ASOS-2
African Surgical OutcomeS-2 Trial

Age ☐☐☐ years   Sex ☐ M ☐ F

ASA ☐ I ☐ II ☐ III ☐ IV ☐ V

Chronic co-morbid disease (tick all that apply): ☐ Hypertension ☐ HIV / AIDS ☐ Diabetes mellitus ☐ COPD / Asthma

Surgical procedure category (select *single* most appropriate):

☐ Gynaecology ☐ Obstetrics ☐ Orthopaedic ☐ Ear, nose and throat ☐ Plastics or breast

☐ Urology ☐ Neurosurgery ☐ Gastro-intestinal or Hepato-biliary ☐ Cardiothoracic/ vascular ☐ Other

Indication for surgery:

☐ Non-communicable disease ☐ Caesarean section ☐ Trauma ☐ Infection

Urgency of surgery: ☐ Elective ☐ Urgent ☐ Emergency

Severity of surgery: ☐ Minor ☐ Intermediate ☐ Major

Start of surgery time (24h) & date: h h : m m   d d m m 2 0 1 9

Postoperative Follow Up

Indicate postoperative care given:

Higher care ward ☐ No ☐ Yes

Increased nursing observations ☐ No ☐ Yes

Assigned a bed in view of nurses' station ☐ No ☐ Yes

Family with patient in ward ☐ No ☐ Yes

Severe complications (tick *all* that apply): Superficial or deep surgical site, or body cavity infection ☐ N ☐ Y Postop day ☐☐

Bloodstream infection or ARDS ☐ N ☐ Y Postop day ☐☐   Pneumonia ☐ N ☐ Y Postop day ☐☐

Urinary tract or AKI ☐ N ☐ Y Postop day ☐☐   Postoperative bleed ☐ N ☐ Y Postop day ☐☐

Cardiac arrest ☐ N ☐ Y Postop day ☐☐   Other severe complication ☐ N ☐ Y Postop day ☐☐

Days in hospital after surgery ☐☐

Status at hospital discharge or 30th postoperative in-hospital day: ☐ Alive & still in hospital ☐ Dead

☐ Alive & discharged → if alive and discharged, was patient transferred to another facility for higher care? ☐ Yes ☐ No

If deceased, photo of clinical note of death uploaded: ☐ Yes   CRF completed and verified by……………. on dd/mm/2019

ASOS-2 unique patient ID ☐☐☐ ☐☐☐ ☐☐☐   ASOS-2 Trial CRF v4 (Control arm)

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

Patient hospital number : ______________   ASOS-2 unique patient ID ☐☐☐ ☐☐☐ ☐☐☐

Definition of 'Indication for surgery': This is the underlying initiating disease/ event which ultimately resulted in the need for surgery. **High care ward:** A postoperative ward which is dedicated to providing increased postoperative care, when compared to the normal postoperative surgical ward. A high care ward can include an intensive care ward. **Increased frequency of nursing observations:** Nursing observations which are conducted more frequently, than the normal frequency of observations on the postoperative ward. **Assigned a bed in view of the nurses' station:** The patient is positioned in a bed close to the nursing station to ensure that the nurses can always see the patient from the nursing station. **Family members to stay with the patient in the ward:** If the family members are asked to stay with the patient on the ward, because of a concern that the patient is at increased risk of death of morbidity in the postoperative period.

Definition of a 'Severe Complication': Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment. **Surgical site infection (superficial):** Infection involving only superficial surgical incision which meets the following criteria: i) Infection occurs within 30 days after surgery and ii) Involves only skin and subcutaneous tissues of the incision and iii) The patient has at least one of the following: a) purulent drainage from the superficial incision, or b) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision and at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, or superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion, or c) diagnosis of a incisional surgical site infection by a surgeon or attending physician **Surgical site infection (deep):** An infection which involves both superficial and deep parts of surgical incision and meets the following criteria: i) Infection occurs within 30 days after surgery if no surgical implant is left in place or one year if an implant is in place and ii) The infection appears to be related to the surgical procedure and involves deep soft tissues of the incision (e.g. fascial and muscle layers) and iii) The patient has at least one of the following: a) purulent drainage from the deep incision but not from the organ/space component of the surgical site, or b) a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or no cultures were taken whilst the patient has at least one of the following signs or symptoms of infection: fever (>38°C) or localized pain or tenderness. A culture-negative finding does not meet this criterion, or c) an abscess or other evidence of infection involving the deep incision is found on direct examination, during surgery, or by histopathologic or radiologic examination, or d) diagnosis of a deep incisional surgical site infection by a surgeon or attending physician. **Surgical site infection (organ/space):** An infection which involves any part of the body excluding the fascia or muscle layers and meets the following criteria: i) Infection occurs within 30 days after surgery and ii) The infection appears to be related to the surgical procedure and involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and iii) The patient has at least one of the following: a) purulent drainage from a drain that is placed through a stab wound into the organ/space, b) organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/ space , or c) an abscess or other, or d) evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination, or e) diagnosis of an organ/space surgical site infection by a surgeon or attending physician. **Bloodstream infection:** An infection which is not related to infection at another site and which meets at least one of the following criteria: i) Patient has a recognised pathogen cultured from blood cultures which is not related to an infection at another site, ii) Patient has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension and at least one of the following: a) common skin contaminant cultured from two or more blood cultures drawn on separate occasions, or b) common skin contaminant cultured from at least one blood culture from a patient with an intravascular line, and a physician starts antimicrobial therapy, or c) positive blood antigen test**. Acute Respiratory Distress Syndrome (ARDS):** Respiratory failure, or new or worsening respiratory symptoms, commencing within one week of surgery; and a chest radiograph or computed tomography scan which demonstrates bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules; and respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic oedema if no risk factor is present. ***Severity grading:*** Severe: PaO2:FiO2 ≤100 mmHg with PEEP ≥5 cmH2O**. *Guidance:*** If altitude is higher than 1000 m, a correction factor should be calculated as follows: (PaO2:FiO2 x [barometric pressure/760 mmHg]). PEEP, positive end-expiratory pressure; CPAP, non-invasive continuous positive airways pressure. **Pneumonia:** Chest radiographs with new or progressive and persistent infiltrates, or consolidation, or cavitation, and at least one of the following: i) fever (>38°C) with no other recognized cause, or ii) leucopaenia (<4,000 white blood cells/mm3) or leucocytosis (>12,000 white blood cells/mm3), or iii) for adults >70 years old, altered mental status with no other recognised cause; and at least two of the following: a) new onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements, or b) new onset or worsening cough, or dyspnoea, or tachypnoea, or c) rales or bronchial breath sounds, d) worsening gas exchange (hypoxaemia, increased oxygen requirement or increased ventilator demand**). *Guidance:*** Two radiographs are required for patients with underlying pulmonary or cardiac disease. The definition may be used to identify ventilator associated pneumonia. **Urinary tract infection:** An infection associated with at least one of the following signs or symptoms which should be identified within a 24 hour period; fever (>38 °C), urgency, frequency, dysuria, suprapubic tenderness, costovertebral angle pain or tenderness with no other recognised cause, and a positive urine culture of ≥105 colony forming units/mL with no more than two species of microorganisms. **Acute Kidney Injury (AKI):** Serum creatinine Increase of 3.0 times baseline within 7 days or increase in serum creatinine to ≥4.0 mg/dL (≥354 µmol/L) with an acute rise of >0.5 mg/dL (>44 µmol/L) or initiation of renal replacement therapy, or urine output ≤0.3 ml/kg/h for 24 hours or anuria for 12 hours ***Guidance:*** Baseline serum creatinine must be measured before surgery but an estimated value can be used if the patient does not have chronic kidney disease. **Postoperative haemorrhage:** Blood loss occurring within 72 hours after the end of surgery which would normally result in transfusion of blood. **Cardiac arrest:** The cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest. **Other severe complications:** If any of the following complications result in a significant prolongation of hospital stay and/or permanent functional limitation or death, then mark 'Other severe complication' as 'Yes'. Note that they will almost always requires clinical treatment. **Critical care admission to treat postoperative complications:** Postoperative complications requiring admission to critical care to treat the postoperative complications or provide critical care support necessitated by the severity of the postoperative complications.

Days in hospital after surgery: Total number of days in hospital after surgery. **Status at hospital discharge or 30th postoperative in-hospital day:** The survival status of the patient at hospital discharge, or at the 30 in-hospital day (if the patient had not yet been discharged following surgery). The study is censored at the 30th in hospital postoperative day. If the patient was discharged alive, indicate whether they were discharged to another facility for higher level of care "yes" or to home/convalescence "no".

ASOS-2 unique patient ID | | | | | | | | | | |

ASOS-2 Trial CRF v4 (Control arm)

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Patient name: ____________________________________ **DOB** d d / m m / y y y y

Patient hospital number : __________________ **ASOS-2 unique patient ID** | | | | | | | | | | |

Guidance for use of paper case record form (CRF)

Remove this page before use in data collection

1. This CRF is provided in a format which can be edited.
2. Baseline data will often be readily available to anaesthetists during surgery whilst follow-up data on complications may be most easily collected by surgeons.
3. Investigators should write the patient name and date of birth on the CRF. When you enter the data on the internet based CRF you will receive an ASOS-2 patient ID. Please write this on the paper CRF as well in case we need to contact you to check your data.
4. Please take care to enter the date clearly and correctly. Mistakes are common data describing time and date.

Patient name: ______________________________ DOB d d m m y y y y

Patient hospital number : ________________ ASOS-2 unique patient ID ☐☐☐ ☐☐☐ ☐☐☐☐