BAOMS BOS Orthognathic PROM project – Protocol

ADMINISTRATION

Organisations

- The British Association of Oral and Maxillofacial Surgeons (BAOMS). The Association has delegated the present project to Professor Ashraf Ayoub (University of Glasgow).
- The British Orthodontic Society (BOS). The Society has delegated the present project to Professor Susan Cunningham (University College London) as (then) BOS Director of Research and Ms Helen Travess (Buckinghamshire Healthcare NHS Trust), as (then) Chair of the COG.
- Saving Faces – The Facial Surgery Research Foundation is the only charity in the UK dedicated to education and research to improve the physical and psychological treatment of all victims of oral cancer and other facial diseases. Saving Faces has close links with BAOMS and supports this project.

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

BAOMS is the leading association and owner of this project and will be data controller.

PROM working group

Name	Institution	Role	Email
Prof Ayoub Ashraf	University of Glasgow	BAOMS QOMS Orthognathic Clinical Lead	Ashraf.Ayoub@glasgow.ac.uk
Prof Susan Cunningham	UCL Eastman Dental Institute	BOS Director of Research	research@bos.org.uk
Ms Helen Travess	Buckinghamshire Healthcare NHS Trust	BOS Chair of COG	chair-COG@bos.org.uk
Mr Michael WS Ho	Consultant Maxillofacial Oncology, Leeds Teaching Hospitals NHS Trust	BAOMS QOMS Clinical Lead	michaelho2@nhs.net
Dr Fabien A Puglia	BAOMS	BAOMS Project Manager	baomsprojectmanager@baoms.org.uk

- Current members of the working group are expected to remain in position until at least the launch of the project (early 2024).
- In time, they should be replaced by their successors within their respective association. Note that BOS Director of Clinical Governance will take the place of Professor Cunningham in view of the fact this project is audit rather than research.
- The working group meets as often as necessary but at least twice a year. Meetings are usually held virtually.

RATIONALE & AIM

Following the publication of the 1st GIRFT report for oral and maxillofacial surgery (OMFS), the British Association of Oral and Maxillofacial Surgeons (BAOMS) initiated a specialty-wide, national quality improvement

and clinical effectiveness programme. This programme of work stretches across several OMFS subspecialties, including orthognathic surgery.

Given the elective nature of orthognathic treatment, the collection of Patient Reported Outcomes and/or Experiences (PRO, PRE) is quite important. Previous PRO questionnaires (known as V3 and V8) were utilised by a number of units for some time but had limitations which affected data collection.

The aim of the BAOMS BOS Orthognathic PROM project is not to develop a new PRO tool but to select the most appropriate existing and validated one(s) to collect information about patients' experiences and outcomes of orthognathic treatment.

CONSIDERATIONS & SPECIFICATIONS

The BAOMS BOS Orthognathic PROM project aims to adopt a contemporary, evidence-based, and sensitive questionnaire. The following aspects were considered:

- A single questionnaire to collect patient outcomes / experiences prospectively, at four time points: (T0) before/at the start of orthognathic treatment, (T1) when the orthodontic treatment is completed /prior to surgery, (T2) 4-8 weeks and (T3) 1-year post-surgery.
- Need to be useful for patients, orthodontists, and surgeons.
- Need to reflect patients' views of the impact of orthognathic treatment on aesthetics, function, and quality of life (QoL) outcomes.
- Robustness for the future as it may take years before a full dataset becomes available.
- Need to be patient-friendly (in term of length and time taken to complete)
- The selected scale(s) ideally needs to be reliable and validated.
- Readiness for analysis and reporting.

INFORMATION GOVERNANCE CONSIDERATIONS / REGULATORY FRAMEWORK

1. The BAOMS BOS Orthognathic PROM is a 'service evaluation' and not research, thus does not require ethic approval (Appendices 1 and 2)
2. The collection of longitudinal PRO data necessitates obtaining patient's consent.

In England and Wales, this means that this project is beyond the remit of the Health Research Authority's Confidentiality Advisory Group (HRA CAG). It does not need to go through the IRAS or the CAG section 251 processes.

The Working Group sought advice from the UK National Caldicott Guardian Council. As no other national body exists that can support such a project from a regulatory perspective, it will rely on approvals from Caldicott Guardians at individual participating hospitals.

In Scotland, the interpretation of the law is slightly different from that in England and Wales. The project may apply to the Public Benefit and Privacy Panel for Health and Social Care (PBPP). Similarly, to England and Wales, the project will rely on approvals from Caldicott Guardians from individual participating Health Boards.

DATA FLOW

Appendix 3 describes the data flow for the BAOMS BOS Orthognathic PROM project.

PRIMARY DATA SOURCE

The patient will provide the primary data by answering questions about their experiences and outcomes of their orthognathic treatment.

DATA COLLECTION

- The project is open to any hospitals interesting in taking part, providing they obtain approval from their Trust / Health Board.
- Patients aged 16 or over, undergoing combined orthodontics/orthognathic surgery or orthognathic surgery-only treatment in the UK are eligible to participate in the project.
- Patient consent will be sought prior to completing their first questionnaire. Consent will require the collection of the patient's name.
- Patient consent will be managed locally using hard copy consent forms which will then be placed in the patient's notes or uploaded to electronic patient records. Upon receipt of consent, patients will be assigned a pseudo-identifier, which will be used to track their PROM data longitudinally in the national study. Participating hospitals will be responsible for keeping the key between patient ID and the data.
- National data collection is **longitudinal, prospective, and anonymous**.
    - Collection time points are T0: before/at the start of orthodontic treatment, T1: when the orthodontic treatment is completed /prior to surgery, T2: 6 weeks post-surgery ± 2 weeks, and T3: 1-year post-surgery ± 3 months.
    - Only patients who have not yet undergone their orthognathic surgery should be included. This includes *de-novo* orthodontic patients, surgery-first patients and patients who may have missed T0 but now reached T1.
    - The PROM questionnaire does not collect direct identifiable information but includes a pseudo-identifier (which includes a Trust ID), patient's age, and sex.
- Data collection will be online. Each participating hospital will be given a **unique** link / QR code to the online questionnaire. Data will be stored in a central repository. Data generated by a hospital will be accessible to registered users from that hospital.

STORAGE

Data is collected and stored in a local version of REDCap held on secure servers, managed by the Barts Research Cancer UK Centre (BCC), Queen Mary University of London (QMUL), London, England.

As leading organisation of this project, BAOMS will act as data controller and will therefore be responsible for the data security.

REDCap is a recognised, widely used data collection software, it will be utilised for the storage of all collected data. It includes a web-based interface for users to manually enter data. It is accessed via an internet browser using two-factor authentication. REDCap also allows direct data submission using "surveys" distributed by public or individual links.

REDCAP & DATABASE ACCESS

Data is accessible to individuals only on a need-to-know basis. The project follows an access control policy to control users' access to data:

1. Each participating hospital should nominate a local lead (at consultant level) to take charge and manage the project locally. A deputy lead might also be chosen.
2. Within REDCap, the nominated clinical lead (and their deputy, if applicable) is only given access to this project and to the section of the database containing the data generated by their own hospital or Trust/Health Board. They are also assigned to a role, which dictates what they can or cannot do to data (e.g., enter, view only, edit, export data).

3. Members of the project's Working Group can view the central/whole dataset but are not allowed download or view Trust/Health Board names. The only exception is the designated data manager (DDM).
4. The DDM is a non-clinical member of the working group who has access to the whole dataset (including Trust/Health Board names) and to process it as and when needed. The DDM has the same level of training in data security as members of staff at the BCC.

Members of staff at the BCC may have access to the whole dataset. Their access is limited to specific purposes, like system maintenance, updates, data back-up, and recovery.

SHARING / TRANSFER

- Access to the central dataset

The only additional people who will have access to the central dataset are those who will be performing data quality check and the statistical analysis to produce aggregated results.

Access to the central dataset by a third party (individuals/institutions) for secondary analysis may be possible following the approval of formal requests to the working group.

- Access to local datasets

Each participating hospital has access to their own data and can use them as appropriate, e.g., for local audit purposes and quality improvement projects.

REPORTING

The Working group will provide monthly reports to BAOMS and BOS about the project's implementation and progress. The reports will include recruitment and summarised PROM quality data.

Results will be presented at the BAOMS and BOS annual meetings or as requested by the Association / Society. The project is not expected to produce results for at least 2 years to allow for the collection of a sufficient sample size / full dataset (3 or 4 time points).

DISSEMINATION

Results will be published in reports and medical/scientific journals, as well as presented at conferences. All the data will be aggregated, it will not be possible to re-identify patients.

RETENTION AND DISPOSAL

Data will be retained for 10 years after the end of the collection of follow-up data.

At the end of this period, the data will be reviewed. If the data could be used for a secondary analysis, the retention period will be extended, otherwise, the data will be completely and securely deleted.

DATA OWNERSHIP & ACCESS

- Participating hospitals retain ownership of the data they generated. BAOMS will curate the dataset on their behalf and have ownership of the central dataset.
- The British Orthodontic Society will have access to the generated data.
- For secondary analysis of the data, potential applicants will need to submit a formal request to the working group. Contact the project manager for more details.

PATIENT AND PUBLIC INVOLVEMENT

Patients have been approached through personal networks groups. Patients were provided with the PRO questionnaire and asked to provide feedback to the Working Group.

Comments and suggestions have been reviewed and considered by the Working Group and were implemented when possible / appropriate. When a comment or a suggestion was in relation to an item from a validated PRO questionnaire (used in the tool), it was not possible to amend them as it could potentially affect the validity the questionnaire.

PUBLICATION

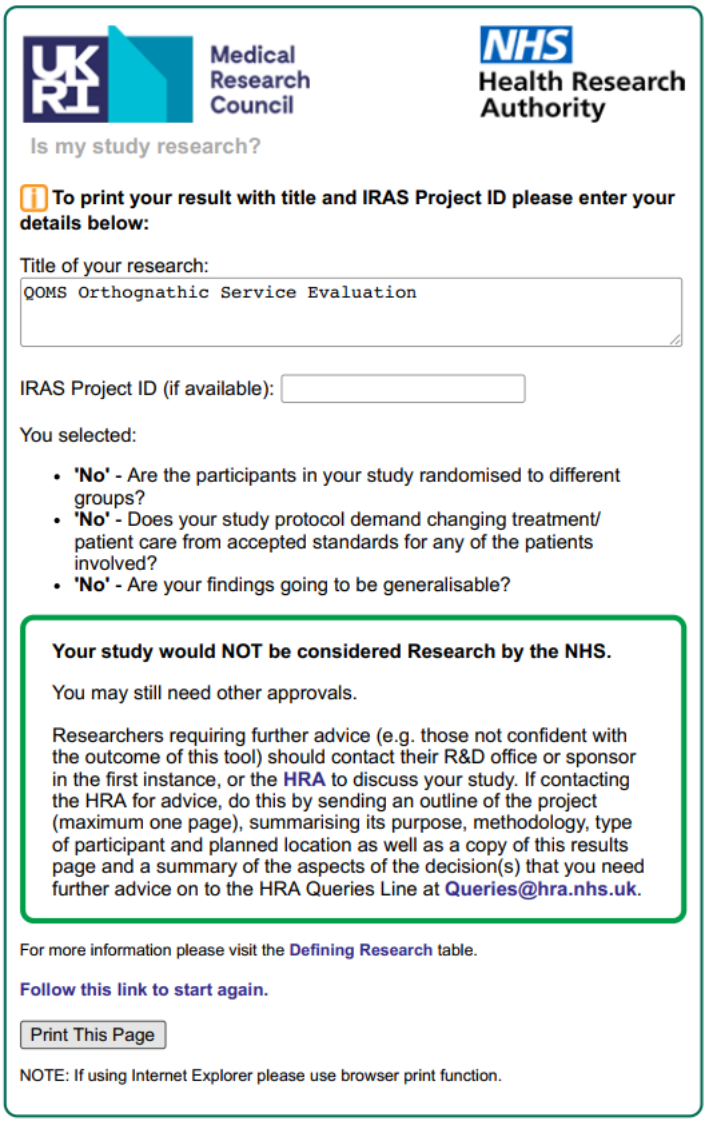
Publications based on the analysis of the generated date will acknowledge the partnership between the British Association of Oral and Maxillofacial Surgery (BAOMS) and The British Orthodontic Society (BOS) in designing the PROM tool and data collection.

Depending on the focus of the publication, papers can be submitted to either The British Journal of Oral and Maxillofacial Surgery (BJOMS) or Journal of Orthodontics which should have first refusal on any publication from this initiative.

TIMELINE

Project launch: 2024

Appendix 1. MRC NHS HRA "Is my study research?" Toolkit – results



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 Orthognathic Service Evaluation

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. MRC NHS HRA "Do I need NHS REC review?" Toolkit – results

Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

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

Title of your research:

QOMS Orthognathic Service Evaluation

IRAS Project ID (if available):

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

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check whether other approvals are required for your study.

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

To understand how research is defined, please visit the **Is my study research?** decision tool.

Follow this link to start again.

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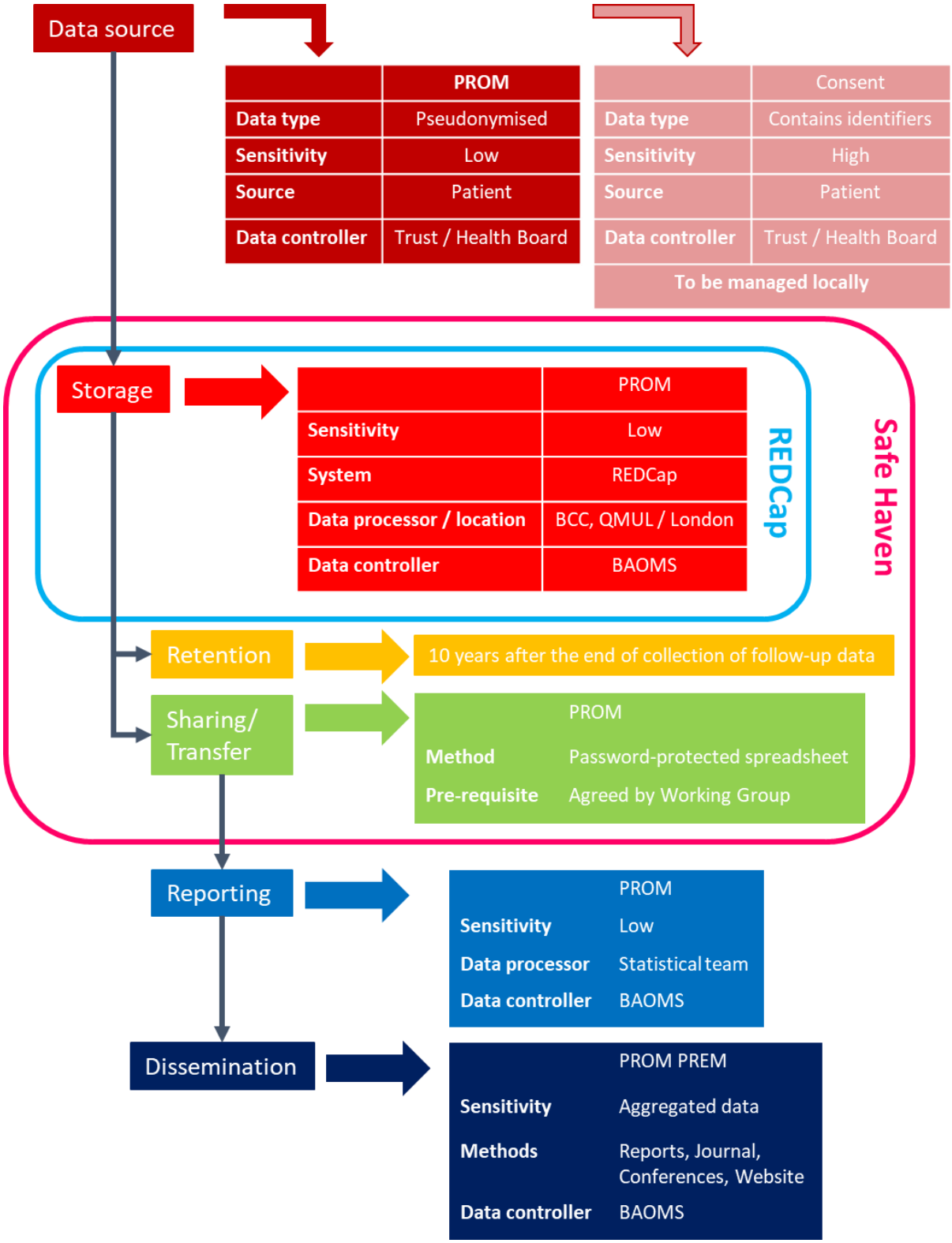
Appendix 3. Data flow

Version: 1.3 date: 01/02/2022



Document version control

Version	Change(s)	Signed off by
1.8	Update links and dates	The Project manager
1.9	Update and finalisation	The Project manager