The South African COVID-19 Surgical Outcomes Study

A prospective observational cohort study of long-term patient-reported outcomes after surgery using a digital health platform

Study protocol v7.1

30 August 2021

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Co-principal investigators

ABSTRACT

Background

The infectious disease COVID-19, caused by coronavirus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) has caused significant disruption in surgical services to patients globally. Data from the COVIDSurg Cohort Study suggest mortality rates of patients infected with SARS-Cov-2 in the perioperative period of up to 25.6% in emergency surgery and 18.9% in elective surgery. Based on estimates by the COVIDSurg Collaborative, large numbers of elective surgical procedures are cancelled. The COVID-19 pandemic has forced healthcare providers to 'shift from patient-centred ethics to public health ethics'. This has had impact on pre-operative testing for COVID-19, and scheduling of surgery. Currently, a provisional recommendation to delay surgery for at least four weeks after a positive COVID test, exists. Weighing the risk of surgery and potential complications during the COVID-19 pandemic, against the benefit of undergoing a surgical procedure to improve quality of life, remains difficult. A study to determine the long term effect of the pandemic on patient-reported outcome may provide guidance on how to safely return to surgical activity that are again more focussed on individualized care. There is also the opportunity to record outcomes that are currently accepted as the standard for understanding longer term recovery after surgery.

Method

A prospective observational cohort study aiming to recruit patients 18 years and older presenting for any surgical procedure at South African hospitals from July 2021 to July 2023. Data will be collected by patients using a digital platform. De-identified data will be extracted from the database at predetermined intervals, and made available to the principal investigator for analysis. Logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors.

Keywords (MeSH terms)

COVID-19

Outcome measures

Perioperative care

Patient-centered care

Cost benefit analysis

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1 ADMINISTRATIVE INFORMATION

1.1 Roles & Responsibilities

1.1.1 SACSOS Collaborative* Steering committee:

1. Hyla-Louise Kluyts, DMed, Sefako Makgatho Health Sciences University
2. Bruce M Biccard, PhD, University of Cape Town
3. Charlé Steyl, FCA (SA), Sefako Makgatho Health Sciences University
4. Rachel Moore, FCS (SA), COVIDSurg SA
5. Maria Fourtounas, FCA (SA), COVIDSurg SA
6. Helen Malherbe, PhD, Rare Diseases South Africa & University of Pretoria
7. Kelly du Plessis, Rare Diseases South Africa

*The SACSOS collaborative is a collaboration of Safe Surgery SA, the COVIDSurg SA investigators and Rare Diseases SA. The COVIDSurg SA study is a prospective cohort study and aims to include ALL adult patients undergoing surgery at South African hospitals. Data will be captured by clinicians. The SACSOS study aims to include all patients being cared for by a clinical team at South African hospitals. Data will be captured by patients themselves – which requires internet access to a web-based platform. Outcomes data not reported by patients will be obtained from hospital administration.

1.1.2 Statistician:

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1.2 Revision Chronology

Date	Protocol Amendment Number	Description
May 2020	1	Original
June 2020	2	Refining research question and objectives. Refining methodology. Refining dataset and variables.
July 2020	3	Additions to Introduction and background. Detailed budget added.
May 2021	4	Minor changes to Introduction. Changes to budget.
June 2021	5	Minor changes to text.
July 2021	6	Change to subtitle. Additions to Steering Committee. Change in Recruitment period.
August 2021	7	Formatting updated. Headings according to STROBE. MRC-approved budget added. MRC-approved timeline & milestones added.

1.3 Trial Registration

1.3.1 Registry

Registered in ClinicalTrials.gov with reference number: _____

1.3.2 WHO Dataset

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov:
Date of registration in primary registry	
Secondary identifying numbers	SMU Ethical approval: SMUREC/M/184/2020:IR UCT Ethical approval: HREC REF:533/2020
Source(s) of monetary or material support	MRC JPRF Research Fund (administrated by the South African Society of Anaesthetists)
Primary sponsor	MRC

Data category	Information
Secondary sponsor(s)	JPRF Research Fund
Contact for public queries	Prof. Hyla Kluyts: hyla.kluyts@smu.ac.za
Contact for scientific queries	Prof. Hyla Kluyts: hyla.kluyts@smu.ac.za
Public title	The South African COVID-19 Surgical Outcomes Study
Scientific title	The South African COVID-19 Surgical Outcomes Study (SACSOS): A prospective observational cohort study of long-term patient-reported outcomes after surgery using a digital health platform.
Countries of recruitment	South Africa
Health condition(s) or problem(s) studied	Covid-19 Peri-operative outcomes Patient rated peri-operative outcomes
Intervention(s)	N/A
Key inclusion and exclusion criteria	• Inclusion: Patients 18 years and older presenting for any surgical procedure at South African hospitals from September 2021 to September 2023. • Exclusion: Patients unable to provide consent to participation; Patients whose legal guardian is unable to provide consent to participation; Patients unable to nominate next-of-kin, guardian or a person of their choice, as their representative during follow up
Study type	Observational Prospective Cohort Study
Date of first enrolment	September 2021
Target sample size	N/A
Recruitment status	Preparing to recruit
Primary outcome(s)	Quality of life (EQ-5D-5L) score at 6 months or 1 year
Key secondary outcomes	• In-hospital mortality • 30 day mortality • In-hospital postoperative morbidity • 30 day postoperative morbidity • Postoperative Intensive Care Unit length of stay • Postoperative hospital length of stay • 30 day quality of recovery, disability and health-related quality of life • Hospital cost

2 INTRODUCTION

2.1 Background

The infectious disease COVID-19, caused by coronavirus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), was declared an international healthcare emergency (30 January 2020) and a pandemic (11 March 2020) by the World Health Organization (WHO). It has spread across the globe, overwhelming healthcare systems by causing high rates of critical illness. Mortality from COVID-19 exceeds 4%, with older people with comorbidities being extremely vulnerable.[1] Data from the COVIDSurg Cohort Study suggest mortality rates of patients infected with SARS-Cov-2 in the perioperative period (7 days preoperative to 30 days postoperative) of up to 25.6% in emergency surgery and 18.9% in elective surgery.[2]

Based on estimates by the COVIDSurg Collaborative,[3] large numbers of elective surgical procedures are cancelled during the disruption caused by the pandemic. It would take a median of 45 weeks to address if a country increases the usual surgical volume by 20% after the pandemic. It is crucial to assess the impact of surgical procedures on outcome during the pandemic to appropriately plan the safe return to surgical activity.

The COVID-19 pandemic has forced healthcare providers to 'shift from patient-centred ethics to public health ethics'.[4,5] This has had implications on pre-operative testing for COVID-19,[6] vaccination,[7] and scheduling of surgery.[8] Currently, a provisional recommendation to delay surgery for at least four weeks after a positive COVID test exists.[9] Weighing the risk of surgery and potential complications during the COVID-19 pandemic,[10,11] against the benefit of undergoing a surgical procedure to improve quality of life,[12,13] remains difficult. Unfortunately, patients may delay seeking care due to fear of the implications of admission to a hospital during the pandemic.[14] A patient-centred research[15,16] project to determine the effect of the pandemic may provide guidance on how to safely return to surgical activity that are again more focussed on individualized care.

It may be appropriate, during the COVID-19 pandemic, to encourage broader participation in health research by adapting a 'citizen science' model.[17] Citizen Science involves non-professionals in data collection. Virtual and online communication has become a global standard of living for people with access to the necessary technology. Patient engagement using an electronic patient-centric platform for perioperative data capture has the potential to contribute significantly to data on surgery in South Africa during the COVID-19 pandemic. There is also the opportunity to record outcomes that are currently accepted as the standard for understanding recovery after surgery, from a South African patient perspective.[18]

The economic impact of the COVID-19 pandemic, though difficult to measure, cannot be disputed. Clinicians have limited access to aggregated data on clinical outcomes after surgery in the South African healthcare sector. The lack of data impacts on efforts to improve the quality of care at a team (micro) or hospital (meso) level.[19] As the cost of healthcare increases, it is becoming more important to demonstrate value.[20] To demonstrate value, the quality of care has to justify the cost of care (value = quality/cost).[21] A previous study was performed to develop a clinical prediction model for hospital cost from a self-assessment questionnaire in patients admitted for elective surgery (publication under review).

The use of digital health is an important step in exploring opportunities for innovative ways to accelerate progress in global health, as described by the World Health Organization.[22] The COVID-19 pandemic reinforces

the need for collaboration in global frameworks for digital health.[23] South Africa has implemented digital health communication before,[24,25] and during, the pandemic.[26] Within the South African health system there exist large disparities, and unequal access to and delivery of surgical care. This study creates the opportunity to obtain evidence on how to bridge the gap using the principles of global surgery strategic planning.

2.1.1 Research question

How does the COVID-19 pandemic in South Africa affect outcome for patients after surgery?

2.2 Objectives

2.2.1 Primary objective

To describe the relationship between patient comorbidities, surgical characteristics and long term (6 months and 1 year) postoperative patient-reported outcome in surgical patients during and following the SARS-CoV-2 pandemic in South Africa.

2.2.2 Secondary objectives

To determine the incidence of in-hospital and 30-day postoperative mortality in adult surgical patients with perioperative SARS-CoV-2 infection in South Africa.

To compare quality of recovery and functional recovery after surgery in patients with and without SARS-CoV-2 infection.

To validate and update a preoperative clinical prediction model for high hospital cost in patients admitted for elective non-cardiac surgery

3 METHODS

3.1 Study Design

SACSOS is a patient-centred prospective observational cohort study.

3.2 Setting

Initially, clinical teams in the South African private health care sector will be approached. In later phases of the study, recruitment will include eligible patients in the South African public health care sector.

Patient engagement and -participation will be sought during the recruitment process by engaging with the clinical team (surgeon, anaesthetist, hospital clinical manager) for individual patient care (at a micro level); in data collection using a patient-centric platform; and in the follow up after surgery.

Recruitment will take place during the period September 2021 to September 2023.

3.3 Organisation

The Steering Committee will be chaired by HK and BB. The study management team will be appointed by the Steering Committee and led by HK and BB. The duties of this team will include administration of all project tasks, communication between project partners (including funders, steering committee members, national and local co-ordinators, etc.), data collation and management and preparation of reports for individual study sites. The Steering Committee is responsible for the scientific conduct and consistency of the project. The Steering Committee will ensure communication between the funder(s), study management team and co-ordinators as necessary.

3.4 Participants

To enable a patient-centred approach, patients will be invited to participate in the study by a member of the clinical team responsible for their care. The study will be conducted in two phases, which may run in parallel at different hospitals:

1. Initial phase - Clinical Team engagement: Clinical teams will be introduced to the study through a call for participation. Data collection by the clinicians for surgery will be optional and postoperative follow up will be limited to in-hospital data collection, censored at 30 days. Postoperative outcomes data will be obtained from hospital administration, including data on duration of hospital stay, mortality, intensive care admission, and theatre- and ward costs (excluding fees and consignment stock).
2. Secondary phase - Patient engagement: Patients will be introduced to the study by members of the clinical team, and participate by capturing data on a web-based patient platform.

3.4.1 Inclusion criteria

- Patients 18 years and older presenting for any surgical procedure at South African hospitals from September 2021 to September 2023.

3.4.2 Exclusion criteria

- Patients unable to provide consent to participation
- Patients whose legal guardian is unable to provide consent to participation
- Patients unable to nominate next-of-kin, guardian or a person of their choice, as their representative during follow up

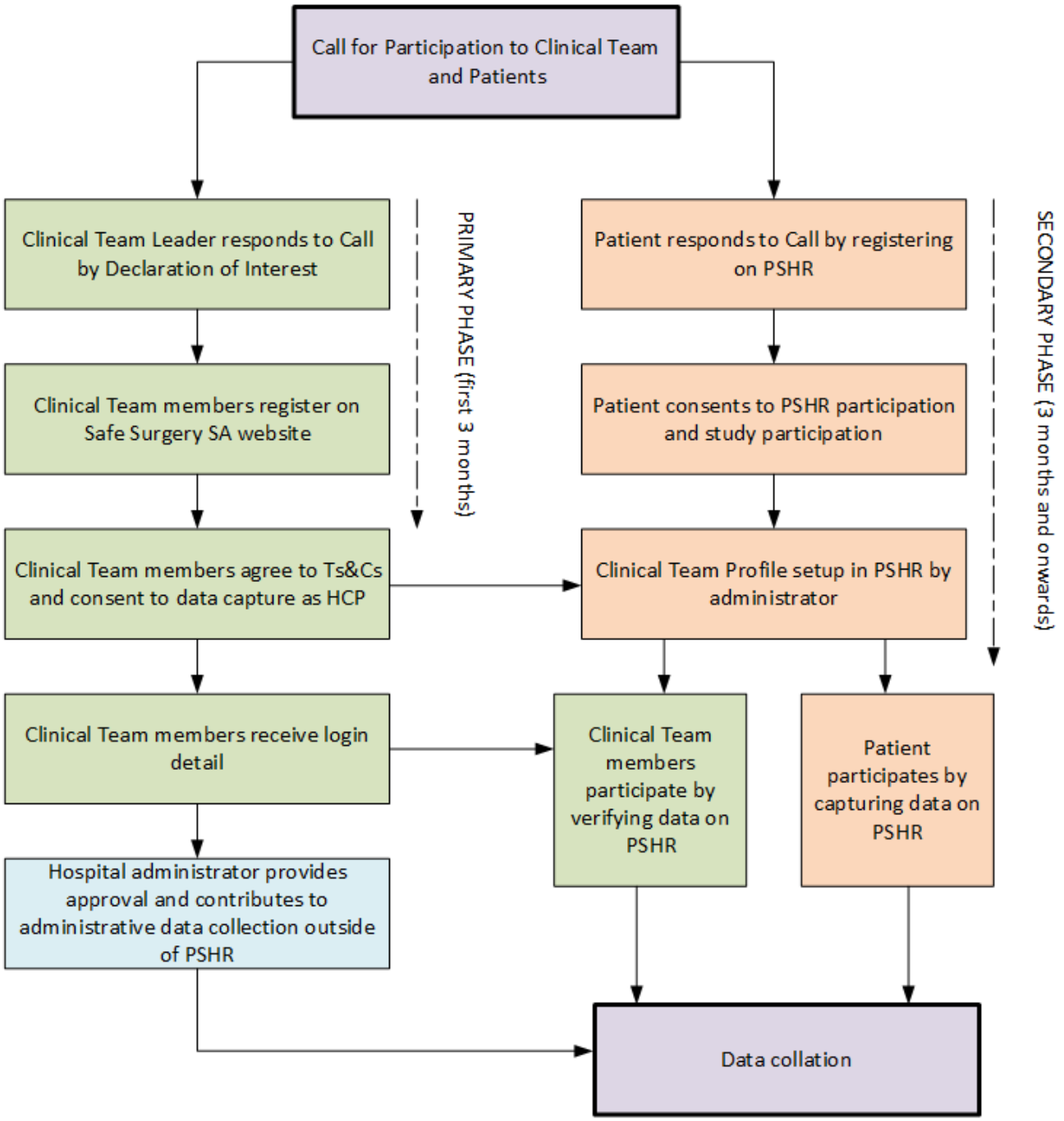
3.4.3 Clinical teams

Participation from providers will be in a team-based approach, including a surgeon, an anaesthetist and the hospital manager at each specific centre. A call for collaboration will be extended to hospital management groups, individual hospital managers, and professional surgical and anaesthesia societies. A core group of participating centres may be identified which provide surgical services in provinces with highest number of apparent COVID-19 transmission at the time.

3.5 Data collection and collation

Patients will be recruited, during the period September 2021 to September 2023.

The study will focus on patient participation with the platform as the primary recruitment method. This will reduce the need for clinician input, and promote greater patient-centeredness. Patient participation and data capturing require internet access to a web-based platform. The proposed recruitment process is illustrated in the following flow diagram:



Legend:
Green: Participation by clinical team members
Orange: Patient participation (note: clinical team profile setup, a result of clinical team member consent to data capture, is a requirement for patient recruitment)
Blue: Hospital participation
PSHR = Perioperative Shared Health Record
HCP = Healthcare Practitioner

Each clinical team will identify a team leader responsible for consenting the patient, and checking data quality and completeness.

3.5.1 Patient data collection:

Data will be collected by patients using the PSHR, a patient-centric platform developed by Safe Surgery South Africa NPC (CIPC registration number 2014/057792/08). Patients will register on the PSHR and provide consent to participation on registration. The anaesthetist member of the intraoperative team will capture and/or verify patient risk factors and procedural data. Members of the clinical team will register for the use of the platform by agreeing to the Terms and Conditions on the Safe Surgery SA website www.safesurgery.co.za. Information on the study will be published on the web site. On registration, the patient will consent to access of data for the surgical procedure by the clinicians in the team involved, e.g. the surgeon and anaesthetist. The anaesthetist will have access to a benchmarking module in the PSHR, to compare data of patients he/she cared for, to aggregated de-identified data in the database. Variables specific to the study will not be included in the benchmarking module. Postoperative data will be collected by the patient, using the PSHR, at 7 days, 30 days, 6 months and 12 months postoperatively. The first postoperative follow-up at 7 days postoperative will be telephonic (subject to funding availability), to sensitize the patient or patient nominee to the subsequent data request. If the patient has been rendered incapacitated due to the surgery at the time of the follow up, follow up will be with the patient's nominee. The patient nominee will be authorised by the patient at the time of registration and consent to participation for the study. Data obtained from the patient's nominee will not be captured in the PSHR, so this person will not require access to the system. The definition of a patient nominee for the purposes of this study would be:

1. The legal guardian of the patient or
2. Next of kin or
3. Any other person of the patient's choosing.

The PSHR is a patient platform that requires patients to register, consent to use, and enter complete demographics including patient identifiers. The platform is a secure web-based platform hosted on a server maintained by a company contracted with Safe Surgery South Africa (SSSA).

De-identified data will be extracted from the database at predetermined intervals by the named SSSA administrator, and made available to the principal investigator for analysis.

3.6 Dataset & Variables:

The dataset is based on variables collected during the first COVIDSurg study.[2] Patient participation using an electronic platform enables data collection up to one year postoperatively. The data collected will include a patient perspective on urgency of surgery during the pandemic, and quality of life measures.

3.6.1 Data from Clinical Teams

Team-specific data will be collected once, including: Name, initials, surname, HPCSA registration number, practice (Board of Healthcare Funders) number and clinical role for each member of the clinical team (surgeon and anaesthetist), and facility name and practice number. The clinical team members will be linked as a team using the practice numbers. All practice members will be required to agree to the Terms and Conditions of the Safe Surgery SA database use. The hospital will be asked to provide administrative data to confirm procedural data, and cost data to validate the clinical prediction model.

3.6.2 Data from Patients

All data will be captured electronically. The variables to be collected are displayed in the following table:

Variable set	Variable	Patient Recruitment arm data set (in the PSHR)
Demographics	Date of Birth	✔
	Sex: male/female	✔
	Weight in kg	What is your weight?
	Height in m	What is your height?
	BMI	Calculation: weight in kilograms divided by height in meters squared.
Comorbid disease	Current smoker	Have you been smoking cigarettes in the past year? Did you smoke before but stopped? How many years have you been smoking/did you smoke? How many cigarettes per day do you smoke/did you smoke?
	Asthma	Do you have asthma?
	Cancer	Have you ever been told you have cancer? Have you ever had an operation for cancer? Have you ever received medication or radiation for cancer? Are you currently receiving medication or radiation for cancer? Have you been told that the cancer is not under control, or has spread?
	Chronic Kidney Disease (Moderate/Severe)	Have you ever had any kidney problems? Do you currently have kidney problems? Have you ever received dialysis? Are you currently receiving dialysis?
	COPD	Are your lungs damaged due to smoking?
	Congestive heart failure	Calculation: Do you wake up at night because of difficulty breathing? Do you get short of breath when lying flat on your back? Do your ankles or legs swell? Do you get short of breath when climbing stairs? Do you wake up coughing at night? 1 = if 'yes' to either of the first two questions and 'yes' to two of the last three questions. 0 = Other than 1
	Diabetes Mellitus	Do you have diabetes (high blood sugar)? If yes, since when? Do you use insulin for the diabetes (high blood sugar)? If yes, for how long?
	HIV infection	Do you have HIV? If yes, since when?
	Hypertension	Do you have high blood pressure? If yes, since when? Do you take medication for high blood pressure regularly?

	Ischaemic heart disease	Have you ever been told that you have a problem with the blood supply to your heart? If yes, when? Have you ever had a heart attack? If yes, when? Have you ever received a stent in the blood supply to your heart? If yes, when? Have you ever had a bypass or surgery of the blood supply to your heart? If yes, when?
	Peripheral vascular disease	Do you have pain in the muscles of your legs during exercise? Do you have cold or blue hands or feet? Have you been diagnosed with disease of the large blood vessels such as the aorta? Have you had surgery to the large blood vessels?
	Stroke	Have you had a stroke?
	TIA	Have you suffered from short-lived weakness in your arms or legs, or short-lived blindness?
	Tuberculosis	Have you ever been treated for tuberculosis?
Quality of life (EQ-5D-5L) preoperatively, postoperatively 6 months & 12 months	Mobility	I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about
	Self-care	I have no problems with washing or dressing myself I have slight problems with washing or dressing myself I have moderate problems with washing or dressing myself I have severe problems with washing or dressing myself I am unable to wash or dress myself
	Usual activities (e.g. work, study, housework, family or leisure activities)	I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities
	Pain / Discomfort	I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort
	Anxiety / Depression	I am not anxious or depressed I am slightly anxious or depressed I am moderately anxious or depressed I am severely anxious or depressed I am extremely anxious or depressed
	EQ-5D-5L score	Calculation
	How long have you been functioning at this level?	In months

COVID-19 diagnosis preoperatively	Were you diagnosed with COVID-19 infection at any time prior to your planned surgery?	Yes / No
	If yes, when?	Date (Only displayed if YES to previous question)
	When was your most recent COVID-19 test done?	Date
	What was the result?	Positive / Negative
	Have you received a COVID-19 vaccine?	Yes / No
	What is the date of vaccination, or the most recent date of receiving more than one dose?	Date (Only displayed if YES to previous question)
Preoperative assessment	ASA PS category	Physical status self-assessment as reported by the patient, based on the ASA PS classification: Are you healthy? OR Have you been suffering from a disease for longer than a few months? If yes, Does the disease affect your daily life only mildly; that is, you can continue with your daily life as previously? OR Does the disease affect your daily life severely; that is, the disease does not allow you to continue with your daily life as previously? OR Is the disease a constant threat to life; that is, the disease is so severe that you must stay in bed to survive?
Procedural data	Urgency of surgery	How urgent do you consider the procedure to be: 1. I can wait for the surgery 2. I cannot live with the problem another month 3. I cannot live with the problem for another week 4. I cannot live with the problem for another day
	Delay to surgical admission	When was the decision made to proceed with surgery?
	Time from admission to operation (pre-op delay)	When is the date of your admission to hospital for the surgical procedure?
		Date of surgical procedure (confirmed by clinician)
	Surgical procedure codes	As on authorization letter (confirmed by clinician)
	ICD10 codes (surgical diagnosis)	As on authorization letter (confirmed by clinician)
Postoperative outcomes at discharge	Postoperative length of stay	How many days did you stay in hospital after the procedure?
	Postop ICU	Did you/the patient spend time after the operation in the Intensive Care Unit (ICU)? Was this planned before the procedure, or not? How many days did you/the patient stay in the ICU?

	Postoperative Morbidity Survey[27]	Were there any complications after the procedure? Did you have to for the first time use oxygen, or get support to breathe? Did you receive antibiotics, or have a fever? Did your kidneys stop working well? Did you have any problems with eating, or use of your gut? Did you have any new heart problems? Did you have any new neurological problems? Did you require any blood product transfusion? Did you need a procedure to take care of wound complications? Did you have any new/unexpected pain after recovering from the procedure?
Postoperative follow up – 30 days	SARS-Cov-2 Related	Were you diagnosed with COVID-19 infection in the month after your surgery? Is yes, when? Did you stay in hospital longer because of COVID-19 disease? Did you receive oxygen because of COVID-19 disease? Did you need help to breathe from machines because of COVID-19 disease? Did you have any other complications, such as blood clots, because of COVID-19 disease? Have you received a COVID-19 vaccine after your surgery? If Yes: What is the date of vaccination, or the most recent date of receiving more than one dose?
	Procedure Related	Were you readmitted to the hospital after the surgical procedure because of complications related to the procedure? Were you admitted overnight in the hospital for ANY reason during the 30 days after you underwent your surgery? In the 30 days after your surgical procedure, how many days did you spend out of hospital?
Postoperative follow up – 6 & 12 months	SARS-Cov-2 - related	Were you diagnosed with COVID-19 infection from one to 6 months (or between 6 and 12 months) after your surgery? If yes, when? Have you received a COVID-19 vaccine between 1 to 6 months (or between 6 and 12 months) after your surgery? What is the date of vaccination, or the most recent date, if you have received more than one dose? Have you had any long-term health damage due to COVID-19 disease.?
Other postoperative outcomes	Patient-centred outcomes	Anaesthesia-related outcomes Quality of Recovery-15[28] WHO Disability Assessment Schedule[29] Days alive and out of hospital at 30 days postop[30] WHO COVID-19 Clinical progression scale[31,32] (optional collection by clinician)

3.7 Data Security, Management and Ownership

Safe Surgery South Africa NPC will act as custodian of data captured using the PSHR platform.

The PSHR platform is secure and the data server is provided by Amazon Web Services (AWS) and hosted by Silicon Overdrive. Silicon Overdrive is a network services provider that specializes in Cloud and Network Security, is a registered AWS partner in South Africa and is part of the APN (Amazon Partner Network)

Data will be de-identified with regards to the patient and the healthcare providers, before being made available for re-use under a Creative Commons license (CC-BY-NC).

Safe Surgery South Africa will obtain cyber insurance for privacy liability, in the event of a data security breach.

3.8 Statistical Methods

Categorical variables will be described as proportions and will be compared using chi-square tests. Continuous variables will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables between groups will be performed using t-tests, one-way ANOVA or equivalent non parametric tests as appropriate. Univariate analysis will be performed to test factors associated with postoperative complications, morbidity and mortality at 30 days.

Missing data patterns will be investigated, and multiple imputation will be considered if it is deemed appropriate to impute variables.

Logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors. Factors will be entered into the models based on their univariate relation to outcome, biological plausibility and low rate of missing data. We will also investigate predictors simultaneously using a combination of a LASSO and a Ridge penalty in order to do variable selection.

Results of logistic regression will be reported as adjusted odds ratios (OR) with 95% confidence intervals. The models will be assessed through the use of sensitivity analyses to explore possible interacting factors and examine any effect on the results.

Poisson models will be used to model the length of stay outcomes with relative risk ratios as measure of association. The cox proportional hazards model may be considered if outcomes are seen as time to event where Hazard ratios will be reported.

Models will be adjusted for clustering if many sites are included in the data.

Prediction models will be internally validated using bootstrapping, as well as cross-validation. Both leave-one-out and K-fold cross validation will be considered. Bayesian models may be considered in order to have distributions of model parameters, rather than only point estimates with 95% confidence intervals. This may provide a different way of understanding the uncertainty in the model parameters changes as more and more data is collected.

3.8.1 Sample size

There is no specific sample size. Statistical models will be adapted to the event rate found in the cohort, and updated as the sample increases. The mortality rate in the COVIDSurg study for infected patients was 23.8%.

3.8.2 Primary outcome

- Quality of life (EQ-5D-5L) score at 6 months or 1 year

3.8.3 Secondary outcomes

- In-hospital mortality
- 30 day mortality
- In-hospital postoperative morbidity
- 30 day postoperative morbidity
- Postoperative Intensive Care Unit length of stay
- Postoperative hospital length of stay
- Quality of recovery (QoR) at 24-48 hours post-operatively
- 30 Day postoperative COVID-19 diagnosis
- Postoperative complications within 30 days
- Readmission to hospital within 30 days
- Days alive and out of hospital at 30 days (DAOH30)
- Functional status (WHODAS score) at 6 months and 1 year
- Hospital cost

3.9 Timeline & Milestones

Year 1 (August 2021 to July 2022)		
Milestone 1: *Deployment of PSHR on web server*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Engage with service providers to deploy PSHR	August to September 2021	PSHR ready for patient and clinician registration and data capture
Milestone 2: *Clinical Team Recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Recruitment of 25 clinical teams from diverse surgical specialities	August to December 2021	Team registration on platform Agreements in place Study material in clinic/consultation rooms
Milestone 3: *Patient Recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Recruitment of 20 patients per clinical team	October to December 202	Patient participation and data capturing in platform for surgical procedure

Milestone 3: *Preliminary report on 6 month patient follow up*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Data analysis of first 500+ patients	January to July 2022	Report (publication) on primary and secondary outcomes 1 & 6 months postop
Milestone 4: *Patient Recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Ongoing recruitment of patients from registered clinical teams	January to July 2022	Patient participation and data capturing in platform for surgical procedure

Year 2 (August 2022 to July 2023)		
Milestone 1: *Clinical Team recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Increase number of clinical teams participating and increase diversity of teams (specialty, geographical location, health sector)	August 2022 to December 2022	Team registration on platform Agreements in place Study material in clinic/consultation rooms
Milestone 2: *Patient Recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Recruit additional patients to the study and increase diversity of patients (social- and cultural backgrounds)	August 2022 to July 2023	Data for additional patients included in database
Milestone 3: *Increase reporting of results*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Data analysis	July 2022 to July 2023	Report (publication and presentation at congresses) on all outcomes including 1 year postoperative Validation and updating of clinical prediction model
Milestone 4: *Digital health (platform) development*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Source funding based on results of study. Engage developers	August 2022 to July 2023	Develop platform to be used for patient engagement in low resource settings.

Year 3 (August 2023 to July 2024)
Milestone 1: *Data Science*

Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Open Science approach to data management, analysis and reporting	August 2023 to July 2024	Impact analysis & implementation of clinical prediction models/risk stratification tools Machine Learning algorhythms
Milestone 2: *Complete recruitment*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Last patients recruited to study to allow for 12 month follow up.	August 2023 to July 2024	Final report (publication and presentation at congresses).
Milestone 3: *Implement PSHR in low resource settings*		
Key Tasks	**Duration (Start-End Date)**	**Deliverable(s)***
Depending on results Milestone 4 in second year (further development of platform) – study protocol amendment Apply to SAMRC for continued funding support	January 2024 to July 2024	Proposal for continuation of study accepted

4 BUDGET

Safe Surgery SA has the digital resources available to support this study. The study is funded by the SA Medical Research Council. Further funding has been obtained from the SA Society of Anaesthesiologists through the Jan Pretorius Research Fund (R50 000).

4.1 SA MRC Financial Contribution

Item	Year 1	Year 2	Year 3	Total Amount requested from the MRC
A. Running Cost				
Consumables				
1. Materials, and supplies				
Deployment of PSHR into new AWS cloud-hosted environment – AWS provider	87 890.00	0.00	0.00	87 890.00
Deployment of PSHR into new AWS cloud-hosted environment - developer	117 595.00	0.00	0.00	117 595.00
AWS maintenance costs	5.00	9 0000.00	90 000.00	180 005.00
PSHR maintenance costs	63 510.00	30 000.00	63 510.00	157 020.00
2. Laboratory including reagents, kits disposable labware /field costs	0.00			0.00
3. Patient participation cost	0.00	0.00	0.00	0.00
4. Office supplies, printing & photocopies, data, sim cards, telephone cost	0.00	0.00	0.00	0.00
Sub Total	**269 000.00**	**120 000.00**	**153 510.00**	**542 510.00**
B. Personnel cost				
1. Research Assistants	31 000.00	48 000.00	0.00	79 000.00
2. Field workers				
Social media content & sharing (patient recruitment)	0.00	36 000.00	0.00	36 000.00
Telephonic Follow up (script prep, call time, staff time, reporting)	0.00	48 000.00	68 490.00	116 490.00
3. Consultants (only allowed with motivation)				
SA MRC Biostatistics Unit (capacity development)	0.00	36 000.00	72 000.00	108 000.00
Sub Total	**31 000.00**	**168 000.00**	**140 490.00**	**339 490.00**
C. Publication cost				
SAMJ	0.00	12 000.00	6 000.00	18 000.00
Sub Total	**0.00**	**12 000.00**	**6 000.00**	**18 000.00**
D. Research travel				
1. Travel to sites (self-funded)				
2. Participant /patient transport (not applicable)				
3. Other, specify				
Sub Total	**0.00**	**0.00**	**0.00**	**0.00**

E. Minor Equipment Cost (not required)				
F. Conferences and Workshops				
1. Local Conferences				
SASA National Congress 2023/2024		Funded by SMU*	Funded by SMU*	
SA Surgery Conference 2023/2024		Funded by SMU*	Funded by SMU*	
Travel	-	-	-	
Accommodation	-	-	-	
Living expenses	-	-	-	
2. International Conferences				
World Congress of Anaesthesia 2025			Funded by SMU*	
Travel	-	-	-	
Accommodation	-	-	-	
Living expenses	-	-	-	
3. **Workshops (not applicable for this study)**				
Travel	-	-	-	
Accommodation	-	-	-	
Living expenses	-	-	-	
Sub Total	**0.00**	**0.00**	**0.00**	**0.00**
VAT 15% (not added according to instructions)				
TOTAL	**300 000.00**	**300 000.00**	**300 000.00**	**900 000.00**

5 ETHICS AND DISSEMINATION

5.1 Ethics approval

Primary ethics approval for the study has been obtained from the Sefako Makgatho Health Research Ethics Committee (SMUREC), Reference number: SMUREC/M/184/2020:IR. SMUREC also approved the Perioperative Shared Health Record (PSHR) database and registry on 6 June 2019. (Appendix A)

Patient consent to participation will be captured in the PSHR for data collection during the second phase of the study. Upon using the PSHR, the patient will also be asked to agree to the Safe Surgery South Africa database Terms and Conditions and consent to data capture in PSHR.

After responding to the call for participation and registering for the study on the Safe Surgery SA web site (www.safesurgery.co.za), the clinical team members responsible for data capture (surgeon and anaesthetist) will agree to the Safe Surgery SA Database Terms and Conditions, and consent to the use of the database. The hospital manager, as a member of the clinical team, will agree to the study in writing, and the agreements will be collected by the study project office.

The protocol, and ethics approval, will be circulated to the research oversight committees of hospital groups outside of the academic sector, as required by involvement, and agreement, of hospital managers.

The prepared patient information and electronic consent to the study is attached as Appendix B.

The following additional information is published on Safe Surgery SA platforms. Forms included on these platforms have been updated since the SMUREC database approval was received, with hyperlinks to forms for withdrawal or objection to data analysis, as required by the Protection of Personal Information Act:

1. Safe Surgery SA Database Terms and Conditions – Appendix C
2. Patient consent to data capture in PSHR – Appendix D
3. Healthcare practitioner consent – Appendix E

5.2 Dissemination

The result of the study with regards to the primary objective (relationship of 6 month quality of life score with patient characteristics, surgical procedure and cost of care) will be published in a peer-reviewed journal as soon as enough data have been collected for analysis.

The result of external validation of a clinical prediction model for cost will be published, and an electronic prediction tool developed for use by researchers and/or clinicians, to identify patients that may benefit from cost-effective perioperative interventions/clinical pathways.

Further reporting will be done at intervals on the Safe Surgery SA website (www.safesurgery.co.za)

5.3 Deliverables

The aim of reporting the results of the study at intervals would be to inform pre-operative shared decision-making, by discussing the risk-benefit ratio of surgical intervention, during the COVID-19 pandemic.

During and after the pandemic, the information may also be used to devise strategies for planning safe return to elective surgery, to limit the impact on the system from cancellation of such procedures.

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7 APPENDICES

7.1 Appendix A: Ethics Approval and Database & Registry Approval

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

Postgraduate Studies, Research Development, Integrity & Ethics
Sefako Makgatho University Research Ethics Committee
(SMUREC)

APPROVAL NOTICE - NEW APPLICATION

21 July 2020

Prof H Kluyts
Department of Anaesthesiology
P.O Box 205
Medunsa
0204

MEETING:	**03/2020**
SMUREC Ethics Reference Number:	**SMUREC/M/184/2020: IR**

The new Application received was reviewed by members of Sefako Makgatho University Research Ethics Committee.

Title:	The South African COVID-19 Surgical Outcomes Study
Principal Investigator:	Prof H Kluyts
Co-workers:	Prof B Biccard (Department of Anaesthesiology & Perioperative Medicine, University of Cape Town Dr H Malherbe (Rare Diseases South Africa)
Department:	Anaesthesiology
School:	Medicine
Type of Research:	Independent Research
Approval Period:	**02 July 2020 – 02 July 2021**

After Ethical Review: Kindly remember to use your protocol number **SMUREC/M/184/2020: IR** on any documents or correspondence concerning your research protocol with the REC. The REC has the prerogative and authority to ask further questions, seek additional information, require further modification, or monitor the conduct of your research and the consent process. A template of the progress report is obtainable from the Research Office and is due on an annual basis for your study irrespective of the approval period. Please note that a number of projects may be selected randomly for an external audit every year. Translation of the consent document in the language applicable to the study participants should be submitted if required.

International Organisation (IORG0008691), **Institutional Review Board** (IRB000010386) Expiry date: 07 December 2021, **Federal Wide Assurance** (FWA000023943) Expiry date: 03 March 2021 and **NHREC No: REC 210408-003**

Sincerely

PROF C BAKER
CHAIRPERSON SMUREC

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UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

G50, G Floor, Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 650 1236
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

14 September 2020

HREC REF:533/2020

Prof Bruce Biccard
Department of Anaesthesia and Perioperative Medicine
D23, New Groote Schuur Hospital
Faculty of Health Science
Email: bruce.biccard@uct.ac.za

Dear Prof Bruce Biccard

PROJECT TITLE: ***SOUTH AFRICA COVID-19 SURGICAL OUTCOMES (SACSOS)***

Thank you for submitting your request to the Faculty of Health Sciences Human Research Ethics Committee for review.

The HREC are comfortable and **approve** the study via the reciprocal process subject to:

- Groote Schuur Hospital institutional approval.

We note that the study has been approved by the relevant HREC at Sefako Makgatho University.

Therefore, the UCT-HREC notes that the primary oversight committee would be Sefako Makgatho University.

Approval is granted for one year until the 30th September 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

HREC REF 533/2020 SC

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

Postgraduate Studies, Research Development, Integrity & Ethics
Sefako Makgatho University Research Ethics Committee (SMUREC)

Prof H Kluyts
Department of Anesthesiology
P.O Box 205
Medunsa, 0204

Dear Prof H Kluyts

RE: APPLICATION FOR REGISTRY AND DATABASE APPROVAL

Researcher: Prof H Kluyts
Department: Anaesthesiology

SMUREC **NOTED** the request for database and registry approval.

Motivation:

Title: The Perioperative Shared Health Record (PSHR) database and data warehouse

The purpose of the PSHR is to collect national multicentre data in the South African healthcare sector on perioperative care with full patient participation (i.e. including patient-generated health data), and to report on this data in such a way as to enable clinicians and groups of clinicians involved in perioperative care to identify areas for quality improvement in surgical- and anaesthesia care.

SMUREC **NOTED** and **APPROVED** the request for the database and registry.

Yours Sincerely,

PROF C BAKER
ACTING CHAIRPERSON SMUREC

06 June 2019

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY
Research Ethics Committee
Chairperson
Date 06/06/2019

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7.2 Appendix B: Patient Information Leaflet & SACSOS Consent Form

Note: The information will be provided electronically, and electronic consent will be obtained. This information and consent is specific to SACSOS, and in addition to the usual information and consent for a patient using the perioperative shared health record (PSHR) developed by Safe Surgery South Africa.

SACSOS INFORMATION TO PATIENT

TITLE OF STUDY:	**South African COVID-19 Surgical Outcomes Study (SASCOS)**
PRINCIPAL INVESTIGATORS:	**Hyla-Louise Kluyts, Safe Surgery South Africa** **Bruce M Biccard, University of Cape Town**

Dear Patient,

You are being invited to consider participating in a research project/study when you undergo the planned surgical procedure.

The study is being co-directed by the ***principal investigators***: Prof Hyla-Louise Kluyts, Safe Surgery South Africa, (email: hyla.kluyts@smu.ac.za) and Prof Bruce M Biccard, University of Cape Town (email: bruce.biccard@uct.ac.za).

The ***study project office*** is Safe Surgery SA NPC, Block A, Willow Wood Office Park, corner 3rd Street & Cedar road, Broadacres, 2021, Cell: +27 67 429 2053, telephone: +27 11 065 9501, Email: admin@safesurgery.co.za www.safesurgery.co.za, CIPC Reg no 2014/057792/08.

The clinical team participating in the study, at each site or hospital, will be the surgeon who will perform the surgical procedure, the anaesthetist for the surgical procedure (these two clinical team members are the ***study doctors***) and the hospital manager.

Before you decide if you would like to participate, we want you to know why we are doing the study, including any risks (anything unexpected that might happen), and what you will be expected to do in the study.

This form gives you information about the study. The *study doctor(s)* will also talk to you about the study and answer any questions you have, or refer you to the *study directors/project office*. We encourage you to discuss this study with your family and anyone else you trust before making your decision. We will ask you to agree to take part, and that you understand the study (your consent). It is important that you know:

- You do not have to join the research study.
- You may change your mind and stop being in the study any time you want.
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

Why should I participate?

With this study, we hope to better understand the impact of the COVID-19 pandemic on patients (how it affects patients such as yourself) undergoing surgery for other conditions in South Africa. Large numbers of elective surgeries (procedures that are booked early and if done at a later stage or delayed for 3 months will not have a different outcome) are being cancelled during the COVID-19 pandemic. We hope that the research study will help to plan the safe return to surgical activity right after the COVID-19 pandemic.

The research project will:

- Describe the relationship between patients' health status, the surgery you undergo, and how patients recover after surgery
- Count the number of surgical patients who recover and those who do not within 30 days after surgery.
- Discover the extent of delay of booked surgery as a result of COVID-19 disease.
- See if there is a connection between breathing (pulmonary) complications after surgery in patients who recover and those who do not.
- Compare how patients with and without COVID-19 disease recover from surgery.

Who can join the study?

Any adult patient (age 18 years and older) that undergoes non-emergency surgery may be included in this study.

How can I join the research study?

You will capture most of the information yourself on an electronic platform: You will have been invited to join the study by a doctor involved in your care. You will register before your surgery for the Perioperative Shared Health Record (PSHR). This is a patient-centered personalised care platform developed by Safe Surgery South Africa NPC. Upon registration, you will be asked to agree to adding data related to your surgical procedure to a database, for the following reasons:

- For the better management of the patient's health care
- For research purposes, where researchers can use registry information for research projects in which the patient will never be identified if such research is published
- For analytical purposes, e.g. create reports for doctors to evaluate themselves, in which patients will not be identified at all

If you agree to the use of your data for research purposes, you will ALSO be asked specifically to participate in this study.

Once you have registered with the PSHR, you will be asked questions about the state of your health before the operation, and your experience after the surgery, and/or outcomes after surgery.

After your surgery, data will be collected by you using the PSHR, at 7 days, 30 days, 6 months and 12 months. The first follow-up at 7 days after your surgery will remind you/your nominee about the data request. If you are unfit as a result of the surgery at the time of the follow up, follow up will be with your nominee. The data obtained from your nominee will be captured separately (not in the PSHR) during telephonic follow up.

Please note that the PSHR is a web-based platform, and you will need internet connection to complete the different sets of questions. The questions that you will be asked after the operation, will have to be answered by you on a device (mobile phone, tablet, or computer) that requires an internet connection. We are unfortunately not able to compensate you for the use of data bundles required to complete these sets of questions.

What questions will I be asked?

You will be asked:

- Basic personal information (age, height, weight etc.)
- About your general health and any other conditions (co-morbidities) you may be affected by in addition to COVID-19.
- Symptoms you may have when you arrive at the hospital for your surgery
- About your COVID-19 diagnosis before and after your surgery
- How long you have had any health condition (co-morbidity) and how it affects you.
- Specific information about your procedure.
- How well you recover after your surgery.
- Patients enrolled via the PSHR will also be asked questions about quality of life.

How safe is it for me to participate?

This study is observational, so no new drug or technique is being studied. The study itself will not affect you physically, so there are no risks. Your personal information will be captured electronically, and there is a risk that the information may be obtained by people not involved in the study (cyber criminals). We will be implementing all possible measures to decrease this risk.

All data will be collected electronically, i.e. by the patient and doctors entering information into a database. The database has been approved by an ethics committee whose job it is to check that measures are in place to protect your privacy.

De-identified data will be extracted from the database at pre-planned intervals by the Safe Surgery South Africa (SSSA) administrator and overseer of the data, and be made available to the principal investigator for analysis. Neither you, the patient, nor your doctors will be identified in the data extracts (de-identified to prevent identification of individual patients and doctors). Only summary data will be presented publicly, and scientific reports issued at intervals throughout the project, including for publication in relevant medical publications as appropriate.

Safe Surgery South Africa, the custodian of the data, will be insured against cyber privacy- or security breach.

Taking part in this research is by your choice and you or your nominee may leave the research study at any point, without any negative outcomes.

In terms of the Protection of Personal Information Act, the following forms are available here:

- Objection to the processing of personal information (form 1)
- Request for correction / deletion of personal information or destroying or deletion of record of personal information (form 2)

There will be no costs to you as the patient to take part in the study and there are no incentives or repayments for joining the study.

Ethics Approval

This study has been ethically reviewed and approved by the Sefako Makgatho Health Sciences University Research Ethics Committee (approval number SMUREC/M/184/2020:IR).

In the event of any problems or concerns/questions you may contact the researchers at Cell: +27 67 429 2053, telephone: +27 11 065 9501 or the SMU Research Ethics Committee, contact details as follows:

Molotlegi Street, Ga-Rankuwa
Pretoria, Gauteng
PO Box 163, Medunsa, 0204
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Telephone: +27 12 521 5617 / 3698
Facsimile: +27 12 521 3749
Email: lorato.phiri@smu.ac.za

SACSOS ELECTRONIC CONSENT WORDING

The South African COVID-19 Surgical Outcomes Study

I have read the information on the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me: to understand how the COVID-19 pandemic affects patients needing surgical procedures. I have not been pressurized to participate in any way.

I understand that participation in this Study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor. When I withdraw, the data that I have contributed up to this point will not be used in the analysis for the study.

If I have any more questions/concerns or doubts about the study I understand that I may contact the researchers through the study project office.

I know that this Study has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC), Sefako Makgatho Health Sciences University. I am fully aware that the results of this results of this Study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

Patient data to be completed electronically:

- Patient identifier to be used
- SA ID number of patient
- First Name
- Initials
- Last name
- Email
- Surgeon
- Patient date of birth
- Sex
- Emergency contact details:
- Emergency contact name
- Emergency contact mobile number
- Emergency contact email address

eConsent

I hereby give consent to participate in this Study.

In the event that I (the patient) am not able to participate due to the impact of surgery (or I am incapacitated or disabled in any way), I appoint _____ as my nominee to provide information in my place after the surgical procedure.

Yes/No

Date of consent:

7.3 Appendix C: Safe Surgery Terms & Conditions

SAFE SURGERY DATABASE

TERMS AND CONDITIONS ("Ts and Cs")

What these Ts and Cs mean

1. By logging into, submitting information and using the Safe Surgery Database ('the Database") you confirm that you understand these terms and conditions and that you agree to abide by it. The latest version of these Ts & Cs will always be available from the Safe Surgery SA office and the Safe Surgery SA website.
2. The Database includes data related to the health status and care of a patient during, before and after surgery and anaesthesia. The data are gathered using various mechanisms or data collection tools, stored in a secure environment.

Why this Database?

3. The Database comprises health information and reports by practitioners and patients on their experiences relating to surgery (before, during and after).
4. It aims to, record on a single database:
    a. information that will allow anaesthetists and other healthcare professionals to timely access information about patients prior to surgery,
    b. important data during surgery,
    c. outcome measures of surgery so as to allow benchmarking of data and drive practice enhancements. In the case of contracted arrangements, such as the Anaesthesiology Event-Based Contract (EBC), to capture and share the data as contracted by the practitioner and consented by the patient,
    d. patient satisfaction measures after surgery,
    e. any other relevant information that will assist the health sector, healthcare professionals and patients in assessing and enhancing the healthcare environment where surgery is concerned.
5. The Database forms a platform from which authorised research projects could be undertaken.

How will this Database be used?

6. The main objective is to ensure better patient care. Every person who contributes their data to this system therefore assists in the achievement of this goal for the greater good of the health sector.
7. SAFE SURGERY SA and its affiliated bodies or authorized researchers, may use the aggregated data, or aggregated data-subsets for further research purposes, reports to relevant stakeholders, presentations to government or regulatory entities, healthcare funders, healthcare policy makers, at conferences and at meetings, so as to assist those entities and the providers of healthcare in creating better health systems and better health outcomes.
8. The Database will also allow doctors to compare themselves with others on the system, without seeing the identities of such other patients or other practitioners.
9. The use of the data and the database for any purpose outside of what is listed in these Ts & Cs is strictly prohibited.

Who is SAFE SURGERY?

10. SAFE SURGERY SA is a not-for-profit entity established in the public interest. It is a programme of SAPORG, the South African Peri-operative Research Group, and associated professional organisations, who are the "affiliated bodies" referred to in these Ts and Cs.

Confidentiality

11. The Database and its owners will never release any identifiable information from any patient or healthcare practitioner without obtaining specific consent to do so by the individual.
12. The information submitted to the Database by patients and practitioners, as well as the data subsequently generated by the Database are subject to strict confidentiality controls in line with the Protection of Personal Information Act, 2013, the National Health Act 2003 and the HPCSA Ethical Rules of 2006.
13. Patient and healthcare data will be stored on the Database, but only used and released in an aggregated, de-identified manner for the uses as outlined in these Ts and Cs.
14. Participating healthcare practitioners may see information that relates to themselves and their patients only.

15. Patients (or those authorized to consent on their behalf) can only see their own information, including historical information, but cannot access another patient's information.

Access to the database or information on the database

16. No third party outside of SAFE SURGERY SA, its affiliated bodies and their authorized members and users, database administrators and expert advisors, may access and/or use the Database for any purpose whatsoever. Only the SAFE SURGERY SA and its authorized users may use the Database for the purposes as set out above.
17. The Database may not be used by any party other than the owner thereof, for any commercial purpose.
18. A practitioner may authorize practice staff to include and/or update information on the database.
19. Authorisation for use of the Database will be in the sole discretion of the Board of SAFE SURGERY SA, and application must be made in the format and by providing information as set by the Board from time to time. Permissions may be subject to conditions, such as compliance with other legal or policy provisions, such as ethics committee approval.
20. Permission must be sought and may also be granted for the use of the Database and/or SAFE SURGERY SA logo on presentations or publications that result from the use of the data on the database.

Security

22. The Database uses all reasonable measures to protect the data from unauthorized- use, access, hacking, cyber-spying, malware, data corruption, abuse and all similar threats to the security of the data. SAFE SURGERY SA has agreements in place with service providers to not only protect the confidentiality and integrity of the data, but also to ensure that adequate levels of security is maintained. In spite of these steps no absolute guarantee can be made in relation to SAFE SURGERY SA being safe from all hacking, free from crashing or other system errors, etc.
23. The SAFE SURGERY SA database is hosted on a server accessible via a webpage, protected by SSL security built into the system.
24. It is the responsibility of every person with log-in access to ensure that their log-on details are kept safe. The Database cannot be held responsible if users share these with third parties and confidentiality is subsequently violated. Such violations are offences under privacy legislation and could also lead to legal action and/or complaints at the Information Regulator and/or the HPCSA.

Property rights

25. SAFE SURGERY SA may at any stage, without prior notice, change the Database, its layout, categories and the likes and may make any upgrade, change or modify the platform, service, software or any aspect of the Database as it may require from time to time.
26. The source codes, logos, text, menus, lists and all other aspects of the platform that constitutes the Database is the exclusive and sole property of SAFE SURGERY SA. The copying and unauthorised use of any such materials are strictly prohibited, and SAFE SURGERY SA reserves the right to institute any appropriate action should any of these rights be violated. SAFE SURGERY SA may use third party software, which is similarly protected.
27. All designs, marks, logos, texts, examples of documents and so forth are subject to copyright and trademark law. The unauthorized use thereof is strictly prohibited.

Duration of data storage

28. The Database will store data indefinitely, as well as the consents and agreements that authorize and relate to such processing of personal- and health information.
29. A patient's information can be removed from the Database when he/she revokes his/her consent to store and share identifiable, personal information. Click here to request removal from the database. According to the Protection of Personal Information Act, any person can also object to the processing of personal information.

Donations, sponsors, grants and advertisements

30. SAFE SURGERY SA and/or the Database may receive donations and sponsorships so as to ensure the sustainability and viability of the project, which will be subject to corporate governance and due diligence controls. No sponsor, grantor or donor will, as a result of such contribution, have access to the database, or through that mechanism secure the use of the database or data-subsets. Publication of such support will be agreed with each sponsor, donor or grantor. Such publication must not be seen as SAFE SURGERY SA, the Database or its Affiliated Bodies endorsing that entity or any of its products or services.
31. The Database reserves the right to sell advertisements that would appear when the database is used or logged into.

32. Donations, sponsors, grants and advertisements should not be seen or construed as SAFE SURGERY SA or the Database endorsing such entities, their products or services, or that SAFE SURGERY SA prefers one entity, product or service provider over another.

Termination of agreement

33. Should circumstances arise that threaten the continued existence of the database, data will be made available per research project according to the agreement with investigators.
34. Should circumstances arise that threaten the continued existence of the database, in cases where data were collected for the purpose of sharing such data between patient and healthcare practitioners, for use during management of the patient, or benchmarking of individual healthcare practitioner practices, consent will be sought for any successor in title or any other entity identified by the Safe Surgery Board as suitable to manage the database on the same basis as before, and provision will be made for individuals to opt out at that time.
35. Should circumstances arise that necessitate the termination or closure of the Database, SAFE SURGERY SA will transfer the existing data, de-identified with regards to patient, healthcare professional and healthcare facility, to associated professional organisations. SAFE SURGERY SA would transfer the same confidentiality and protection criteria along with the data. The organisation would accept the data on those same terms.
36. SAFE SURGERY SA will not be responsible or liable for any consequence flowing from the termination and the subsequent deletion of information stored on the Database.

Disclaimer and Reservation of rights

34. Patients, practitioners and entities participate and, where so authorized, use the Database and/or the data contained therein at their own risk. By participating in the Database, patients, practitioners and entities indemnify SAFE SURGERY SA from any claim, loss, damage or liability (including legal costs on an attorney and own client basis) for or in relation to any claims arising from the participation in, use of, or any allegedly unethical, negligent act or omission of SAFE SURGERY SA and/or any allegation that SAFE SURGERY SA operates in- or facilitates contravention of the ethical- or applicable legal rules.
35. SAFE SURGERY SA reserves the right to:
    a. Discontinue the Database without prior notice, should it be appropriate.
    b. Terminate the participation of any practitioner, should the practitioner violate any of the terms and conditions contained herein.
    c. Take any action reasonably required in order to ensure compliance, or enhanced compliance, with legislation and ethics, and/or to ensure data and/or platform integrity.

7.4 Appendix D: Patient Consent Safe Surgery

PATIENT CONSENT TO INCLUSION OF PERSONAL- AND HEALTH INFORMATION INTO THE SAFE SURGERY SA DATABASE

I, the person who completes the information on the Safe Surgery website, hereby declare that I have been informed of the Safe Surgery database, and its objectives and uses, when I reviewed the Safe Surgery Terms and Conditions, and I hereby consent, freely and voluntarily, to participate.

I understand and agree to the following:

1. I agree to the inclusion of personal- and health data into a database.
2. I understand that I will supply certain information, which will assist my healthcare team to assess my health status, my health information and/or comments after the surgery.
3. I understand that apart from the use of my information in relation to my own healthcare, my data will be included in a database that will be used for health -research, -policy, -systems and -financing purposes.
4. I understand that patient names and any other personal identifiers will be included in the database, but when data is released from the database, it will be done in a manner that is aggregated and de-identified. The data will be included in a larger database with other patients' data and also data from the practitioners who treated the patient and/or the facilities where the patient was treated and/or operated on. Such information will not link back to any patient- specific data and/or to a specific patient.
5. All information will be handled in accordance with the Protection of Personal Information Act, the National Health Act, the Promotion of Access to Information Act and the ethical rules that bind healthcare professionals
6. The database is secure, and reasonable mechanisms are in place to ensure that there is no unauthorised access to any information stored.
7. I can at any stage withdraw from participating in the database, which withdrawal notice I will provide in writing to admin@safesurgery.co.za.
8. I understand that if I have any questions relating to this consent or the database, I can discuss it with my doctor or his/her designated staff.

I therefore agree to the collection, storage and use of the patient's information on the database:

☐ For the better management of the patient's health care

☐ For research purposes, where researchers can use registry information for research projects in which the patient will never be identified if such research is published

☐ For analytical purposes, e.g. create reports for doctors to evaluate themselves, in which patients will not be identified at all

7.5 Appendix E: Health Care Professional Consent Safe Surgery

AGREEMENT AND CONSENT BY HEALTHCARE PROFESSIONAL TO TAKE PART IN, AND HAVE INFORMATION PROCESSED, AS PART OF THE SAFE SURGERY DATABASE.

By clicking "I agree" below, I provide my consent to participate in, share information and allow for the processing of information for the purposes of the Database as outlined below. In doing so I also agree to the terms and conditions that accompany the Database.

The Safe Surgery Database:

1. Gives the patient the opportunity to provide information before- and feedback after the procedure. To see the list of information that form part of the database, please click *here.
2. Gives all the doctors in the treatment team and their authorized staff the right to see the patient's information, including information on previous procedures.
3. Stores information about the how the procedure went, and also the outcomes after the procedure.

From the above information I will be able to review my patient's peri-operative information and health outcomes, and be able to add important information. I will also be able to generate reports that compare me and my patients to the rest of the database.

Security

I understand that the database is secure, and the managers and administrators of the Database have taken all reasonable measures to protect my data from, for example, hacking or unauthorized access. All persons who access the database, or who enter information on the database, are contractually and ethically bound by confidentiality.

I understand that the Database is housed and the data stored on servers that are based outside of the borders of South Africa, and the Database uses Amazon Web Services. By agreeing to have information included in the Database, I consent to the data being stored using the server hosted overseas, subject to the security measures outlined in the Terms and Conditions.

Access and confidentiality

I also understand that only the patient's own healthcare team will be able to access that patient's current and previous information. The healthcare team and staff will not be able to view or access any other patients' or healthcare provider's information.

I understand that I, as the doctor, remain legally liable for all persons who access the system on my behalf. I undertake to ensure that my staff are familiar with this agreement and their duty to maintain confidentiality. In some cases patients would need support from my staff to sign up to the Database, and/or to complete information on the database.

Uses of the Database

Apart from allowing patient input and feedback that helps me, the doctor, better anticipate the patient's peri-operative journey and manage outcomes, the Database will also be used for:

- Research purposes, where researchers can use Database information for research projects in which the patient or the providers will never be identified if such research is published
- For analytical purposes, e.g. create reports for me to compare myself and my patients with others on the system. I will not see other providers' or patients' identifiable information in these reports, nor will they see mine.

I understand that I may at any stage opt out of the Database, and I can do so by clicking on the button where I can review this consent.

I hereby agree to participate in the uses of the database as indicated above:

AGREE DON'T AGREE

Note that if you do not agree, you and your patients cannot participate in the database, and you will not have access to the information that come from the patient's completion of the pre- and post-operative questionnaires. You have to obtain such information through personal and other contact with the patient and other healthcare providers.

***POP-UP on info we collect:**

List of information that you will provide and that will be stored as part of the database. The information is similar to what would otherwise be captured by the hospital and doctors in patient files:

- **Demographic details:** name(s) and surname; photo; identity, passport of drivers licence nr; date of birth; gender; allergies; contact numbers; email address; language preference.

- **About the operation**: it's date; whether it is elective, urgent or emergent; the procedure and diagnostic codes that the doctor have provided; the name of the surgeon, the name of the anaesthetists and the hospital where the operation will take place.

- The **before operation questionnaire**, which includes questions of the patient's health before s/he goes for the operation

- The **after the operation questionnaire**, which includes questions on whether the patient is happy with the outcome, pain, nausea, infections, or complications, if applicable and communication with the anaesthetist

- The doctor also records **details on the procedure**: the anaesthetic plan, how long it took and the billing codes used, etc. are stored. The doctor will also complete health details after the operation, such as infections, cardiovascular information and complications, if any. S/he also records how many days the patient was in hospital after the procedure, the level of care and details on discharge.