






Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure			SSP No: CL04 Version No: 1.0 Supersedes: None Effective Date: 19 th October 2021
Title: Anthropometry Procedures			
	NAME	SIGNATURE	DATE
PREPARER	Isaiah Njagi		24 th June 2021
Q.A. AUTHORITY	Aisha Bwika		16 th October 2021
APPROVING AUTHORITY	Robert Bandsma		17 th October 2021

APPROVED

1.0 PURPOSE

- Diagnosis of Severe Malnutrition is anchored on measurements of body characteristics such as how heavy or tall a child and presence of body swelling characteristic of undernutrition. It is important to make an accurate diagnosis of SAM for management of the child and to ensure that correct participants are enrolled in the trial.
- This SSP is designed to specify procedures for accurate and reliable anthropometric measurements of study participants.
- This SSP will cover:
 - Weight measurement Calibration of weighing scales
 - Height measurement
 - MUAC measurement

2.0 RESPONSIBILITY

- 2.1** The SSP applies to clinicians, nurses and fieldworkers who will be screening patients for eligibility to the PB-SAM study. It is important that each study site use the same equipment and procedures (as described below) so that the data collected at each site can be combined into a single data set.
- 2.2** For these data to be comparable across measurers and study sites over the course of the study, all anthropometric procedures must be standardized. The procedures need to be internally consistent, within and between the study sites.
- 2.3** However, control and assurance of the accuracy and reliability of these measurement is the responsibility of the Site Principal investigator

3.0 DEFINITIONS

- 3.1 MUAC:** Mid-upper arm circumference
- 3.2 cm:** Centimetres
- 3.3 mm:** Millimetre
- 3.4 Kg:** Kilogram
- 3.5 g:** Gram

4.0 EQUIPMENT/MATERIALS

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4.1 Length board

4.2 Calibrated weighing scale

4.3 Calibration stones 0.5kgs, 1kg, 2kgs

4.4 Marker pen

4.5 MUAC tape

5.0 METHODOLOGY

5.1 Weight measurement

5.1.1 *If the child is aged 2 years or older, and can stand, use the step-on scales. Prepare the scales by placing on level ground. To help level the scales, look at the bubble and try to get it central (this isn't mandatory). Ask the mother to help if the child is scared. Tap the scale with your foot. 0.0kg should show on the screen. The child should stand in the middle of the scales and keep still.)*



5.1.2 *If the child is aged less than 2 years, use the lying scales. To help level the scales, look at the bubble and try to get it central (this isn't mandatory). Ask the mother to help if the child is scared. Sit or lie the child on the scale. Older children who weigh less than 15.0kg may stand on the lying scale, but you must lift them on and off to prevent damage to the scale from children stepping on the edge.*



5.1.3 *Record the weight (it will be to 2 decimal places).*

5.1.4 *If the child is very scared of both scales, you can use the Tare method. Weigh the mother on the step-on scales. With the mother still standing on the scales, press the '2 in 1' button. The screen will display 0.0kg. Pass the child to the mother. Record this weight.*



5.2 Calibration and care of the weighing scale

5.2.1 Calibrate the scales Once a week, e.g. On Monday Mornings and document on the calibration record form.

5.2.2 To calibrate, ensure that the scale is placed on an even, flat surface. Check whether the scale is level using the bubble on the far right-hand leg of the scale. If you find that the scale is not level, the legs of the scale may be individually adjusted until the bubble lies in the centre of the window. There must be enough light to read the display.

- 5.2.3 Turn on the scale by pressing the START button so SECA 88888 and then 0.000 appears. Mark the value that appears on the calibration form (see Table 2). The scale should be kept on position [2] (up to 20kg with 10g precision) always. To change the position, hold down the NET button for several seconds. Please note: in newer version of the scales, the selection between position [1] and [2] is automatic.
- 5.2.4 Beginning with the 0.5kg weight, place the weight in the middle of the scale. The display should now read 0.500. Mark the value on the calibration form.
- 5.2.5 Repeat this process with the 1kg, 2kg, 3kg 5kg weights. This will allow checking across the full range of weights required for this study. Record the obtained values on the calibration form.
- 5.2.6 Also calibrate the scale using the tare function. Place the 0.5kg on the scale, press the NET button for 2 seconds. The word NET appears. Wait until the display stops flashing and shows 0.000. Then place the 2kg weight on the scale and check that the value is 2kg. If the reading deviates from the expected value, remove the weight, ensure that the scale is on an even surface and that nothing is interfering with the weighing platform.
- 5.2.7 Repeat the measurement again. If the scales fail calibration, use a different set of scales (calibrated Seca 376) and inform the site coordinating clinician.
- 5.2.8 The Seca weighing scale should be stored at normal indoor temperatures and protected against humidity. If it has been transported under hot conditions, it should be put in a cool, dry place for 15 minutes before using it. The scale should be handled with care under all circumstances.
- 5.2.9 Important: the lithium batteries must be replaced every 4 months (before any indication to replace the batteries is given). This is because batteries reaching the end of their lifetime can generate measurement errors that can remain undetected for several weeks. Please make a logbook of dates for battery replacement for each piece of equipment that is battery-operated. In the unlikely event that replacement batteries cannot be found, each baby scale is supplied with a main electrical adaptor or electrical plug that is to be used under these circumstances. Note that the batteries must be removed from the scale before using the electrical adaptor.

5.3 Method: height/length measurement

5.3.1 If the child is aged 2 years or older, and can stand, use the stadiometer.

Help the child to stand with feet central, and heels, bottom, shoulders and head against the board. Help the child to hold their head level (not looking down or up). If the child's back is arched, gently push their tummy in so they achieve their full height. Slide the headpiece down level with the top of the child's head. Record the height indicated by the red pointers to the nearest 0.1cm.



5.3.2 If the child is aged less than 2 years, and/or cannot stand on the infantometer.

Lay the child on the scale ensuring that the vertex of the child's head is at the same level with the head end of the scale. There should be no space between the child's head and the head end of the scale. Position the child's shoulders and bottom centrally on the scale. Using one hand, gently but firmly hold down the child's bottom and knees, so the legs are straight. If the child's back is arched, gently push their tummy in so they achieve their full length. Using your other hand, bring the bottom of the stadiometer up to meet the child's feet. Bend the child's feet to 90 degrees (as if they are standing) and bring the bottom of the stadiometer to the bottom of their feet. Take the measurement here, ensuring the bottom of the stadiometer is level on both sides. Record the length to the nearest completed 0.5cm.

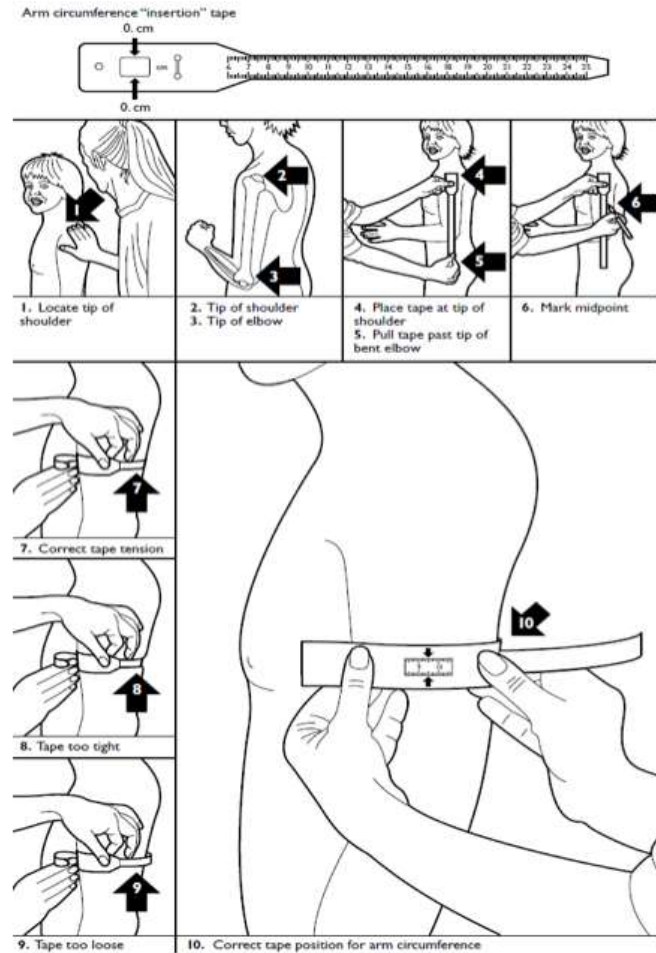


5.3.3 Clean the stadiometer/infantometer using a towel (dry dirt) and wipe (wet dirt, stains).

5.4 Method: MUAC

5.4.1 Ask the mother to remove any clothing that may cover the child's left arm. Keep your work at eye level. Sit down when possible. For small children, have them in the mother's lap.

5.4.2 Calculate the midpoint of the child's LEFT upper arm by first locating the tip of the child's shoulder (Arrows 1 and 2) with your fingertips. Bend the child's elbow to make a right angle (Arrow 3). Place the end of the measuring tape on the tip of the shoulder (Arrow 4) and pull it straight down past the tip of the elbow (Arrow 5). Hold your finger on the location of the length. Bend the tape up in half so that the end of the tape meets the length you measured. Place the tape back on the tip of the shoulder and assistant will be ready with a pen to mark the midpoint on the arm (Arrow 6).



5.4.3 Straighten the child's arm and wrap the tape around the arm at midpoint. Make sure the numbers are right side up and the tape is flat around the skin (Arrow 7). Make sure tape passes below window with the zero arrows and is inserted through the small slot to the right of the measuring window.

5.4.4 Inspect the tension of the tape on the child's arm. Make sure the tape has the proper tension (Arrow 7) and is not too tight or too loose (Arrows 8-9).

5.4.5 When the tape is in the correct position on the arm with the correct tension, read and call out the measurement to the nearest 0.1cm (Arrow 10). Then loosen the tape and record the measurement.

5.4.6 Children aged 6 months or above with a MUAC of less than 11.5cm may be malnourished and should be referred for further assessment.

6.0 Appendix 1: Calibration Log**Calibration Record**

Site: _____

Equipment	Date of calibration	Weighing scale working well? Y/N	Action taken and re-calibration date	Staff initials

7.0 REFERENCES

7.1 PB-SAM Study Protocol

7.2 WHO Hospital Care for children 2013

8.0 DOCUMENT CHANGE HISTORY**Version Table:**

Version 1.0: Title: Anthropometry Procedure	Dated: 19th October 2021	SSP No.: CL04	No. Pages: 8
Version 2.0: Title:	Dated:	SSP No.:	No. Pages:
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE

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SSP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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