SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 3

- Trial activities, paperwork and CRFs
- Assessment schedule

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | WM Research Collaborative | NWRC North West Research Collaborative

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Health-related Quality of Life (summary)

SUNRRISE

What	When	How	To note…
EQ-5D & SF-12	**Post-consent & Pre-op**	**QoL Booklet**	• If not complete pre-op, do not complete post-op
EQ-5D & SF-12	**Day 7** (-2/+3)	**QoL Booklet**◊ or **Patient Diary**	
Daily questions	**Post-discharge to Day 30***	**Patient Diary**	* Day 30 assessment - may be completed at 30-44 days
EQ-5D	**Day 14 & 21** (+/-2)	**QoL Booklet**◊ or **Patient Diary**	• Call patient weekly (if discharged) to check if any problems
EQ-5D & SF-12	**Day 30** (+14)	**QoL Booklet**◊ or **Patient Diary**	
WHQ	**Day 30***	**Patient Diary**	• Completed by patient on day of Day 30 assessment independently
Daily questions	**Post-Day 30*** if ongoing SSI	**Patient Diary (Continuing Involvement)**	• Extra diary only for participant with ongoing SSI at Day 30 assessment.

◊ Based on feedback from feasibility phase, we suggest using the booklets whilst the patient is in hospital

Health-related Quality of Life

SUNRRISE

- Assessed by EQ-5D-5L & SF-12 questionnaires and daily questions in the Patient Diary

  Booklet and diary supplies… Contact the Trial Office surrise@trials.bham.ac.uk
- Assessed at:
  - **Baseline: QoL Booklet (EQ-5D-5L and SF-12)**
    - After consent and **Prior** to surgery (where patient is able to complete)
    - Patients are to provide responses to the questions relating to their health **before** the episode that lead to an emergency laparotomy being required
  - **Day 7: EQ-5D-5L and SF-12**
    - Included in Patient Diary but QoL booklet can be used if still an in-patient
  - **Day 14 & 21: EQ-5D-5L**
    - Included in Patient Diary but QoL booklet can be used if still an in-patient
    - Research team to call patient weekly (if discharged) to check if any problems
  - **Day 30: EQ-5D-5L and SF-12**
    - Included in Patient Diary but QoL booklet can be used if necessary

Based on feedback from feasibility phase, we suggest using the booklets whilst the patient is in hospital

Health-related Quality of Life

SUNRRISE

Patient Diary

- Diary contains:
  - Daily questions relating to wound and health resource usage
  - EQ-5D-5L and SF-12 included at required time points
  - Wound Health Questionnaire
- To be given to patient on discharge for daily completing until the day 30 assessment
  - Add Trial Number and dates to the diary, and cross-out "days" that are not needed
  - Also give a pre-addressed, freepost envelope
- Wound Health Questionnaire
  - This is found at the end of the Patient Diary
  - To be complete by patient **before** Day 30 wound assessment
    - Check it has been completed, and if not, ask the patient to do so before conducting review
    - Does not need to be completed if the patient is an inpatient

Health-related Quality of Life

SUNRRISE

Patient Diary

- At the day 30 assessment…
  - if undertaken in-person, collect completed diary from the patient
  - if undertaken remotely, ask the patient to post it using pre-addressed, freepost envelope

If the patient has not completed the diary, for whatever reason, whilst unfortunate it does not negate the requirement for the day 30 assessment

- If SSI still present (ongoing SSI) at Day 30, patient to be asked to complete further diary; **Patient Diary (Continuing Involvement)**
  - Give/post diary to patient along with pre-addressed, freepost envelope (to return completed diary)
  - To be completed until healed/SSI resolved i.e. discharged from district nursing care
  - Regularly contact patient to check if any problems AND to find out if additional Continuing Involvement diary needed

Follow Up

SUNRRISE

Time point	Activity	CRF
Immediately post-op		In-theatre Form

- **The allocation should not be recorded in the operative note/patient records**
  - State that the patient is participating in the SUNRRISE Trial and the dressing used was either SUNPD or surgeon's preference – labels/stickers are provided

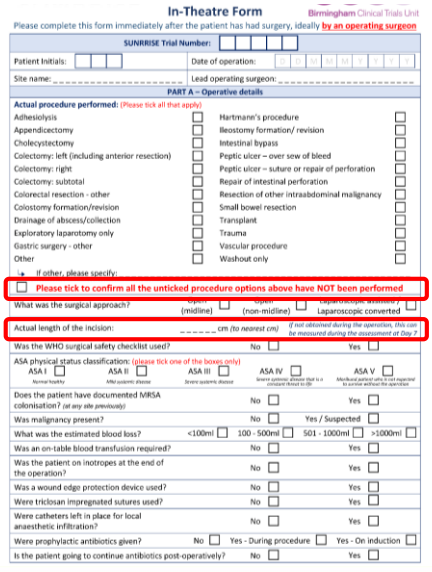
- It may not be possible to prevent any mention in the patient's medical e.g. by ward staff during the patient's admission.
  - The first wound review at day 7 (or discharge if sooner) is not blinded and so is not impacted
  - The second wound review at day 30 is blinded so measures must be take to ensure the assessor is blind to the allocation – the CRF for that assessment asked the assessor to confirm they are blind.

Remember to send out the GP letter

Follow Up

SUNRRISE

Tips on completing the In-theatre Form…


In-Theatre Form

Birmingham Clinical Trials Unit

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

SUNRRISE Trial Number:

Patient Initials: Date of operation: D D M M Y Y Y Y

Site name: Lead operating surgeon:

PART A – Operative details

Actual procedure performed: (Please tick all that apply)

Adhesiolysis	☐	Hartmann's procedure	☐
Appendicectomy	☐	Ileostomy formation/ revision	☐
Cholecystectomy	☐	Intestinal bypass	☐
Colectomy: left (including anterior resection)	☐	Peptic ulcer – over sew of bleed	☐
Colectomy: right	☐	Peptic ulcer – suture or repair of perforation	☐
Colectomy: subtotal	☐	Repair of intestinal perforation	☐
Colorectal resection - other	☐	Resection of other intraabdominal malignancy	☐
Colostomy formation/revision	☐	Small bowel resection	☐
Drainage of abscess/collection	☐	Transplant	☐
Exploratory laparotomy only	☐	Trauma	☐
Gastric surgery - other	☐	Vascular procedure	☐
Other	☐	Washout only	☐

↳ If other, please specify:

☐ Please tick to confirm all the unticked procedure options above have NOT been performed

What was the surgical approach? Open: ☐ (midline) Open: ☐ (non-midline) Open/Converted: ☐ Laparoscopic converted ☐

Actual length of the incision: _____ cm (to nearest cm) If not obtained during the operation, this can be measured during the assessment at Day 7

Was the WHO surgical safety checklist used? No ☐ Yes ☐

ASA physical status classification: (please tick one of the boxes only)

ASA I ☐ Normal healthy | ASA II ☐ Mild systemic disease | ASA III ☐ Severe systemic disease | ASA IV ☐ Severe systemic disease that is a constant threat to life | ASA V ☐ Moribund patient who is not expected to survive without the operation

Does the patient have documented MRSA colonisation? (at any site previously)	No ☐	Yes ☐
Was malignancy present?	No ☐	Yes / Suspected ☐
What was the estimated blood loss?	<100ml ☐ 100 - 500ml ☐ 501 - 1000ml ☐ >1000ml ☐	
Was an on-table blood transfusion required?	No ☐	Yes ☐
Was the patient on inotropes at the end of the operation?	No ☐	Yes ☐
Was a wound edge protection device used?	No ☐	Yes ☐
Were triclosan impregnated sutures used?	No ☐	Yes ☐
Were catheters left in place for local anaesthetic infiltration?	No ☐	Yes ☐
Were prophylactic antibiotics given?	No ☐ Yes - During procedure ☐	Yes - On induction ☐
Is the patient going to continue antibiotics post-operatively?	No ☐	Yes ☐

In-Theatre Form

Birmingham Clinical Trials Unit

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

Skin prep used:	Aqueous betadine ☐	0.5% Aqueous Chlorhexidine ☐	2% Aqueous Chlorhexidine ☐	
(please tick only one)	Alcoholic betadine ☐	0.5% Alcoholic Chlorhexidine ☐	2% Alcoholic Chlorhexidine ☐	
	Other ☐	If other, please specify:		
Was adhesive or 'incise' drape used?	No ☐	Yes – iodine-impregnated ☐	Yes – plain incise drape ☐	
Was a wound/incision wash performed?	No ☐	Yes – Betadine ☐	Yes – Saline / Water ☐	Yes – other ☐
Before closing, were gloves changed?			No ☐	Yes ☐
Before closing, were instruments changed?			No ☐	Yes ☐
How was the skin closed?	Staples ☐	Interrupted sutures ☐	Continuous sutures ☐	
Grade of operating surgeon:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Grade of surgeon closing fascia:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Grade of surgeon closing skin:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Total duration of operation:				

PART B – COVID-19

Does the patient have any COVID-19 symptoms on the day of surgery?			No ☐	Yes ☐
Does the patient have proven antibodies to SARS-CoV-2?	No ☐	Yes ☐	Not tested/ Not known ☐	
What is the patient's SARS-CoV-2 virus status on the day of surgery?		Screened positive ☐	Screened negative ☐	
		Screened but result unknown ☐	Not screened ☐	
Has the patient had a positive SARS-CoV-2 swab result or clinical diagnosis of COVID-19?			No or Unknown ☐	Yes ☐
↳ If Yes, how long before surgery was the diagnosis?	Day of Surgery ☐	1-7 days ☐	8-14 days ☐	
	15-28 days ☐	5-6 weeks ☐	7-8 weeks ☐	3-4 months ☐	5-6 months ☐	6+ months ☐

PART C – Dressing

What dressing was applied to the laparotomy wound? (please tick all that apply)

SUNPD ☐ Conventional occlusive dressing ☐ Skin glue ☐ No dressing ☐ Other ☐ If other, please specify:

↳ If SUNPD: Size of dressing used: 10cm x 20cm ☐ 10cm x 30cm ☐ 10cm x 40cm ☐ Other (specify below) ☐

LOT number: If other, please specify:

Was the dressing applied in accordance with the randomised allocation? Yes ☐ No ☐

↳ If no, please provide the reason for non-compliance:

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date: D D M M M M Y Y Y Y

PI declaration – I can confirm that the data reported on this form are accurate.

Full Name (PRINT NAME):

Signature: Date: D D M M M M Y Y Y Y

Trial Schema: Detailed – Follow-up

SUNRRISE

Summary of trial events, time points and activities associated with FU

SITE ACTIVITY	EVENT / TIME POINT	PATIENT ACTIVITY
SUNPD removed (if present) Complete Day 7 CRF and assess the wound Add TNo to Patient diary, cross out unnecessary pages and give to patient Arrange Day 30 follow-up	Day 5-10 post-op (or at discharged if sooner)	Comment on wound pain and dressing acceptability Complete QoL
Contact patient on Day 14 and 21 to ensure Patient Diary (including QoL) are being completed	Between discharge and follow-up	Complete Patient Diary: • Daily questions • EQ-5D on Day 14 and 21
BLINDED assessment of wound Complete Day 30 CRF Collect Patient Diary Ensure Day 30 QoL have been completed *If ongoing SSI*, add TNo to Patient diary (Continuing Involvement) and give to patient	Day 30-44 post-op	Before review, complete Bluebelle wound healing questionnaire (ideally at home) Complete QoL Comment on wound pain
Contact patient regularly to ensure Patient Diary being completed and to arrange return	If ongoing SSI After Day 30 assessment	Complete Patient Diary: • Daily questions
Complete Return to Theatre form	Any time between the operation and Day 30	Returns to theatre
Complete SAE form within 24 hours of becoming aware and send to BCTU straightaway		Experiences an SAE (e.g. prolonged hospital stay or re-admission)

Follow Up

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Time point	Activity	CRF
5-10 days post-op (or discharge if sooner)	Wound review by assessor	Wound Assessment Day 7 (or discharge if sooner)

- **Review for day 7 wound assessment…**
  - **Should not be earlier than 5 days post-op UNLESS completed on discharge**
  - **Should not be later than 10 days post-op**
  - **Undertaken as in-person review with visualisation of wound**
    - **If discharged unexpectedly, contact patient to complete review remotely and document this (e.g. file note sent will CRF or annotation on CRF**
  - **Assesses the period from index operation to date of assessment; discussion with patient, review of medical notes and as well as visual inspection of the wound**
- **Day 7 wound assessor should be trained** but does not have to be blind to the allocation
- **Removal of intervention (SUNPD)** on day 7 at the latest
  - *If the wound assessment on day 5, the SUNPD is removed on day 5 and the wound assessment is performed*
  - *If the wound assessment on day 9, the SUNPD is removed on day 7 and replaced with a standard dressing and on day 9 when the wound is reviewed*

Follow Up

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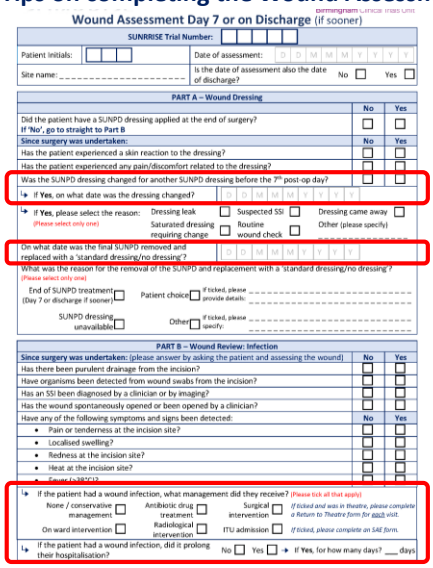
Tips on completing the Wound Assessment Day 7 or Discharge (if sooner) CRF…


Wound Assessment Day 7 or on Discharge (if sooner)

SUNRRISE Trial Number:

Patient Initials: Date of assessment: D D M M M Y Y Y Y

Site name: Is the date of assessment also the date of discharge? No Yes

PART A – Wound Dressing

	No	Yes
Did the patient have a SUNPD dressing applied at the end of surgery? If 'No', go to straight to Part B		
Since surgery was undertaken:	**No**	**Yes**
Has the patient experienced a skin reaction to the dressing?		
Has the patient experienced any pain/discomfort related to the dressing?		
Was the SUNPD dressing changed for another SUNPD dressing before the 7th post-op day?		

If Yes, on what date was the dressing changed? D D M M M Y Y Y Y

If Yes, please select the reason: (Please select only one) Dressing leak, Suspected SSI, Dressing came away, Saturated dressing requiring change, Routine wound check, Other (please specify)

On what date was the final SUNPD removed and replaced with a 'standard dressing/no dressing'? D D M M M Y Y Y Y

What was the reason for the removal of the SUNPD and replacement with a 'standard dressing/no dressing'? (Please select only one)

End of SUNPD treatment (Day 7 or discharge if sooner), Patient choice, If ticked, please provide details:

SUNPD dressing unavailable, Other, If ticked, please specify:

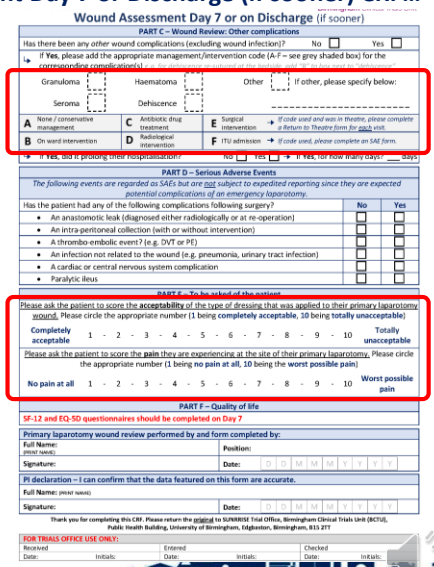
PART B – Wound Review: Infection

Since surgery was undertaken: (please answer by asking the patient and assessing the wound)	**No**	**Yes**
Has there been purulent drainage from the incision?		
Have organisms been detected from wound swabs from the incision?		
Has an SSI been diagnosed by a clinician or by imaging?		
Has the wound spontaneously opened or been opened by a clinician?		
Have any of the following symptoms and signs been detected:	**No**	**Yes**
• Pain or tenderness at the incision site?		
• Localised swelling?		
• Redness at the incision site?		
• Heat at the incision site?		
• Fever (>38°C)?		

If the patient had a wound infection, what management did they receive? (Please tick all that apply)

None / conservative management, Antibiotic drug treatment, Surgical intervention (If ticked and was in theatre, please complete a Return to Theatre form for each visit.), On ward intervention, Radiological intervention, ITU admission (If ticked, please complete an SAE form.)

If the patient had a wound infection, did it prolong their hospitalisation? No Yes → If Yes, for how many days? ___ days


Wound Assessment Day 7 or on Discharge (if sooner)

PART C – Wound Review: Other complications

Has there been any other wound complications (excluding wound infection)? No Yes

If Yes, please add the appropriate management/intervention code (A-F – see grey shaded box) for the corresponding complication(s).

Granuloma, Haematoma, Other, If other, please specify below:

Seroma, Dehiscence

A None / conservative management, C Antibiotic drug treatment, E Surgical intervention → If code used and was in theatre, please complete a Return to Theatre form for each visit.

B On ward intervention, D Radiological intervention, F ITU admission → If code used, please complete an SAE form.

If Yes, did it prolong their hospitalisation? No Yes → If Yes, for how many days? ___ days

PART D – Serious Adverse Events

The following events are regarded as SAEs but are not subject to expedited reporting since they are expected potential complications of an emergency laparotomy.

Has the patient had any of the following complications following surgery?	No	Yes
• An anastomotic leak (diagnosed either radiologically or at re-operation)		
• An intra-peritoneal collection (with or without intervention)		
• A thrombo-embolic event? (e.g. DVT or PE)		
• An infection not related to the wound (e.g. pneumonia, urinary tract infection)		
• A cardiac or central nervous system complication		
• Paralytic ileus		

PART E – To be asked of the patient

Please ask the patient to score the acceptability of the type of dressing that was applied to their primary laparotomy wound. Please circle the appropriate number (1 being completely acceptable, 10 being totally unacceptable)

Completely acceptable 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Totally unacceptable

Please ask the patient to score the pain they are experiencing at the site of their primary laparotomy. Please circle the appropriate number (1 being no pain at all, 10 being the worst possible pain)

No pain at all 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Worst possible pain

PART F – Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 7

Primary laparotomy wound review performed by and form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date: D D M M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate.

Full Name: (PRINT NAME)

Signature: Date: D D M M M Y Y Y Y

Thank you for completing this CRF. Please return the original to SUNRRISE Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

FOR TRIALS OFFICE USE ONLY:

Received Date: Initials: Entered Date: Initials: Checked Date: Initials:

Follow Up

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Time point	Activity	CRF
30-44 days post-op	Wound review by assessor BLIND to allocation	Wound Assessment Day 30

- **Ensure patient's review for 30 day wound assessment is arranged**
  - **MUST not be earlier than 30 days post-op**
  - **Should not be later than 44 days post-op**
  - **Undertaken either:**
    - **In-person review with visualisation of wound**
    - **Remotely by real-time remote video consultation**
  - **Assesses the period from index operation to 30 days; discussion with Patient, consideration of Patient Diary, review of medical notes as well as visual inspection of the wound**
- Ensure 30 day wound assessor is **blind to the allocation** (dressing used) and **trained**
  - someone not previously involved in the patient care, nor had site of the previously completed CRFs
  - Avoid accidental unbinding - assessor should complete the wound assessment (Part A & B of CRF) before consulting medical notes to assist with other parts of CRF

How will this be arranged at your site? Who by? When?

Follow Up

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Time point	Activity	CRF
30-44 days post-op	Wound review by assessor BLIND to allocation	Wound Assessment Day 30

- The **primary endpoint** assessed so it is critical the review is completed at the time and in the manner required in the protocol
  - Arrange early and discuss with participant
  - Check when calling patients at Day 14 and Day 21 if will still be attending so can address any problems as early as possible
- **REMEMBER:** £10 reimbursement to each participant towards travel expenses where day 30 review is completed in-person
  - The format this takes and logistics are to be decided locally
- If this is not achieved:
  - it should be completed as soon as possible after day 44 – a late assessment will still provide valuable data
    ensure PI is made aware
  - As for all protocol deviations, the reason it was not achieved needs to be provided – the CRF allows for this information to be recorded

Follow Up

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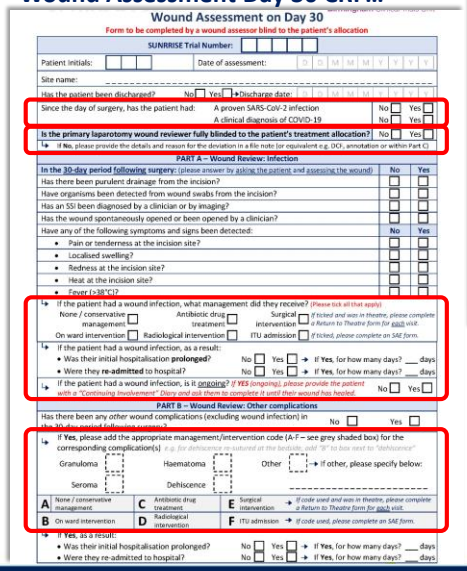
Tips on completing the Wound Assessment Day 30 CRF…


Wound Assessment on Day 30

Form to be completed by a wound assessor blind to the patient's allocation

SUNRRISE Trial Number:

Patient Initials: Date of assessment:

Site name:

Has the patient been discharged? No Yes → Discharge date:

Since the day of surgery, has the patient had: A proven SARS-CoV-2 infection No Yes; A clinical diagnosis of COVID-19 No Yes

Is the primary laparotomy wound reviewer fully blinded to the patient's treatment allocation? No Yes

If No, please provide the details and reason for the deviation in a file note (or equivalent e.g. DCF, annotation or within Part C)

PART A – Wound Review: Infection

In the 30-day period following surgery: (please answer by asking the patient and assessing the wound)	No	Yes
Has there been purulent drainage from the incision?		
Have organisms been detected from wound swabs from the incision?		
Has an SSI been diagnosed by a clinician or by imaging?		
Has the wound spontaneously opened or been opened by a clinician?		
Have any of the following symptoms and signs been detected:	No	Yes
• Pain or tenderness at the incision site?		
• Localised swelling?		
• Redness at the incision site?		
• Heat at the incision site?		
• Fever (>38°C)?		

If the patient had a wound infection, what management did they receive? (Please tick all that apply)

None / conservative management; Antibiotic drug treatment; Surgical intervention (If ticked and was in theatre, please complete a Return to Theatre form for each visit.); On ward intervention; Radiological intervention; ITU admission (If ticked, please complete an SAE form.)

If the patient had a wound infection, as a result:
• Was their initial hospitalisation **prolonged**? No Yes → If Yes, for how many days? ___ days
• Were they **re-admitted** to hospital? No Yes → If Yes, for how many days? ___ days

If the patient had a wound infection, is it ongoing? If YES (ongoing), please provide the patient with a "Continuing Involvement" Diary and ask them to complete it until their wound has healed. No Yes

PART B – Wound Review: Other complications

Has there been any *other* wound complications (excluding wound infection) in the 30-day period following surgery? No Yes

If Yes, please add the appropriate management/intervention code (A-F – see grey shaded box) for the corresponding complication(s) e.g. for dehiscence re-sutured in the theatre, add 'E' to box next to 'Dehiscence'

Granuloma; Haematoma; Other → If other, please specify below:

Seroma; Dehiscence

A None / conservative management; C Antibiotic drug treatment; E Surgical intervention → If code used and was in theatre, please complete a Return to Theatre form for each visit.

B On ward intervention; D Radiological intervention; F ITU admission → If code used, please complete an SAE form.

If Yes, as a result:
• Was their initial hospitalisation prolonged? No Yes → If Yes, for how many days? ___ days
• Were they re-admitted to hospital? No Yes → If Yes, for how many days? ___ days

PART C – Wound Review: Method and timing

The protocol requires wound review be undertaken in-person (or by remote video consultation at 30-44 days post-operatively. If this is not achieved, either in how the review is completed or when it is done, the details and reasons for the deviation need to be documented.

How was the review conducted? In-person with visualisation of wound; Remotely with visualisation of wound by video call; Remotely without visualisation of wound by telephone call → Please explain why below; Other → If Other, please specify: → Please explain why below

If NOT conducted as required in the protocol, please explain why:

Was the wound review completed in the window required in the protocol? No Yes

If NOT conducted when required in the protocol, please explain why:

PART D – Serious Adverse Events

The following events are regarded as SAEs but are not subject to expedited reporting since they are expected potential complications of an emergency laparotomy.

Has the patient had any of the following complications following surgery?	No	Yes
• An anastomotic leak (diagnosed either radiologically or at re-operation)		
• An intra-peritoneal collection (with or without intervention)		
• A thrombo-embolic event? (e.g. DVT or PE)		
• An infection not related to the wound (e.g. pneumonia, urinary tract infection)		
• A cardiac or central nervous system complication		
• Paralytic ileus		

PART E – Wound Heath Questionnaire (to be asked of the patient)

This is a repeat of the questionnaire in the diary. Please ask the questions and give options to the patient. Under each heading, please tick the ONE box that is most relevant to their experience.

Since you left hospital after having surgery....	Not at all	A little	Quite a bit	A lot
1. Was there redness spreading away from the [illegible]schema/cellulitis)				
17. Has your wound be… abscess)				
18. Have you had an operation under general anaesthetic for treatment of a problem with your wound?				

PART F – Wound Pain (to be asked of the patient)

Please ask the patient to score the **pain** they are experiencing at the site of their primary laparotomy wound. Please circle the appropriate number (1 being no pain at all, 10 being the worst possible pain)

No pain at all 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Worst possible pain

PART G - Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 30.

Primary laparotomy wound review performed by and form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date:

Discontinuation & Withdrawal

SUNRRISE

- Patients may withdraw at any time
- If a patient decides to withdraw the details should be documented in the medical notes and the **SUNRRISE** Trial Office informed ASAP using the Patient Discontinuation Form

In SUNRRISE, withdrawal is a <u>patient</u> decision AND they can selectively withdraw.

A patient should be followed up no matter what "happens" unless the patient specifically decides they wish to withdraw.

- For patient's who withdraw and agree to the collection of routinely recorded information, along with those that die or are lost to follow-up, where possible data will be provided based on the information in the patient's medical notes.

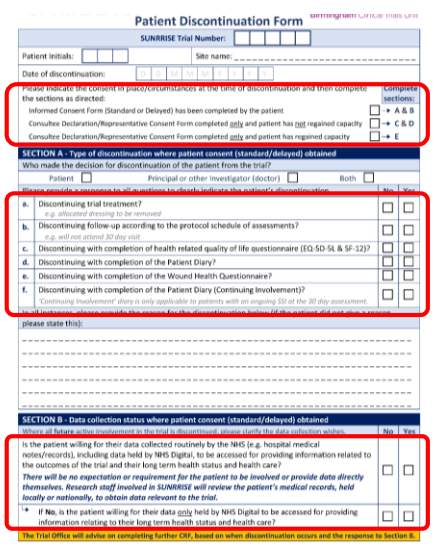
Discontinuation & Withdrawal

Example of types of withdrawal in **SUNRRISE** may include:

- **Withdrawal from trial-specific treatment:**
  - Patient will not complete treatment as per the **SUNRRISE** protocol. Follow-up according to the protocol would still be requested
- **Withdrawal from trial-specific follow-up:**
  - Patient has had trial treatment but does not wish to be followed up according to the protocol
  - The patient will be followed up according to standard practice
  - It must be confirmed that the patient has agreed that follow-up data collected at standard clinic visits may be used in the final analysis
- **Complete withdrawal:**
  - Patient is not willing to be followed up for trial purposes at any further visits, i.e. only data collected prior to the withdrawal of consent can be used in the final analysis

Discontinuation & Withdrawal

Tips on completing the Patient Discontinuation Form…


Patient Discontinuation Form

SUNRRISE Trial Number:

Patient Initials: Site name:

Date of discontinuation:

Please indicate the consent in place/circumstances at the time of discontinuation and then complete the sections as directed: Complete sections:

Informed Consent Form (Standard or Delayed) has been completed by the patient → A & B

Consultee Declaration/Representative Consent Form completed only and patient has not regained capacity → C & D

Consultee Declaration/Representative Consent Form completed only and patient has regained capacity → E

SECTION A - Type of discontinuation where patient consent (standard/delayed) obtained

Who made the decision for discontinuation of the patient from the trial?

Patient Principal or other Investigator (doctor) Both

Please provide a response to all questions to clearly indicate the patient's discontinuation. No Yes

a. Discontinuing trial treatment? e.g. allocated dressing to be removed

b. Discontinuing follow-up according to the protocol schedule of assessments? e.g. will not attend 30 day visit

c. Discontinuing with completion of health related quality of life questionnaire (EQ-5D-5L & SF-12)?

d. Discontinuing with completion of the Patient Diary?

e. Discontinuing with completion of the Wound Health Questionnaire?

f. Discontinuing with completion of the Patient Diary (Continuing Involvement)? 'Continuing Involvement' diary is only applicable to patients with an ongoing SSI at the 30 day assessment.

In all instances, please provide the reason for the discontinuation below (if the consultee/representative did not give a reason, please state this):

SECTION B - Data collection status where patient consent (standard/delayed) obtained

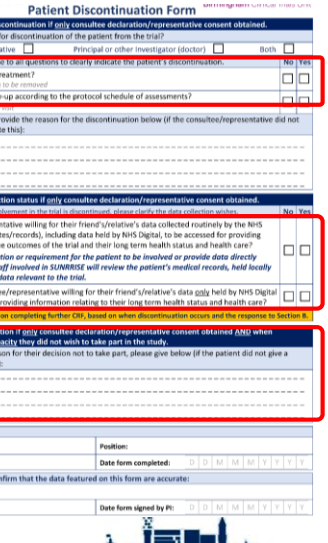
Where all future active involvement in the trial is discontinued, please clarify the data collection wishes. No Yes

Is the patient willing for their data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care?

There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.

If No, is the patient willing for their data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.


Patient Discontinuation Form

SECTION C – Type of discontinuation if only consultee declaration/representative consent obtained.

Who made the decision for discontinuation of the patient from the trial?

Consultee/representative Principal or other Investigator (doctor) Both

Please provide a response to all questions to clearly indicate the patient's discontinuation. No Yes

a. Discontinuing trial treatment? e.g. allocated dressing to be removed

b. Discontinuing follow-up according to the protocol schedule of assessments? e.g. will not attend 30 day visit

In all instances, please provide the reason for the discontinuation below (if the consultee/representative did not give a reason, please state this):

SECTION D - Data collection status if only consultee declaration/representative consent obtained.

Where all future active involvement in the trial is discontinued, please clarify the data collection wishes. No Yes

Is the consultee/representative willing for their friend's/relative's data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care?

There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.

If No, is the consultee/representative willing for their friend's/relative's data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.

SECTION E - Discontinuation if only consultee declaration/representative consent obtained AND when participant regained capacity they did not wish to take part in the study.

If patient provided a reason for their decision not to take part, please give below (if the patient did not give a reason, please state this):

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date form completed: D D M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate:

Full Name: (PRINT NAME)

Signature: Date form signed by PI: D D M M Y Y Y Y

Assessment Schedule

Activity/CRF	Pre-theatre	In-theatre	Day 7 post-op (-2/+3 days)	Day 14 post-op (± 2 days)	Day 21 post-op (± 2 days)	Day 30 post-op (+ 14 days)	Day 30+
Patient identification and screening	On-call surgical team						
Patient consent • Standard	Patient & Member of the research team						
Patient consent • Delayed (UK only)	Consultee/Representative & Member of the research team	Patient & Member of the research team when capacity regained					
Randomisation form	Started pre-theatre by the research team	Surgeon or member of the research team					
In-Theatre form		Ideally an operating surgeon, or member of the research team					
Wound Assessment Day 7 or on Discharge (if sooner)[1,2]			Member of the research team				
EQ-5D-5L	Completed by the participant		Completed by the participant	Completed by the participant	Completed by the participant	Completed by the participant	
SF-12	Completed by the participant		Completed by the participant			Completed by the participant	
Patient diary			Completed daily by the participant following discharge from hospital until they undergo the Day 30 wound review				Patients to continue with a diary if they have an ongoing SSI
Bluebelle wound healing questionnaire						Completed by the participant independently, and then by the participant with a blinded member of the research team reviewing wound	
Wound Assessment Day 30[1]						Completed by a blinded member of the research team as an **in-person or remote (video) review**	
SAE reporting		All serious adverse events by member of the research team using SAE form or wound assessment CRF if excluded from expedited reporting					Related serious adverse events only
Return to theatre form		Member of the research team for any return to theatre following patient returning to theatre					
PI Declaration form for CFR data							Completed by PI at the end of each participant's involvement

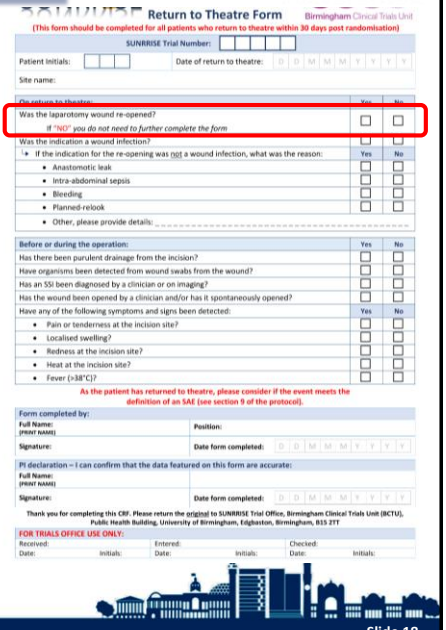
[1] Assessment of pain undertaken by a member of the research team by asking the participant and recording the response on the CRF
[2] Score of patient acceptability of dressing undertaken by a member of the research team by asking the participant and recording the response on the CRF

Return to theatre

- CRF to be completed for any returns to theatre
- If the laparotomy wound is <u>not</u> reopened only the first question needs to be completed

Intervention following a return to theatre…

- If SUNPD removed during a theatre visit <u>and</u> within 7 days of the index laparotomy, <u>SUNPD will be reapplied</u> to the wound at the end of the procedure
  - **The treatment period remains 7 days from the index laparotomy.**
- If theatre visit is after 7 days of the index laparotomy, regardless of the randomised allocation, at the end of the operation a dressing of the surgeon's choice will be applied (as long as this is not a SUNPD)



Return to Theatre Form — Birmingham Clinical Trials Unit

(This form should be completed for all patients who return to theatre within 30 days post randomisation)

SUNRRISE Trial Number:

Patient Initials: Date of return to theatre: D D M M Y Y Y Y

Site name:

On return to theatre:	Yes	No
Was the laparotomy wound re-opened?	☐	☐
If "NO" you do not need to further complete the form		
Was the indication a wound infection?	☐	☐
If the indication for the re-opening was not a wound infection, what was the reason:	Yes	No
• Anastomotic leak	☐	☐
• Intra-abdominal sepsis	☐	☐
• Bleeding	☐	☐
• Planned-relook	☐	☐
• Other, please provide details:	☐	☐

Before or during the operation:	Yes	No
Has there been purulent drainage from the incision?	☐	☐
Have organisms been detected from wound swabs from the wound?	☐	☐
Has an SSI been diagnosed by a clinician or on imaging?	☐	☐
Has the wound been opened by a clinician and/or has it spontaneously opened?	☐	☐
Have any of the following symptoms and signs been detected:	Yes	No
• Pain or tenderness at the incision site?	☐	☐
• Localised swelling?	☐	☐
• Redness at the incision site?	☐	☐
• Heat at the incision site?	☐	☐
• Fever (>38°C)?	☐	☐

As the patient has returned to theatre, please consider if the event meets the definition of an SAE (see section 9 of the protocol).

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date form completed: D D M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate:

Full Name: (PRINT NAME)

Signature: Date form completed: D D M M Y Y Y Y

Thank you for completing this CRF. Please return the original to SUNRRISE Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

FOR TRIALS OFFICE USE ONLY:

Received: Date: Initials: Entered: Date: Initials: Checked: Date: Initials:

Case report forms (CRF)

SUNRRISE

- CRFs will be paper records completed on site
  - CRFs are considered complete when all data fields are completed unambiguously or the data is marked as unobtainable
- Corrections should made by:
  - Striking through incorrect entry with a single line (without obscuring the original entry) ~~2016~~
  - Entering correct information adjacent to incorrect entry ~~2016~~ 2017
  - Including initials and date ~~2016~~ 2017 JB 22-Sep-2018
- Principal Investigator (or delegate) must:
  - Promptly review and sign-off CRF data at the end of a participant's involvement *(PI only)*
  - Sign and date Inclusion/Exclusion Criteria (randomisation form) *(PI or delegate)*
- Originals to be returned to the **SUNRRISE** Trial Office and true copies kept at site, EXCEPT the consent/declaration forms where a copy will be sent to the **SUNRRISE** Trial Office and original kept at site in ISF
  - We suggest posting consent/declaration and randomisation forms (as they contain patient identifiers) together but separately to other forms
- Guidelines are provided in the Investigator Site File

Questions about completing CRFs?
Get in touch…
0121 414 9012 / 077 8510 2378
sunrrise@trials.bham.ac.uk

Supplies of CRFs (paper or electronic)… Contact the Trial Office sunrise@trials.bham.ac.uk

Case report forms (CRF)

SUNRRISE

CRF Name	Contents	Window	Duty on log required for completion	Training Required
Randomisation	Eligibility criteria checklist, confirmation of eligibility, operative details, demographics, allocation	n/a	K, *For eligibility section of form*: D (doctors only)	Study-specific
In-theatre	Further operative details, allocation delivery	n/a	J	Study-specific
Wound Assessment Day 7 or on Discharge (if sooner)	SUNPD treatment (if applicable), unblinded Wound Review for infections and complications and SAEs.	Day 5-10	K **&** O	Study-specific **&** Wound Assessment
Wound Assessment Day 30-37	Eligibility criteria checklist, confirmation of eligibility, operative details demographic data, allocation	Day 30-44	K **&** O	Study-specific **&** Wound Assessment
Return to Theatre	Return to theatre details, Wound Review for infection	n/a	K & *ideally* O	Study-specific & *ideally* Wound Assessment
Patient Discontinuation	Type of discontinuation(s), reasons for discontinuation(s), data collection status	n/a	K	Study-specific
PI Declaration Form for CRF Data	Confirmation of completeness and accuracy of all CRF data	n/a	M	Study-specific
SAE	Event information, seriousness and causality		H, *For causality section of form*: I (PI only)	Study-specific

Delegation log duties: **D**. Confirm patient eligibility (doctors only), **H**. SAE reporting, **I**. Causality assessment of SAE (PI only), **J**. Completion of In-Theatre Form and assoc. DCFs, **K**. Completion of other CRFs and assoc. DCFs, M. CRF review and sign off & SDV (PI only*), **O**. Wound assessment

CRFs are expected within to arrive at the Trial Office within 7 days of completion – after this reminders with be sent

Data clarification forms (DCF)

- All missing, erroneous and/or ambiguous data will be queried via a DCF
  - Each query is assigned a unique reference number
- Query resolutions should always be provided on the DCF form (or as part of a file note)
- **No changes should ever be made to the copy of the completed CRF after the original has been sent to the SUNRRISE Trial office**
- DCF should be completed by anyone that has been delegated the duties of completing CRFs and DCFs
- The original completed DCF should be returned to the **SUNRRISE** Trial office
- A photocopy of the DCF should be kept at site it should be attached to the associated CRF

Staff from BCTU will transcribe data from paper CRFs and DCFs into the trial database

PI declaration for CRF Data

- PI is required to compete "Declaration Form for CRF Data" for each participant
  - Once all required CRFs have been completed and provided to the SUNRRISE Trial Office, and any data queries resolved
  - Review CRFs and confirm all data featured are accurate
  - Due approximately 3 weeks after the Day 30 assessment is completed BUT it may be preferred to wait until it is requested by the **SUNRRISE** Trial Office, who will only do so after all (if any) query are resolved
- CRFs may include a "PI declaration" section BUT following the implementation of the "Declaration Form for CRF Data", this does not need to be completed on the individual CRFs before sending to the **SUNRRISE** Trial Office
  - This was originally used to document the local PI confirmation that all the data featured on the form are accurate and demonstrate oversight
  - This section has been retain to allow this mode of data sign-off to continue if preferred

Source data

- Source data is defined as: all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial
- QoL questionnaires and Patient Diaries will be considered source data. This data is entered directly onto the forms and these are clearly identified and detailed below:
  - EQ-5D-5L
  - SF-12
  - Patient Diary
- **The CRFs are not the source data for clinical information**
- In order to allow for the accurate reconstruction of the trial and clinical management of the participant, source data will be accessible and maintained
- **Source data (except for QoL) is kept as part of the participants' medical notes, generated and maintained at site**

Source data

- Medical notes to be completed following consultations with the participants
- All entries to be signed and dated by the person making the entry (or equivalent according to local systems/policies)
  - where decision made by someone other than the staff making the entry they too should also sign and date the entry e.g. nurse making the entry but the decision is made by a clinician
- Include who is responsible for completing the source data i.e. the research team or the participant (for example in the use of questionnaires)
- Key events to be recorded include:
  - date provision of the subject with the PIS
  - date of consent, eligibility decision
  - randomisation
  - treatment and dosing decisions relating to clinical care
  - trial visits/follow-up
  - adverse events
  - withdrawal, termination and end of trial involvement

SUNRRISE

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…

sunrrise@trials.bham.ac.uk