QOMS Trauma workstream – Protocol

PROJECT DETAILS

Project Title: QOMS Trauma workstream

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

Working Group:

Name	Position / Institution
Geoff Chiu	Consultant OMFS, East Lancashire Hospitals NHS Trust / QOMS Audit Lead for ODA and Trauma
David Laraway	Consultant OMFS, NHS Greater Glasgow and Clyde / SSIG Deputy Lead for Trauma
Niall McLeod	Consultant OMFS, University Hospitals Coventry and Warwickshire NHS Trust, SSIG Lead for Trauma
David Tighe	Consultant OMFS, East Kent Hospitals University NHS Foundation Trust / QOMS Deputy Clinical Lead (2021-2024)
Michael Ho	Consultant OMFS / Leeds Teaching Hospitals NHS Foundation Trust / BAOMS Reconstruction Deputy Lead / QOMS Clinical Lead, BAOMS (2021-2024)
Fabien Puglia	Project manager / BAOMS

Project rollout Date: Summer 2021 / revised 2023 **Review date:** 2025

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

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.

BACKGROUND

When QOMS was set up, discussions with the then SSIG Lead and Deputy Lead led to the following decisions for the trauma audit:

- The conditions to be audited: mandibular fractures and isolated orbital wall fractures
- The quality of care metrics: unexpected return to theatre and readmissions within 90 days after discharge and, for isolated orbital wall fractures, visual complications at 90 days after discharge.

An initial registry, that included both conditions, was developed and rolled out in the summer 2021 and ran until July 14th, 2023 when it was revised and replaced by two separate registries (mandibular fractures and isolated orbital wall fractures).

AIM & EXPECTED BENEFITS

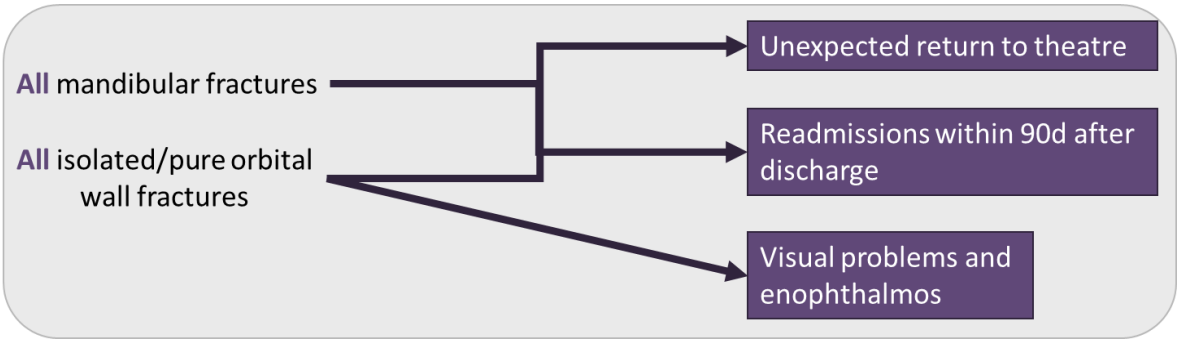
The QOMS Trauma registry allows for the collation of real-world data can lead to benefits for patients, surgeons, participating institutions, and commissioners. Its overarching aim is to measure and improve quality of care.

- 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

INCLUSION CRITERIA & QUALITY OF CARE METRICS

Mandible fractures: all patients diagnosed and treated under OMFS care for a mandible fracture.

Isolated orbital wall fractures: all patients diagnosed and treated under OMFS care for an isolated orbital wall fracture. Patients presenting with fractures extending to neighbouring bones (frontal, zygoma… but not nasal bones) are to be excluded.



There are no other inclusion or exclusion criteria.

INFORMATION GOVERNANCE

The Trauma registries follow the principles of Information Governance of the QOMS Project.

- The registries are NOT research projects but service evaluations, and therefore do not require ethical approval (see Appendix 1).
- The registries, as part of the QOMS Project, can collect patient identifiable information without patient consent, as section 251 support from CAG in England and Wales and PBPP approval in Scotland have been obtained.
    - In England only, since 2022, the registries 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).

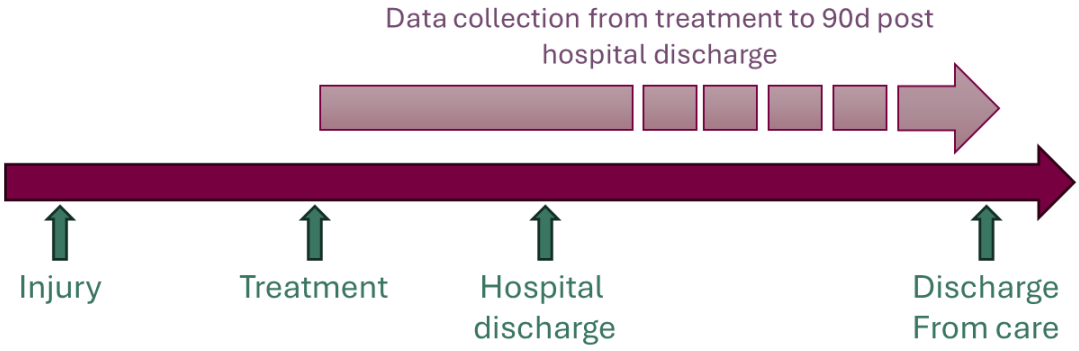
DATA COLLECTION PROCESS

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 Documents 1a (Mandible) and 1b (Orbit)

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 Trauma registries.

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.

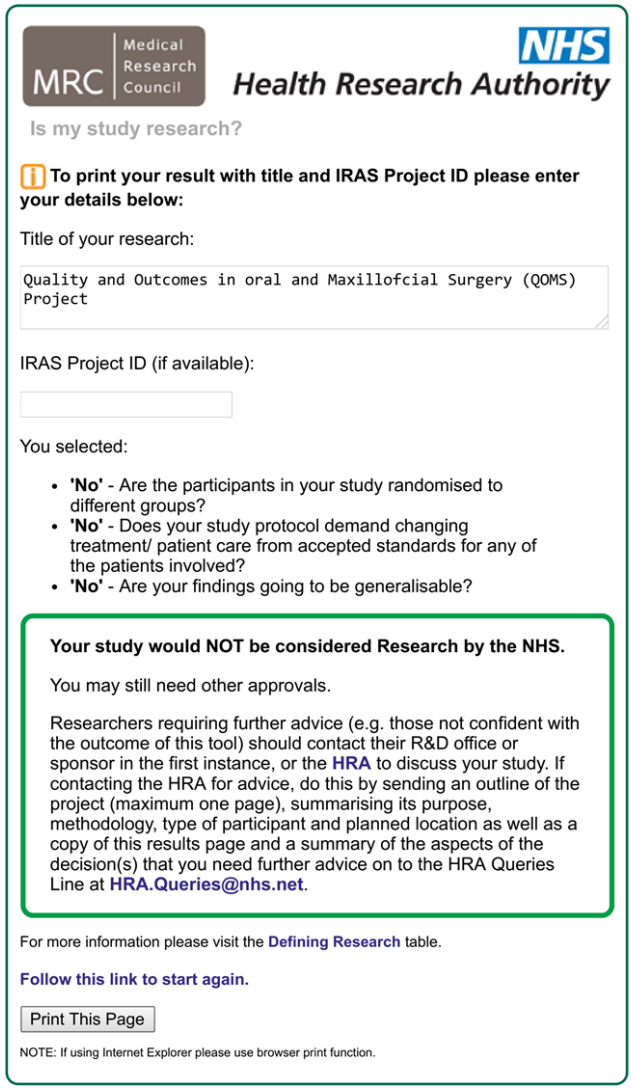
Individuals responsible for collecting data will be acknowledged as "collaborators" and listed in publications.

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 26/11/2024	New	F Puglia (PM)



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 Maxillofcial 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.

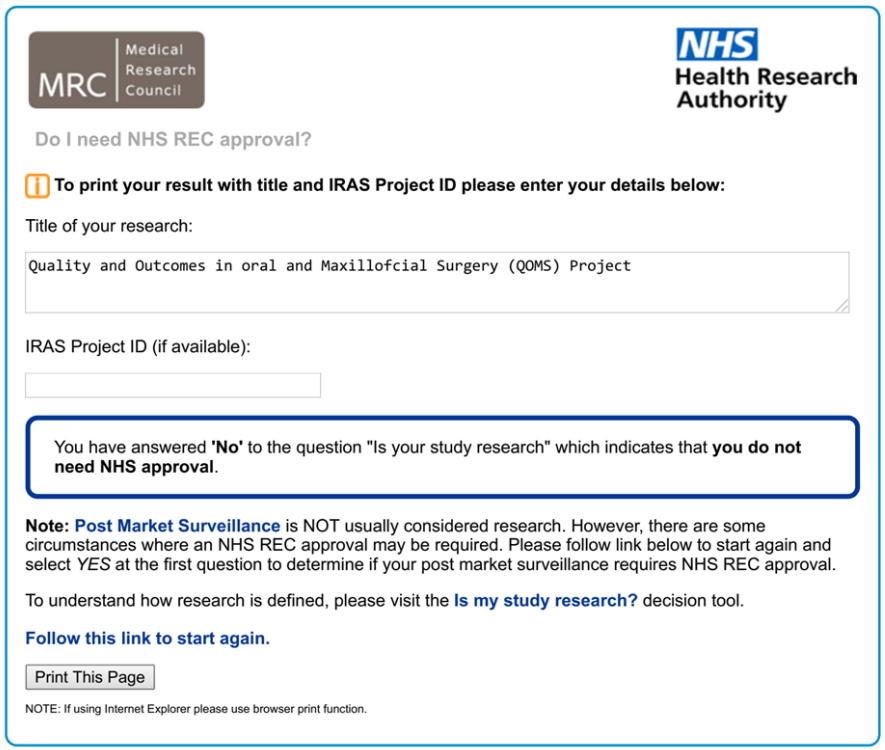
Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the **HRA** to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising 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 Maxillofcial 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.

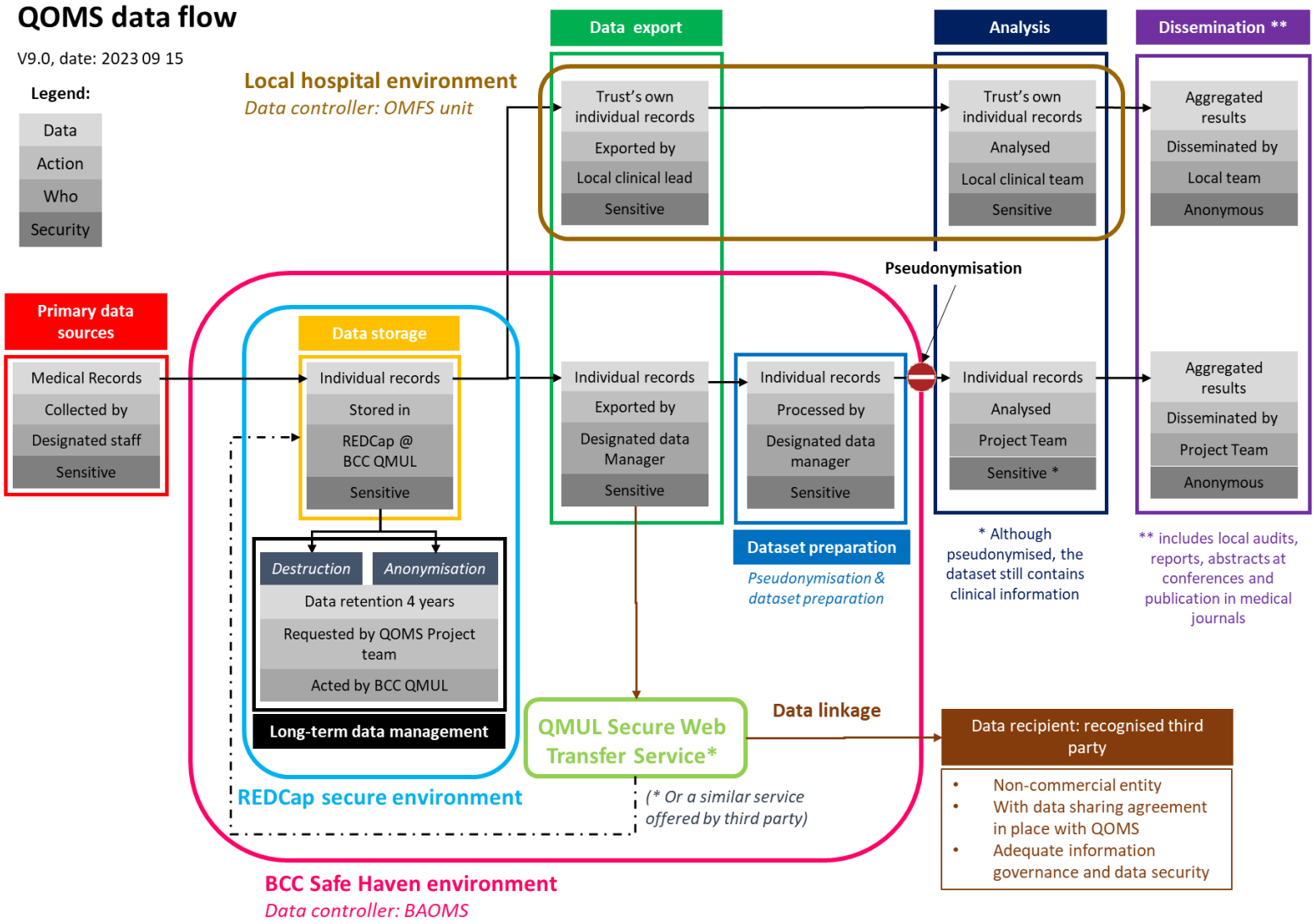
Follow this link to start again.

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



APPENDIX 3. PATIENT AND PUBLIC INVOLVEMENT PANEL DISCUSSIONS

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