HOW TO ASSESS ELIGIBILITY

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

ELIGIBILITY IN THE WOMAN-2 TRIAL

Inclusion criteria

Women with moderate or severe anaemia, who have given birth vaginally and for who the responsible clinician is substantially uncertain whether to use TXA.

Exclusion criteria

- Who are not legally adult (<18 years) and permission not provided by a guardian
- With a known allergy to TXA or its excipients
- Who develop PPH before umbilical cord is clamped/cut

ELIGIBILITY IN THE WOMAN-2 TRIAL

Criteria	Comments
Women with moderate or severe anaemia	Hb <10 g/dL as assessed on arrival to hospital
Vaginal Delivery	Women with planned vaginal delivery will be considered for the trial. Eligibility confirmed at the delivery of the baby's anterior shoulder
Legally adult (if <18, guardian present)	Women must be 18 years or older unless permission is provided by her guardian
Where the responsible clinician is substantially uncertain whether to use TXA in that particular patient	• If clinician is certain or there is a clear indication for the use of TXA, the participant should NOT be randomised • If there is a clear contraindication to the use of TXA, the participant should NOT be randomised • If the clinician is uncertain about the use of TXA in a particular participant, the participant SHOULD be randomised
Without PPH before umbilical cord is cut or clamped	Women who develop PPH before the cord is cut or clamped will be excluded as there is evidence that TXA improves outcomes in these women

THREE STAGES OF ELIGIBILITY SCREENING

1. Anaemia screening at admission

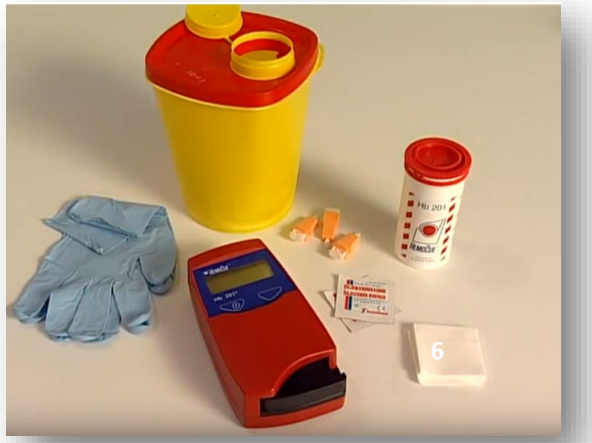
2. Initial assessment of eligibility after admission, before delivery

3. Final eligibility check at delivery

STAGE 1: ANAEMIA SCREENING AT ADMISSION

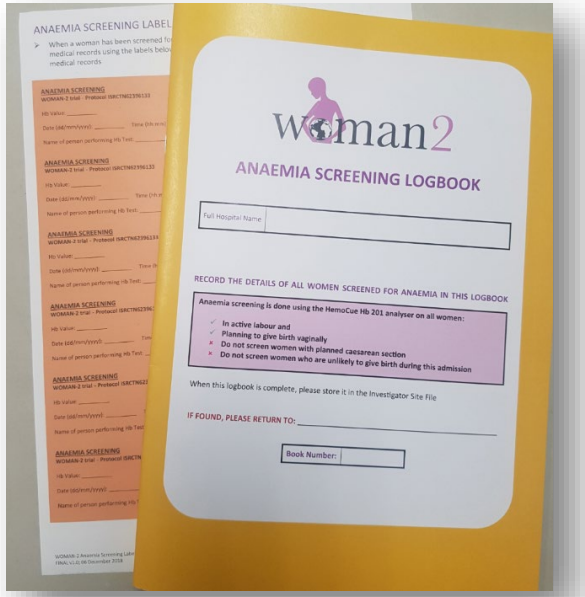
Screen women with HemoCue analyser if:

- Planned vaginal birth
- Already in active labour
- DO NOT screen women with planned caesarean
- DO NOT screen women who are unlikely to give birth during this admission



What materials will you need?

- HemoCue Hb 201 analyser and consumable
- WOMAN-2 Anaemia Screening Logbook
- WOMAN-2 Anaemia Screening Labels



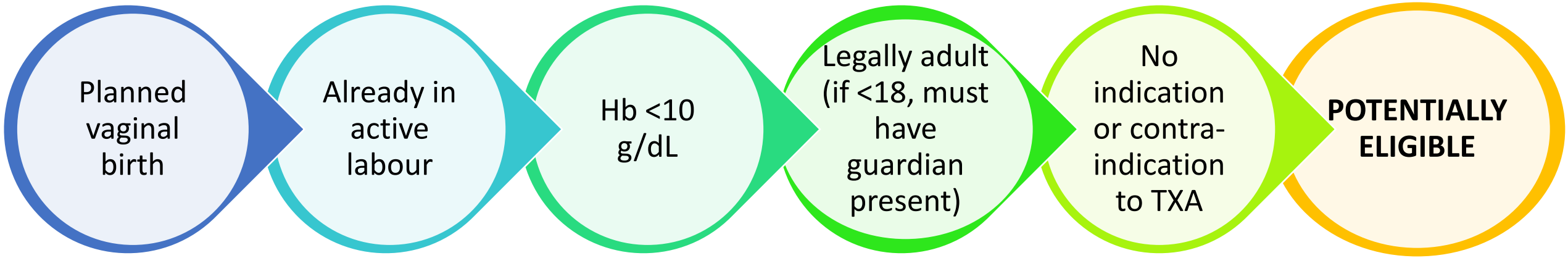
Documenting anaemia screening

- Give results to woman
- Enter results in the Anaemia Screening Logbook
- Record results in woman ’s medical records. Place WOMAN-2 anaemia screening labels on front of medical record

STAGE 2: INITIAL ASSESSMENT OF ELIGIBILITY (BEFORE DELIVERY)

After a women as been admitted, an **initial assessment of eligibility** should be carried out.

Review the anaemia screening result in woman's medical records and check the woman is/has:



If eligible, follow appropriate consent procedure:

1. Obtain permission to approach the woman from her clinician
2. Obtain fully informed consent if the woman has capacity
   - Obtain verbal agreement if woman does not have full capacity
   - Obtain fully informed consent as soon as woman has regained capacity
3. Record consent procedure used.

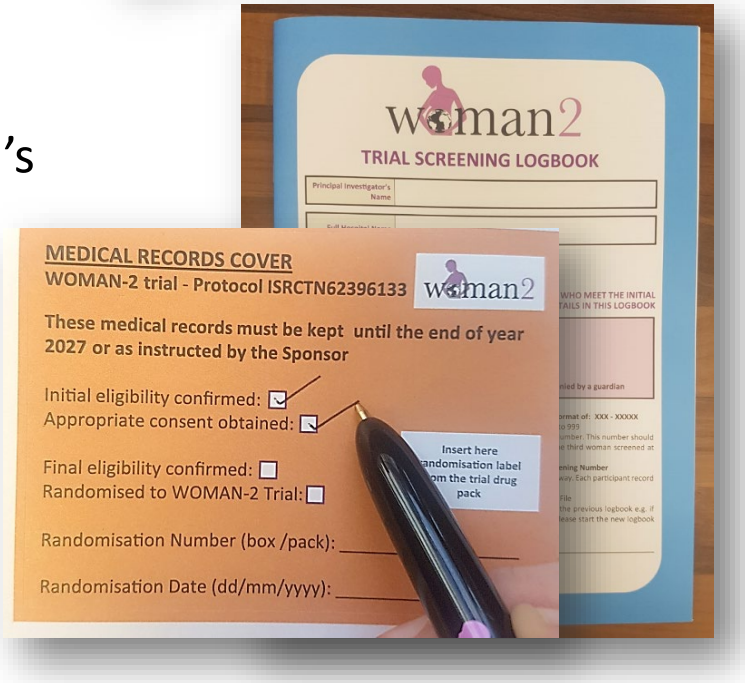
STAGE 2: INITIAL ASSESSMENT OF ELIGIBILITY (BEFORE DELIVERY)

What materials will you need?

- Woman's medical records.
- Trial Screening logbook.
- Participant Information Sheet and Informed Consent Form.
- WOMAN-2 Consent Labels.
- WOMAN-2 Medical Records Labels.
- Case Report Form (CRF) Booklet.

Documenting initial assessment of eligibility

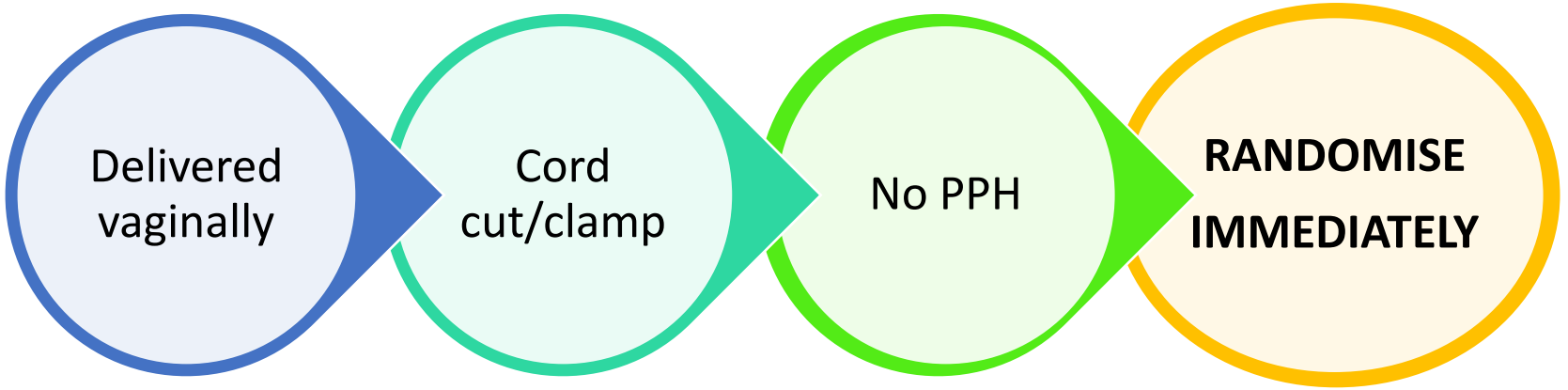
- Record details in trial screening logbook.
- Fix the WOMAN-2 medical records cover label to the **front** of the woman's medical records and complete accordingly.
  - Tick to confirm the woman is eligible.
  - Tick to confirm appropriate consent obtained.
  - Leave all other sections blank. These can be completed at the point of delivery and randomisation.



- Record consent procedure used in medical records.
- Complete appropriate sections A-G of the Baseline Form in your CRF booklet.

STAGE 3. FINAL ELIGIBILITY CHECK

A final eligibility check should be carried out **at delivery of the baby's anterior should and up to when the cord is cut/clamped:**



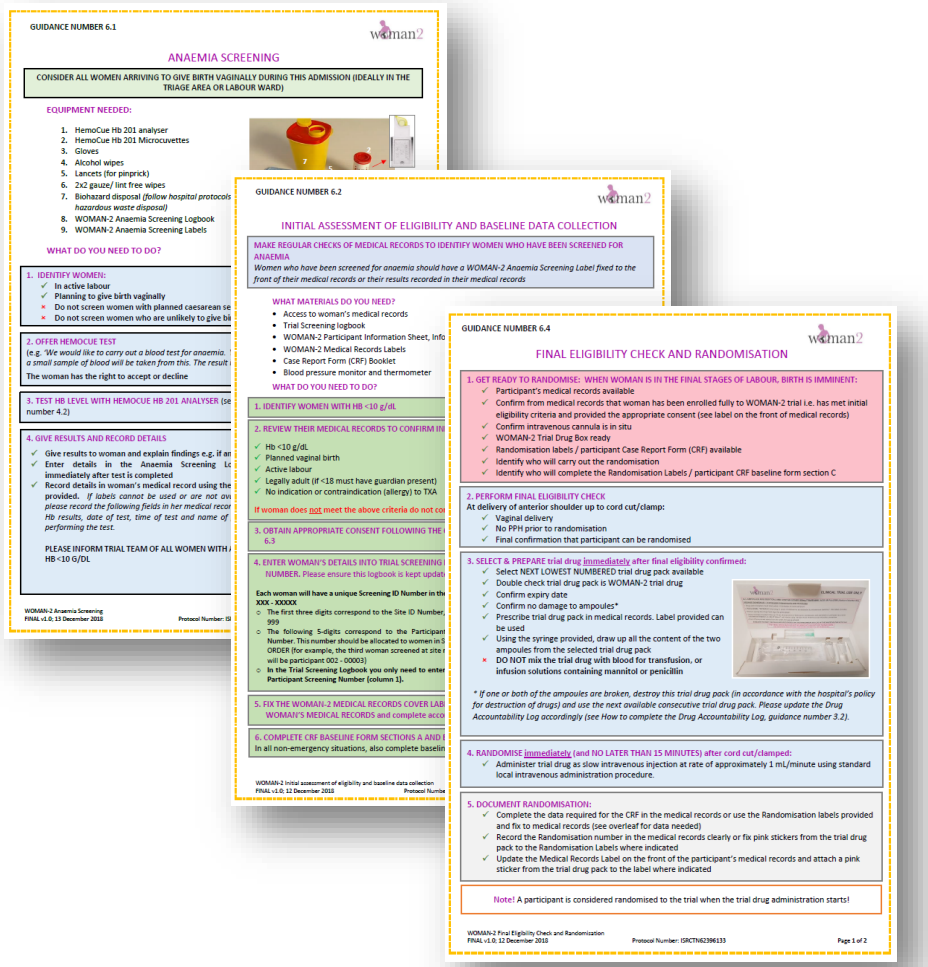
FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 6:

1. Anaemia screening, guidance number 6.1.

2. Initial assessment of eligibility and baseline data collection, guidance number 6.2.

3. Final eligibility check and randomisation, guidance number 6.4.



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