28/01/2021

BAOMS COVID19 Oral & Maxillofacial Surgery (OMFS) Trauma 2021
Service Evaluation Protocol

We hope this finds you well in these uncertain and worrying times. We would like to request your kind assistance again with a repeat service evaluation of trauma, following on from the first audit completed in 2020.

The pandemic continues to cause untold changes to our working practice and training. Hopefully the second wave has now peaked and new cases are in decline. Hospital emergency and critical care services are on the frontline of Covid-19 management, with re-deployment of personnel from other disciplines to support them. The focus is on trying to reduce the inexorable rise in mortality associated with Covid-19 infection However, this re-deployment of healthcare system effort may impact significantly on the management of other acute health conditions including oral and maxillofacial trauma.

High-quality data for our specialty will allow for the mitigation of the consequences of the current crisis and policy planning at regional and hospital level for both this outbreak and possible future pandemics.

To contribute to Covid-19 OMFS trauma audit, please secure appropriate approvals and senior surgeon leadership, according to local Trust regulations. This short protocol has been written in an attempt to support that process. An investigator-led, non-commercial, non-interventional study is extremely low to zero risk. This study does not collect any patient identifiable information and data will **not** be analysed at individual hospital-level.

Any hospital that has an emergency department affected by Covid-19 and/or deals with OMFS trauma is eligible for participation. This study can be performed prospectively, retrospectively or using a mixed model, dependent on the phase of Covid-19 infection in your hospital.

Many thanks in anticipation for taking part in this important service evaluation project for our specialty

Peter Brennan
Chair of BAOMS Council

28/01/2021

COVID-19 OMFS Trauma 2021 Service Evaluation

On January 4th, 2021, the Prime Minister announced a 3rd lockdown period to try and control the COVID-19 epidemic in the UK.

Primary aim

- To evaluate how the management of patients presenting with a OMFS trauma was affected during the COVID-19 pandemic lockdown initiated in January 2021.
- To compare the patient management during the 1st lockdown (April – July 2020) and 3rd lockdown (Jan 2021 – on-going).

Secondary aims

- To explore variation in the selection of patients for treatment during the COVID-19 pandemic.
- To evaluate the impact of the COVID-19 pandemic on those treatment pathways.

Inclusion criteria

Any centres treating patients presenting with OMFS trauma are eligible for participation. There are no other inclusion/exclusion criteria.

Study period

Starting from January 4th, 2021, all patients who have presented with OMFS trauma to an OMFS department, whether or not they underwent surgery should be captured.

Primary outcome measures

- Patient's characteristics
- Treatment during hospital stay for OMFS trauma infection cases.
- Proportion of patients and the specific treatment alteration(s) where provision of standard of care treatment was compromised during COVID-19 pandemic.

Data collection

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure, encrypted system. REDCap has previously been successfully used for a range of other international cohort studies.

At least one designated collaborator at each participating site will be provided with REDCap project server login details, allowing them to securely submit data on to the REDCap system. Collaborators from one hospital will not be able to see records from other hospitals.

The present instance of REDCap server is managed by the Barts CRUK Centre, Queen Mary University of London (BCC, QMUL). Only anonymised data will be uploaded to the database. No patient identifiable data and no specific dates will be collected.

To obtain access to REDCap, the local COVID-19 lead should submit to the Project manager the following information: the names, a work email addresses (nhs.net or hospital.nhs.uk) and the name of the hospital/trust of each collaborator. For hospital requesting access for a group

of clinicians at once, a table (Word document) to collect that information will be made available in the BAOMS members' area QOMS page.

Data collected will include clinical presentation, treatment and outcomes. Data can be collected prospectively, or retrospectively.

Local approvals

The principal investigator at each participating site is responsible for obtaining necessary local approvals (e.g., service evaluation, audit approval, research ethics committee or institutional review board approval). Local approvals should cover inclusion of all OMFS trauma types within this study. Collaborators will be required to confirm that relevant local approval is in place at the time of uploading each patient record to the study database. The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.

Where an audit approval is needed, this can be either registered as service evaluation, or to benchmark against an auditable standard.

Prior to formal local study approval, collaborators may wish to collect data on an electronic spreadsheet or paper CRF's which can be downloaded from the QOMS page in the BAOMS members' area. **No patient identifiable data can leave the local NHS Trust/Health Board** however. No patient identifiable data will be included on the REDCap data collection tool.

Analysis

A detailed statistical analysis plan will be published online in the BAOMS members' area QOMS page.

Analyses will be performed by the project working group, with appropriate input from a biostatistician, when necessary. This will be overseen by an independent data monitoring committee (DMC). Reports will include description of outcomes in the cohort. Interim analyses may be performed regularly but may not be released. The frequency of subsequent analyses will be agreed with the DMC. The decision to submit data for publication will be agreed by the BAOMS Subspecialty Interest Groups for OMFS trauma, the QOMS Project Team, and the DMC.

Hospital-level data will not be released or published.

Authorship

All collaborators from sites who contribute at least 10 patients will be recognised on any resulting publications as PubMed-citable co-authors. Flexible to service demands, no authorship limits will be imposed at a centre level; as many collaborating investigators are required, and work to support the project will be recognised on all future outputs.