

SUNRRISE **Single Use Negative pResure dressing for Reduction In Surgical site infection following Emergency laparotomy**

Site-specific Training Presentation

PART 4

- Safety reporting

UNIVERSITY OF
BIRMINGHAM



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Welcome to study-specific training PART 4 for the SUNRRISE trial which covers safety reporting. Please do pause this video where necessary to allow yourself more time to review the content. A PDF version of this presentation can be downloaded from the training page of the SUNRRISE website.

Adverse Events (AE)

Any untoward medical occurrence in a participant or clinical trial subject participating in the trial which does not necessarily have a causal relationship with the intervention received.

- ❑ All AEs should be documented in the patient's medical notes and assessed for seriousness and causality (relatedness)
- ❑ The safety profile of the SUNPD is well characterised so unlikely the SUNRRISE will reveal any new safety information
- ❑ Only data on selected events within 30-days post-surgery period will be collected in SUNRRISE/reported to the trial office
- ❑ AEs collected/reported on the Wound Assessment Day 7 CRF:
 - > Skin reaction to the applied dressing
 - > Pain/discomfort related to the applied dressing

- An adverse event is any untoward medical occurrence experienced by trial participant, which does not necessarily have to be related to or caused the intervention or trial participation.
- All adverse events should be documented in the participant's medical notes and assessed for seriousness (i.e. is it a serious adverse event) and causality (i.e. is it related)
- The safety profile of PICO 7, which is the SUNPD used in SUNRRISE is well characterized, so it is unlikely that the trial will reveal any new information.
- Therefore, only selected events within the 30-day post-op period will be collected in SUNRRISE and reported to the trial office.
- In terms of adverse events, we are collecting skin reactions and pain and discomfort relating to the applied dressing, which are captured using the Wound Assessment Day 7 CRF.

Serious Adverse Events (SAE)

An untoward occurrence that:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Or is otherwise considered medically significant by the Investigator

- As SUNPD are available and often used within the NHS - there are no SAEs anticipated as a unique consequence of participation in the trial

Expedited reporting of SAEs to BCTU

- All events that meet the above definition, and not otherwise excluded
- However, we expect the following events to always be reported as SAEs:
 - Entero-cutaneous fistula
 - Fascial dehiscence
 - Death

! Dehiscence is often used to describe the breakdown of the wound where the skin has opened but the fascia is intact - not an SAE as not fascial dehiscence

- Serious adverse events are adverse events that result in death, are life threatening, require hospitalisation or prolong an existing one, result in significant or persistent disability or incapacity, or are otherwise considered medically significant by the local investigators.
- SUNPDs, such as PICO 7, are widely used in the NHS and there are no anticipated SAEs as a unique consequence of trial participation.
- Expedited reporting of SAEs to BCTU means the completion and return of an SAE form. All events that meet the above definition of an SAE should be reported to the SUNRRRISE trial office unless they are otherwise excluded, and we will cover what events *are* excluded and the types of exclusion later.
- We require some events, as shown, are to always be reported as SAE in the expedited manner, irrespective of whether it is classed as an AE or SAE.
- Please note that dehiscence is often used to describe the breakdown of the wound where the skin opens but the fascia remains intact. This superficial dehiscence does not need to be reported as an SAE and will be collected on the Wound Assessment CRFs. Only full thickness or deep dehiscence needs to be reported as an SAE.

Reporting exclusions

- SAEs that are expected and unrelated **do not require expedited reporting** using the SAE Form, instead data within 30-days post-surgery period will be collected using the Wound Assessment Day 7 and Day 30 CRF:
 - Anastomotic leak
 - Paralytic ileus
 - Intra-peritoneal collections (with or without intervention)
 - Thrombo-embolic events
 - Infections not related to the wound (e.g. pneumonia, urinary tract infections)
 - Cardiac or central nervous system complications
- SAEs that are **that are protocol excluded from reporting**:
 - SAEs that are related to symptoms or progression of the participant's disease
 - SAEs that are related to a pre-existing condition
 - Pre-planned hospitalisation
- All SAEs should be documented in the patient's medical note and should be assessed for causality (relatedness)

- The SAE reporting exclusions in SUNRRISE fall into 2 groups.
- The first are SAEs that we are expected and unrelated, and as a consequence, they do not require expedited reporting using the SAE form, instead the data is collected on the wound assessments CRFs. The protocol defined list of events is as shown and they are expected potential complications of an emergency laparotomy.
- The second are SAEs that are excluded in the protocol from any reporting to the trial office. The protocol defined list of events is as shown.
- As mentioned, all adverse events, including serious ones, should be documented in the patient's medical notes and assessed causality, regardless of whether or not they are reported or require reporting to the Trial Office.

SAE reporting

- ❑ Reporting period:
 - All events occurring from randomisation to 30 days post-surgery
 - After 30 days post-surgery if event judged to be at least possibly related to the use of SUNPD
- ❑ Reporting process:
 - SAE that require expedited reporting...
 - Complete SAE form immediately after becoming aware of the event, certainly no later than **24 hours** after, and fax or email to the Trial Office at BCTU: SUNRRISE@trials.bham.ac.uk or **0121 415 8871**
 - Faxed SAE forms must be accompanied by SAE Fax Cover (supplied)
 - Countersigned by the PI (or delegate)
 - Follow-up information must be submitted until clinical recovery
 - SAE that do not require expedited reporting...
 - Recorded on Wound Assessment CRFs and submitted accordingly
- ❑ **Report SAEs to your Trust as required by local SOPs**

- When reporting SAEs the protocol defined reporting period should be considered. Any and all events that occur between randomisation and day 30 are to be reported, irrespective of whether or not they are related. After day 30, only events that are thought to potentially be related to the SUNPD or trial need to be reported.
- The process for reporting expedited SAEs is to complete the SAE form when you become aware of an event and send it to the trial office; either faxing or emailing it to the contact details shown. When faxing, cover sheets to accompany the form can be found in the investigator site file. SAE forms should be countersigned by the PI or delegate. However, please note that if countersignature cannot be readily obtained, the un-countersigned form should be sent straightway and then the countersigned form sent as soon as possible afterwards. Events will be followed up until the patient recovers, with interim updates submitted when appropriate.
- As mentioned, SAEs that do not require expedited reporting are collected on and reported using the wound assessment CRFs.
- Please note that you will need to report any SAEs that occur to your trust using your local processes and procedures.

Damaged/faulty SUNPD and resulting events for manufacturers

- ❑ The manufactures of the device (SUNPD) require reporting of:
 - Misuse of device causing a serious injury
 - Any allegation of deficiencies related to the device e.g.
 - Device received damaged, mislabelled, cosmetic or functional issues
 - If the device does not perform as expected due to failure, both post-op and during surgery
- ❑ If an adverse event occurs as a consequence of the misused or faulty/damaged device, this also need to be reported.
- ❑ Events that do not need reporting are:
 - Events unrelated to the device
 - Pain not associated with the surgery or the device
 - Events collected for any reason that are unrelated to the device; illness, expected swelling, expected pain, pre-existing conditions, unrelated hospitalisations

**Contact the SUNRRISE
Trial Office as soon as
you become aware –
we will assist you with
the reporting process**

- The PICO 7 manufacturers, Smith and Nephew, also have event reporting requirements.
- The events relate to the misuse of the devices causing serious injury or deficiencies with the device as shown.
- If an adverse event occurs as a consequence of these, this also needs to be reported.
- If you become aware of such events, please contact the trial office and we will assist you with the reporting process.
- Events that do not need reporting are as shown.

Thank you

Please remember to document your training:

- ❑ Online - using electronic SUNRRISE Training Record;
<https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD>
- ❑ Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File



Please contact us if you have any questions...

sunrise@trials.bham.ac.uk



- Thank you for watching the SUNRRISE study-specific PART 4 training video on safety reporting.
- Please ensure you document the completion of this training. This can readily be done using our online training record tool which can be accessed using the link shown, which is also found on the training page of the SUNRRISE website, or by using the QR code shown. Alternatively, the paper training log found in your local investigator site file can be completed and a copy sent to the SUNRRISE Trial Office.
- If you have any queries, please get in touch.