used at least once daily (different time from brushing)
- Floss and/or interdental brushes (as appropriate) to be used daily
- Corsodyl (chlorhexidine gluconate) 0.2% mouthwash to be used twice daily for 1 week prior to radiotherapy

Denture hygiene instruction

- Don't wear dentures during the course of radiotherapy if possible
- Rinse dentures after every meal in cold running water
- Clean dentures at least once daily with a toothbrush and 5,000 ppm Duraphat fluoride toothpaste
- Steep in Miltons (1 in 80 dilution) overnight if the denture is made of plastic only
- Alternatively, steep in Corsodyl (chlorhexidine gluconate) 0.2% overnight if the denture has metal components

A dental treatment plan will be formulated for each patient to ensure adequate dental fitness prior to radiotherapy. Consultants in Restorative Dentistry, will oversee patients' treatment plans. Dental treatment required pre-radiotherapy (e.g. restorations and extractions) will be co-ordinated by the School of Dentistry in line with current practice, including the possibility of routine treatment within the primary care setting (i.e. completed by the patient's general dental practitioner).

To facilitate the micro-costings study, all patients will be asked to retain details of any treatment costs that they incurred from their general dental practice. Patients will be asked to provide this cost information at follow-up appointments (for example, with the production of invoices). Information on the cost of dental treatment incurred will be recorded on each patient's anonymised questionnaire booklet completed at the subsequent follow-up appointment.

Treatment planning components:

May include any combination of the following:

<u>1. Extractions</u>

The following table is intended to guide the decision-making process for pre-radiotherapy dental extractions in line with current practice.[17-21] The decision to undertake extractions should be taken after careful consideration of individual tooth prognosis, tooth abutment potential, and the patient's medical history (see also 'SPECIAL CASES' below).

	Molars	**Premolars**	**Anteriors**
Apical disease	YES	YES when both marginal ridges lost	YES if post-crown
Furcation disease	YES	YES	N/A
Grade II mobile or worse	YES	YES	YES
Loss of >50% marginal bone loss	YES	YES	YES
Crown with secondary caries	YES	YES if post-crown	YES if post-crown
Crown with subgingival margins	YES	YES	NO
Caries or toothwear with suspected pulpal involvement	YES	YES when both marginal ridges lost	NO
Previous RCT/non-vital tooth	YES	YES when both marginal ridges lost	NO
Caries/tooth margin >1mm subgingival	YES	YES	YES
Root caries >1 surface	YES	YES	YES
Root perforation/ resorption/ fracture/ retained instrument	YES	YES	YES
Periodontal pocket >5mm	YES	YES	YES

SPECIAL CASES
Dental phobic patients – may consider additional extraction of any tooth with caries.

Impacted/unerupted teeth – extract when in communication with oral cavity, carious, or other pathology suspected (e.g. cyst formation, resorption of adjacent teeth).

Retained roots/apices – leave when no pathology and encased entirely within bone.

Patients deemed to have poor prognosis or to receive palliative treatment only – may limit number of extractions on this basis.

Dental neglect (toothbrushing <1x per day, intake of >5 sugar attacks per day, caries affecting >75% of remaining teeth) – may consider additional extraction of teeth or complete dental clearance.

Patients with oral cancer – additional teeth in close proximity to tumour may require removal as part of the oncology surgical approach.

Patients taking bisphosphonate medications – need to liaise with Oral Surgery or Maxillofacial Team.

2. Dental restorations ("fillings")

Permanent restorations should be undertaken where possible.

Minimum = Render tooth caries-free (including crown removal where appropriate) and adequate temporization (e.g. with glass ionomer restoration).

Minimum when a tooth has been diagnosed with pulpal/apical pathology = 1st stage RCT and adequate temporization (e.g. with glass ionomer restoration).

3. Non-surgical periodontal treatment
Non-surgical periodontal treatment to remove supra and subgingival calculus and plaque.

Protocol for post radiotherapy dental assessments

Participants will be followed-up at 6 months, 12 months, and 24 months post-radiotherapy.

Patients will undergo dental assessment on a Wednesday morning or afternoon in the Prosthetics Department of the School of Dentistry, Belfast. The following measurements will be collected (using the same methods and examiners outlined above): charting of dental caries, 6-point clinical attachment loss and probing pocket depth charting, stimulated salivary flow rate, mouth opening, oral hygiene practice, dietary assessment, quality of life, patient reported xerostomia, micro-costings study.

N.B. – For each patient, all efforts must be made to ensure that saliva collection is undertaken at a similar time of day for each of the four dental assessment appointments (i.e. the pre-radiotherapy assessment appointment and the three post-radiotherapy assessment appointments). This is due to the diurnal variation in saliva production. Patients will be asked to refrain from smoking, eating and drinking, and other forms of oral stimulation (e.g. oral hygiene) 90 minutes prior to the collection of saliva at post-radiotherapy assessment appointments. These instructions will be explained and provided in writing, and attached with the post-radiotherapy assessment appointment letter as a reminder to patients.

Radiographs
The decision to prescribe, take, and interpret dental radiographs for the purposes of diagnosis and treatment-planning should be made on a case-by-case basis and follow current clinical practice. There should be clear justification for the medical exposure of patients in line with the Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.[15] The following criteria, adapted from the FGDP's Selection Criteria for Dental Radiography[16], is intended to guide the decision-making process:

DPT – suspected bony pathology (e.g. osteoradionecrosis, cyst), gross caries or periodontal disease assessment, wisdom tooth assessment.

IOPAs - symptomatic teeth, clinical signs (sinus, swelling), caries with suspected pulpal involvement, toothwear with suspected pulpal involvement, previous RCT, crowned teeth, heavily restored teeth with restoration in close proximity to pulp, clinical attachment loss >6mm, furcation disease.

Bitewings – where visualization of approximal surfaces of posterior teeth impeded.

Radiographic evidence of secondary caries or caries into dentine will be recorded on each patient's Oral Health Assessment Form as above.

Other special investigations
Electric pulp test – caries with suspected pulpal involvement, toothwear with suspected pulpal involvement, heavily restored teeth with restoration in close proximity to pulp.

Patients' general dental practitioners will also be asked to immediately inform the research team if they carry out any dental treatment during the course of the study.

Prevention and treatment planning post-radiotherapy

At each visit, patients will receive standardised oral hygiene and dietary advice (as above). Consultants will oversee treatment plans for the restoration of dental health. Required treatment will be co-ordinated by the School of Dentistry in line with current practice, including the possibility of routine treatment within primary care.

Extractions
The decision to undertake extractions should be taken after careful consideration of individual tooth prognosis, tooth abutment potential, the patient's medical history and other cancer related factors e.g. radiotherapy dose to mandible/maxilla. It is recommended that extractions be limited to teeth that are deemed unrestorable (see box below).[17-21] All dental extractions should be undertaken in a hospital dental setting and following liaison with an Oral Surgery or Maxillofacial Surgery team.

> UNRESTORABLE TEETH:
> Subgingival caries/tooth margin >1mm
> Periodontal pocket >5mm at one or more sites non-responsive to non-surgical periodontal treatment
> Grade II mobile or worse
> Apical pathology not responsive to orthograde root canal therapy
> Root fracture/perforation/resorption

Clinical data transfer and storage

Oral Health Assessment forms will be stored in each patient's clinical notes as they form an integral part of each patient's overall clinical assessment. Relevant anonymised data relating to dental caries, periodontal disease, saliva flow, and mouth opening will be transferred to a password-protected data spreadsheet on an encrypted password-protected Centre for Public Health, Queen's University computer. Information will be recorded alongside each patient's anonymous code. Please note the register of patients' Dental Health and H&C numbers and anonymous codes will be stored on a separate password-protected spreadsheet on a Belfast Health and Social Care Trust computer.

Radiation dose and tumour location determination

Patients will receive radiotherapy as prescribed by their Consultant Clinical Oncologist. The Clinical Oncologist will also plan individual tissue exposures in line with current practice. There will be no alteration or experimentation with radiotherapy dose or the radiotherapy treatment plan for the purposes of conducting this research study.

Using additional research software (Non-Clinical Eclipse System by Varian Medical Systems UK Ltd), radiation dose exposures to the teeth and 'spared' parotid gland will be calculated after the teeth and parotid glands have been contoured on each patient's radiotherapy planning CT scan. The Clinical Oncologist will contour the parotid glands in line with current practice. A dentist will contour the teeth on patient-anonymised CT scans. Tumour location will be determined from the initial referral letter sent by the Head and Neck Cancer Multidisciplinary Team.

The dentist will be blinded to patient details when contouring teeth on CT scans. A 'unique identifier' will be generated for each patient's CT scan. A member of the clinical radiotherapy team (not involved in the study) will securely store a list of patients' 'unique identifiers' and H&C numbers on a Belfast Health and Social Care Trust computer. The dentist will then input radiation dose data (doses to the teeth and to the 'spared' parotid gland) alongside each patient's 'unique identifier' onto a separate password-protected spreadsheet stored on an encrypted password-protected Centre for Public Health, Queen's University Belfast computer.

Sample size

Sample size calculations were conducted based upon an independent samples t-test and correlation coefficient. Assuming the standard deviation of the number of carious teeth in post-radiotherapy head and neck cancer patients is 4.0 (based upon the results of a 10-year School of Dentistry audit conducted by the applicant fellow) and comparing patients receiving over 20 Gray to the 'spared' parotid gland with those receiving under 20 Gray (based upon a 80%/20% distribution seen in the Cancer Centre radiation dose audit), we would require a total sample of 150 patients with available data to have over 80% power to detect a difference of 3.0 in the mean number of carious teeth between the under 20 Gy and over 20 Gy groups as statistically significant at the 5% level. Furthermore a sample size of 150 patients would allow 80% power to detect, as significant at the 5% level, a correlation coefficient of 0.22 for the association between radiation dose to the 'spared' parotid gland (Gy) and the number of carious teeth. Assuming 30% dropout we would therefore need to recruit 215 patients.

Statistical analysis

Primary outcome measures to be analysed include: (1) the number of carious teeth and (2) the presence of periodontal disease.

(1) Initial comparisons between the radiation dose to the 'spared' parotid gland and the number of carious teeth will be performed using independent t-tests (categorising radiation dose as <20Gy and >20Gy) and ANOVA (categorising radiation dose as <20Gy, 20-30Gy, 30-40Gy, and >40Gy) as appropriate. Adjusted analysis will be performed using multiple linear regression, with the number of carious teeth as the outcome variable, radiation dose to the 'spared' parotid gland as an explanatory variable

(categorised as above) along with potential confounding variables: dental radiation dose, oral hygiene practice, diet, and mouth opening. Without categorising radiation dose, a separate analysis will be conducted using linear regression with the number of carious teeth as the outcome variable and radiation dose to the 'spared' parotid gland (Gy) as the explanatory variable to give the increase in the number of carious teeth per 10 unit increase in Gray. If the number of carious teeth is not normally distributed transformations will be used prior to analysis or equivalent non-parametric techniques will be used.

(2) Initial comparisons of the association between radiation dose to the 'spared' parotid gland (categorised as above) and the presence of periodontal disease (Yes/No) will be performed using chi-square tests. Adjusted analysis will be performed using logistic regression with presence of periodontal disease as the outcome variable, radiation dose to the 'spared' parotid gland as the explanatory variable and dental radiation dose, oral hygiene practice, diet, smoking, medical history, and mouth opening as potential confounders.

Similar analyses will be undertaken to determine the effects of dental radiation dose and tumour location on the number of carious teeth and the presence of periodontal disease in post-radiotherapy head and neck cancer patients.

Secondary outcomes to be analysed include: quality of life, salivary flow rate, diet, oral hygiene practice, mouth opening, xerostomia (all change from baseline); tooth loss, and denture wear. Dichotomous outcomes will be analysed using chi-square tests and logistic regression as above. Continuous outcomes will be analysed as above, apart from variables with baseline measurements, for which ANCOVA will be used to compare outcome measurements adjusting for baseline.[22] Adjusted analyses will use multiple linear regression models as above but with baseline measurements as an additional explanatory variable.

Micro-costings analysis

A micro-costings analysis will be undertaken to evaluate patient and healthcare costs in relation to the diagnosis and treatment of pre- and post-radiotherapy dental disease.

-Patient costs to be evaluated include: total cost of travel to dental appointments, total time off work to attend for dental treatment, total cost of dental treatment incurred pre and post-radiotherapy (general or private practice), total out-of-pocket expenses (e.g. pain-relief medications). Patients will also be asked to state their gross annual income in order to be able to quantify their individual economic burden of dental disease.[23]
-Healthcare costs to be evaluated include:
(1) clinical and administration hospital costs for pre- and post-radiotherapy dental assessments and treatment via the National Schedule of Reference Costs for NHS Trusts.[24]
(2) remuneration of primary care dental practitioners via the Statement of Dental Remuneration made available by the Business Services Organisation.[25]

Cost savings due to improved treatment planning of patients will also be hypothesised.

Distress protocol

If any participant shows emotional distress or anxiety during one of the study visits, the examiner will follow the protocol outlined below to ensure the safety of the research participant.

The assessment appointment will be stopped. Distressed participants will be invited to take a break in the private side clinic of the Prosthetics Department in the School of Dentistry, Belfast, and, if appropriate, to discuss their concerns or worries with the examiner, a family member, or friend. A senior clinician (one of the Restorative Dentistry Consultants) may also be invited into the side room. The participant will be supported to recommence the assessment if they decide to do so. Alternatively, the assessment may be rearranged. Any participant has the right to withdraw from the study at any time and those who do not wish to continue will be provided with the contact details of the research team and relevant support agencies (e.g. their GP or Macmillan Cancer Support).

In all instances, participants will be encouraged to contact their oncologist, their dentist, or their GP if they have any further worries or concerns about their participation in the study.

Where appropriate, a resolution will be found. This may involve simply reassuring the patient or offering remedying treatment where appropriate. Remedying treatment may include (in line with current clinical practice):
-Management of dry mouth (e.g. through the use of saliva substitutes, constant sips of water).
-Management of toothache (e.g. through root canal treatment, dental extraction).
-Management of limited mouth opening (e.g. through the use of a Therabite device, jaw exercises).
-Management of osteoradionecrosis (e.g. oral surgery/maxillofacial surgery referral, pharmacological measures).

Calibration of examiners

Two qualified dentists will act as examiners for the study. They will undertake all of the pre- and post-radiotherapy dental assessments. The examiners are already employed within the School of Dentistry, Belfast, Belfast Health and Social Care Trust. Both dentists will undergo calibration prior to the commencement of the study (approximately 3 months beforehand). [2]

The calibration session will re-educate examiners on the processes involved in the clinical assessment of head and neck radiotherapy patients. This will be led by Consultants in Restorative Dentistry. The calibration session will be undertaken outside of Belfast Health and Social Care Trust normal working hours and will be accredited as a 'Continual Professional Development' study session for both examiners. Topics to be covered include: dental caries assessment, periodontal assessment, measurement of stimulated salivary flow rate, ruler measurement of mouth opening, prescribing of dental radiographs, pre- and post-radiotherapy dental extractions, and instructing patients on oral hygiene, denture hygiene, and diet.

Inter-examiner consistency regarding the assessment of dental caries and the assessment of periodontal disease indices will be determined via a series of clinical photographs, radiographs, and artificial phantom-heads in the Clinical Teaching Lab, 2nd floor, School of Dentistry, Belfast. Agreement between examiners will be determined by the calculation of the kappa statistic. The target level of agreement will be 0.81-1.00

(almost perfect agreement). Where there are major discrepancies, inter-examiner differences will be reviewed and resolved by group discussion.

Both examiners are currently involved in the pre- and post-radiotherapy dental assessment of head and neck cancer patients in the Prosthetics Department, School of Dentistry, Belfast, as part of their current job role. They already undertake dental caries and periodontal disease indices assessments, as well as the ruler measurement of mouth opening and the determination of salivary flow rates, on a day-day basis.

Spreadsheets

Separate password-protected spreadsheets will be created on an encrypted password-protected Queen's University computer/laptop as follows:

1. Four clinical data spreadsheets containing patients' anonymous codes alongside data from their clinical assessment (caries, periodontal assessment, stimulated salivary flow, mouth opening, questionnaire results). This data will be input by one of the dental examiners within the private side clinic in the Prosthetics Department of the School of Dentistry, Belfast, after each clinical session has ended. There will be one spreadsheet for each of the four dental assessment appointments.

2. A radiotherapy dose spreadsheet containing patients' 'unique identifiers' alongside their radiotherapy dose data (dose to teeth, dose to spared parotid gland, location of the tumour). This will be input by the dental examiner tasked with contouring teeth on each patient's radiotherapy planning CT scan.

The following information will retained securely within the Trust (via a Belfast Health and Social Care Trust computer) and with password-protected access:

1. A list of patients' H&C and Dental Health numbers alongside their anonymous codes. To be stored by the applicant fellow.

2. A list of patients' H&C numbers alongside their CT scan 'unique identifiers'. To be stored by a member of the clinical radiotherapy team on a Belfast Health and Social Care Trust computer.

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