QUALITY AND OUTCOMES IN ORAL AND MAXILLOFACIAL SURGERY (QOMS) PROTOCOL - SHORT VERSION -

March 2019

CONTENT

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Note to the reader: the present document is a shorter version of the actual protocol. If you wish to read the whole document, please contact either BAOMS office (office@baoms.or.g.uk) or QOMS Project manager (baomsprojectmanager@baoms.org.uk).

INTRODUCTION

Modern healthcare is facing a series of challenges:

1. The upward health expenditure has become unsustainable,
2. Populations in Western countries are undergoing several transitions (ageing population, rise of non-chronic diseases…),
3. Healthcare system are permanently underfunded,
4. There are unwarranted variations in services, access and outcomes between and within countries.

Under those circumstances, commissioners have to ensure that expenditure is directed towards services that deliver a demonstrable benefit in health-related well-being to patients and towards services that provide the highest quality of care (value-based purchasing). Commissioners in their deliberations on purchasing are likely to take a negative view where there is an absence of data supporting those aspects of care.

In general, a high-quality provider dispenses safe, effective, efficient and patient-centred care, and is committed to the continuous improvement of those domains. This statement raises questions for a large proportion of surgical activity in general, and oral and maxillofacial surgery (OMFS) in particular: what are the best possible outcomes and their associated care practices? What is the correct surgical procedure in a given situation? Providing answers to these key questions should be the focus of any effective quality management or quality improvement (QI) system with the consequence of reducing variation by coalescing performance around the best performers and generalising knowledge of best practice.

Currently, there is little in the way of systematic collection of data indicative of effectiveness or quality across OMFS and no consensus on appropriate metrics. Reflecting these realities, the President of the British Association of Oral and Maxillofacial Surgeons (BAOMS) 2018, Mr Ian Martin, has determined that BAOMS should provide leadership on this issue. It is the President's view that implementing systematic QI in OMFS, and ensuring effectiveness of care provided based upon appropriate metrics is key to the continued successful development of OMFS care in the NHS and reflects the core culture of the Association. It also recognises the imperative for quality management across the NHS.

The BAOMS QI initiative has taken form as the Quality and Outcomes in oral and Maxillofacial Surgery (QOMS), a collaboration between BAOMS and the National Facial and Oral Research Centre (NFORC) / Saving Faces™, with support from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD). The project's design reflects the constraints and culture of the NHS and the needs of the specialty. It proposes to collect and report outcome data for whole surgical teams functioning within an acute hospital and not for an individual surgeon so that improving care becomes a whole team activity with surgeon leadership. This approach is more likely to yield meaningful numerator and denominator values and have the additional effect of fostering team cohesion.

Further details about the project were published in the July 2018 editorial of the British Journal of Oral and Maxillofacial Surgery.

PROJECT'S AIMS AND OBJECTIVES

OVERALL AIM

To set up and develop a sustainable quality management and clinical effectiveness programme that will deliver continuous improvement in the care of patients undergoing OMFS within all parts of the NHS and will demonstrate health-related benefits to patients from selected OMFS activities.

OBJECTIVES

Objective 1. Quality management

To put in place a system to measure quality of care in OMFS with views to develop benchmarks in OMFS practice and improve quality of care though QI activities.

Objective 2. Clinical effectiveness

To develop a platform to collect appropriate care data to establish practice-based evidence of clinical effectiveness for the management of certain conditions or safety of certain treatment in OMFS.

Objective 3. Continuous personal and career development

To promote clinicians' participation in the programme, support their appraisal and revalidation process. The project will try to develop and nurture QI skills and culture throughout the specialty and to see a coalescence of outcomes around the very best performers across all quality metrics.

Objective 4. Research

To perform secondary analysis (e.g. data-mining, modelling) of the data held. This objective will only be addressed once QOMS has achieved enough maturity and collected enough data. QOMS anticipates requiring ethics approval down the line to fulfil that objective.

SECTION 1: PREPARATORY PHASE

PROTOCOL DEVELOPMENT

A protocol is an important document that contributes to the overall quality assurance of a project. [2] The 'QOMS protocol' sets out to the objectives, design considerations and the processes of QOMS. It provides the working definitions for the metrics used to assess quality of care, the information about how data will be processed, and how results should be interpreted and disseminated.

METRICS SELECTION

Types of metrics: the Donabedian model accounts for three types of measures of care: **input** variables like **structure** measures, which reflect healthcare system or settings and **process** measures describing the actual care received by the patients, and **outcome** variables/measures, which reflect the impact of "care" on the health status of patients. Whichever type they are, those measures need to be specific, measurable, achievable, relevant to the users or the providers and time-specific.

Surgical risks and volume must be considered when selecting metrics for a procedure. It should be added that in this context 'surgical risk' represents the intrinsic risks of a surgical procedure, regardless of the additional risks associated with the patient's health (e.g. frailty, comorbidities…).

- **Procedures with low volume and low risk** should not be high priority for QI and the focus should be instead on the procedures described below.
- **Procedures with low volume and high risk**: procedure volume, a structural measure highly correlated with mortality and morbidity in major surgery, is likely to be the only practical quality indicator, although it needs to be re-tested for OMFS.
- **Procedures with high volume and high risk** are assessable using direct outcome measurements.
- **Procedure with high volume and low risk** are more problematic. These procedures are likely best judged by process measures and patient-reported outcome measures (PRO / PROMs).

Issues surrounding some low-volume procedures (e.g. rare diseases) or treatment choice (e.g. implants) could be addressed using a disease or an intervention registry.

COMMUNICATION

QOMS requires a solid communication strategy to engage with the BAOMS membership from the start and later down the line to ensure effective dissemination of its findings.

Engagement: we are going to develop a communications strategy designed to deliver "positive, clear, and consistent framing of key messages to reaffirm the aim and value" of QOMS.

Dissemination: QI projects need to be reported first, locally, persuasively and persistently to members of our own institutions and communities of practice and second, and more formally, through dissemination to a wider audience through publication.

SECTION 2: LESSONS LEARNED & CONSIDERATIONS

DATA ACQUISITION

1. Direct data collection should be limited for each surgical activity. The project aims to collect 3 metrics for each activity as well as, where necessary, a selected number of risk-adjustment variables.
2. To avoid duplication, where possible, metrics or useful data should be selected which are already gathered in the care process or by other audits / registries.
3. To collaborate with other audits / registries to organise data push from OMFS members into those data repositories and to set up data sharing agreements.
4. The project team must facilitate the process helping the surgical teams navigate the necessary approval hurdles (clinical effectiveness, Caldicott Guardian…) at a local level.
5. The database could be designed to replace the medical notes, e.g. by allowing transfer or printing.
6. Direct data extraction from existing administrative database should be set up.

DATA QUALITY

1. To give ownership of the project to the membership and to bar the use of data for competitive purposes whilst acknowledging commissioning care based on published 'quality metrics' is a positive development.
2. To have process in place to quality assure the data and if necessary to go back to the units to query missing data and mistakes. This might be time consuming and difficult but will drive data quality up across the specialty.
3. To give units the opportunity to perform their own analysis to confirm or deny findings.
4. To trust that other data collection initiatives that might be used by the project, have stringent quality assurance procedures in place.

SUSTAINABILITY AND SUPPORT OF THE PROJECT IN THE FUTURE BY BAOMS COUNCIL

The President has already addressed this by seeking the support of future elected Presidents. To maintain momentum and ensure the Council's continued focus on the project, it would be desirable to add the outcomes project to the portfolio of a current council member. That elected office holder would liaise with the Project's clinical lead and project manager and report on activity at council meetings. Furthermore the elected council member would also chair the meetings of the QOMS Steering Committee.

USE OF THE DATA

1. Patients, their representatives and the general public have to be reassured that the data collected (1) are necessary and have benefit (i.e. improving care), (2) will be treated lawfully in terms of confidentiality.
2. A consistent positive message around the need to demonstrate that there is value to patients in our surgical activity and that we are a specialty who recognizes the need to engage in QI will be important.
3. QOMS will not collect (and thus report) individual surgeon data. QOMS will also need to develop different levels of reporting, e.g. national annual report, individual department reports. No department will know the identity of the other departments on any report. All national presentation and reporting of data will be anonymised. No department will be permitted to use the data for what might be seen as competitive advantage on website or printed material. QOMS must however acknowledge that if successful, data pertaining to quality of care might being de-anonymised for use by CCG's for the purposes of planning/purchasing care based on quality metrics.
4. BAOMS will not make the data available to third parties including the Departments of Health in the four nations (DH).
5. The data in QOMS will be accessible based upon rules integral to the technological build.

IT

The development of the data entry and management system will be contracted to a commercial entity with expertise and experience in the delivery of this type of project.

WHO ARE THE OTHER STAKEHOLDERS IN THIS INITIATIVE?

NFORC / Saving Faces ™, NCEPOD

NHS England, NHS Wales, NHS Northern Ireland, NHS Scotland

In addition, BAOMS exists for colleagues in the **Republic of Ireland** and how they might be integrated in to QOMS will be explored.

Patient and Public Involvement (PPI)

ETHICAL AND LEGAL ISSUES

1. The QOMS project will seek to obtain clinical data without consent through HRA CAG Section 251 for England and Wales, or equivalent process through PBPP in Scotland. Consent might be sought from patients in Northern Ireland, where no process equivalent to Section 251 application is in place yet.
2. Although consent WILL NOT be sought from patients (except maybe in NI), it WILL be sought from database users as their name, surname, email address... will be stored.
3. QOMS or some of its components may need to be reviewed and approved by an Ethics Committee. QOMS as a whole will need approval from local Caldicott guardians.
4. The collection of identifiable data will allow QOMS to link with existing datasets, e.g. administrative dataset, like Hospital Episode Statistics (HES) for England, or other registries or audits. Data sharing agreements will need to be drawn.

SECTION 3: SURGICAL PROCEDURES AND METRICS

The Cleft, Craniofacial and Aesthetics subspecialties decided not to participate in QOMS at this point in time. The Trauma, Salivary, and Temporomandibular Joint (TMJ) subspecialties will develop specific registries (Table 3). The Oncology, Reconstruction, Trauma, Orthognathic, Oral and Dentoalveolar and Skin subspecialties agreed on procedures and metrics (Table 4).

Table 3. QOMS Registries

Subspecialty	**Conditions / Procedures**	**Type**
Reconstruction	Mandibular reconstruction	Patient-specific implant registry (safety and surveillance)
Salivary	Salivary gland cancers	Disease registry to assess clinical effectiveness
TMJ	Arthroplasty and ankylosis	Disease registry to assess clinical effectiveness. The registry will be administered independently of QOMS but the data will form part of the QOMS annual report.

Table 4. Procedures and metrics

Subspecialty	Procedures	Conditions	Metrics
Oncology	Resection (with or without reconstruction)	Oral cavity and oropharynx Squamous Carcinoma Cell (SCC) (all cases)	Margins
	Elective or therapeutic lymphadenectomy	Oral cavity or oropharynx SCC (previously untreated primary)	Number of lymph nodes*
	Major head and neck surgeries (resection / neck dissection and reconstruction)	Head and neck cancers	Unexpected return to theatre (RTT) In hospital mortality
Oral and dentoalveolar	Dentoalveolar surgeries	All	Waiting time Appropriateness of tier attribution
	Third molar extraction	All	Postoperative surgical complications
Orthognathic	Le Fort I osteotomy Mandibular ramus osteotomy	All	PROM Unexpected RTT Readmissions Length of stay (LoS)
Reconstruction	Free tissue transfer	All	LoS
	Free tissue transfer	Oral and Head and Neck cancers	Flap survival
	Head and Neck / Maxillofacial Reconstructions (Free tissue transfer, Grafts, Locoregional flaps, Prosthetic)	Oral and Head and Neck cancers	Time (d) to commencement of adjuvant radiotherapy if required.
Trauma	Mandibular fractures	All	Unexpected RTT within 90 days Readmissions within 90 days
	Orbital wall fractures	All	Unexpected RTT within 90 days Readmission within 90 days Visual problems and enophthalmos at 90 days

Skin	Complete excision	Non-melanoma skin cancers	Rates Margins Site Complications / Infection

* To support the 'New Interventional Procedure' Audit Requirements, the Sentinel Lymph Node Biopsy in Early Oral Cancer might be integrated into the audit.

SECTION 4: PROJECT GOVERNANCE

IT

The IT solution will address the Project's needs (data collection, creation/management of database, help/technical support and providing server for hosting database). Data will be stored on and accessed from servers located at **?** and administered by **?**.

QOMS COMMITTEES AND SUB-GROUPS

The Project Team will be the executive body of the project and deal with its day-to-day running. It will be headed by the Clinical Lead and include the project manager, the chairs of the sub-groups (namely the clinical lead for IT, clinical lead for data management, and clinical lead for site visits and quality assurance) and NFORC personnel (Appendix B). The Project Team will report to and be part of the Steering Committee. The Steering Committee will also include the leads and deputy leads of the participating SSIGs, and external advisors and consultants (Appendix B). It will be chaired by an elected member of the BAOMS Council and overseen by the BAOMS Council. Steering Committee members will have a voting right on the project decisions. Finally, the Advisory Committee will be simply the Steering Committee with the addition of external guests, specialists, who would have been invited to attend by the Committee for their expertise and advice but who would have no voting rights. Composition and responsibilities of the Committees, Project Team and Sub-groups are respectively presented in Table 5 and Appendix B.

Table 5. Roles and responsibilities of QOMS Committees and sub-groups

	Functions
BAOMS Council	Oversight
Steering Committee	● Overall responsibility for registry development, set-up and implementation, ● Oversight: making sure QOMS follows the protocol Strategic direction ● Development: selection and review of metrics, review ● Sign off data monitoring, data analysis as well as strategic direction, oversight and allocation of registry resources ● Data sharing agreement ● Publication policy ● Handling of complaints regarding the conduct of the project, holding project executive team to account
Project Team	● Implementation reviewing formal access requests and ethical assessment

	● Support local groups / project manager will facilitate this in every way possible preparing documentation and assisting in obtaining the necessary approval of Trust and Health Board Clinical Effectiveness Departments and where possible enlisting the support of those departments in data collection by using existing sources of NHS data
Data sub-group	● Data processing and reporting ● Communication with surgical teams ● Produce newsletters and public updates for wider audience ● Produce graphics and tables for embedding into Trust intranet portals so quality outcomes can be seen with other department information
IT sub-group	● IT requirements ● Database management access
Clinical Site Assessment sub-group	Organise visits of best performer sites and of sites requiring help with change

LOCAL SITES

Composition of local QOMS Teams: each participating site will have a local QOMS Team made up of volunteers from the local OMFS clinical staff. Each local QOMS Team will be composed of a local clinical lead and a deputy lead to cover and audit delegates. Local clinical leads will (1) be responsible for the implementation of QOMS at their site, (2) act as the point of contact between the local QOMS and Project Teams (e.g. queries to and from the Project Team) and (3) in coordination with the Project Team, also manage audit delegates, e.g. with their selection. Audit delegates will be responsible for entering data and addressing queries.

Members of the local QOMS Teams: local clinical leads will be local surgeons. Audit delegates will either be consultants entering their own data or junior members of staff entering data on behalf of consultants. Participation of other non-clinical staff members should be discussed with the Project Team. Local Clinical Leads could also be Audit delegates. In case a consultant has delegated data entry to another users, they will need to check and lock the records entered on their behalf. The exact process of verification for QOMS will depend on the capabilities of the IT system and the willingness/ability to commit of the surgeons to perform that task. Our final choice will be informed following piloting. Local QOMS Team will also be responsible for informing their managers and Caldicott Guardians (or equivalents) about the audit activities (the Project Team will support them with all appropriate documentation and in any other way they can).

Access to the audit system: local clinical leads, audit delegates and whoever else will need access to the database will have to register as a user. The registration process will depend on the IT system. This point will be specified once an IT provider has been selected. Users will have to agree to the System's Terms & Conditions. Users will be assigned different access privileges according to their roles and their needs to access data.

Relationships between Local QOMS and Project Teams: the relationship between local QOMS Teams and the (central) Project Team will evolve with time. For example, in the setup phase, the Project

Team should help in building the local team and support them in obtaining local approval. In the initiation phase (piloting), the Project Team should teach local audit delegates how to use the webtool. Finally, during active data collection, the Project Team should follow up the progress of the local team with regular quality checks and feedback.

BAOMS Regional Clinical Outcomes Lead: The BAOMS regional representative for OMFS has a responsibility to the Association to provide leadership on Clinical Audit, Quality Outcomes, and Quality Improvement at the regional level. Three Regional Leads will serve on the QOMS Steering Committee on a rotating basis. The Regional Leads will assist Local QOMS teams in providing support, advice, and organisation of regional audit meetings. However, like all other clinicians the Regional Leads will not have access to the identified outcome metrics for any unit other than their own. The Regional leads will also play a role in site visits for local teams who perform significantly better than the average of peers. The position of Regional Clinical Outcomes Lead will have a 3-year term of office, with an optional extension of 2 years.

OTHER GOVERNANCE ENTITY

Governance requirements mean that QOMS will need to appoint or assign some roles / functions to either individuals or entities:

- A **data controller** is a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be processed. By contrast, any person (other than an employee of the data controller) who processes the data on behalf of the data controller is a **data processor**.

→ The data controller for QOMS will always be a non-clinical member of the Project Team. Their responsibilities will include exporting data with identifiers for linkage, collating data and preparing datasets.

- A **data protection officer** (DPO) assist an organisation to monitor internal compliance, inform and advise on data protection obligations, provide advice regarding Data Protection Impact Assessments and act as a contact point for data subjects and the supervisory authority. According to the ICO, a DPO can be an existing employee or externally appointed but they must be independent, an expert in data protection, adequately resourced, and report to the highest management level.

→ Choosing a DPO For QOMS will be a member of the organisation hosting QOMS.

DATA PROCESSING

Data processing refers to about anything done with data and includes collection, recording, storing, using, analysing, combining, disclosing or deleting. Under GDPR, data processing must follow seven key principles. Personal data are information about a particular **living** individual. Health data are classified as special category data (SCD), which are more sensitive and need more protection and require **both** a lawful basis and a separate condition for processing to be identified.

Legitimate interest seems to be the most appropriate for QOMS out of the six lawful basis, according to the Information Commissioner's Office's (ICO) lawful basis interactive guidance tool. Legitimate

interest is the most flexible lawful basis for processing and may be the most appropriate basis when (1) the processing is not required by law but is of a clear benefit to the user or others; (2) there's a limited privacy impact on the individual; the individual should reasonably expect you to use their data in that way; and (3) you cannot, or do not want to, give the individual full upfront control (i.e. consent) or bother them with disruptive consent requests when they are unlikely to object to the processing. Relying on legitimate interests means that the users are taking on extra responsibility for considering and protecting people's rights and interests. Although not required by GDPR, it is recommended for the Project's audit trail, to complete a legitimate interest assessment (LIA) to (1) identify a legitimate interest, (2) show that the processing is necessary to achieve it, and (3) balance it against the individual's interests, rights and freedoms. Legitimate interest cannot be assumed to always be the most appropriate lawful basis for processing.

QOMS seems to fall within the scope the following **conditions for processing special category data:**

- (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;
- (i) processing is necessary for reasons of **public interest in the area of public health**, such as protecting against serious cross-border threats to health or **ensuring high standards of quality and safety of health care** and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;
- (j) processing is necessary for **archiving purposes in the public interest, scientific or historical research purposes or statistical purposes** in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

SECTION 5: QOMS DESIGN AND LIFE CYCLE

QOMS is a complex intervention, built around 3-year cycles:

- Year 1: Baseline. Data are collected while no changes are implemented.
- Year 2: QI. Data are collected as changes are tested using for example the Model for Improvement (MFI) - Plan Do Study Act (PDSA) framework.
- Year 3: Impact assessment / Implementation. Data are collected to see if the changes of Year 2 have been implemented / sustained and if quality of care has improved.

At the end of each cycle (year 3), a review will take place whereby metrics will be assessed and kept for the next round or replaced by new ones. For metrics to be retained, they must serve a purpose. New surgical procedures will require some measurement of health-related benefit. Addition of a new measurement must be accompanied by the loss of a previously employed metric so that there is no overall increase in the burden of work associated. In deciding upon adoption or removal of any quality metric, four criteria should be applied: the variable must be measurable and actionable by the OMFS

team and show evidence of variation associated, and have a meaningful impact upon patient outcome. [10, 32]

Section 6: Definitions of the target population and participating sites

Patient populations

- Audit Database: All patients undergoing a **specific procedure** for the treatment of a condition in the OMFS department of a hospital within the data collection period will be eligible for entry.
- Registry: All patients fulfilling the inclusion/exclusion criteria of the registry will be eligible for being included.

Participating sites

OMFS departments within NHS hospitals based in the UK will be eligible to participate to QOMS but their participation will not be mandatory and they will be able to choose to participate or withdraw at any point, regardless of size or location. It is hoped that as QOMS becomes established and recognised as useful, participation will increase and departments will actively seek participation.

Where a department performs a low number of any given procedure, QOMS made the decision from the onset that for those hospitals, some department-level analyses may not performed as they may compromise patient confidentiality and would not be fair. However, those data will be retained for risk adjusting and standard-setting purposes.

Once validated and tested in NHS institutions the QOMS Project Team will endeavour to extend participation to the membership working in the Republic of Ireland.

Section 7: Data collection

Principles

Data collection should be easy, reliable, efficient and not wasteful. It is a critical process of any project and needs to address several imperatives. It must be standardised across participating sites. For each performance metrics, it must specify data sources, definitions and format. The data collected will include identifiers, the numerator and denominator to calculate each metrics and a limited number of confounding variables.

A detailed handbook describing why and how data items are collected will be produced and made freely available on the BAOMS website section dedicated to the project. The handbook will also provide clear definitions of fields to improve consistency of data point choice. A helpdesk will be available to support units with their queries.

Data sources

Data can come from different sources. It is an important factor to consider as it determines ease-of-access and quality.

Primary sources: To assess quality of care, data generated during every-day care will be collected. This concerns information about the patient, their surgery and recovery afterwards. Some information will be provided directly by the patient (e.g. perception about general health) or by clinicians (e.g. surgeons, doctors and nurses) and will include information about the type of surgery, anaesthesia and care received before, during and after surgery. In some instances, patients may be contacted by the surgical team to complete a short questionnaire prior to and/or in the weeks / months following surgery, only if the patient has consented and is still willing to do so.

Secondary sources: this refers to another database. Secondary here means data have been processed according to the rules of that other database. Secondary sources are used either to avoid duplication of data collection / reduce workload, to verify denominator data accuracy or to get additional, complementary data, like a long-term picture of care. Obtaining data from another source is called (data) linkage.

DATA COLLECTION PROCESS

Data collection will be prospective and depending on the surgical volume of the selected procedures and resources, either **continuous** (i.e., complete enumeration: **all** eligible cases should be entered in the database) or not. When not continuous, data collection could be either a **snapshot** (i.e. **all** eligible cases should be entered in the database for a limited period of time, e.g. for 3 months between February 1st 2019 and April 30th 2019) or based a **representative sample** (the latter implies the use of a clearly specified sampling procedure subjected to audit). [2]

CLINICAL REPORT FORMS

Clinical report forms (CRFs) for each audit and registry will be developed to collect the necessary data items for the project. An informative and well-structured CRF simplifies the database design and validation. CRF development should follow a multidisciplinary approach, involving clinicians, statisticians, data managers and IT developers.

Which data items should be collected? Item selection is a critical factor. Smaller datasets may encourage participation and have good case ascertainment and data completeness; however, they may not be fit for purpose. Large datasets may be limited by significant missing data. Database flexibility is an option but may be expensive and complicated, but one that is inflexible can become outdated as clinical practice develops. To reduce workload and avoid the collection of 'nice to know' data, the relevance of each data item should be assessed with regard to the objectives of the Project.

How should data be collected? QOMS has to acknowledge that individual sites and surgeons may favour means to enter data based on background, computer literacy or access… Therefore, data entry will be made possible via (1) a web-based tool (webtool), which is the recommended/preferred method, (2) Downloadable versions (pdf) of the CRFs and (3) the use of pre-formatted Excel spreadsheet to upload data. (→ Future development)

ORGANISATIONAL AUDIT

The local clinical lead from each site will be asked to complete a resource/institution questionnaire once every three years, i.e. once a QOMS cycle. The results of the organisational audit will used (1) to assess the state of the specialty at the local, regional and national levels, (2) to help establish groups

of similar units for comparisons, (3) to adjust some of the metrics, and (4) finally to interpret the results.

SECTION 8: DATA QUALITY

Data monitoring will be done by specialists.

PRINCIPLES

Information that support data quality will be available to users when entering data (e.g. built-in help in the webtool) and as a central document, the "QOMS data management manual". This manual will cover data items, data collection, management and quality assurance for QOMS. The final document will be agreed by the QOMS Steering Committee and the BAOMS Council and made available to all stakeholders and potential sites to help them decide whether or not to participate.

DATA CLEANING

Data cleaning is the process of detecting and resolving data problems to improve quality. Based on the needs and resources of the project, QOMS will start by looking into the QA indicators described in Table 10 according to the agreed schedule (Table 11). Data are validated on a number of levels:

- Individual form/patient: missing, unusual, illogical and invalid data,
- Individual site: duplication and unusual patterns; data collection reliability,
- Overall and hospital levels comparisons to ensure sites are all collecting and validating data to the same rules: case ascertainment, accuracy and completeness.

Table 10. Quality assurance indicators

Quality	Domains	Indicators	Level
Accuracy	Internal consistency	% errors	<5%
	Domain checks	Bias	
	Inter-rater reliability	% errors	<5%
	External validity (data source and/or reference dataset)	Agreement	
Completeness	Missing data / Don't know	Rate	<5%
Capture	Case ascertainment	Coverage	>90%
		Gaming	
		Bias	

Table 11. Schedule of recurring reporting tasks

Task	Frequency
Email	Daily

Update dataset (~ back-up), Database fault and errors	Weekly
Recruitment number, Form completion rate, Missing data, Specific investigation	Monthly
Report	Yearly

SECTION 9: STATISTICAL ANALYSIS

Data analysis will be done by specialists.

PRINCIPLES

Analysing QI data is no different from other types of data. The analysis should be sharply focused on the appropriate objectives and should be as simple as possible, subject to avoiding misleading oversimplification. In particular, it is essential that the compilation, presentation and statistical interpretation of performance measures should be (seen as) impartial.

Each metric will have its own descriptive sheet that details why and how it is collected, calculated and analysed.

PROCEDURE FOR LINKAGE AND MINING ADMINISTRATIVE DATABASE

Record linkage to other data sources such as administrative databases or other databases can play an important and central role in audit and registry programmes by augmenting their value. Linkage can be probabilistic and deterministic linkage. Whenever possible QOMS will adopt a **deterministic strategy** to link data. This means that we will need to identify common participants between databases using unique identifiers, like patient identifiable data (PID).

The process of linkage will be the responsibility of the Project's data controller who will:

- Produce the list of identifiers to link datasets,
- Collate datasets,
- Anonymise and distribute the resulting dataset for analysis.

Any exchange of data between QOMS and other trusted third-party institutions will be done under a defined data-sharing agreement, whereby the security, planned uses, control and fate of the data are clearly defined. In cases where QOMS is the recipient of secondary data, we will rely on the donor institution's data sharing agreement and vice et versa.

DATASET PREPARATION AND SELECTION OF FINAL SAMPLE

For each analysis, the final sample needs to be described (how many records are included, excluded) and justified. Flowcharts can be used to summarise sample selection.

ANALYSIS PLAN

This section assumes that data quality checks have been performed prior to analysis and that the results are satisfactory.

Unit of analysis: patient care episode

Statistical package: there are several statistical packages available either requiring a license like SPSS or STATA, or open source like R or WEKA. The choice of the statistical package will be led by the Data Sub-group.

Description: the statistical analysis will be performed **by ?** under the direction of the Project's Data Sub-Group **using ?**. The analytical plan will be prepared by the Data Sub-Group in collaboration with ? and reviewed and agreed by the Project Team and Steering Committee.

1. Description of the data (i.e. count and proportions for categorical data, mean and standard deviation (SD) for normally distributed data, median and interquartile range (IQR) for non-normally distributed data) and calculate the crude rates for each metrics.
2. Simple analysis: comparisons between levels of categorical data (e.g. sex), simple correlations and univariate analysis between expected confounding and outcome variables.
3. Adjustment of the metrics and potentially more complex analyses (e.g. sensitivity analysis).

Adjustment

Some metrics will need to be adjusted to account for the effects of some known or suspected confounders and risk factors. Those variables will need to be selected on one-on-one basis and limited to a pre-defined, agreed number. Confounders will be systematically selected and adjustment applied (e.g. sex, age or BMI...). Risk factors will also be adjusted for according to their known importance as published in the literature and data availability and on a case-by-case basis. Adjustment techniques currently used in audits include logistic and linear regressions, Bayes classification models, Decision Tree and artificial neural network.

Metric adjustment can be considered as an evolving system. It will need to be updated regularly in view of new publications and findings. Until enough data has been collected in the first instance (probably the first year of the study), no risk adjustment will be possible unless previously published algorithms are used at the outset.

SECTION 10: INTERPRETATION

PRINCIPLES

Interpreting the results of the analysis is an important part of the process. Based on the results, one has to explicitly state whether targets (objectives, questions…) have been met and how confident one is of the results. Thus those targets need to have a sound basis, take account of prior (and emerging) knowledge about key sources of variation, and be integral to the project design. Interpretation also needs to avoid the pitfall of being absolute: metrics should be seen as 'screening devices' and not be over interpreted.

IDENTIFICATION OF GOOD PRACTICE AND SHORTCOMINGS IN QUALITY OF PATIENT CARE

Assessing quality of care means that on the one hand QOMS will identify areas of good practice and on the other hand the gaps between the actual and expected quality of care being delivered to patients. Participating departments should easily be able to determine their levels of performance in relation to the identified shortcomings in quality of care. In reference to that last point, simply identifying gaps in quality of care is not enough, QOMS should support participating sites to

understand the causes of their shortcomings, through provision of examples of analysis of variation and root cause analysis of audit findings and case studies.

The contributions of existing processes, systems and tools should be recognized explicitly in order to guide participating sites to implement the right actions to achieve improvements in care.

SECTION 11: REPORTING

PRINCIPLES

Reporting should focus on showing findings to help answer questions in line with the Project's objectives using the simplest mode of presentation and avoid being misleading. Simplicity does not mean discarding measures of uncertainty either in tables or figures and it is therefore almost always necessary to give an indication of variability. Where the conclusions are for immediate action or discussion, graphical methods will typically be best; where further analysis and comparison may be involved a tabular mode may well be preferred. How data are presented should be considered at the design stage (data collection and analysis) and included in the protocol.

For QOMS, numerator (and denominator?) data will be submitted to the Project Team via the webtool. Based on the types of analysis done, data is likely to be reported using control and bar charts or funnel plots. Statistical advice will be sought to ensure reporting is of a high standard. Case studies and awards at conferences can be used as a means of maintaining momentum and sharing best practice. Lay versions of the reports / summaries will be produced for the general public, including patients and their representatives.

No participating department will be able to access the data (inputs and outputs) of any other department. They only have access to their own data compared with the national average and to their peers (anonymised). Only non-clinical members of the project team will have access to departmental identifying data.

PRELIMINARY DATA AND PEER REVIEW OF CASES

Data collected should be formally reviewed by participating sites through a local peer group process prior to publication. Participating sites should be able to carry out their own ad-hoc analyses of their data. The peer review process should include the analysis of risk-adjusted results and cases not consistent with good practice at local level and involve preparation for implementation of improvements.

Participating sites should be able to correct or modify their data held in the national clinical audit related to their performance prior to publication, if evidence of error or inappropriate interpretation in data collection is supplied to the Project Team. There can be concerns about gaming of results if participating clinicians review their own data prior to national publication of findings. However, a study of clinicians identifying 650 medical exceptions to quality-of-care measures concluded through a peer review panel that 93.6% of the exceptions identified were appropriate, 3.1% were inappropriate and 3.3% were of uncertain appropriateness.[2] After clinical staff received direct feedback about inappropriate exceptions, 42% changed management. The peer review process took less than 5 minutes per case. The IT system also collects metadata accessible by the Project Team, which will allow to check if and how data were modified.

Graphical representations

Commonly representations of QI data include box plots, control charts, bar charts and funnel plots.

Online and real-time reporting

→ Future development

Procedures to identify / select similar units

Similar units will be identified using data modelling as the project matures and will involve the application of weighted values to variables of relevance to the procedure under consideration. Some factors are likely to be derived from the organisational audit (i.e. provider factors) and others from the different case mix profiles. → To develop further

Registry data

Adverse events

In parallel to its QI activities, QOMS is also interested in clinical effectiveness and will include two specialised registries (Table 3). The Salivary Gland Cancers registry will deal with disease management while the Reconstruction Implant registry will be concerned with safety and surveillance. One aspect those registries may deal with is adverse events.

The broadest definition, which directly ties in adverse events to QI, is "instances which indicate or may indicate that a patient has received poor quality care". An adverse event has to have the following three key characteristics:

- **Negativity**: the nature of the event is undesirable, untoward, or detrimental to the healthcare process or to the patient. Effects can be classified according to their (medical) severity.
- **Impact**: the event has some negative impact or potential impact on a patient or patients. In some instances, the definition can be restricted to only include events where the patient has suffered some definable and identifiable ill effect.
- **Causation**: the event results from some part of the healthcare process. A suspected or established event to a healthcare process is called a reaction.

Another aspect of adverse events to consider is whether they are expected or not, i.e. is the event a known risk / side effect or totally new?

Reporting adverse events

Clinicians should systematically report adverse events and indicate whether a causal link to the treatment can be established, serious events to be at least possibly related are reportable.
There are several factors to consider:

1. What constitutes a serious event?
2. Should the definition be established from a medical perspective only or should it incorporate patient's perspectives?
3. How long after a treatment occur can an event happen (days, weeks, months, years?)
4. Should adverse events be reported on an individual basis or aggregated?

SECTION 12: WEBTOOL

Data is collected using a web-based tool (webtool) developed **using/by ?**. Data are stored centrally in servers **hosted by ?**. The webtool will be accessible via a link on the BAOMS website to the NFORC website, which will be hosting the logging page. Links to other audits of interests to BAOMS will also be present on the logging page. Each individual wishing to use the webtool to collect and/or access data needs to be registered with the Project team. They will be assigned a unique username and password, the latter will need to be changed upon logging in for the first time. The project team will attribute each user a role (e.g. audit delegate, local clinical lead, consultant), which carries a range of privilege with regard to data access (Table 12).

Table 12. User level and privilege access to the registry

	User level			
Privilege	**Audit Delegate**	**Unit Audit lead**	**Global administrator**	**Data controller**
Create / Edit	No	Yes	Yes	No
Create record	Yes	Yes	No	No
Save	Yes	Yes	No	No
Submit	Yes	Yes	No	No
Unlock	No	Yes	Yes	No
Delete	No	No	Yes	No
Search	Yes	Yes	Yes	No
See confidential information (local)	Yes (unlocked records only)	Yes (unlocked and locked records)	No	N/A
Download anonymised dataset (local)	No	Yes	No / Yes	N/A
See confidential information (global)	No	No	No / Yes	Yes
Download anonymised dataset (global)	No	No	Yes	Yes
Download identifiers	No	No	No	Yes
Metadata access and download	No	No	Yes	Yes

SECTION 13: INFORMATION GOVERNANCE

Information governance is the framework that brings together all the legal rules, guidance and best practice to ensure necessary safeguards for personal information. Data processing refers to about anything done with data and include collection, recording, storing, using, analysing, combining, disclosing or deleting.

DATA FLOW

Given the nature of the project, QOMS needs to adopt a hybrid data management structure, i.e. it must incorporate both a centralised and decentralised system to manage the flow of data between the participating sites and data storage facilities. Every user needs to access all or part of the database to perform different tasks. The storage solution needs to be a central, secure repository.

→ See Appendix J. Detailed data flow (provisional)

DATA SOURCES

→ See "Data sources" section of this document

INTELLECTUAL PROPERTY POLICY AND DATA SHARING

Intellectual property (IP) with respect to registries is a complex issue. There are a number of different aspects, including database rights, copyright, confidence and contract rights, all of which are governed by National and EU legislation. The exact framework for defining IP with regards to registries has not yet been developed, and because different groups often manage various components, registries are potentially exposed to the risk of contention.

Furthermore, it is important that any release of data (such as release to trusted third parties responsible for analysis or publication) is done under a defined data-sharing agreement, whereby the security, planned uses, control and fate of the data are clearly defined.

Local team should be able to access and download their OWN data for checks and individual site-level analysis.

→ To develop further

DATA STORAGE AND RETENTION/DISPOSAL

Data storage and retention falls under the principle of 'storage limitation' in GDPR. Briefly, the starting point of storage limitation is that **personal data cannot be kept for longer than it is needed**. There are no indication as to how long data can be kept; that decision relies with the users who must justify not only how long data can be retained, based on their purposes for processing but also why data in a form that permits identification of individuals are kept. Two provisions are included in GDPR: (1) **completely** anonymised data can be retained indefinitely and (2) personal data can be kept for longer for public archiving, scientific or historical research purposes or statistical processes. In cases where no retention period for personal data has been decided, regular reviews should be put in place to assess if those records and information are still needed. Finally, when data held is no longer needed, it can be erased or anonymised.

QOMS will collect personal data, some of which will be (potential) identifiers. Access to identifiers will be needed for data management purposes at the local level, for future linking of data with other audits or registries and administrative databases. Linking data to administrative databases can have three purposes, a) to collect missing data or consolidating the data held (other information and data quality), b) for data quality assessment, e.g. case ascertainment and c) to look into the long-term outcomes, e.g. morbidity and mortality of patients. The Project needs to develop a policy that describes the standard retention periods, schedules reviews into the types of records and information held, their use and retention and considers the challenges of retaining data.

In conclusion, audits within QOMS will hold personal data (including identifiers) for up to 5 project cycle, i.e. 15 years. Registry activities within QOMS will hold personal data indefinitely. Given the scope of QOMS, the need to keep personal data is will be assessed individually and regularly for each OMFS subspecialty audit or registry.

SECTION 14: EVALUATION

→ To develop further

PRINCIPLES

It is becoming increasingly recognised that initiatives, like QOMS, and other public health programmes are 'complex interventions'. Despite the importance of effect size to assess the success or failure of an intervention, they do not inform users on how reproducible or generalizable an intervention is. Complex interventions are context dependent and their evaluation needs to capture the information necessary for their interpretation and future use. In 2015, the MRC updated their guidance on "Process evaluation of complex interventions" to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes.

1. **Description of intervention and its causal assumptions** set the theoretical background behind the complex intervention: what assumptions underpin the basis and mechanisms of the work. Making those assumptions explicit is important to assess the foundation of the work and inform aspects of the intervention the evaluation should focus on.
2. **Implementation: what is implemented, and how?** Process evaluation has to capture the fidelity, dose and the reach of the intervention. Complex interventions are tailored to the settings where they are being implemented. Fidelity refers to those changes and whether they are mere adaptations to make the intervention fit a particular context or changes that could actually undermine the intervention, sometimes referred to "dilution". Dose refers to the extent or the depth of the intervention. Finally, the process evaluation also needs to assess whether the intervention reached its intended audience and how.
3. **Mechanisms of impact: how does the delivered intervention produce change?** The process evaluation need to test the putative causal pathways, described in step 1, to inform or disprove them and potentially identify alternatives.
4. **Context: how does context affect implementation and outcomes?** Understanding context is critical in interpreting and potentially generalising the findings of any evaluation as external (contextual) factors may act as a barrier or facilitator to the project's implementation and effects.

Process evaluation should be implemented using both quantitative and qualitative techniques. However, a given intervention may need several evaluations over its lifetime. In the initial stage, the evaluation helps to assess the feasibility of the intervention and optimising its design and evaluation. Later stages should be aimed towards assessing the effectiveness of the intervention (quantity, quality and generalisability).

HOW TO EVALUATE QOMS

A priori factors to be included in the evaluation of QOMS may include:

- Level of participation: 65% of UK NHS OMFS Departments by the end of 2020 as a target, submitting meeting data quality thresholds.
- Satisfaction and Participation surveys, submitted to the whole BAOMS membership or to participating sites only and could assess whether and why a site / a surgeon took part or didn't in QOMS and their wider opinion on the project…

Table 14. Quality metrics for the evaluation of the project

Metrics	Explanation
Level of participation	1. The governance board should establish a target level of participation in a national clinical audit by eligible organizations or services and publish the participation rate in relation to the target. 2. Recruitment data (i.e. size of datasets, N)
Reliability of data	The governance board should establish a target level of reliability of data collected and publish the findings of reliability testing of data collected. Reliability testing or independent validation of data collection should demonstrate that the reliability of data collected for the clinical audit is at least 90% or an equivalent kappa score.
Timeliness of reports on preliminary data	Reports of preliminary data collected should be supplied to participating sites for local review in real time or within a deadline of weeks following submission of the data, the deadline to be established by the governance board.
Timeliness of complete reports	Complete reports of national clinical audits are supplied to participating sites and other stakeholders within a deadline of weeks of the deadline for review of preliminary data by participating sites, the deadline to be established by the governance board.
Evidence of improvements in quality	Evidence of improvements in the quality of care from one time period to the next of the clinical audit must be sufficient to justify continuation of a national clinical audit, in view of the resources committed to the audit. The governance board should establish and apply measures of success in judging the effectiveness of the clinical audit.

SUSTAINABILITY

QOMS aims to measure and compare quality of care across OMFS departments and to initiate and promote changes to improve quality of care and to reduce unwarranted variations and to develop QI knowledge and experience amongst its participants. QOMS represents a significant investment not only for BAOMS (funding) but also the participants, collaborators and the Project Team (resources and time). Therefore the changes in practice created by QOMS activities have to be sustained not only for

the duration of the project (or phase) but on the long-term. Achieving the transition from initial success to long-term sustainability is a challenge. [49] Indeed, self-reported measures have shown that up to 60% of programmes are sustained (at least in part), while studies using more objective measures of sustainability (such as independent observation) report lower rates of sustainability from 6.7% to 45%. [50, 51]

ECONOMIC EVALUATION

→ To develop further - after a complete audit cycle

SECTION 15: PUBLICATION POLICY

PRINCIPLES

There is an ethical obligation to disseminate findings of potential scientific or public health importance. Scientific peers shall be informed of study results in a timely fashion by publication in the scientific literature and presentations at scientific conferences, workshops, or symposia. Presentations at meetings should not be considered as a substitute for publication in the peer-reviewed literature. Authorship of study reports should follow the guidelines established by the International Committee of Medical Journal Editors (http://www.icmje.org/). All authors should meet the criteria for authorship, and all people who meet the criteria should be authors. Potential conflicts of interest, financial and non-financial, should be disclosed. Agreement to adhere to these guidelines should be described in the protocol. Finally, sponsors (government agencies, private sector, etc.) shall be informed of study results in a manner that complies with local regulatory requirements. Sources of research funding should always be acknowledged, whether results are presented orally or in writing. An efficient communication strategy should target different levels and include site-specific reports to each participant site, an overall report to be disseminated through BAOMS, formal peer-reviewed publication(s) endorsed by stakeholders or discussions of the findings at national meetings with a view to quality improvement initiatives.

PUBLICATION PLAN

NATIONAL REPORTS

Detailed reports will be produced annually and supplemented by 3 yearly reports detailing a project cycle.

THE ANNUAL REPORT

The annual report will appear in an electronic format on the BAOMS website as well as in a downloadable PDF print format and will contain, but not be limited to, the following headings:

- A statement of who prepared the report with acknowledgement of other key contributors,
- Explanatory notes for both public and professionals,
- An overview of Oral and Maxillofacial Services in the UK and Ireland pertinent to QI,
- A detailed report on each of the procedures, metrics, risk adjustment, case ascertainment, including detail on source of any data obtained under a data sharing arrangement with a partner audit/registry.

1. Introduction/ Explanatory notes

This will detail the procedures covered in the report presenting risk-adjusted hospital level rather than individual consultant findings. We do not recommend that units should be ranked according to the metrics. Chance statistical variation will explain most, if not all, the variation seen and ranking the data is therefore only likely to be misleading. The project will however focus on the best performing units as well as any units appear to be performing 2 (alert) and 3 (alarm) standard deviations below the mean.

2. Accuracy of the Clinical Data

The report will contain information on the validation processes employed to ensure data veracity. The project will estimate the expected number of procedures that should have been entered into the dataset for each participating unit. If surgeons or units do not submit data on all their patients the outcome information produced may not be representative of their practice. Information on case ascertainment will be provided to each unit to show the level of data completeness. A case ascertainment rate of greater than 85% is regarded as adequate. Where the case ascertainment rate is in the range 70-84% this will be indicated as sub-optimal and caution in interpretation is strongly advised. Estimated case ascertainment rates of less than 70% are regarded as inadequate and this will be indicated in the reporting.

After initial analysis the data will be sent to each participating unit for checking along with the estimated case ascertainment rate giving surgeons an opportunity to correct the data prior to final analysis.

3. Format of Reporting

The annual report will depict observed versus expected (national average) data in a variety of appropriate graphical formats including, but not limited to, funnel plots and run charts. On the website and downloadable format this will be anonymised. Each unit will be provided with a report which identifies their own data in relation to all other participating teams. On the electronic format units will be able to select similar departments by size, volume of activity, and social deprivation category of patients for a more focused comparison.

Notes on interpretation of graphically depicted data will be included in both electronic and printable versions of the report.

4. Recommendations

Where possible specific recommendations will be made to surgeons, units and NHS Trusts that will realise the QI goal of the project. This will primarily be based upon interrogation of the practice of the best performing departments on a risk-adjusted basis.

THREE-YEARLY REPORT

This report will detail the findings of a project cycle summarising the annual reports and providing data on any progress made during the 3-year cycle.

Publication will follow a meeting of the Steering Committee at which the 3 year data will be presented. This meeting will focus on the utility of the metrics applied. That meeting will be followed by consultation with the membership on any changes deemed necessary. Commentary and result of those deliberations will be described in the 3-yearly report.

In each 3-year cycle, an organisational audit describing the delivery of OMFS services across the membership will be undertaken and this will also be included in the 3 yearly report.

SECONDARY PUBLICATIONS

Quality Improvement initiatives have an ethical obligation to ensure that the maximum possible benefit to patients and clinicians is derived from the data input. Secondary publications are an important component of this and the project will support and facilitate the use of anonymised data for this purpose and all participating members are able to request data. This request will take the form of an outline of the proposed project and follow the template below which has been derived from the SQUIRE 2.0 recommendations.

Request for QOMS Data – Reporting
1. Proposed title of secondary publication
2. Problem description: nature and significance of the problem
3. Available knowledge: summary of what is currently known about the problem, including relevant previous studies
4. Rationale: informal or formal frameworks, models, concepts, and or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) were expected to work.
5. Specific aim: Purpose of the publication

In preparing manuscripts authors should adhere to the SQUIRE 2.0 guideline.
Individual participating units will be encouraged to publish other analyses based on their site-specific data. The order of author's names in publications based on site-specific analyses will be the responsibility of the local Principal Investigator.
The Project Team will review and approve all site-specific analyses and papers sent for publication proposed by local teams if they reference national QOMS data, with the goal of maintaining internal consistency of material and methods and to ensure they do not go against the principles and objectives of the QOMS project.
Clinicians will be encouraged to present local results at conferences and meetings. When clinicians are invited to international or regional meetings to present all or part of the project, the project team should be informed of the details of the type, venue and organizers of the meeting and will keep an archive of all materials presented at meetings and make them available.

OTHER COMMUNICATIONS

PRESS

Press enquiries will be honoured unless there are some operational or scientific reasons for withholding information. Only one individual will be authorized to interact with the press (the local lead or public relations officer of their institution) at every site in coordination with the Project Team. In the multicentre context, the Project Team will respond to queries concerning the overall project design or results. The Project team will define the type of queries that may be answered locally and those that must be referred for response to the Project Team.

Publicity concerning study results in preparation will be avoided.

SOCIAL MEDIA

The use of Twitter© by NASBO constitutes a good example of the use of social media in a registry. Twitter© was only used to communicate news, updates and results to collaborators throughout the different phases of the NASBO (initiation, progress and outcomes). The communication strategy changed according to the priorities for engagement with collaborators, e.g. site recruitment, data collection or validation.

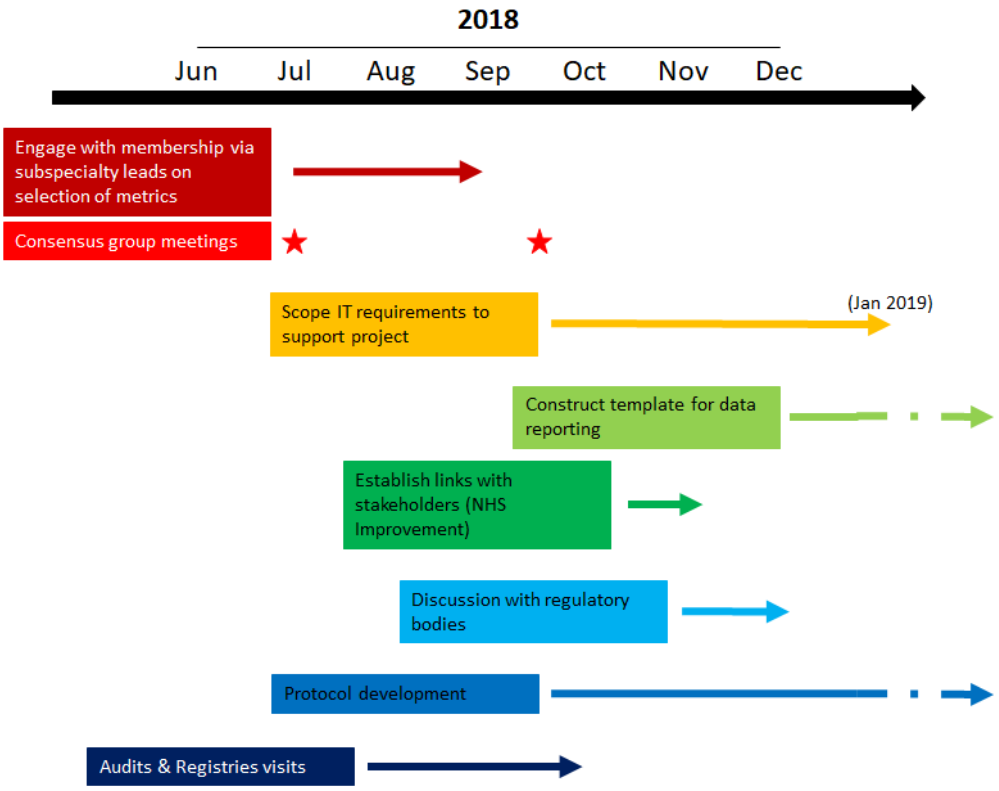
WHERE TO PUBLISH

The project imposes no conditions on journal titles to which manuscripts can be submitted but request that where a subscription title is favoured it should be submitted to the British Journal of Oral and Maxillofacial Surgery. The project does not have funds to support publication in open-access journals.

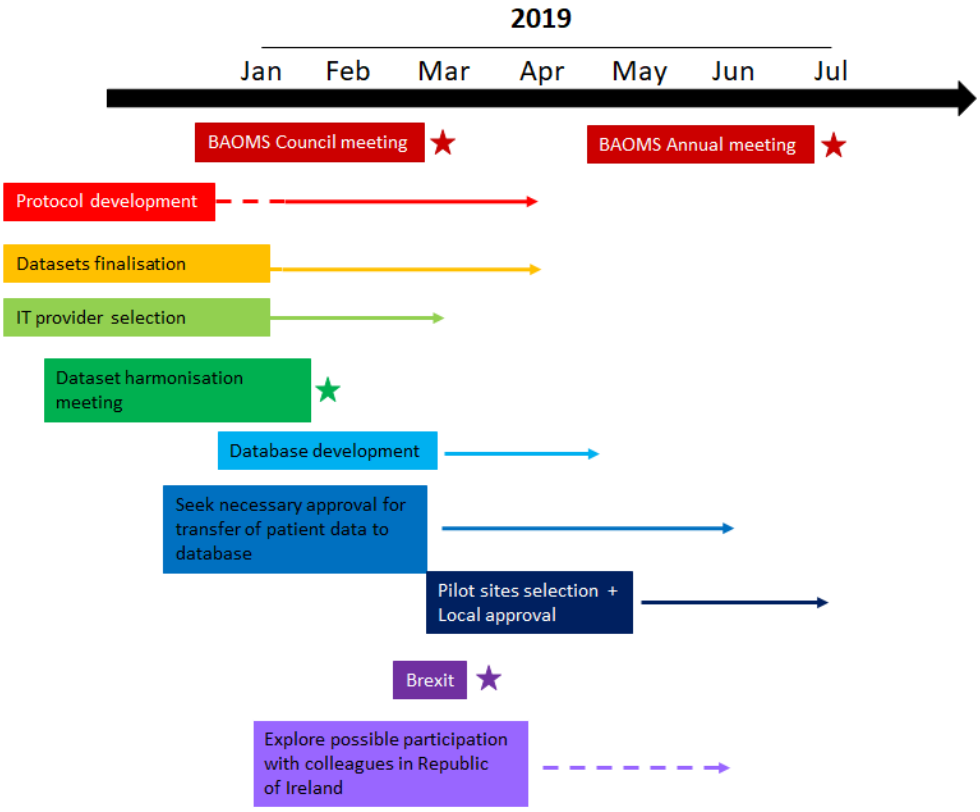
REVISED TIMELINE

If there is little or no knowledge about variation of the selected metrics, the timeline should in time be modified to include a staged implementation of the project to allow essential variation to be explored and (better) understood. Further revisions in the light of pilot studies should be anticipated in the overall timetable. Any modification to the project should be documented in the protocol to provide an audit trail of revisions to the process: when and why they occurred and their impacts.

Timeline 2018



Provisional timeline 2019



APPENDICES

The long version of this document contain a series of proposed documents (Project policies, patient information and information, administrative documents…) that once refined and finalised will need to be approved by the Steering Committee:

- Appendix A. Public and Patient Involvement Policy
- Appendix C1 and C2. Outlier Policy and Guidance for site visits
- Appendix D. Patient Information Leaflet and Patient's consent form
- Appendix E. Site Registration Form and Terms and Conditions
- Appendix F. Privacy & Fair Processing Policy
- Appendix G. Standard letter to Caldicott Guardian
- Appendix I. Data request / sharing policy and form

APPENDIX B. COMPOSITION OF THE STEERING COMMITTEE, PROJECT TEAM AND AND SUB-GROUPS

Correct as of <insert date>

Group name	**Role**	**Name**
Steering Committee	Chair: BAOMS elected Council Representative	David Keith (?)
	Clinical Adviser Data	David Tighe
	Clinical Adviser IT	Geoff Chiu
	Clinical Lead (05/2018 -)	McMahon, Jeremy
	Clinical Site assessment team/chair	Cyrus Kerawala
	Communications Lead	Sian Evans
	Lay representative	Joy, Alice Regas, Constantinos
	NCEPOD	Marisa Mason
	NFORC	Hutchison, Iain
	Patient representative(s)	
	Project Manager (05/2018 -)	Puglia, Fabien
	BAOMS Regional Clinical Lead	
	SSIG Deformity (Dep)	Bhatt, Vyomesh
	SSIG Deformity (Lead)	Sneddon, Ken
	SSIG ODA (Dep)	Chauhan, Max

	SSIG ODA (Lead)	Chiu, Geoff
	SSIG Oncology (Dep)	Crank, Stephen
	SSIG Oncology (Lead)	Chan, Chi-Hwa
	SSIG Paed (Lead)	Altman, Keith
	SSIG Reconstruction (Dep)	Nugent, Michael
	SSIG Reconstruction (Lead)	Ho, Michael
	SSIG Salivary (Dep)	Broderick, Damian
	SSIG Salivary (Lead)	Vassiliou, Leandros-Vassilios
	SSIG Surgery (Dep)	Anand, Rajiv
	SSIG Surgery (Lead)	Holt, Don
	SSIG TMJ (Dep)	Dodd, Martin
	SSIG TMJ (Lead)	Saeed, Nadeem
	SSIG Trauma (Dep)	Graham, Richard
	SSIG Trauma (Dep)	Perry, Mike
	SSIG Trauma (Lead)	Balasundaram, Indran
	Statistics Adviser / Statistician (?)	
	Trainee Representative	
Project Executive Team	Clinical Lead (Chair)	Jeremy McMahon
	Communications Lead	
	CSA sub-group Chair	Cyrus Kerawala
	Data sub-group Chair	David Tighe
	IT sub-group Chair	Geoff Chiu
	NCEPOD	Marisa MAson
	NFORC representative	Fran Ridout
	NFORC representative	Sharon Cheung
	Project Manager	Fabien Puglia
	Statistics advisor / Statistician	

QOMS sub-groups		
Data	NFORC	Fran ridout
	Data clinical adviser (Chair?)	David Tighe
	Project Manager	Fabien Puglia
	Statistics advisor / Statistician	
IT	NFORC	
	Clinical Adviser (Chair?)	Geoff Chiu
	Professional IT consultant	
	Project Manager	Fabien Puglia
Clinical Site Assessment (CSA)	Chair?	Cyrus Kerawala

APPENDIX J. DETAILED DATA FLOW (PROVISIONAL)