**QOMS Covid-19 Oral & Maxillofacial Surgery (OMFS) trauma and infection audits: Protocol**

As the Covid-19 epidemic in the UK unfolds, it is apparent to clinical teams that it is having a major effect on the nature of care provided and the resources available of both emergency and surgical services. The lack of hindsight (we have not experienced such a health crisis in living memory in Western countries) and foresight (what was happening elsewhere) means that the National Health Service is under-prepared to manage the pandemic. With very little evidence to guide them, clinicians, service provider management, and policy makers are having to make (difficult) decisions, the scope and impacts of which are uncertain and will remain so until we are able to collect and analyse high-quality data.

Hospital emergency and critical care services are on the frontline of the 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 SARS-CoV-2 ARDS. However, this re-deployment of heathcare system effort may impact significantly on the management of other acute health conditions including oral and maxillofacial trauma and dental infection. The Covid-19 epidemic raises important questions: are those patients positive or not for SARS-CoV-2? Should / are they being tested? Are they at increased risks of contracting Covid-19 during hospital visit / stay? How are health professionals managing those patients?...

High-quality data 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 future pandemics.

To contribute to Covid-19 OMFS trauma and dental infection audits, you must first secure appropriate approvals and senior surgeon leadership, according to local regulations. This short protocol has been written to support that process. This 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 hospital-level.

Any hospital that has an emergency department affected by COVID-19 and/or deals with OMFS trauma and dental infections 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.

*Patrick Magennis*

*Chair BAOMS*

**Covid-19 OMFS trauma and infection audit**

*Protocol V2.0*

**Primary aim**

* To evaluate the management and outcomes of patients presenting with a OMFS trauma or dental infection during the Covid-19 pandemic.

**Secondary aims**

* To assess the 30-day outcomes in OMFS trauma patients who have been operated on.
* To explore the scale of resource constraints related to the Covid-19 pandemic, and their impact on outcomes of those conditions.
* 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 or dental infection are eligible for participation. Centres will be stratified according to their burden of Covid-19 infections using data from the UK Government. There are no other inclusion/exclusion criteria.

**Study period**

Investigators should identify a start date, which represents the start of formal changes in care provision caused by Covid-19 in their hospitals. From that date onwards, all patients who have presented with OMFS trauma or an infection of odontogenic origin, whether or not they underwent surgery should be captured. We envisage most sites completing registration before May 15th 2020 and when applicable, completing follow-up in the months following the end of the epidemic. However, changes to dates may be necessary as the disease changes, and we may develop a third phase for longer follow-up in selected sites with the capacity to do so.



**Figure 1.** Timeline for patient identification within Covid-19 OMFS trauma and infection audit

**Primary outcome measures**

* Treatment (including Covid-19 infection rate) during hospital stay for both OMFS trauma and infection cases.
* Complications for up to 30 days after surgery for OMFS trauma cases.
* Proportion of patients and the specific treatment alteration(s) where provision of standard of care treatment was compromised during Covid-19 pandemic.

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| **Follow-up period for operated trauma patients:*** During admission – between surgery and discharge (with Day 0 as the day of surgery).
* After discharge for up to 30 days (with Day 0 as the day of discharge)
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**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. 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. REDCap has previously been successfully used for a range of other international cohort studies. 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 where required, depending on the Covid-19 status of your hospital. A centre-level survey will collect data on departmental decision-making processes, and the impact of Covid-19 on elective surgical services in each included hospital.

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| **Roles within the data collection team**The principal investigator at each site should identify a team to:* Identify eligible patients.
* Proactively identify patients with a new decision for surgery during the study window.
* When applicable, acquire outcome data at 30 days postoperatively for operated patients,

No limits to the size of this team are imposed and can be flexible to local capacity and service demands. |

**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 Quality Outcomes in Maxillofacial Surgery (QOMS) Project Team with appropriate input from a biostatistician. This will be overseen by an independent data monitoring committee (DMC). Reports will include description of outcomes in the cohort. The first analysis will be performed once 100 patients have been entered onto the database in each of the trauma and odontogenic infection components of this service evaluation, and 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 one patient 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.