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1. CRADLE Vital Sign Alert

The CRADLE Vital Sign Alert device detects heart rate and blood pressure and calculates shock index, the most consistent predictor of maternal morbidity in a high-risk population. Results are displayed on a traffic light providing a visual trigger for action when abnormalities in the vital signs are detected. The battery can be recharged using a standard micro USB and will last for over 200 measurements.

Best practice for taking blood pressure:

To use the cradle device:

- Before taking the blood pressure, the patient should remain seated and at rest for 5 minutes.
- Ensure the patient is seated with feet on the floor. If this isn’t possible, they should lie on their left side and check the BP in left arm.
- Support the arm on a table/cushion or by their side. The arm should be at the level of the heart.
- Explain the procedure and gain permission
- Remove all tight clothes from around the arm.
- Explain what the patient will experience:
  - Tight feeling
  - Minor discomfort perhaps
  - Pins and needles in fingers
- Ask her not to talk during the measurement.
Common Errors
Wrong size cuff:

- There are two cuff sizes for the device, standard or large.
- The standard cuff will fit most women (arm circumference 22cm-32cm).
- When you fit the cuff the metal bar should cross the black marker.
- If it does not then the cuff is too small, change to the large cuff (arm circumference 32cm – 42cm).

Wrong position of the cuff:

- The Velcro should be tightened so that the cuff is secure on the arm but not tight.
- You should be able to insert two fingers between the cuff and the arm.
- The yellow tab should be two fingers width above the elbow crease.

Wrong patient position:

- Blood pressure should always be checked in the sitting position.
- Her legs should not be dangling or crossed. Her feet should be supported or on the ground.
- If the patient cannot sit up, lie her on her left side and make sure to document this. Check BP in the inferior arm.
- If the patient cannot turn on her side, place a wedge under her right hip. Check BP in the inferior arm.

Taking the measurement

- Fit the cuff to the participant.
- Ensure the cuff is attached to the blood pressure machine.
- Turn the device on.
- Pump approximately 40 mmHg higher that the expected systolic blood pressure value.
- A beep will sound and flashing arrows will disappear when you have reached the appropriate pressure, this will be at a number over 180.
- NOTE: If you have not pumped enough, the following pointers will appear again and flash telling you to pump higher.
- After pumping, the measurement will be taken automatically and shown on the screen.
- Ask the participant to relax, not to move and not to tense their arm muscles until the measurement results are displayed.
• The patient should breathe normally and not talk.
• During the measurement, the pulse indicator flashes on the display and a beep sounds every time a heartbeat is detected.
• The result, comprising the systolic and the diastolic blood pressure value and the pulse rate is displayed and a longer beep sound is heard.
• Record the measurements in the database.
• Repeat the process to get a second measurement and record the measurement in the database.
• If the two measurements differ by more than 10mmHg, repeat the measurement a third time and record the values in the database.

Error Messages

• If an error occurs during the measurement, the measurement is interrupted and an error message is displayed.
• Check the cuff is in the correct position, is attached correctly to the device and that the patient is still and quiet.
• Then try again.

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Potential cause and remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;&lt;X 1 &gt;&gt;</td>
<td>Signal too weak</td>
<td>The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement</td>
</tr>
<tr>
<td>&lt;&lt;X 2 &gt;&gt;</td>
<td>Error signal</td>
<td>During the measurement, error signals were detected by the cuff, cause for instance by movement or muscle tension. Repeat the measurement keeping your arm still.</td>
</tr>
<tr>
<td>&lt;&lt;X 3 &gt;&gt;</td>
<td>No pressure in the cuff</td>
<td>An adequate pressure cannot be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and it is not too loose. Repeat the measurement.</td>
</tr>
<tr>
<td>&lt;&lt;X 5 &gt;&gt;</td>
<td>Invalid result</td>
<td>The measuring signals are invalid and no result can therefore not be displayed. Read through the checklist</td>
</tr>
<tr>
<td>&lt;&lt;HI&gt;&gt;</td>
<td>Pulse or cuff pressure too high</td>
<td>The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Relax and repeat the measurement.</td>
</tr>
<tr>
<td>&lt;&lt;LO&gt;&gt;</td>
<td>Pulse too low</td>
<td>The pulse is too low (less than 40 beats per minute). Relax and repeat the measurement.</td>
</tr>
</tbody>
</table>
Identifying abnormal vital signs and the clinical response

The CRADLE VSA measures blood pressure (BP) and heart rate (HR), and automatically calculates the shock index (SI).

- When measurement is complete, you will see a traffic light. These lights indicate whether the results are within normal limits or higher/lower than normal.
- If they are higher or lower than normal you will see either an “Up arrow” (↑) or “Down arrow” (↓).
- It is important that everyone understands both the lights and the arrows when deciding how to manage patients.
- SI is a calculation of HR divided by Systolic Blood Pressure.
- It is the best vital sign for prediction of maternal severe morbidity such as significant blood transfusion or admission to higher level care facility.

<table>
<thead>
<tr>
<th>Table 1. Classification of High blood pressure and CRADLE VSA RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td>Severe hypertension</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>Borderline low BP</td>
</tr>
<tr>
<td>Very low BP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Shock Index (SI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td>Severe shock</td>
</tr>
<tr>
<td>Shock</td>
</tr>
<tr>
<td>Normal</td>
</tr>
</tbody>
</table>
• If the results show red repeat the reading again immediately.
• If the results show yellow repeat again in 15 minutes of rest.
• If yellow or red light shows once only, measure vital signs a third time and follow pathway of most consistent light (i.e. if results show yellow then green, check a third time, if the third result is yellow then act on this as it is the most common result).

a) **Green light:**

• BP <140 systolic and <90 diastolic and shock index <0.9.
• The woman is likely to be healthy.
• Continue with normal care.

b) **Yellow light and up arrow:**

• Systolic BP ≥140 & ≤159 and/or diastolic ≥90 & ≤109.
• This is raised BP and this patient may have preeclampsia.
  Action is needed.
• Manage as you would normally e.g. measure urine dipstick, check for signs and symptoms (e.g. headaches, visual disturbance) and act accordingly.
• If in the community, transfer when practical (preferably within 24 hours).

c) **Yellow light and down arrow:**

• Shock Index (HR/Systolic BP) is ≥0.9 and <1.7.
• This result can be common in pregnant women, however; It may indicate that the mother is developing infection or bleeding. The patient needs to be assessed to decide what action is required.
• If she is well (no bleeding, no signs of infection, feels well) she may have anaemia, dehydration, an irregular heart rhythm or endocrine disease or her blood pressure may be low in pregnancy. Consider undertaking routine checks for these when possible.
• If she is unwell e.g. vaginal bleeding, fever, discharge, constant abdominal pain or if she feels unwell e.g. feverish, pale, sweaty, breathless:
  - Resuscitate as necessary e.g. keep warm, elevate legs.
  - Transfer urgently (preferably within 4 hours).
  - If bleeding, uterine massage after delivery of placenta, control of bleeding e.g. misoprostol, oxytocin, depending on what’s available.
  - If sepsis, consider starting antibiotics if available.
d) **Red light and up arrow:**
- Systolic ≥160 and/or diastolic ≥110
- This is very raised BP and indicates urgent action is needed
- Manage as you would normally e.g. measure urine dipstick, check for signs and symptoms and act accordingly
- Give antihypertensives if available e.g. methyldopa, nifedipine, Labetalol.
- Consider magnesium sulphate (intramuscular), if available
- If in the community, transfer as soon as possible (preferably within 4 hours)
- Monitor the baby.
- If BP remains uncontrolled and gestation appropriate, seek senior advice regarding need to deliver.

e) **Red light and down arrow:**
- Shock Index (HR/Systolic BP) is ≥1.7
- This may indicate serious infection or bleeding, urgent action is needed

i) **In community or hospital:**
- Stay calm. Do NOT leave the woman alone.
- Get HELP
- Assess the mother
- Is she pale, sweaty, cold, breathing fast, drowsy or confused?
- Is she unwell e.g. vaginal bleeding, fever, discharge, constant pain?
- Keep her warm and elevate legs if possible.

ii) **In hospital:**
- Stay calm. Do NOT leave the woman alone.
- IV fluids give quickly through a large bore cannula e.g. 2 litres in first hour
- Collect blood to test haemoglobin; do an immediate cross-match
- Catheterise the bladder to monitor input/output
- Decide on the cause of shock and manage as you would normally
- If bleeding, transfuse blood, give uterotonics such as IV oxytocin, misoprostol or Carboprost.
- Consider operative interventions if appropriate and available
- If severe infection, keep hydrated, give IV antibiotics
Care and Maintenance of the CRADLE VSA

a) **Cleaning CRADLE VSA**

- Clean the device only with a soft, dry cloth.
- Cleaning the cuff:
  - Take out the bladder.
  - Fold and place the cuff cover inside a washing bag.
  - Wash the cuff cover with warm water and a mild detergent in a washing machine.
  - Air dry the cuff. DO NOT iron the cuff cover.

b) **Charging VSA**

- If the batteries are almost empty, the battery display will flash and a partly filled battery is displayed. The device will still work reliably but it should be charged.
- If the batteries are flat, the battery display will flash and a flat battery is displayed. The device will not work until charged.
- The battery will last for 200 measurements.
- Depending how often the devices will be used in your area they will need charging at least once a week.
- The manager of each area should allocate a person to be responsible for this task and a safe designated place for the devices to be charged and stored.
- To charge the device connect it to the mains electricity using the charger or to a computer using the USB cable.
- During the charging process, the charging indicator will light up in orange.
- When the battery is completely charged, the charging indicator will light up in green.
- The device cannot be used while it is being charged.
- To improve the battery life of the device, charge the batteries until the charging indicator turns to green before using the machine for the first time and do not let the battery run down completely.

c) **Security and Care of Devices**

- The manager of each area should allocate a safe designated place for the devices to be stored when not in use.
- Devices are portable and where possible should be attached to firmer objects such as trolleys or tables using the cable wire and ferrules provided.
- Never attempt to open the devices, keep them out of direct sunlight and away from moisture.
2. Masimo Pulse Oximetry

The Masimo pulse oximetry device allows the measurement of a number of non-invasive spot check measurements. For the PRECISE study, we will be using this device to measure \( \text{SPO}_2 \) (functional oxygen saturation of arterial haemoglobin) and the haemoglobin concentration of women.

Setting up the pulse oximetry device

Attach the sensor cable to the device. Each sensor only allows for 1000 spot checks so these will need to be replaced. The number of measurements remaining on the sensor is displayed in the top right corner of the screen.

The main power screen is a touch screen where the results are displayed and allows for navigation of the device to change settings.

The home/power button allows navigation back to the homepage as well as allowing the device to be powered on and off.

The device can be charged by plugging the device in through mains electricity.

There are two sensitivity modes for taking measurements, NORM (normal) and APOD (Adaptive probe off detection sensitivity). For most participants, we want the setting to be APOD. However, if there is strong light and you are failing to get a reading, you should change the setting to NORM.

To do this:

- In the top right corner there is a downwards arrow. Press this and options will appear.
- Select sensitivity
- Change the sensitivity from APOD to NORM

If you have changed the sensitivity to NORM, ensure you change it back to APOD for future participants.
Taking the measurement

- To turn the device on/off hold down the ‘Home’ button for 2 seconds. The Home button will illuminate green when the power is on.

- You need to enter a label for the data and the participant’s gender. On the label field enter the participant ID. This will allow you to open her results again at a later date, if they are needed.

- Attach the probe to the woman. When choosing a finger, ensure it is the appropriate size for the sensor. Use the attachment to check the finger is the correct size. Place the finger in the measurement callipers, if the colour present is green, the finger is the correct size. If it is red, the finger is too small or large so select another finger.

- Once the sensor initialises, a progress bar will display at the top of the device until a SbHb is recorded.

- The spot check measurements are displayed for 5 minutes or until the sensor is removed. Once you have the SpHb measurement, remove the sensor from the participant.

- Record the SpHb and pulse oximetry in the database.

- Press ‘Done’, this will take you back to the home screen.
## Common Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Potential causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low SIQ message (low signal quality)</td>
<td>• Sensor is damaged or not functioning</td>
<td>• Verify sensor type</td>
</tr>
<tr>
<td></td>
<td>• Improper sensor type or application</td>
<td>• Check if blood flow to the sensor site is restricted</td>
</tr>
<tr>
<td></td>
<td>• Excessive motion</td>
<td>• Check the placement of the sensor. Move the sensor to another finger</td>
</tr>
<tr>
<td></td>
<td>• Low perfusion</td>
<td>• Minimise or eliminate motion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Set the settings to maximum sensitivity.</td>
</tr>
<tr>
<td>Difficulty obtaining a reading</td>
<td>• Inappropriate sensor or sensor size</td>
<td>• Allow time for parameter reading to stabilise</td>
</tr>
<tr>
<td></td>
<td>• Low perfusion</td>
<td>• Verify proper sensor type and size for the participant and re-apply senor</td>
</tr>
<tr>
<td></td>
<td>• Excessive motion artefact</td>
<td>• Check if blood for to sensor site is restricted</td>
</tr>
<tr>
<td></td>
<td>• Excessive ambient lighting</td>
<td>• Replace sensor</td>
</tr>
<tr>
<td></td>
<td>• Interference from line frequency induced noise</td>
<td>• Shield the sensor from excessive or strobing light</td>
</tr>
<tr>
<td>Parameter readings displayed as dashes</td>
<td>• Parameter may not be stabilised</td>
<td>• Allow time for parameter reading to stabilise</td>
</tr>
<tr>
<td></td>
<td>• Device may not be configured with the parameter</td>
<td>• Verify proper sensor type and size for the participant and re-apply senor</td>
</tr>
<tr>
<td></td>
<td>• Sensor is not compatible with the parameter</td>
<td>• Check if blood for to sensor site is restricted</td>
</tr>
<tr>
<td>Dimly lit parameters</td>
<td>• Low quality signal</td>
<td>• Replace sensor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Verify device and sensor are compatible with the parameter</td>
</tr>
<tr>
<td>Unexpected parameter readings</td>
<td>• Low SIQ or Pi values</td>
<td>• Assess the participant</td>
</tr>
<tr>
<td></td>
<td>• Inappropriate sensor size or sensor measurement location</td>
<td>• Verify proper sensor type and size for the participant and re-apply senor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Check if blood for to sensor site is restricted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Replace sensor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Minimise or eliminate motion at the measurement site</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Set to MAX sensitivity</td>
</tr>
</tbody>
</table>
To find previous measurements taken, on the home screen, click on the clipboard icon on the bottom left of the screen. This will bring up all the measurements taken using the label provided. You will be able to search these by participant ID.

Care and Maintenance of the device

- When cleaning the device use a soft damp cloth with one of the following cleaning solutions: 70% Isopropyl alcohol, Cidex plus (3.4% glutaraldehyde) or 10% chlorine bleach to water solution. Wipe the surface until it is free of any residues. Wipe again with a clean cloth. Do not use the device until it is properly dry.
- Battery – when the battery run time is significantly reduced, completely discharge and recharge the battery.
- The manager of each area should allocate a safe designated place for the devices to be stored when not in use.
3. Phone Ox

The Lionsgate pulse oximetry probes allow the measurement of the $\text{SPO}_2$ (functional oxygen saturation of arterial haemoglobin) and the heart rate. This device can be used on all women attending clinical care.

Setting up the pulse oximetry device

The Lionsgate sensors are compatible with any android device on which the OxPulse app has been downloaded. The app will be sent to the team from the King’s Coordinating team. Download the application on to each tablet required by:

- Plug the tablet in to the computer
- Transfer the pulseox.apk file to the downloads file in the tablet by dragging it in to the correct folder

- On the tablet, got to the downloads folder and click on the app to open it. This should add the app to the homescreen of the tablet so it is easily found
To attach the Lionsgate sensor to the tablet, you need to attach it a microUSB converter. Then plug the sensor into the port where you would normally charge the device.

Taking a measurement

The app will record the pulse oximetry and the pulse waves for one minute. It will only allow you to start recording the measurement when a good signal is received. The signal quality is shown on the app by the signal strength bar on the left hand side of the screen, red shows poor, orange shows it is getting better and green shows a good signal.
1. Attach the probe to the woman’s finger. Ask her to stay still and calm so you can obtain a good reading.
2. Once the app has a good signal and allows you to start the measurement, click the ‘Start’ button.
3. The app will record the data for one minute. You can see the progress of the app by the time bar.
4. If the signal drops off because the woman moved too much or the signal is poor, you can reset the reading by pressing the reset button.

Once the reading is complete, the following screen will appear which summarises the data.

a. **For non-PRECISE participants**, do not save the data. You can record the data for clinical purposes how do not save the data and upload the data to the PRECISE database. Click ‘Cancel’ on the top left corner to return to the homescreen where you can start a new measurement.

b. **For PRECISE participants** you must save the data and upload it to the PRECISE database. To this click on the done button.
5. Enter the PRECISE participant ID into the ID box, either by typing it in or by scanning the QR code using the tablet’s camera. Record any comments in the comments field.

6. If you type the ID in the box, you must press the ‘Enter’ button to return to the main screen, if you click the ‘Back’ button on the tablet, you will close the app and lose the data.
7. To take a new reading, press the ‘Back’ button and it will take you to the homescreen where you can take a new reading.
8. At the end of every day, or when you have a stable internet connection, upload the data to the database. To do this, press the ‘Upload’ button. The app will tell you when it is uploading data and when it is complete.
4. Anthropometry Measurements

One of the aims of the study is to investigate how maternal nutrition regulates placental function and how placental regulation of nutrient supply influences fetal growth. The way we will determine the influence of nutrition and nutrient supply is through anthropometric measurements, such as height and weight, of both the women and their babies at different time points in the study.

In order for the data to be comparable across different sites and data collectors, it is necessary to implement standardised procedures to ensure that measurements are being collected consistently by all data collectors. Each member of staff taking anthropometric measurements should be fully trained in how to take accurate and precise measurements of both infants and adults. In addition, they should undergo regular monitoring (standardisation) and, where necessary, re-training, to ensure the procedures are consistent within and between the multiple study sites to allow the data to be pooled.

Each site should appoint a lead anthropometrist who will then oversee training and regular monitoring of the other measurers. During training the lead anthropometrist should ensure measurers understand the reason for implementing specific procedures and the importance of adhering to them.

Equipment and Calibration

When using the anthropometry equipment, the scales, stadiometer and infantometer must be calibrated to ensure you can get precise readings. The measuring tapes do not need to be calibrated. The calibration should be recorded (see appendix 1 for calibration log).

Seca baby scale – this should be calibrated twice per week using a 5kg calibration weight if in a fixed location, or if moved, every time it is used.

- Ensure the scales are on a flat, even surface
- Turn the scales on so that the weight ‘0.000’ appears
- Place the 5kg weight in the middle of the scales. The display should now ready 5.00kg.
- If the reading does not say ‘5.00’, remove the weight, ensure the scales is on a flat surface and nothing is interfering with the weighing platform. Repeat the measurement again. Record the value on the calibration form (see appendix 1)
- If the reading still deviates, inform the lead anthropometrist.

Harpenden Infantometer – this should be calibrated twice a week using calibration rods if in a fixed location, or if moved, every time it is used.

- Ensure the infantometer is on a flat even surface
- Check the minimum value on the display with the minimum value on the board. Mark the minimum value on the calibration form
- Use the calibration rod (the length may vary across sites), and place this between the headboard and the footboard and take a reading. Check that the display reads the expected value and record this on the calibration form.
• Review the calibration form. If there are constant deviations of more than 3mm from the expected length, repeat the process.
• If the reading still deviates, inform the lead anthropometrist.

Seca adult scales - these should be calibrated twice per week using 40kg of calibration weights if in a fixed location, or if moved, every time they are used.

• Ensure the scales are on a flat even surface
• Turn the scales on so that the weight '0.000' appears
• Place weights totalling 40kg in the middle of the scales. The display should now read 40.0kg.
• If the reading does not say '40.0', remove the weight, ensure the scales are on a flat surface and nothing is interfering with the weighing platform. Repeat the measurement again.
• If the reading still deviates, inform the lead anthropometrist.

Seca adult stadiometer - this should be calibrated twice a week using calibration rods if in a fixed location, or if moved, every time it is used.

• Ensure the stadiometer is on a flat even surface
• Using a calibration rod (the length will vary across sites), place the rod under the headboard ensuring it is perfectly vertical. Place the headboard on the rod and read the value displayed. Record this value on the calibration form.
• Review the calibration form. If there are constant deviations of more than 3mm from the expected length, repeat the process.
• If the reading still deviates, inform the lead anthropometrist.

Measurement Procedures

Maternal weight

1. The woman should wear minimal, light clothing.
2. Ask the mother to remove any heavy objects and take off her shoes.
3. Ensure the scales are on a perfectly flat surface with no obstructions.
4. Turn the scales on by gently pressing a foot on the surface of the scales.
5. Ask the mother to stand on the scales, placing her feet on the footmarks pasted on the scales, and remain still until the weight appears. Make sure that the mother is not leaning on something or holding onto anything and that nothing is holding or touching her (or her clothing).
6. Read and record the weight in the database.
7. Please take the weight measurement twice more and record on the form as it appears on the display, i.e. to one decimal place. The average weight will then be calculated from the three measurements.

Maternal standing height

1. Ask the subject to remove their shoes and any headwear or hair ornaments. Measure the thickness of any irremovable braids/corn rows with a small plastic ruler and deduct this from the total height at the end.

2. Ensure the participant stands upright with their heels, buttocks and shoulders against the measuring rod. Heels should be together, feet parallel to each other and pointing forward. The back should be as straight as possible, which may be achieved by rounding or relaxing the shoulders and manipulating the posture. The knees should be straight.

3. Ask the subject to look straight ahead and hold her head in a Frankfort horizontal plane (this is the line between the lower left orbit and upper margin of the external auditory meatus).

4. The measurer should stand in front of the participant and stretch them upwards to the fullest extent by applying gentle traction by holding their head at each side over the mastoid process (just behind the ear). The subject’s heels must be watched to make sure they do not leave the ground while traction is being applied.

5. Slide the measuring slide or head piece down until it touches the top of the head.

6. Read off the measurement in centimetres and to the nearest mm below the counter and record.

7. Repeat the process to obtain two measurements.

Maternal sitting height

This is to measure the distance between the sitting surface and the top of the woman’s head.

1. Ask the subject to remove shoes and any headwear or hair ornament. Measure the thickness of any irremovable braids/corn rows with a small plastic ruler and deduct this from the total height at the head. Ask her to sit on the table or chair where the stadiometer has been placed, calibrated, and secured against the wall. Place books or boards below the subject’s feet as necessary to ensure that legs are bent at a 90 degree angle.

2. Place feet and knees together. Subject’s hands should be resting on her thighs. The lower back, shoulders, and back of the head should be pressed to the stadiometer along the midline.
3. Stand in front of the subject to ensure that she is centred.

4. The Frankfort plane (line between the lower left orbit and upper margin of the external auditory meatus, i.e. the upper boundary of the ear hole) must be horizontal. The correct position to achieve this means the subject should be looking straight ahead. The head should not be tilted upwards or downwards.

5. The measurer should stand in front of the participant. The measuring slide or head-piece is then lowered onto the head so that it is touching without bending and the reading taken in centimetre and to the nearest mm below the counter and recorded.

6. Repeat the process to obtain two sitting height measurements.

Maternal lower leg length

1. Ask the subject to remove shoes and be seated in a chair. Make sure lower leg is visible.

2. Adjust knee bend angle to 90 degrees, placing books or boards beneath the subject’s foot as needed. Adjust foot so that big toe is pointing forward.

3. In the inner left ankle, locate the middle point of the bony protrusion. Draw a mark.

4. In the inner front of the left knee, locate the dip between the patella and the top of the tibia. Tracing over from this point with your finger, locate the point on the inner side of the left knee that is directly above the mark on the left ankle. Draw a mark.

5. Use a soft tape measure to measure the distance between these two marks, using the zero end of the tape measure at the ankle. The tape measure should be perpendicular to the floor.

6. Record the measurement in centimetres and to the nearest full mm.

7. Repeat the process to obtain two lower leg length measurements.

Maternal mid upper arm circumference

1. You must use a tape that is appropriate/specially manufactured for the purpose (e.g. is non-stretchy).

2. Before taking the arm circumference, you need to identify the point at which the measurement is taken. The mid upper arm landmark is taken as the point on the lateral side of the upper arm, midway between the lateral border of acromion and the tip of the olecranon when the arm is flexed to 90 degrees.
3. The subject should be asked to stand with their arm hanging freely. Stand to the side of the subject and feel for the lower border of the acromion process of the scapula. This is easily located as the outer and the lowest border of the flat bony prominence over the shoulder.

4. The olecranon is the most proximal process of the ulna and can be easily identified as the point of the elbow.

5. Place the upper end of the measuring tape on the acromial process and run the tape down along the arm to touch the tip of the olecranon process. Read the distance between these 2 points and note it on the form. Divide the distance by 2 and mark the halfway point with a pen. This point is the standard midpoint.

6. The participant must be sitting and the arm hanging straight but relaxed. The mid upper arm circumference (MUAC) is taken at the position of the standard. After determining the midpoint of the upper arm, follow the four steps below to measure the MUAC:

   **Focus:** Thread the tape around the arm. Hold the two ends of the tape with a grasp (with the index finger and thumb of each hand).

   **Secure:** Hold the tape with the index finger and thumb with your right hand only at the junction where the tape passes through the slot.

   **Inspect:** Look and feel the tension of the tape around the arm for any noticeable gaps or the tape pulling too tight. Adjust the tension of the tape if necessary, re-secure and re-inspect.

   **Read:** Make sure not to pull the tape as you read the measurement.

7. Record the arm circumference in centimetres and to the nearest mm.

8. Repeat the process to obtain two measurements. You don’t need to remove the tape after each measurement for the second record, but just release and take the second reading while maintaining the tape at the midpoint.
Infant weight

1. Check the scale is on a flat, level surface, with no obstructions.

2. Turn scale on.

3. The baby should be naked. In cold climates, an incandescent light bulb can be positioned over the scale to warm the surface of the weighing pan, making it more comfortable for the baby. In cultures where it is unacceptable for the baby to be undressed, the scale can be tared using a blanket (see instruction in box below).

4. Place the baby carefully on the scale and wait for the baby to stop moving.

5. Once the baby has stopped moving, record the weight on the form in grams.

6. Repeat the process to obtain two measurements.

**NOTE:** If the baby is agitated and cannot be calmed, ask for the mother’s help. If the baby remains very agitated, it is best to give the baby back to the mother until he/she calms down.

Infant length

1. The measuring board should be placed on a raised hard surface so that it is level and stable.

2. Foot and headwear must be removed from the child.

3. The measurement is best achieved by the presence of two people. If two staff members are not available, ask the mother/caregiver for support. The infant should be placed on the board with their head positioned against the head board. The child’s head could glide down as the child moves, making a gap between the head and the base of the board. To reduce the gap, make sure you move the child’s whole body by lifting the child from the hips. DO NOT PULL THE CHILD’S NECK as this will artificially lengthen the body. The head should be held gently but firmly so the Frankfort plane is vertical (a vertical line between the ear canal and lower border of eye socket is perpendicular to the measuring board).
4. To keep the infant’s head in the correct position, the measurer should gently cup their hands over the infant’s ears.

5. The second (lead) measurer, positions the infant so the spine and legs are straight and the toes point vertically. Gentle pressure is applied to the knees to straighten the legs. Sometimes it is very difficult to get the toes to point vertically. In this case the legs should be lifted up simultaneously so that the knees are straight but the legs bend 45 or more degrees at the hip, until the toes can be brought up, or the ankle bent to 90 degrees. The legs can then quickly be lowered so the heel touches the plate.

6. To take the measurement, slide the footboard so that it touches the infant’s feet. The soles of the feet should be flat with the toes pointing vertically. If the infant bends their toes, gently stroke the soles slightly and draw the footboard up when they unbend their toes. Take care that the knees are straightened only as far as they can without harming the infant. Be aware that for newborns and very preterm infants, it is impossible to straighten their knees to the same degree as older infants as they can be very fragile and easily injured if too much pressure is applied to the legs. Therefore, only minimum pressure should be applied.

7. When taking the measurement the footboard should be pressed against the feet gently so there is a small compression of the tissue on the feet. The measurement should be recorded to the last completed 1mm. For example, if the measurement is between 61.3cm and 61.4cm, record 63.3cm.

8. Repeat the process to obtain two measurements. You don’t need to take the child off the board after each measurement, but just release the foot piece and readjust the child before taking the second recording (Repeat steps 3-7). When you are finished taking the measurement, gently pick the child up, while supporting both the head and the body, and return the child to the mother/caregiver.
Infant mid-upper arm circumference

1. You must use a tape that is appropriate/specially manufactured for the purpose (e.g. is non-stretchy).

2. Before taking the arm circumference, you need to identify the point at which the measurement is taken. The mid upper arm landmark is taken as the point on the lateral side of upper arm, midway between the lateral boarder of acromion and the tip of the olecranon when the arm is flexed at 90 degrees.

3. The infant should be held with their arm hanging freely. Stand to the side of the infant and feel for the lower border of the acrominion process of the scapula. This is easily located as the outer and the lowest border of the flat bony prominence over the shoulder.

4. The olecranon is the most proximal process of the ulna and can be easily identified as the point of the elbow.

5. Place the upper end of the measuring tape on the acromial process and run the tape down along the arm to touch the tip of the olecranon process. Read the distance between these 2 points and note it on the form. Divide the distance by 2 and mark the halfway point with a pen. This point is the standard midpoint. After determining the midpoint of the upper arm, follow the below four steps to measure the MUAC:

   **Focus:** Thread the tape around the arm. Hold the two end of the tape with a grasp (with the index finger and thumb of each hand).

   **Secure:** Hold the tape with the index finger and thumb with your right hand only at the junction where the tape passes through the slot.

   **Inspect:** Look and feel the tension of the tape around the arm for any noticeable gaps or the tape pulling too tight. Adjust the tension of the tape if necessary, re-secure and re-inspect.

   **Read:** Make sure not to pull the tape as you read the measurement.

6. To obtain the arm circumference, the infant’s arm must be hanging straight but relaxed. The mid upper arm circumference (MUAC) is taken at the position of the standard midpoint. Ensure the tape measure is held closely to the skin, and touches everywhere, but is not too tight as to indent the skin.

7. Record the arm circumference in centimetres and to the nearest mm.

8. Repeat the process to obtain two measurements. You don’t need to remove the tape after each measurement, but just release and take the second reading while maintaining the tape at the midpoint.

Infant head circumference

A metal tape measure marked in centimetres and millimetres is used to measure head circumference.

1. Any hair ornaments or head bands should be removed.
2. The infant is held on the assistant measurer or mother’s lap. The lead measurer sits by the side of the mother or measurer holding the infant.

3. Loop the tape ensuring the side of the tape with centimetres is on the outside for the reading, with the zero end in the inferior position.

4. The measurer anchors the tape just above the eyebrows, with the zero point on the tape closest to them. The tape is then positioned at the back of the head over the fullest protuberance of the skull. The second measurer can help to position the tape correctly, i.e. by keeping it level on the other side of the head.

5. Once the tape is in the correct position, pull the tape tightly to compress the hair and skin. Be careful not to pull the tape too tightly as to injure the infant.

6. Take the reading in centimetres to the last completed 1mm and remove the tape from the infant’s head.

7. Record the measurement in the database.

8. Repeat the process to obtain two measurements.

Main sources of error

Error in infant measurements can come from the child being agitated and therefore making it difficult to take accurate measurements. If a baby is crying, reassure the mother and explain you are not hurting them. It may be best to delay the measurements rather than taking an inaccurate one.

Digit preference – when the anthropometrist rounds up or down to get ‘0’ or ‘5’. When we analyse the data we will look at how often each of the digits is used as a final number. We would expect each digit to be used about 10% of the time; however if ‘0’ or ‘5’ are being used much more frequently, it is suggesting the team are rounding their measurements.

Data transposition is when the numbers are transposed when written; for example, 39.8 is recorded instead of 38.9. Measurements should be recorded straight away to minimise any errors in the number recorded.

Errors with scales can appear when the batteries are low. Ensure you have spare batteries on site for the scales to ensure you get accurate readings.

The accuracy and precision of measurements are independent of each other and are determined by the anthropometrist and the instruments.

Accuracy

- If the instrument is not calibrated correctly, it will give values which are too low or high compared to the true value. It is important the equipment is calibrated frequently to ensure accurate measurements are obtained.
- Measurer accuracy means they consistently obtain measurements close to the true value. If the measurer is inaccurate, it means they constantly record values higher than the true value (positive bias) or lower than the true value (negative bias). Measurers should be trained so that they obtain values similar to those of the lead anthropometrist, as they are considered the ‘gold standard’. Lack of accuracy will be identified through the standardisation sessions.

**Precision**

- Instrument precision will be affected if the equipment is not calibrated frequently. Decalibrated equipment is not precise and any measurements taken will not be accurate.

- Measurer precision is determined by consistently measuring using the same technique. If precise, the measurer will record the same value when re-measuring the same child (within a time period when the child has not grown or the equipment has become decalibrated). Lack of precision will be identified in the standardisation sessions where two measurements are taken from the same child on the same day but not at exactly the same time. If a measurer is precise, these two measurements will be similar to each other and similar to the gold standard.

**Quality control**

To ensure we are collecting reliable data, standardisation sessions are held to ensure the measurers are following the recommended techniques, to monitor their accuracy and precision and, if required, take corrective measures. The measurers repeat measurements on a minimum of 10 volunteers. The repeated measurements are independent, i.e. each measurer measures all 10 volunteers and then measures them all in a second round, recording the results on a separate form. These test-retest data will be entered into a customised spreadsheet to calculate reliability statistics. Depending on the number of measurers at a site, one or two days is required for the standardisation sessions which should take place every 6 months.

**Standardisation Procedure**

Lead anthropometrists should aim to work with groups of no more than 5 measurers at a time, to prevent upsetting those being measured. Each measurer will measure 10 different participants twice, however they will take a break between measurements to check for precision. Starting with the first participant, the lead anthropometrist takes the required measurement followed by each of the measurers in turn. Each measurer should record their own measurements for each participant on their anthropometry standardisation form (see Appendix 2). After each measurement, all the forms containing measurements should be given to the lead anthropometrist. The group should then repeat the process a second time, re-measuring each participant starting with the first participant measured. They must record their measurement on the second part of the standardisation form (see Appendix 2).

The measurements taken by the measurers should then be compared to those taken by the lead anthropometrist to ensure the measurers’ precision and accuracy. Measurers who have consistently recorded measurements which deviate from the lead anthropometrists should then undergo re-standardisation training with the lead anthropometrist.
Standardisation Data Analysis

**Precision**

To measure the accuracy of the measurers, we have to compare each of their values to those of the lead anthropometrist. Each measurement type has a level of deviation that is acceptable, for example in infant length, it is acceptable for the measurer to be up to 0.7cm different from the lead anthropometrist before the measurer is considered to be inaccurate. The acceptable levels of deviation are in the table below.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Acceptable deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant length</td>
<td>0.7cm</td>
</tr>
<tr>
<td>Infant head circumference</td>
<td>0.5cm</td>
</tr>
<tr>
<td>Infant weight</td>
<td>5g</td>
</tr>
<tr>
<td>Infant mid-upper arm circumference</td>
<td>0.5cm</td>
</tr>
<tr>
<td>Adult standing height</td>
<td>0.7cm</td>
</tr>
<tr>
<td>Adult sitting height</td>
<td>0.7cm</td>
</tr>
<tr>
<td>Adult weight</td>
<td>5g</td>
</tr>
<tr>
<td>Adult mid-upper arm circumference</td>
<td>0.5cm</td>
</tr>
<tr>
<td>Adult lower leg length</td>
<td>0.5cm</td>
</tr>
</tbody>
</table>

If the measurers’ results are similar to those of the gold standards, they are said to be unbiased. However, if the measurements deviate from the gold standards, they are said to be biased.

The ‘Technical Error of Measurement’ (TEM) shows how precise a measurer is. The TEM compares the measurers’ own values when they have measured the same subject multiple times to see if they are consistently getting the same measurement. If they consistently get the same measurement, they are said to be precise. If however, a measurer gets significantly different values when measuring the same subject, they are said to be imprecise.

The table below demonstrates the variance in precision and accuracy which can be observed during training and standardisation activities. The measurements of the lead anthropometrist represent the “Gold Standard” both in terms of precision and accuracy and which all measurers should aim for; the measurements taken by measurers 1 and 2 vary little, if at all, from the measurements taken by the lead anthropometrist and these measurers therefore do not require retraining or re-standardisation. The measurements taken by measurers 3, 4 and 5, however, demonstrate unacceptable degrees of variance from the Gold Standard; these measurers should therefore be required to undergo re-standardisation training with the lead anthropometrist until they achieve the same level of precision and accuracy as the lead anthropometrist.
<table>
<thead>
<tr>
<th>Measurer</th>
<th>Measurement</th>
<th>Precision</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>Mean</td>
</tr>
<tr>
<td>Lead Anthropometrist</td>
<td>50.1</td>
<td>50.1</td>
<td>50.1</td>
</tr>
<tr>
<td>1</td>
<td>50.1</td>
<td>50.1</td>
<td>50.1</td>
</tr>
<tr>
<td>2</td>
<td>50.2</td>
<td>49.8</td>
<td>50.0</td>
</tr>
<tr>
<td>3</td>
<td>48.1</td>
<td>52.5</td>
<td>51.3</td>
</tr>
<tr>
<td>4</td>
<td>48.2</td>
<td>48.6</td>
<td>48.4</td>
</tr>
<tr>
<td>5</td>
<td>52.3</td>
<td>52.5</td>
<td>52.4</td>
</tr>
</tbody>
</table>

The measurements should be entered into the PRECISE data analysis spreadsheet where the values will automatically be calculated and will inform the team if measurers need to be re-trained.
5. Symphyseal-fundal height

The woman should lie in the supine position and should have an empty bladder. To measure the uterine height:

1. Use a metric tape which is non-elastic. Use the tape measure with the measurements on the underside to prevent bias.
2. Hold the 0cm marking of the tape in one hand at the upper border of the symphysis pubis bone.
3. Pass the tape in a straight line from the symphysis pubis over the uterus to the fundus uteri until you feel resistance from the abdomen wall. Ensure the tape measure stays in contact with the skin.
4. Fold the measuring tape at the level of the fundus. Turn the tape so you can read the measurement in cm and record this in the database.
6. TraCer

The TraCer device is a low-cost tool being developed to estimate the gestational age of pregnancies in settings where full ultrasound scans are not readily available. This tool is designed to be used by health care workers who are not trained in the use of ultrasound however with basic instruction, the aim is for suitable images to be captured for the gestational age to be calculated.

The gestational age will be calculated from the trancerebellar diameter (TCD) and head circumference (HC). The TCD correlates with GA and is relatively protected from the influence of fetal growth restriction and remains reliable throughout pregnancy. Where the TCD is not available (this can be hard to measure later in pregnancy) the HC can be used to estimate the gestational age. Growth charts relating TCD and HC to gestational age have been developed by the INTERGROWTH-21\textsuperscript{st} study and equations from that study are being used by TraCer.

Data Acquisition

The TraCer device comprises of a tablet (Huawei MediaPad M5 light) and a Konted wireless ultrasound probe. Using these devices, short video loops of the fetus’ head are acquired from which the TCD and HC can be measured and the GA derived. From each participant, three videos will be saved on to the tablet which are transferred to the Oxford Coordinating team for analysis.

Training and Standardisation

As the health care workers performing the scans are not necessarily trained sonographers, we will need to certify each of them to ensure they are acquiring suitable images for the gestational age estimation. For estimating gestational age using TraCer, the user needs accurately acquire video clips which contain the transcerebellar diameter (TCD) and the head circumference (HC).

The training process for those using the device is:

1. **Training by a trained sonographer.** Here the main fetal structures will be highlighted and the user will be shown how to locate the correct planes for obtaining the TCD and HC videos. This will be practical training where the trainee can practice scanning.

2. **Manuals and training videos.** The user should read/watch the training manual and video which will give details as to how to obtain the images required.

The health worker will send their first 20 scans for review by the coordinating team in Oxford. Here both the TCD and HC will be measured as well as the video quality checked by an experienced sonographer in the co-ordinating team.

If 80% of videos obtained are deemed to be good quality, the health worker will be certified in obtaining videos for the TraCer study. If the videos are not deemed good quality, the health worker will receive feedback, be re-trained and their subsequent 10 scans will be reviewed.
Quality Control

A team member to lead the ultrasound component of the study should be identified. This person will be responsible for:

1. Managing the devices - ensuring they are all fully charged, are signed in/out and for notifying the team of any issues
2. Managing updates to the app – replacing the old version of the app with new versions
3. Sending data to the Coordinating team and working with them on any discrepancies with the data

As we will be measuring and evaluating each video, we will monitor the quality of videos we are receiving from sites. Monthly reports will be circulated which will summarise the quality of data we are receiving and will highlight any issues with those performing the scans. These reports will be sent to the site’s Clinical Lead from the Coordinating Unit.

Setting up the device

1. Ensure you have a Huawei tablet and a Konted ultrasound probe.
2. Turn on the tablet and the probe.
3. Open the wifi connections. To do this, pull down on the top of the screen so the menu below appears. Then hold down on the wifi button and it will open the wifi connections.

4. In the list of wifi networks, select the wireless probe. The probe will start with the letters SS-1, it will then have a string on numbers and letters in the format SS-1 GEBGFA658. Each probe has a unique serial number which can be found on the probe. This number is in the format SN:WSBPgFA658.
5. If the last three numbers of the probe available on the wifi connection matches the serial number of the probe you would like to use, press connect. If the wifi asks for a password, enter the serial number of the probe AFTER the SN: in lower case for example SN:WSBPgFA658 would be entered as wsbpgfa658
6. The probe should then be registered on the tablet.
Performing the scan

1. Open the app from the homescreen

2. **Enter your PRECISE sonographer ID.** This is a two digit number code that will be assigned by the Oxford Ultrasound Team. Press the Submit button.

3. **Enter the participant ID.** (This is a code of the form XXX-XXXXX). Press the Submit button.

4. Pair the ultrasound probe to the tablet.
   - Once this screen appears, click on the ‘Connect probe’ button
   - This opens up the wifi connections. The probe will be listed, it will start with SS-1
• Select the probe, it will then ask you to connect. Once connected press the back arrow to return to the scanning screen

If the tablet cannot pair to the ultrasound probe the steps to fix this are above in the section ‘Setting up the device’

5. Once connected the screen below will appear. To activate the probe, press the button on the probe:

6. Optimising imaging: You can alter the brightness on the app to make the image clearer. To do this, click on contrast settings and change the brightness with the slider. You can also adjust the magnification using the depth function.
7. **Start scanning:**

We want to capture images of the fetus’s head circumference (HC) and transcerebellar diameter (TCD). To do this, using gel between the probe and the maternal abdomen, place the probe on the maternal abdomen over the pubic symphysis (see image below).

This is the initial starting position for the scan. To find the HC and TCD:

- Using slow, purposeful movements, move the probe on the abdomen up towards the maternal head; sideways movements may also be needed, until you identify the fetal head – you will recognise the oblong white skull.
- Once you have done this, identify the midline falx in the skull.
- By gently tilting or sliding the probe try to get to have this midline horizontal. This image gives you the baby’s head circumference.

*Figure of the fetal head circumference*– the cartoon shows where this is in the fetus
8. Once you have located the imaging plane where you see the head circumference of the fetus, gradually rotate the probe until you see the cerebellum – it looks like an “8” shape or dumbbell.

Once you have located the HC and TCD, press the Red Record Button, the red button will start pulsing and the app will automatically record a video for 8 seconds. Gently move the probe to capture the head circumference and the cerebellar diameter.

10. Once the video has stopped recording, the video will be automatically re-play the video on a loop. Review the video to ensure the HC and TCD are clearly captured.

Either:

a. If the video has the HC present, Press the Green Accept (✓) button to save the video

Or:

b. If the video does not clearly capture the HC, Press the Reject (X) button. This allows you to re-take the scan.

12. Repeat steps 5-7 above to acquire videos two and three.

13. Once you have three videos recorded, you will be taken to the video review dashboard.
You should review each video again to ensure you are happy with the data quality. To review a video, click on the video you want to select and it will re-play.

- If you choose to accept the video, it will take you back to the dashboard.
- If you chose to reject the video and re-take another, it will take you to the data acquisition screen for you to record a new video.

If you are happy with all three videos, press ‘End Examination’ and the videos will be saved.

14. If you are unable to collect three videos, click ‘End Examination’ to end scan acquisition. This can only be done once a video has been recorded, you cannot end the examination before attempting to record a video.

When you click ‘End examination’, it takes you to the video review dashboard and will allow you to review the videos you have acquired and save them.
You should try to collect three videos for each participant. Ending the examination early is only to be used when getting three scans is not possible. If three scans are not possible, record this ‘Incomplete Scan log’ (see Appendix 4).

Data back-up and storage

The ultrasound videos are stored securely on the tablet. These should be sent to the Oxford Ultrasound Team weekly where the videos will be backed up and analysed.

To send videos, you must have a good internet connection. However, if the internet does cut out half way through upload the images will not be lost. To share the videos, a username and password will be supplied by the Oxford Ultrasound Team.

1. On the home screen, press the button ‘Sign in as admin to upload videos’

2. The FTP for the server needs to be entered along with the port number. To do this, click on the cog on the top right corner of the screen. Enter the server host address and port number (this will be confirmed with each site).
3. Once the server information has been entered, return to the home screen and enter the assigned username and password.

4. Then press the Upload files button to send the data. Once the videos are uploading, you will see a bar to show the uploading status.

5. Once all the videos are uploaded, a message will appear saying the upload is complete. Inform the Oxford Ultrasound Team that videos have been sent.

Care and Maintenance of the Ultrasound devices

Charging the devices

- The probes will need regular charging. We recommend you charge them daily once you have completed the scans for the day as the battery life is approximately 3 hours.

- The battery charge is seen on the display. When the battery is low, only one bar will be left on the icon below.

- To charge the probes, connect to mains electricity, to a computer using the USB cable or through the wireless charging device. Note: the quickest way to charge the device is through the mains electricity. The slowest way is using the wireless device.

- When the device is fully charged, the battery icon will stop flashing
• The device cannot be used when charging.

• The tablets need regular charging. We recommend these are charged daily. The power left in the device can be seen on the home screen in the top right corner.

• The tablets can be used whilst charging.

Security and Care of Devices

• The manager of each area should allocate a safe designated place for the devices to be stored when not in use.

• Devices are portable and where possible should be attached to firmer objects such as trolleys or tables using the cable wire and ferrules provided.

• Never attempt to open the devices, keep them out of direct sunlight and away from moisture.

• Treat the probe with great care as you would with an ultrasound device.
7. Sample Collection

Maternal blood

**Required supplies:**

- 1 x maternal blood kit
- 1 x serum vacutainer (red cap)
- 1 x EDTA vacutainer (purple cap)
- Gauze sponges
- Sharps container
- Tourniquet
- Antiseptic wipes
- Gloves

Blood should be collected by a trained phlebotomist, midwife or research technician. This SOP does not detail the entire collection process.

1. Attach a unique participant ID label to each of the collection tubes and to the label on the kit bag.
2. A certified phlebotomy technician should draw blood into each of the vacutainer tubes using the blood collection kit provided. The order of the draw is: 6 ml serum tube (red top) then 7ml EDTA tube (purple top).
3. The serum tube should be inverted gently 5 times slowly (not shaken) to ensure that the reagents mix with the blood sample.
4. The EDTA tube should be inverted gently 8 to 10 times slowly (not shaken) to ensure that the reagents mix with the blood sample.
5. Record the time of sample collection, either write this on the kit bag or scan the participant ID into Baobab to record the sample collection time.
6. Set the timer for 30 minutes as soon as the blood draw has been completed as a reminder to centrifuge the tubes.
7. Place serum tube in the rack to clot at room temperature for 30 minutes after blood draw.
8. Place the EDTA tube in the rack for processing.
Urine

Required supplies:

1 x urine kit

1 x 90ml urine collection cup

1. Provide woman with the participant ID-labelled urine collection cup.

2. Ask the woman to provide a sample:
   - Ask her to remove the lid from the urine collection cup.
   - Begin to urinate into the toilet.
   - Pass the collection container into the urine stream.
   - Urinate at least 30 to 59 ml into the collection container.
   - Finish urinating into the toilet.
   - Screw the lid and return the container to the PRECISE lab technician for processing.

3. Collect the urine cup, ensure the lid is screwed on tightly and record the time of sample collection, either write this on the kit bag or scan the participant ID into Baobab to record the sample collection time.

When the woman cannot produce any urine at the study facility

Urine collection by the woman at home WILL NOT BE DONE in this study. Where for any reason, other than pathological, a woman is not able to provide urine during the visit, the study teams should take the following actions:

1. Explain to the woman that the urine sample collection is an important part of the study and that the study team will provide them bottled water to drink to help them fill their bladder and to be able to pass urine.

2. Explain that they may be asked to stay at the facility or return to the facility (if their homes are in close proximity to the facility) within 30 minutes or whenever they feel the urge to void.

3. Impress upon them to stay at the facility and explain that there may be instances where when they are at home and feel the urge to pass urine, they may not be able to hold till they return to the facility and the opportunity might be missed.

4. If for some reason they are unable to wait at the facility, the study team should proceed with the blood sampling and retain the remaining kit separately (to avoid label confusion). THIS IS TO BE PERFORMED ONLY EXCEPTIONALLY, as it can lead to substantial labelling and misidentification problems.
Cord blood

Required supplies:

1 x cord blood kit
1 x serum vacutainer (red cap)
1 x EDTA vacutainer (purple cap)
Gauze sponges
Sharps container
Gloves

Cord blood collection must be completed at the latest within 30 minutes after delivery of the placenta to avoid clotting of blood. Cord blood should be collected by a trained midwife or research technician. In case of time delays proceed to SOP section 5.6 (delayed cord blood collection).

If the delivery takes place at home, the placenta should be transported to the laboratory for processing as soon as possible.

1. Immediately after delivery of the placenta, place two clamps on the cord, one as close to placenta as possible, and the other at the end of the cord.
2. Record the time of placenta delivery by writing this on the kit bag.
3. Wear personal protective equipment including eye protection and 2 sets of gloves. Have extra gauze available as the cord blood can be under high pressure.
4. Identify the fetal vein and using clean dry gauze wipe excess blood and fluids from a small 2-3 cm area of the fetal vein for a clear puncture.
5. Insert the needle into the vein, following the direction of the vein. Avoid puncturing all the way through the vein.
6. Collect 6 ml of blood into the serum tube (red cap) and then collect 7 ml of blood into the EDTA tube (purple cap).
7. The serum tube (red cap) should be inverted gently 5 times slowly (not shaken) to ensure that the reagents mix with the blood sample.
8. The EDTA tube (purple cap) should be inverted gently 8 to 10 times slowly (not shaken) to ensure that the reagents mix with the blood sample.
9. Remove collection needle from cord vein and dispose of in sharps container.
10. Set timer for 30 minutes as soon as the blood draw has been completed as a reminder to centrifuge both tubes.
11. Record the time of sample collection, either write this on the kit bag or scan the participant ID into Baobab to record the sample collection time.
12. Attach a participant ID label to each of the collection tubes and to the kit label.
13. Transfer the samples to the laboratory for processing.

**Vaginal Swabs**

**Required supplies:**

1 x vaginal swab kit

2 x FluidX tubes pre-filled with protease solution (stored in the freezer)

2 x FluidX tubes pre-filled with TE buffer (take the 2ml tubes with orange tubes from the kits and fill with 1ml of TE solution stored in the fridge)

Gloves

1. Participants will be asked to lie on a couch, having removed their underwear, with a sheet over their waist to maintain dignity. The participant will be asked to bend their legs with their feet together moved close to their bottom; knees moved outwards.

2. The research nurse/midwife wearing latex free gloves will part the labia and gently insert conjoined four swabs (2 eSwabs and 2 dacron swabs) into the mid-vagina (approximately 4-5 cm) and rotate gently 360° for 15-20 seconds. The exposure is needed for the vaginal fluid to enter the swab stick. Failure to retain the stick for this duration might result in insufficient vaginal fluid collection, making the sample useless.

3. After removal of swabs from vagina, take the 2 eswabs, and cut off the top of each swab and place one into each of the 1.8 ml pre-barcoded FluidX tubes with orange caps.

4. Take the two pre-made tubes with the PBS+protease inhibitor in them (green cap). Carefully open each of the two tubes and cut off the swab tip. Make sure that the tip is covered by the fluid (by gently rotating the tube before freezing).

5. Keep tubes on ice for transportation to the laboratory. Please note that the sample must be processed within an hour of collection.

6. Record the time of sample collection, either write this on the kit bag or scan the participant ID into Baobab to record the sample collection time.

**Heel prick**

**Required supplies:**

1 x lancet

1 x Heel prick kit

Gloves

Disinfectant
Cotton wool or gauze

1. Flip over the card cover to expose the active zone (circle), but not touching the active zones on the paper.

2. Clean the selected area of skin with a skin disinfectant and allow to dry for 30 seconds. Warming up of the foot facilitates dilatation of blood vessels and ensures faster and easier protocol completion.

3. Position the foot with the puncture site downwards. Take care to keep away from bony prominences. Press the loaded lancing device against the skin and push the white plunger.

4. While holding the foot correctly, apply and release pressure to allow a drop of blood to form. Allow a large drop of blood to collect.

5. Once a drop of blood has formed, lightly touch the drop to the pre-printed circle on the blood spot card, allowing it to soak onto the circle. Allow sufficient quantity of blood to soak through to completely fill the pre-printed active zone on the filter paper. Do not layer successive drops of blood or apply blood more than once in the same collection circle.

6. Record the time of sample collection, either write this on the kit bag or scan the participant ID into Baobab to record the sample collection time.
## Appendix 1. Equipment Calibration Form

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Infantometer</th>
<th>5 kg weight</th>
<th>Baby scale</th>
<th>Length</th>
<th>Adult scales</th>
<th>40kg</th>
<th>Adult stadiometer</th>
<th>Length</th>
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</table>


Appendix 2. Sample Anthropometry Standardisation Form

**FIRST MEASUREMENT SERIES**
(Head Circumference, Length, MUAC)

SESSION NUMBER

CHILD’S NAME

CHILD NUMBER

MEASURER’S NAME

HEAD CIRCUMFERENCE . (cm)

LENGTH . (cm)

MID UPPER ARM CIRCUMFERENCE . (cm)

**SECOND MEASUREMENT SERIES**
(Head Circumference, Length, MUAC)

SESSION NUMBER

CHILD’S NAME

CHILD NUMBER

MEASURER’S NAME

HEAD CIRCUMFERENCE . (cm)

LENGTH . (cm)

MID UPPER ARM CIRCUMFERENCE . (cm)
## Appendix 3: PRECISE TraCer Incomplete Scan Log

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<th>PTID</th>
<th>Date of scan</th>
<th>Number of Scans Completed (please circle)</th>
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