

Section 6: Collecting Step 3 data: Biochemical Measurements

Overview

Introduction This section provides information on taking biochemical measures required under Step 3 of the STEPS Instrument.

Intended audience This section is designed for use by those fulfilling the following roles:

- Field team supervisors
- Step 3 data collectors
- STEPS Survey Coordinator.

In this section This section covers the following topics:

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Biochemical Measurements Overview

Introduction

Step 3 includes selected biochemical measurements that require taking urine and blood samples.

Step 3 blood testing is usually conducted jointly for all the participants who have completed Step 1 and 2 the day before and had given consent for Step 3. This is usually done at a convenient community setting, closer to the homes of the participants. Step 3 urine samples are usually collected by the participants the evening before the blood testing, and the samples are brought to the Step 3 site the next day.

What you will learn

In this module, you will learn:

- what the biochemical measures are and what they mean
 - the process of urine collection and instructions for participants
 - the fasting process and instructions for participants
 - what equipment will be needed
 - how to take biochemical measurements
 - how to record the results.
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Learning outcome

The learning outcome of this section is to understand what the biochemical measures are and how to accurately prepare participants, take the measurements and record results.

Recording results and field logistics

Since results for Steps 1 and 2 and results for Step 3 will have to be recorded at different times and places (Step 1 and 2 usually in the household, Step 3 usually at the Step 3 site), Step 1 and 2 data will need to be linked to Step 3 data at a later point in time. The participant identification number (PID) plays a crucial role here, since it is the variable used for matching the data. Additionally, it is recommended to use stickers with a unique bar or QR codes for each participant.

The Step 3 Appointment Card (Part 6, Section 2) is an important form in this process: the PID (either automatically or manually generated for Step 1 and 2) should be written on the form, and the participant should bring the form with her/him to the appointment for the Step 3 measurements. The same PID will then be used to record the Step 3 information of the participant. The bar or QR code should be printed on a sticker that is placed on the Step 3 Appointment Card. This code should be scanned with the Android device twice: once by the interviewer before Step 1 and 2 data are collected, and once by the Step 3 data collector before recording Step 3 results.

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Biochemical Measurements Overview, Continued

Recording results and field logistics (cont.)

Options for recording of Step 3 data include:

- recording on a separate set of Android devices, specifically for Step 3, and linking of the data at the end of the entire field work period;
 - recording on paper, and entering of Step 3 data into the Android devices where Step 1 and 2 data are already recorded during regular (ideally daily) field team meetings, for example each evening after data collection.
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Required forms

The following forms should be used for Step 3:

- Consent Form 2 (Step 3)
- Step 3 Appointment Card
- Instructions for Spot Urine Collection
- Fasting Instructions
- Participant Feedback Form Step 3
- Step 3 Registration Form.

Note: These forms can be found in Part 6, Section 2.

Dry vs. wet chemistry for blood testing

There are two main blood chemistry screening methods: dry and wet chemistry. Dry chemistry means that blood is taken from the fingertip, while wet chemistry means that a venous blood sample is drawn. See Part 2, Section 1 for further information on dry and wet chemistry.

Note: In this section, only the dry chemistry method is described since wet chemistry is done directly at the laboratory.

Urine Collection

Introduction Urine samples are taken from eligible participants to measure urinary sodium and creatinine.

24-hour Urine Collection vs Spot Urine Collection The “gold-standard” approach to assessing population salt intake is to obtain urine samples collected over 24 hours (to avoid diurnal variations) on a representative sample of the population. However, this approach is difficult to do well, and provides significant challenges in terms of skills and resources, particularly when done as part of large scale, comprehensive population health surveys in low and middle income countries.

Several new important research papers have concluded that it is possible to accurately estimate average population 24 hour salt intake from spot urine samples. Spot urine samples are collected as part of a STEPS survey.

Scheduling Spot Urine Collection Participants will be asked to collect their urine in the evening before fasting, and take it with them to the appointment for blood testing the next morning.

Material needed for Spot Urine Collection In order for them to collect their urine, participants will be provided with a container, a bag, and instructions for urine collection.

Instructions for Spot Urine Collection Instructions for spot urine collection are listed in the table below:

| | |
|--|---|
| 1. We are asking you to collect a sample of your urine (pee) in the evening before you commence your fast. |  |
| 2. When you go the bathroom (toilet) void urine (pee) into the container. Once the container is half full finish voiding in the toilet. Screw on the lid tightly and place the container in the zip closable plastic bag (do not remove labels). |  |
| 3. Write down the time you collect your sample: | ____:____ |
| 4. Place container filled with urine (pee) in the zip closable plastic bag and store upright in a cool, dark place. |  |
| 5. Bring your container filled with urine in the zip closable plastic bag and this instruction sheet to the Step 3 site. |  |

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Urine Collection, Continued

General guidelines for urine collection

General guidelines for urine collection include:

- Samples should be kept at a dark place (no direct exposure to sunlight)
- Samples should be kept cool, if possible (this is because of the smell; heat won't change sodium or creatinine levels in the sample);
- Participants should take any prescribed medication as usual on the day they provide the urine sample;
- Participants should NOT fast before they take their sample;
- Contamination of the sample with blood should be avoided (women having their period should use a tampon).

Samples should be excluded from the analysis

- From pregnant women
 - If the participant has fasted before taking the sample
 - If the sample is contaminated with blood.
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Urinary Sodium and Creatinine Measurement

Introduction Urinary sodium and creatinine are measured to determine population levels of high salt intake, a risk factor mainly for hypertension and cardiovascular disease.

Storing of urine samples There is no specific temperature at which samples should be stored, although it is sometimes more convenient to freeze them.

Transport of urine samples and Laboratory analysis In most countries, urine samples will be analysed at a central laboratory by a laboratory technician. Results of this analysis will need to be recorded on the Android devices, in order to have each participant's data complete. The participant ID plays a crucial role here, since it is the variable used for matching the data.

If samples are stored frozen/unfrozen for future use or sent elsewhere for analysis, then there may be need to consider further consent taking to account of cultural beliefs.

Blood Collection

Introduction Blood samples are taken from eligible participants to be used to perform tests to measure blood glucose and blood lipids.

Infection control Infection control procedures appropriate for the setting should be followed.

Whole blood is more infective with regard to blood borne disease than centrifuged serum or plasma. There may be an increased risk in handling whole blood and universal precautions should be adopted.

Units of measurement The table below shows the standard units of measurement for biochemical tests used in STEPS and their upper and lower limits for data entry purposes on the Android devices.

| Blood Test | Unit | Minimum | Maximum |
|-----------------------|--------|---------|---------|
| Fasting glucose | mmol/L | 1.1 | 33.3 |
| Total cholesterol | mmol/L | 2.59 | 10.36 |
| HDL | mmol/L | 0.30 | 2.59 |
| Fasting triglycerides | mmol/L | 0.56 | 5.65 |

| Blood Test | Unit | Minimum | Maximum |
|-----------------------|-------|---------|---------|
| Fasting glucose | mg/dl | 20 | 600 |
| Total cholesterol | mg/dl | 100 | 400 |
| HDL | mg/dl | 10 | 100 |
| Fasting triglycerides | mg/dl | 50 | 500 |

Participant fasting requirements To obtain accurate results, participants must fast for at least 8 hours before blood collection (12 hours if triglycerides are also measured). This is particularly important for the measurements of blood glucose as well as triglycerides, if applicable.

Most blood samples are to be taken in the morning. This means participants must not to eat or drink anything (except plain water) from about 10 pm the night before.

Diabetic patients on medication are required to bring their tablets and insulin with them and to take them after their blood measurement if possible (if they have not done so, they should inform the relevant laboratory staff).

Note: Fasting Instructions for Step 3 can be found in Part 6, Section 2.

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Blood Collection, Continued

Preparing the participant

After greeting the participant, and asking them to take a seat, follow the steps below to prepare the participant for a blood test:

| Step | Action | | | | |
|--------------------------------------|--|-------|---|--------------------------------------|---|
| 1 | Fill in the following details on the Step 3 Registration Form: <ul style="list-style-type: none"> • Date • Participant ID (if not already filled in) • Participant Name (if not already filled in) • check if Consent Form 2 has been signed • scan the participant QR code. | | | | |
| 2 | Ask the fasting question (first question on the instrument under Step 3, Code B1) and record the answer. | | | | |
| 3 | If the participant has not fasted correctly, then: <ul style="list-style-type: none"> • explain that to get accurate results participants need to fast for a minimum of 8 hours (12 hours if triglycerides are being measured); • ask if they would try fasting again and come back for a blood test the following day. If the participant agrees to come back the following day, then: <ul style="list-style-type: none"> • give the participant an appointment time and fasting instructions; • note the time of the new appointment in the Step 3 Registration Form; • inform the supervisor. | | | | |
| 4 | <table border="1"> <thead> <tr> <th>If...</th> <th>Then explain to the participant that...</th> </tr> </thead> <tbody> <tr> <td>The participant has fasted correctly</td> <td> <ul style="list-style-type: none"> • blood is going to be collected from a small prick on the finger; • tests will be done on: fasting blood sugar, cholesterol, fasting triglycerides and HDL. </td> </tr> </tbody> </table> | If... | Then explain to the participant that... | The participant has fasted correctly | <ul style="list-style-type: none"> • blood is going to be collected from a small prick on the finger; • tests will be done on: fasting blood sugar, cholesterol, fasting triglycerides and HDL. |
| If... | Then explain to the participant that... | | | | |
| The participant has fasted correctly | <ul style="list-style-type: none"> • blood is going to be collected from a small prick on the finger; • tests will be done on: fasting blood sugar, cholesterol, fasting triglycerides and HDL. | | | | |

Measurement of Blood Glucose and Lipids

Introduction Blood sugar tests are taken to measure for raised blood sugar levels which are a risk factor for diabetes.

Blood cholesterol tests are taken to measure total cholesterol and HDL cholesterol levels.

Triglyceride tests are taken to measure the fasting levels of natural fats and oils in the bloodstream.

Equipment required Dry chemistry equipment and supplies required for blood glucose and lipid tests include:

- a device that measures blood glucose and lipids (such as: Cardiochek PA, Refloton Plus, Cholestech LDX), or separate devices that measure blood glucose and lipids;
 - batch of sufficient reagent test strips (note: for some devices, combined strips measuring several items are available);
 - single use lancets;
 - capillary tubes and plungers for collection of the right amount of blood;
 - cotton balls and swabs;
 - gloves;
 - disposable container.
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Preparing the device Follow the appropriate device instructions to set up, prepare and use the meter for blood tests.

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Measurement of Blood Glucose and Lipids, Continued

Measurement procedure Follow the steps below to take blood measurements and record the results. Note that you should also read the instructions provided with the device carefully.

| Step | Action |
|------|---|
| 1 | Put on gloves. |
| 2 | Remove a test strip, put it into the machine and close the test strip box. The strips are sensitive to heat and humidity, so only take one strip at a time and close the box tightly. |
| 3 | Rub and kneed a fingertip to help withdraw blood (rub the side of the participant's finger closest to the thumb). |
| 4 | Wipe or swab the fingertip by using a sterile swab. |
| 5 | Lance the massaged place on the fingertip with lancing device. |
| 6 | Allow a hanging blood drop to form without applying too much pressure. |
| 7 | Carefully collect the blood with the capillary tube until the blood reaches the mark on the tube. Put the blood onto the test field without touching it. Note: The test field must be completely covered with blood. If too little blood is applied, do not rub it in or apply a second drop, but repeat the measurement with a fresh test strip. |
| 8 | Give the participant a cotton ball to press on the puncture. |
| 9 | Wait for the measurement to be displayed. The results are usually displayed in mmol/L or mg/dL. |
| 10 | Record the results of the readings on the Android device and on the Participant Feedback Form (Step 3). Also tick the corresponding boxes on this form. |
| 11 | Record Technician ID, Device ID, time of day and answer to medication questions (B6 for glucose, B9 for lipids) on the Android device. |

Completing the Participant Feedback Form (Step 3)

Introduction

After having completed the Step 3 measurements, the participant should be informed on his/her results. The Participant Feedback Form (Step 3) can be used in order to give the participant feedback on his blood measurements (see Part 6, Section 2). This form stays with the participant after having completed the survey.

Filling in the Participant Feedback Form

Please follow the following guidelines when completing the Participant Feedback Form:

- fasting blood glucose: record the result for fasting blood glucose in mmol/L or mg/dL;
 - fasting blood glucose classification: tick the appropriate box;
 - total blood cholesterol: record the result for total blood cholesterol in mmol/L or mg/dL;
 - total blood cholesterol classification: tick the appropriate box;
 - HDL cholesterol: record the result for HDL cholesterol in mmol/L or mg/dL;
 - HDL cholesterol classification: tick the appropriate box;
 - fasting triglycerides: record the result for fasting triglycerides in mmol/L or mg/dL;
 - fasting triglycerides classification: tick the appropriate box.
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