

CovidSurg-3: Outcomes of surgery in COVID-19 infection**Study Protocol version 2.5
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Summary

- Any hospital worldwide that can participate in one or both components of CovidSurg-3:
 - Patient-level component: Collection of 30-day outcome data for all consecutive patients with confirmed SARS-CoV-2 infection in the 7 days before or 30 days after surgery. **No** changes should be made to normal patient care/ follow-up pathways.
 - Hospital-level component: Collection of aggregated case-mix data.
- Collaborators will be PubMed-citable co-authors on publications their data contributes to.

1 Background

Data collected in 2020 found patients with perioperative SARS-CoV-2 infection to be at increased risk of postoperative mortality (up to 24% at 30-days), pulmonary complications (up to 51% at 30-days), and venous thromboembolism¹⁻⁵. Perioperative SARS-CoV-2 infection has been associated with increased mortality, morbidity, longer length of stay, and increased health system burden compared to SARS-CoV-2 negative patients⁶⁻⁸.

During the first COVID-19 wave, over 28 million elective operations worldwide were either cancelled or delayed⁹. This enabled redistribution of staff and resources to meet COVID-19 demand, but resulted in substantial treatment delays, including for cancer patients¹⁰⁻¹¹. COVID-19 lockdowns were associated with increased preoperative delays for cancer patients¹⁰. During lockdowns one in seven cancer patients did not undergo planned surgery¹⁰.

In 2020 CovidSurg captured outcomes on over 190,000 patients across >2,000 hospitals in 116 countries. This resulted in data-driven guidance for surgical systems during the pandemic, including:

- Guidance regarding the optimal delay prior to surgery following SARS-CoV-2 infection⁴.
- The establishment of COVID-19-free surgical pathways to reduce nosocomial infection and complication².
- The non-effectiveness of preoperative isolation¹².
- Optimal preoperative SARS-CoV-2 screening protocols¹³.
- Potential benefits of preoperative vaccination¹⁴.

The Omicron SARS-CoV-2 variant of concern was first reported on 25 November 2021 and has rapidly spread worldwide¹⁵. There is a high-level of evidence indicating Omicron has increased transmissibility and potential to evade immunity¹⁶⁻¹⁸. However, there is little robust evidence regarding disease severity associated with Omicron in both vaccinated and unvaccinated patients (including in surgical patients), nor is there data to guide patient risk stratification during Omicron COVID-19 waves¹⁸.

COVID-19 has significant detrimental impacts on surgical systems and patient outcomes. CovidSurg has provided the best available evidence to guide delivery of safe surgery during the pandemic. However, CovidSurg data were collected in 2020 when the wildtype SARS-CoV-2 virus was dominant, and therefore there is a need for renewed rapid data collection to guide global practice in 2022 onwards.

2 CovidSurg-3

CovidSurg-3 has two separate components:

- Patient-level component: Collection of outcome data for patients with peri-operative SARS-CoV-2.
- Hospital-level component: Collection of aggregated case-mix data. Hospitals in countries with low community SARS-CoV-2 infection rates **can** contribute towards this component.

Hospitals can choose to participate in:

- Patient-level component only, or
- Hospital-level component only, or
- Both components. *If possible, hospitals are encouraged to participate in both components.*

2.1 Primary objective

To determine the predictors for mortality and postoperative pulmonary complications in patients who develop perioperative SARS-CoV-2 infection in the contemporary setting. This will inform future risk stratification, decision making, and patient consent.

2.2 Secondary objectives

- To determine 30-day mortality in patients with peri-operative SARS-CoV-2 infection.
- To determine 30-day postoperative pulmonary complication and venous thromboembolism rates in patients with peri-operative SARS-CoV-2 infection.
- To evaluate implementation of SARS-CoV-2 mitigations and adaptations (vaccination, preoperative testing, COVID-free surgical pathways, patient selection).
- To determine the frequency of peri-operative SARS-CoV-2 infection.
- To determine the frequency of same-day elective surgery cancellations.

2.3 Hospital lead role

The hospital lead has responsibility for whichever study components (i.e. patient-level and/or hospital-level) that their hospital participates in. If participating in the patient-level component, the hospital lead should:

- Set up a patient-level data collection team.
- A REDCap login will only be issued to the hospital lead, so they are responsible for data upload.
- Submit authorship details (including ORCID IDs) for all their team members at the end of the study.
- Complete a hospital-level resource survey at the end of the study (e.g. number of hospital beds etc).

If participating in the hospital-level component, the hospital lead should recruit collaborators to collect case-mix data, ensuring there is no overlap in data collection between collaborators.

2.4 Authorship

All collaborators must have a publicly accessible ORCID account. This can be set up for free at <https://orcid.org/register>. Collaborators are responsible for ensuring they have correctly completed their name on their ORCID profile. No post-publication authorship changes will be permitted.

A corporate authorship model will be used. Collaborators will be recognised on resulting publications as PubMed-citable co-authors*. This means that collaborators are listed in both the article (PDF or supplement) and also on PubMed, which is the gold-standard index. Since services such as Scopus and ResearchGate are third-parties, we are unable to guarantee that publications will be correctly indexed by them.

The patient-level and hospital-level component data may be used for different analyses. Individuals will be included in the authorship for specific publications based on whether the data they contributed is used for that particular analysis.

*For an example, see PubMed entry for previous CovidSurg paper in The Lancet: pubmed.ncbi.nlm.nih.gov/32479829/ (click "expand" under 'COVIDSurg Collaborative' to see a full list of PubMed-citable co-authors).

Number of collaborators eligible for authorship:

- Patient-level component: up to **five collaborators** (including the hospital lead) will be recognised in the authorship for each team.
- Hospital-level component: **one collaborator** will be recognised in the authorship for each 14-day data collection period for a particular body region. This means up to 4 collaborators can participate per body region throughout the overall data collection window, and multiple collaborators can participate at the same time by collecting data for different body regions.

3 Patient-level component

3.1 Inclusion criteria

Patients should be included if:

- They underwent surgery performed by a surgeon in an operating theatre, **AND**
- They had a positive SARS-CoV-2 PCR swab or rapid antigen test (if confirmatory PCR swab is not available) within 7 days before or 30 days after surgery. Patients should be included regardless of whether a specific variant is suspected or unknown.

Patients should be excluded if:

- They underwent minor procedures listed in Appendix 1 as excluded.
- Their SARS-CoV-2 infection was diagnosed more than 7 days before surgery (regardless of their symptomatic status at the time of surgery) or beyond 30 days after surgery.
- SARS-CoV-2 infection was suspected based on clinical signs or radiology, but not confirmed by a PCR test or rapid antigen test.
- Patients who have had a positive rapid antigen test followed by a negative confirmatory PCR test should be excluded.

All consecutive patients fulfilling inclusion criteria across all specialties should be captured.

Individual participating centres can apply an age cut-off to the inclusion criteria (e.g. to include children only, adults only, or both children and adults).

All surgical specialties are included. Patients can be included regardless of surgical indication (benign surgery, cancer surgery, trauma, obstetric), anaesthetic type (local, regional, general), surgical approach (minimally invasive surgery, open surgery), or whether it is day-case or inpatient surgery.

3.2 Study period & patient enrolment

The overall patient inclusion period is 13 December 2021 to 28 February 2022. Patients can be included if they were operated between these dates (inclusive).

Whenever possible, patients should be identified prospectively:

- At the time of surgery (positive SARS-CoV-2 PCR swab before surgery).
- At the time of positive SARS-CoV-2 PCR swab (patients in whom SARS-CoV-2 is diagnosed within the 30 days following surgery). Strategies to identify patients could include searching electronic health records or laboratory test results, accessing a hospital COVID dashboard / COVID handover list, identifying patients on dedicated COVID wards, or by asking colleagues in different specialties to inform you of any postoperative patients who test positive for SARS-CoV-2.

This extension to CovidSurg was initiated in response to the emergence of the Omicron variant. It may take participating hospitals several weeks to secure study approvals. Therefore, the following approaches can be taken with respect to defining the patient inclusion period:

- Hospitals can choose to only prospectively enrol patients from the date of study approval to 28 February 2022. However, each team must enroll consecutive patients for **at least** 4 weeks. Therefore, if taking this approach, data collection must start on 1 February 2022 or earlier.
- Some hospitals will have treated many SARS-CoV-2 patients during their local 'Omicron wave' before study approvals are granted. It is important to capture their experience, so **retrospective patient identification and data entry is permitted**. E.g. if study approval is granted on 7 February 2022, they could retrospectively enrol patients operated on 13 December 2021 to 6 February 2022, and then prospectively enrol patients operated on 7 February 2022 to 28 February 2022.
- If permitted, prior to formal local study approval, collaborators prospectively collect data on hard copy case report forms. Data should not be uploaded to REDCap before study approval confirmed.

3.3 Outcomes

The primary outcome is 30-day mortality. Secondary outcomes (definitions provided in Appendix 2) are:

- 30-day COVID-19 pulmonary complications, a composite of pneumonia, acute respiratory distress syndrome (ARDS), and /or unexpected postoperative ventilation.
- 30-day venous thromboembolism, a composite of deep vein thrombosis and pulmonary embolism.

3.4 Follow-up

30-day postoperative outcomes should be collected for all patients. As this is an observational study **NO** changes should be made to normal patient pathways. Therefore, no additional patient follow-up should be completed for this study beyond what is normal practice at the hospital. Follow-up data can be collected at 30-days based on written patient notes, computer records, or telephone or in-person follow-up (if patients are normally followed-up at 30-days at the hospital).

3.5 Data collection

Data collected will be on comorbidities, SARS-CoV-2 status, surgery, and outcome (please see case report form at the end of this document and the data dictionary in Appendix 6). Only anonymised data will be uploaded to the database. **No patient identifiable data will be collected.**

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 system. Hospital Leads will be provided with REDCap project server login details, allowing them to securely submit data on to the REDCap system. REDCap has been successfully used for previous CovidSurg studies. The REDCap server is managed by the University of Birmingham, UK.

3.6 Analysis

A statistical analysis plan is provided in Appendix 3; this is summarised below.

The analysis will describe the primary and secondary outcomes in the cohort. Outcomes will be reported stratified by age, sex, ASA grade, urgency of surgery, grade of surgery, and country income. Hierarchical multivariable, mixed-effects logistic regression will be used to identify risk predictors of 30-day mortality and 30-day postoperative pulmonary complications summarised as odds ratios and 95% confidence intervals.

We anticipate recruitment from approximately 400 hospitals around the world with a mean of 5 patients per hospital, providing a sample size estimate of 2,000 patients.

Hospital-level data will not be released. Country-level analyses will only be conducted with permission of National Leads. Local investigators can access their local data at any time directly from REDCap

3.7 Local approvals for the patient-level component

The study will be conducted in accordance with national and international guidelines and legislation, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration.

This is an **investigator-led, non-commercial, observational** (no changes to normal patient care) study which is extremely low risk; only routinely available non-identifiable data will be collected.

Hospital Leads are responsible for obtaining necessary local approvals at each participating site in line with hospital and country regulations. Collaborators will be required to confirm that local approval is in place at the time of uploading each patient record to the study database.

This study is an extension of previous CovidSurg projects. If your hospital participated in CovidSurg-1 or CovidSurg Week, please approach your ethics committee/IRB to explore whether this extension can be processed as an amendment to the previous approval.

Please refer to Appendix 5.1 for further guidance on requesting amendments

If a new approval is needed, please explore with your ethics committee/IRB whether it is possible to expedite the process in view of the urgency of the pandemic/ Omicron wave.

Possible pathways to register this study include:

- Research (e.g. research ethics committee or institutional review board approvals). Written patient consent should only be taken if required by your local ethics committee.
- Service evaluation or clinical audit (this should be the default approval process in the UK). Specific audit standards are defined in Appendix 5.2 based on benchmarking against UK and international data and guidelines.

4 Hospital-level component

One collaborator can participate per 14-day data collection block (listed below). They should complete the proforma below capturing all patients undergoing surgery for one or more body regions listed below. Up to 4 collaborators can participate per body region, collecting data over consecutive 14-day blocks. Collaborators should agree participation with their Hospital Lead, to ensure there is no overlap in data collection.

Data collection **MUST** be mapped to one or more body regions defined below; this is to ensure that consistent data is collected across all participating hospitals. **ALL** elective and emergency surgical activity relating to the selected body region(s) should be captured, even if it is split between different surgical units in the hospital.

In small hospitals a single collaborator may choose to capture data for all patients undergoing surgery.

Surgery is defined as an operation performed by a surgeon in an operating theatre, with the exception of minor procedures listed in Appendix 1. Emergency surgery is defined as surgery on an unplanned admission. Elective surgery is defined as surgery on a planned admission. Patients should only be counted as having tested positive for SARS-CoV-2 in peri-operative period if they have a positive SARS-CoV-2 PCR swab or rapid antigen test (if confirmatory PCR swab is not available) within 7 days before or 30 days after surgery.

Cancellation on the planned day of surgery means any operation which is scheduled as an elective case which is cancelled for any reason on the day when it was planned to take place. This does not include operations cancelled *before* the day when the operation was planned to take place (e.g. an operating list which is cancelled three weeks in advance, this should not be included).

4.1 Data collection blocks

Collaborators should collect data during one or more of the 14-day blocks below (all blocks are inclusive of the start and end date). If appropriate, by agreement with the Hospital Lead, start dates for data collection blocks can be amended, maintaining data collection over 14 consecutive days):

- 3 January 2022 – 16 January 2022
- 17 January 2022 – 30 January 2022
- 31 January 2022 – 13 February 2022
- 14 February 2022 – 27 February 2022

Collaborators can choose to collect data for multiple 14-day blocks or multiple specialties, if appropriate.

4.2 List of body regions

A breakdown of key procedures mapped to body regions is provided in Appendix 1.

Body region	Note
Blood vessels (vascular)	Includes aorta, arteries, veins
Brain	Includes skull
Colon, rectum and small bowel	Includes appendix
Eyes (ophthalmology)	
Female reproductive system	Includes fallopian tubes, ovaries, uterus, vagina
General surgery	Includes breast, endocrine, hernia and miscellaneous emergency surgery (see Appendix 1)
Head & neck	Includes ear, nose, mouth, salivary glands, tonsils, larynx, pharynx, maxillofacial surgery, and surgical tracheostomy
Heart	Includes mediastinum and pericardium
Hepatobiliary system	Includes bile ducts, gallbladder, liver, pancreas, spleen
Lung	Includes pleura and chest wall
Musculoskeletal	Includes bones, joints, muscles, tendons, and spinal surgery
Obstetric	
Oesophagus and stomach	
Skin (plastic surgery)	Includes burns surgery and flaps
Urinary and male reproductive systems	Includes kidney, bladder, ureter, prostate, testicles, renal transplant

4.3 Proforma

This proforma will be completed electronically on the REDCap system. No login will be required to submit this data, meaning that once submitted, it will not be possible to edit the data. A separate proforma will be completed for each body region and data collection period.

	Elective	Emergency
For selected body region:		
Total patients operated during the week		
Elective cases cancelled on the planned day of surgery		Not applicable
Patients who tested positive for SARS-CoV-2 in peri-operative period		
Across the whole hospital*:		
Total patients operated during the week		

*A hospital is pragmatically defined as a self-sufficient surgical facility that is under unified management.

Examples:

- A surgical facility consisting of a single building and this is the only facility run by that management: considered as a single hospital.
- A surgical facility consisting of several different buildings in close proximity to each other that are run by the same management: considered as a single hospital.
- Several surgical facilities under unified management but in different geographic locations with minimal sharing of staff or resources (i.e. each facility self-sufficient): considered as separate hospitals.
- Several surgical facilities in different buildings that are clustered in close proximity to each other, but each run by a different management: considered as separate hospitals.

4.4 Reasons for cancellation of elective surgery

If any elective surgeries are cancelled on the planned day of surgery, collaborators should provide a breakdown (using the list below) for the main reason why these surgeries were cancelled:

- Patient has tested positive for SARS-CoV-2
- Lack of ward bed
- Lack of ICU bed
- Operating theatre not available
- 'Over-run' of operating theatre during preceding case(s)
- Equipment/ instrument problem / unavailability
- Staff (surgeon, anaesthetist, theatre staff etc) unavailable
- Patient did not attend
- Patient/family refused surgery
- Change in patient's medical status
- Incomplete preoperative work-up
- Finance related issues
- Other reason

In addition, a breakdown should be provided for the number of patients for whom COVID-19 contributed to the reason for cancellation (e.g. insufficient ITU bed capacity due to COVID-19 admissions, or surgeon unavailable as self-isolating with SARS-CoV-2 infection).

4.5 Local approvals for the patient-level component

Hospital Leads are responsible for obtaining necessary local approvals at each participating site. If the hospital is participating in the patient-level component, we suggest that the hospital-level component is included within an overall submission including both the patient-level and hospital-level components.

If the hospital is not participating in the patient-level component, we suggest to explore with your ethics committee/IRB/ equivalent whether the need for formal study approval can be waived, as **only anonymised, aggregated (administrative) data will be collected.**

6 References

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Baseline Form

[1-1] Date of operation: _____
 Only week (not full date) collected on REDCap

[1-2] Age at surgery: [a] 0-4 weeks;
 [b] 5-52 weeks; [c] 1-4y; [d] 5-9y; [e] 10-17y |
 [f] 18-29y; [g] 30-39y; [h] 40-49y; [i] 50-59y;
 [j] 60-69y; [k] 70-79y; [L] 80-89y; [m] ≥90y

[1-3] Sex
 [a] Female
 [b] Male

[1-4] Revised Cardiac Risk Index
Please tick all that apply
 [a] History of ischemic heart disease
 [b] History of congestive heart failure
 [c] History of cerebrovascular disease
 [d] Diabetes mellitus (type 1 or type 2)
 [e] Pre-operative creatinine >2 mg/dL /
 176.8µmol/L
 [f] None of the above

[1-5] ASA
 [a] Grade 1
 [b] Grade 2
 [c] Grade 3
 [d] Grade 4
 [e] Grade 5

[1-6] Preoperative respiratory support
 [a] None
 [b] Supplemental oxygen only
 [c] Non-invasive ventilation
 [d] Mechanical ventilation

[1-7] Was the patient given VTE prophylaxis? (tick all that apply)
 [a] Mechanical prophylaxis
 [b] Pharmacological prophylaxis
 [c] None of the above

SARS-CoV-2 Form

[2-1] Was the patient operated in a segregated COVID-19 free surgical pathway?
 [a] No
 [b] Yes – segregated pathway in a hospital that DOES admit COVID-19 patients
 [b] Yes – segregated pathway in a hospital that does NOT admit COVID-19 patients

[2-2] Preoperative screening tests in the 7 days before surgery? (tick all that apply)
 [a] SARS-CoV-2 swab (PCR) test
 [b] Rapid antigen test (e.g. lateral flow test)
 [c] None of the above

[2-3] Timing of SARS-CoV-2 diagnosis
 [a] Preoperative diagnosis (up to 7 days before surgery)
 [b] Postoperative diagnosis (within 30 days after surgery)

[2-4] Method of SARS-CoV-2 diagnosis (tick all that apply)
 [a] SARS-CoV-2 PCR swab
 [b] Rapid antigen test (e.g. lateral flow test)

[2-5] Confirmed or suspected SARS-CoV-2 variant
 [a] Alpha
 [b] Beta
 [c] Gamma
 [d] Delta
 [e] Omicron
 [f] Other
 [g] Not known

[2-6] Has the patient had a positive SARS-CoV-2 PCR swab or rapid antigen test more than 7 days before surgery?
 [a] No
 [b] Yes

If yes: Timing of most recent positive test more than 7 days before surgery
 <2 weeks | 2-6 weeks | 7 weeks - 4 months | 5-6 months | 7-8 months | 9+ months

[2-7] Has the patient had COVID-19 vaccination?
 [a] No
 [b] Yes

If yes: (a) Number of doses: _____
(b) For each dose, vaccine administered:
 dose 1: _____ | dose 2: _____ | dose 3: _____
(c) Timing of most recent dose
 <2 weeks | 2-6 weeks | 7 weeks - 4 months | 5-6 months | 7-8 months | 9+ months

Intraoperative Form

[3-1] Urgency of surgery
 [a] Elective (planned admission for surgery)
 [b] Emergency (unplanned admission)

[3-2] Procedure: _____

[3-3] General anaesthesia
 [a] No
 [b] Yes

[3-4] Indication for surgery
 [a] Benign disease / obstetric
 [b] Malignancy
 [c] Trauma

[3-5] Operative approach
 [a] Planned open surgery
 [b] Planned and performed as minimally invasive
 [c] Minimally invasive surgery converted to open

30-day Outcomes Form

[4-1] Mortality
 [a] Alive at 30 days
 [b] Died within 30 days of surgery

[4-2] Complications
Please tick all that apply
 [a] Pneumonia
 [b] Acute respiratory distress syndrome
 [c] Unexpected ventilation
 [d] Pulmonary embolism
 [e] Deep vein thrombosis
 [f] None of the above

[4-3] Postoperative critical care (ITU) admission
 [a] None
 [b] Yes – planned critical care admission
 [c] Yes – unplanned critical care admission