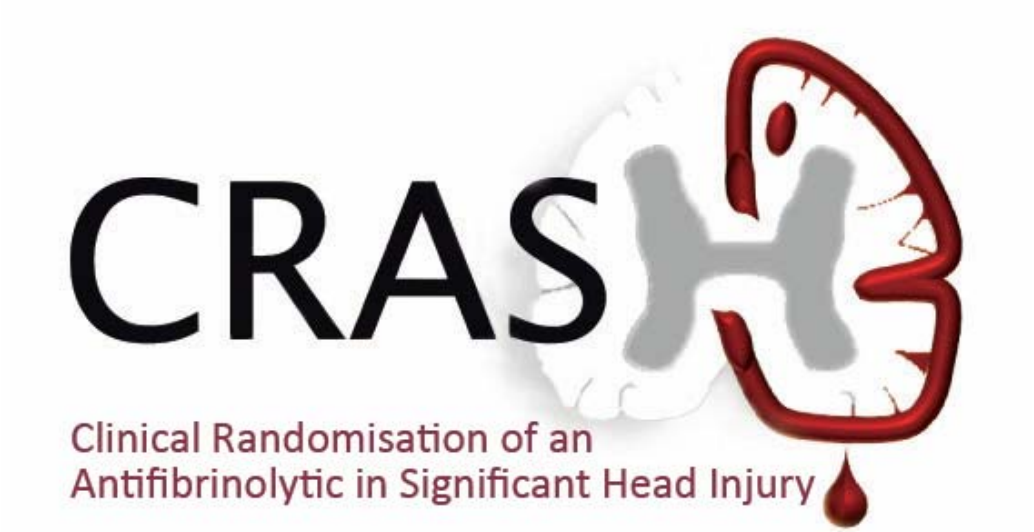
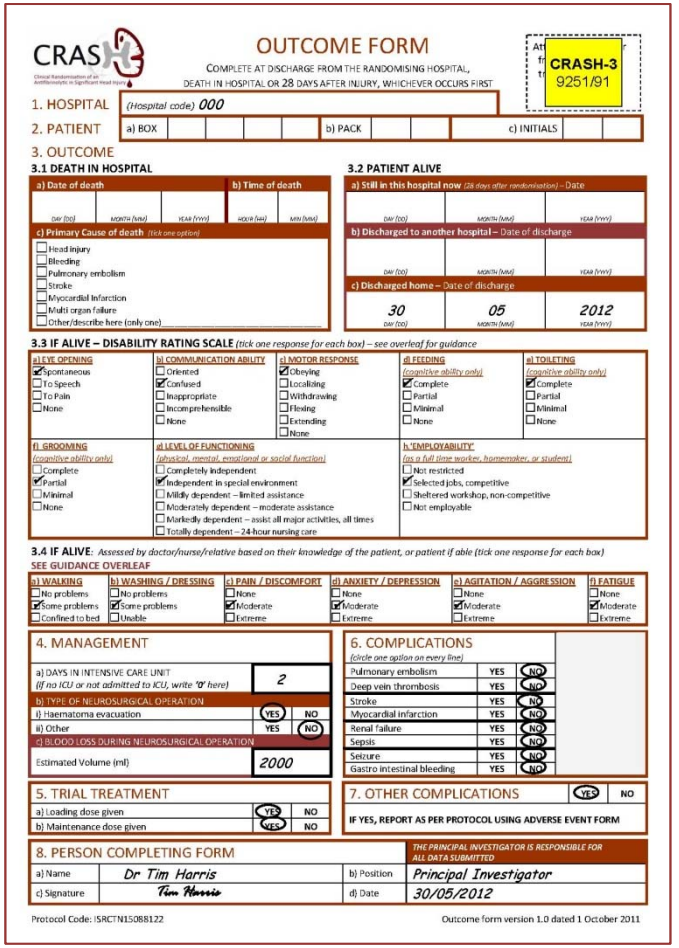



# How to complete the outcome form

Protocol Code: ISRCTN15088122
V 1.0 date 30 Jan 2012

# Completing the outcome form

- The Outcome Form should be completed at:
  - 28 days from randomisation OR
  - at prior death, discharge or transfer
- If transfer is soon after randomisation, a follow-up outcome should be obtained
- Days are counted from the date of randomisation (28 days = exactly 4 weeks) eg a patient randomised on 1 July: outcome due 29 July
- Use a paper form to capture the outcome data directly from the patient's medical records
- Please use permanent ink when completing the form



CRASH-3

OUTCOME FORM

COMPLETE AT DISCHARGE FROM THE RANDOMISING HOSPITAL, DEATH IN HOSPITAL OR 28 DAYS AFTER INJURY, WHICHEVER OCCURS FIRST

CRASH-3 9251/91

1. HOSPITAL (Hospital code) 000

2. PATIENT a) BOX b) PACK c) INITIALS

3. OUTCOME

3.1 DEATH IN HOSPITAL

a) Date of death b) Time of death

c) Primary Cause of death (tick one option)

- Head injury
- Bleeding
- Pulmonary embolism
- Stroke
- Myocardial infarction
- Multi organ failure
- Other/describe here (only one)

3.2 PATIENT ALIVE

a) Still in this hospital now (28 days after randomisation) – Date

b) Discharged to another hospital – Date of discharge

c) Discharged home – Date of discharge: 30 / 05 / 2012

3.3 IF ALIVE – DISABILITY RATING SCALE (tick one response for each box) – see overleaf for guidance

| a) EYE OPENING | b) COMMUNICATION ABILITY | c) MOTOR RESPONSE | d) FEEDING (cognitive ability only) | e) TOILETING (cognitive ability only) |
|---|---|---|---|---|
| ☑ Spontaneous | ☐ Oriented | ☑ Obeying | ☑ Complete | ☑ Complete |
| ☐ To Speech | ☑ Confused | ☐ Localising | ☐ Partial | ☐ Partial |
| ☐ To Pain | ☐ Inappropriate | ☐ Withdrawing | ☐ Minimal | ☐ Minimal |
| ☐ None | ☐ Incomprehensible | ☐ Flexing | ☐ None | ☐ None |
| | ☐ None | ☐ Extending | | |
| | | ☐ None | | |

| f) GROOMING (cognitive ability only) | g) LEVEL OF FUNCTIONING (physical, mental, emotional or social function) | h) "EMPLOYABILITY" (as a full time worker, homemaker, or student) |
|---|---|---|
| ☐ Complete | ☐ Completely independent | ☐ Not restricted |
| ☑ Partial | ☑ Independent in special environment | ☑ Selected jobs, competitive |
| ☐ Minimal | ☐ Mildly dependent – limited assistance | ☐ Sheltered workshop, non-competitive |
| ☐ None | ☐ Moderately dependent – moderate assistance | ☐ Not employable |
| | ☐ Markedly dependent – assist all major activities, all times | |
| | ☐ Totally dependent – 24 hour nursing care | |

3.4 IF ALIVE: Assessed by doctor/nurse/relative based on their knowledge of the patient, or patient if able (tick one response for each box)

SEE GUIDANCE OVERLEAF

| a) WALKING | b) WASHING / DRESSING | c) PAIN / DISCOMFORT | d) ANXIETY / DEPRESSION | e) AGITATION / AGGRESSION | f) FATIGUE |
|---|---|---|---|---|---|
| ☐ No problems | ☐ No problems | ☐ None | ☐ None | ☐ None | ☐ None |
| ☑ Some problems | ☑ Some problems | ☑ Moderate | ☑ Moderate | ☑ Moderate | ☑ Moderate |
| ☐ Confined to bed | ☐ Unable | ☐ Extreme | ☐ Extreme | ☐ Extreme | ☐ Extreme |

4. MANAGEMENT

a) DAYS IN INTENSIVE CARE UNIT (If no ICU or not admitted to ICU, write '0' here): 2

b) TYPE OF NEUROSURGICAL OPERATION

i) Haematoma evacuation: (YES) NO

ii) Other: YES (NO)

c) BLOOD LOSS DURING NEUROSURGICAL OPERATION

Estimated Volume (ml): 2000

6. COMPLICATIONS (circle one option on every line)

| | | |
|---|---|---|
| Pulmonary embolism | YES | (NO) |
| Deep vein thrombosis | YES | (NO) |
| Stroke | YES | (NO) |
| Myocardial infarction | YES | (NO) |
| Renal failure | YES | (NO) |
| Sepsis | YES | (NO) |
| Seizure | YES | (NO) |
| Gastro intestinal bleeding | YES | (NO) |

5. TRIAL TREATMENT

a) Loading dose given: (YES) NO

b) Maintenance dose given: (YES) NO

7. OTHER COMPLICATIONS: (YES) NO

IF YES, REPORT AS PER PROTOCOL USING ADVERSE EVENT FORM

8. PERSON COMPLETING FORM — THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL DATA SUBMITTED

| | | | |
|---|---|---|---|
| a) Name | Dr Tim Harris | b) Position | Principal Investigator |
| c) Signature | Tim Harris | d) Date | 30/05/2012 |

Protocol Code: ISRCTN15088122 — Outcome form version 1.0 dated 1 October 2011

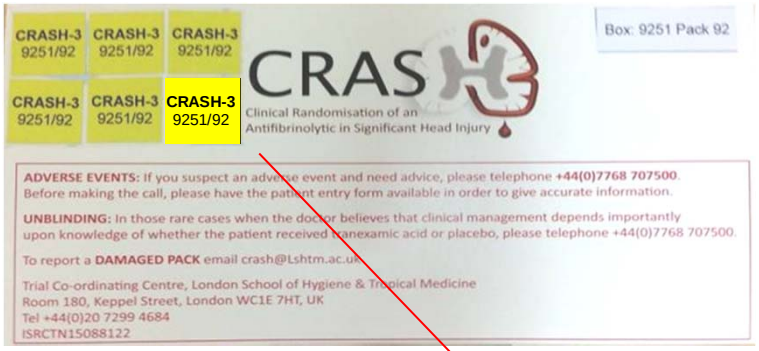
# Completing the outcome form

## 1. HOSPITAL (CODE)

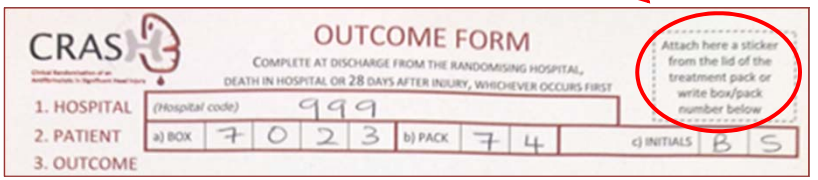
Enter the trial ID number for your hospital – this is the 3-digit code on the contact sheet in your study file

## 2. PATIENT

**(a+b)** – There is space at the top of the form for the yellow sticker from the drug pack (the randomisation number). If you don't have the sticker please write the box/pack number clearly in the space provided.




**(c)** – Patient initials from the first name and last name eg Amara Kumara Star will be AS – if only one name is known enter that single initial.



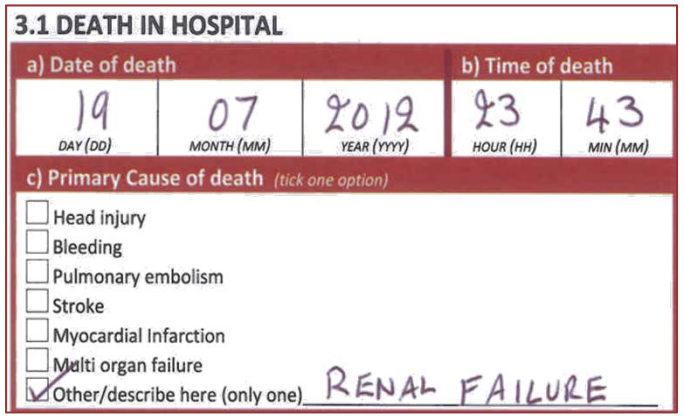
# Section 3.1 – Outcome death in hospital

***Only complete if the patient dies***

a) Enter date of death in the format DD/MM/YYYY eg 19/07/2012

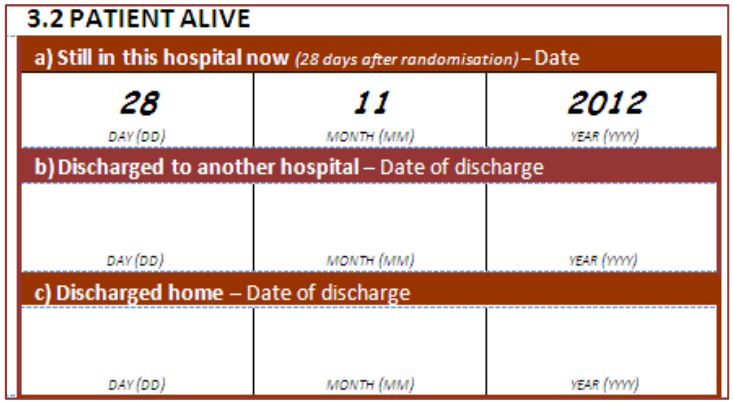
b) Enter the time of death in the format hh/mm eg 23/43

c) Indicate (with a tick ✓) the primary cause of death – if more than one cause, please enter **ONLY the main cause**



# Section 3.2 – Outcome patient alive

***Only complete if the patient is alive***



| 3.2 PATIENT ALIVE | | |
|---|---|---|
| **a) Still in this hospital now** *(28 days after randomisation)* – Date | | |
| ***28*** DAY (DD) | ***11*** MONTH (MM) | ***2012*** YEAR (YYYY) |
| **b) Discharged to another hospital** – Date of discharge | | |
| DAY (DD) | MONTH (MM) | YEAR (YYYY) |
| **c) Discharged home** – Date of discharge | | |
| DAY (DD) | MONTH (MM) | YEAR (YYYY) |

Enter the date of discharge, transfer, or still in hospital at 28 days in the format DD/MM/YYYY eg 28/11/2012

Only one line to be completed

# Section 3.3 – Status if alive

Complete the DISABILITY RATING SCALE questions **a–h** following the guidance on reverse of the outcome form.

See HOW TO COMPLETE THE DSR presentation for guidance on this section

**3.3 IF ALIVE – DISABILITY RATING SCALE** *(tick one response for each box) – see overleaf for guidance*

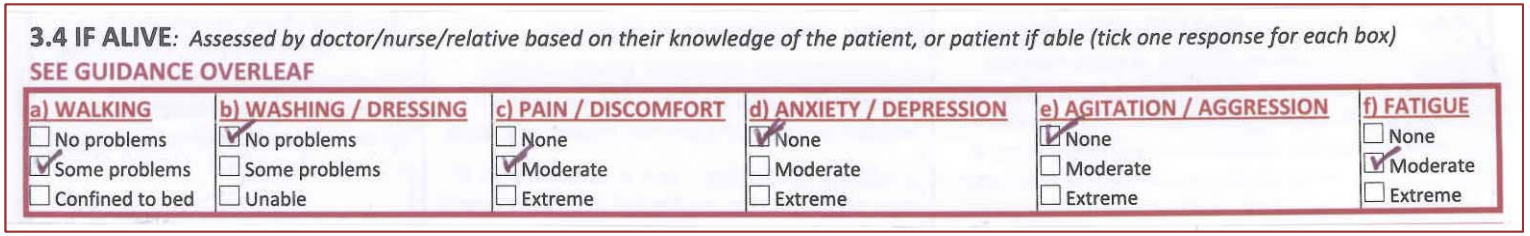
| a) EYE OPENING | b) COMMUNICATION ABILITY | c) MOTOR RESPONSE | d) FEEDING | e) TOILETING |
|---|---|---|---|---|
| ☐ Spontaneous | ☐ Oriented | ☐ Obeying | *(cognitive ability only)* | *(cognitive ability only)* |
| ☑ To Speech | ☑ Confused | ☑ Localizing | ☐ Complete | ☐ Complete |
| ☐ To Pain | ☐ Inappropriate | ☐ Withdrawing | ☑ Partial | ☑ Partial |
| ☐ None | ☐ Incomprehensible | ☐ Flexing | ☐ Minimal | ☐ Minimal |
| | ☐ None | ☐ Extending | ☐ None | ☐ None |
| | | ☐ None | | |

| f) GROOMING | g) LEVEL OF FUNCTIONING | h) EMPLOYABILITY |
|---|---|---|
| *(cognitive ability only)* | *(physical, mental, emotional or social function)* | *(as a full time worker, homemaker, or student)* |
| ☐ Complete | ☐ Completely independent | ☐ Not restricted |
| ☑ Partial | ☐ Independent in special environment | ☐ Selected jobs, competitive |
| ☐ Minimal | ☐ Mildly dependent – limited assistance | ☐ Sheltered workshop, non-competitive |
| ☐ None | ☑ Moderately dependent – moderate assistance | ☑ Not employable |
| | ☐ Markedly dependent – assist all major activities, all times | |
| | ☐ Totally dependent – 24-hour nursing care | |

**You must tick one box for response to each of the eight questions**

# Section 3.4 – Status if alive

Complete the Assessment questions **a–f** following the guidance on reverse of the outcome form.



**3.4 IF ALIVE**: *Assessed by doctor/nurse/relative based on their knowledge of the patient, or patient if able (tick one response for each box)*

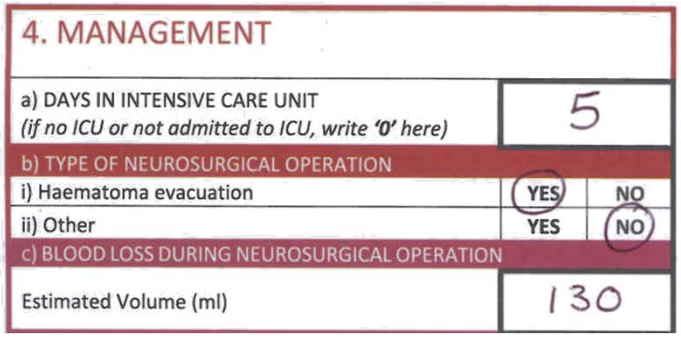
SEE GUIDANCE OVERLEAF

| a) WALKING | b) WASHING / DRESSING | c) PAIN / DISCOMFORT | d) ANXIETY / DEPRESSION | e) AGITATION / AGGRESSION | f) FATIGUE |
|---|---|---|---|---|---|
| ☐ No problems | ☑ No problems | ☐ None | ☑ None | ☑ None | ☐ None |
| ☑ Some problems | ☐ Some problems | ☑ Moderate | ☐ Moderate | ☐ Moderate | ☑ Moderate |
| ☐ Confined to bed | ☐ Unable | ☐ Extreme | ☐ Extreme | ☐ Extreme | ☐ Extreme |

**You must tick one box for response to each of the six questions**

# Section 4 – Management

***IT IS ESSENTIAL THAT ALL QUESTIONS ARE ANSWERED***



| 4. MANAGEMENT | | |
|---|---|---|
| a) DAYS IN INTENSIVE CARE UNIT *(if no ICU or not admitted to ICU, write '0' here)* | 5 | |
| b) TYPE OF NEUROSURGICAL OPERATION | | |
| i) Haematoma evacuation | (YES) | NO |
| ii) Other | YES | (NO) |
| c) BLOOD LOSS DURING NEUROSURGICAL OPERATION | | |
| Estimated Volume (ml) | 130 | |

**4a)** Please write **0** if there is no ICU department or if the patient was not admitted to ICU – part day counts as 1

**4b)** Please ensure you circle one choice on EACH LINE – do not leave any without circling either YES or NO

(*the estimated blood loss volume refers only to the volume lost during the first neurosurgical operation after randomisation*)

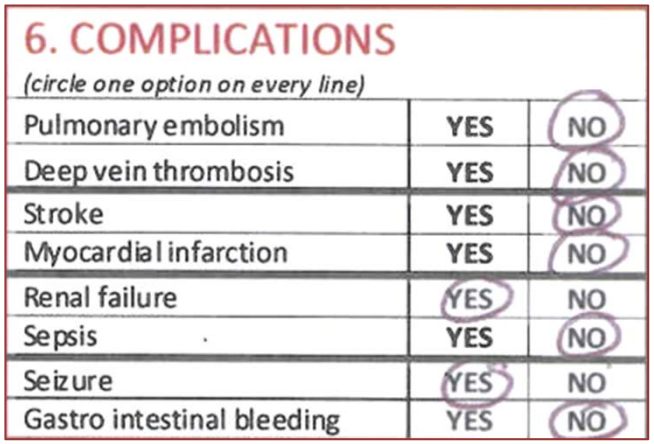
# Section 5 – Trial treatment

***Please ensure you circle one choice on EACH LINE***

| 5. TRIAL TREATMENT | | |
|---|---|---|
| a) Loading dose given | YES | NO |
| b) Maintenance dose given | YES | NO |

- You must circle one choice for EACH dose – do not leave blank
- If either dose is **only partially given** it must be entered here as NO
- Only a fully administered dose will be YES

# Section 6 – Complications
# Section 7 – Other complications



**6. COMPLICATIONS**

*(circle one option on every line)*

| | | |
|---|---|---|
| Pulmonary embolism | YES | NO |
| Deep vein thrombosis | YES | NO |
| Stroke | YES | NO |
| Myocardial infarction | YES | NO |
| Renal failure | YES | NO |
| Sepsis | YES | NO |
| Seizure | YES | NO |
| Gastro intestinal bleeding | YES | NO |

- All complications listed must be a confirmed diagnosis
- You must circle either YES or NO for ALL complications
- Any complication not listed here but fulfils the Adverse Event criteria (see Protocol page 13) should be reported using the 'Adverse Event Reporting Form'

# Section 8 – Person completing the form

***This section must be completed in full – it is a declaration that the data is valid***

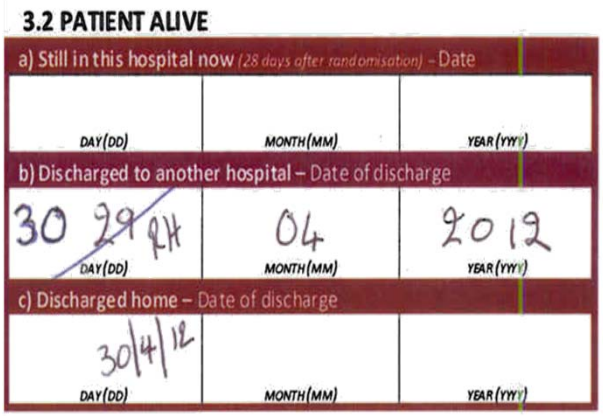
| 8. PERSON COMPLETING FORM | | | THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL DATA SUBMITTED |
|---|---|---|---|
| a) Name | ROBIN HOOD | b) Position | CONSULTANT |
| c) Signature | R Hood | d) Date | 4/6/12 |

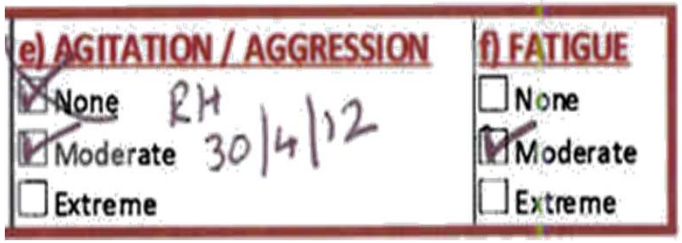
# Corrections

If you enter an incorrect value on the form:

- cross out the incorrect value so it is still visible
- enter the correct value alongside
- enter the date and your initials next to each change

## EXAMPLES



**Please store original forms in Section 16 of your Study File**

**SEE SEPARATE GUIDANCE ABOUT HOW TO SEND THE DATA FORMS TO THE TCC**

CRASH

Clinical Randomisation of an Antifibrinolytic in Significant Head Injury

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