Impact of COVID-19 on Emergency Surgical Admissions (CovidICE)

Protocol Version 2

Protocol date 11th May 2020

Short Title

CovidICE

Chief Investigators

Mark Bignell

Consultant Emergency and Colorectal surgeon

Oxford University Hospitals NHS Foundation Trust

[mark.Bignell@ouh.nhs.uk](mailto:mark.Bignell@ouh.nhs.uk)

Giles Bond-Smith

Consultant Emergency and HPB surgeon

Oxford University Hospitals NHS Foundation Trust

[giles.Bond-Smith@ouh.nhs.uk](mailto:giles.Bond-Smith@ouh.nhs.uk)

Chris Lewis

Consultant Emergency and General surgeon

Oxford University Hospitals NHS Foundation Trust

[chris.Lewis@ouh.nhs.uk](mailto:chris.Lewis@ouh.nhs.uk)

Giovanni D. Tebala

Consultant Colorectal and Emergency Surgeon

Oxford University Hospitals NHS Foundation Trust

[Giovanni.tebala@ouh.nhs.uk](mailto:Giovanni.tebala@ouh.nhs.uk)

Supported by

****



**Study Summary**

| Study Title | Impact of COVID-19 on Emergency Surgical Admissions |
| --- | --- |
|  |  |
| Internal ref. no. (or short title) | CovidICE |
|  |  |
| Study Design | Observational. |
|  |  |
| Study Participants | An adult (over age of 18 years) presenting to surgical assessment unit with acute surgical conditions |
|  |  |
| Planned Size of Sample | During COVID-19 the number of attendances has significantly dropped which is the impetus for this study. It is not clear how many participants will be included |
|  |  |
| Follow up duration | N/A – Study period as below |
|  |  |
| Planned Study Period | March 1st - April 30th 2019 and 2020  This allows data capture running up to lockdown as well as the immediate period after. Data will be collected from the same time period last year to act as a control. |
|  |  |
| Research Question/ Aim(s) | The proposed snapshot audit aims to investigate the impact of Covid-19 on surgical emergency units across the country and to determine if any particular subset of patients are particularly affected by self-isolation. |

**Background**

Covid-19 is a worldwide pandemic affecting all continents. In the UK social isolation has been used to control the impact of the virus on the NHS. This has meant an almost complete cessation of elective surgical work across the NHS as advised by the Royal College of Surgeons1 with significantly reduced capacity within primary care due to a combination of strict triage of patients and sickness within the workforce2. It would be expected that this reduction in capacity would result in an increase in attendances across emergency services within secondary care but this has failed to materialize with a reduction in attendances in all emergency departments including surgical emergency units3. In Italy, strict local and national measures have been taken to reduce the spread of the virus, mostly based on international guidelines and experiences. Many hospitals managed to maintain an acceptable level of oncologic and emergency surgery, despite an evident reduction of capacity and restrictions in terms of beds and workforce. A reduced attendance to surgical emergency departments has been reported also in Italy. It is unclear whether this reduction is across all surgical conditions or targeted at specific disease processes. Understanding the impact of Covid-19 may provide invaluable data to help plan the delivery of acute surgical care in the latter stages of the pandemic but also in longer term planning of surgical units nationally in the future. Hence the urgent need to undertake this snapshot audit.

**Aim**

The proposed snapshot audit aims to investigate the impact of Covid-19 on surgical emergency units and to determine if any particular subsets of patients are particularly affected by self-isolation. Secondary aim is also to compare the effect of different national guidelines and policies on the impact of Covid-19 on the activity of surgical emergency units.

Tertiary aim is to use the data to see if the management of surgical patients can safely be transferred to an ambulatory setting, alleviating the burden on inpatient beds.

**Study Outcomes**

*Primary Outcome*

To assess the change in number of attendances to SEU during the lockdown period in UK and in Italy and discuss the reasons of any eventual difference, should it be related to different policies and guidelines.

*Secondary Outcomes*

Change in relative proportion of conditions contributing to discharge diagnosis between two study period

Change in Operative and non-operative rates

Complication rate

LOS

Readmission rate

Mortality rate

**Methodology**

*Study design*

Multicenter, International observational study

*Study setting*

Surgical emergency units in hospital settings who are responsible for the delivery of care to patients with acute surgical problems

NFAS has connections with at least 16 hospitals, all of whom have a record in running and recruiting to surgical trials. It is expected further sites will be interested to participate when the trial is fully advertised.

*Inclusion Criteria*

Patients over the age of 18 who are referred to surgical emergency units by one of three methods;

Emergency department, general practice or internal referral from non-surgical specialities.

*Exclusion criteria*

Patients who are referred to the unit as a result of a post-operative complication with 30 days of surgery.

The prevalence of emergency surgery will be significantly different over the two study periods and between sites resulting in the introduction of bias.

*Patient Recruitment*

Patients will be identified by the study lead at each site. These will meet the inclusion criteria above.

*Local approvals*

The PI for each site will need to obtain local approval in line with local trust practice. The PI will be responsible for ensuring the accuracy of the data collected and ensure all members of the team are GCP trained. Data cannot be collected by a hospital until approval at a local level has been obtained

This trial is an observational study with no changes to patient care. There is no commercial involvement. Non-identifiable data will be collected on an Excel spreadsheet and these will be sent to any of the CIs at their NHS email addresses.

This project should be registered as either a service evaluation or a clinical audit.

Due to the clinical severity of this Covid-19 pandemic and the need to produce data which may have significant clinical impact it is hoped that local sites will expedite the approval process.

*Data Collection*

Participating sites will need to confirm approval at a local level by returning their site form to any of the CIs along with the names of the team participating. Data will be collected retrospectively from 1st March -30th April for both 2019 and 2020. It is possible that a further period of data collection may be required once lockdown is released.

An excel spreadsheet for each participating site will be completed and sent to OUH NHS trust who will amalgamate and analyse the data. No identifiable data will be collected and the spreadsheets will be sent through NHS E-mail accounts. There will be no need for individual sites to maintain a key to allow identification of patients and hence trial subject numbers will not be needed.

The database will collect demographic data along with details on attendances for two time periods; March and April 2019 and March and April 2020. This will allow a direct comparison.

It is proposed that this data will be easy to collect and should be available to OUH to amalgamate by the 8th June 2020. Data for subjects will only be included if it is 95% complete and this will be checked by the team at OUH.

*Analysis*

The data will analysed appropriately by a statistician at the University of Oxford. No individual hospital data will be analysed. Analysis will primarily compare time periods for all the participating sites as a whole but if sufficient sites are recruited then regional analysis may be undertaken.

**Authorship**

Local team collaborators will be eligible for PubMed-citable co-authorship as collaborators, provided a validated dataset is returned by the closing date of the project. There is no maximum of collaborators per local team. Centres with >5% missing data will be excluded from the analysis and the contributing local team removed from the authorship list.

**Dissemination**

The project will be submitted for presentation at national and international surgical conferences. Manuscript(s) will be prepared following close of the project.

**Role of Study Sponsor and Funder**

Oxford University Hospitals will act as sponsor for the trial since they employ all four CIs. Participating sites will be responsible for appointing a PI and registering the study as an observational study with their local audit department. This study is supported by the National Forum for Acute Surgery (NFAS) and the Association of Surgeons of Great Britain and Ireland (ASGBI).

There is no funding for this study.

**References**

1. COVID-19: Good practice for surgeons and Surgical teams

<https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/coronavirus/covid-19-good-practice-for-surgeons-and-surgical-teams/>

1. Guidance and standard operating procedures. General practice in the context of Coronavirus (COVID-19)

<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0133-COVID-19-Primary-Care-SOP-GP-practice_V2.1_6-April.pdf>

1. Emergency Department Syndromic Surveillance System: England. Data to March 2020. Public Health England

https://www.gov.uk/government/publications/emergency-department-weekly-bulletins-for-2020

**Appendix 1 - Data Collection**

*General*

Presenting complaint

Attendance date

Age

Sex (M/F)

Smoker (yes / No / Ex)

ASA

Clinical Frailty Score

*Diagnosis and Management*

Referral Source (ED / GP / Internal referral)

Diagnosis

Radiological Investigation (None / USS / CT / MRI)

Admission (Yes / No)

Primary Treatment (Antibiotics / Surgery / Wait and Watch)

Operation (Yes / No - If yes name of operation)

Reoperation (Yes / No - If yes what was indication)

LOS (days)

*Discharge*

Discharge diagnosis

Readmission (Yes / no, if yes provide details)

**Appendix 2 - Trial Registration Document**

Interested sites should register this trial with their local audit department. The registration form below needs to completed and returned with confirmation of audit approval by the local audit department. This form needs to be completed before data can be collected. On receipt of this form the excel data sheet will be forwarded to the local PI

Completed excel data sheets need to be returned by the **24th May 2020** to be included in the analysis

95% of the data fields need to be completed for the data to be included for analysis

|  | Name | Email Address |
| --- | --- | --- |
| Prinicipal Investigator |  |  |
| Local team |  |  |
|  |  |  |
|  |  |  |

Name of hospital trust..........................................................................................................................

Confirmation of audit approval attached

Signature of PI............................................................................... Date...........................................

Please return to any of;

[Mark.bignell@ouh.nhs.uk](mailto:Mark.bignell@ouh.nhs.uk)

[Giles.Bond-Smith@ouh.nhs.uk](mailto:Giles.Bond-Smith@ouh.nhs.uk)

[Chris.Lewis@ouh.nhs.uk](mailto:Chris.Lewis@ouh.nhs.uk)

Giovanni.Tebala@ouh.nhs.uk