**GlobalSurg-CovidSurg Week: Determining the optimal timing for surgery**

**following SARS-CoV-2 infection**

**APPENDICES TO THE STUDY PROTOCOL**

These Appendices provide additional information to the main GlobalSurg-CovidSurg Week study protocol. They should be read in conjunction with the main study protocol, which is available from <https://globalsurg.org/surgweek/>.

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**Appendix 1: Literature review**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has affected most countries, with the World Health Organisation declaring a pandemic on 11 March 20201. As an estimated 28 elective million operations were postponed due to the initial pandemic wave2, there is an urgent need to restart surgical services. However, due to the pro-inflammatory cytokine and immunosuppressive responses to surgery and mechanical ventilation3-4, patients undergoing surgery are a vulnerable group who may be particularly susceptible to SARS-CoV-2 related pulmonary complications.

CovidSurg, an international, observational cohort study, provided cross-specialty, patient-level outcomes data for patients undergoing surgery who acquired perioperative SARS-CoV-2 infection. The initial findings of CovidSurg were published in *The Lancet*5. A total of 1128 patients were included across 24 countries. The overall 30-day mortality was 23.8% (268/1128). Pulmonary complications occurred in 51.2% (577/1128) of patients; these patients accounted for 82.6% (219/265) of all deaths. These pulmonary complication and mortality rates are greater than those reported for even the highest risk patients before the pandemic (high-quality, multi-national pre-pandemic studies established overall baseline rates of postoperative pulmonary complications of up to 10% and mortality rates of up to 3% surgery6-8).

Even in communities with low rates of community SARS-CoV-2 transmission, the number of patients with a previous SARS-CoV-2 infection will increase over time, in both elective and emergency surgical settings. Although a number of guidelines have been published for the management of surgical patients during the SARS-CoV-2 pandemic9-11, these are mainly based on expert opinion. In addition, there is little evidence-based guidance regarding the management of patients with previous SARS-CoV-2 infection.

CovidSurg-Cancer study was a prospective cohort study of patients undergoing curative elective cancer surgery during the pandemic12. In this cohort there were 122 patients from 78 hospitals in 16 countries with a previous SARS-CoV-2 positive swab and who were not suspected to have active infection at the time of surgery. In a multivariable analysis, previous SARS-CoV-2 infection was found to be associated with increased odds of postoperative pulmonary complications compared to those without previous infection (10.7% [12/122] versus 3.6% [16/448], adjusted odds ratio 3.84, 95% confidence interval 1.51-9.74, p=0.004)13.

The small sample size available from this cohort is a significant limitation, as it is not possible to robustly determine whether the risk of SARS-CoV-2 reduces over time, or whether it may be safer to operate on particular patient groups (e.g. patients who had asymptomatic SARS-CoV-2). Further research is therefore urgently needed to validate these figures in a larger series, explore whether different effects are seen in asymptomatic SARS-CoV-2 infections and patients with symptomatic COVID-19, and investigate the role of repeat swab testing.

References:

1. World Health Organisation. 2020. WHO announces COVID-19 outbreak a pandemic. Accessed 19 April 2020 at http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic.
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3. Besnier E, Tuech JJ, Schwarz L. We Asked the Experts: Covid-19 Outbreak: Is There Still a Place for Scheduled Surgery? "Reflection from Pathophysiological Data". World J Surg 2020; 44(6): 1695-8.
4. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020; 395(10223): 497-506.
5. COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. Lancet. 2020;396(10243):27-38.
6. Kirmeier E, Eriksson LI, Lewald H, et al. Post-anaesthesia pulmonary complications after use of muscle relaxants (POPULAR): a multicentre, prospective observational study. Lancet Respir Med 2019; 7(2): 129-40.
7. Neto AS, da Costa LGV, Hemmes SNT, et al. The LAS VEGAS risk score for prediction of postoperative pulmonary complications: An observational study. Eur J Anaesthesiol 2018; 35(9): 691-701.
8. Tu RH, Lin JX, Li P, et al. Prognostic significance of postoperative pneumonia after curative resection for patients with gastric cancer. Cancer medicine 2017; 6(12): 2757-65.
9. Coccolini F, Perrone G, Chiarugi M, et al. Surgery in COVID-19 patients: operational directives. World J Emerg Surg 2020; 15(1): 25.
10. CovidSurg Collaborative. Global guidance for surgical care during the COVID-19 pandemic. Br J Surg. 2020 Apr 15. doi: 10.1002/bjs.11646.
11. Tao KX, Zhang BX, Zhang P, et al. [Recommendations for general surgery clinical practice in novel coronavirus pneumonia situation]. Zhonghua Wai Ke Za Zhi 2020; 58(0): E001.
12. COVIDSurg Collaborative. Elective cancer surgery in COVID-19 free surgical pathways during the SARS-CoV-2 pandemic: An international, multi-centre, comparative cohort study. In Press (Journal of Clinical Oncology, August 2020).
13. COVIDSurg Collaborative. Delaying cancer surgery for patients with a previous SARS-CoV-2 infection. In Press (Br J Surg, Aug 2020).

**Appendix 2: Study periods**

In order to facilitate mini-team registration and avoid overlap between mini-teams, the following study periods will be used (all times are local time and are time of operation start – “knife to skin”):

Period 1: 00:00 on 5 October 2020 to 23:59 on 11 October 2020

Period 2: 00:00 on 12 October 2020 to 23:59 on 18 October 2020

Period 3: 00:00 on 19 October 2020 to 23:59 on 25 October 2020

Period 4: 00:00 on 26 October 2020 to 23:59 on 1 November 2020

Each period consists of 7 consecutive days.

Each mini-team will collect data from **at least one** period but they may optionally choose to collect data over two, three, or four periods. Multiple mini-teams can participate in the same specialty in the same hospital collecting data over distinct study periods. Mini-teams collecting data in the same specialty in the same hospital must **not** overlap in the periods in which they collect data, as this would duplicate data collection.

**Appendix 3: 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.

The minor procedures that are excluded are based on those identified by Abbott et al1. 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 theraaeutic) |
| Obstetrics | Any vaginal delivery (normal delivery, breech delivery, forceps delivery, vacuum delivery) |
|  | Repair of obstetric laceration |
| Ophthalmology | Removal of foreign body from cornea |
| Orthopaedics | Bone biopsy |
|  | Injection in to joint |
|  | Muscle biopsy |
| Otolaryngology | Nasendoscopy (diagnostic or therapeutic) |
| Packing of cavity of nose |
| Thoracic surgery | Bronchoscopy (diagnostic or therapeutic) |
| 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 or therapeutic) |
| Percutaneous nephrostomy |
| Percutaneous nephrolithotomy (PCNL) |
| Vascular surgery | Transluminal (endovascular) procedures on arteries (diagnostic or therapeutic), including with open cut down to the artery |
| Transluminal (endovascular) procedures on veins (diagnostic or therapeutic) |
| Other | Insertion of central venous catheter/ line (CVC) |
| Lumbar (spinal) puncture |
| Percutaneous tracheostomy |
| Skin biopsy (including shave biopsy of skin) |
| Therapeutic epidural injection |

\*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.

**Appendix 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 trial1.

**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 definition2 will be used:

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| Acute Respiratory Distress Syndrome criteria - ALL 4 CRITERIA REQUIRED | |
| 1. **Timing** | Within 1 week of known clinical insult or worsening respiratory symptoms |
| 1. **Chest imaging** | Bilateral opacities (not fully explained by effusions / collapse / nodules). |
| 1. **Origin** | Respiratory failure (not fully explained by cardiac failure / fluid overload). |
| 1. **Oxygenation** | Mild: 200mmHg < PaO2/FIO2 ≤ 300mmHg with PEEP or CPAP ≥5cm H2O  Moderate: 100mmHg < PaO2/FIO2 ≤ 200mmHg with PEEP ≥5cm H2O  Severe: PaO2/FIO2 ≤ 100mmHg with PEEP ≥5cm H2O  *CPAP: continuous positive airway pressure; FIO2: fraction of inspired oxygen; PaO2: partial pressure of arterial oxygen; PEEP: positive end-expiratory pressure.* |

**Postoperative pneumonia**

The US Centers for Disease Control (CDC) definition of pneumonia3 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 <4x109) or leucocytosis (white cell count >12x109).
* 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 classification5, 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.

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| **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.  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.  *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  grade I complications; including blood transfusions; total parenteral nutrition.  *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  *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).  *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.

**Appendix 5: Statistical analysis plan**

The GlobalSurg-CovidSurg Week is registered at clinicaltrials.gov with registration NCT04509986 (https://clinicaltrials.gov/ct2/show/NCT04509986).

The primary aim of GlobalSurg-CovidSurg is to determine the optimal timing for surgery following SARS-CoV-2 infection. The primary outcome is 30-day mortality. The secondary outcome is postoperative pulmonary complication (see appendix 4).

The analysis will be based on a comparison of mortality rates between patients preoperatively infected with SARS-CoV-2 and those presumed to be unexposed at the time of surgery. The preoperatively infected group will be stratified by time since diagnosis (if known), severity of initial SARS-CoV-2 infection, and whether they are symptomatic at the time of surgery.

The study will be conducted according to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) and SAMPL guidelines (Statistical Analyses and Methods in the Published Literature).

Non-parametric data will be summarised with medians and interquartile ranges and differences between groups tested using the Mann-Whitney U test. The χ2 test was used for categorical data. Missing data will be included in flowcharts and summary tables, allowing denominators to remain consistent in calculations.

Hierarchical multivariable, mixed-effects logistic regression will be used to explore the associations with the primary and secondary outcome measure, summarised as odds ratios and 95% confidence intervals (C.I.). Clinically plausible patient, disease, operation and location specific factors have been selected a priori for inclusion in adjusted analyses, in order to identify independent predictors of adverse outcomes after surgery.

We anticipate recruitment from approximately 1000 hospitals around the world with a median of 25 patients per hospital, providing a sample size estimate of 25,000 patients.

Sensitivity analyses will be performed including only those patients who had a positive swab.

Analyses will be performed using the R Foundation Statistical Program version 3.1.1 (packages: finalfit, tidyverse).

**Appendix 6: REDCap online data collection**

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. The REDCap server is managed by the University of Birmingham, UK. Only anonymised data will be uploaded to the database. No patient identifiable data will be collected.

REDCap databases at the University of Birmingham have been successfully used for a number of international studies, including:

* CovidSurg Study (1,040 participating sites across 85 countries), reference: COVIDSurg Collaborative. *Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study*. Lancet. 2020;396(10243):27-38. doi:10.1016/S0140-6736(20)31182-X.
* European Society of Coloproctology 2017 Left Colon and Rectal Resection Study (335 participating sites across 49 countries), reference: 2017 European Society of Coloproctology (ESCP) Collaborating Group. *The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections - Executive Summary*. Colorectal Dis. 2018;20.
* Right Iliac Fossa Treatment Study (290 participating sites across 5 countries), reference: RIFT Study Group on behalf of the West Midlands Research Collaborative. *Identifying children at low-risk of appendicitis: systematic review and prospective, multicentre validation of risk prediction models in children presenting with right iliac fossa pain.* Lancet Child Adolesc Health 2020; 4: 271–80.

The REDCap database used for the GlobalSurg-CovidSurg Week study is run by the NIHR Global Health Research Unit on Global Surgery, within the University of Birmingham Virtual Machine architecture which is physically secured. The architecture is the responsibility of the Storage and Virtualisation Team at the University of Birmingham, Edgbaston, Birmingham, B15 2TT. “At rest” encryption is in place on the database server. Raw data will be stored and will remain at the Birmingham site; it will not be offshored to any other location. The site is physically secure. The virtual hosting service is designed to have no single point of failure with physical redundancy deployed for server, network and storage infrastructure. The virtual server software supports live migration of virtual machines between the physical servers called hosts. Live migration is automatically performed to balance the server load across available infrastructure. On physical server failure the virtual machine is automatically restarted on another host. During host maintenance or intrusive maintenance of the virtual server software, virtual machines are manually migrated to prevent any interruption to service. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure. All virtual machines are not installed on a single physical server but a range of hosts on which virtual machines automatically live migrate on. Therefore, since there is no one physical location for our machine, it can be considered physically secure. All physical infrastructure and the virtual server software are maintained by the University of Birmingham IT Services. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure.

The security of the study REDCap database system is governed by the policies of the University of Birmingham UK, in accordance with the requirements of the General Data Protection Regulations (GDPR). The study will be conducted at collaborating sites in accordance with the country-specific data protection requirements. Once data collection is complete, the electronic research files containing anonymised data will be stored on secure non-networked desktop computers for up to 25 years, in line with current regulations. Access will be restricted to the researchers themselves. Personal data will remain securely at local hospitals.

No sensitive or identifiable data will be collected on the database; the patient’s clinical team will only upload anonymised data. Access to data will be restricted, each individual collaborator entering data for GlobalSurg-CovidSurg Week will have their own username and password. Each patient will be allocated a unique study number at entry. The central research team will not have any access to patient identifiable data. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable. The anonymised data generated by the study will be held centrally at the University of Birmingham UK, and be analysed by Omar Omar (Senior Statistician, University of Birmingham).

**Appendix 7: Study approvals processes**

Collaborators at each participating site are responsible for obtaining necessary local approvals in line with their hospital’s regulations.

In all approvals processes it should be highlighted that this is an investigator-led, non-commercial, observational (no changes to normal patient care) study which is extremely low risk, as only routinely available non-identifiable data will be collected.

**Substantial amendments in hospitals that participated in CovidSurg or CovidSurg-Cancer**

In hospitals that already participated in either the CovidSurg and/or CovidSurg-Cancer studies, collaborators should discuss with the relevant committee (e.g. research ethics committee or institutional review board) whether the GlobalSurg-CovidSurg Week study can be registered as a substantial amendment to the existing CovidSurg / CovidSurg-Cancer approval.

The reasons why a substantial amendment may be appropriate are:

* All the studies are coordinated by the same research group (CovidSurg Collaborative, based at the University of Birmingham, UK).
* All the studies are focused on the same topic: the impact of SARS-CoV-2 infection on postoperative outcomes.
* The primary (30-day mortality) and secondary (30-day pulmonary complications) outcome measures remain the same across all studies.
* The principles of the data collection are the same in all the studies. They are all observational studies which do not require any changes to normal patient care. No additional tests or follow-up are required in any of these studies.
* The data collection platform is the same in all the studies. Data can be anonymised and uploaded to a secure, online REDCap database. The same REDCap server will be used for GlobalSurg-CovidSurg Week as for the CovidSurg / CovidSurg-Cancer studies.

For reference, the key differences between the GlobalSurg-CovidSurg Week study and the CovidSurg / CovidSurg-Cancer studies are:

* Data collection in GlobalSurg-CovidSurg Week will be expanded to include all patients undergoing surgery in order to capture comparator data.
* Whilst the core data points have remained the same, some additional data points have been added on the case report form to address issues raised by the evolving literature on SARS-CoV-2.

**Study approvals in the UK**

In the United Kingdom GlobalSurg-CovidSurg should be **NOT** be registered as research. Instead the study should be registered as **clinical audit**. This is because:

* The study is measuring the delivery of current care (see audit standards below).
* It will be collecting routine patient data only; all data will be collected from existing medical records.
* No changes will be made to patients' pathways; they will receive normal care.
* All data will be anonymised on the study database.

Please see Appendix 8 below for (1) a print out of result from the Health Research Authority 'Is my study research', (2) confirmation from the South East Scotland Research Ethics Service (reference NR/161AB6) that the study does not require ethical approval in the United Kingdom.

The following audit standards will be assessed in this study:

* **“Emergency Admissions: all patients should be tested on admission.”** Audit standard 100%. Based on NHS England guidance: Operating framework for urgent and planned services in hospital settings during COVID-191.
* **“Elective Admissions: patients should isolate for 14 days prior to admission. This should be supplemented with a pre-admission test [if feasible].”** Audit standard for patient isolation, 100%. Based on NHS England guidance, as above1.
* **“There should be a physical separation of COVID-19 positive and COVID-19 negative patients”.** Audit standard 100%. Based on Royal College of Surgeons of England guidance: Recovery of surgical services during and after COVID-192.

The study has been registered as clinical audit at the lead centre, University Hospitals Birmingham NHS Foundation Trust (reference CARMS-16328), please see Appendix 8.

1. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/05/Operating-framework-for-urgent-and-planned-services-within-hospitals.pdf
2. https://www.rcseng.ac.uk/-/media/files/rcs/coronavirus/rcs-guidance--recovery-of-surgical-services--updated-26-may-2020.pdf).

**Appendix 8: Lead centre study approval documentation**

The lead centre for this study is University Hospitals Birmingham NHS Foundation Trust.

The study has been registered as clinical audit at the lead centre.

Below please find below:

* Confirmation of registration of the study as clinical audit at University Hospitals Birmingham NHS Foundation Trust (reference CARMS-16328).
* A print out of result from the Health Research Authority 'Is my study research' confirming that in the United Kingdom this study is not considered research and can therefore be registered as clinical audit / service evaluation.
* Confirmation from the South East Scotland Research Ethics Service (reference NR/161AB6) that the study does not require ethical approval in the United Kingdom.

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