Haemorrhage alleviation with tranexamic acid - Intestinal system

WHAT TO DO IF A PATIENT DEVELOPS AN UNEXPECTED PROBLEM?

If a patient develops an unexpected problem

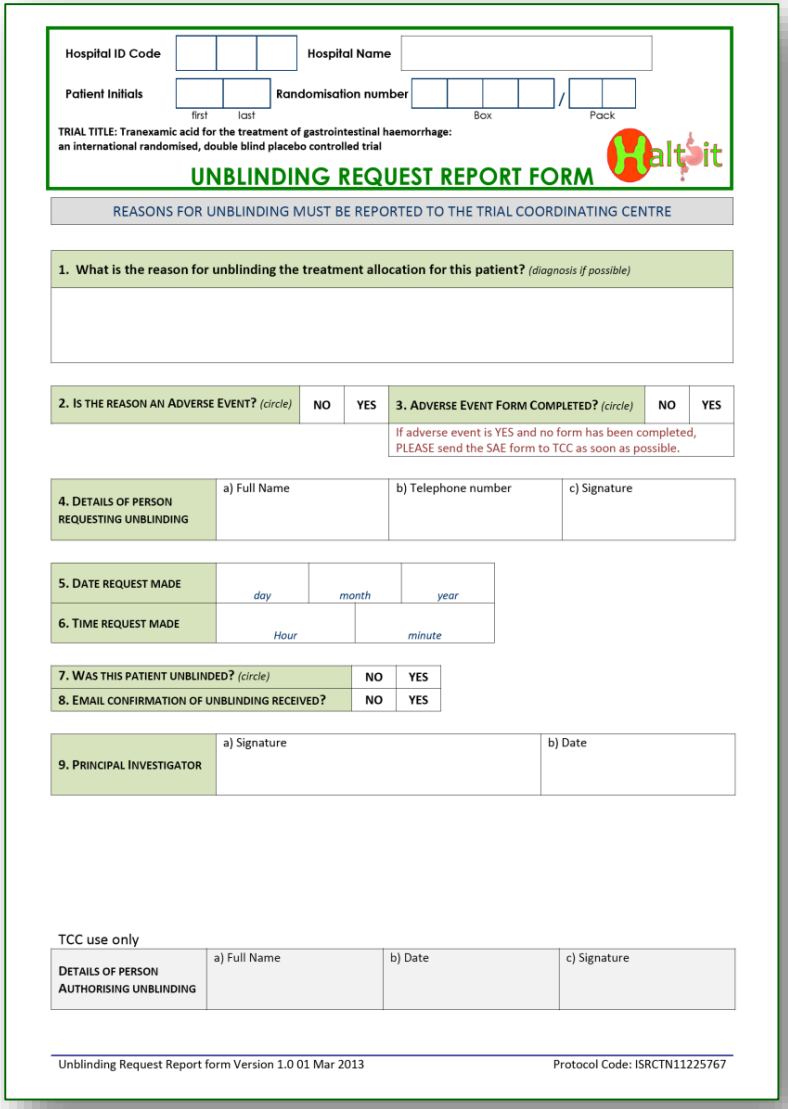
- If you have concerns about a patient in the trial, you should first contact the Principal Investigator or his/her delegate at your hospital

- Advice about the trial (not clinical care) is available from the TCC – see posters and Study File for contact information

Unblinding the treatment allocation

- In general there should be no need to unblind the allocated treatment. **If some contraindication to TXA develops after randomisation (e.g. the patient becomes anuric and the clinical team is concerned about acute renal failure and risk of TXA accumulation), the trial treatment should simply be stopped and all usual standard care given.**
- Unblinding should be done only in those rare cases when clinical management depends on knowing what the patient received.
- For urgent unblinding, a 24-hour telephone service is available. Details are provided in the Study File and on wall posters.
- The caller will be told whether the patient received TXA or placebo by email or fax; this is to ensure that the TCC staff remain blind to the study treatment

Unblinding the treatment allocation



Hospital ID Code | Hospital Name

Patient Initials (first, last) | Randomisation number (Box / Pack)

TRIAL TITLE: Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial

UNBLINDING REQUEST REPORT FORM

REASONS FOR UNBLINDING MUST BE REPORTED TO THE TRIAL CORDINATING CENTRE

1. What is the reason for unblinding the treatment allocation for this patient? *(diagnosis if possible)*

2. Is the reason an Adverse Event? *(circle)* NO YES

3. Adverse Event Form Completed? *(circle)* NO YES

If adverse event is YES and no form has been completed, PLEASE send the SAE form to TCC as soon as possible.

4. Details of person requesting unblinding — a) Full Name | b) Telephone number | c) Signature

5. Date request made — day | month | year

6. Time request made — Hour | minute

7. Was this patient unblinded? *(circle)* NO YES

8. Email confirmation of unblinding received? NO YES

9. Principal Investigator — a) Signature | b) Date

TCC use only

Details of person authorising unblinding — a) Full Name | b) Date | c) Signature

Unblinding Request Report form Version 1.0 01 Mar 2013 Protocol Code: ISRCTN11225767

- An Unblinding Request Report form must be completed by the person who requested the unblinding
- TCC will send you a blank form immediately a request for unblinding has been granted
- If necessary, an Adverse Event Report must be completed

For further information see presentation titled 'Adverse Event reporting and completing the report form'

Complications – reported as outcomes

Mortality:

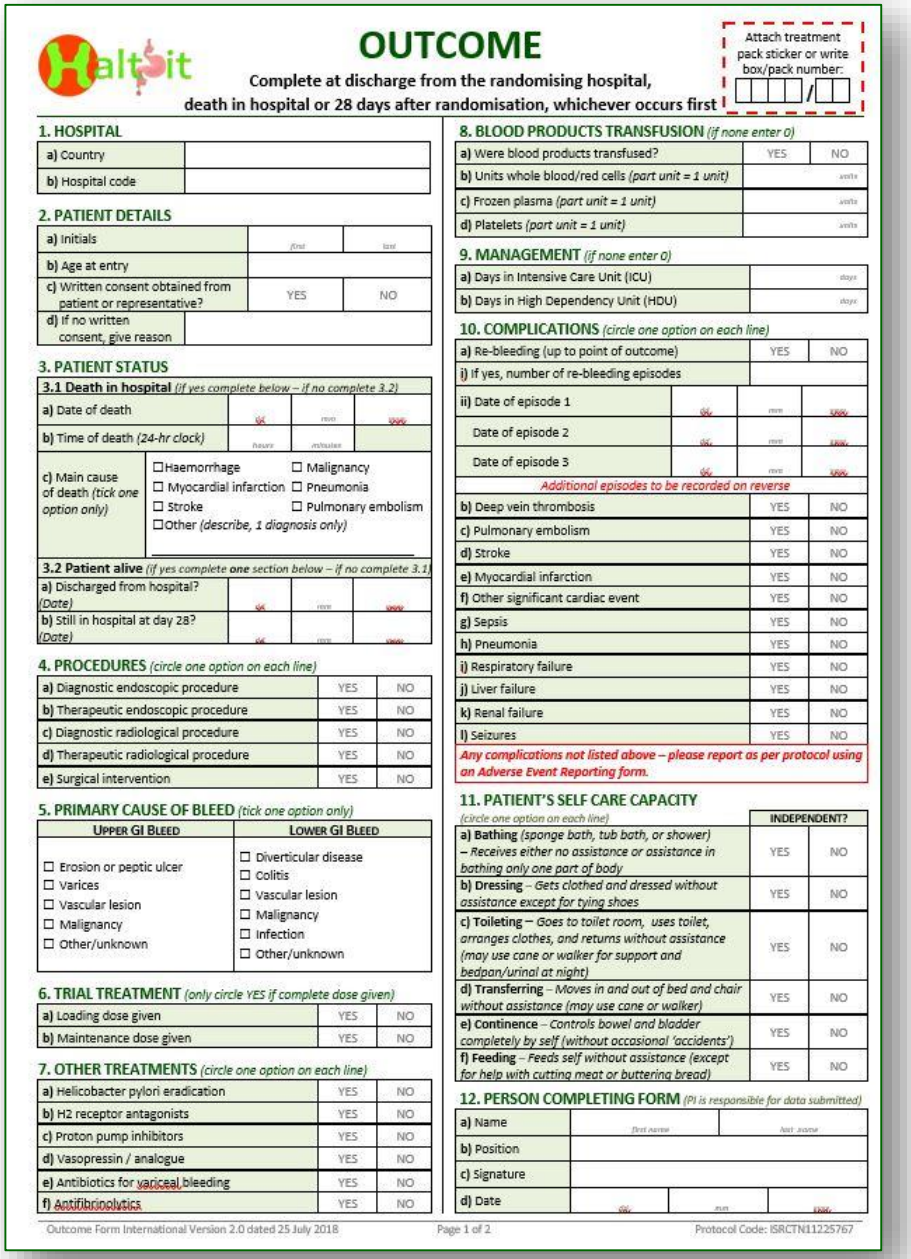
primary outcome routinely captured (including primary cause)

Other relevant medical events:

expected complications of GI bleeding collected:

- Re-bleeding
- Deep vein thrombosis
- Pulmonary embolism
- Stroke
- Myocardial infarction
- Other significant cardiac event
- Sepsis
- Pneumonia
- Respiratory failure
- Liver failure
- Renal failure
- Seizures

Outcomes routinely reported to the independent Data Monitoring Committee (DMC) for unblinded review



HALT it

OUTCOME

Complete at discharge from the randomising hospital, death in hospital or 28 days after randomisation, whichever occurs first

Attach treatment pack sticker or write box/pack number: ☐☐☐☐/☐☐

1. HOSPITAL

a) Country	
b) Hospital code	

2. PATIENT DETAILS

a) Initials	first	last
b) Age at entry		
c) Written consent obtained from patient or representative?	YES	NO
d) If no written consent, give reason		

3. PATIENT STATUS

3.1 Death in hospital *(if yes complete below – if no complete 3.2)*

a) Date of death	dd	mm	yyyy
b) Time of death *(24-hr clock)*	hours	minutes	

c) Main cause of death *(tick one option only)*

☐ Haemorrhage ☐ Malignancy
☐ Myocardial infarction ☐ Pneumonia
☐ Stroke ☐ Pulmonary embolism
☐ Other *(describe, 1 diagnosis only)*

3.2 Patient alive *(if yes complete one section below – if no complete 3.1)*

a) Discharged from hospital? *(Date)*	dd	mm	yyyy
b) Still in hospital at day 28? *(Date)*	dd	mm	yyyy

4. PROCEDURES *(circle one option on each line)*

a) Diagnostic endoscopic procedure	YES	NO
b) Therapeutic endoscopic procedure	YES	NO
c) Diagnostic radiological procedure	YES	NO
d) Therapeutic radiological procedure	YES	NO
e) Surgical intervention	YES	NO

5. PRIMARY CAUSE OF BLEED *(tick one option only)*

Upper GI Bleed	Lower GI Bleed
☐ Erosion or peptic ulcer	☐ Diverticular disease
☐ Varices	☐ Colitis
☐ Vascular lesion	☐ Vascular lesion
☐ Malignancy	☐ Malignancy
☐ Other/unknown	☐ Infection
	☐ Other/unknown

6. TRIAL TREATMENT *(only circle YES if complete dose given)*

a) Loading dose given	YES	NO
b) Maintenance dose given	YES	NO

7. OTHER TREATMENTS *(circle one option on each line)*

a) Helicobacter pylori eradication	YES	NO
b) H2 receptor antagonists	YES	NO
c) Proton pump inhibitors	YES	NO
d) Vasopressin / analogue	YES	NO
e) Antibiotics for variceal bleeding	YES	NO
f) Antifibrinolytics	YES	NO

8. BLOOD PRODUCTS TRANSFUSION *(if none enter 0)*

a) Were blood products transfused?	YES	NO
b) Units whole blood/red cells *(part unit = 1 unit)*		units
c) Frozen plasma *(part unit = 1 unit)*		units
d) Platelets *(part unit = 1 unit)*		units

9. MANAGEMENT *(if none enter 0)*

a) Days in Intensive Care Unit (ICU)	days
b) Days in High Dependency Unit (HDU)	days

10. COMPLICATIONS *(circle one option on each line)*

a) Re-bleeding (up to point of outcome)		YES	NO
i) If yes, number of re-bleeding episodes			
ii) Date of episode 1	dd	mm	yyyy
Date of episode 2	dd	mm	yyyy
Date of episode 3	dd	mm	yyyy

Additional episodes to be recorded on reverse

b) Deep vein thrombosis	YES	NO
c) Pulmonary embolism	YES	NO
d) Stroke	YES	NO
e) Myocardial infarction	YES	NO
f) Other significant cardiac event	YES	NO
g) Sepsis	YES	NO
h) Pneumonia	YES	NO
i) Respiratory failure	YES	NO
j) Liver failure	YES	NO
k) Renal failure	YES	NO
l) Seizures	YES	NO

Any complications not listed above – please report as per protocol using an Adverse Event Reporting form.

11. PATIENT'S SELF CARE CAPACITY

(circle one option on each line)

	INDEPENDENT?	
a) **Bathing** *(sponge bath, tub bath, or shower) – Receives either no assistance or assistance in bathing only one part of body*	YES	NO
b) **Dressing** – *Gets clothed and dressed without assistance except for tying shoes*	YES	NO
c) **Toileting** – *Goes to toilet room, uses toilet, arranges clothes, and returns without assistance (may use cane or walker for support and bedpan/urinal at night)*	YES	NO
d) **Transferring** – *Moves in and out of bed and chair without assistance (may use cane or walker)*	YES	NO
e) **Continence** – *Controls bowel and bladder completely by self (without occasional 'accidents')*	YES	NO
f) **Feeding** – *Feeds self without assistance (except for help with cutting meat or buttering bread)*	YES	NO

12. PERSON COMPLETING FORM *(PI is responsible for data submitted)*

a) Name	first name	last name
b) Position		
c) Signature		
d) Date	dd	mm yyyy

What should be reported as AE or SAE?

- **In hospital**, any untoward medical event that occurs up to 28 days after randomisation and **NOT** collected on the outcome form, should be reported
- If a patient is discharged or transferred to another hospital, they should be given an ALERT CARD which should contain information on who to contact if they develop any problems

- **After discharge,** report any untoward medical event, which develops up to 28 days after randomisation (including those listed on the outcome form)
- For each adverse event, an Adverse Event Report form must be completed (see in Study File section 7)
- For further information see presentation titled 'Adverse Event reporting and completing the report form'

JOIN THE GLOBAL COLLABORATION

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