# GlobalSurg-CovidSurg Week: Determining the optimal timing for surgery following SARS-CoV-2 infection

## INVESTIGATOR PACK

This Investigator Pack provides detailed information to support GlobalSurg-CovidSurg Week data collection. This document supplements the main study protocol, which is available from https://globalsurg.org/surgweek/.



It is likely that as the study progresses that the Investigator Pack will be updated to address queries from collaborators. An up to date Investigator Pack will be available from our website at https://globalsurg.org/surgweek all times.

## SECTION 1: LIST OF EXCLUDED PROCEDURES

The GlobalSurg-CovidSurg Week study will include all operations (elective or emergency) performed in an operating theatre by a surgeon, excluding minor procedures. All surgical specialties are included. Both day case surgery and inpatient surgery are included. Both children and adults are included. Patients with **any SARS-CoV-2 status** (positive at any time, negative, not tested) are included.

For endoscopic procedures (diagnostic or therapeutic) those that are usually performed in an operating theatre by a surgeon are included. Endoscopic procedures that are usually performed outside of an operating theatre (e.g. in an endoscopy suite) or by a non-surgeon are excluded.

The minor procedures that are excluded are adapted from those identified by Abbott et al[1]. These are listed below.

| Specialty | Excluded procedures |
|---|---|
| Abdominal surgery | Ascitic drain (drainage of peritoneal cavity) |
| | Endoscopic ultrasound |
| | Laparoscopic ultrasound |
| Breast surgery | Breast biopsy |
| Cardiac surgery | Insertion of cardiac pacemaker |
| | PCI: percutaneous coronary intervention |
| | Transluminal balloon angioplasty of coronary artery |
| Colorectal surgery | Colonoscopy (diagnostic or therapeutic) |
| | Flexible sigmoidoscopy (diagnostic or therapeutic) |
| | Proctoscopy (diagnostic or therapeutic) |
| Dental procedures | Implantation of tooth |
| | Insertion of dental prosthesis |
| | Orthodontic operations |
| | Restoration of tooth |
| | Extraction of tooth |
| Gynaecology | Cervical biopsy |
| | Colposcopy (diagnostic or therapeutic) |
| Obstetrics | Any vaginal delivery (normal delivery, breech delivery, forceps delivery, vacuum delivery) |
| | Surgical termination of pregnancy |
| Ophthalmology | Removal of foreign body from cornea |
| Orthopaedics | Bone biopsy |
| | Injection in to joint |
| | Muscle biopsy |
| Otolaryngology | Laryngoscopy (diagnostic or therapeutic) |
| | Nasendoscopy (diagnostic) |
| | Packing of cavity of nose |
| Thoracic surgery | Bronchoscopy (diagnostic) |
| | Insertion of chest drain |

| | |
|---|---|
| Upper gastrointestinal surgery | ERCP: endoscopic retrograde cholangiopancreatography (diagnostic or therpaeutic) |
| | Liver biopsy |
| | OGD: Oesophago-gastro-duodenoscopy (diagnostic or therapeutic) |
| Urology* | Bladder biopsy |
| | Extracorporeal shock wave lithotripsy (ESWL) |
| | Flexible cystoscopy (diagnostic) |
| | Percutaneous nephrostomy |
| Vascular surgery | Endovenous laser treatment (EVLT) for varicose veins |
| | Insertion or removal of dialysis catheter |
| | injection into varicose vein of leg |
| | Transluminal (endovascular) procedures on arteries (diagnostic or therapeutic), including with open cut down to the artery |
| | Transluminal (endovascular) procedures on veins (diagnostic or therapeutic) |
| | Insertion or removal of Hickmann line |
| Other | Insertion of central venous catheter/ line (CVC) |
| | Insertion of chest drain |
| | Lumbar (spinal) puncture |
| | Percutaneous tracheostomy |
| | Skin biopsy (including shave biopsy of skin) |
| | Therapeutic epidural injection |
| | Vacuum dressing |

*Note: transurethral resection of the prostate (TURP), transurethral resection of bladder tumour (TURBT), rigid cystoscopy under general anaesthesia, and insertion of ureteric stent should be included.

1. Abbott TEF, Fowler AJ, Dobbs TD, Harrison EM, Gillies MA, Pearse RM. Frequency of surgical treatment and related hospital procedures in the UK: a national ecological study using hospital episode statistics. Br J Anaesth. 2017;119(2):249-257.

# SECTION 2: GUIDE TO USING THE REDCAP SYSTEM

## (1) Setting up your REDCap account

Once your REDCap account has been processed, you will receive an automated email (please see below) with a username and a link to log into REDCap to set your password (please note, this may go to your spam folder).

[This message was automatically generated by REDCap]

You have been given access to the REDCap project named "GlobalSurg-CovidSurg Week Data - Europe". Using your user name "hmann_test", you may log in to the project using the link below.

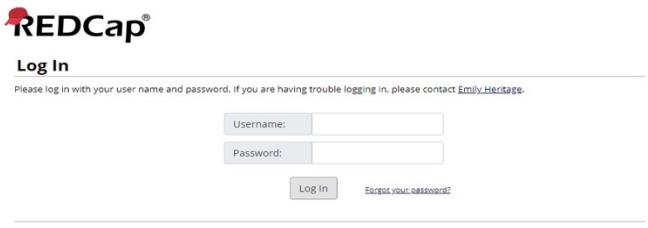
https://globalsurgery.redcap.bham.ac.uk/

## (2) Logging in to REDCap

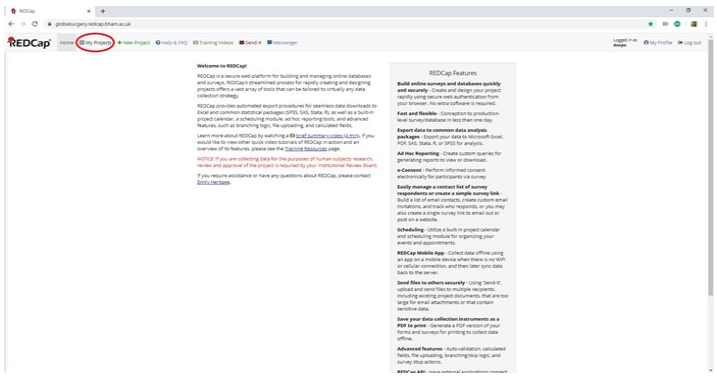
1. Go to: https://globalsurgery.redcap.bham.ac.uk/

This can be viewed on a tablet and mobile device via your web browser but select Desktop mode, as otherwise it will be harder for you to work out where everything is.

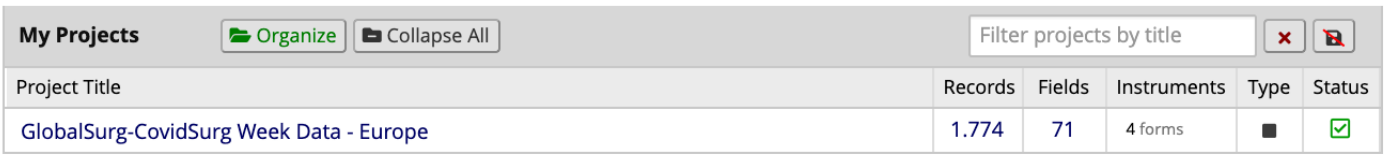
2. You will be presented with this screen to fill in your login details:




3. Once you are logged in you will be at the home page. Click on “My Projects” on the left-hand side of the menu bar running across the top of the screen.



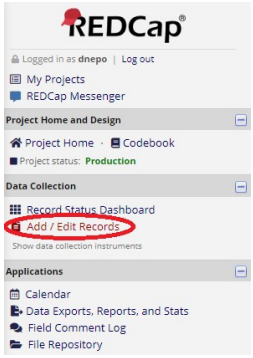
4. You will be presented with access to the GlobalSurg-CovidSurg Week project.



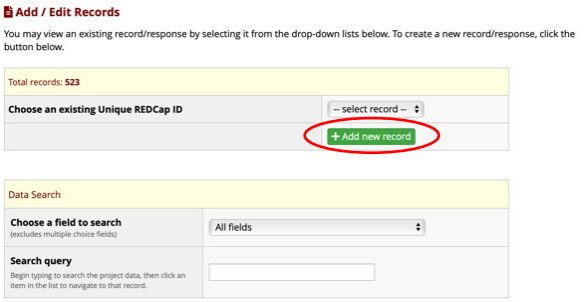
5. Click on the “GlobalSurg-CovidSurg Week” link to go to the project. Please note: the exact wording on the link will depend on your geographic location (e.g. it could be GlobalSurg-CovidSurg Week – Europe, or GlobalSurg-CovidSurg Week – Africa etc).

## (3) Creating a new record & managing REDCap IDs

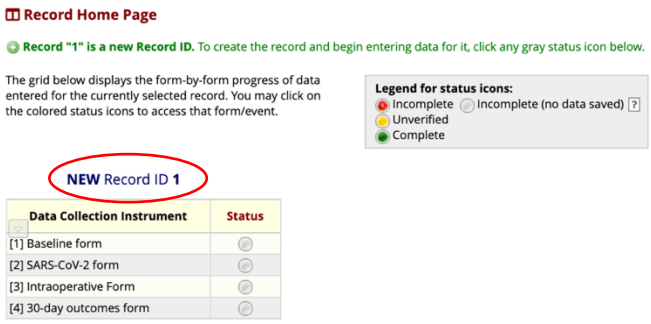
1. On left hand menu click on “Add / Edit Record”




2. Click the green “add new record” button to add a new patient to the database




3. An important part of the next screen is the REDCap ID. This will be the only identifier for your patient on the database. Therefore, you may want to keep a **local cross-reference of REDCap ID versus patient details** so that you are able to return to identify your patients on REDCap, e.g. so that you can edit REDCap records later. You can either keep this cross reference (1) on paper (please see appendix XX for a template) in a locked, secure office, or (2) in an encrypted spreadsheet on a password protected computer.




In the screenshot above the REDCap ID would be "1". In practice REDCap IDs for your patients will be in the format "XXXX-N" where "XXXX" is the code for your data access group (DAG) an "N" is a unique number assigned to each of your records (this will start with 1 for your first record and sequentially increase

for each patient). For example record 1739-1 would be the first record entered by the DAG with the code 1739.

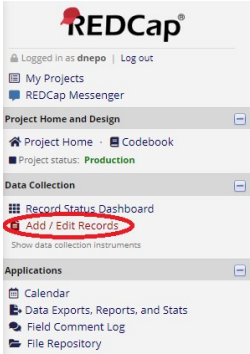
4. To start entering data, click on the next to "[1] Baseline Form" and it will take you to the baseline data page.

5. Once you have filled out all the relevant details, click the blue **"Save & Exit Record"** button at the bottom of the page to close the data entry form. Alternative you can click the blue "**Save & Go To Next Form"** button to move to the next form for that patient.

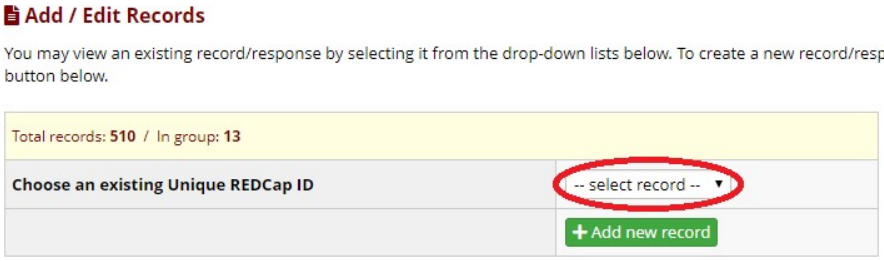
## (4) Editing patient records on REDCap

1. On left hand menu click on "Add / Edit Record"

*Please note, you will need to know the REDCap ID for the patient whose data you wish to edit.*

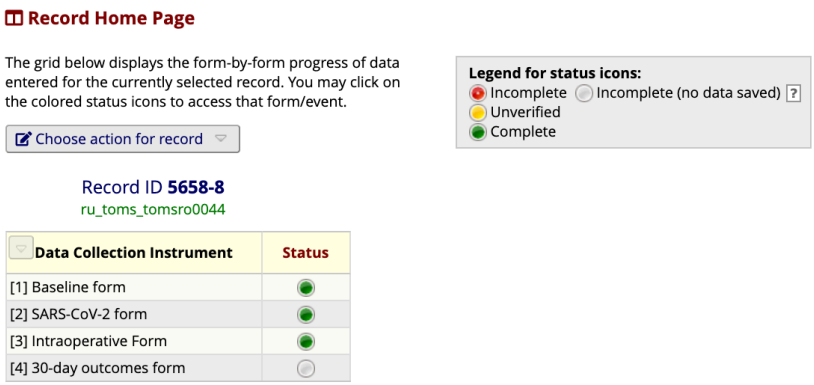



2. Click on 'select record' (see below) and a drop-down list will appear of all records linked to your mini-team.




3. Scroll down to the record you want to edit and click on it.

4. You will now see the list of forms for the patient you selected. Click on the button in the "Status" column to access the form that you would like to edit. Click on the button for the form you wish to view, to proceed to that form.



## (5) Mark a record for removal from the study

Collaborators are unable to directly delete records on REDCap. Instead, please use the 'record inclusion/ exclusion' field to flag records that should be excluded from the analysis. This field can be found at the end of the 30-day follow-up form.

**Record inclusion / exclusion from analysis**

**Should this record be included in the analysis?**

* must provide value

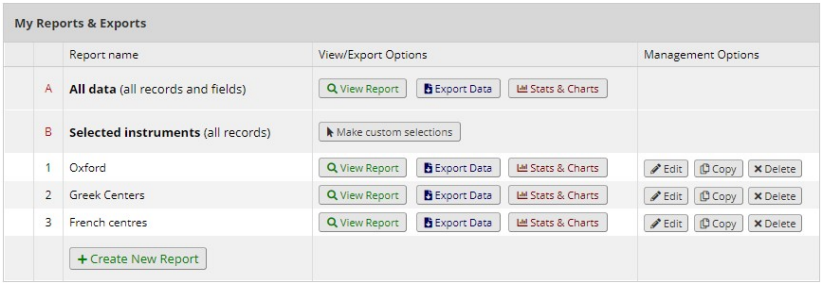
- Include - this is a valid record for a patient who fulfils inclusion criteria
- Exclude - patient does not fulfil inclusion criteria
- Exclude - patient did not undergo surgery (operation cancelled)
- Exclude - duplicate record
- Exclude - patient withdrew consent
- Exclude - test/practice record or record created by error

reset

## (6) Download data entered from your hospital

1. On left hand menu click on “Data Exports, Reports, and Stats” (see below)


2. You will then see the options to view this data.
You can either click on “View Report” which will show you the data in your browser and you can look through it.



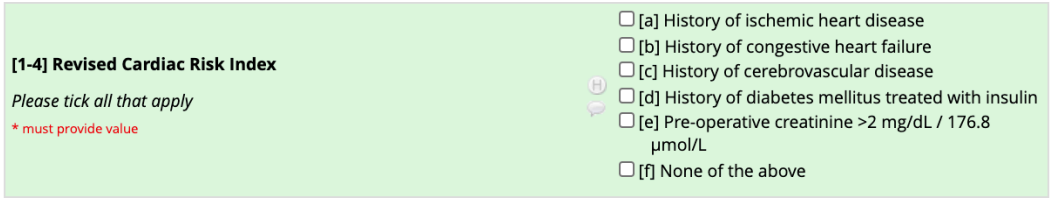
3. The other option which is “Export Data” which will pop-up the download options. From these options select “CSV / Microsoft Excel (labels) and click "Export data" in the bottom right of the box.

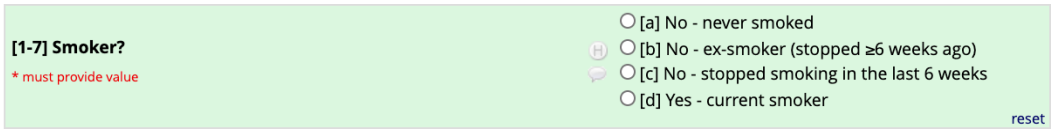
4. This will now bring up another pop-up. Click on the Excel-CSV icon to download the file.

## SECTION 3: DATA DICTIONARY

This document will guide you through data entry for the key data fields for GlobalSurg-CovidSurg Week. Please complete all fields that appear on each REDCap record. In order to provide high quality data to inform the global surgical community, it is essential that all data is as complete as possible.

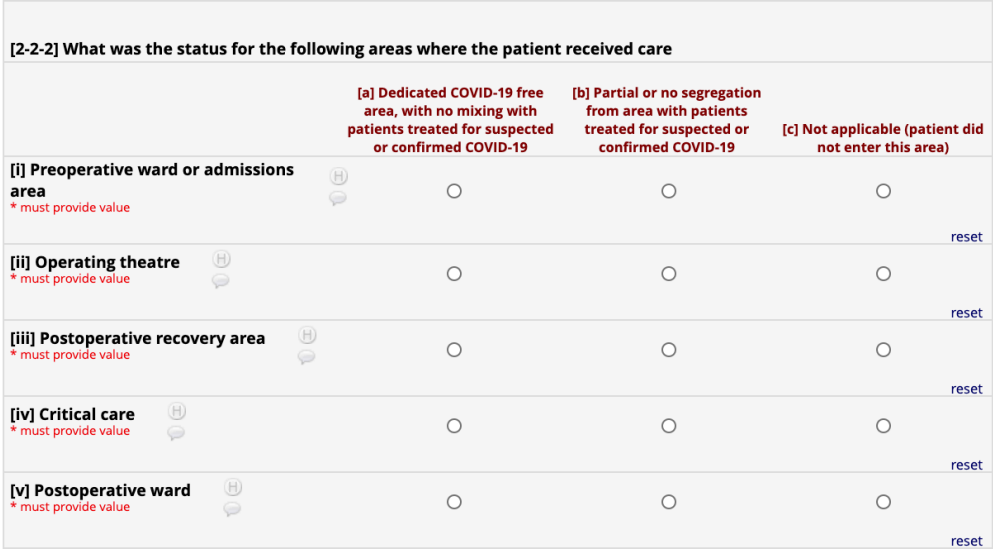
## [1] BASELINE INFORMATION FORM

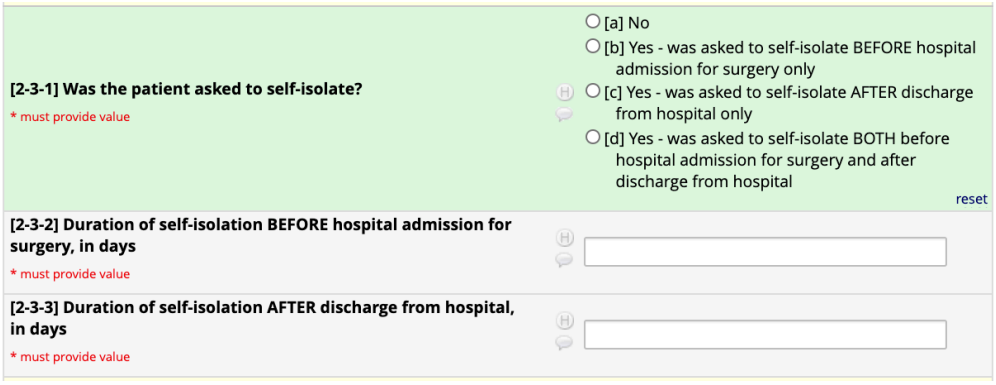
| **Data field**<br>***REDCap variable name*** | **Notes** |
|---|---|
| **[1-1] Study period**<br>*period* | We have pre-defined set dates for each period, however, you may adapt these dates locally by agreement with all collaborators. |
| **[1-2] Age**<br>*age* | Select appropriate age band based on the patient's age on the day of surgery. |
| **[1-3] Sex**<br>*sex* | Sex as assigned at birth. |
| **[1-4] Revised Cardiac Risk Index**<br>*rcri* | Tick all the appropriate options for this patient.<br>• Cerebrovascular disease includes both stroke and transient ischaemic attack (TIA).<br>• Diabetes mellitus includes both type 1 and type 2 diabetes mellitus – only select this option if the patient was on insulin in the week before surgery.<br>• Preoperative creatinine refers to creatinine measured prior to hospital admission (if available). If pre-admission creatinine is not available, please use the first available creatinine on hospital admission.<br><br>If there is no hospital record to confirm that a patient does / does not have a comorbidity, please record the patient as not having that comorbidity.<br><br>If the patient has none of these comorbidities, please tick "None of the above".<br><br>  |
| **[1- 5] Respiratory Comorbidities**<br>*resp_comorb* | Please tick all of the options as appropriate for the patient.<br>• Asthma/COPD includes any patients who have been diagnosed with the condition, regardless of their current treatment.<br>• If you select option [c] Other respiratory comorbidity, please specify details in the box [1-5-2] that appears below.<br>• If the patient does not have any respiratory comorbidities, please tick "None of the above".<br><br>  |

| | |
|---|---|
| **[1-6] American Society of Anesthesiologists (ASA) grade**<br>*asa* | ASA grade at the time of surgery.<br>Definitions:<br>(1) Healthy person<br>(2) Mild systemic disease (e.g. hypertension).<br>(3) Severe systemic disease (e.g. severe ischaemic heart disease).<br>(4) Severe systemic disease that is a constant threat to life.<br>(5) A moribund person who is not expected to survive without the operation.<br>Full definitions are available from: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system |
| **[1-7] Smoking status of the patient**<br>*smoking* | Please tick as appropriate. Please note that there are two options for patients who previously smoked but no longer smoke depending on how long ago they stopped smoking.<br>  |

**CONTINUE TO NEXT PAGE FOR THE SARS-COV-2 FORM**

## [2] SARS-COV-2 FORM

| Data field<br>*REDCap variable name* | Notes |
|---|---|
| **[2-1] Treatment of COVID-19 patients at this hospital**<br>*admit_covid* | • Please select "no" if the hospital does not admit **any** patients for the treatment of COVID-19.<br>• Please select "yes" if the hospital does admit patients for the treatment of COVID-19 under any specialty (e.g. including COVID-19 patients admitted to medical specialties). |
| **[2-2-1] COVID-19 free surgical pathway**<br>*hotcold* | A segregated COVID-19 free surgical pathway is defined as a hospital policy of segregation of all area in which this patient was treated, away from areas treating COVID-19 patients (including operation theatre, recovery area, critical care and ward). However, within this definition staff members may be involved in the care of both COVID and non-COVID patients.<br><br>If you have selected that the patient was not on a COVID-19 free surgical pathway, please complete the expanded form **[2-2-2]** to describe whether each of the areas (preoperative ward/ admissions area, oeprating theatre, recovery area, critical care, postoperative ward) listed were:<br>a) Dedicated COVID-19 free area, with no mixing with patients treated for suspected or confirmed COVID-19.<br>b) Partial or no segretation from area with suspected patients treated for suspected or confirmed COVID-19.<br>c) Not applicable (patient did not enter this area)<br><br>  <br>[2-2-2] What was the status for the following areas where the patient received care<br>[a] Dedicated COVID-19 free area, with no mixing with patients treated for suspected or confirmed COVID-19 / [b] Partial or no segregation from area with patients treated for suspected or confirmed COVID-19 / [c] Not applicable (patient did not enter this area)<br>[i] Preoperative ward or admissions area * must provide value<br>[ii] Operating theatre * must provide value<br>[iii] Postoperative recovery area * must provide value<br>[iv] Critical care * must provide value<br>[v] Postoperative ward * must provide value<br>reset |
| **[2-3-1] Self Isolation**<br>*self_isolation* | Self-isolation is defined as a practice of limiting social contacts in order to reduce the likelihood of contracting SARS-CoV-2 infection. For example, when someone self-isolates they **may** be advised to:<br>• Not go to work or school/ college.<br>• Avoid public places<br>• Avoid public transport and taxis.<br>• Not have visitors in their home (including visits from friends or family).<br>• Exercise at home.<br>Specific arrangements for self-isolation may differ between countries. |

<table>
<tr><td></td><td>If your answer indicates that the patient was asked to self-isolate before and/or after hospital admission, you will be asked to enter the duration of their self-isolation in <u>whole</u> days.<br><br> 
</td></tr>
<tr><td>[2-4-1]<br>SARS-CoV-2 infection<br>sars_diagnosis</td><td>Please complete this form based on the FIRST time the patient had a positive SARS-CoV-2 test result (swab / rapid antigen / antibody test).<br><br>If the patient has not had a positive SARS-CoV-2 test result, please complete based on the FIRST time they were diagnosed with SARS-CoV-2 clinically or based on CT scan.<br><br>For patients diagnosed based on a SARS-CoV-2 swab PCR test, the timing of diagnosis should be determined by whether the swab was taken before surgery (preoperative diagnosis) or after surgery (postoperative diagnosis). If a swab was taken before surgery but the result was only available after surgery, they should still be recorded as having a preoperative diagnosis.<br><br>If the patient has not had a diagnosis of SARS-CoV-2 Infection, please select "no".<br><br> 
</td></tr>
<tr><td>[2-4-2]<br>SARS-CoV-2 diagnosis<br>diagnosis_how</td><td>If SARS-CoV-2 was diagnosed, question [2-4-2] will appear, as below:<br><br>Please select at least one option.<br>Multiple options can be selected if appropriate.<br><br> 
</td></tr>
<tr><td>[2-4-3] to [2-4-6]<br>Preoperative diagnosis of SARS-CoV-2 questions</td><td>If SARS-CoV-2 was diagnosed at any time before surgery, questions [2-4-3] to [2-4-6] <u>may</u> appear, as below:<br><br>[2-4-3] Please select the period of time between when the patient was initially diagnosed with SARS-CoV-2 and when the surgery was performed.</td></tr>
</table>

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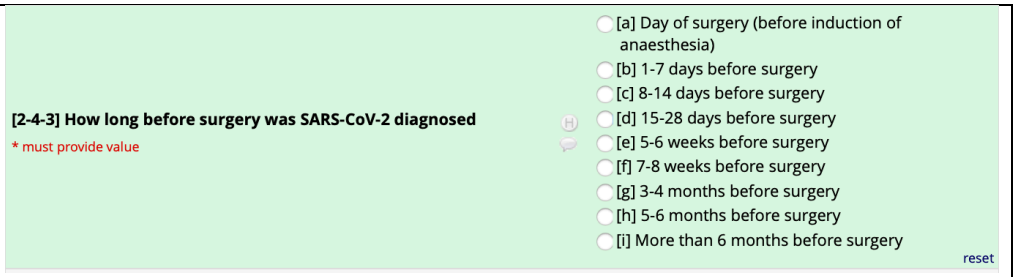
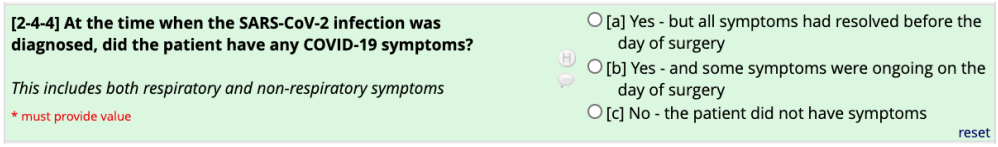
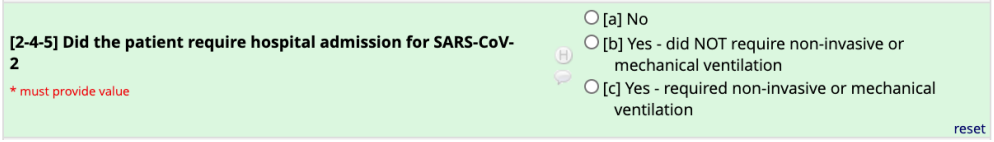
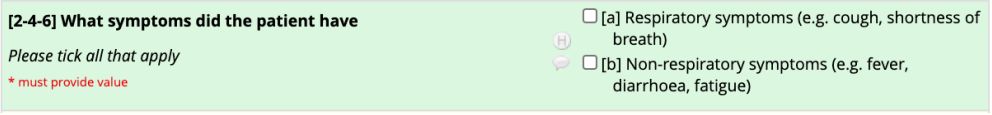
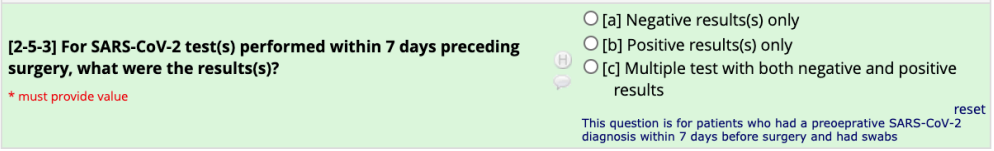
<td>


<br><br>
[2-4-4] At the time, when the SARS-CoV2 infection was diagnosed, did the patient have any COVID-19 symptoms? This can include both respiratory symptoms (e.g. cough, shortness of breath) and / or non-respiratory symptoms (e.g. fever, sore throat) that are thought to be directly related to the COVID-19 infection.
<br><br>


<br><br>
[2-4-5] Include any hospitalisation directly related to COVID-19. If the patient was already in hospital when they were diagnosed, please select that they required hospitalisation.
<br><br>


<br><br>
[2-4-6] If you indicated that the patient had symptoms, please indicate whether these symptoms were respiratory and/or non-respiratory.
<br><br>


</td>
</tr>
<tr>
<td>[2-5-1] Pre-operative screening of SARS-CoV-2<br>screening</td>
<td>Please indicate all the tests that were used to screen for SARS-CoV-2 in the 7 days before surgery. These tests could be performed in hospital as an outpatient or inpatient, or in the community. Include chest x-rays and CT thorax scans even if these were not specifically performed to screen for SARS-CoV-2.</td>
</tr>
<tr>
<td>[2-5-2] to [2-5-4] Preoperative screening questions</td>
<td>
If SARS-CoV-2 screening was performed using SARS-CoV-2 swab (PCR) test and / or rapid antigen test, questions [2-5-2] to [2-5-4] appear as explained below:
<br><br>
[2-5-2] will only appear for patients who had a preoperative SARS-CoV-2 diagnosis and had screening with SARS-CoV-2 (PCR) swab and/or rapid antigen test.
<br><br>


</td>
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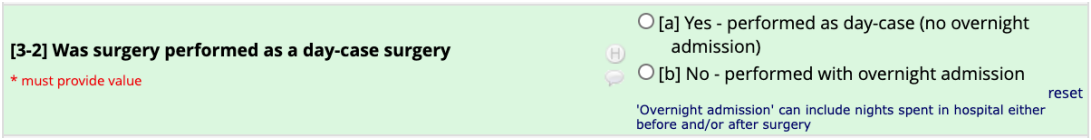
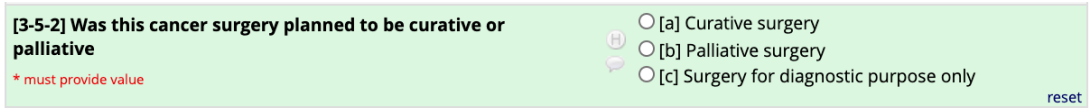
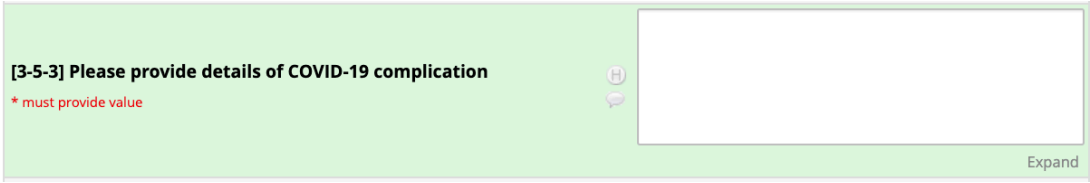
| | |
|---|---|
| | **[2-5-3]** will only appear if the patient (1) did not have a SARS-CoV-2 diagnosis, or (2) had a postoperative SARS-CoV-2 diagnosis, or (3) is recorded as having had a negative test result in [2-5-2].<br><br>If the patient had multiple negative test results please enter details for the last negative test the patient had before surgery (i.e. most recent negative test preceding surgery).<br><br>If this field appears, please indicate (i) the **timing of when the test was taken** relative to when the patient had surgery [i.e. when specimen taken rather than when result was received], and (ii) if the patient was screened with both SARS-CoV-2 swab (PCR) test and rapid antigen test, whether the test result you are reporting here was a swab test or rapid antigen test.<br><br>**[2-5-4]** will only appear if the patient is recorded as having had a positive test result in [2-5-2].<br><br>If the patient had multiple positive test results please enter details for the last positive test the patient had before surgery (i.e. most recent positive test preceding surgery).<br><br>If this field appears, please indicate (i) the **timing of when the test was taken** relative to when the patient had surgery [i.e. when specimen taken rather than when result was received], and (ii) if the patient was screened with both SARS-CoV-2 swab (PCR) test and rapid antigen test, whether the test result you are reporting here was a swab test or rapid antigen test. |

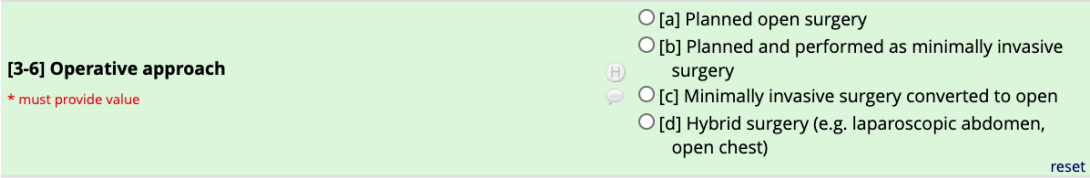
**CONTINUE TO NEXT PAGE FOR THE INTRAOPERATIVE FORM**

## [3] INTRAOPERATIVE FORM

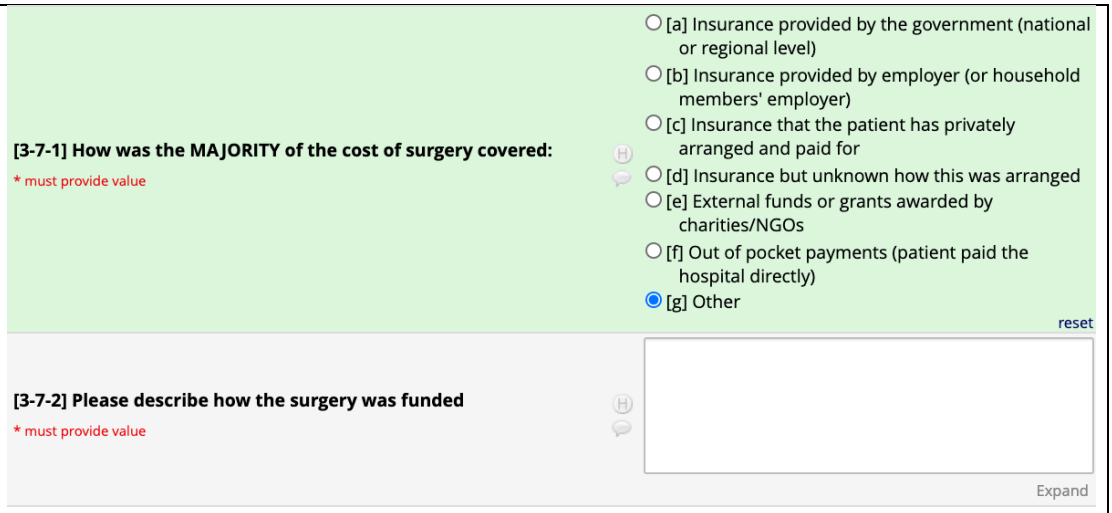
| **Data field**<br>***REDCap variable name*** | **Notes** |
|---|---|
| **[3-1] Urgency of Surgery**<br>*urgency* | For this study, urgency of surgery is determined by whether surgery took place on a planned hospital admission or not<br>• Elective surgery: <u>planned</u> admission to hospital for surgery.<br>• Emergency surgery: <u>unplanned</u> admission to hospital. Surgery may take place on the same day as the patient is admitted to hospital, or several days or weeks after hospital admission. |
| **[3-2] Daycase**<br>*day_case_surgery* | Day case surgery is defined as a patient attending hospital, being operated, and discharged home all on the same day, with no overnight stay in hospital.<br><br>If a patient was planned to have day-case surgery but actually they required overnight admission, then "no – performed with overnight admission should be selected".<br><br>  |
| **[3-3] Procedure**<br>*procedure* | The drop-down menu includes an extensive list of procedures. Please choose the most suitable code for the <u>main</u> procedure that the patient underwent. For example, if a patient underwent appendicectomy and laparoscopic washout, please record this as appendicectomy (the main procedure performed).<br><br>If the specific procedure a patient had is not listed, there are general options within each body system (e.g. 'BRAIN & SKULL - any other procedures not listed') which can be selected; further detail can then be entered in the 'additional detail' free text box below the procedure dropdown field.<br><br>If you are collecting data on paper forms, please write down the full procedure name on in the space provided on the form. You can later select the most appropriate code when you are entering the data on to REDCap.<br><br>  |
| **[3-4] Anaesthesia**<br>*anaesthesia* | Please tick the boxes for each type of anaesthesia that the patient had. |
| **[3-5-1] Indication for Surgery**<br>*indication* | The indications for surgery are defined as follows:<br>• Benign disease: any disease/ condition that is not a cancer or related to trauma, obstetrics, or COVID-19.<br>• Malignancy: suspected or confirmed cancer.<br>• Trauma: any cause of injury, including burns. |

<table>
<tr><td></td><td>
<ul>
<li>Obstetric: procedures relating to childbirth, most commonly Ceserean section.</li>
<li>Complication of COVID-19: surgery required for a pathology directly related to COVID-19 infection (e.g. mesenteric ischaemia though to be caused by COVID-19).</li>
</ul>
If you answered [b] Malignancy, a further question [3-5-2] will appear. Please record what the intent of the surgery was:
<ul>
<li>Curative: to remove the cancer completely, or to enable definitive treatment to cure the patient. If a patient undergoes surgery with the aim of removing the cancer and cure but this proves to not be possible, they should still be recorded as having had curative intent.</li>
<li>Palliative: to relieve symptoms related to the cancer, knowning that that the surgery will not cure the patient.</li>
<li>Surgery of diagnostic purpose only included cases such as staging laparoscopy where the</li>
</ul>


If you answered [e] Complication of COVID-19, a further data field [3-5-3] will appear - please enter further details about the COVID-19 complication the patient had that required surgery.


</td></tr>
<tr><td>[3-6] Operative Approach<br>operative_approach</td><td>
Minimally invasive surgery is defined as any technique that makes use of specific instruments designed to reduce the invasiveness of the procedure / incision required. For example, this can include laparoscopic, thoracoscopic, arthroscopic, and robotic procedures. Laparoscopy-assisted procedures (i.e. where a small incision is made to allow extra-corporeal anastomosis, or to have an extraction site for the specimen) should be recorded as "planned and performed as minimally invasive surgery".<br><br>
"Minimally invasive surgery converted to open" includes any procedure which initially started as minimally invasive but where a decision was made during the surgery to switch to an open approach.<br><br>
"Hybrid surgery" are those cases where an open approach is used for one body compartment (e.g. abdomen) and a minimally invasive approach is used for another body compartment (e.g. chest). An example might be in some oesophagectomy procedures.


</td></tr>
<tr><td>[3-7-1] Cost of Surgery</td><td>If you have selected option [g] Other, a further data field [3-7-2] will appear - please enter further details here about how the patient's care was funded.</td></tr>
</table>

| | |
|---|---|
| *surg_supp* |  |
| **[3-8] Dexamethasone administration before surgery**<br>*dex_preop* | This question only relates to systemic (oral, intravenous, intramuscular) administration of dexamethasone. The use of other steroids should **not** be recorded here. Any intraoperative administration of dexamethasone should be recorded here as "yes". |
| **[3-9] Dexamethasone administration after surgery**<br>*dex_postop* | This question only relates to systemic (oral, intravenous, intramuscular) administration of dexamethasone. The use of other steroids should **not** be recorded here. If a patient received dexamethasone both as treatment of COVID-19 and for other reasons, please record "Yes – as treatment for COVID-19". |

**CONTINUE TO NEXT PAGE FOR THE 30-DAY OUTCOMES FORM**

## [4] 30-DAY OUTCOMES FORM

**The 30-day outcomes should only include complications / mortality up to and including postoperative day 30 (the day of surgery is day 0).**

**PLEASE REMEMBER TO REVIEW FIELD [2-4-1] 'SARS-COV-2 INFECTION' AT 30-DAYS TO ENSURE THAT ANY POSTOPERATIVE SARS-COV-2 INFECTIONS ARE CAPTURED**

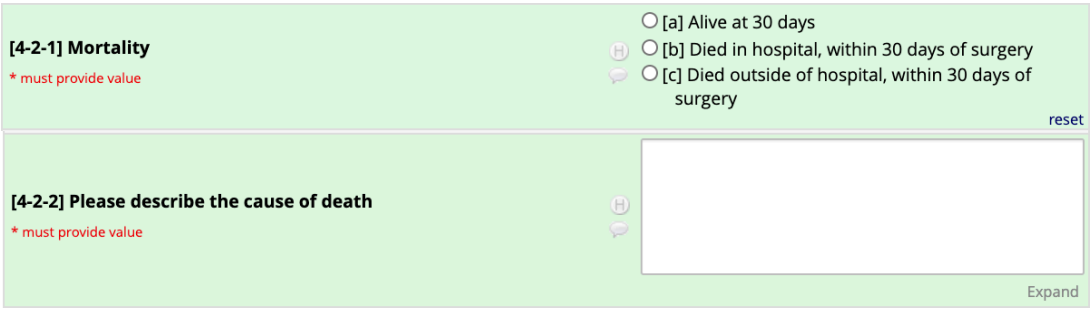
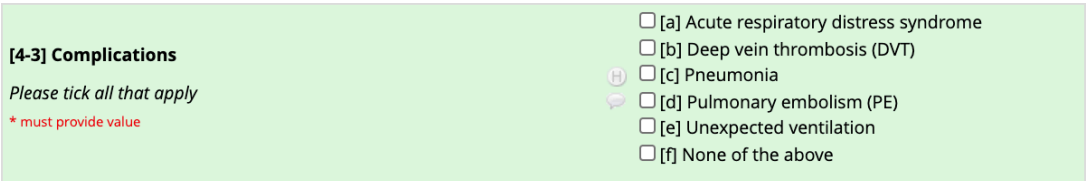
The 30-day outcomes form should be completed after the patient has reached postoperative day 30. The form can be completed either on day 30 or at any point after this.

Please note that 30-day follow-up should be based on existing hospital records. For this study there should be no changes to normal patient care/pathways, so no additional clinic or telephone follow-up should be completed for this study.

The 30-day follow-up should be based on all information routinely available at 30-days. This can include:

- Inpatient hospital notes (paper or electronic) relating to the index admission and any readmissions that the patient has had.
- Records from outpatient (clinic) reviews or telephone calls.
- Review of electronic hospital records to identify readmissions
  Review of electronic hospital records to identify patients recorded as having died.

[PLEASE SEE NEXT PAGE FOR DATA FIELDS]

| **Data field**<br>***REDCap variable name*** | **Notes** |
|---|---|
| **[4-1] Follow up completion**<br>*howfu* | Please select all the infromation sources used to complete 30-day follow-up. |
| **[4-2-1] Mortality**<br>*mortality* | This is the primary outcome measure for the study. Please take particular care that 30-day mortality is accurately recorded for **all** patients.<br><br>Include a patient was initially discharged from hospital, but subsequently died in hospital following re-admission, record this as [b] Died in hospital.<br><br>If you selected [b] Died in hospital or [c] Died outside of hospital, a further data field **[3-5-3]** will appear - please enter further details about the cause of death.<br><br>  |
| **[4-3] Complications**<br>*complications* | From the list provided, please select all the complications the patient experienced up to and including postoperative day 30. If the patient did not experience any of the listed complications, please tick "None of the above".<br><br>Please refer to the Appendix XX for full definitions of these complications.<br><br>Please note, we are not collecting data on any other specific complications.<br><br>  |
| **[4-4] Clavien Dindo Grade**<br>*clavien_dindo* | Please select the **highest** Clavien-Dindo complication grade the patient experienced up to and including postoperative day 30.<br><br>Please refer to the Appendix XX for full explanation of the Clavien-Dindo grading scale.<br><br>Please note: the Clavien-Dindo complication data field will only appear if you have indicated in [4-1] that the patient was alive at postoperative day 30. This is because patients who died will be automatically marked as Clavien-Dindo Grade V. |

## SECTION 4: OUTCOME DEFINITIONS

### Postoperative pulmonary complications

Postoperative pulmonary complications will be a secondary outcome. It is a composite of postoperative pneumonia, acute respiratory distress syndrome (ARDS) and unexpected ventilation. This outcome was adapted from the PRISM randomised controlled trial[1].

### Unexpected ventilation

Unexpected postoperative ventilation was defined as:

- Any episode of non-invasive ventilation, invasive ventilation, or extracorporeal membrane oxygenation after initial extubation after surgery, **or**
- Patient could not be extubated as planned after surgery.

### Acute Respiratory Distress Syndrome

Acute Respiratory Distress Syndrome (ARDS) is an acute diffuse, inflammatory lung injury, leading to increased pulmonary vascular permeability, increased lung weight, and loss of aerated lung tissue with hypoxemia and bilateral radiographic opacities. The Berlin consensus definition[2] will be used:

| **Acute Respiratory Distress Syndrome criteria - ALL 4 CRITERIA REQUIRED** | |
|---|---|
| **1. Timing** | Within 1 week of known clinical insult or worsening respiratory symptoms |
| **2. Chest imaging** | Bilateral opacities (not fully explained by effusions / collapse / nodules). |
| **3. Origin** | Respiratory failure (not fully explained by cardiac failure / fluid overload). |
| **4. Oxygenation** | Mild: 200mmHg < $PaO_2/FIO_2$ ≤ 300mmHg with PEEP or CPAP ≥5cm $H_2O$<br>Moderate: 100mmHg < $PaO_2/FIO_2$ ≤ 200mmHg with PEEP ≥5cm $H_2O$<br>Severe: $PaO_2/FIO_2$ ≤ 100mmHg with PEEP ≥5cm $H_2O$<br>*CPAP: continuous positive airway pressure; $FIO_2$: fraction of inspired oxygen; $PaO_2$: partial pressure of arterial oxygen; PEEP: positive end-expiratory pressure.* |

### Postoperative pneumonia

The US Centers for Disease Control (CDC) definition of pneumonia[3] will be used, modified to accommodate limited availability of radiological facilities at some participating centres:

At least **one** of the following:

- Fever (>38°C) with no other recognised cause.
- Leucopaenia (white cell count <$4x10^9$) or leucocytosis (white cell count >$12x10^9$).
- For adults >70 years old, altered mental status with no other recognised cause.

AND at least **two** of the following:

- New onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements.
- New onset or worsening cough, or dyspnoea, or tachypnoea.
- Rales, crackles or bronchial breath sounds.
- Worsening gas exchange (hypoxaemia, increased oxygen requirement).

Wherever possible, the diagnosis should be confirmed with a chest radiograph. The following findings confirm pneumonia:

- New or progressive and persistent infiltrates.
- Consolidation.
- Cavitation.

## Deep vein thrombosis

Deep vein thrombosis (DVT)[3-4] is defined as lower limb deep vein thrombosis with or without symptoms, proven by:

- Lower extremity ultrasonography revealing non-compressibility at the trifurcation of the popliteal vein or above, **or**
- Computed tomography (CT) venography demonstrating a constant intraluminal filling defect above the trifurcation of the popliteal vein.

## Pulmonary embolism (PE)

Pulmonary embolism (PE)[3-4] is defined as:

- Symptomatic PE confirmed by imaging (computed tomography pulmonary angiogram (CTPA) demonstrating new intraluminal filling defect in a subsegmental or greater sized pulmonary artery; or ventilation/perfusion scanning with a high probability of PE; or pulmonary angiograph demonstrating PE), **or**
- Fatal PE discovered at autopsy or as judged by the clinical team.

## Clavien-Dindo Classification System

Adverse post-operative events may be classified as:

- **Failure of treatment** – This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- **Sequelae**: The recognised consequences of a given procedure; for example, gut malabsorption following a large small bowel resection or immune deficiency following splenectomy.
- **Complication**: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification[5], the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade III).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is intra-operative death; this is classified as grade V.
- All post-operative adverse events are included, even when there is no direct relationship to the surgery.
- All adverse events within the follow-up period (30 days) are included, including following discharge.
- Diagnostic procedures are not included. For example, a diagnostic oesophagoduodenoscopy

(OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade IIIa complication. Since negative exploratory laparotomies are considered to be diagnostic procedures, they should not be recorded as complications.

| Grade | Definition (examples listed in italics) |
|---|---|
| **I** | Any deviation from the normal postoperative course without the need for pharmacological (other than "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention.<br><br>Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics.<br><br>*Examples: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.* |
| **II** | Requiring pharmacological treatment with drugs beyond those allowed for<br><br>grade I complications; including blood transfusions; total parenteral nutrition.<br><br>*Examples: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.* |
| **III** | Requiring surgical, endoscopic or radiological intervention<br><br>*Examples: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures; return to theatre for any reason* |
| **IV** | Life-threatening complications requiring critical care management; brain haemorrhage; or ischemic stroke (excluding TIA).<br><br>*Examples: Pneumonia with ventilator support, renal failure with filtration; SAH; stroke* |
| **V** | Death of a patient |


1. Pearse, R.M., et al., The Prevention of Respiratory Insufficiency 366 after Surgical Management 367 (PRISM) Trial. Report of the protocol for a pragmatic randomized controlled trial of CPAP to 368 prevent respiratory complications and improve survival following major abdominal surgery. 369 Minerva Anestesiol, 2017. 83(2): p. 175-182.
2. ARDS Definition Task Force, Ranieri V, Rubenfeld, GD, Thompson, BT, Ferguson, ND, Caldwell, E, Fan, E, Camporota, L, Slutsky, AS. Acute respiratory distress syndrome: the Berlin Definition. JAMA. 2012;307(23):2526-33.
3. Shalhoub J, Lawton R, Hudson J, Baker C, Bradbury A, Dhillon K, et al. Graduated compression stockings as adjuvant to pharmaco-thromboprophylaxis in elective surgical patients (GAPS study): randomised controlled trial. BMJ. 2020 May 13;369:m1309.
4. van der Hulle T, Cheung WY, Kooij S, Beenen LFM, van Bemmel T, van Es J, et al. Simplified diagnostic management of suspected pulmonary embolism (the YEARS study): a prospective, multicentre, cohort study. Lancet. 2017 Jul 15;390(10091):289-297.
5. Clavien P, Barkun, J, de Oliveira, ML, Vauthey, JN, Dindo, D, Schulick, RD, de Santibañes, E, Pekolj, J, Slankamenac, K, Bassi, C, Graf, R, Vonlanthen, R, Padbury, R, Cameron, JL, Makuuchi, M. The Clavien-Dindo classification of surgical complications: five-year experience. Annals of surgery. 2009;250(2):187-96.

SURG-WEEK
PROSPECTIVE INTERNATIONAL COHORT STUDY

NIHR Global Health Research Unit on Global Surgery

Mini-team details

## Locally maintained patient list

*– this is the only place identifiable information should meet REDCap ID*



| | |
|---|---|
| Hospital: | Specialty/(ies): |
| Patient inclusion period: *XX October 2020 - XX October 2020* | |
| Mini-team members: | |
| This CovidSurg Week form is to be kept: *Physical or Online Location* | |

| | Hospital Number | Date of birth | Date of index operation | Theatre location | Unique REDCap ID |
|---|---|---|---|---|---|
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**Please first contact your local CovidSurg team with any queries**

| | Role | Name | Contact email |
|---|---|---|---|
| | Mini team lead | | |
| | Hospital lead | | |
| | National lead | | |

*Visit https://globalsurg.org/surgweek/ to review the protocol or contact the central team.*

Please see the data dictionary in the Investigator Pack for detailed definitions. Download from https://globalsurg.org/surgweek

## Baseline Form

**[1-1] During which study period was the patient operated:** [a] Period 1; [b] Period 2; [c] Period 3; [d] Period 4

**[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] Pre-operative treatment with insulin
- ❑ [e] Pre-operative creatinine >2 mg/dL / 176.8µmol/L
- ❑ [f] None of the above

**[1-5-1] Respiratory Comorbidities:**
*Please tick all that apply*
- ❑ [a] Asthma
- ❑ [b] COPD
- ❑ [c] Other respiratory comorbidity
  **[1-5-2]** if yes, detail: _____
- ❑ [d] None of the above

**[1-6] ASA:**
- ❑ [a] Grade 1
- ❑ [b] Grade 2
- ❑ [c] Grade 3
- ❑ [d] Grade 4
- ❑ [e] Grade 5

**[1-7] Smoking status:**
- ❑ [a] No - never smoked
- ❑ [b] No - exsmoker, stopped ≥ 6 weeks ago
- ❑ [c] No - stopped in the last 6 weeks
- ❑ [d] Yes - current smoker

## Intraoperative Form

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

**[3-2] Day-case surgery:**
- ❑ [a] Performed as day-case (no overnight admission)
- ❑ [b] Performed with overnight admission

*(overnight admission can include nights spent in hospital either before and/or after surgery)*

**[3-3] Procedure:** _____

**[3-4] Anaesthesia:**
*Please tick all that apply*
- ❑ [a] General anaesthesia
- ❑ [b] Epidural anaesthesia
- ❑ [c] Spinal anaesthesia
- ❑ [d] Nerve block
- ❑ [e] Local anaesthesia / sedation

**[3-5-1] Indication for surgery:**
- ❑ [a] Benign disease
- ❑ [b] Malignancy
  **[3-5-2]** was this surgery planned to be:
  - ❑ [a] Curative surgery
  - ❑ [b] Palliative surgery
  - ❑ [c] Diagnostic procedure only
- ❑ [c] Trauma
- ❑ [d] Obstetric
- ❑ [e] Complication of COVID-19
  **[3-5-3]** if yes, detail complication:
  _____

**[3-6] Operative approach:**
- ❑ [a] Planned open surgery
- ❑ [b] Planned and performed as minimally invasive surgery
- ❑ [c] Minimally invasive surgery converted to open
- ❑ [d] Hybrid surgery (e.g. laparoscopic abdomen, open chest)

**[3-7-1] How was the MAJORITY of the cost of surgery supported?**
- ❑ [a] Insurance provided by the government (national or regional level)
- ❑ [b] Insurance provided by employer (or household members' employer)
- ❑ [c] Insurance that the patient has privately arranged and paid for
- ❑ [d] Insurance but unknown how this was arranged
- ❑ [e] External funds or grants awarded by charities/ NGOs
- ❑ [f] Out of pocket payments (patient paid the hospital directly)
- ❑ [g] Other
  **[3-7-2]** if yes, detail: _____

**[3-8] Was dexamethasone given at anaesthetic induction?** *Please only record data regarding dexamethasone and not other steroids*
- ❑ [a] No
- ❑ [b] Yes

**[3-9] Was dexamethasone given anytime after surgery up to 30 days postoperative?**
*Please only record data regarding dexamethasone and not other steroids*
- ❑ [a] No
- ❑ [b] Yes – as treatment for COVID-19
- ❑ [c] Yes – for reasons unrelated to COVID-19

Patient REDCAP No:

## 30-day Outcomes Form

**[4-1] How was follow-up completed**
*Please tick all that apply*
- ❑ [a] Inpatient hospital records
- ❑ [b] Post-discharge in-person clinic follow-up
- ❑ [c] Post-discharge telephone follow-up

**[4-2-1] Mortality**
- ❑ [a] Alive at 30 days
- ❑ [b] Died in-hospital, within 30 days of surgery
- ❑ [c] Died after discharge, within 30 days of surgery

**[4-2-2] If patient died, what was the cause of death:**

_____

**[4-3] Complications:**
Please refer to definitions in protocol appendix
*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

**[4-4] Clavien-Dindo:**
- ❑ [a] No complications
- ❑ [b] Grade I
- ❑ [c] Grade II
- ❑ [d] Grade IIIa/b
- ❑ [e] Grade Iva/b
- ❑ Grade V (Please note: this option will not appear on REDCap, as patient should be recorded as having died in question 4-2-1)

**SURG-WEEK**
PROSPECTIVE INTERNATIONAL COHORT STUDY

**CRF version 3: 14 October 2020**

# SARS-CoV-2 Form

*See page 1 for the Baseline, Intraoperative, and 30-day Outcomes Forms* 2

## COVID-19 free surgical pathway

**[2-1] Was the patient operated in a hospital which admits patients for treatment of COVID-19?**
- ❑ [a] No
- ❑ [b] Yes

**[2-2-1] Was the patient operated in a completely segregated COVID-19 free surgical pathway?**
*Please see Investigator Pack for definition*
- ❑ [a] Yes
- ❑ [b] No

**[2-2-2]** If no, for each of the following areas where the patient received the following care, were they:
- [a] Dedicated COVID-19 free area, with no mixing with patients treated for suspected or confirmed COVID-19
- [b] Partial or no segregation from area with patients treated for suspected or confirmed COVID-19
- [c] Not applicable (patient did not enter this area)

[i] Preoperative ward or admissions area: [a] or [b] or [c]
[ii] Operating theatre: [a] or [b] or [c]
[iii] Postoperative recovery area: [a] or [b] or [c]
[iv] Critical area: [a] or [b] or [c]
[v] Postoperative ward: [a] or [b] or [c]

## Self-isolation

**[2-3-1] Was patient asked to self-isolate?**
- ❑ [a] No
- ❑ [b] Yes – asked to self-isolate **BEFORE** hospital admission for surgery only
- ❑ [c] Yes – asked to self-isolate **AFTER** discharge from hospital only
- ❑ [d] Yes – asked to self-isolate **BOTH** BEFORE hospital admission for surgery and AFTER discharge from hospital

If patient was asked to self-isolate:
**[2-3-2] Duration of self-isolation BEFORE hospital admission:**
_____days (max 30 days)
**[2-3-3] Duration of self-isolation AFTER discharge from hospital:**
_____days (max 30 days)

## SARS-CoV-2 status*

**[2-4-1] SARS-CoV-2 infection**
- ❑ [a] No SARS-CoV-2 infection
- ❑ [b] Yes – preop diagnosis (at **ANY** time before surgery)
- ❑ [c] Yes – postop diagnosis (within 30 days after surgery)

If SARS-CoV-2 was diagnosed:
**[2-4-2] How was the SARS-CoV-2 confirmed?** *(tick all that apply)*
- ❑ [a] SARS-CoV-2 swab (PCR) test
- ❑ [b] Rapid antigen test
- ❑ [c] IgG antibody test
- ❑ [d] IgM antibody test
- ❑ [e] CT thorax scan
- ❑ [f] Clinical diagnosis based on history and examination

If SARS-CoV-2 diagnosis pre-operatively:
**[2-4-3] How long before surgery was SARS-CoV-2 diagnosed?**
- ❑ [a] Day of surgery (before induction of anaesthesisa)
- ❑ [b] 1-7 days before surgery
- ❑ [c] 8-14 day before surgery
- ❑ [d] 15-28 days before surgery
- ❑ [e] 5-6 weeks before surgery
- ❑ [f] 7-8 weeks before surgery
- ❑ [g] 3-4 months before surgery
- ❑ [h] 5-6 months before surgery
- ❑ [i] More than 6 months before surgery

**[2-4-4] At the time when the SARS-CoV-2 infection was diagnosed did the patient have <u>any</u> COVID-19 symptoms?**
- ❑ [a] Yes – but all symptoms had resolved before surgery
- ❑ [b] Yes – some symptoms were ongoing on the day of surgery
- ❑ [c] No – the patient did not have symptoms

**[2-4-5] Did they required hospital treatment for SARS-CoV-2**
- ❑ [a] No
- ❑ [b] Yes - did **NOT** require non-invasive / mechanical ventilation
- ❑ [c] Yes - required non-invasive or mechanical ventilation

If preoperative SARS-CoV-2 was symptomatic:
**[2-4-6] What symptoms did the patient have?** *(tick all that apply)*
- ❑ [a] Respiratory symptoms (e.g. cough, shortness of breath)
- ❑ [b] Non-respiratory symptoms (e.g. fever, diarrhoea, fatigue)

If SARS-CoV-2 diagnosed more than 7 days before surgery based on a SARS-CoV-2 swab (PCR) or rapid antigen test:
**[2-4-7] Did the patient have a repeat SARS-CoV-2 swab (PCR) or rapid antigen test after their initial diagnosis, up 7 days preceding surgery?**
- ❑ [a] No
- ❑ [b] Yes – most recent result was positive
- ❑ [c] Yes – most recent result was negative

## Screening for SARS-CoV-2 in the 7 days before surgery

**[2-5-1] Were any of the following used to screen the patient for SARS-CoV-2 in the 7 days before surgery?**
*For each option, please tick if the test/ investigation was performed in the 7 days before surgery, even if the result was only received after surgery*
- ❑ [a] CT thorax scan
- ❑ [b] Chest x-ray
- ❑ [c] SARS-CoV-2 swab (PCR) test
- ❑ [d] Rapid antigen test
- ❑ [e] SARS-CoV-2 antibody test
- ❑ [f] Clinical screening (history, examination)
- ❑ [g] None of the above

If SARS-CoV-2 swab (PCR) or rapid antigen tests were performed **within 7 days preceding surgery**:
**[2-5-2] For SARS-CoV-2 test(s) performed within 7 days preceding surgery, what were the the test result(s)?**
- ❑ [a] Negative result(s) only
- ❑ [b] Positive result(s) only
- ❑ [c] Multiple tests with them having both negative and positive results

**[2-5-3] Timing of the most recent NEGATIVE test preceding surgery (0-7 days before surgery):** _____ days
Was this a: [a] SARS-CoV-2 swab (PCR) test; [b] rapid antigen test

**[2-5-4] Timing of the most recent POSITIVE test preceding surgery (0-7 days before surgery):** _____ days
Was this a: [a] SARS-CoV-2 swab (PCR) test; [b] rapid antigen test

***Please complete the form based on the FIRST time the patient had a positive SARS-CoV-2 test result (swab / rapid antigen / antibody test).**
**If the patient has not had a positive SARS-CoV-2 test result, please complete based on the FIRST time they were diagnosed with SARS-CoV-2 clinically or based on CT scan.**