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# **The incidence of new carious lesions and tooth loss in patients who have received radiotherapy for Head and Neck Cancer and been placed on a preventative Fluoride and CCP-ACP regime: a retrospective case series from a single unit**

*A Data Management Plan created using DMPonline-test*

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**Template:** University of Manchester

## **Project abstract:**

The incidence of head and neck cancer has increased by nearly 25% over the last 10 years in the UK and is expected to continue to rise. There are approximately 11,700 new cases of head and neck cancer every year making it the 8th most common cancer in the UK. A large proportion of patients with head and neck cancer have radiotherapy as part of their primary treatment which is associated with significant dental morbidity. Radiotherapy to the head and neck region puts patient at increased risk of dental caries. This is predominantly believed to be due to reduced salivary flow (xerostomia) as saliva provides numerous protective mechanisms against caries. Fluoride has been shown to reduce the risk of caries developing and for this reason patients undergoing radiotherapy to the head and neck region are routinely treated with a fluoride prevention regime at the Manchester Dental Hospital. All patients who undergo radiotherapy are advised to:

- Brush teeth for two minutes with with a fluoride toothpaste
- After toothbrushing, apply Tooth Mousse with a finger around the teeth. Spit out any excess and leave without rinsing for 5 minutes
- After Tooth Mousse, apply a pea sized amount of high fluoride toothpaste (Duraphat 5000) into a soft splint (made by the dentist) and place in the mouth for 30 minutes.

**Aims** To investigate the development of new carious lesions and subsequent extractions due to caries in patients who have had radiotherapy for head and neck cancer and received a preventative regime consisting of fluoride and CPP-ACP (Tooth Mousse) therapy at a single unit. **Objectives** Determine the number of new carious lesions and teeth requiring extraction by assessing clinical and radiographic records.

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## Manchester Data Management Outline

- No

No funding will be required

- Yes - only institution involved
- Re-use existing data (please list below)

Data extracted from patient records.

Patient: 1,2, 3 etc

Baseline characteristics:

Age

Gender

Site of tumour

Staging of tumour

Mode of treatment

Date of presentation at the MDT

Date radiotherapy completed

Date surgery completed

Number of teeth present

- Other storage system (please list below)

The data generated will be recorded on anonymised data collection sheets and stored in the Dental Hospital NHS study site only.

- Not applicable
- Not applicable
- < 5 years
- Anonymised personal data
- Personal information

Using the Dental Laboratory computer records, a list of patients who have received Fluoride trays will be generated. This list will be kept in the clinical records department. This is a secure location where a large number of clinical records are kept. Once the relevant information has been recorded, this list will be destroyed. The clinical records will not be removed from site at any point. All data recorded on the data collection sheet will be anonymous with no personal identifiable information. Each patient will be assigned a number starting at 1 and this will continue working down the list.

- No

The initial list of patients generated by the Dental Laboratory will be destroyed as soon as the relevant anonymised data has been collected. This is not anticipated to take more than 3 months

- No
- Not applicable
- No

Carly Taylor

23/11/2018

## **Project details**

To investigate the development of new carious lesions and subsequent extractions due to caries in patients who have had radiotherapy for head and neck cancer and received a preventative regime consisting of fluoride and CPP-ACP (Tooth Mousse) therapy at a single unit.

[General Data Protection Regulation \(GDPR\)](#)  
[University of Manchester Records Retention Schedule](#)

## **Responsibilities and Resources**

Martin Breslin (Masters Student in Fixed and Removable Prosthodontics)

N/A

## **Data Collection**

This will be a retrospective case series.

Data to be analysed will be:

Number of carious teeth  
Specific teeth affected by caries  
Number of teeth affected by extractions  
Specific teeth affected by extractions

Additional factors recorded will be:

Age  
Site of tumour  
Staging of tumour  
Date of primary treatment  
Mode of treatment  
Development of osteoradionecrosis (ORN)  
Specific sites involved in ORN, Pre-disposing factors for ORN.

The University of Manchester Dental Laboratory keeps computerised records of all laboratory lab work provided. A printed list will be generated of all patients who have had fluoride trays constructed since 2009. This list will then be used by the main investigator to assess patient notes. It is common for patients receiving a fluoride regime to be followed up at regular intervals. At each follow up, a full dental examination is carried out. Any record of extraction or caries will be recorded. This is likely to include analysis of dental radiographs. The number of teeth extracted and number of teeth which have developed caries since starting radiotherapy will be recorded on a data collection sheet. All data collection will be carried out by one person.

## **Documentation and Metadata**

The research is being undertaken as part of a Masters Degree Dissertation in Fixed and Removable Prosthodontics.  
Data will be analysed with descriptive statistics. These will include frequency distribution, central tendency and dispersion.

## **Ethics and Legal Compliance**

This study will be anonymised and non-interventional. Ethical approval will be sought through an IRAS application as clinical records will need to be accessed.

Patient notes containing sensitive personal data will need to be accessed for recording data. It will not be practical to obtain consent from each patient prior to accessing their notes. In some cases, it may even be impossible if the patient is deceased.

The list of patients generated in the dental laboratory will be kept in the clinical records department. This is a secure location where a large number of clinical records are kept. Once the relevant information has been recorded, this list will be destroyed.

Clinical records will be accessed on site at the University Dental Hospital. Data will be recorded by working through the list and recording the appropriate data. No personal identifiable information will be recorded on the data collection sheet. Each patient will be assigned a numerical value, starting at 1 and working down the original list of patients until all notes have been accessed. At no point will patient records be taken off site.

Subsequent analysis of the information will therefore be carried out on completely anonymous data.

N/A

## **Storage and backup**

Data collection sheets will not contain any personal identifiable information.

All patients will be assigned a numerical value starting at one and continuing as the list is worked through to identify eligible patients.

The anonymised data will be analysed on a University laptop using an encrypted spreadsheet.

The initial patient list generated by the Dental Laboratory will be kept in the University of Manchester Dental Hospital Clinical Records department. This is a secure location where clinical records are kept. Clinical records are only accessible to members of the clinical records department or clinical members of staff involved in patient care who may access clinical records by making a formal request. Once the relevant anonymise data has been recorded this list will be destroyed.

## **Selection and Preservation**

The initial patient list will be destroyed once the relevant anonymised data has been collected. This is not anticipated to be longer than 3 months. The data analysis will be presented as part of a Masters Degree Dissertation

The data analysis will be presented as part of a Masters Degree Dissertation

## **Data Sharing**

The data analysis will be presented as part of a Masters Degree Dissertation

All collected data will be completely anonymised