QOMS Patient-specific implant for mandible reconstruction registry – Protocol

PROJECT DETAILS

Project Title: QOMS Patient-specific implant for mandible reconstruction registry

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PSI Working Group:

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Project rollout Date: 2024 TBC **Review date: TBC**

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

INTRODUCTION

Mandibular defects represent a major challenge for modern maxillofacial surgery. Partial or total losses of the lower jaw inevitably result in functional disorders (chewing, swallowing, breathing and speaking) and morphological issues (cosmetic deficiencies, facial disproportion), both contributing to a patient's social maladaptation, permanent disability, mental disorders and decreased quality of life.

Losses of the lower jaw can be the result of (malignant and benign) tumour resection, infection (osteomyelitis), treatment (iatrogenic, e.g. radiation and drug-associated osteonecrosis), trauma and syndromic conditions (e.g. hemifacial microsomia, the first and second branchial arch syndrome, Pierre Robin sequence and Goldenhar syndrome) and can also affect structures adjacent to the mandible like the tongue, the buccal mucosa or the skin.

The reconstruction of mandibular segmental defects follows well-established biomechanical principles in relation to the defect site and size, the quality of surrounding soft tissues, and the patient's general health status. Procedures to treat these defects and restore function and cosmesis include free bone grafting procedures (or free tissue transfer), endoprostheses (conventional reconstructive plates and implants based on computer-aided design and manufacturing [CAD/CAM]), or a combination of both, depending on the clinical situation.

Industry has moved rapidly into this market. When commercial companies are used to assist in the planning and fabrication of cutting guides and custom fixation plates, the costs per patient are considerable. The rapidly expanding range of options available to surgeons from device companies creates a need for a registry of device use. Experience with other technological advances involving

implantable devices demonstrates a clear need for the post-marketing surveillance of outcomes to identify patient safety issues at the earliest possible stage.

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

The patient-specific implant for mandible reconstruction (PSI) registry will be operated as a “satellite” registry of the Oncology & Reconstruction one. It will be dedicated solely to patients treated for mandibular defects with patient-specific implants. It is important to note that although the PSI and OR registries are linked (to avoid double data entry), independent cases (i.e. not in the OR registry) can still be added.

RATIONALE

A recent systematic review (Goodson et al. (2019) J Cranio-Maxillo-Facial Surg 47) on the quality and volume of available evidence relating to the benefits and limitations of ‘three-dimensionally-printed’ titanium PSI in mandibular reconstruction indicated that of the 52 papers included, 20 (38%) were considered as non-evidence and highly biased (i.e. case-reports), 11 (21%) were prospective clinical studies and no randomised controlled trials were found. The risk of bias was either high (N=9) or moderate (N=2) for those 11 prospective clinical studies. No studies were considered to be ‘low-risk’. The paucity of strong evidence can be explained by the fact that each case / treatment is unique and that reporting as case reports and series is somewhat unavoidable.

The same review successfully highlighted the potential benefits and limitations of the use of PSI to reconstruct mandibles (Table 1). The imbalance between benefits and limitations and the presence of points in both columns probably reflects the lack of objective studies in the field. This list can however help identify points that could be assessed by a registry (e.g. planning and surgery, patient outcomes and safety…).

Table 1. Identified benefits and limitations for the use of PSI to reconstruct mandibles (Goodson et al. (2019) J Cranio-Maxillo-Facial Surg 47)

Themes	Benefits	Limitations
Surgical technique	• Reduced duration of surgery • Novel designs • Complex designs • Enhanced/novel surgical techniques and options, collaborative/multidisciplinary approach • Alternative to/avoiding free-flap reconstruction	• Lack of flexibility to surgical plan
Appearance & Social Function	• Amenable to combining with tissue engineered materials • Reproduction of 'ideal' morphology using mirroring techniques • rather than basing morphology on preoperative diseased mandible • Aesthetics/lower border contour	-
Mastication & Dental	• Improved quality of life • Planning for/simulation of functional movement in articulation/ • mastication • Optimised reproduction of dental occlusion • Augmented dental implant rehabilitation	• Limited dental rehabilitation with implant-only reconstructions
Safety & Complications	• Optimised/improved osseo-integration and biological safety (non-cytotoxicity) • Reduction in specific complications/recovery time	• Limitations in condylar reconstructions
Logistics	• Improved accessibility to design and planning software • Improves accessibility to printed implants • Speed of implant production • Economics • Planning and design can now be performed without the need for ionising radiation/CT	• Economics • Duration of planning, design and fabrication • Complexity of planning, design and fabrication

AIM & EXPECTED BENEFITS

A registry specific to the use of PSI for mandibular reconstruction allows for the collation of real-world data can lead to benefits for patients, surgeons, participating institutions, and commissioners. The overarching aim of the PSI registry is to measure and improve quality of care.

By combining the 'real-world' national data of patients undergoing mandibular reconstruction with PSI, we could:

- Produce some high(er) quality data that could be used to produce to guidelines and recommendations. Registry data are the next best things after RCTs.
- Assess the state of the field in the UK by identify circumstances / conditions where PSI are beneficial or detrimental.
- Measure quality of care and identify variations in practice.
- Measure patient outcomes, both objective like mouth opening, dental occlusion and subjective like quality of life.

INFORMATION GOVERNANCE

The PSI registry will follow the same principles of Information Governance as the other QOMS registries.

- The PSI registry is NOT a research project but a service evaluation, it therefore does not require ethical approval (see Appendix 1).
- The PSI registry is an add-on to the Oncology & Reconstruction registry and data collection is without patient consent. Amendments to existing national IG approval will be submitted to CAG (England and wales) and PBPP (Scotland).
- 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: 10 years after the end of collection of follow-up data. Data retention for the registry will be reviewed on a regular basis.
- Population: Patients presenting with a **mandibular defect** (of any origin) and treated **with a patient-specific implant with or without concomitant tissue transfer(s).**
- 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).

DATA COLLECTION PROCESS

Consent: N/A

Clinical data

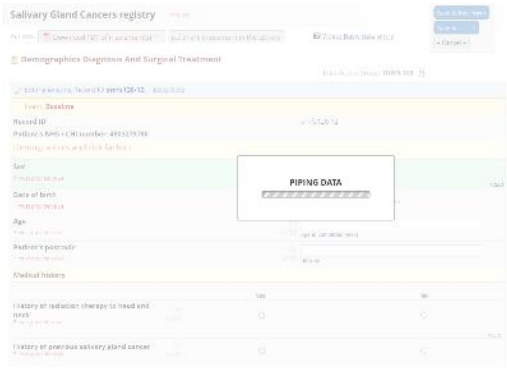
Data collection will be done directly either by dedicated members of staff (data coordinators) or by surgeons. Each user will be provided with a unique username and password to access the online registry. User's access to data will be limited to data collected in a user's institution.

Cross-project piping

Patients undergoing mandibular reconstruction with patient-specific implant may 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 registries.

Before entering data in the PSI registry, please make sure the patient already has a record in the OR one. If for some reasons, a patient is not in the OR registry, simply enter data in the PSI as you normally would.

You will notice a "buffering" every time a PSI record opens. The data from the OR registry are automatically transferred into the registry.



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":

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 Patient-specific implants for mandibular 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

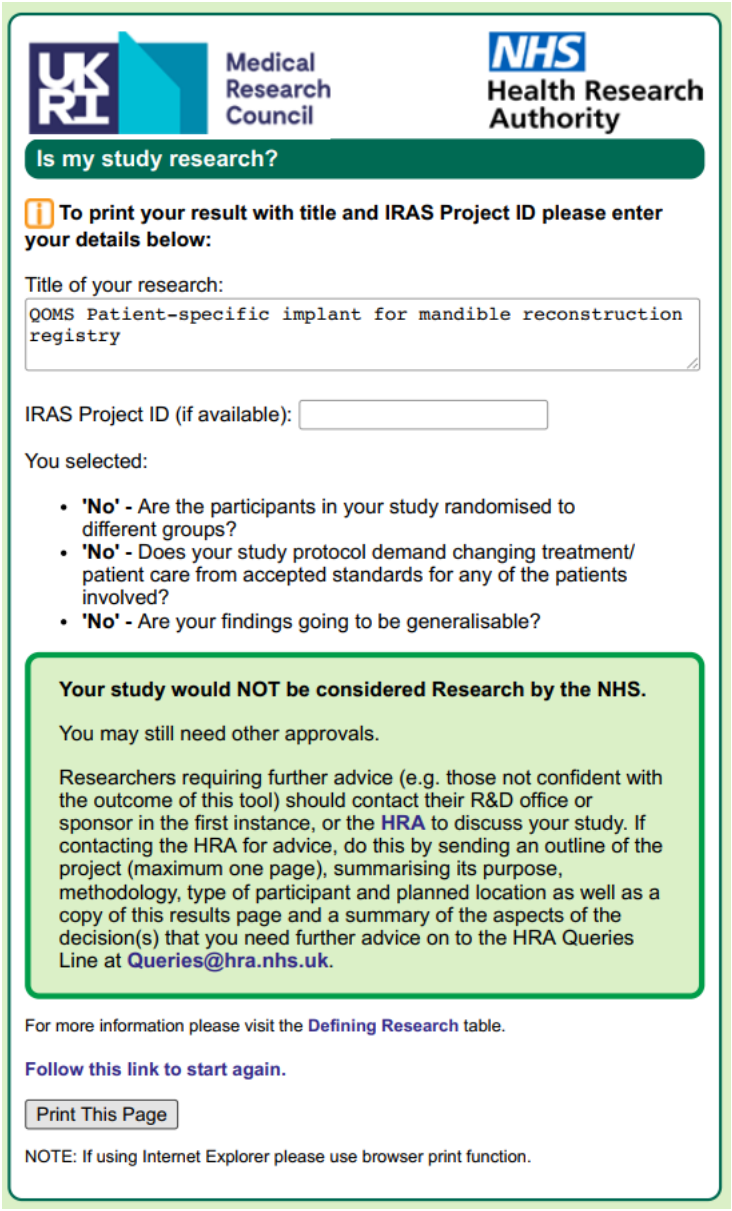
1. Make sure you and your colleagues are happy to contribute to QOMS. Contact the project manager to discuss what taking part to QOMS entails in terms of resources, time commitment, logistic… and answer any queries you may have.
2. Contact your Information Governance department
    a. If you are already contributing to the QOMS Oncology & Reconstruction registry, you need to inform them that the registry's remit now include the Patient-specific implant for mandible reconstruction questionnaire.
    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, obtain your own QR code / link to the OR registry and organise a REDCap training session.

Version control

Version / Date	Changes	Approved by
1.3 / 18/01/2024	Launch	F Puglia (PM)
1.4 / 29/01/2024	Cross-project piping added	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 Patient-specific implant for mandible reconstruction 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.

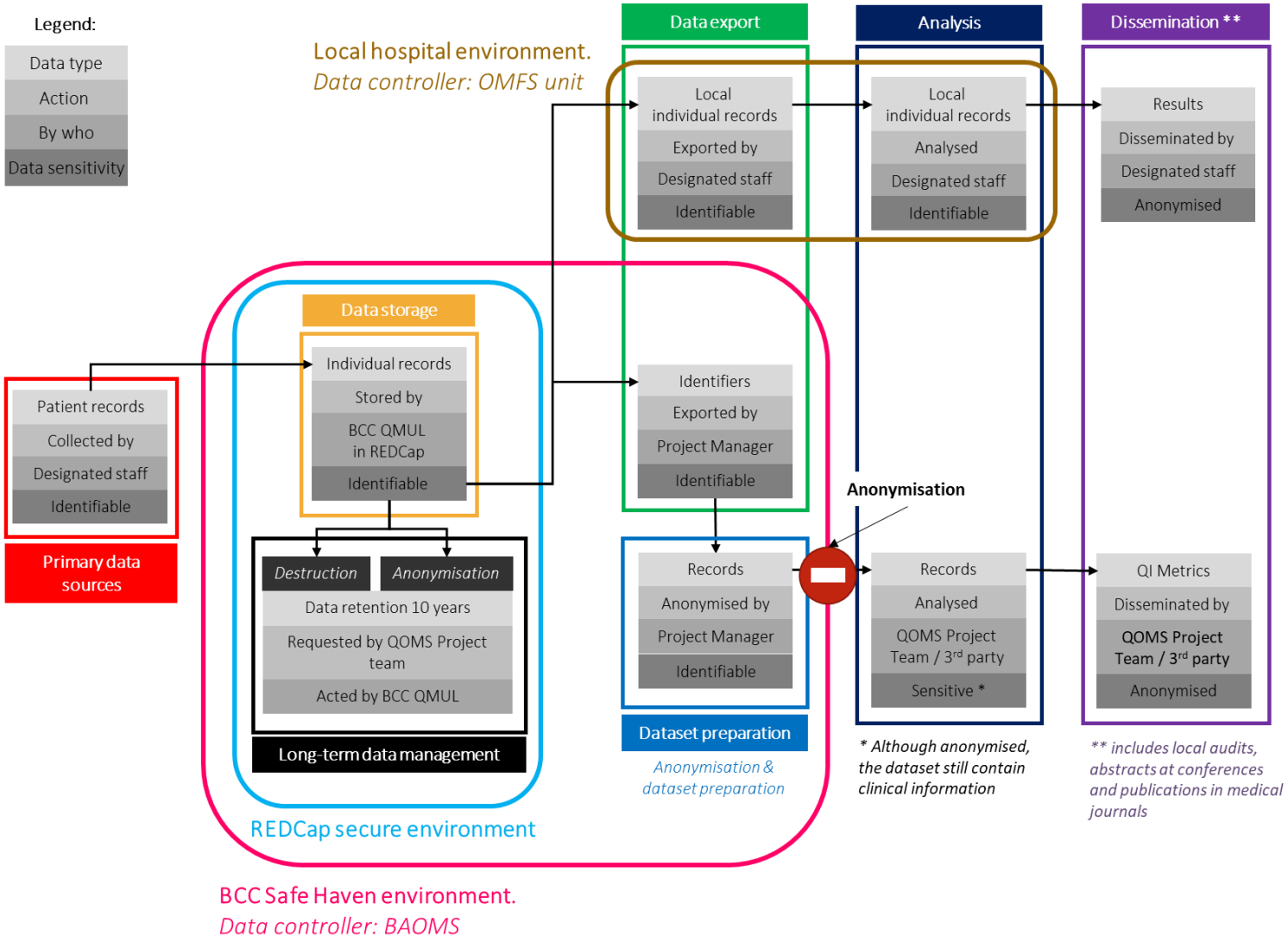
For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

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

APPENDIX 2. DATA FLOW



APPENDIX 3. PATIENT AND PUBLIC INVOLVEMENT PANEL DISCUSSIONS

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