African Critical Illness Outcomes Study

Standard Operating Procedures Manual

This is a manual of Standard Operating Procedures (SOPs) to help you to successfully run ACIOS at your hospital. This manual consists of 3 sections:

1. Preparing your hospital site and your hospital's '*clinical research team*',
2. Collecting data,
3. Handling and managing data.

Contents

Section 1: Preparing your hospital site and your hospital's '*clinical research teams*'

Standard Operating Procedure for preparing your hospital site

Purpose

The purpose of this SOP is to outline the procedure for **preparing your hospital site** to conduct the ACIOS study successfully.

Scope

This SOP applies to National Leads, Hospital Leads and '*clinical research teams*' in the hospital.

Allowable Exceptions

This SOP is a suggestion which may need to be adapted to fit your setting.

Requesting permission from hospital management

Please ensure that all ethical approvals are in place for the study.

Please ensure that you have permission from hospital management to do the study. Please note that many hospitals have a standard form for requesting permission to conduct a study. Appendix 1 has the Study Synopsis, which you may want to include in your submission to hospital management.

After securing local hospital permissions, present the study to the Heads of Clinical Divisions for approval, and then inform the leadership or heads of each ward about the study and the planned date of data collection. We also recommend that you send a confirmatory reminder a few days before data collection and the day before data collection.

We encourage you to have open lines of communication with hospital management, heads of departments and heads of wards, to ensure that you answer any questions or concerns that they may have. If questions arise to which you do not know the answer, feel free to direct the questions to support@safesurgery.co.za or it@safesurgery.co.za or to use the study WhatsApp group to ask any questions.

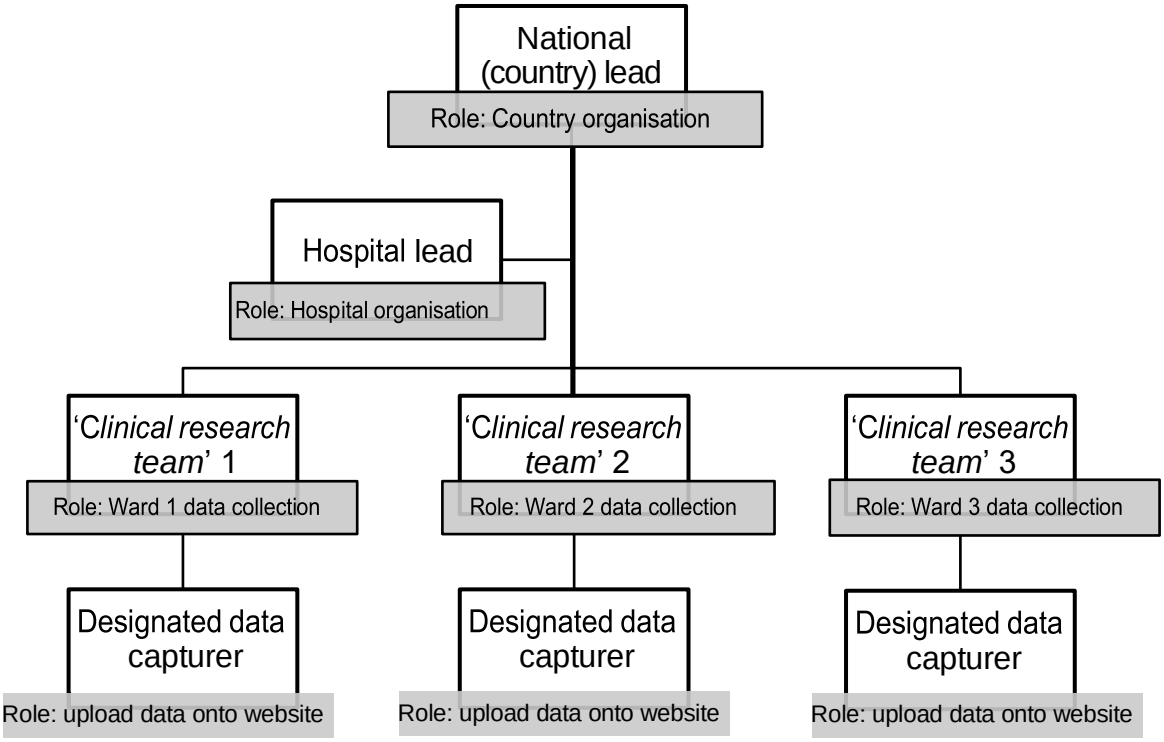
Informed consent

As per the protocol, we are using a Broadcasting document. This means you don't need to ask each patient for consent. Instead, the broadcasting signs (Appendix 2) stating that data are being collected can be placed within the wards.

Establishing your team

The success of this project requires a committed '*clinical research team*'. We recommend that you establish and agree upon roles and expectations for each person in the '*clinical research team*'.

The '*clinical research team*' should be medical staff or students who have been trained in conducting the vital signs clinical assessments required for data collection. We recommend that each ward or cluster of wards has a '*clinical research team*' with a team leader, and that there is a hospital lead overseeing each of these '*clinical research teams*'. Below is a diagrammatic example of how you may want to structure your team:



Equipment

A proposed strategy for equipment to be used by the '*clinical research team*'.

1. The ideal would be for the '*clinical research team*' to have their own equipment for the first day of the study when the vital signs of all hospital patients are measured. The equipment should include an oximeter (to measure heart rate and saturation), a blood pressure manometer (machine) or sphygmomanometer and a watch with a second hand to measure the respiratory rate.
2. If it is not possible for the researchers to use their own equipment for the study, then please approach each hospital ward, to confirm at what time during the day it would be acceptable to use the ward monitoring equipment without disrupting clinical service provision in the ward.

Equipment should be checked at least a week before conducting the study. Equipment should be disinfected and the battery level checked before the study begins. Where necessary, spare batteries should be bought.

Standard Operating Procedure for preparing your '*clinical research teams*'

Purpose

The purpose of this SOP is to outline procedure for preparing your '*clinical research teams*' to conduct the ACIOS study successfully within the hospitals.

Scope

This SOP applies to National Leads, Hospital Leads and '*clinical research teams*' in the hospital.

Allowable Exceptions

This SOP is a suggestion which may need to be adapted to fit your setting.

Training the hospital 'clinical research teams' for data collection

Practical training is mandatory for all members of the '*clinical research teams*' who will be collecting data. The Hospital Leaders should meet and go through the case report form (CRF) and ethical issues regarding the measurement and collection of data with the '*clinical research teams*'. There is an ethical consideration when the study team observes a patient that is critically ill (see definitions below) requiring urgent care. On these occasions, the '*clinical research team*' will immediately notify the ward treating physicians about the patient's condition and provide them with the patient's vital signs. Practical training should include how to complete all the fields in the case report form (CRF), including the vital signs.

Please ensure that:

1. If it is unclear how to complete any of the sections of the CRF, and the answer cannot be found in the definitions provided on the case record form (CRF) (Appendix 3), then please post the question on the National ACIOS WhatsApp group. The ACIOS Steering Committee will then be able to post a standard response on how to complete the specific question.
2. The '*clinical research teams*' know which values identify a critically ill patient, and they know to notify ward staff of these patients. Below are the criteria of a critically ill patient. To be classified as critically ill, a patient need only fulfil <u>one</u> of the criteria i.e. conscious level or respiratory or circulatory.

Criterion	**Vital signs**	**Classified critically ill**
Conscious level	*Conscious level (AVPU Scale)*	P or U (only respond to pain, or unconscious)
Respiratory	*Respiratory rate per minute*	<8 or >30
	Oxygen saturation (%)	<90
Circulatory	*Heart rate per minute*	<40 or >130
	Systolic blood pressure (mmHg)	<90

Coordination

Please ensure:

1. The local ward leadership (doctors and nurses) are aware and agreeable to the study.
2. The Head Nurse of the Ward is aware and in agreement with the time that the '*clinical research team*' will arrive to conduct data collection.
3. Please comply with infection prevention control (IPC) procedures during patient contact. <u>In wards containing patients with compromised immune systems, please see these patients first. With wards containing patients with contagious diseases, please ensure that these patients are seen last.</u>

The role of hospital leaders or designated ward leaders

Hospital leaders or designated ward leaders should work closely with the ward '*clinical research teams*'. At the start of the study, the Hospital Leader or designated ward leader should join the ward '*clinical research team'*. They should request that all the medical notes are at the patient's bedside. They should ask the nurse in charge if he or she wants the '*clinical research team*' to write the vital signs results that they have measured, into the medical notes. The '*clinical research team*' should confirm if there are any immunocompromised patients who should be seen first, and patients who are potentially contagious who should be seen last.

The Hospital Leader or designated ward leader should start data collection with the '*clinical research team*' to help them improve the quality and speed of data collection, and to be available for questions. The Hospital Leader or designated ward leader should double check the first few CRFs to ensure that they are complete and legible. All CRFs should be kept in a study folder. The Hospital Leader or designated ward leader should ensure that the team know when to disinfect vital signs monitoring equipment and when to recheck vital signs or data because of potentially abnormal values.

The Hospital Leader or designated ward leader should ensure that the '*clinical research team*' knows how to complete the screening log, and how to track in-patients who are not in the ward at the time of vital sign and data collection. The '*clinical research team*' needs to ensure that they return to complete the observations of the patients who were not in the ward at the time of vital sign and data collection.

Once all the in-patients have been seen in the ward, the folder containing all CRFs should be given to the '*designated data capturer*' of the '*clinical research team*', and the folder should be secured in a locked office before uploading the data to the ACIOS database.

Section 2: Data collection

2.1. CRF

We believe that data collection for the CRF will take about 5 minutes per patient to complete. This should allow you to organise and plan the time needed for data collection in each ward.

African Critical Illness Outcomes Study (ACIOS) – Patient CRF

Clinical assessment

Date of assessment: d d | m m | y y y y

Vital signs done by the investigating team: ☐Y ☐N **If no, specify** ☐Vital signs from patient records ☐Not done

Position of patient:

☐Lying flat on back(<30°) ☐Lying on side ☐Head-up(30°-60°) ☐Sitting(>60°) ☐Head-down ☐Other

Airway patency: ☐Normal ☐Partial obstruction ☐Complete obstruction

Conscious level (AVPU): ☐Alert ☐Responds to Voice ☐Responds to Pain ☐Unresponsive

Heart rate ☐☐☐ **/min** **Oxygen saturation** ☐☐ **%** **Respiratory rate** ☐☐ **/min**

Systolic blood pressure ☐☐☐ **/mmHg** **Diastolic blood pressure** ☐☐☐ **/mmHg**

Currently receiving IV fluids ☐Y ☐N **Receiving oxygen (now)** ☐Y ☐N

Receiving vasopressor/inotrope (now) ☐Y ☐N **Airway action (now)** ☐Y ☐N

Circle the worst pain you had in the last 24 hours: 0 (no pain) 1 2 3 4 5 6 7 8 9 10 (worst pain you can imagine)

Other information

Date of hospital admission: d d | m m | y y y y **Urgency of admission:** ☐Emergency/acute ☐Elective

Age ☐☐☐ **years** **Sex** ☐M ☐F

Ward type: ☐Medical ☐Surgical ☐Maternal ☐Other

Ward level: ☐General ward ☐High care unit/HDU ☐ICU

Main category for admission: ☐Non-communicable disease ☐Maternal health ☐Trauma ☐Infection

Known chronic disease or pregnancy (tick all that apply):

☐Pregnant ☐Hypertension ☐Diabetes ☐Cancer ☐COPD / Asthma

☐Heart Disease ☐HIV / AIDS ☐Tuberculosis ☐Other ☐None

Any surgery during this admission: ☐Y ☐N **Treatment limitations (e.g. not for resuscitation):** ☐Y ☐N

Follow-up

Total days in hospital from admission to discharge ☐☐

Status at 7th day in-hospital after clinical assessment: ☐Discharged Alive ☐Alive still in-hospital ☐Died

Date of discharge or death d d | m m | y y y y

ACIOS unique patient ID ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

✂ -

Patient name: ______________________ DOB d d | m m | y y y y

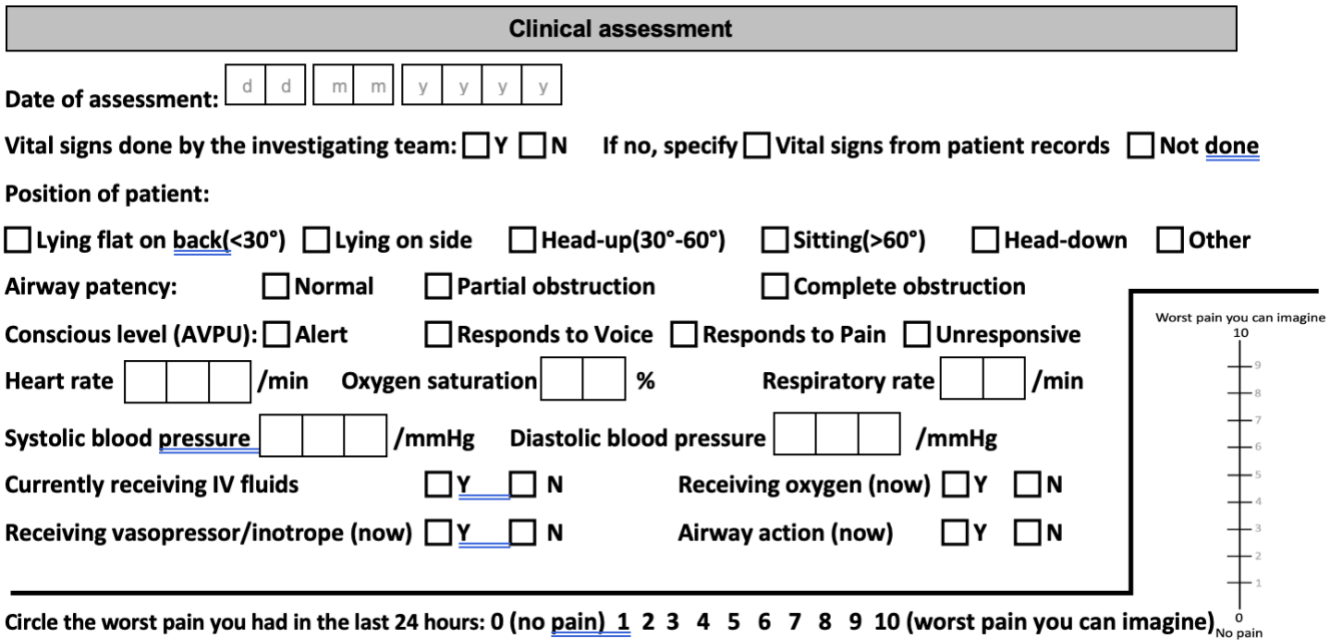
Patient hospital number______________________ Ward ______________ Bed______________

2.2. Inclusion criteria

Patients included in the study are all admitted in-hospital patients 18 years or over who have been admitted for inpatient care in any department or ward in participating hospitals. Therefore all outpatients and patients in emergency departments who have not being admitted for ongoing inpatient care are excluded. All admitted patients registered in the ward at the time the '*clinical research team*' does the vital signs assessment for the study in the ward will be included in the study. Any patients admitted to the ward after the '*clinical research team*' has completed the data capture in the ward, will not be included in the study, even if they are admitted later on the same day.

2.3. SOP for the clinical assessment

All data for the clinical assessment must be collected by the '*clinical research team*' on the predetermined date for data collection. Please do not copy the vital signs data (i.e. heart rate, respiratory rate, blood pressure and oxygen saturation) measured by the normal ward clinical team.



Abnormal findings are defined as below, and demand the use of the 'recheck strategy' indicated here.

	Recheck if	Recheck strategy
Conscious level	V, P, or U	By another data collector – consensus reached by discussion or ask supervisor
Oxygen saturation	<92% or bad pulse curve	Change finger or probe. Wait for 1 minute or until stable
Heart rate (pulse oximeter)	<50 and >125/min or bad pulse curve	Confirm with BP-machine and pulse. Use value in the middle
Systolic blood pressure	<105 mmHg No reading	Recheck 2 times. (total 3 times) Use the value in the middle. Call supervisor.
Respiratory rate	<10 or >20	Recheck 2 times. (total 3 times) Use the value in the middle.

Don't get stuck with a patient. **Ask the Hospital Leader or the ward lead of the 'clinical research team' to finalise any data which is confusing.**

Airway patency

Normal –	An unobstructed airway.
Partial obstruction –	Indicated by stridor, secretions in the airway identified by gurgling, or snoring
Complete obstruction –	See-saw chest movement (chest down and abdomen up with attempted breathing against a closed glottis). Complete obstruction is an airway emergency and requires calling the attending clinical team immediately.
Patient intubated –	An intubated patient with an endotracheal tube will have the airway patency assessed as above i.e. normal, partial or complete obstruction.

Conscious level (AVPU)

AVPU is a simple way to assess the consciousness level of a patient. Look at the patient and see if they are awake before stimulating them. Wake the patient up kindly if asleep. Measurement of conscious level: is the patient Alert = A. If they are not alert but they respond to your voice = V. If they don't respond to voice but respond to a painful stimulus = P. If they remain unresponsive even with a painful stimulus = U (unresponsive).

A – Alert spontaneously. Includes being alert after being woken from sleep. Includes drowsy and agitated. Patient can obey commands and socially adequately answer questions.

V – Verbal stimulus is required to achieve a response. Patient does not become alert. Includes markedly confused patients, but not those clearly awake and slightly disorientated.

P – Requires painful stimulus to achieve a response.

U – Unresponsive.

Heart rate

Record the heart rate value from the pulse oximeter or electronic blood pressure cuff. If using a pulse oximeter, ensure the pulse oximeter has a stable curve (wait at least 10 seconds before recording).

Oxygen saturation

Oxygen saturation is a measure of how much oxygen is being carried by haemoglobin. This will be checked using pulse oximeters. For pulse oximeters to work, they require a strong signal i.e. strong pulsations to the fingers. This might be affected if the patient has cold hands or nail polish on.

- Make sure the pulse oximeter is ON.
- Put the probe on the finger,
- Wait for the curve on the oximeter to stabilise (wait at least 10 seconds),
- Record the reading,

Respiratory rate

Look at the patient's chest movements. Count the number of respirations for 30 seconds using a watch that measures seconds and then multiply by 2 to get breaths per minute.

Try to not let the patient know you are counting their respiratory rate, do not talk to the patient or let the patient talk when counting.

Blood pressure

- The patient's arm should be by their side and the upper-arm at heart level. No legs crossed (differs 8/5 mmHg!). When feasible, use the preferred position i.e. sitting or semi-sitting.
- Place the cuff on the exposed arm 2cm (approximately two finger-breadths) above the elbow. The palm should be facing upwards.
- Make sure the tubing is placed at the centre of the arm facing the front, and that the sensor is correctly placed.
- Pull the end of the cuff so that it is wrapped evenly and firmly around the arm.
- Check that the tightness of the cuff is appropriate: You should be able to just slip two fingertips beneath the cuff, near its edge at the top end. When the cuff inflates it should not cause any painful sensation.
- The tubing should be aligned with the brachial artery (front side of the elbow).
- Press the power button and wait for the machine to inflate and deflate automatically until it gives a reading of both systolic and diastolic.

Currently receiving IV fluids/vasopressor/inotrope/oxygen

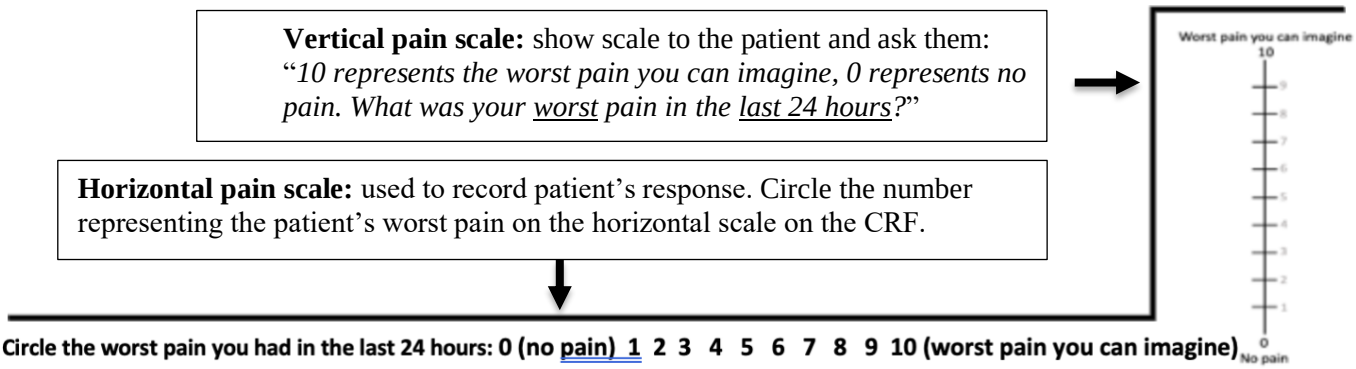
Select 'yes' if at the time of assessment, the patient is receiving IV fluids evident by IV fluids hanging at the bedside and currently dripping into an intravenous cannula, or the patient has been receiving fluids as described within the previous few minutes but is now finished and a new fluid is being prepared to be administered. If patients who have fluids hanging but the IV is closed and so no fluids are flowing, so be reported as not 'currently receiving IV fluids'.

Airway action

Any action to open the airway or maintain a free airway. For example: chin lift, jaw thrust, oro-pharyngeal airway, naso-pharyngeal airway, intubated patient.

Pain

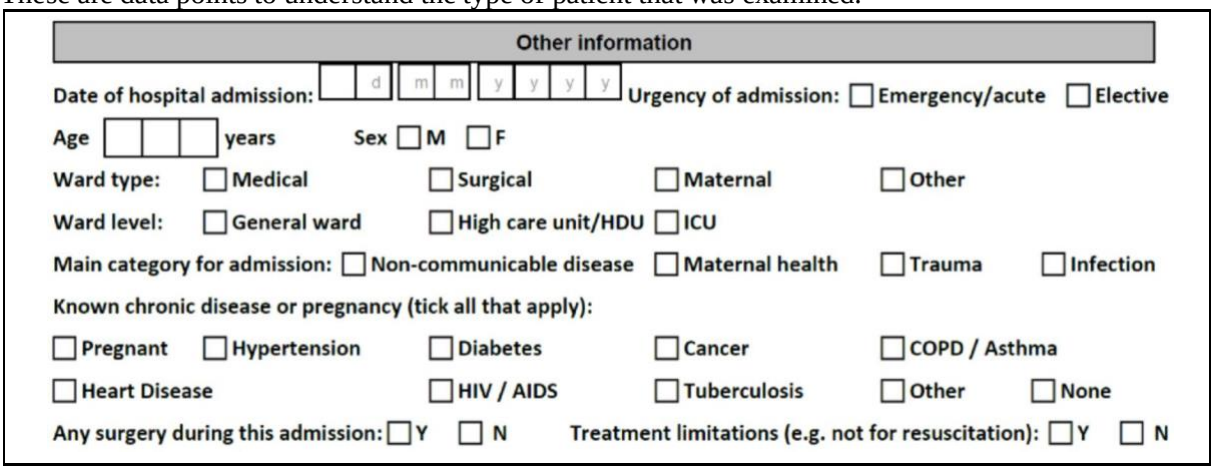
We want to know each patient's worst pain in the last 24 hours.



If a patient is struggling to understand the numbers on the scale, show them the vertical scale, ignore the numbers, and instruct them to *"indicate on the scale where was your worst pain in the last 24 hours if the top of the scale represents the worst pain you can imagine and the bottom of the scale represents no pain."*

2.4. SOP for the other information

These are data points to understand the type of patient that was examined.



Other information

Date of hospital admission: [ ][ ] d [ ][ ] m [ ][ ][ ][ ] y Urgency of admission: ☐ Emergency/acute ☐ Elective

Age [ ][ ][ ] years Sex ☐ M ☐ F

Ward type: ☐ Medical ☐ Surgical ☐ Maternal ☐ Other

Ward level: ☐ General ward ☐ High care unit/HDU ☐ ICU

Main category for admission: ☐ Non-communicable disease ☐ Maternal health ☐ Trauma ☐ Infection

Known chronic disease or pregnancy (tick all that apply):

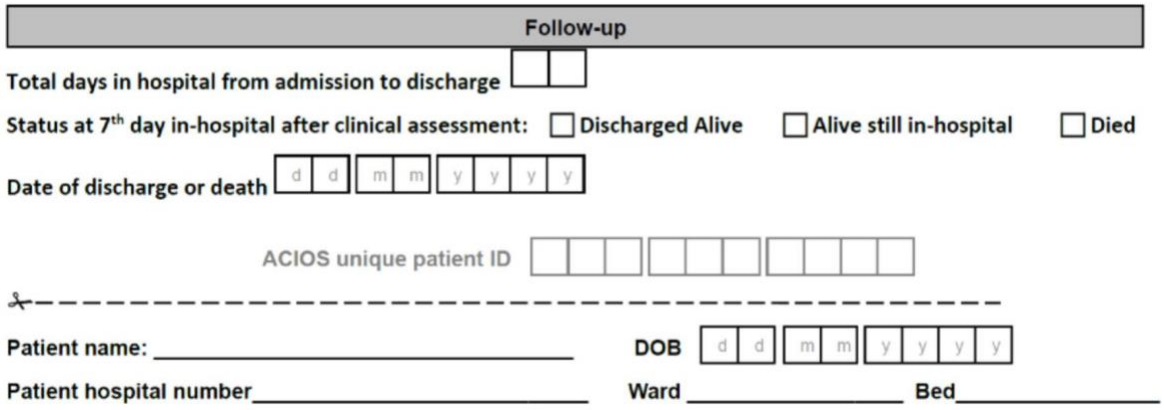
☐ Pregnant ☐ Hypertension ☐ Diabetes ☐ Cancer ☐ COPD / Asthma

☐ Heart Disease ☐ HIV / AIDS ☐ Tuberculosis ☐ Other ☐ None

Any surgery during this admission: ☐ Y ☐ N Treatment limitations (e.g. not for resuscitation): ☐ Y ☐ N

2.5. SOP for the follow-up

Each patient will be followed up daily until discharge or demise for a maximum of 7 days after initial assessment.



Section 3: Handling and managing data

Each patient is given an ACIOS unique patient ID code, which will be automatically generated from RedCap database when data are submitted. This will ensure that the patient data is anonymised in the data registry. Please ensure that the ACIOS unique patient ID code is written on the CRF.

After the 7-day follow-up, please do not remove the identifiable information (patient's name, hospital number, ward, and bed number) and ACIOS unique patient ID code from the CRF. This will allow the central data administrators to address any data queries back to the hospital leaders using the ACIOS unique patient ID code, which will then allow the hospital leaders to verify any data that is queried. Please ensure that the patient CRFs are stored in a locked office at the hospital site.

We believe that data uploading to the ACIOS database will take about 3 minutes per patient to complete. This should allow you to organise and plan the time needed for data uploading for your hospital.

Appendix 1: Study synopsis

The African Critical Illness Outcomes Study (ACIOS)

BACKGROUND

The number of patients with critical illness has not been accurately quantified, although data suggests that it exceeds 10% for hospital inpatients, and the in-hospital mortality of critically ill patients is between 18-82%. In Africa, the prevalence of critical illness is likely to be higher due to a greater burden of disease, and the associated mortality higher due to limited resources.

This is a prospective, observational study to rapidly establish the prevalence of critical illness in in-hospital adult patients in Africa, and the resources available to provide essential critical care (care that should be available to every patient in the world) and factors associated with mortality.

Rapid dissemination of these findings may help mitigate mortality from critical illness in Africa. These points provide the rationale for the African Critical Illness Outcomes Study (ACIOS).

STUDY OBJECTIVES

The objectives of this study are to determine:

1. The proportion of hospital patients who are critically ill,
2. The mortality associated with critical illness,
3. The proportion of critically ill patients who receive essential emergency and critical care,
4. The relationship between essential emergency and critical care provision, and mortality, and
5. The availability of resources necessary to provide essential emergency and critical care.

STUDY DESIGN

An African multi-centre prospective observational cohort study of adult (≥18 years) in-hospital patients. Patient follow up will be for a maximum of 7 days in-hospital.

The primary outcome is in-hospital mortality in adult hospital patients with and without critical illness in Africa.

The intention is to provide a representative sample of the mortality, the risk factors associated with mortality in adult patients with critical illness, and the resources available and interventions provided to treat critical illness in Africa. This study will run between September and November 2023.

PREPARATORY WORK

This study will be run by the African Perioperative Research Group (APORG), with a network of over 600 hospitals in more than 40 African countries which has successfully conducted the African Surgical Outcomes Study (ASOS), the ASOS-2 Trial, the African COVID-19 Critical Care Outcomes Study (ACCCOS) and the African Paediatric Surgical Outcomes Study (ASOS-Paeds).

IMPORTANCE OF THIS STUDY

To decrease the mortality associated with critical illness in Africa, it is important to rapidly establish the potential risk factors for mortality, and resources available to manage these patients. The APORG network has the capacity to provide these data timeously.

Appendix 2: Broadcasting document

IMPORTANT PATIENT INFORMATION

A research study is being conducted at ..... Hospital.

The research study is being done by Dr ……. from the Department of ……..

Why is this research study being done?

To understand how sick patients are in hospital.

Why are we telling you about this research study?

All patients in this hospital are part of the research study. It is a requirement that some details pertaining to your clinical care are entered into a research study folder. Information from this folder will be used anonymously to understand how sick patients are in hospital, and what we might be able to do to improve the care for sick patients.

Will this research study affect my care while I am in hospital?

No. You will still receive the same care while you are in hospital.

Will my name or any personal details be kept by this research study?

No. Your name and personal details will not be kept as part of this research study. All information from the notes will be kept strictly confidential.

Are there any risks or benefits associated with this project?

No. There are no risks or direct benefits associated with this research study.

Who should I contact if I have any questions or concerns?

Please contact Dr ……..…. on telephone……..….

If you have questions about your rights or welfare as a participant, please contact the UCT Faculty of Health Sciences Human Research Ethics Committee on +27 (0)21 406 6338.

Appendix 3: Definitions provided on the case record form (CRF)

Definition:

Position of patient: The position the patient is in the bed/chair when the investigating team arrive at the bedside. The number of degrees refers to the angle of the head and body compared to the legs.

Airway patency: Normal is an unobstructed airway. Partial obstruction may be indicated by stridor, secretions in the airway identified by gurgling, or snoring. Complete obstruction is evident by a see-saw chest movement (chest down and abdomen up with attempted breathing against a closed glottis). Complete obstruction is an airway emergency and requires calling the attending clinical team immediately.

Conscious level AVPU: Measurement of conscious level. Is the patient Alert = A. If they are not alert but they respond to your voice = V. If they don't respond to voice but respond to a painful stimulus = P. If they remain unresponsive even with a painful stimulus = U (unresponsive).

Currently receiving IV fluids: At the time of clinical assessment, the patient is receiving IV fluids if IV fluids are hanging at the bedside, and currently dripping into an intravenous cannula, or the patient has been receiving fluids as described within the previous few minutes but is now finished and a new fluid is being prepared to be administered.

Receiving oxygen (now): At the time of clinical assessment, the patient is receiving oxygen if supplementary oxygen is currently flowing into a nasal cannula, face mask or other delivery device that is correctly fitted so that oxygen is entering the patient's lungs.

Receiving vasopressor/inotrope (now): Ongoing care with a vasopressor or inotrope infusion – for example noradrenaline, adrenaline, dopamine or dobutamine.

Airway action (now): An action to open the airway or maintain a free airway. For example: chin lift, jaw thrust, oro-pharyngeal airway, naso-pharyngeal airway, intubated patient.

High care unit/HDU: A unit or ward or part of a ward which is dedicated to providing an increased level of care when compared to a general ward. High care units often have increased nurse:patient ratios, more equipment and more advanced care such as oxygen, CPAP, vasopressors etc. This does *not* include units with mechanical ventilation, as that is an ICU. Includes recovery rooms providing an increased level of care.

ICU: A unit or ward which is dedicated to providing an increased level of care when compared to a general ward or high care unit including mechanical ventilation.

Main category for admission: The main diagnosis or reason that the patient is being treated in hospital.

Treatment limitations: A patient has a treatment limitation if the clinical team have made the clinical judgement that some treatments would not be in the patient's best interest. For example "DNR" (do not resuscitate in the event of a cardiac arrest), or "Not for ICU" in the event of deterioration.

Days in hospital: Total number of days in hospital from admission.

Status at hospital discharge or 7th day in-hospital after clinical assessment: The survival status of the patient at hospital discharge, or at the 7th day after clinical assessment (if the patient had not yet been discharged). The study is censored at the 7th day after clinical assessment.

Guidance for use of paper case record form (CRF)

1. Investigators should write the patient's name and date of birth on the bottom of the CRF. When you enter the data on the internet based CRF you will receive an ACIOS patient ID. Please write this on the paper CRF as well in case we need to contact you to check your data.
2. The clinical assessment and the patient's vital signs MUST be completed at the same time by the investigating team. Only in exceptional circumstances can the vital signs data be taken from the medical records.
3. Please take care to enter the date clearly and correctly. Mistakes are common data describing time and date.