QOMS Restorative Dentistry for HN cancer patients registry – Protocol

PROJECT DETAILS

Project Title: QOMS Restorative Dentistry for oral cancer patients registry

Project Lead: Michael WS Ho (michael.ho2@nhs.net)

RD Working Group:

Name	Position / Institution	Email
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Project rollout Date: 2024 (TBC) **Review date: TBC**

Funding: British Association of Oral and Maxillofacial Surgeons (BAOMS)

INTRODUCTION

Oral cancer is the 15th most common cancer (12th most common in men and 16th in women) in the UK, accounting for around 2% of all new cases. In absolute numbers, there are 8,846 people in the UK diagnosed annually with mouth cancer and an estimated 3,034 people lost their life to mouth cancer in the UK last year. In the last decade, the incidence of and number of deaths from mouth cancer have risen by 34% (by 103% over the last 20 years, in England only) and the by 46%, respectively. Mouth cancers are also more prevalent in men (M:F ratio of 19:10).

In addition to the cancer treatment (surgery, chemotherapy and radiotherapy), part of the patient's journey involves assessing their overall oral health to decide whether some teeth should be kept or extracted. This can lead to various oral complications, including oral defects, function impairment (chewing, swallowing, breathing and speech), tissue deformation (aesthetics), and trismus in patients.

Maintaining and restoring function and aesthetics is essential and represent a significant challenge that befall to restorative specialists. Restorative dentist is key within the head and neck MDT, from dental pre-assessments to complex oral rehabilitations following extensive surgical management.

The ability to achieve total rehabilitation of all oral functions however depends

- Tumour factors: site and stage of disease
- Patient factors: age, lifestyle habits, oral hygiene, status of dentition, status of the available bone and soft tissues following treatment in the oral cavity and overall prognosis of the patient.
- Treatment-related factors: impact of treatment(s) on all oral cavity structures and function (bones, mucosa, salivary glands.
- Physician-related factors: expertise of the MDT in providing cancer care and rehabilitative care of all oral functions.

The recently published (Oct 2022) NHS's Clinical standard for restorative dentistry provides a list of performance indicators to be collected to benchmark and measure the quality of care provided by Restorative Dentistry:

- PREMs/PROMs
- Waiting list information
- Waiting times for initial appointment & from assessment to treatment
- Numbers of failed attendances (FTA/DNA)
- Written care plans in place
- Details of treatment provided
- Serious Untoward Incidents (SUI) reported
- Planned and unplanned follow up appointments
- Plaudits and complaints

QOMS

The Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) project is the quality improvement and clinical effectiveness programme for Oral and Maxillofacial Surgery (OMFS), initiated by the British Association of Oral and Maxillofacial Surgeons (BAOMS).

QOMS operates a series of clinical registries across several OMFS subspecialties (oral and dentoalveolar surgery, trauma, oncology, reconstruction, non-melanoma skin cancers and orthognathic surgery) either as audits / service evaluations to measure the quality of care provided to patients or as disease- or procedure-specific registries to look at medium to long-term patient outcomes to guide recommendations for patient treatment and management.

The QOMS Restorative Dentistry for oral cancer patients (RD) registry will be operated as a "satellite" of the Oncology & Reconstruction (OR) registry. The two registries will be linked (to avoid double data entry) but independent cases (i.e. not in the OR registry) could still be added.

RATIONALE

- There is little or no data available on the restorative dentistry / oral rehabilitation service for oral cancer patients in the UK.
- Because of the potential of treatment on a patient's quality of life, the new registry will collect PROM.

The QOMS Restorative Dentistry will include 2 sections to collect:

- **Clinical data**. In England and Wales, section 251 support from CAG has been granted. Similar support will be sought for Scotland (PBPP). Data collection can be performed without patient consent.
- Patient-reported outcome measures. **This part of the work will be consented.**

AIM & EXPECTED BENEFITS

Registries allow for the collation of real-world data that can then benefits for patients, surgeons, participating institutions, and commissioners. The overarching aim of the RD registry is to measure

the quality of care of restorative dentistry treatment provided to (oral) cancer patients and where necessary improve it by:

- Producing some high(er) quality data that could be used to produce to guidelines and recommendations. Registry data are the next best things after RCTs
- Assessing the state of the field in the UK
- Measuring the quality of care and identify variations in practice
- Measuring patient outcomes

INFORMATION GOVERNANCE

This registry will follow the same general principles of Information Governance as other QOMS registries.

- The RD registry is NOT a research project but a service evaluation, it therefore does not require ethical approval (see Appendix 1).
- Collection of patient identifiable information: Yes
- Lawful basis for the collection and processing of personal data (GDPR):
  - Article 6(f): processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
  - Processing of special categories of personal data – Article 9(h): processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3.
- For the collection of clinical data, condition to satisfy the Common Law Duty of confidentiality: (where applicable) Approval from devolved governments to collect confidential / personal data without patient consent (HRA CAG section 251 in England and Wales and PBPP in Scotland).
- For the collection of PROM data, condition to satisfy the Common Law Duty of confidentiality: **Consent**. Patient consent will be sought before the start of data collection. A patient information leaflet is available in Appendix 2.
- Data is collected and stored in an instance of the Research Electronic Data Capture (REDCap) system, hosted and managed by the Barts Cancer Research UK Centre (BCC), Queen Mary University of London (QMUL).
  The Barts CR-UK Centre (BCC) has a valid NHS Digital DSPT toolkit (EE133904-ECC04) and is ISO 27001 certified (Cert. No. 225111).
- Data processing: see data flow in Appendix 3.
- Data retention: 4 years after the end of collection of follow-up data. Data retention for the registry will be reviewed on a regular basis.
- Population: Patients affected by **oral cancer** and being under the care of **restorative dentistry / oral rehabilitation service**.
- Data access is under access control policy:

  - Local clinical lead(s) of participating departments will be given full access (including patient identifiable information) to the records entered in the registry for their own institution only. They will be able to view, edit and download that data to use it locally.
  - Access to the whole dataset is limited to the designated data manager (Fabien Puglia), who is a non-clinical member of the QOMS team. Other members of the QOMS team will only have access to anonymised information.
- Access to the central dataset by any party (individuals/institutions) will require a formal request, via the online data request form. Applicant must demonstrate that they will adhere to relevant information governance regulatory framework. Applications will be reviewed by the PSI working group (as described in SOP).
- The RD registry is subject to the National Data Opt-out in England.
- The work will need to be registered / approved by the hospital / trust / health board's information governance team.

Specific considerations for the collection of clinical data

- The RD registry is an add-on to the Oncology & Reconstruction registry and data collection is without patient consent. CAG Approval has been obtained in England and Wales. A PBPP (Scotland) amendments needs to be submitted.
- Data collection will be done directly either by dedicated members of staff (e.g. data coordinators) or by surgeons.

Specific considerations for the collection of patient-report outcomes

- Consent and data collection for PROM is managed online via REDCap.
- A patient information leaflet is available in Appendix 2.
- Each participating hospital will be provided with their own unique link (QR code) to the OR registry

DATA COLLECTION PROCESS

Clinical data: Data collection will be done directly either by dedicated members of staff or by surgeons. Each user will be provided with a unique username and password to access the online registry. User's access to data will be limited to data collected in a user's institution.

Consent: Each participating hospital will be provided with their own unique link (QR code) to the OR registry. PROM and clinical data collections are two separate processes, the latter being possible with the former.

Patient reported outcome measures (PROM)

PROM will be collected at 3 time points (baseline / pre-treatment, 18mo and 36mo post-surgery) using the OHIP-14 tool (see below).

Oral Health-Related Quality of Life (OHRQoL) is a multidimensional construct that includes a subjective evaluation of the individual's oral health, functional well-being, emotional wellbeing, expectations and satisfaction with care, and sense of self. The measurement of OHRQoL provides not only the treatment need and outcome but also provides data based on which can support research, provision and planning of restorative dentistry services. The Oral Health Impact Profile (OHIP) was

developed in 1994 and short form (OHIP-14) realised 3 years later. The OHIP questionnaires were developed to specifically assess the quality of life of patients affected by malocclusion.

Cross-project piping

Patients undergoing oral rehabilitation for HN cancer should already be captured in the QOMS Oncology & Reconstruction. Several fields are identical between the two registries. To avoid duplication, we have set up a cross-project piping module from the two.

Before entering data in the Restorative Dentistry registry, please make sure the patient already has a record in the OR one.

You will notice a "buffering" every time a Restorative Dentistry record opens. The data from the OR registry are automatically transferred into the registry (left)

If there are several records that need "piping", instead of opening them each individually, go to "Record Status Dashboard" and click on "Pipe All Records" (right)

Left

Right

TIMELINE

Patient's clinical journey

BAOMS BOS Orthognathic PROM Project

DATASET

See Supporting Document 1 (SD1)

PATIENT AND PUBLIC INVOLVEMENT

A patient and public involvement session was organised in December 2023. The panel were satisfied with the way QOMS handles data and respect patient's rights and did not have any concerns about extending the remit of the QOMS Oncology & Reconstruction registry to include the QOMS Restorative Dentistry for oral cancer patients registry.

DATA OWNERSHIP

Participating organisations will retain the ownership of the data they entered, while the ownership of the central dataset will be BAOMS. BAOMS will curate data on behalf of participating organisations.

PUBLICATION POLICY

The British Journal of Oral and Maxillofacial Surgery (BJOMS) will have first refusal of any peer reviewed output from this initiative.

Individuals responsible for collecting data will be acknowledged as "collaborators" and listed in publications.

HOW TO GET STARTED

1. Make sure you and your colleagues are happy to contribute to QOMS. Contact the project manager to discuss what taking part to QOMS entails in terms of resources, time commitment, logistic… and answer any queries you may have.
2. Contact your Information Governance department
    a. If you are already contributing to the QOMS Oncology & Reconstruction registry, you need to inform them that the registry's remit now include the Restorative Dentistry questionnaire BUT you still need to register the PROM component of it.
    b. If you are new to QOMS, you need to register the audit with your hospital / Trust / Health Board
    c. In any case, if you need to complete any forms, contact the project manager to help you with it.
3. Once the audit is registered (or during that process), contact the project manager to sort out your and your colleagues' access to REDCap and organise a REDCap training session.

Version control

Version / Date	Changes	Approved by
1.0 / 12/01/2024	Original	F Puglia (PM)
1.1 / 29/01/2024	Cross-project piping added	F Puglia (PM)
1.2 / 05/04/2024	Amendments & corrections	F Puglia (PM)

APPENDICES

APPENDIX 1. HRA MRC TOOL KIT "IS MY STUDY RESEARCH?"

Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

QOMS Restorative Dentistry for oral cancer patients

IRAS Project ID (if available): NA

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the **HRA** to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **Queries@hra.nhs.uk**.

For more information please visit the **Defining Research** table.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

APPENDIX 2. PATIENT INFORMATION LEAFLET

You have been given this leaflet because you have been referred to undergo restorative dentistry treatment as part of your treatment for your cancer. The surgeons, restorative dentists and other health professionals who care for you would like to invite you to take part in this QOMS Restorative Dentistry PROM project.

Please read this leaflet carefully. It explains who we are, what we are doing & how we treat your information to guarantee your confidentiality and anonymity.

WHY WAS I GIVEN THIS LEAFLET?

Restorative dentistry refers to treatment to replace teeth that had to be removed as part of the treatment to remove your cancer.

As part of the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) project, a quality improvement programme led by the British Association of Oral and Maxillofacial Surgeons (BAOMS), we want to hear how your quality of life is affected by your condition before and after treatment.

To do that, we would like to complete a questionnaire at before the start of your restorative dentistry treatment and 18 months after your surgery to remove your cancer.

WHY ARE YOU COLLECTING THIS INFORMATION?

We want to find out how your quality of life has been affected by your condition and by your treatment. We hope this information, received directly from patients, will help clinicians and NHS commissioners understand more about this type of treatment and therefore improve care for patients in the future. Secondary evaluations may also be performed to look at how different aspects of the patients' experience is affected by other factors. This is where anonymised data is looked at some time later to potentially explore other aspects of your care linked to the data collected.

WHAT WOULD TAKING PART INVOLVE?

Participation will take up a little bit of your time. If you agree to take part, you will be asked by your clinical team to complete a questionnaire about how your quality of life is affected by your condition and your treatment at the 2 time points described above.

WHAT INFORMATION ABOUT ME ARE YOU COLLECTING?

Apart from your answers to the questionnaire, we need to collect your contact details (name, email address or phone number) to be able to contact you to complete the follow-up questionnaire 18 months after your surgery and your NHS/CHI number to be able to relate your answers to your conditions.

WHAT WILL HAPPEN TO MY INFORMATION?

The information from your consent and questionnaires will be collected and stored on secure computers managed by the Barts Cancer Research UK Centre at Queen Mary University of London (BCC, QMUL). Access to your answers will be restricted to your clinical team and a limited number of approved members from QMUL and the project team. Some of your information will be later shared with a statistician, to be analysed. No identifiable information will be shared with them or any other third party.

IS MY INFORMATION SAFE?

Yes, your information is safe. Very strict rules and secure procedures are in place to ensure that your information is kept safe. The systems and procedures in place at QMUL comply with international standards and QMUL continuously monitor and adapt them as necessary to maintain security over the lifetime of the project.

HOW LONG WILL MY DATA BE KEPT FOR?

Records of your consent will be kept for 4 years after the end of data collection. Your answer to the questionnaires will be kept for at least 4 years but this could be extended.

CAN I NOT TAKE PART?

Participation is voluntary and you can change your mind at any stage without it affecting your care. If you decide to not take part, when you complete the consent form, this will not affect your care in any way.

If you change your mind about taking part, you can withdraw at any point without providing any reasons. Simply let know your treating team. You will be asked whether you want all your information removed or whether you are happy for us to keep the information we have from your questionnaires so far, but we will not be contacting you for follow-up.

WHO IS ORGANISING AND FUNDING THIS STUDY?

The surgeons in BAOMS and restorative dentists have designed this project. BAOMS leads this project and, as data controller, is responsible for looking after your information and using it properly. The costs for the project are being supported by BAOMS.

WHO HAS REVIEWED THIS INITIATIVE?

This project has been reviewed by BAOMS and by patient representatives. The project has also been reviewed and authorised by this hospital for data protection and security prior to their participation.

WHAT IF THERE IS A PROBLEM?

If there is a problem, please tell your clinician in the first instance, or someone else at the hospital. If you still have concerns, you can lodge a complaint with the Information Commissioner's Office (ICO), the supervisory authority in the UK responsible for the implementation and enforcement of data protection law, if you have concerns about the way your personal data is being handled. You can contact the ICO via telephone (0303 123 1113) or email (W: https://ico.org.uk/concerns/).

FINDING OUT MORE

If you would like further information or have any questions, please contact:

BAOMS | Royal College of Surgeons of England, 38/43 Lincoln's Inn Fields, London WC2A 3PE | E: qoms@baoms.org.uk | W: https://bit.ly/ppi_qoms

APPENDIX 3. DATA FLOW

APPENDIX 4. PATIENT AND PUBLIC INVOLVEMENT PANEL DISCUSSIONS

Area of concerns / discussions	Discussion points	Answers / Action points
None reported		