# Complications and uSAES

This manual describes how to report complications and unexpected serious adverse events/uSAEs in STEPCARE .

## Contents



## 1 Terminology

This terminology is used because standard terminology in drug trials (according to Good Clinical Practice) is not applicable in a trial which includes severely ill patients after cardiac arrest.

The stepcare trial will report on specific adverse events relevant to the interventions, these will be collected in the complications section of the eCRF.

## 2 Time frame

Complications and uSAEs should be collected if they occur in the ICU, during the first **seven** days after randomisation. Events that occur after discharge to a step-down unit or another ICU (not part of the trial) should not be collected in the eCRF. Events that occur after ICU-readmission should not be reported.

# 3 Complications

The list of events below should be completed in the "Complications"-section of the eCRF. If they have occurred during the first seven days of ICU care select "Yes", if they have not occurred, select "No". These events do **not** correspond to standard SAEs. As such, **no** data regarding the relation to the intervention or follow-up need to be recorded.

- **Sepsis** According to Sepsis III criteria, sepsis or septic shock
- **Pneumonia**
  Clinical diagnosis based on:
  1. Purulent tracheal secretions
  2. Radiographic infiltrate
  3. A decreased P/F ratio (<32 kPa // < 240 mmHg)
  4. Elevated white blood cell count or temperature above 38°C
- **Arrhythmic Complications**
  1. Recurrent cardiac arrest Defibrillation or chest compressions
  2. Other Arrhythmia Requiring cardioversion, an anti-arrhythmic drug, or temporary pacing
- **Venous Thromboembolism**
  1. Pulmonary Embolism
  2. Deep Vein Thrombosis
  3. Cooling-catheter related thrombus
- **Ischemic complications**
  1. Mesenteric ischemia
  2. Limb ischemia
  3. Digitial Necrosis
- **Sedation complications**
  1. Unplanned extubation
  2. Unplanned intubation during hospital stay
  3. Antipsychotics used
- **Bleeding**
  Bleeding is classified as follows:
  1. **Severe or Life threatening:** Intracerebral haemorrhage or, bleeding resulting in substantial hemodynamic compromise requiring treatment.
  2. **Moderate:** Bleeding, requiring blood transfusion but not resulting in hemodynamic compromise.
  3. **Mild:** Bleeding that does not meet above criteria.

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# 4 uSAES

uSAES in the STEPCARE-trial are events that are **unexpected**. That is, they are not part of the normal events which might occur to a severely ill patient being treated in an ICU after cardiac arrest. As death is an expected event this should not be reported as a uSAE per default.

Any adverse events related to the complications in section three do **not** need to be reported.

Only unexpected events with that are possibly related to the intervention should be reported

In addition the event should fulfil one one of the following criteria:

- Results in death
- Is life threatening
- Results in persistent or significant disability or incapacity

## 4.1 What not to report

- **Rearrest** - A second arrhythmia is an expected event after myocardial infarction and/or global myocardial ischemia. It is also captured in the complications section. However if the patient rearrests due to an unexpeted reason (for example: Anaphylaxis and PEA-arrest) this should be reported)
- **Reintubation**- Expected event in an ICU
- **Sepsis or pneumonia** - expected events that are also captured in the complications section
- **Worsening neurological function** - expected in survivors after cardiac arrest
- **Bradycardia, atrial fibrillation etc** - expected after cardiac arrest
- **Electrolyte abnormalities** - expected in any ICU patient
- **Evolving myocardial infarction** - Any complication related to the cause of the arrest should be considered as an expected event.

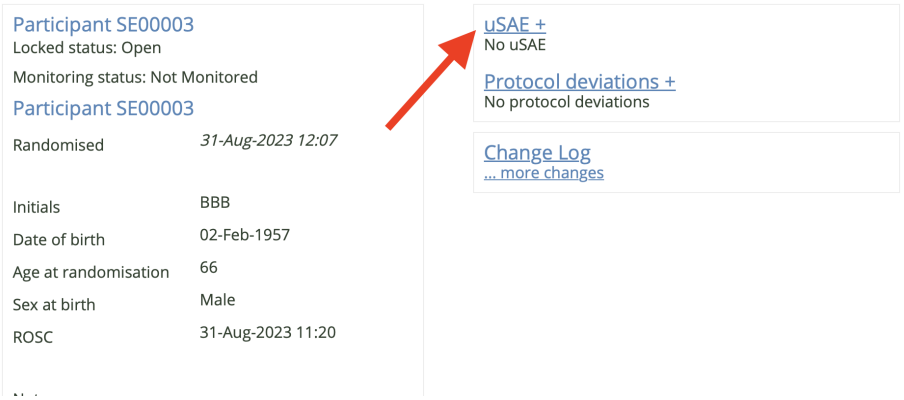
## 4.2 Examples

1. A patient develops worsening haemodyamics, raised lactate and an increased need for vasopressors during the intervention.
   Expected after cardiac arrest - **not** a uSAE
2. Continuous bleeding from insertions sites during the intervention requiring transfusion.
   Expected after CA and coronary angiography - **not** a uSAE, but should be reported in the complications section
3. Coagulopathy develops with increased INR.
   Expected as part of multiorgan failure after ROSC - **not** a uSAE
4. Allerigic reaction to a third vasopressor added to achieve a MAP of 85
   Report as a uSAE

## 4.3 How to report a uSAE

If you are unsure about if an event constitutes a uSAE, contact the sponsor for a discussion.

Click here:




Enter the date and description of the event at select if there is any possible relation to the intervention.