Plan Overview

A Data Management Plan created using DMPonline

Title: 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

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Template: University of Manchester Generic Template

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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.

ID: 34083

Last modified: 06-02-2019

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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

Manchester Data Management Outline

1. Is this project already funded?

- No

Will you be applying for funding from any of the following sources? If your funder isn't listed, please enter in the free text box provided.

No funding will be required

3. Is The University of Manchester the lead institution for this project?

- Yes - only institution involved

4. What data will you use in this project (please select all that apply)?

- 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

5. Where will the data be stored and backed-up during the project lifetime?

- University of Manchester Research Data Storage Service (Isilon)

The data generated will be recorded on anonymised data collection sheets on an encrypted University laptop and saved using the Research Data Storage service

6. If you will be using Research Data Storage, how much storage will you require?

- < 1 TB

The chief investigator and MSc Student will have access to this through computers on campus or VPN

7. If you have a contractual agreement with a 3rd party data provider will any of the data associated with this project be sourced from, processed or stored outside of the institutions and groups stated on your agreement?

- Not applicable

8. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

This is in line with the University Records Retention Schedule

Questions about personal information

Personal information or personal data, the two terms are often used interchangeably, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

9. What type of person identifying information will you be processing (please select all that apply)?

- Anonymised personal data
- Personal information

10. Please provide details of how you plan to store, protect and ensure confidentiality of the participants' information as stated in the question above.

In order to identify the appropriate patients, a list will be generated of patients who have received fluoride trays since 2009 using the University of Manchester Dental Laboratory computer records. This will be generated by the Chief Dental technician within the lab and will be done as a one off search on the computer records. The patient numbers (and no other details) will be recorded on a clinical records request form. A formal request to access paper clinical records will then be made to the clinical records department. Clinical records will be accessed on site at the University Dental Hospital Clinical Records department (and will not be removed from this department at any point). The computer system has been in use since 2017 so clinical computer notes will need to be assessed from this date. In the event that clinical notes have been recorded on the computer system, these will be accessed on a clinical computer within the Dental Hospital. Data will be recorded on a data collection sheet. No personal identifiable information will be recorded on the data collection sheet. Each patient will be assigned a number, starting at 1 and working through the clinical records in turn. This will ensure that all recorded data is completely anonymised.

11. If you are storing personal information will you need to keep it beyond the end of the project?

- No

No personal information will be stored. Clinical records will not be removed from the Clinical Records Department. In the event that information is stored on computer clinical records, these will be accessed on a computer in the Dental Hospital clinical setting. The MSc student is a dentist who has access to clinical records within the Dental hospital and treats patients as part of their MSc programme. All data recorded on data analysis sheets will be completely anonymised and it will not be possible to link this data back to any patients. The data collection sheets and subsequent data will be kept for 5 years in line with the Records Retention Schedule

12. Sharing person identifiable information can present risks to participants' privacy, researchers and the institution. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the

University of Manchester? This includes using 3rd party service providers such as cloud storage providers or survey platforms.

- No

13. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

14. Are you planning to use the personal information for future purposes such as research?

- No

15. Who will act as the data custodian or information asset owner for this study?

Carly Taylor

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

12/01//2019

Project details

What is the purpose of your research project?

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.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

General Data Protection Regulation (GDPR)
University of Manchester Records Retention Schedule

Responsibilities and Resources

Who will be responsible for data management?

Martin Breslin (Masters Student in Fixed and Removable Prosthodontics)

What resources will you require to deliver your plan?

N/A

Data Collection

What data will you collect or create?

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.

How will the data be collected or created?

The University of Manchester Dental Laboratory keeps computerised records of all laboratory work provided. A computer search will be conducted to identify patients who have had fluoride trays constructed since 2009. The clinical records of these patients will then be assessed. 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 on an encrypted university laptop. All data collection will be carried out by one person.

Documentation and Metadata

What documentation and metadata will accompany the data?

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

How will you manage any ethical issues?

This study will be anonymised and non-interventional.
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.

Clinical records will be accessed on site at the University Dental Hospital. Data will be recorded on a data collection sheet on an encrypted University laptop. 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 through the clinical records in turn At no point will patient records be taken off site. The anonymised data will be saved on a secure University storage space (to be obtained from The University Research Data Storage Service), and analysed on a University laptop using an encrypted spreadsheet.
Subsequent analysis of the information will therefore be carried out on completely anonymous data. Ethical approval will be sought from NHS REC and HRA

How will you manage copyright and Intellectual Property Rights (IPR) issues?

N/A

Storage and backup

How will the data be stored and backed up?

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 records are assessed in turn
The anonymised data will be analysed on a University laptop using an encrypted spreadsheet.
All data generated will be analysed by the Clinical Masters student and Chief Investigator. The initial data will be analysed in the clinical records department/Dental Hopsital and recorded on the data collection sheet and saved on the University Research Data Storage Service for future analysis. All subsequent analysis will be based on information from the data collection sheets which will not contain identifiable patient information.
The highly secured University data storage space will be requested from The University Research Data Storage Service, and used to store the data. The Chief Investigator and the MSc student will have access to this secure storage space at all times. This space will be accessible through the University Virtual Private Network (VPN).

How will you manage access and security?

No clinical records will be taken off site. All data recorded on data collection sheets will be completely anonymised and it will not be possible to trace this information back to the patients.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

The data analysis will be presented as part of a Masters Degree Dissertation. The data collection sheets and subsequent analyses will be kept for 5 years in line with the Records Retention Schedule

What is the long-term preservation plan for the dataset?

The data analysis will be presented as part of a Masters Degree Dissertation
The data will be stored for five years in line with the University Records Retention Schedule

Data Sharing

How will you share the data?

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

Are any restrictions on data sharing required?

All collected data will be completely anonymised