QOMS TMJ registries – Protocol

PROJECT DETAILS

Project Title: QOMS Temporomandibular Joint (TMJ) registries

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Project rollout Date: January 2025 **Review date:** 6mo after launch

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

INTRODUCTION

Source: MSD Manual and NICE guidelines

Temporomandibular disorders (TMDs) are a group of musculoskeletal conditions involving the temporomandibular joint (TMJ) and surrounding/associated structures. Presenting symptoms may include pain, clicking and limited mouth opening.

TMDs are related to problems with TMJ surrounding structures (masticatory muscles and ligaments) or internal derangements of the joint itself. They are typically multi-factorial in origin but can be summarised by the bio-psycho-social model. Direct or indirect micro- and macro-trauma, systemic disorders, infections, and acute malocclusion may play a role.

Treatments can range / escalate from non-surgical (e.g. rest, NSAI drugs, bite splints and physiotherapy) to surgical options (e.g. arthroscopy and total prosthetic replacement, the latter usually for end-stage degenerative disease).

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 or workstreams (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 TMJ registries are an addition to the existing core QOMS workstreams.

RATIONALE

TMJ replacement registry

- Evidence about the benefits of TMJR on patient outcomes and the long-term safety and efficacy of the various prostheses used are available from single site studies /audits. There is currently no robust national outcome data collection for the procedure.
- One of the NICE recommendations is that "Clinicians should submit details on all patients treated by total prosthetic replacement of the temporomandibular joint to the British Association of TMJ Surgeons UK register." There has not been a workable alternative to the BATS TMJ replacement registry since it collapsed in 2019.
- **Patient-reported outcome measures:** Due to the lack of validated PROM tool specific to TMJ replacement, the working group has decided not to include PROM in this registry. This decision will be regularly reviewed in view of advances in the field.

TMJ Arthroscopy registry

There is no strong evidence about patient outcomes.

AIM & EXPECTED BENEFITS

Registries specific to TMJ arthroscopy and replacement allowing for the collation of real-world data can lead to benefits for patients, surgeons, participating institutions, and commissioners. The aims of the two registries are to measure and improve quality of care provided by TMJ surgeons in the UK.

By combining the 'real-world' national data of patients undergoing these procedures, we could:

- Produce some high(er) quality data that could be used to produce guidelines and recommendations. Registry data are the next best thing after RCTs.
- Assess the state of the field in the UK
- Measure quality of care and identify variations in practice.
- Measure patient outcomes like mouth opening, pain and diet quality, as well as complications.

The TMJ Replacement registry would also fulfil one of the NICE recommendations and allow the collection of safety and efficacy data.

INFORMATION GOVERNANCE

The two TMJ registries follow the same principles of Information Governance as the other QOMS registries.

- They are NOT research but service evaluations, and therefore do not require ethical approval (see Appendices 1a and 1b).
- 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.
- 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).
- Collection of patient identifiable information:
  - Yes for the TMJ Arthroscopy registry and for prospective* cases for the TMJ replacement registry (** < 1 year from the start of data collection*).
  - No for retrospective** cases for the TMJ replacement registry (*** > 1 year from the start of data collection*).
- When collected, patient identifiers will include NHS/CHI number (not hospital number), DOB and date of surgery, age and sex. For retrospective cases, direct patient identifiers will NOT be collected but age, sex and a partial date of surgery will be partial (date of surgery will always be 15/MM/YYYY).
- Data collection will be done directly either by dedicated members of staff (data coordinators) or directly 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.
- Population: Patients undergoing TMJ arthroscopy and total TMJ replacement procedures.
- 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 registries for their own institution only. They will be able to view, edit and download and use the data locally.

- Access to the whole dataset is limited to the project 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 third party (individuals/institutions) will require a formal request, via the online data request form. Applicants must demonstrate that they will adhere to relevant information governance regulatory framework. Applications will be reviewed by the QOMS executive group (as described in SOP).

DATA COLLECTION PROCESS

Consent: N/A

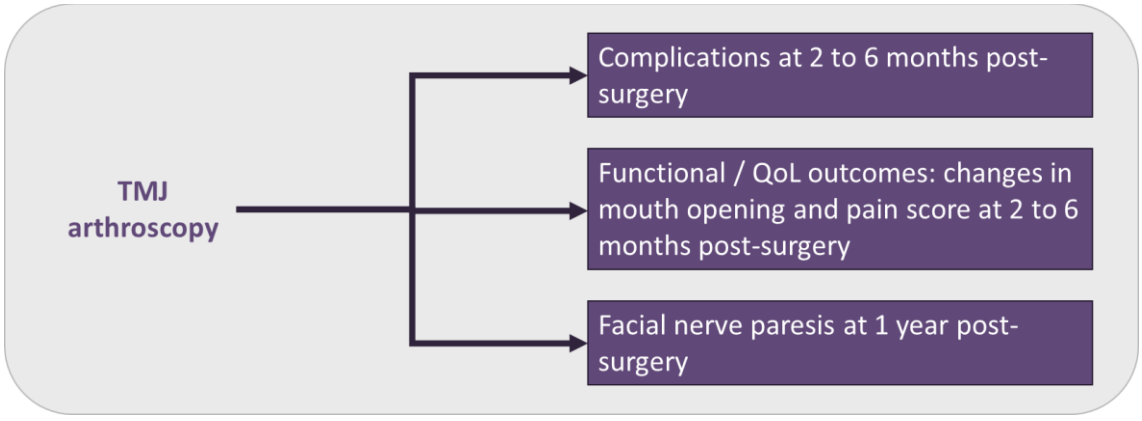
Clinical data: Data collection will be done directly either by dedicated members of staff (data coordinators) or by surgeons. Each user will be provided with a unique username and password to access the online registry. A user's data access will be limited to data collected in their own institution.

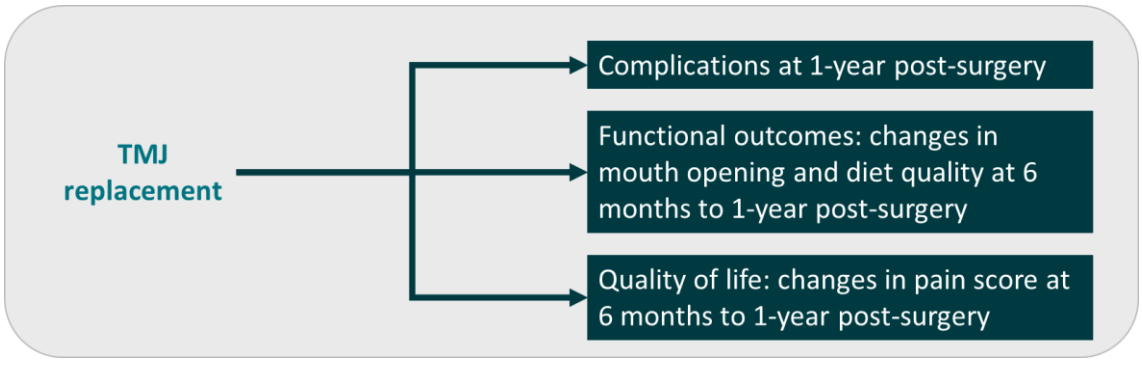
Prospective data collection will include patient identifiers, while retrospective data collection will be anonymised. Here "retrospective" means records older than 1 year at start date of data collection and as far back as 2019 (when the previous BATS TMJ Database collapsed).

DATASET

See Supporting Document 1 (SD1) and 2 (SD2) for TMJ Arthroscopy and TMJ Replacement, respectively.

QUALITY-OF-CARE METRICS





PATIENT AND PUBLIC INVOLVEMENT

Two groups of patients were approached through surgeons' networks. The first was approached to review the questionnaires for the two TMJ registries, while the second was invited to discuss the rationale, objectives, processes and set-up of the registries.

Overall, patients thought that establishing these two registries is positive and could see the benefits to patients, healthcare professionals and commissioners. They were satisfied with the way the registries were set up and the data collected and the information governance arrangements.

A summary of discussions and points made by the patients is provided in Appendix 3.

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 (*PENDING NATIONAL IG OUTCOMES*)

1. Make sure you and your colleagues are happy to contribute to QOMS. Contact the project manager to discuss what taking part to these QOMS registries 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, you need to inform them that the project has been extended to include those two new procedures.
    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, if needed, organise a REDCap training session.

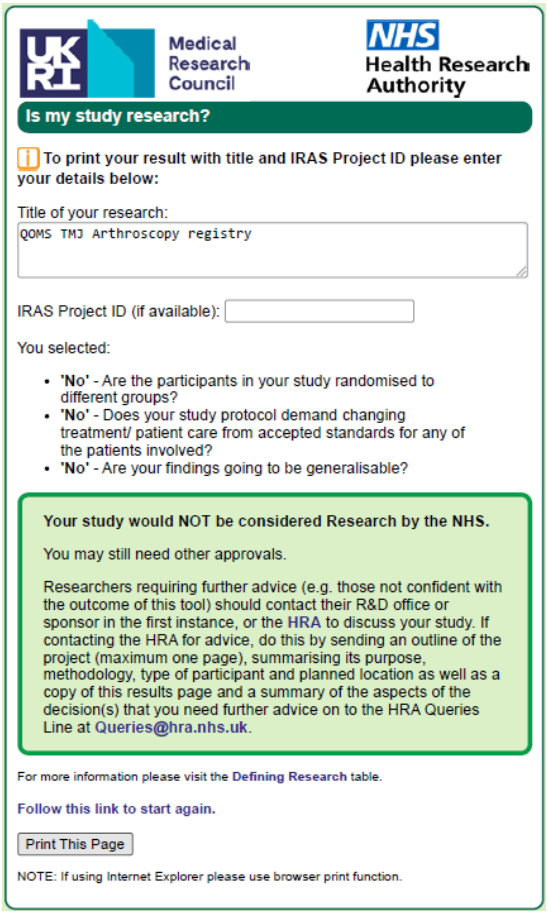
Version control

Version / Date	Changes	Approved by
Version 1.0	Original	

APPENDICES

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

1a. QOMS TMJ Arthroscopy registry



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 TMJ Arthroscopy registry

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 Queries@hra.nhs.uk.

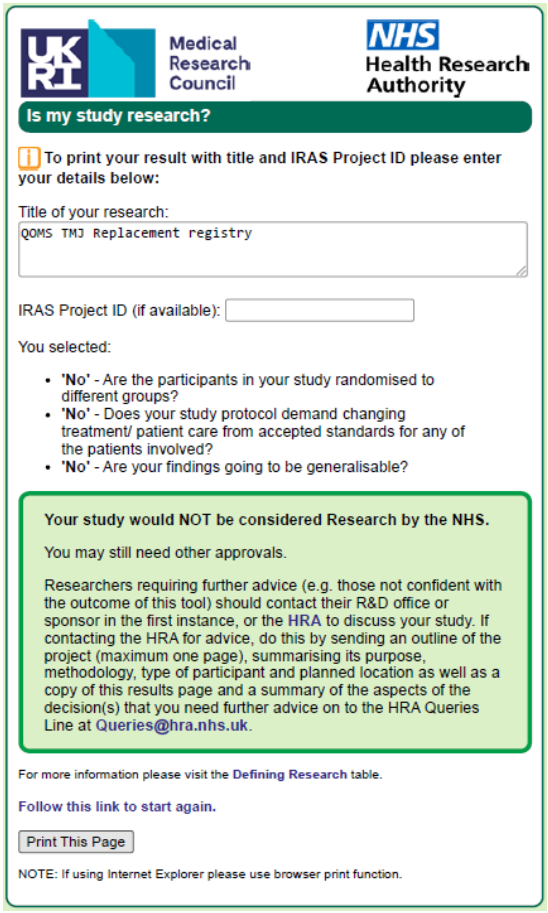
For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

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

1b. QOMS TMJ Replacement registry



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Title of your research:

QOMS TMJ Replacement registry

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
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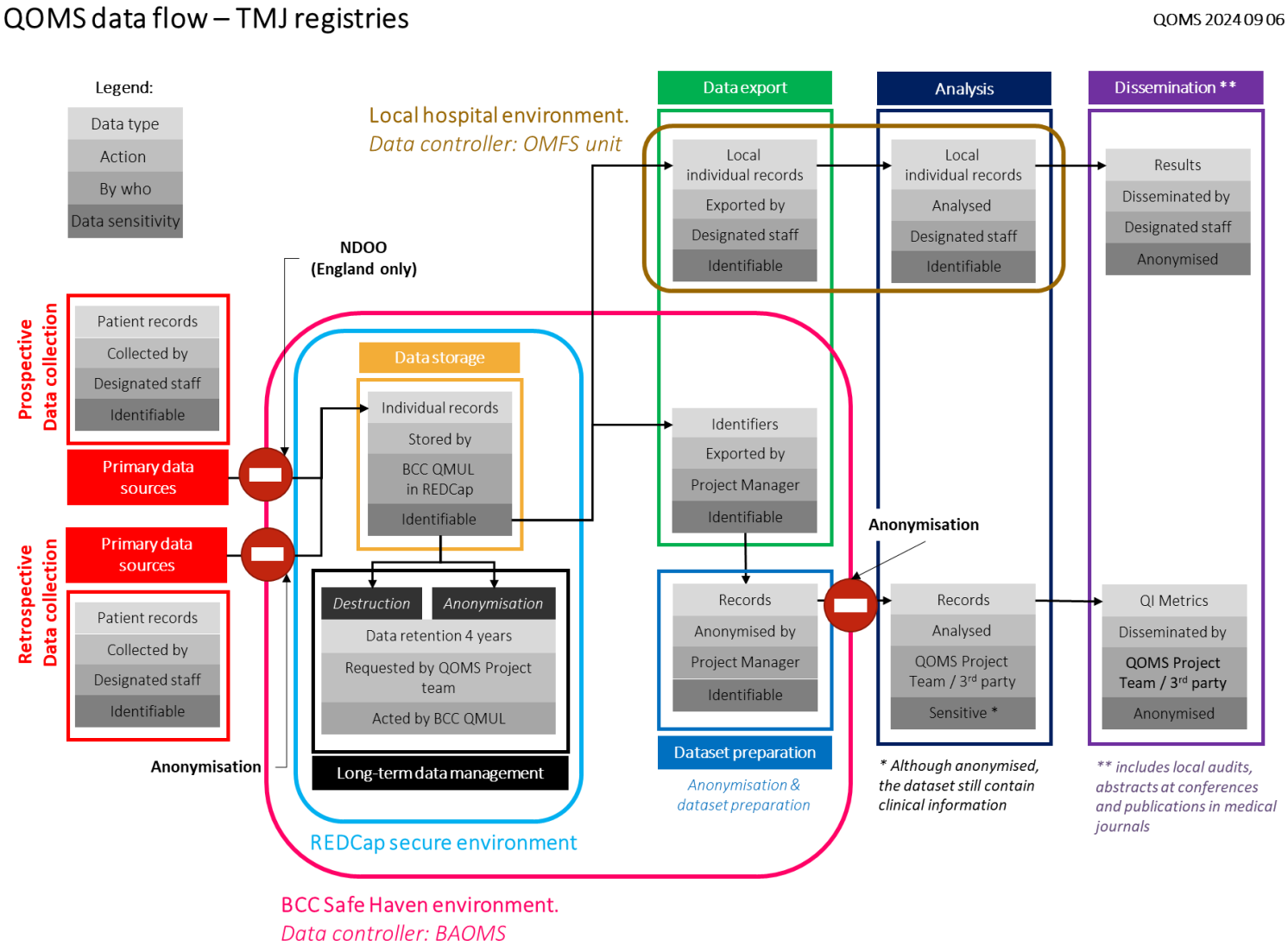
APPENDIX 2. DATA FLOW



APPENDIX 3. PATIENT AND PUBLIC INVOLVEMENT PANEL DISCUSSIONS

Area of concerns / discussions	Discussion	
Jargon in the questionnaire	The clinical questionnaires are aimed at medical professionals (surgeons, nurses…) who should understand their content. If necessary, definition or clarifications will be provided.	Consider adding a glossary of terms for patients in any shared documents
Lack of direct patient reported outcome measures. Patient experience's questionnaire?	Patients understood our decisions to not include PROM in the registries (i.e. the lack of TMJ-specific and validated PROM tool). One patient suggested to ask patients to provide "a simple concise account of their own surgical experience and quality of life in their own words (collected like a survey online for example that can be anonymised for data extraction), would be what I would consider informative." Patients from both groups suggested the use of a "generic" PROM (QoL) might still be beneficial for the project. One of the issue with this approach is how this information could or would be used by surgeons (e.g. if a patient reports being "depressed", what can it done?) → lack of direct "actionability"	Some QoL aspects, directly related to the conditions (pain, eating score…), are already collected. Other QoL issues could be related to the conditions, coincidental and/or difficult to measure. It was decided Can't get any more anything more practical, compromise integrity of data. We acknowledge the need for a TMJ-specific PROM tool, which is currently not available. We will not be adding any QoL question for now as we want to keep the questionnaire succinct and concise to get registries off the ground. To be considered at review (1 year TBC)
Include a free text question for reason for surgery	Already done (only for TMJ replacement) To be considered for TMJ arthroscopy?	To be considered at review (1 year TBC)
Post-op care - cooling machine therapy and therabite?	To be considered?	Add question in TMJR about the adjuvant therapy (TATA): 1. HiloT, 2. Therabite, 3. Orastretch, 4, SaL input 5. Physio, 6, Ice packs, 7. Botox, 8, other +FT
Medical history (ENT issues, such as hearing difficulties before and/or after, and/ or other ongoing dental issues, especially relating to the wisdom teeth)	To be considered?	Add question in TMJR about any significant issues postop (TATA): related to hearing, dental problems
Continued care	Need for adjuvant treatments (e.g. botox), referral to other services (e.g. pain managements…)	To be considered at review (1 year)