CovidSurg Blue Phase Appendix

CovidSurg was set up rapidly to match the urgency of the SARS-CoV-2 pandemic.In those initial stages of the pandemic little was known about the impact of COVID-19 on surgery. To address these uncertainties the CovidSurg protocol noted that the data items collected in the study might evolve over time, accordingly to global knowledge.

Data from the first 1000 patients has been analysed and submitted for publication, showing a significant detrimental impact of SARS-CoV-2 infection on surgical outcomes. Based on this analysis and on feedback from our collaborators, we have refined the way some data points are collected and we added clarifications to the protocol in this appendix.

In order to help you identifying the documents related to this phase of the study, we coloured their background in blue.

WELCOME TO THE BLUE PHASE OF COVIDSURG!

This appendix includes:

- Protocol clarifications
- Data points that were retired from REDCap
- > Data points that were slightly changed to improve data quality

WHAT IS REQUIRED FROM YOUR TEAM?

- You do not need to seek a new study approval. The Blue Phase is a direct continuation of the original CovidSurg and only introduces small changes. There is no identifiable data being collected.
- Effective immediately, retired data fields should not be collected for any patients. These data fields have been hidden on REDCap.
- If your team included patients in the first CovidSurg paper, those records are now locked (unable to be edited) and don't neet to be updated.
- > All the remaining records are not locked and need to be updated (patients not included in the first CovidSurg paper). This records are not locked so we kindly ask you to update all your records on your REDCap that you are able to edit (as those patients will only be included in the next papers).



PATIENTS NOT INCLUDED In the first paper



LOCKED RECORDS (NON EDITABLE ON REDCAP) No need to update

RECORDS UNLOCKED (EDITABLE ON REDCAP) PLEASE UPDATE THESE RECORDS THESE RECORDS WILL BE INCLUDED IN UPCOMING PAPERS

PROTOCOL CLARIFICATIONS

Patient inclusion / exclusion:

Percutaneous procedures (e.g. insertion of central venous catheters, interventional radiology procedures) should be **excluded**.

Bedside procedures (e.g. in the intensive care unit, unless due to the pandemic operations are routinely being performed in the intensive care unit that would normally be performed in theatre) should be **excluded**.

Index procedure definition:

- If a patient undergoes multiple surgeries before their SARS-CoV-2 diagnosis, then the index operation should be taken as the first operation that took place in the 30 days preceding SARS-CoV-2 diagnosis.
- If a patient undergoes multiple surgeries after their SARS-CoV-2 diagnosis, then the index operation should be taken as the first operation they had after SARS-CoV-2 diagnosis (this operation should be within 7 days of SARS-CoV-2 diagnosis in order for the patient to be eligible for inclusion).

REDCAP CHANGES

DATA POINTS RETIRED	
AVPU (consciousness level)	This was found to be non-informative for most patients. Glasgow Coma Scale (GCS) will continue to be collected specifically for neurosurgery patients.
Arterial blood gas (ABG) measurements	This has been unavailable for >70% of patients. None of the ABG components will be collected in the future (PaO2, PaCO2, lactate, bicarb).
Albumin	This has been unavailable for >30% of patients.
Urea	This has been unavailable for >20% of patients.
Creatinine	This has been unavailable for >20% of patients.
SpO2 and FiO2	A separate data field records the preoperative level of respiratory support. This has been found to be easier to accurately complete than SpO2/ FiO2.
NEW DATA POINTS INTRODUCED	
Designation of non-covid wards, theatres, ICUs	The role of 'cold' or 'clean' hospitals is a key area of uncertainty in current practice. We will collect granular data to directly address this.
SARS-CoV-2 diagnosis	The role of pre- and peri-operative testing is a key area of uncertainty in current practice. Data fields relating to SARS-CoV-2 diagnosis have been redesigned to collect more granular data which will allow deeper analysis.
Body mass index (BMI)	There is emerging evidence suggesting that obesity is a major risk factor for poor outcomes in COVID-19. BMI will be collected as a categorical variable.
HIV infection	It has been proposed that human immunodeficiency virus (HIV) co-infection may complicate COVID-19
Preoperative delay	One of the most frequently entered patient groups are patients with hip fractures. Preoperative delay is known to be an important risk factor in these patients, as well as in other emergency patients. This will be collected as a categorical variable.
BCG vaccination status	There is weak evidence to suggest that previous Bacillus Calmette–Guérin (BCG) vaccination may be associated with better outcomes in COVID-19.
Data lock	This has been added as the final data point on the REDCap form. This will allow you to confirm that a patient is eligible and has completed 30-day follow-up. Any patients who are not eligible for any reason can be flagged for deletion using this field.

Surgical outcomes in **COVID-19** patients

Patient **REDCap ID**:

Month of operation in 2020: Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | not stated

Age: 0-4w | 4-52w | 1-9y | 10-16y | 17-19y | 20-29y | 30-39y | 40-49y | 50-59y | 60-69y | 70-79y | 80-89y | 90y+ Weight (children only): Kg

Sex: Female | Male

ASA Grade: 1 | 2 | 3 | 4 | 5

NIHR Global Health Research Unit on Global Surgery CovidSurg

BMI:

Underweight (<18.5) □ Moderately obese (30-34.9) Normal/healthy weight □ Severely obese (35-39.9) (18.5 - 24.9) \Box Very severely obese (\geq 40) Overweight (25-29.9)

Comorbidities:

Current smoker	Dementia
□ Asthma	Diabetes Mellitus
Cancer	HIV infection
Chronic Kidney Disease	Hypertension
(Moderate/Severe)	Myocardial Infarction
	Peripheral Vascular
Congenital abn (cardiac)	Disease
Congenital abn (non cardiac)	□ Stroke/TIA
Congestive heart failure	Other:

BCG/Tuberculosis(TB) status

Vaccine - <15yrs ago | Vaccine - 15>yrs ago | TB diagnosis <15yrs ago | TB diagnosis >15yrs ago | Close contact with individual with known TB <15yrs ago | Close contact with individual with known TB >15yrs ago | No previous BCG vaccine/TB exposure | BCG vaccination/TB exposure unknown

Urgency of surgery:

Immediate | Urgent | Expedited | Elective

Findings at admission:

□ Abdominal pain □ Haemoptysis Dysphoea Mvalgia □ Nausea/vomiting Cough Diarrhoea □ Sputum Fatique □ Other: \Box Fever >38C

rpm Heart rate: Resp rate: bpm Systolic BP: _____mmHg Diastolic BP: _____ mmHg

Tests performed to investigate SARS-CoV-2 status:

Last available data from before surgery:

	CT	CT	Swab	Swab
	(neg)	(pos)	(neg)	(pos)
4-7 days prior surgery				
1-3 days prior surgery				
Day of surgery (preop)				
After surgery (during index admission)				
After discharge from index admission (within	□ n 30 days d	□ of surger	Д у)	

How was SARS-CoV-2 confirmed?

□ Positive swab – result received before surgery □ Positive swab – result received after surgery □ CT scan of chest confirming COVID-19 – before surgery □ CT scan of chest confirming COVID-19 – after surgery Clinical diagnosis/chest X-Ray – before surgery Clinical diagnosis/chest X-Ray – after surgery

Pre-op investigations:

aemoglobin:g/L	WCC:	10^9/L CRP:	mg/L
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Pre-op x-ray: □ Not performed □ Yes- normal □ Yes- abnormal

Pre-op chest CT: □ Not performed □ Yes- normal □ Yes- consolidation □ Yes- ground glass opacity □ Yes- pulmonary infiltration □ Yes- other abnormality

Management

Time from admission to operation (pre-op delay) <6 hrs | 6-23 hrs | 24-47 hrs | 48-71 hrs | 72+hrs

Primary organ/system operated:

Anaesthesia: Local | Regional | General

Surgical diagnosis: _____

Procedure completed:

Environment in which patient cared for: Operative theatre: Designated COVID theatre | Designated non-COVID theatre | No designation for theatre ITU: Designated COVID ITU area Designated non-COVID ITU area | No designation for ITU Postop ward: Designated COVID ward | Designated non-COVID ward No designation for this ward

Treatment

Did patient receive NSAIDs?

No | Yes- before admission | Yes- after admission | Both

Patient received during index admission?

□ Antibiotics □ IV Immunoglobulins Antivirals □ Interferon □ Quinine/derivative □ IL-6 blocker □ Corticosteroids Antiviral (name & dose): Corticosteroid (name & dose):

Renal dialysis during index admission?

No | Yes but not at 30 days after surgery | Yes and ongoing dialysis at 30 days after surgery

Pre-op respiratory support:

i ie op ieopilatory suppor	••
□ None	□ Non-invasive ventilation
Low-flow O2	Invasive vent
□ High-flow O2	□ ECMO

Post-op respiratory support:

	Non-invasive ventilation
Low-flow O2	Invasive vent
□ High-flow O2	

Duration of post-op mechanical ventilation: 1-23h | 24-47h | 48-71h | 72-167h | 168h+

Outcomes

Mortality: Died (on table) \Box Died (on day 0-7) Died on day 8-30) Re-operation: Yes | No Post-op ICU: I No □ Planned from theatre □ Alive (in hospital) □ Alive (other hospital) □ Alive (at rehab) □ Alive (at home)

Unplanned from theatre Unplanned from ward

Complications:

□ Acute kidney injury □ Acute respiratory distress syndrome (ARDS) □ Anastomotic leak Bleeding reg. transfusion □ Cardiac arrest reg. CPR \Box Coma for >24hr Deep Vein Thrombosis □ Graft/prothesis/flap fail □ Myocardial infraction

 Pneumonia □ Pulmonary embolism □ Respiratory failure □ Sepsis □ Septic shock □ Stroke/TIA SSI superficial □ SSI deep □ SSI organ/space □ Urinary tract infection □ Wound dehiscence

Total length of stay: days

CovidSurg Data Completion Guide

INTRODUCTION

- The following pages will guide you through data entry for CovidSurg. Please complete <u>all</u> 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.
- Please note, we are using the same REDCap project for both CovidSurg and CovidSurg-Cancer studies for which patients may be eligible for either or both. Therefore, if a patient is included in both studies (CovidSurg and CovidSurg-Cancer) you may see slightly different cancer-specific fields.

 To help you ensure that your data is complete, we will intermittently send 'data completion request' emails. A spreadsheet will be attached to the
email you receive. In this spreadsheet:
 Each case entered from your centre is on a separate row.
 The first column indicates the REDCap ID number that can be used
to identify the patient on the REDCap database.
 Each column in the spreadsheet relates to a different critical data
item. The guide below indicates how the headings on the columns
the spreadsheet match to data fields on the online REDcap
database.
 If 'missing' is written in a cell, this denotes this specific data item is
missing for that patient.
 Please examine each case/row and note the missing fields per case.
 To enter any missing data on to the online REDCap database:
 Log into REDCap
 Selected the CovidSurg project
 Navigate to 'Add/ Edit Records' in the left hand side menu under
'Data Collection'.
 Under the 'select record' dropdown list, select the record ID you
need to edit

BASELINE INFORMATION FORM

Spreadsheet Field Label	REDCap Field and Notes		
Month	Month operated This is the patient was operated. If yo information on the month of operation	ur centre does not have approval to submit , please select "not stated".	
Age	Patient age		
Sex	Patient sex		
ASA	ASA at time of surgery Full definitions are available from: https://www.asahq.org/standards-and- guidelines/asa-physical-status-classification-system		
BMI	Body mass index (BMI) Body mass index (BMI) * must provide value	 Underweight: BMI < 18.5 Normal (healthy weight): BMI 18.5-24.9 Overweight: BMI 25-29.9 Moderately obese: BMI 30-34.9 Severely obese: BMI 35-39.9 Very severely obese: BMI ≥40 	
	 Please select the appropriate BMI category This may be calculated with the formula: BMI (kg/m²) = mass (kg) / (height(m))² An online BMI calculation is also available from: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm 		
	Co-morbidity		
Comorbidity	Co-morbidity (tick all that apply)	 Current smoker Asthma Current cancer diagnosis Chronic kidney disease (moderate/severe) Chronic obstructive pulmonary disease (COPD) Congenital abnormality - cardiac Congenital abnormality - non-cardiac Congestive heart failure Dementia Diabetes mellitus Human immunodeficiency virus (HIV) infection Hypertension Myocardial infarction Peripheral vascular disease Stroke/ TIA Other (including other lung disease) 	
	Please confirm that this patient has no comorbidities	Other (including order for galaxies)	
	 Tick <u>all</u> boxes that apply If the co-morbidity you would li (including other lung disease)' relevant details. An option for HIV infection is n If the patient has no co-morbid option 'This patient has no con below the list of comorbidities. have been ticked. 	where the enter is not listed, tick 'other and a free text box will appear to enter the now available lities, please confirm by selecting the norbidities' on the data field immediately This field will only show if no comorbidities	

ТВ	Bacillus Calmette-Guérin Bacillus Calmette-Guérin (BCG) / tub that apply) More than one option ca	n (BCG) / tuberc erculosis status (tick all in be selected. T	ulosis status (BCG vac ago BCG vac Tubercu Close cc tuberc Close cc tuberc BCG vac Store cc tuberc No prev BCG vac	tick all that ap traine - last vaccinated losis - diagnosed less losis - diagnosed less losis - diagnosed 15 o ontact with an individu ulosis under 15 years ontact with an individu ulosis 15 or more yea ious BCG vaccination traination and TB exposition	Dply) less than 15 years 15 or more years ago than 15 years ago or more years ago ual known to have ago ual known to have rs ago or TB exposure sure history unknown
	If the BCG vaccination a last box 'BCG vaccination	and TB exposure on and TB expos	history is unk ure history un	nown please known'	select the
Urgency	Urgency of surgery Full definitions are availa For patients in CovidSur	able from: https:/ rg-Cancer this w	//www.ncepod ill appear on ti	.org.uk/classi he 'managem	fication.html
	Symptoms on hospital a	dmission			
	Symptoms on hospital admission (tick all that apply)		 Abdomi Breathle Cough Diarrho Fatigue Fever (> Haemop Myalgia Nausea, Sputum Other 	nal pain essness (dyspnoea) ea 38 celsius) htysis /vomiting	
Baseline_Sx	Please confirm that this patient had of admission * must provide value	no symptoms at the tim	e 🕞 🔿 This pat 🥪 admiss	ient had no symptom sion	s at the time of
	 This is only coll Tick all symptom If the symptom y text box will apped If the patient had by selecting the admission' on the field will only shot Please mark which tests 	lected for emerges is that may apply ou would like to ear to enter the r no symptoms a option 'This patie e data field imme ow if no symptom s were performed	gency patien /. enter is not lis elevant details t the time of a ent had no syr ediately below <u>hs have been to</u> d to investigate	ts. eted, tick 'othe s. dmission, ple nptoms at the the list of syr ticked. e SARS-CoV-	er' and a free ase confirm time of mptoms. This -2 status,
	their timing, and the resu Please mark which tests were perfo	ult rmed to investigate SARS		iming, and the resul	t
		CT thorax scan (negative for SARS- CoV-2)	CT thorax scan (positive for SARS-CoV- 2)	Swab (negative for SARS-CoV-2)	Swab (positive for SARS-CoV-2)
	4-7 days before surgery 😕				
	1-3 days before surgery 😑				
	Day of surgery - preoperative 🗧				
	After surgery, during index admission	8 🗭 🗆			
	After discharge from index admission, within 30 days of surgery	(H) @			
	Select each test used to columns, then choose the	investigate SAF	RS-CoV-2 stat which it was p	us and its res erformed fror	ult from the m the rows.

	You may select more than one option. Plea	ase select <u>all a</u> pply.	
	How was SARS-CoV-2 infection confirmed (tick all that apply)		
		 Positive SARS-CoV-2 swab - result received before surgery Positive SARS-CoV-2 swab - result received after surgery 	
	How was SARS-CoV-2 infection confirmed (tick all that apply)	 C1 scan of the chest confirming SARS-Cov-2 - result received before surgery 	
Diagnosedhow	* must provide value	CT scan of the chest confirming SARS-CoV-2 - result received after surgery	
		Clinical diagnosis or chest x-ray - suspected before time of surgery	
		Clinical diagnosis or chest x-ray - suspected after time of surgery	
	 Please confirm how SARS-Cov-2 infection was confirmed. 		
	You may select more than one option. Please select all that apply		
Last Available Data From Before Surgery (E.G. Recorded In Anaesthetic Room Pre-Anaesthetic Induction)			
Resp	Respiratory Rate (breaths per minute)		
HR	Heart rate (beats per minute)		
	Systolic Blood Pressure (mmHg) Diastolic blood pressure (mmHg)		
	Systolic blood pressure (mmHg)		
SBP	* must provide value		
DBP 2	Diastolic blood pressure (mmHg) * must provide value		
 Please ensure that these are entered the correct way round (i systolic blood pressure should be greater than the diastolic blood pressure) 		ed the correct way round (i.e. the reater than the diastolic blood	

CONTINUE TO NEXT PAGE FOR THE PREOPERATIVE INVESTIGATIONS FORM

PREOPERATIVE INVESTIGATIONS FORM

Spreadsheet Field Label	REDCap Field and N	lotes	
Haemo	 Haemoglobin (g/L) Please ensure to enter the recorded haen The normal range will be approximately 1 If your lab reports haemoglobin in g/dL (normultiply this value by 10 to get the value in the value in	noglobin in g/L. 10-170 g/L. ormal range 11-17 please n g/L	
WBC	White cell count (10 ⁹ /L)		
CRP	C-reactive protein (mg/L)		
Chest imaging before surgery			
CXR	Preoperative chest x-ray		
Chest_CT	Preoperative computed tomography (CT) scan of Preoperative computed tomography (CT) scan of the chest (please tick all that apply) * must provide value	f the chest Not performed Yes - normal Pes - consolidation Yes - ground glass opacity Yes - pulmonary infiltration Yes - other abnormality	
	 More than one option can be selected. Ple If a CT scan was not performed tick 'not p 	ease tick all that apply. performed' only.	

CONTINUE TO NEXT PAGE FOR THE MANAGEMENT FORM

MANAGEMENT FORM

Spreadsheet Field Label	REDCap Field and Notes
Preopdelay	 Time from admission to operation (preoperative delay) This field will only appear for emergency patients. This is the time for hospital admission to start of surgery in theatre.
Anaesthesia	 Anaesthesia type Please tick all that apply if more than one type of anaesthesia was used
	Surgical indication Surgical indication * must provide value Constraint of the second
Indication2	Surgical diagnosis/ indication This field is OPTIONAL in case you wish to give additional details
	 This field will not appear for patients who are also included in CovidSurg-Cancer. Please select the most appropriate option for surgical indication. If you want to add further details or clarificiation of the surgical diagnosis, enter this information in the 'surgical diagnosis/ indication' free text field
	Surgical procedure completed Main surgical procedure completed - please select closest matching procedure
Surgical_procedure	If no appropriate procedures are listed, please enter free text below Procedures are listed by organ/ system operated. Please note that this list is searchavle by keyword.
	Surgical procedure completed This field is OPTIONAL in case you wish to give additional details
	 Please choose the closest matching surgical procedure from the drop down menu. If more than one procedure was performed, enter the primary procedure only Please used the 'surgical procedure completed' field to add further details or clarification of the procedure For patients who are also included in CovidSurg-Cancer, this field will apprear a little differently.

Please mark what environment the patient was cared for			
(One selection allowed per column)	Designated COVID treatment area (only COVID patients treated there)	Designated non-COVID treatment area (only non- COVID patients treated there)	No designation for this area (either COVID or non-COVID patients can be treated there)
Operating theatre * must provide value	0	0	0
Intensive care unit (leave blank if not applicable)	B	0	reset
Postoperative ward H	0	0	

CONTINUE TO NEXT PAGE FOR THE COVID-19 TREATMENT FORM

COVID-19 TREATMENT FORM

Spreadsheet Field Label	REDCap Field and Notes		
NSAIDs	 Did the patient receive non-steroidal anti-inflammatory drugs (NSAIDs) - any agent, any dose Please select the most appropriate option for any NSAID at any dose given 		
Treatments	At any point during the index hospital admission At any point during the index hospital admission did the patient receive * must provide value	 did the patient receive None of the treatments listed below Antibiotics Antivirals Quinine or derivative Corticosteroids Intravenous immunoglobulins Interferon IL-6 blocker 	
	 Please tick all COVID-19 treatments listed. Tick as many as apply. Options should be ticked regardless of the specific durg/dose administered. Options should be ticked if the patient received them at any point in the 30 days following surgery. If none of the treatments listed were given, tick 'None of the treatments listed below'. 		
Dialysis	Renal dialysis - at any point during the index hospital admission		
Respsupport	Preoperative respiratory support		
Respsupport2	 Postoperative respiratory support Preoperative respiratory support (please tick all that apply) * must provide value Please select the type of respiratory sup theatre recovery. Please take particular care to note patien ventilation, invasive mechanical ventilation oxygenation, as these are the key second. If ventilation was received, a separate for "Duration of preoperative invasive mechanical received precision of preoperative invasive mechanical ventilation ventilation of preoperative invasive mechanical ventilation ven	 None Low-flow supplemental oxygen High-flow supplemental oxygen Non-invasive ventilation Invasive mechanical ventilation Extracorporeal membrane oxygenation (ECMO) port given after the patient left the nts who received non-invasive on, or extracorporeal membrane membrane ndary outcomes. add will appear underneath, titled anical ventilation or ECMO". eived ventilation or ECMO 	

CONTINUE TO NEXT PAGE FOR THE SURGICAL OUTCOMES FORM

SURGICAL OUTCOMES FORM

Spreadsheet Field Label	REDCap Field and Notes		
Mort7	Outcome at 30 days after surgery Outcome at 30 days after surgery *must provide value Please ensure this field is completed as a	 Died - on-table Died - on days 0-7 after surgery Died - on days 8-30 after surgery Alive - remains admitted in hospital Alive - transferred to another hospital Alive - discharged to a rehabilitation centre Alive - discharged home 	
Reop	The primary endpoint of the study. Re-operation or re-intervention This includes any re-operation or re-intervention, including interventional radiology, endoscopy, or surgery.		
ICU	Postoperative intensive care admission We are interested in timing of intensive care admission relative to the index procedure. If a patient returned to the ward after the index procedure, but subsequently was reoperated and went to intensive care from theatre at the end of the reoperation, this should be recorded as "unplanned from ward".		
Day_Complications	Complications (if any) Complications (if any) Please confirm that this patient did not have nay postoperative complications *must provide value Please tick all complications that occu, whether directly related to the original Please take particular care to note pn the key secondary outcomes. If a complication occurred that is not li and a free text field will appear to enter If the patient did not experience any co selecting the option 'This patient has a immediately below the list of possible show if no complication have been tice	Acute kidney injury Acute respiratory distress syndrome (ARDS) Anastomosis leak Bleeding requiring transfusion Cardiac arrest requiring CPR Coma >24 hours Deep vein thrombosis Graft/ prosthesis/ flap failure Myocardial infarction Pneumonia Pulmonary embolism Sepsis Septic shock Stroke/ cerebrovascular accident Surgical site infection - superficial or deep Surgical site infection - organ space Urinary tract infection Wound dehiscence Other complication This patient did not have any postoperative complications reset urred within 30 days of surgery operation or not. Reumonia and ARDS as these are isted, select 'other complication' er the relevant details complications, please confirm by no comorbidities' on the data field complications. This field will only ked.	
Hosp_Stay	 Total length of postoperative stay Please enter the total length of postoperative stay up to the 30th postoperative day., counting the day of surgery as day 0 If the patient was re-admitted within this 30 day period, please only include the length of stay during the index/ first admission 		

Datalock2	Data lock- please update this field once surgery	the patient has reached 30-days post
	Data lock - please update this field once the patient has reached 30-days post surgery * must provide value	 This patient is eligible for inclusion and has reached 30-days post-surgery This patient is eligible for inclusion but has NOT yet reached 30-days post-surgery This patient is NOT eligible for inclusion and should be deleted
	 Please pay particular attention to appropriate case inclusion If a suspected or clinically diagno come back as negative at any tin no longer eligible for inclusion in option in this case 	this field as it is crucial to ensuring psed COVID patient's investigations ne during the 30 day period, they are CovidSurg. Please select the last