BAOMS BOS Orthognathic PROM registry - user guide

This document was developed to guide organisations who wishes to take part / contribute to the BAOMS BOS Orthognathic PROM registry.

PROJECT DETAILS

Project Title: BAOMS BOS Orthognathic PROM registry (thereafter referred to as "PROM registry")

Project Lead: Ashraf Ayoub (Ashraf.Ayoub@glasgow.ac.uk)

Project manager: Fabien Puglia (baomsprojectmanager@baoms.org.uk)

Project rollout Date: September 2023 (pilot) **Review date:** End of 2024

Funding / Lead organisation: British Association of Oral and Maxillofacial Surgeons (BAOMS) | Royal College of Surgeons of England | 38/43 Lincoln's Inn Fields | London WC2A 3PE | E: office@baoms.org.uk

WHAT DO I NEED TO DO TO BE ABLE TO CONTRIBUTE TO THE PROM REGISTRY

- Any hospital providing combined orthodontic/orthognathic surgical treatment can take part in this project. Hospital's participation is voluntary. Hospitals can join or leave the project at any time.
- The first thing to do is to consult with your orthognathic surgeon and orthodontist colleagues to make sure they are on board to roll out with this project in your hospital and decide who will lead the project locally, the lead should be a consultant.
- The second step is to contact your hospital / trust / health board's information governance / audit department to enquire what the steps to register this project are. Data collection should only begin once governance approval has been obtained. It is **your** responsibility to arrange for local approval.
    - You may be asked to complete and sign forms (e.g., a data protection impact assessment or DPIA). The working group has already produced a DPIA for the project, that can be submitted to your hospital or used to complete your hospital's own form.
    - Your hospital / trust / health board might also ask to sign a data sharing agreement with BAOMS. That is not a problem. We can either use the project's or one provided by your hospital / trust / health board. The project manager can help you with that too.
- Once approval has been obtained, contact the project manager who will help you setting up and getting started (getting your QR code, access to the online database…).

WHAT IS THE BAOMS BOS ORTHOGNATHIC PROM REGISTRY?

The PROM project is a collaboration between the British Association of Oral and Maxillofacial Surgeons (BAOMS) and the British Orthodontic Society (BOS) to develop a 'state-of-the-art' tool to collect PROM for orthognathic patients. This 'new' tool is expected to replace existing V3 and V12 questionnaires.

Patients who undergo orthognathic treatment are consented **before** taking part in the project. They will then be asked to complete the new PROM questionnaires at 4 time points (see table below).

Those time points were chosen to be able to measure the effects of the different components of treatment. No time point beyond T3 was selected as we wish to optimise data collection and resources and avoid attrition.

Time point	When	Content
T0	Before orthodontic treatment starts	• Quality of Life Questionnaire For Patients Having Corrective Jaw Surgery • Morbidity questionnaire
T1*	On completion of pre-surgical orthodontic treatment and before surgery (e.g. joint planning meeting?)	• Quality of Life Questionnaire For Patients Having Corrective Jaw Surgery • Morbidity questionnaire
T2	Post-surgery, between 4 and 8 weeks	• Quality of Life Questionnaire For Patients Having Corrective Jaw Surgery • Process of care questionnaire (Body-Q™) • Morbidity questionnaire
T3	Post-surgery, 1 year (± 3 months)	• Quality of Life Questionnaire For Patients Having Corrective Jaw Surgery • Morbidity questionnaire

(T1 will be the baseline for surgery-first patients or if T0 was missed)*

INFORMATION GOVERNANCE FOR THE PROM REGISTRY

- The PROM registry is **NOT a research project** but an audit / service evaluation, it therefore does not require ethical approval.
- Population: Patients undergoing orthodontic and/or orthognathic treatment at any stage of the patient journey.
    - This means also that the registry may collect data about children and other vulnerable patients if they are undergoing orthognathic treatment.
- Patient identifiable information are not collected centrally (in the registry) but participants' details are kept locally.
    - The working group has developed a patient tracker spreadsheet, which will be shared with you when you are ready to set up the project in your hospital.
    - This information does not leave the hospital / trust / health board, apart from gender and age, which are collected as part of the PROM questionnaire.
    - It is **your** responsibility to keep this information safe by following your hospital / trust / health board's policies.
- The PROM registry is fully consented. A patient information leaflet and a consent form are available (Appendix 1a and 1b).
    - Data collection for a patient should not start before they are consented.
    - There is no system in place to consent paediatric patients (<16 years of age).
- No clinician details are collected. Hospital / trust / health board's identity are encrypted.

- *For England and Wales only*. Because the PROM registry is consented, the National data opt-out does not apply. Participating patients retain all their patient's rights including to object to the processing of their data, and to withdraw at any point without giving reason.
- Your organisation is the data controller, while BAOMS and any subcontractors are the data processors.

WHY IS THE PROM REGISTRY CONSENTED?

Data collection involves the collection of patient-reported outcome (PRO). Patients need to consent to complete the PRO questionnaire.

ARRANGEMENTS FOR THE PROM REGSITRY

- 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 an NHS Digital DSPT toolkit and an ISO 27001 certification.
- Patients directly submit their data onto the online database.
- 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.
- Data access is under access control policy:
    - Each participating hospital will have a designated clinical lead (at the consultant level). They are given full access to the records entered in the registry for their own institution only. They are able to view, edit and download that data to use it locally.
    - Access to the whole dataset is limited to the project manager (Fabien Puglia), who is a nonclinical member of the working group. Other members of the working group only have access to anonymised information.
- Access to the central dataset by any third party (individuals/institutions) requires a formal request, via the online data request form.
    - Applicant must demonstrate that they will adhere to relevant information governance regulatory framework.
    - Applications are reviewed by the PROM Working Group (process similar to that described in the QOMS "Data Request" SOP).
    - If the application is approved, no identifiable information will be shared with the third party and a summary of their proposal will be published on the BAOMS website.

DATA COLLECTION PROCESS

- **Consent:** The consent process is managed locally. Printed patient information leaflets and consent forms will be available to the patients at clinics. A copy of the signed consent form will be given to the patient.
- **Patient Reported Outcomes (PROs):** Patients will be given an identifier in clinics and asked to complete the PROM questionnaire online. They can either use a departmental digital device (e.g., tablet) if available or their own smartphone by scanning a QR code.
    - The QR code is unique to the participating hospital
    - Alternative data collection solutions should be discussed with the working group.

WHO HAS REVIEWED THE PROM REGSITRY?

The BAOMS BOS Orthognathic PROM registry was developed by consultants in oral and maxillofacial surgery and orthodontics. A group of patients was convened to discuss the set up and plans for the registry.

DATA OWNERSHIP

Participating organisations will retain the ownership of the data they entered, while the ownership of the central dataset will be with BAOMS. BAOMS will curate data on behalf of participating organisations.

PUBLICATION POLICY

The British Journal of Oral and Maxillofacial Surgery (BJOMS) or the Journal of Orthodontics 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.

SUMMARY

How to get started

1
- Engage with surgical and orthodontic colleagues to discuss participation.

2
- Contact project manager to discuss the project.

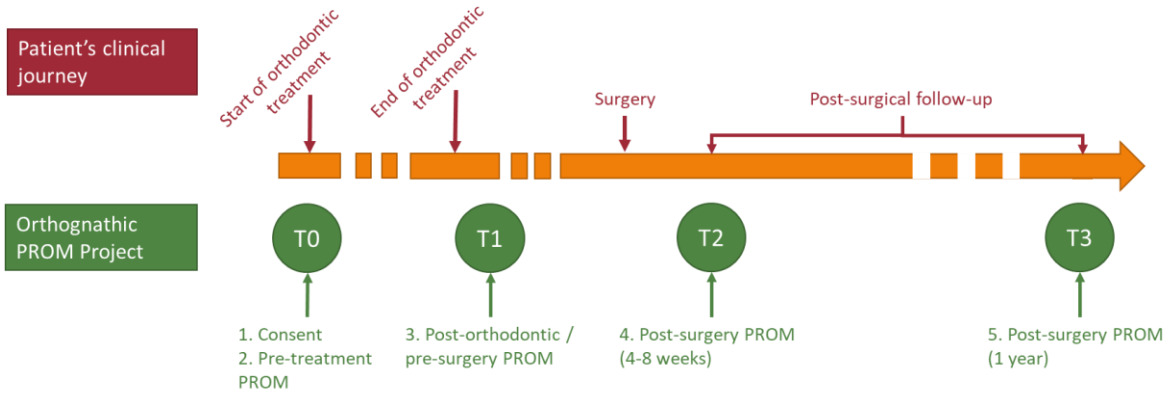
3
- Decide how to implement the project locally: choose lead(s) to coordinate / manage the project.

4
- Information governance: contact your hospital's audit department to register the project.

5
- Pilot
- Print material for patients (leaflets, consent forms and posters)

6
- Start collecting data

What is the data collection timeline?



Note: If a patient misses T0, they can still be included if they can complete T1, T2 and T3. Surgery-first patients will also only complete T1, T2 and T3.

APPENDICES

Appendix 1a. Patient information leaflet

You have been given this leaflet because you have been referred for corrective jaw treatment. The surgeons, orthodontists and other health professionals who care for you would like to invite you to take part in this BAOMS BOS Orthognathic PROMs project.

Please read this leaflet carefully. It explains who we are, what we are doing & how we treat your information to guarantee your confidentiality and anonymity.

WHY WAS I GIVEN THIS LEAFLET?

Orthognathic treatment refers to treatment to reposition the teeth (orthodontics) and/or the upper, lower or both jaws (orthognathic surgery).

The British Association of Oral and Maxillofacial Surgeons (BAOMS) and the British Orthodontic Society (BOS) want to hear your opinion about your treatment and how you feel, before and after treatment.

To do that, we would like to complete a questionnaire at various stages of your treatment (i) prior to the start of your orthodontic treatment, (ii) immediately prior to your surgery, (iii) 4-8 weeks after surgery and (iv) 1 year after surgery.

WHY ARE YOU COLLECTING THIS INFORMATION?

We want to find out how your quality of life has been affected by your condition and by your treatment. We hope this information, received directly from patients, will help clinicians and NHS commissioners understand more about this type of treatment and therefore improve care for patients in the future. Secondary evaluation may also be performed to look at how different aspects of the patients' experience affect each other; this is where anonymised data is looked at some time later to potentially explore other aspects of your care linked to the data collected.

WHAT WOULD TAKING PART INVOLVE?

Participation will take up a little bit of your time. If you agree to take part, you will be asked by your clinical team to complete a questionnaire about your motivations, outcomes, and experiences of your orthognathic treatment at the 4 time points described above.

WHAT INFORMATION ABOUT ME ARE YOU COLLECTING?

Your answers to the questionnaires will be stored completely separately to your consent form. Only your clinical team will be able to link your questionnaire responses with your personal details. No information that could identify you directly is collected as part of the questionnaire.

WHAT WILL HAPPEN TO MY INFORMATION?

Your consent form will be stored as part of your clinical record at the hospital where you are being treated. The information from your questionnaires will be collected and stored on secure computers managed by the Barts Cancer Research UK Centre at Queen Mary University of London (BCC, QMUL). Access to your answers will be restricted to your clinical team and a limited number of approved members from QMUL and the project team. No identifiable information is being collected.

IS MY INFORMATION SAFE?

Yes, your information is safe. Very strict rules and secure procedures are in place to ensure that your information is kept safe. The systems and procedures in place at QMUL comply with international standards and QMUL continuously monitor and adapt them as necessary to maintain security over the lifetime of the project.

How long will my data be kept for?

Records of your consent will be kept for 10 years after the end of data collection. Your answer to the questionnaires will be kept for at least 10 years but this could be extended.

Can I not take part?

Participation is voluntary and you can change your mind at any stage without it affecting your care. If you decide to not take part, when you complete the consent form, this will not affect your care in any way.

If you change your mind about taking part, you can withdraw at any point without providing any reasons. Simply let know your treating team. You will be asked whether you want all your information removed or whether you are happy for us to keep the information we have from your questionnaires so far, but we will not be contacting you for follow-up.

Who is organising and funding this study?

The surgeons in BAOMS and the orthodontists in BOS have designed this project. BAOMS leads this project and, as data controller, is responsible for looking after your information and using it properly. The costs for the project are being supported by BAOMS.

Who has reviewed this initiative?

This project has been reviewed by BAOMS, BOS and by patient representatives. The project has also been reviewed and authorised by this hospital for data protection and security prior to their participation.

What if there is a problem?

If there is a problem, please tell your clinician in the first instance, or someone else at the hospital. If you still have concerns, you can lodge a complaint with the Information Commissioner's Office (ICO), the supervisory authority in the UK responsible for the implementation and enforcement of data protection law, if you have concerns about the way your personal data is being handled. You can contact the ICO via telephone (0303 123 1113) or email (W: https://ico.org.uk/concerns/).

Finding out more

If you would like further information or have any questions, please contact:

BAOMS | Royal College of Surgeons of England, 35/43 Lincoln's Inn Fields, London WC2A 3PE | E: qoms@baoms.org.uk | W: https://bit.ly/qoms-at-baoms

Appendix 1b. Consent form

Patient sticker

BAOMS BOS Orthognathic PROM project - Consent form

Before signing this consent form, please read carefully the accompanying patient information leaflet (version: 2.0, Date: 18/01/2024) and ask your clinical team any questions you may have. Once you are satisfied, please

complete the consent form below if you are happy to consent to the collection of your personal information – note you must initial all boxes to be eligible to take part.

Please **initial** or tick the boxes below

1. I confirm that I am the patient and that at the time of signing this consent form, I am at least 16 years of age or more. ☐
2. I confirm that I have read the participant information leaflet (version 1.6, date: 01/02/2022). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. If I choose to withdraw, I understand that no further information will be collected about me and that I will no longer be asked to complete questionnaire for this project. ☐
4. I understand that the information collected may be used and shared to support secondary analysis. ☐
5. I understand that my name will be collected as part of the consent process. Consent forms will be kept in the hospital where it was collected and will not be shared with any other organisations. No identifiable information will be collected as part of the questionnaire. ☐
6. I AGREE to take part in this project and for my information to be collected. ☐

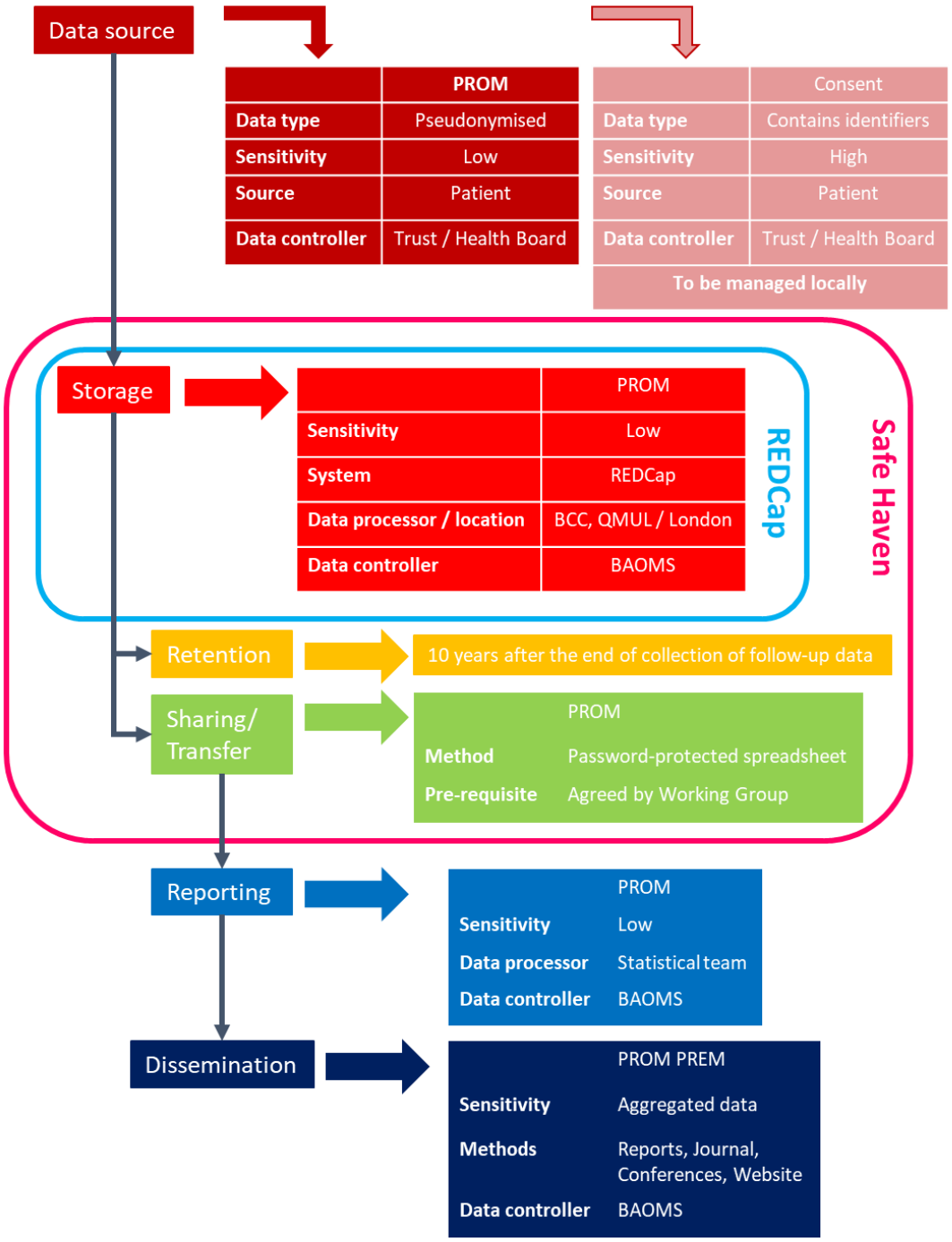
Patient's name and signature:

To be completed by the Person taking consent: I confirm that I have discussed the collection and storage of information for the BAOMS BOS Orthognathic PROM project.

Name and signature of the person taking consent: **Date of consent:**

For more information, please contact: BAOMS | Royal College of Surgeons of England, 38/43 Lincoln's Inn Fields, London WC2A 3PE | E: qoms@baoms.org.uk | W: https://bit.ly/qoms-at-baoms

The original of this form should be kept in the patient's note and one copy should be given to the patient.

Appendix 2. Data flow

BAOMS BOS Orthognathic PROM 01/02/2022