NIHR Global Health Research Unit on Global Surgery

NIHR Global Research Unit on Global Surgery
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RE: CovidSurg-3 study approval

To Whom It May Concern:

I am writing to you regarding study approval for the CovidSurg-3 study. In order to participate in the study, collaborators must ensure that the study is registered and approved with respect to all applicable local and/or national regulations.

In hospitals which have already participated in the GlobalSurg-CovidSurg Week ("Surg Week") study, collaborators should explore with the relevant committee (e.g. research ethics committee or institutional review board) whether this extension (CovidSurg-3) can be registered as a substantial amendment to the existing SurgWeek approval.

Background to the SurgWeek study

SurgWeek collected data on patients operated in October 2020 and led to data-driven guidance for surgical systems during the pandemic, including: (i) guidance regarding the optimal delay prior to surgery following SARS-CoV-2 infection, and (ii) the role of preoperative isolation. However, since SurgWeek data were collected new treatments and vaccines have been developed and new SARS-CoV-2 variants of concern (most recently Omicron) have emerged. Therefore, there is a need for renewed rapid data collection to guide global practice in 2022 onwards.

Relationship of CovidSurg-3 to SurgWeek

The patient-level component of CovidSurg-3 is a direct extension of SurgWeek. Based on what we have learnt since the SurgWeek study was run, some study definitions for CovidSurg-3 have been clarified to reflect current practice.

The following key features are broadly consistent between the two studies:

- The broad aims of both studies are similar; to define the impact of perioperative SARS-CoV-2.
- Inclusion criteria for both studies are similar. The SARS-CoV-2 case definition in CovidSurg-3 has been restricted to patients with positive SARS-COV-2 PCR swab or rapid antigen test to reflect the greater availability of SARS-Cov-2 testing now than in 2020. In addition, CovidSurg-3 will only collect data on patients with perioperative SARS-CoV-2, unlike SurgWeek which collected data on all patients undergoing surgery. This is because the previously collected non-SARS-CoV-2 data from SurgWeek can be used as a baseline comparator

for data from patients with perioperative SARS-CoV-2 in CovidSurg-3. Therefore, the significant work of capturing all patients undergoing surgery is not justified at this time.

- The primary (30-day mortality) and secondary (30-day pulmonary complications) outcome measures are the same for both studies.
- The follow-up procedures for both studies are the same for both studies.

The table below summarises the changes to the case report form from SurgWeek to CovidSurg-3.

Data points removed	
Respiratory comorbidities	This has not been prioritised for collection in CovidSurg-3.
Smoking status	This has not been prioritised for collection in CovidSurg-3.
Day case surgery status	This has not been prioritised for collection in CovidSurg-3.
Costs of surgery	This has not been prioritised for collection in CovidSurg-3.
Dexamethasone use	This has not been prioritised for collection in CovidSurg-3.
Clavien-Dindo grade	This has not been prioritised for collection in CovidSurg-3.
Preoperative self-isolation	This has not been prioritised for collection in CovidSurg-3.
SARS-CoV-2 symptoms and treatments	This has not been prioritised for collection in CovidSurg-3.
Data points changed	
Date of surgery	Week rather than month of surgery will be collected. Information on week of operation is important in order to match to country-level statistics on spread of the Omicron variant.
Preoperative screening	This has been simplified in light of the existing evidence, to focus on SARS-CoV-2 PCR swab and rapid antigen screening only.
COVID-free pathways	This has been simplified in light of the existing evidence.
Anaesthesia	This has been simplified to ease data collection.
Indication for surgery	This has been simplified to ease data collection.
Mortality	This has been simplified to capture 30-day mortality status only.
New data points added	
VTE prophylaxis	Since CovidSurg-1, evidence has emerged that perioperative SARS-CoV-2 increases venous thromboembolism (VTE) risk. Therefore, to inform assessment of VTE rates, information on prophylaxis will be captured.
SARS-CoV-2 variants	Since CovidSurg-1, new SARS-CoV-2 variants have emerged whose impact on surgery is unknown.
Previous infection	Since CovidSurg-1, some patients have had SARS-COV-2 infection. The impact of previous SARS-CoV-2 infection on outcomes of peri-operative SARS-CoV-2 is unknown.

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SARS-CoV-2 vaccination	Since CovidSurg-1, SARS-COV-2 vaccines have been developed. The impact of SARS-CoV-2 vaccination on outcomes of peri-operative SARS-CoV-2 is unknown.

Why a substantial amendment may be appropriate

The reasons why a substantial amendment may be appropriate are:

- CovidSurg-3 is coordinated by the same research group (CovidSurg Collaborative, based at the University of Birmingham, UK) as SurgWeek.
- All the studies are focused on the same topic; the impact of SARS-CoV-2 infection on postoperative outcomes.
- The primary and secondary outcome measures are the same in both studies.
- The principles of the data collection are the same in both studies. Both are observational studies which do not require any changes to normal patient care. No additional tests or follow-up are required.
- The core data points collected in CovidSurg-3 will be broadly the same as in SurgWeek; some additional data points have been added to address issues relating to vaccination and previous infection.
- The data collection platform is the same in for both studies. Non-identifiable data will be uploaded to a secure, online REDCap database. The same REDCap server will be used for CovidSurg-3 as for SurgWeek.

Yours faithfully,

Dmitri Nepogodiev, MBChB MPH
On behalf of the CovidSurg-3 steering group

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