

QOMS Oncology & Reconstruction registry – Protocol

PROJECT DETAILS

Project Title: QOMS Oncology & Reconstruction registry

Project Lead: David Tighe

Working Group:

Name	Position / Institution
Chi-Hwa Chan	Consultant OMFS, Bedfordshire Hospitals NHS Foundation Trust / BAOMS Oncology SSIG Lead (2019-2021)
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David Tighe *	Consultant OMFS, East Kent Hospitals University NHS Foundation Trust / QOMS Deputy Clinical Lead (2021-2024)
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Jeremy McMahon *	Consultant OMFS, NHS Greater Glasgow and Clyde / QOMS Clinical Lead (2018-2021) / BAOMS
Fabien Puglia *	Project manager / BAOMS

Project rollout Date: Summer 2021

Review date: 2027

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

(* current members of the working group)

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 was initiated in 2018 following the publication of the [1st GIRFT report for OMFS](#). The report found that there was no comprehensive set of clinical outcome measures for OMFS and recommended an efficient and patient-focused outcomes audit programme for OMFS be delivered.

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. QOMS is already running an audit / service evaluation for oncology & reconstruction and another for mandibular trauma.

BACKGROUND

Oncology and Reconstructions are two separate OMFS subspecialties with a significant overlap. It was decided from the onset that they would be led together as one large audit.

The delivery of oncology for tumours located in the head and neck region is managed by several surgical specialties, mainly ENT and OMFS. The focus of the latter tends on the oral cavity and oropharynx sites.

The delivery of reconstructive procedures is also managed by several surgical specialties (ENT, Plastics and OMFS).

- ➔ QOMS Oncology & Reconstruction registry focuses on OMFS but other specialties (ENT, Plastics) can also contribute.
- ➔ QOMS Oncology & Reconstruction registry collects data on all Head and Neck cancers but the reporting focuses on tumours located in the oral cavity and oropharynx, specifically, squamous cell carcinoma (SCC), which represent the majority of the tumours treated.
- ➔ The reconstruction arm of the registry focuses on tissue transfers (free and pedicled flaps) to correct defects in the HN region.

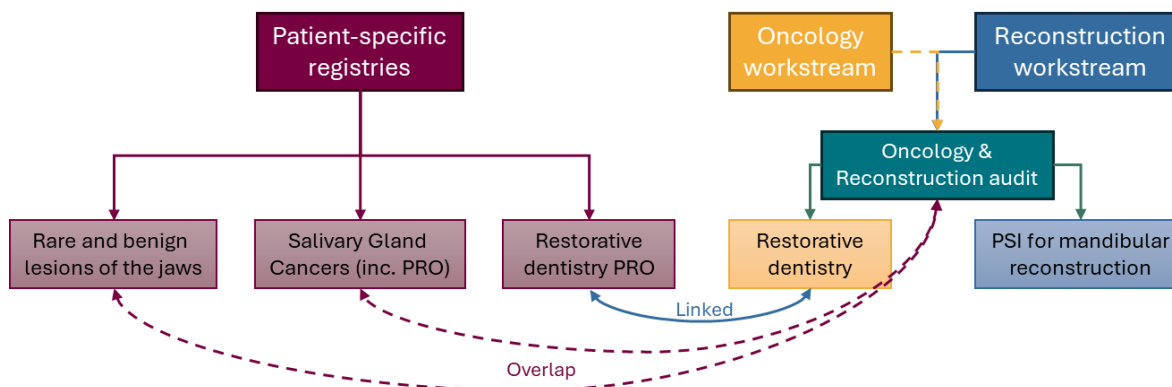
In 2022, a new section was added to the QOMS Oncology & Reconstruction registry to collect clinical data on sentinel lymph node biopsy.

In 2024, the following modules (i.e. smaller registries linked to a main, larger one) were added to collect data on a specific subgroup of patients undergoing:

- Either mandibular reconstruction involving the use of patient specific implants (patient-specific implants for mandibular reconstruction [PSI] module).
- Or oral rehabilitation following the treatment of an oral cancer (restorative dentistry [RD] module). This module was developed and is run by consultants Restorative Dentists. The RD module include also a PRO which necessitates patient consent.

In 2024, two separate **consented** registries were launched collecting data on salivary gland cancers (SGC) and rare and benign lesions of the jaws (RLJ). Although independent, patients may have also been captured in the QOMS Oncology & Reconstruction registry.

Relationship between registries within the Oncology and Reconstructions workstreams



Each of these additional registries has their own protocol.

Recommendations and guidelines

- Homer JJ and Winter SC (Ed.) United Kingdom National Multidisciplinary Guidelines, Sixth Edition J Laryngol Otol . 2024 Apr;138(S1):S1-S224. [doi: 10.1017/S0022215123001615](https://doi.org/10.1017/S0022215123001615)

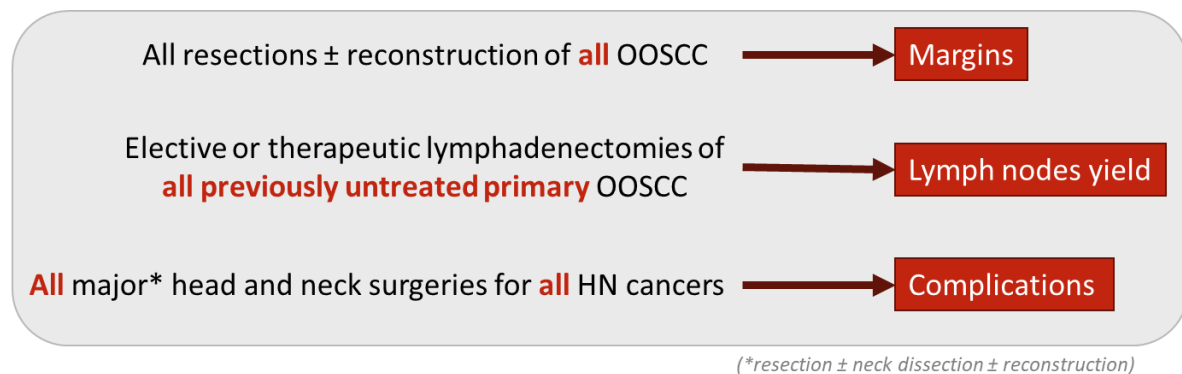
AIM & EXPECTED BENEFITS

The QOMS Oncology & Reconstruction registry allows for the collation of real-world data can lead to benefits for patients, surgeons, participating institutions, and commissioners. Its overarching aim is to measure and improve quality of care.

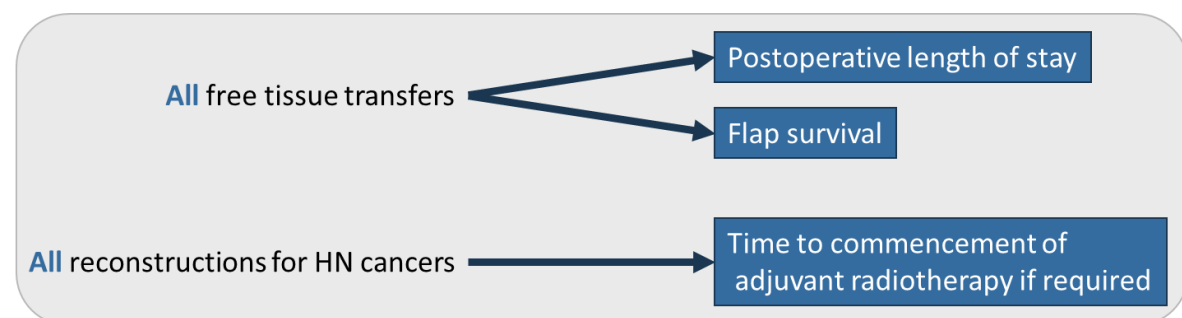
- To develop benchmarks for OMFS practice
- To produce hospital-level comparative performance data and promote QI activities
- To support surgeons to embrace an open/transparent culture in practice
- To reassure patients that quality of care is being monitored and improved
- To support surgeons in their appraisal and revalidation

QUALITY OF CARE METRICS

Oncology



Reconstruction



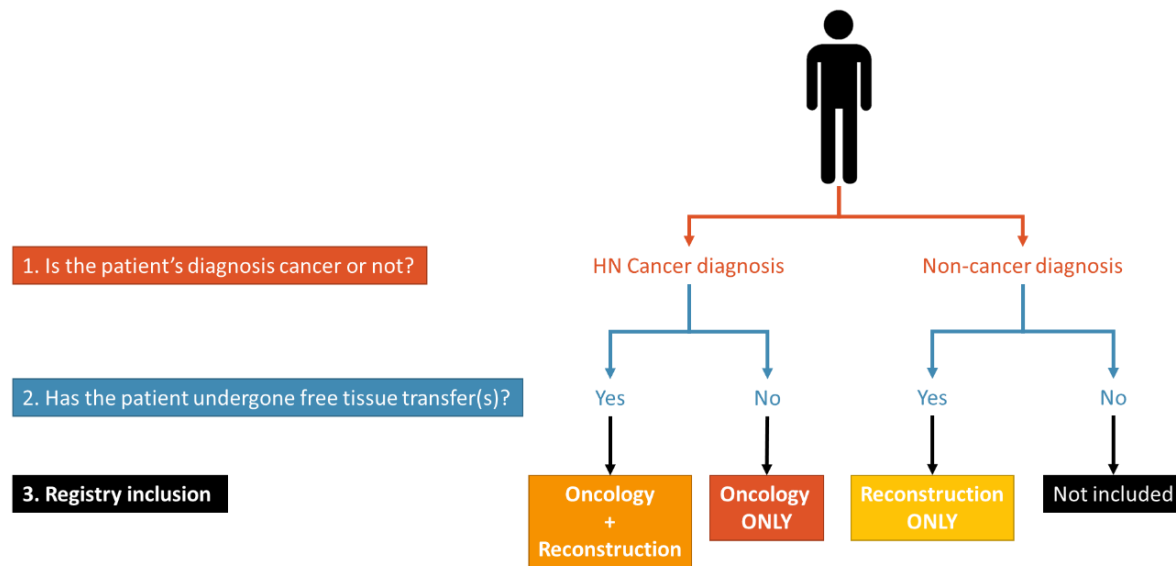
INCLUSION / EXCLUSION CRITERIA

Oncology: all patients diagnosed and treated surgically for a primary tumour located in the head and neck region.

Reconstruction: all patients undergoing free tissue transfer to repair a defect (whichever its origin or aetiology) in the head and neck region.

There are no other inclusion or exclusion criteria.

Figure. Inclusion and exclusion in the Oncology & Reconstruction registry



INFORMATION GOVERNANCE

The Oncology & Reconstruction (OR) registry follows the principles of Information Governance of the QOMS Project.

- The OR registry is NOT a research project but a service evaluation, it therefore does not require ethical approval (see Appendix 1).
- The OR registry, as part of the QOMS Project, can collect patient identifiable information without patient consent, as it has obtained section 251 support from CAG in England and Wales. Application for PBPP approval in Scotland is being prepared.
 - In England only, since 2022, the OR registry must comply with the national data opt out (NDOO)
- Collection of patient identifiable information: Yes
- Data collection will be done directly either by dedicated members of staff (data coordinators) or by surgeons.
- 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 2.
- 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.
- 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 QOMS Team (as described in SOP).

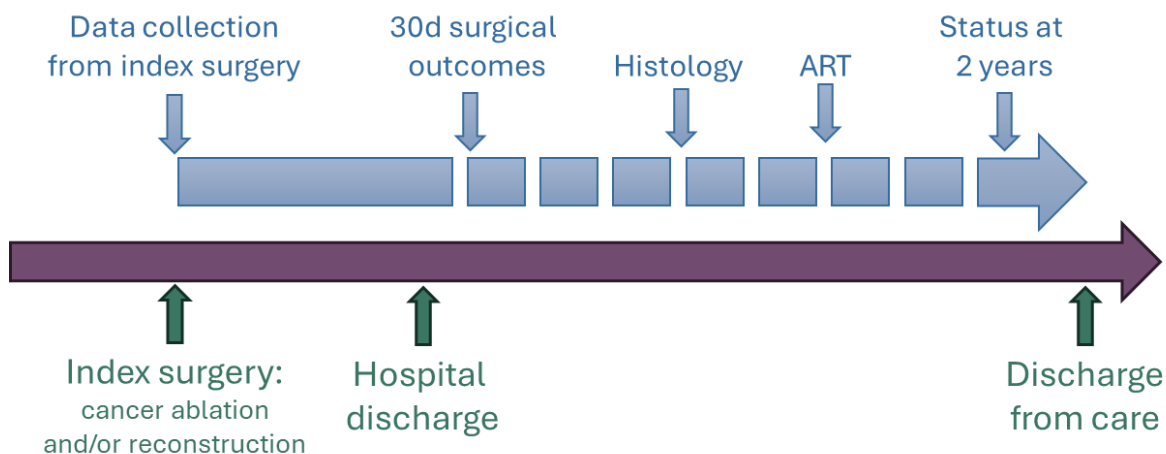
DATA COLLECTION PROCESS

Consent: N/A

Clinical data:

- Data collection will be done directly either by dedicated members of staff (data coordinators) 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.
- Data collection should normally be prospective, but we have obtained a CAG amendment to collect data retrospectively (in that case, data collection must be anonymous).
- Data collection is continuous
- Data censure takes usually place in late June / Early July (date TBC) for report to be produced by the end of that year or as soon as possible thereafter.

Timeline:



DATASET

See Supporting Document 1 (CRF)

PATIENT AND PUBLIC INVOLVEMENT

A patient and public involvement session was organised prior to the start of data collection (2021). The panel were satisfied with the way QOMS handles data and respect patient's rights and did not have any concerns about the QOMS Oncology & Reconstruction 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 to register the audit (a project level registration, i.e. one application for several QOMS audits, should be possible). 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, obtain your own QR code / link to the OR registry and organise a REDCap training session.

Version control


Version / Date	Changes	Approved by
1.0 12/11/2024	New	F Puglia (PM)
1.1 26/11/2024	Corrections + Timeline added	F Puglia (PM)
1.2 04/12/2024	Corrections + new figures added	F Puglia (PM)
1.3 23/02/2026	Update	F Puglia (PM)

APPENDICES

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



Medical Research Council



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:

Quality and Outcomes in oral and Maxillofacial Surgery (QOMS) Project

IRAS Project ID (if available):

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 HRA.Queries@nhs.net.

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.



Medical Research Council



Health Research Authority

Do I need NHS REC approval?

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

Title of your research:

Quality and Outcomes in oral and Maxillofacial Surgery (QOMS) Project

IRAS Project ID (if available):

You have answered 'No' to the question "Is your study research" which indicates that you do not need NHS approval.

Note: Post Market Surveillance is NOT usually considered research. However, there are some circumstances where an NHS REC approval may be required. Please follow link below to start again and select YES at the first question to determine if your post market surveillance requires NHS REC approval.

To understand how research is defined, please visit the [Is my study research?](#) decision tool.

Follow this link to start again.

[Print This Page](#)
 NOTE: If using Internet Explorer please use browser print function.

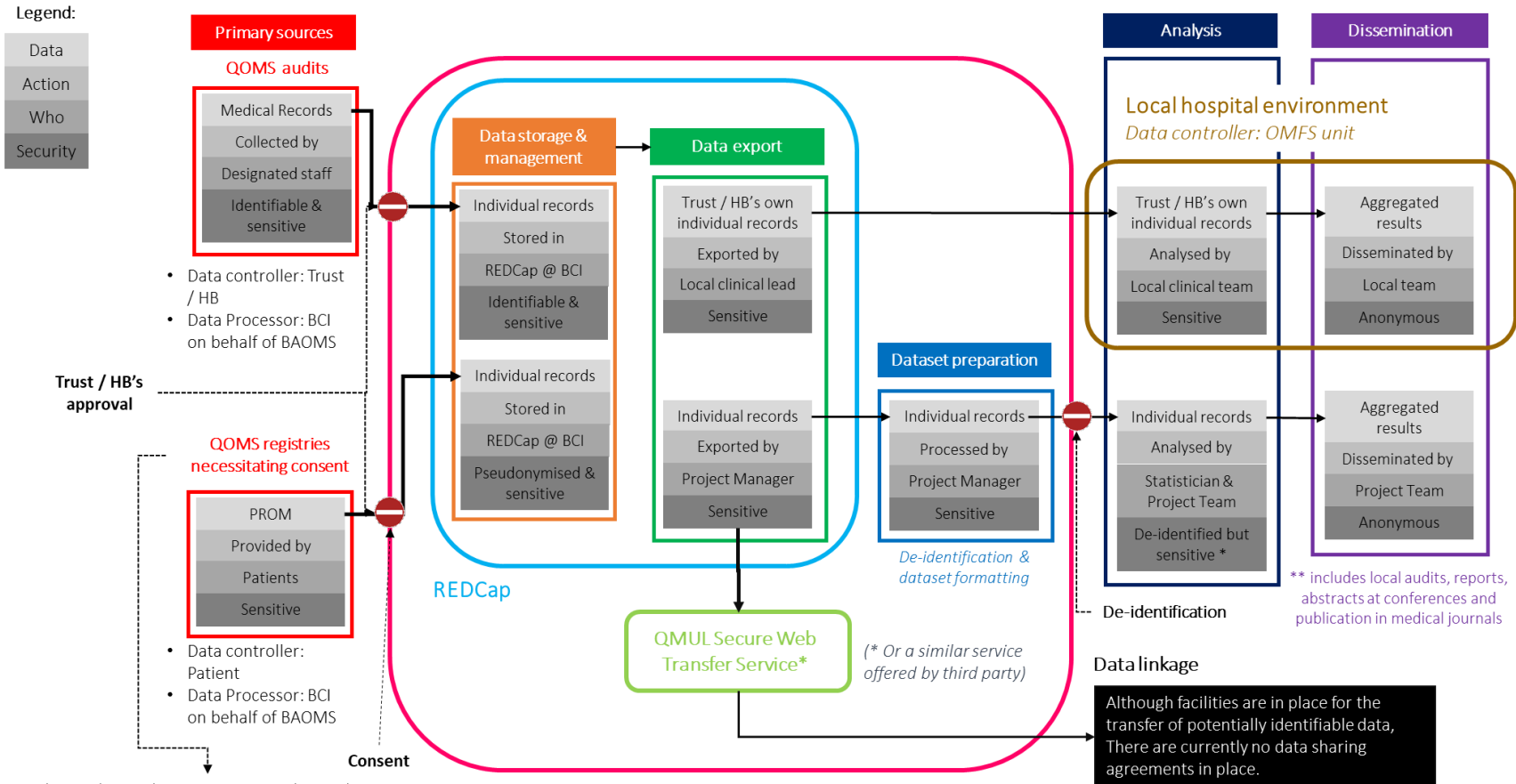
Left: "Is my study research?" toolkit

Right: "Do I need NHS REC approval" toolkit

APPENDIX 2. DATA FLOW

QOMS data flow: QOMS audits & patient registries

V11.0, date: 2026 01 13



This applies to the BAOMS BOS Orthognathic PROM, the Restorative Dentistry / Oral rehabilitation audit (PROM) as well as the "Salivary Gland Cancers" and "Rare and Benign Lesions of the Jaws" registries.

BCI Safe Haven environment
 Data controller: BAOMS / Data processor: Barts Cancer Institute, QMUL

APPENDIX 3. PATIENT AND PUBLIC INVOLVEMENT PANEL DISCUSSIONS

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