PRECISION-CARRS

Field & Lab Manual

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List of Abbreviations

µl	Micro Litre
AIIMS	All India Institute of Medical Science
ARB	Angiotensin II Receptor Blocker
AUDIT-C	Alcohol Use Disorders Identification Test Concise
BC	Buffy Coat
BMI	Body Mass Index
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CCC	Central Coordinating Centre
CEBs	Census Enumeration Blocks
CHF	Congestive Heart Failure
CIMT	Carotid intima-media thickness
CT	Computed Tomography
DNA	Deoxyribonucleic Acid
DSE	Dobutamine Stress Echocardiogram
ECG	Electrocardiogram
ECHO	Echocardiogram
EDTA	Ethylene Diamine Tetra acetic Acid
EP	EDTA Plasma
FI	Field Investigator
FPC	Fluoride Packed Cells
HbA1c	Glycated Hemoglobin
HHID	Household ID
HRQoL	Health- Related Quality of Life
HRT	Hormone Replacement Therapy
ICF	Informed Consent Form
ID	Identification Code
LMP	Last Menstrual Period
LV	Left Ventricular
MRI	Magnetic Resonance imaging
NHANES	National Health And Nutrition Examination Survey
NS	Normal Saline
OCPs	Oral Contraceptive Pills
OSA	Obstructive Sleep Apnea
P-CARRS	Precision-Cardiovascular Disease Phenotyping and Pathophysiological Pathways in the CARRS Cohort (Centre for Cardio metabolic Risk Reduction in South Asia)
PBS	peripheral blood smear
PCI	Percutaneous Coronary Intervention
PID	Participant ID
PIS	Participant Information Sheet
PP	Plasma Proteins
PTCA	Percutaneous Transluminal Coronary Angioplasty
PVD	Peripheral Vascular Disease
QOL	Quality of Life
RBC	Red Blood Cell
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
S	Serum
SARS-CoV	Severe Acute Respiratory Syndrome Coronavirus
VA	Verbal Autopsy
WB	Whole Blood

OVERVIEW OF THE FIELD MANUAL

This manual is a part of the Precision Cardiovascular Disease Phenotyping and Pathophysiological Pathways in the CArdiometabolic Risk Reduction in South Asia (CARRS) cohort (**Precision-CARRS**). This document is designed for the field staff who will be involved in data collection for the first round follow up of Precision-CARRS. Apart from them the internal and external monitors / evaluators should also follow this manual during monitoring and process of evaluation.

The field manual is an operational guide for Precision-CARRS. It includes instructions, description of all the study tools, points to consider, and more. The manual should be used for training of the field staff. It is also a guidebook for the monitors and evaluators.

CHAPTER 1 | FIELD VISIT

A. PRE-VISIT

Before visiting the field, the team should see if the items mentioned in the pre-visit checklist and list containing the participant information is with them.

1. Pre-visit checklist:

It is Field Investigator's (FI) responsibility to make sure that s/he has a complete set of items prior to arriving at the participant's home. It is recommended that FI should verify from the checklist given below. Each FI should have the following materials:

1. Fully charged tablet (with the updated software)
2. Participant list with correct HHIDs, PIDs and updated address including phone numbers
3. Participant Information sheet and Informed consent form (PIS+ICF)- Annexure 1
4. Printouts of the following (in case the tablet malfunctions):
    a. Precision-CARRS main questionnaire – Annexure 2
    b. Blood pressure & anthropometry form, Tanita form (hardcopy, in case tab abruptly stopped working)- Annexure 3
    c. Event modules – Annexure 4
    d. Short questionnaire for non-responders – Annexure 5
    e. Verbal autopsy form –Form VA- Annexure 6
5. Instruction sheet for the participant- blood & urine sample- Annexure 7
6. Explanation for specialised testing (for field workers)-Annexure 8
7. Non-stretch measuring tape (SECA Tape)
8. Blood Pressure (BP) instrument (Omron HEM-7121)
9. Bio impedance measuring device (Tanita, BC-601 in Delhi, BC-535 in Chennai)
10. Standing height using Stadiometer (123 portable stadiometer in Delhi; 214 portable stadiometers in Chennai, SECA)
11. Hand dynamometer (Delhi and Chennai, JAMAR digital dynamometer)

2. Obtaining participant information:

Before visiting the participant, please obtain a list of participant details - name; household ID (HHID); Participant ID (PID); contact details (phone number and address) of participants and latest contacts extracted from the latest data. We will request the participant for updated information and if there is change in the information, please note the information in the tab correctly and if there is no change, please select the option "same as previous" in the provided space in the tab.

B. DURING THE FIRST ROUND OF VISIT

It is very crucial for FI to build rapport with the participants. This will help in reducing the number of loss-to-follow up and refusals. FI should request the participants to inform if s/he changes her/his place of residence. This will help to track participants and minimize loss to follow-up.

Also, in this visit if the participant is available the FI should explain the study in detail and give answers to their questions and if the participant is ready to give informed consent, fill their forms and take their BP and anthropometric measurements (visit 1). FI should also remind the participant that s/he will be required to see and click photographs of the participant's medical records, prescriptions, and other related documents, and request the participant to keep them handy during the interview. The FI should take appointment for biospecimen collection (visit 2) and their visit to AIIMS in Delhi/ V scans in Chennai (visit 3) for their ECG, ECHO, Arterial Stiffness, CT scan and CIMT (carotid intima-media thickness), keeping in mind participant's convenience.

C. POST VISIT ACTIVITIES

Field Investigators should verify that all the questions have been administered and the form is complete. FI should thank the participant for their time.

Instructions

Before leaving the participant's home, the FI must:

1. Check the questionnaires for completeness.
2. Check that all materials have been picked up.

Once FI has left the house, s/he should review the questionnaire again and note any other omissions or inconsistencies s/he remembers. Upon reaching the field office the FI should review the questionnaire again and if s/he believes that a response has been incorrectly entered, missing or any other discrepancy has been found s/he would contact the participant to verify the response. After confirming the response, again check the form for completeness and save the form. The FI can save the form as:

1) "Save as complete" (if all the information is complete); or
2) "Save as incomplete" (if some information is still pending)

After saving the form, the FI should sync the forms to the server and inform the team supervisor, who will inform the data manager.

1. Appointment Reminder Calls before blood sampling

During the first visit, the FI shall inform the participant about all the tests that will be done during their second visit and third visit. Appointment shall be taken and provide the verbal as well as the written instruction sheet (Annexure 7) to the participant. A day before a scheduled appointment, FI should call the participant to confirm the appointment. Occasionally, participant may not remember, so FI should be prepared to answer questions and handle non- response. If a participant requests to change the time or date of the scheduled appointment, it is necessary that the appointment be rescheduled, and a new appointment obtained. FI should also remind that s/he will be required to review the participant's medical records, prescriptions, and other related documents, and request the participant to keep them handy during the blood collection, if not done earlier during the interview.

2. Returning Reports to Study Participants

Reports of blood pressure and anthropometric measurements should be given to participant at the same time of taking the measurements. Within 7-10 days of bio-specimen collection during Precision-CARRS visit, the lab team should be able to provide the reports of the blood specimens. Reports duly signed by the head of the biochemistry department should be delivered to the participant. It is preferable that FI gives the reports to the concerned person or to the next of kin if the participant is not available. In case of abnormal findings, participant should be advised to consult her/ his physician.

D. FLOW CHART OF PRECISION-CARRS COHORT

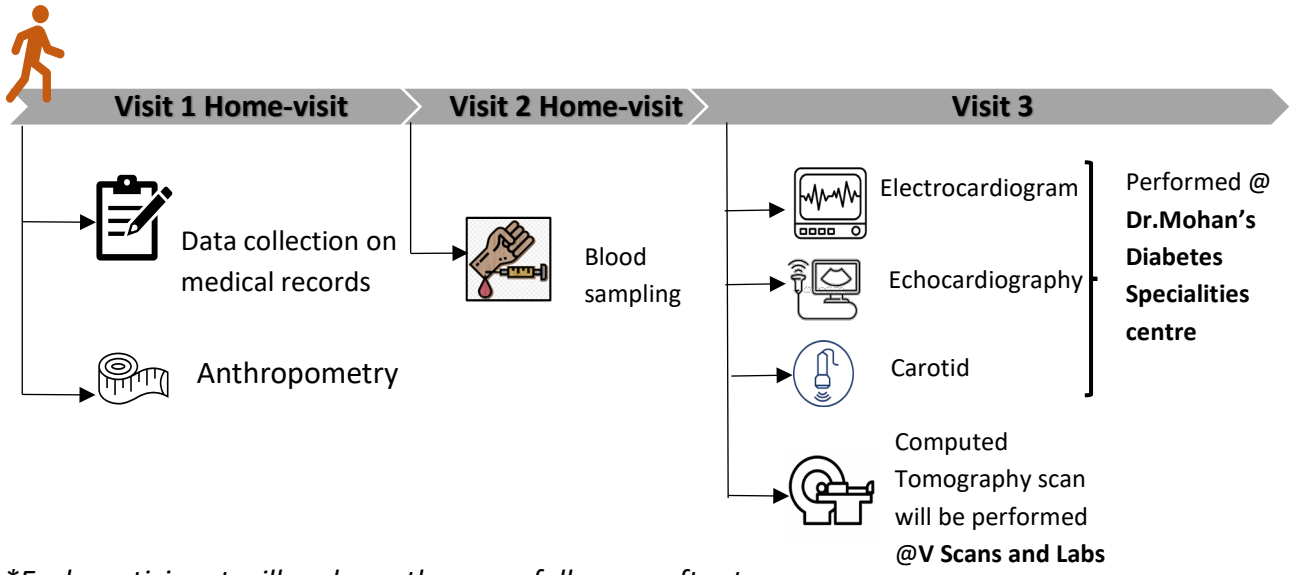
1. Delhi

- **Visit 1 Home-visit**: Data collection using electronic data capture (tablets). Anthropometric measurements
- **Visit 2 Home-visit:** Blood and urine sample collection
- **Visit 3 @ AIIMS:**
  1. ECG
  2. Echocardiography
  3. Arterial stiffness
  4. Carotid ultrasound

  → AB-6 Ward, 6th Floor: Department of Endocrinology, AIIMS, New Delhi

  5. CT SCAN → Department of Cardiac Radiology, Ground floor, Cardiothoracic Centre, AIIMS, New Delhi

2. Chennai



**Each participant will undergo the same follow-up after two years*

E. PARTICIPANT CONFIDENTIALITY

All information obtained while conducting the study will be kept confidential as specified by the Indian law. FI cannot share any information (obtained by questionnaire, administration, record abstraction, or observation) related to any participant to anyone other than the study team members and only when necessary.

Points to remember

1. Make a phone call to the participant a day prior to the blood collection visit and visit to AIIMS (Delhi)/ V-scan (Chennai) to confirm the appointment and their availability.
2. It is important to prepare for each visit one day prior to the visit.
3. Check the availability of all study tools before going to the field.
4. It is very important to maintain confidentiality of all information.
5. Check all available medical records. If the relevant records are not available request the participant for another appointment to review the records.
6. Reports of bio-specimen, anthropometry and blood pressure should be handed over to the participant alone.
7. FI must:
    a) Write all the problems in detail in the comment section or which would be described by the participant during home visit.
    b) Whenever you visit the participant's house again, please read the comment section.

CHAPTER 2 | INTERVIEWING TIPS AND TECHNIQUES

1. Establish a rapport with the person you are interviewing – this is a FRIENDLY interview. Be courteous. Give your name. Thank her/him for agreeing to spend this time with you.
2. Explain the purpose of the interview. Tell her/him how much time you expect will be needed to complete the interview (e.g., "This will be a 45 minutes - 1 hour conversation").
3. The interview should be conducted in a location within the home that is comfortable, well-lit, private, where there are minimal interruptions, and no audio or visual distractions such as a television or radio.
4. Although FI may suggest an ideal interview setting, s/he must comply with the participant's wishes. Ideally, the setting should enable the participant to feel comfortable discussing any concerns about the study or in responding to the questions in the interview.
5. As a rule, it is preferred that the FI talk with the participant alone so that the participant's responses are not influenced by the presence of other people.
6. If a participant insists that someone else be present, the FI should accept the request. When conducting the interview, however, the FI can take only one response, and the response must be that of the participant.
7. Be patient. Listen to what the person says, help her/him give you the correct answer, but do not make assumptions or answer for the person. Accept the response, if it is within the range of expected answers.
8. Clarify responses that seem outside of expected answers. Note the reason for deviation from the normal response.
9. Signal the respondent when you move to another section (e.g., We are now turning to the next section of the interview").
10. Control the conversation. A little small talk is okay, but do not let it go on for very long or the interview will take too much time. Stick to the questions in the questionnaire in the tab. Answer interviewee questions but try to stick to the topic. Limit participation from third parties.
11. Keep up the pace of the conversation; do not get bogged down on one question. Move on and come back to a question if you have to.
12. Paraphrase to check for understanding if the individual's response is unclear.
13. Express appreciation at the closure of the interview; explain briefly again what happens with the data collected.
14. FI should always try to complete the interview at one sitting. Sometimes it may be necessary for the participant to take a short break during the interview. However, if it becomes obvious that s/he cannot complete the interview and s/he is willing to continue the interview at another time, FI should schedule another appointment within a few days. FI must document the situation fully and indicate if the participant will continue with the interview or not.
15. If a participant has any problem, try your best to resolve it.
16. If you are unable to resolve, tell her/him that you will return with appropriate answers within a day or two after discussing with supervisor and always follow it up.

CHAPTER 3 | CODING PROCEDURES

A. INTRODUCTION

A common coding procedure was followed by the participating sites. Unique identification codes (ID) are assigned to the study sites, sub districts/Zones/Towns, Wards, Census enumeration Blocks (CEBs). All these codes combined constituted the cluster ID. Households were assigned household ID. ID numbers were also assigned to the interviewers and laboratory technician who will be involved in collection of data. Ensure appropriate IDs obtained from the list are entered correctly in all forms (questionnaire, blood pressure and anthropometry, tanita and verbal autopsy forms).

Coding used in the Precision-CARRS survey	
Participant ID	Search for the unique participant ID provided to each participant who has consented to participate in the study. Enter the unique 5-digit or 6-digit PID provided for CARRS1 or CARRS2 participants, respectively and search, the detailed information of that PID will appear in the tab.
Household ID	Enter the 5 digit or 6-digit household ID provided for CARRS1 and CARRS2 participants, respectively.
Interviewer ID	Enter the four-digit unique interviewer ID provided to you
Cohort	Select cohort 1 or 2 if the participant is from CARRS1 or CARRS2, respectively.

CHAPTER 4 | PARTICIPANT INFORMATION SHEET & CONSENT PROCEDURES

A. INTRODUCTION

We would take consent from the esteemed participants of CARRS cohort study and ask them to provide their informed consent to be a part of PRECISION-CARRS study. The consent process provides the mechanism by which an individual can make an informed decision regarding participation in the study and provides for the protection of a participant's rights as a subject in human research.

The consent form, Form-A (Annexure 1) has two parts, Participant Information Sheet (PIS) and the signature page. The field staff should be thoroughly familiar with the documents and the procedures for obtaining informed consent. This chapter provides specific instructions for obtaining consent.

B. LEARNING OBJECTIVES

After completing this chapter, the field staff will be able to:

1. Understand the procedure for participant information and consent
2. Complete the process for participant consent.
3. Resolve queries of participants and their family members.
4. Handle refusal at participant level.

C. CONSENT FOR P-CARRS

During **Visit 1**, the field staff will greet the participant and inform that this study is extended for another five years (2022 - 27). They share the copy of the Participant Information Sheet (PIS) in the language of their preference (Hindi/English/Tamil) with them. They will explain the contents of the consent document and its purpose and answer any questions which the participant may have regarding the study or her/his involvement in the study. The participant should be instructed to read the consent document carefully. It might be suggested to her/him that s/he underline any words that are not recognized or understood, or that s/he stop and ask questions as the document is read. The participant should be given ample time to read the document. If s/he has trouble reading the document, the interviewer may read the document aloud just as written.

After reading the document, the FI must be certain that the participant understands:

1. The purpose of the study
2. What constitutes participation in the study including the interview, measurements, blood sample collection & visit to AIIMS (Delhi)/V-scan (Chennai) for further tests (mentioned before).
3. The potential risks and benefits associated with the study.
4. Their rights and responsibilities as a study participant
5. The voluntary aspect of the study and the fact that they can refuse to participate in selected components.

After the individual has read the PIS (first part of Form-A), it is important to invite questions from the participant. The FI should offer to explain any words or phrases that may be unclear.

Once it is established that the participant has a clear understanding of the study requirements, the FI will advise the potential participant to sign and date two copies of the signature form (second part of Form-A). The interviewer will also sign and date both copies. Participant information sheet and one copy of the consent form will be given to the participant for their records.

D. HANDLING REFUSALS

If the participant refuses to be interviewed or the answer to the Q1. of the main questionnaire i.e. "Does the participant agree to be interviewed?" is "No", then the short questionnaire (Annexure 5) should be filled and save the form as "save incomplete". Visit the participant at least 3 times and if s/he still refuses then save the form as "complete form."

The interviewer should attempt to identify the reason and address her/his concerns. However, the interviewer must be sensitive to the participant's wishes and not compel her/him. If after attempts to explain and address concerns the participant still refuses, the reason for refusal must be documented on the short questionnaire. After filling the short questionnaire, the interviewer should thank the participant for her/his time and leave the house.

Points to remember

1. Greet the participants and remind them about the study.
2. The field staff should endeavour to acquire all information about the study to resolve participant queries and handle refusals.
3. The field staff should document all refusals, shifted cases, & deaths.

CHAPTER 5 | INSTRUCTIONS FOR USING THE QUESTIONNAIRE

A. OVERVIEW

This chapter provides instructions for filling the questionnaire for Precision-CARRS study. The list of sections of the questionnaire is provided below. The questionnaire is included in Annexure 2.

List of Sections of the Questionnaire

Questionnaire	Description
SHORT QUESTIONNAIRE	
SECTION 1	**RESPONSE AND CONTACT OF THE PARTICIPANT**
PART 1A	Response of the participant
PART 1B	Participant information
PART 1C	Details of contacts
SECTION 2	**INFORMATION ON CARDIOMETABOLIC EVENTS**
SECTION 3	**INFORMATION IN CASE OF DEATH**
MAIN QUESTIONNAIRE	
QUESTIONNAIRE-Part I	
SECTION 1	**RESPONSE AND CONTACT OF THE PARTICIPANT**
PART 1A	Response of the participant
PART 1B	Participant information
PART 1C	Details of contacts
QUESTIONNAIRE-Part-II	
SECTION 2	**MEDICAL HISTORY**
PART 2A	Cardiovascular history
PART 2B	Cardiometabolic diseases and their risk factors
PART 2C	Cancer
PART 2D	Kidney disease
SECTION 3	**TREATMENT HISTORY**
PART 3A	Outpatient
PART 3B	Inpatient
SECTION 4	**EYES**
SECTION 5	**COVID-19**
SECTION 6	**DETAILS OF TOBACCO AND ALCOHOL USE, DIET AND PHYSICAL ACTIVITY**
PART 6A	Tobacco use
PART 6B	Alcohol use
PART 6C	Diet
PART 6D	Physical activity
PART 6E	Sleep details
SECTION 7	**PATIENT HEALTH QUESTIONNAIRE-9**
SECTION 8	**QUALITY OF LIFE (EQ-5D)**
SECTION 9	**DEMOGRAPHIC & SOCIO-ECONOMIC DETAILS**
PART 9A	Demographic details
PART 9B	Socio-economic details
SECTION 10	**FEMALE REPRODUCTIVE HISTORY**
SECTION 11	**MEDICAL DOCUMENTS**
SECTION 12	**FRIED FRAILTY QUESTIONNAIRE**
SECTION 13	**MINI-COG**

Instructions

1. FI should explain each question to the participant and answer any question the participant may have.
2. FI should assure the participant that s/he has the right to refuse to answer any question.
3. For HHID and PID check the IDs provided in the list and select properly.
4. FI must read all questions EXACTLY as they are written and in the proper order.

B. SHORT QUESTIONNAIRE

This questionnaire will be filled for all the non-responders. It should be filled for all, whose response will be "2" (No) for Q1 i.e. "Does the participant agree to be interviewed?" in the main follow-up questionnaire.

SECTION 1: RESPONSE AND CONTACT OF THE PARTICIPANT

This section consists of 2 parts.

PART 1: RESPONSE AND CONTACT OF THE PARTICIPANT

1. **Does the participant agree to be interviewed?**
   Write "1" if the participant agrees to be interviewed and "2" if the participant refused to give an interview/ shifted / not interested/ not alive etc.

2. **If YES, what is the present address**
   Write "1" if the address is same as last follow-up and "2" if it has changed. If "2" continue with this section, otherwise, **skip to Q6**.

3. **If changed, note the current address [If filled, please skip to Part 1A]**:
   If the participant's address has changed, ask the participant to provide his/her contact details, and complete postal address.
   NOTE: If filled then skip to Part 1A "Details of contact."

4. **If NO, what is the reason for non-response?**
   Depending on the response from the participant enter code in the boxes against the list of the reasons of non-response. If the response is not listed in the form, select "others" and specify.

   If the answer is 2,4,5 or 7 complete question 5.

   Fill the questionnaire of all the participants whether they have shifted within 200kms of study site or have moved to other city/town. Request the participant for telephonic interview.

   If the answer is 6 for the above question skip this questionnaire and please complete verbal autopsy form (annexure 6).

5. If "**Refused,"** reasons for refusal.
   If the participant has refused to be interviewed or the answer of Q6 is 1 (shifted, traceable but not interested), 2 (hard refusal), 3 (soft refusal) or 5 (could not complete the survey and will be available

for next year follow up), then select the reason for refusal given in Q5. You can choose multiple reasons of refusal.

6. **Q6 and Q7. In case you move from current residence, whom can we contact to obtain your new contact address or telephone numbers? (Ask details of two different contacts)**
Please carry the list obtained from the data manager with contact details (phone number and addresses) of the participants and two contacts while making a telephone call to them. Request for updated information. If there is no change please write "same as previous" in the provided space and if s/he wishes to change, either name/address and telephone numbers of the contact person, please complete these questions and make changes in the software as well. This contact person should be someone who will always know where the participant is living and how to get in touch with her/him and in case of their change of resident, they know where they had gone and know how to contact them. It should be someone who is not likely to move with the participant.

Try to have contact numbers /address of the people (n=2) who knows the participant well and in case of their change of resident, they know where they had gone and know how to contact them.
Try not to have the contact numbers of people living in the same house (because there is a high probability that they will also move with them).

If the participants are living in their own house (permanent) and won't move out of that place then also, ask them for the contact details. Request them politely that this contact detail will help them to contact them if they would go out due to some reason.

If the participant doesn't have any relative living in the study site (in the same city), ask them to give the contact number of their employer. If they resist thinking that we'll bother them. Tell them politely that we'll call them ONLY when we won't be able to contact you.

NOTE: DO NOT LEAVE THIS BOX EMPTY.

The FIs shall take a copy of name, contact details and other information from the list given by the data manager and while meeting them/making a phone call ask if there is any change in the information collected previously. If there is a change, fill the address otherwise write "same as previous" in Q6 and 7.

8) Hometown contact telephone
In the case participants hometown is different from current city, please note the name and contact details of relative/friend from his/her hometown who will always know where the participant is living even if changes the city and how to get in touch with her/him. Also, **include landmarks in the address.**

PART II: SECTION 1 RESPONSE AND SURVIVAL STATUS

1. **Who is responding to this form?**
In this question, fill "1" if the answered by the CARRS participant and "2" if the details are collected from proxy (any person other than the CARRS participant).
NOTE: If answered by the CARRS participant go to Q3.

1a. If Proxy, what is the relation with the participant?
If response for Q 1 is filled "2" (Proxy- if the information provider is other than CARRS participant), ask how the participant is related to him/her. Write "1" for family member, "2" for friend, "3" for neighbour and if any other, write code "4" in the provided box and specify the relationship.
In Q 1a and 2 will be filled if response in Q 1 is "2".

2. **What is the participant's survival status?**

In this question, we will note whether the participant is alive (1), deceased (2) or his/her survival status is unknown (3).

NOTE: If "2" go to section 3.

If "3", write notes in the comment section.

3. **Does the participant or proxy, ready to provide few information?**

Ask the participant/proxy politely whether s/he ready to provide the information. If yes, write "1" and move to next section otherwise end the questionnaire and thank the participant.

SECTION 2: INFORMATION ON CARDIOMETABOLIC EVENTS

1. **Since the last CARRS visit, has the participant told by a doctor that s/he had any following disease? [Yes=1; No=2; Don't know=3]**

If the response for Q3 of section 1 is "1" (yes), ask whether the participant had been told by a doctor that s/he had myocardial infarction (MI), angina, stroke, heart failure, diabetes or hypertension since the last visit.

NOTE: If the response to any of these diseases is yes ("1") then go to 1a otherwise go to Q2.

1a. **Is the date of event/diagnosis known? [Yes=1; No=2; Don't know=3]**

1b. **If yes, when was the most recent event?**

1c. **If yes, when was the diagnosis made?**

Question 1a will be asked when the response for any diseases (mentioned in Q1) is yes. Ask if they remember the date of the most recent event (for MI, angina, heart failure and stroke) or when the disease was diagnosed (diabetes and hypertension). If yes, write "1" in the provided space and write the date in MM/YY format in Q1b.

Example: If a participant says that s/he had heart disease 5 years back than subtract the 5 years from the current year (example- 2022) and write that year which will be 2017 then ask the month of that event.

2. **Since the last CARRS visit, has the participant undergone the following procedure/s? [Yes=1; No=2; Don't know=3]**

In this question ask whether the participant had undergone the following procedures- coronary angioplasty or stent, coronary bypass graft, renal dialysis, kidney transplant or amputation of lower limb since the last visit (6^{th} fup for CARRS1 & 1^{st} fup of CARRS2). If yes, then write "1" for that procedure and go to Q 2a otherwise thank the participant and end the questionnaire.

2a. **Is the date of procedure/s known? [Yes=1; No=2; Don't know=3]**

Question 2a will be asked when the response for any procedure (mentioned in Q2) is yes. Ask if they remember the date on which they undergo that procedure. If yes go to Q2b otherwise thank the participant and end the questionnaire.

2b. **If yes, when was participant's latest procedure?**

In this question ask the exact date (when s/he had undergone the latest procedure) in MM/YY format.

EXAMPLE: If a participant says that he/she had a kidney transplant 5 years back than subtract the 5 year from the current year (example- 2022) and write that year which will be 2017 and write the month also.

SECTION 3: INFORMATION IN CASE OF DEATH

This will be filled if response for Q2 in section 1 is "2" (Deceased).

1. **If deceased, is the date of participant's death known?**
   [Yes=1; No=2]
   In this question ask, if the respondent remember the date of participant's death. If response will be filled "1" (yes) then go to Q2 otherwise skip to Q3.

2. **If yes, what is the date of death?**
   In this question, write the exact day, month, and year (DD/MM/YY) of participant's death.
   NOTE: In case "proxy" do not remember the day than just write month and year and write "99" in day box.

3. **Does the interviewee agree to provide details about the participant's death?**
   Ask if the proxy agrees to provide the detail about participant's death. If response will be filled "1" (yes) than fill the verbal autopsy form (Annexure 6) otherwise thank the proxy and ends the questionnaire

Points to remember

1. Informing participants and obtaining their consent is the most important part of the study
2. The field staff should endeavour to acquire all information about the study to resolve participant queries and handle refusals
3. The field staff should have a thorough understanding of the "Participant Information Sheet" and consent form.
4. The field staff should document all refusals

C. MAIN QUESTIONNAIRE

SECTION 1: RESPONSE AND CONTACT OF THE PARTICIPANT

PART 1: RESPONSE OF THE PARTICIPANT

The purpose of these questions is to gather basic information about the participant. This section consists of **17 questions**. Below are specifications for questions requiring additional clarification.

1. Does the participant agree to be interviewed?
   Write "1" if the participant agrees to give an interview and move to part 1B Q1 (Name of the participant) and if the participant refused to give an interview/ not interested then visit them 2 more times (on different days), try to persuade them and after the 3rd visit fill the short questionnaire (if the participant agrees).

2. **If "No"** – what is the reason for non-response?
   Depending on the response from the participant enter code in the boxes against the list of the reasons of non-response. If the response is not listed in the form, select "others", and specify.
   If the answer is 2, 4, 5 or 7 complete Question-3.
   Visit all the participants who have shifted within 200kms of study site or have moved to other city/town where our other teams are working. If the participant has shifted to outside Delhi (places nearer to Delhi), try to contact him/her and ask whether they would like to give interview and blood /urine sample. If they live at more than 200 kms, try to contact the participants telephonically. Request the participant for telephonic interview.

If the answer is 6 for the above question skip this questionnaire and please complete verbal autopsy form (Annexure 6).

3. If refused, reason for refusal?
   You can fill multiple answers in response to this question and if you choose the option "777", please specify the reason.

PART 1B: PARTICIPANT INFORMATION

1) Question 1-4, Name of the participant, gender, father's name, mother's name, spouse name
   If the participant agrees to be interviewed, this question will appear. After selecting the PID, HHID will appear and after checking the PID write the name, age (in completed years), father' and mother' name of the participant in the tab. Check the PID, HHID again and if it is correct then check the name of the participant and confirm the name and spelling with the participant. Continue filling the questionnaire if the information is correct, otherwise correct the information in the tab before syncing the data.

PART 1C: CONTACT DETAILS OF THE PARTICIPANT

1. **Email id:** Ask the participant if s/he has a valid and working email id. If yes, note down the email id. After writing, kindly recheck with the participant. If no, move to the next question.

2. **Question 2-3, Mobile number 1 and 2 (self-new or current):** Ask for the current mobile numbers of the participants using which we can contact the participants. Try to take all the available and working contact numbers from the participant.

3. **Does the participant have Aadhaar card?**

3a. If yes, Aadhar card number

Ask the participant whether s/he has an Aadhaar card. If the participant has Aadhaar card (write "1" in the provided box, then ask them to show the card. Write the "12" digit number in the provided boxes.

NOTE: If no / refused to provide, then write 2 or 3 respectively and **skip to next question. Collecting this information is not mandatory.**

4. **Question 5, What is the present address?**
   Write "1" if there is no change in the address or it is "same as previous follow-up" and "2" if it has changed. If "2" continue with this section, otherwise, **skip to Q6**.

4a. Changed address, note the current address?

If there is change in the address, please write the complete postal address of the participant in the tab.

5. **Questions 6-11: Name, address and mobile numbers of the 1st and 2nd contact person**
   Please carry and show the list obtained from the data manager/field supervisor with contact details (phone number and addresses) of the participants and two contacts. Request for updated information. If there is no change please write "same as previous" in the provided space and if s/he wishes to change, either name/address and telephone numbers of the contact person, please complete these questions and make changes. This contact person should be someone who will always know where the participant is living and how to get in touch with her/him and in case of their change of resident, they know where they had gone and know how to contact them. It should be someone who is not likely to move with the participant. Try to have contact numbers /address of the people (n=2) who knows the participant well and in case of their change of resident, they know where they had gone and know how to contact them. Try not to have the contact numbers of people living in the same house (because there is a high probability that they will also move with them). If the participant is living in their own house

(permanent) and won't move out of that place then also, ask them for the contact details. Request them politely that this contact detail will help us to contact them if they would go out due to some reason. If the participant doesn't have any relative living in the study site (in the same city), ask them to give the contact number of their employer. If they resist thinking that we'll bother them. Tell them politely that we'll call them ONLY when we won't be able to contact you.

Please note the name and contact details of relative/friend who will always know where the participant is living even if s/he changes the city and how to get in touch with her/him. Also, **include landmarks in the address.**

NOTE: DO NOT LEAVE THIS BOX EMPTY.

The FIs shall take a copy of name, contact details and other information from data manager and take it to the field and ask if there is any change in the information collected previously. If there is a change then fill the address otherwise select "same as last follow-up" in Q6 and 9.

SECTION 2: MEDICAL HISTORY

The purpose of these questions is to gain knowledge of the participant's medical history and related risk factors, diabetes, hypertension, hyperlipidemia, heart disease, stroke, kidney problem and cancer. Below are specifications for questions that require additional clarification.

PART 2A: CARDIOVASCULAR HISTORY

SOME DEFINITIONS

What is heart attack, angina, heart failure?

1. **Heart attack:** Condition where blood supply to a part of heart stops leading to death of heart tissue. Heart needs constant supply of blood. If that stops then the heart tissue is deprived of oxygen and it dies. Symptoms include chest pain, chest discomfort, radiating pain to the left upper limb, angle of the mouth, shortness of breath, sweating nausea, vomiting.
2. **Angina:** Angina refers to condition where pain originates from heart. The pain is due to the decreased blood supply of oxygen rich blood to the heart. Sometimes patients might perceive the pain a tightness, constriction or pressure on the chest or heart. The pain also can occur in your shoulders, arms, neck, jaw, or back. Angina pain may even feel like indigestion.
3. **Heart failure:** Condition in which heart cannot pump blood effectively. The causes for heart failure are diabetes, hypertension, heart attack, faulty heart valve etc. Symptoms include shortness of breath, swelling of legs, weakness, decreased appetite, bloating of stomach etc.
4. **Stroke:** Stroke is a condition where blood supply to brain stops. Due to this part of the brain affected by lack of blood supply dies and the body functions are affected. Person affected by stroke can have weakness of limbs, slurring of speech, loss of bladder control, blurring of vision, confusion etc.
5. **Paralysis:** Unable to move the affected body part/s due to stroke.
6. **Weakness:** Able to move, but unable to function the affected body part/s normally due to stroke.
7. **PVD:** PVD stands for Peripheral Vascular Disease. In this condition the arteries supplying blood to arms and legs are affected. There is narrowing or complete occlusion of arteries. So, the blood supply is decreased or stopped completely. This leads to pain on walking, pain even while resting, loss of sensation, gangrene, trauma etc.

8. **Bypass surgery** is a procedure commonly done on diseased heart. In this procedure, a blocked blood portion of the blood vessel is bypassed using a graft (piece of vein). It is similar to taking a short route when there is a block or jam on the main road.

9. **Angiogram/angioplasty:** Angiogram is a diagnostic procedure carried out to examine the condition of blood vessels supplying the heart. It is mainly done to know if any blockages are present inside the blood vessels of heart. It is similar to X- ray of bones. It is a therapeutic procedure carried out to clear blockages present in the blood vessels supplying the heart.
10. **Amputation:** It is a surgical procedure where a limb or a part of limb is removed from the body. This leads to loss of function and deformity. Amputation surgeries are performed in cases of uncontrolled infection, diabetes, severe trauma, gangrene etc. toes, foot, legs, fingers, arms are commonly amputated.
11. **Dialysis:** is a procedure where waste products and excess water are removed artificially from our body. Normally, kidneys carry out these functions in our body. But when they are damaged then dialysis needs to be done regularly. There are different types of dialysis, commonest one being the one done in the hospital.
12. **Echocardiography**: It is a test done to know the condition of the heart. In this test sound waves are used to know the structure and function of the heart. While performing this test we can actually see the movement of heart and flow of blood within the heart. This test is better than X ray of heart as it gives us a lot more information.

*(**NOTE**: If response is auto-populated as Yes or answers to any of the below question (angina, heart failure, myocardial infarction and/or stroke) is "**Yes**" - **Detailed Event Form (Annexure 4)** will be filled. The detailed event form will contain modules to collect: records/documents, symptoms, and any tests, treatments, length of stay)*

1. **Since our last visit with you in year auto-populate, have you been diagnosed with or has a doctor or other health professional ever told you that you have?**

   1a. Heart attack
   1b. Angina
   1c. Heart failure
   1d. Physician diagnosed irregular heart rhythm
   1e. Stroke
   1f. Peripheral vascular disease (PVD) (claudication, ischemic rest pain)

   Ask the participant if since the last visit, s/he has been diagnosed with or has a doctor or other health professional ever told that s/he have suffered from 1a) heart attack, 1b) angina, 1c) heart failure, 1d) irregular heart rhythm (arrhythmia), 1e) stroke, or peripheral vascular disease (PVD). For PVD, prompt the participant by asking if s/he has pain or cramping **(not due to arthritis)** in your calves or legs when walking that is relieved by resting?

   If "YES" – when was it diagnosed (since the last interview)?
   If the participant had said yes for Q1, ask him/her the date when it was diagnosed (since the last visit). Record the response in months and years, if they don't know the date exactly, then encourage them to recollect ad ask them to give an approximate answer. Write the response in months and years.

   EXAMPLE-1: If you went to a participant in year 2016 (age 73 years), and now (year 2023) the participant is 80 years old, and he had stroke at 78 years. Then the answer to this question would be 2021 (year; 2023-2). For getting information about month ask whether it's during winters/summers/rainy season; during/near any particular festival, holiday etc.

Step-1: This will be calculated by calculating the participants year of his/her birth 2023-80=1943.
Step-2: Then adding 78 because, he had suffered from the last stroke at 78 yrs (1943+78=2021), 2021 is the year in which he had suffered from the last stroke.

1b(i) If "Yes" – Over the past 4 weeks, on average, how many times have you had chest pain, chest tightness, or angina?
(4+/day – 1; 1-3/day – 2; 3/week – 3; 1-2/week – 4; <1/week – 5; none over past 4 weeks – 6)
If the participant had said yes for Q1b then ask the participant over the past 4 weeks, on an average how many times did s/he feel the chest pain, chest tightness, or angina. Choose the appropriate option.

1b (ii) Over the past 4 weeks, on average, how many times have you had to nitroglycerin (tablets under your tongue or spray) for your chest pain, tightness, or angina?
(4+/day – 1; 1-3/day – 2; 3/week – 3; 1-2/week – 4; <1/week – 5; none over past 4 weeks – 6)

If the participant had said yes for Q1b, ask the participant over the past 4 weeks, on an average, if s/he had put any tablets under their tongue or spray (nitroglycerin) for your chest pain, tightness, or angina. Choose the appropriate option.

1e(i) If "Yes" for stroke – did person:
1. Receive physical therapy?
2. Receive speech therapy
3. Any residual weakness / paralysis of arms, legs, or side?
4. Any residual speech concerns?
5. Any surgical procedure for stroke: (Craniotomy for decompression or stenting of cranial vessels)

If the participant had said yes for stroke and was diagnosed by the physician, ask the participant if they have received any physical therapy, or speech therapy; if they have any residual weakness/ paralysis of arms, legs, or side; or any residual speech concerns; or had undergone ay surgical procedure (craniotomy for decompression or stenting of cranial vessels) for stroke.

2. Since our last visit with you, have you had any of the following procedures or therapies?

2a. Balloon angioplasty of your heart blood vessels (procedure to open up or stent blood vessels of heart)?
2b. Open-heart surgery (coronary bypass surgery)?
2c. Procedure to open up or stent blood vessels in arms or legs?

Ask the participants, if since the last visit s/he had undergone any procedures or therapies 2a) Balloon angioplasty of your heart blood vessels (procedure to open up or stent blood vessels of heart); 2b) Open-heart surgery (coronary bypass surgery) 2c) Procedure to open up or stent blood vessels in arms or legs?

Write appropriate code- yes=1, No=2 or don't know=999 in the provided space.

2a-2c. When was the procedure/therapies performed?
If the participant had said yes for Q2 (2a or 2b or 2c), ask him/her the date when it was performed (since the last visit). Record the response in months and years, if they don't know the date exactly, then encourage them to recollect ad ask them to give an approximate answer. Write the response in months and years.

3. Have you had an amputation of the lower limb?
General definition of amputation is the removal of a body extremity by trauma or surgery. Surgical removal of whole or part of limb/s is conducted as a lifesaving procedure in certain disease conditions. Record the response as "Yes" or "No". If the response is "No", then skip to Q4 (Functional status).

3a. If yes, since the last visit, when was it amputated
Record the response in years and months when he/she underwent the amputation.

3b. What was the level of amputation?

If answer was "Yes" to Q3, ask her/him to indicate the level of the amputation. Write the appropriate code in the box. If both the limbs are amputated note the highest level of amputation.

3c. What was the cause for the most recent amputation?

Try to get information from the participant about the cause of amputation. Write the appropriate code in the box (**Injury=1; Diabetes=2; infection=3; diabetes & injury=4; diabetes and infection=5; and Others=777**). If the reason for amputation is "others" then specify the reason in the provided space.

4. **FUNCITIONAL STATUS:** Please select an option which best summarizes your ability to do physical activities. Readout the statements and ask the participant which option best summarises their ability to do physical activities.

PART 2B: CARDIOMETABOLIC DISEASES AND THEIR RISK FACTORS

1. **If no prior history, since our last interview, have you been told by a doctor that you have any of the following diseases? (*Since the last interview*)**

If "2" or "999" for Q1- skip to part 2C (Cancer)

This question refers to the new diagnosis of any of the conditions [diabetes (high blood sugar), hypertension (high blood pressure), hyperlipidemia (high blood cholesterol) since the last interview by a doctor. Please try to ascertain that the diagnosis was made by a qualified allopathic doctor. Read out the different conditions as it appears on the tab and select the response as either "Yes" or "No" or "Don't know". The FI needs to ask Q1d (Part 2B) of only those conditions to which the participant says "Yes" in Q1 (1a, 1b, or 1c) otherwise **skip to Part 2C (Cancer)**.

NOTE: If the answer is "YES" for any of the options provided in the Q1 then fill the details of the selected disease in this section of the questionnaire. Below are specifications for questions that require additional clarification and are common to high blood pressure/ diabetes/ high blood cholesterol.

Many participants refer "Low BP" as BP problem. Please ascertain whether it was "high BP" to be sure.

Instructions

1. Write '1', '2' or '999' depending on the response of the participant in the box provided for each disease.
2. Do not write the subjective feeling of the participant; it must be a confirmed diagnosis by a doctor.
3. If the answer is "YES" to any of the choices in Q1, then go to Q1a otherwise go to Part 2C (Cancer).

1d. If "YES" - <u>since how many years</u> have you had any of the following diseases: Hypertension/Diabetes/ Hyperlipidemia?

Remember in this question we need to ask **SINCE HOW MANY YEARS (duration), not age.**

This question tries to assess the number of years since the diagnosis of high blood pressure/hypertension; diabetes/high blood sugar; Hyperlipidemia/ High Blood Cholesterol by a doctor. Please note that it refers to time since diagnosis. Enter the response in years and months.

<u>EXAMPLES</u>:

Example 1: If we have visited a 60 year participant 3 years back and at that time she did not have diabetes but now she is diabetic, was diagnosed with diabetes 1 year (at 59 year). Then for this, the answer would be **1 year (in year) and 00 (in months).**

Example 2: If time since diagnosis is 6 months then write 0 in years and 6 in months.

NOTE: If less than a year then write 0 in years and relevant figure in months.

2. **For your health, are you following/taking any of these treatments?**
   If "YES" – complete **Medication Documentation** process.

   This question tries to know regarding different treatment strategies being followed by the newly diagnosed participant to control high blood pressure/ hypertension; diabetes/ high blood sugar; hyperlipidemia/ high blood cholesterol. Read out the option one by one and enter response as either "Yes" or "No". If the participant is not following any of the treatment strategies, then write "Yes" for the option "None". Various treatments are as follows:

   2a. Prescribed allopathic drugs (English/modern)
   2b. Prescribed dietary modification
   2c. Prescribed physical exercise
   2d. Traditional medicine/Therapy* other than yoga
   2e. Yoga or Meditation

**Traditional medicine/therapy include Ayurveda, Unani, Homeopathy, Tibetan, Naturopathy*
**prescribed : by health care professionals*

SOME DEFINITIONS

1) **Allopathic drugs** also known as English medicine in India / prescription medicine.

2) **Diabetes:** Metabolic disorder where blood glucose level is elevated. This is due to either total lack of insulin or decreased level/function of insulin.

3) **Hypertension:** Condition in which the pressure in the vessels carrying blood from heart to different organs of the body is persistently raised. Normally, every time the heart beats, it pumps blood into the blood vessels. Blood pressure is the force of blood pushing against the walls of the blood vessels.

4) **What is blood pressure? What is "Systolic" & "Diastolic" pressure mean?**
   Blood pressure is measured as systolic and diastolic pressures. "Systolic" refers to blood pressure when the heart beats while pumping blood. "Diastolic" refers to blood pressure when the heart is at rest between beats. You most often will see blood pressure numbers written with the systolic number above or before the diastolic number, such as 120/80 mmHg. *(The mmHg is millimetres of mercury—the unit used to measure blood pressure.)*

PART 2C: CANCER

1. Since our last visit with you in _____, have you been told by a doctor that you have cancer? *(Since the last interview)*

   This question refers to the new diagnosis (since the last interview) of cancer. Please try to ascertain that the diagnosis was made by a qualified allopathic doctor. Write the code of the response as either "Yes" or "No" or "Don't know".

   NOTE: If the answer to this question is "NO" or DON'T KNOW then **skip** to **Part 2D** (Kidney disease).

1a. If "Yes" - which site?

If the participant has cancer in more than one site include them as well. Write the appropriate code.

Note: It's a multiple choice question

1b. How was it detected?

Ask the participant how the cancer at each site (in case of multiple site selection) was detected i.e. had symptoms=1; at routine check-up or screening=2; not sure/don't know=999).

1c. At what stage it was diagnosed?

Ask the participant at what stage the cancer was diagnosed at each site (in case of multiple site selection). Select the appropriate codes.

1d. When were you diagnosed with it? ***(Year of diagnosis)***

Please note, here you need to write the year at which cancer was diagnosed (newly diagnosed since last interview). Please write the year in YYYY format.

2. **If "Yes"** - what treatments did you receive (multiple choice)? **Yes$_1$; No$_2$; Don't know$_{999}$**

Ask the participant what kind of treatment (Surgery, hormone therapy, radio therapy, chemotherapy, palliative treatment, or non-allopathic treatment) s/he received after his/her diagnosis of cancer (newly diagnosed since the last visit). Can select multiple treatment.

PART 2D: KIDNEY DISEASE

1. Since our last visit with you in _____, have you been told by a doctor that you have kidney disease? *(Since the last interview)* Yes$_1$; No$_2$; Don't know$_{999}$

This question refers to the new diagnosis (since the last interview) of kidney stone/kidney disease/kidney failure. Please try to ascertain that the diagnosis was made by a qualified allopathic doctor.

Ask the participant with which kidney problem (kidney stone, kidney disease or kidney failure) the participant is/was suffering from. Write the code of the response as either "Yes" or "No" or "Don't know".

If "Yes" for kidney disease, kidney stone or kidney failure go to Q2:
If "2" or "999" skip to Q4

2. Since our last visit with you, have you seen a kidney doctor or a nephrologist?

Choose the appropriate option.

3. Have you ever undergone the following tests?

3a Urine test to check for protein leak
3b Kidney ultrasound
3c Kidney biopsy

Ask the participant if s/he has undergone any test- urine test to check for protein leak, kidney ultrasound or kidney biopsy. Choose the appropriate code (Yes=1, No=2, Don't remember=666, Don't know=999).

4. Are you currently undergoing maintenance dialysis?

Ask the participant if s/he is cuurently undergoing maintence dialysis. If yes, go to Q4a oterwise, skip to Q5

4a. If "Yes" - date of dialysis initiation:

Ask the participant when the dialysis was initiated.

5. Have you ever undergone kidney transplant?

This question is self-explanatory. If "2" or "999, skip to section 3.

5a. If "Yes" - date of kidney transplant:

If yes for Q5, ask the participant when the transplantation of kidney was done.

SOME DEFINITIONS

1. **Dialysis:** It is a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly. It often involves diverting blood to a machine to be cleaned. Normally, the kidneys filter the blood, removing harmful waste products and excess fluid and turning these into urine to be passes out of the body. If your kidneys are not working properly- because you have advanced chronic kidney disease (kidney failure)- the kidney may not be ablet o clean the blood properly. Waste products and fluid ca build up to dangerous levels in your body. Left untreated, this can cause a number of unpleasant symptoms and eventually be fatal. Dialysis filters out unwanted substances and fluids from the blood before this happens.
2. **Transplantation:** It is a surgical procedure where a new organ is placed inside the body of a person in place of a damaged organ. Common organs which are transplanted are heart, kidney, cornea etc. transplantation surgeries are the final modality of treatment in most cases and cost a lot. After transplantation, the person has to take lot of medication for long duration so that the transplanted organ works correctly.

SECTION 3: TREATMENT HISTORY

The purpose of this section is to gain knowledge about the treatment history of participants over a period of one year. This section is divided into two parts (outpatient and inpatient) to capture the details of treatment related to outpatient visit. Below are specifications for questions that require additional clarification.

PART 3A: OUTPATIENT

This part of the section is to elicit the outpatient treatment history of the participants.

1. Are you undergoing treatment as an outpatient for any of the following reasons?

Ask the participant if in the past 1 year they have taken any they are taking any the tab that lists the cardio-metabolic disease, their risk factors and their complications –

- Heart disease
- Stroke
- Diabetes
- Diabetic complications (infections, retinopathy, nephropathy, etc)
- High blood pressure
- Chronic kidney disease
- Cancer
- Other disease

Ask the participant to select the disease/s from the list for which s/he had been undergoing treatment as an outpatient (in the past 1 year). If the participant does not have any of these diseases or is being treated as an outpatient for some other disease or has one or more of the above-mentioned diseases but has not been treated as an outpatient in last one year, then enter "2" in the boxes against the disease mentioned.

If respondent has undergone treatment as an outpatient for other than mentioned diseases, please specify the name of the diseases in the provided space.

Note: If the answer to any of the above is "Yes" go to the next question (Q2) **OTHERWISE** skip to **PART-3B: INPATIENT.**

What is Chronic Kidney disease?

Chronic renal disease is a progressive loss in renal function over a period of months or years. Chronic kidney failure reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can accumulate in your body. Then dialysis becomes essential.

2. **How many times did you visit a health facility/doctor/therapist in past 12 month?**
Write the number of times respondent visited a health clinic/doctor/ therapist/ lab/rehabilitation centre etc in past 12 months for treatment of above-mentioned diseases (Part 3A Q1).
** Include all the investigations examples blood tests, urine tests, ECG, echocardiogram, X ray, CT, scan/MRI, dialysis, ultrasound etc*

3. **Type of health facility/doctor/therapist *(Multiple choice)***
Write the code for type of setting (government=1; private=2; charity=3; others=4) the participant was visiting due to his/her above mentioned conditions (in Q1) in past 12 months. If the participant got treated in a camp, then please select "others", please specify "camp" in the corresponding column.

- A government hospital is a hospital which is owned by a government and receives government funding. This type of hospital provides medical carefree of charge, the cost of which is covered by the funding the hospital receives.
- A private hospital is a hospital owned by a profit company or a non-profit organisation and privately funded through payment for medical services by patients themselves, by insurers, governments through national health insurance schemes, or by foreign embassies.
- A charitable hospital, or charity hospital, is a non-profit hospital that provides treatment for poor and uninsured people who can't purchase treatment.

PART 3B INPATIENT

1. **Did you go to a hospital emergency room in the past 12 months?**
Ask the participant if s/he had admitted in the hospital emergency room in the past 12 months. If yes, move to Q1a, otherwise skip to Q2.

   1a. If "Yes" - how many times?
   Here, write the number of times the participant had admitted in the hospital emergency room in the past 12 months.

2. **Were you kept in the hospital for observation for any illness in the past 12 months?**
Ask the participant if s/he was kept in the hospital for any illness (admitted in morning and discharged by evening) in the past 12 months.

   NOTE: Admitted in the morning and discharged by evening.

   2a. If yes, how many times?
   If the answer to Q2 is yes, then write the number of times the participant had been kept for observation for any illness in the past 12 months.

3. **Were you hospitalized for any illness in the past 12 months?** *(Admitted for overnight stay)*

Ask the participant if s/he was hospitalised (admitted for overnight stay) for any illness in the past 12 months.

NOTE: Admitted for overnight stay.

3a. If "Yes" - how many times?
If the answer to Q3 is yes, then write the number of times the participant had been hospitalised (admitted for overnight stay) for any illness in the past 12 months.

3b. Were you admitted for any of the following reasons?
Ask the participant if s/he had admitted for heart disease, stroke, diabetes, diabetic complications (infections, retinopathy, nephropathy etc), high blood pressure, chronic kidney disease, cancer, or any other disease in the past 12 month. If yes, for any of these, pls write the length of the stay (in days) at the hospital. If yes for other reason, pls specify and write the length of stay in the provided space.

Ex: if the participant was admitted in the hospital once in the past 1 year for high blood pressure and diabetes for 10 days then write "01" in Q3a and in 3b select "yes" for blood pressure and diabetes and for the length of stay, write 10 for both the diseases. Similarly, if the participant had hospitalised twice in past 1 year, 1st for diabetes and 2nd time for heart disease then Q3b will open twice and you can write the reasons of hospitalisation separately.

4. **Do you have medical records related to hospitalization / surgical procedure?**

   4a. **If "Yes**" - ask the participant to show the medical records and note the diagnosis in a chronological order separately for hospitalization due to illness and surgical procedures mentioned above in the space provided below. If "No", skip to section 4.

5. **Ask the participant if s/he has the medical records related to the hospitalisation and surgical procedures**. If yes, click the photographs of all the records using the tabs and record the diagnosis in the chronological order (1- Hospitalisation; 2- Surgical procedures; 3- comments, if any) in the provided space. In case of paucity of time, the FIs can fill these details later (by looking at the photographs of the medical records)

SECTION 4: EYES

1. **Since our last visit with you, have you ever seen a doctor for difficulty with your eyesight other than your ordinary power glasses (spectacles)?**
   Select "Yes" or "No" as mentioned by the participant. Please ask the participant to exclude difficulty in eyesight for which spectacles have been prescribed.

2. **Since our last visit with you in auto-populate, has an eye doctor ever told you that you have:**
   In this question try to find out the diagnosis for poor vision. If the response is "Yes" for the previous question, then ask this question and write the code **(Cataract=1; Retinopathy=2; Both (cataract and retinopathy)= 3; Others=777)** for the stated response. If others, then specify the reason in the provided space.

3. **If selected "retinopathy" or "both (cataract & retinopathy)" for question 2, what was the cause for the retinopathy?**
   If the participant has/had retinopathy or both (Cataract and retinopathy), ask the participant what the cause of the retinopathy was- hypertension, diabetes, both (hypertension & diabetes) or any other. If others, then specify the reason in the provided space.

4. **If selected "retinopathy" or "both (cataract & retinopathy)" for question 2, when was the retinopathy diagnosed?**
   If the participant has/had retinopathy or both (Cataract and retinopathy), ask the participant **when** (in year and month) was the retinopathy diagnosed.

   Example: In year 2022, if the participant had replied that s/he had diagnosed with retinopathy 2 years back then the answer would be 2022-2= 2020 (20). Then, ask them at which month it was diagnosed.

5. **Since our last visit with you in auto-populate, have you undergone laser therapy (Photocoagulation) anytime?**
   Laser therapy / photocoagulation is a surgical procedure using laser beam/ focused light on the eye to treat a number of eye diseases such as diabetic retinopathy, age related macular degeneration, glaucoma, etc.

   5a. If "Yes" for laser therapy (Photocoagulation), when?
   If yes for Q5 or the participant had undergone laser therapy (photocoagulation) at any time then ask when (in year and month) s/he had it done.

   Example: In year 2022, if the participant had replied that s/he had undergone laser therapy (photocoagulation) 6 years back then the answer would be 2022-6= 2016 (16). Then, ask them at which month it was done.

SOME DEFINITIONS

1. **What are diabetic complications – retinopathy, neuropathy, nephropathy?**
   a. **Diabetic retinopathy** is a complication of diabetes that affects the eyes. It's caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina).
   b. **Diabetic neuropathy:** High blood sugar can injure nerve fibres throughout your body, but diabetic neuropathy most often damages nerves in your legs and feet. Depending on the affected nerves, symptoms of diabetic neuropathy can range from pain and numbness in your extremities which lead to diabetic foot and ulcers.
   c. **Diabetic Nephropathy:** Reduced blood flow to your kidneys and the presence of a protein called albumin in your urine make your body retain more water and salt. This can cause symptoms such as weight gain, ankle swelling, fatigue and loss of appetite. Diabetic nephropathy is the leading cause of end-stage kidney disease, resulting in the need for dialysis or kidney transplantation.

SECTION 5: COVID-19

1. **Have you experienced COVID-19 disease, the condition caused by SARS-CoV-2 infection, since March 2020?**
   Ask the participant if the s/he EVER experienced COVID-19 disease since March 2020.

   1a. If yes, how was it diagnosed?
   If the participant had said yes for experiencing COVID-19 disease, then ask how it was diagnosed and choose from the given options: Home COVID-19 antigen test, RT-PCR or based on the symptoms of COVID-19 disease.

2. **How many episodes/events of the infection did you experience?**
   If the answer to Q1 is yes, ask how many episodes/events of the infection the participant suffered from.

Count 2 episodes if the participant responded 2 episodes of COVID-19 if it was diagnosed after 21 days of 1st diagnosis.

3. **Were you hospitalised for COVID-19 disease?**
   Through this question we would like to capture if the participant has been hospitalised due to COVID-19 disease.

4. **Have you experienced long COVID-19 symptoms (fatigue, brain fog, loss of smell, joint pain etc)?**
   Ask the participant if s/he had any COVID-19 symptoms that persists for long time.

5. **Have you taken the COVID-19 vaccination?**
   Ask the participant if s/he had taken COVID-19 vaccination. If the answer is no, skip to Section-6.

   5a. How many doses have you received?
   If the participant had taken COVID-19 vaccination, ask how many doses that have received (1 dose=1, 2 doses=2)

   5b. Name of the vaccine taken:
   Ask the name of the vaccine taken for COVID-19 and if the name is not given in the list, select others and specify the name of the vaccine.

6. **Have you taken Precautionary (i.e., booster) dose?**
   Ask the participant if s/he had taken COVID-19 booster/ precautionary vaccination. If the answer is no, skip to Section-6.

   6a. Name of the booster vaccine taken:
   Ask the name of the vaccine taken as a booster dose and select the name as per the answer given by the participant. If the name is not given in the list, select others and specify the name of the vaccine.

SECTION 6: TOBACCO AND ALCOHOL USE, DIET, PHYSICAL ACTIVITY AND SLEEP DETAILS

PART 6A: TOBACCO USE

The purpose of this part is to gather information about tobacco use.

1. Have you **EVER** used tobacco in any form (smoking, chewing, snuff, etc.)?
   Here, we are asking if the participant have EVER used tobacco in any form i.e., smoking (cigarette, cigar, hookah, bidi); chewing (gutkha, pan, khaini); and/or any other form (tobacco paste/powder, snuff)" in his/her life. If participant says "yes" then write "1". If participant says "no" then write "2."

   NOTE: If the participant is not using tobacco currently but used it in past then, the answer to this question should be "Yes." If the answer is "2" then skip to part 6B (Alcohol use).

2. **If yes, in what forms have you EVER consumed tobacco?**
   Here we are interested in different forms of tobacco. If participant uses cigarette, bidi, cigar, hookah mark "Yes" in smoked form. Likewise, if the participant uses gutkha, pan, khaini mark "Yes" in chewed form. Mark "Yes" in other form if the participant consumes tobacco paste/ powder and snuff.

   NOTE: It is possible that person may be using/used more than one form of tobacco.

3. **Do you currently consume tobacco?**
   "Currently" means tobacco consumed within the past six months.

Here, we are asking participant's use of tobacco in any form i.e., smoking (cigarette, cigar, bidi); chewing (gutkha, pan, khaini); and/or any other form (tobacco paste, snuff)" within last 6 months. If participant says yes, then write "1". If participant says no, then write "2" and skip to Q6.

NOTE: If a participant claims to have discontinued tobacco consumption within last 6 months, then the answer to this question is "Yes". If she/he had discontinued more than 6 months, then write "2" in the provided space.

4. **If "yes" what type?**
   Here we are interested in different forms of tobacco that is consumed by the participant CURRENTLY. If participant uses cigarette, bidi, cigar select "Yes" in smoked form. Likewise, if the participant uses gutkha, pan, khaini select "Yes" in chewed form. Select "Yes" in other form if the participant consumes tobacco paste and snuff.

   Example: If the participant consumes only gutkha then select "Yes" in the corresponding column for chewed form and for smoking form and any other form write "No."

5. **If smoking forms, how many packs/numbers per day?**
   If the participant has been currently using tobacco in smoking form, then ask, how many cigarettes/bidis/cigars or how many packs s/he smokes in a day.

6. **At what age did you first start smoking regularly?**
   Note the age when the participant first started smoking regularly. Write "666" in the box if the participant doesn't remember.

   Please note that in this question (Q6), we need to write the age of the participant (in completed years) at which the participant started smoking regularly.

   If participant says that he/she doesn't remember the age help him/her to remember the age of initiation, ask them to relate it to some major event of their life if he/ she still doesn't remember the year of initiation then write "666" in the provided space and move to the next question.

   Example: This can be ascertained if the participant is 70 years old and says he started smoking 40 years ago, that means at that time s/he was 30 years (70-40). So, the age at which the participant started smoking was (70-40year=30 years).

7. **At what age did you first start consuming smokeless tobacco product regularly?**
   Note the age (in completed years) when the participant started using the smokeless tobacco product regularly. Write "666" if the participant doesn't remember.

PART 6B: ALCOHOL USE

The purpose of this part is to gather information about alcohol consumption.

1) **Have you EVER consumed alcohol?**
   Here, we are asking if the participant have EVER consumed alcohol in his/her life. If participant says "yes" then write "1". If participant says "no" then write "2".
   The Alcohol Use Disorders Identification Test-Concise (AUDIT-C) is a brief alcohol screening instrument that reliably identifies persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). It is a modified version of the 10-item Alcohol Use Disorders Identification Test developed by the WHO and published in 1998.
   It has 3 questions and is scored on a scale of 0-12. Each question has 5 answer choices valued from 0 points to 4 points.
2) **If yes, how often did you have a drink containing alcohol in the past year?**

Ask the participant how often s/he had a drink containing alcohol in the past year. Select from the options given: Never=1, Monthly or less=2, 2-4 times a month=3; 2-3 times a week=4, ≥4 times a week=5.

3) **How many drinks containing alcohol did you have on a typical day when you were drinking in the past year?**

Ask the participant on a **typical day** how many drinks containing alcohol did s/he drinks in the past year. Choose from the options: 1 or 2 drinks=1, 3-4 drinks=2, 5-6 drinks=3, 7-9 drinks=4, ≥10 drinks=5

standard drink of Beer: 360 ml

standard drink of Wine: 150 ml

standard drink of Spirit: 45 ml

4) **How often did you have six or more drinks on one occasion in the past year?**

Ask the participant "how often did s/he have **six or more drinks** on **one occasion** in the past year. Choose from the options- Never, less than monthly, monthly, weekly, daily, or almost daily.

PART 6C: DIET

The next questions ask about fruits and vegetables that the participant usually consume. As you answer these, please think of a typical week in the last year

Serving size is standardised to 100 grams of fruit/ vegetable.

1. **In a typical week, on how many days do you eat fruit?**

   Typical week refers to a normal week when the diet is not affected by cultural, religious, or other event. The answer to this question will range from 0-7. Write "0" if the participant doesn't eat any fruit on a typical week. If the participant doesn't remember write "666" in the provided space.

   1a. How many servings of fruit do you eat on one of those days?

   Ask the participant to think of one day s/he can recall easily. Ask how many servings of fruits s/he consumed on one of those days. One serving is equal to 100grams.

2. **In a typical week, on how many days do you eat vegetables?**

   Typical week refers to a normal week when the diet is not affected by cultural, religious, or other event. If the participant doesn't remember write "666" in the provided space.

   2a. How many servings of vegetables do you eat on one of those days?

   Ask the participant to think of one day s/he can recall easily. Ask how many servings of vegetables s/he consumed on one of those days. One serving is equal to 100grams.

PART 6C: PHYSICAL ACTIVITY

This part of the form will be used to obtain physical activity information from the participant for the study. In this part, the participant will be asked about the time spent doing moderate activity and time spent sitting/ reclining in a **typical week**.

1. **How much time do you usually spend sitting or reclining on a typical day?**

   This question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, sitting in bus; train; reading, playing cards or watching television], **but do not include time spent sleeping.**

   Consider total time spent at work sitting, in an office, reading, watching television, using a computer, doing hand craft like knitting, resting etc.

   NOTE: Do not include time spent sleeping. Consider total time (in hours and minutes) spent sitting/reclining at work at the desk working, in class during lectures, during travel (driving, traffic jams,

sitting in bus; car; train; metro etc); at home watching television, in front of a computer, and any other (chatting, playing cards etc).

2. **Do you undertake any moderate physical activities for minimum of 150 minutes in a week?**
   This is physical activity that increases the heart rate, such as walking fast, climbing stairs, jogging, cycling, dancing, playing sports and games, yoga, carrying/moving moderate loads (<20kg), etc.

   Ask the participant to think about moderate-intensity activities. Activities are regarded as **moderate intensity** if they cause small increases in breathing and/or heart rate.

   Example are washing (bating and brushing carpets, wringing clothes (by hand), gardening, digging dry soil (with spade), weaving, woodwork (chiseling, sawing, softwood), mixing cement (with shovel), laboring (pushing loaded wheelbarrow, operating jackhammer, walking with load on head, drawing water, tending animals etc.

   Write "Yes" if the participant is involved in a "Moderate Intensity activity" in a **typical week** for a minimum 150 minutes in a typical week (at least 10 minutes continuously) otherwise select "No."

   "Typical week" means a week when the participant is engaged in his/her usual activities.

   Probe very high responses (over 4 hrs) to verify.

PART 6D: SLEEP DETAILS

In this section we will ask questions to assess the sleep habits (snoring and breathing during sleep) of the participant. The questions are self- explanatory. Below are specifications for questions requiring additional clarification.

1. **How many hours of sleep do you usually get at night (or your main sleep period)?**
   Explain the participant that you are referring to average hours of sleep per night or your main sleeping period (can be daytime if the person does night shifts). Enquire for the average hours of sleep separately for the weekday and weekends.

2. **STOP questionnaire: A tool to screen patients for obstructive sleep apnea (OSA).**
   It's a concise tool to measure obstructive sleep apnea. It is a condition in which a person stops breathing for a brief period during sleep. Here, we are going to ask 4 questions related to snoring, tiredness during the daytime, stopped breathing during sleep, and hypertension. The questions are self-explanatory. (Yes=1; No=2, don't know=999)

   a. **Snoring:** Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?
   b. **Tired:** Do you often feel tired, fatigued, or sleepy during daytime?
      This question is asked even after complete rest at night do you often feel tired, fatigued, or sleepy during daytime
   c. **Observed**: Has anyone observed you stop breathing during your sleep?
      Ask this question to the person who sleeps next to the participant or any other person from that household.

SECTION 7: PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

These questions are negative. Be sensitive to the participant's feelings. Explain to them you wish them well, but this is part of survey.

The field interviewers need to **write the codes** of the option to indicate their answers.

Not at all=1; Several days=2; More than half the time; Nearly every day=4

Over the **last 2 weeks**, how often have you been bothered by any of the listed problems

If the participant is literate, show him/her the options and record the responses as stated otherwise ask the questions with the statement:

In this section focus of the questions are on the various behaviours and problems in daily life and if he/she was bothered by any of the following problems in last two weeks.

- **"Not at all"** means: The participant is not bothered by the said problem in last two weeks
- **"Several days"** means: Many days but less than half of the days during the last two weeks.
- **"More than half days"** means: More than a week in the last two weeks.
- **"Nearly every day"** means: Almost every day.

Read out the statement (or Participant reads, if literate)- "In the last two weeks, have you been bothered by any of the following problems".

NOTE: Ask whether the participant has been bothered about any of the following 9 problems in last 2 weeks. If s/he said, "Not at all" write "1" OTHERWISE write the code for nay option given "Several days"; "More than half days" and Nearly every day" in the provided box.

1. **Little interest or pleasure in doing things:** This question asks about loss of interest/pleasure in most things during last two weeks. Respondent will reply as "Not at all" or "Several days; "More than half days" and Nearly every day." Write the appropriate code in the provided box.

2. **Feeling down, depressed, or hopeless:** This question asks about having a feeling of no- worth/ no good or low self-esteem during last two weeks. Respondent will reply as "Not at all" or "Several days; "More than half days" and Nearly every day." Write the appropriate code in the provided box.

3. **Trouble falling or staying asleep or sleeping too much:** This question asks about trouble in falling asleep or staying asleep during last two weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or nearly every day." Write the appropriate code in the provided box.

4. **Feeling tired or having little energy:** This question asks about feeling tired or low on energy most of the time in last 2 weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or nearly every day." Write the appropriate code in the provided box.

5. **Poor appetite or overeating:** This question asks about problem of loss of appetite or overeating in last 2 weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or nearly every day." Write the appropriate code in the provided box.

6. **Feeling bad about yourself-or that you are a failure or have let yourself or your family down:** This question asks about problem of feeling bad about yourself in the last 2 weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or nearly every day". Write the appropriate code in the provided box.

7. **Trouble concentrating on things, such as reading the newspaper or watching TV:** This question asks about problem of not able to concentrate on things like reading the newspaper, watching TV and other usual things in the last two weeks. Respondent will reply as "Not at all" or "Several days" or "More than half days" or "Nearly every day". Write the appropriate code in the provided box.

8. **Moving or speaking so slowly that other people could have noticed. Or the opposite being so fidgety or restless that you have been moving around a lot more than usual:** This question is regarding moving/speaking so slowly, that it could be notified by others or about being fidgety/ restless in the last

2 weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or nearly every day". Write the appropriate code in the provided box.

9. **Thoughts that you would be better off dead or of hurting yourself in some way:** This question is about thinking of death of your own/ someone else's or in general in the last 2 weeks. Respondent will reply as "Not at all" or "Several days or "More than half days" or "nearly every day". Write the appropriate code in the provided box.

10. **If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**
    If the participant has given code 2 or 3 or 4 any problem out of the 9 problems (given in the previous question) then the FI shall ask the participant that "how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?" For this question, four options ("Not difficult at all=1; Somewhat difficult=2; Very difficult=3 and Extremely difficult=4") have been given. Please write code of one option only.

SECTION 8: QUALITY OF LIFE

This section of the questionnaire is self-explanatory and is used to understand the quality of life of the participant.

Record the responses as stated otherwise ask the questions with the statement.

"Please indicate which statement best describes your state of health ***"today."***

1. **Mobility:** This question is about the mobility of the respondent today. Please read out all the option fully and let the participant choose the option which he/she thinks as correct. Write the appropriate code in the provided space.

2. **Self- care:** This question is about the ability of the respondents to take care of themselves (like brushing teeth, combing hair, taking bath etc.) today. Please read out all the option fully and let the participant choose the option which he/she thinks as correct. Write the appropriate code in the provided space.

3. **Usual activities (e.g., work, study, housework, family, or leisure activities):** This question is about the ability of the respondents to carry out their usual activities today. Please read out all the option fully and let the participant choose the option which he/she thinks as correct. Write the appropriate code in the provided space.

4. **Pain/ discomfort:** This question is about the pain/discomfort which respondent face today. Please read out all the option fully and let the participant choose the option which he/she thinks as correct. Write the response accordingly.

5. **Anxiety/ Depression:** This question is about the anxiety/depression what respondent faced today. Please read out all the option fully and let the participant choose the option which he/she thinks as correct. Write the response accordingly.

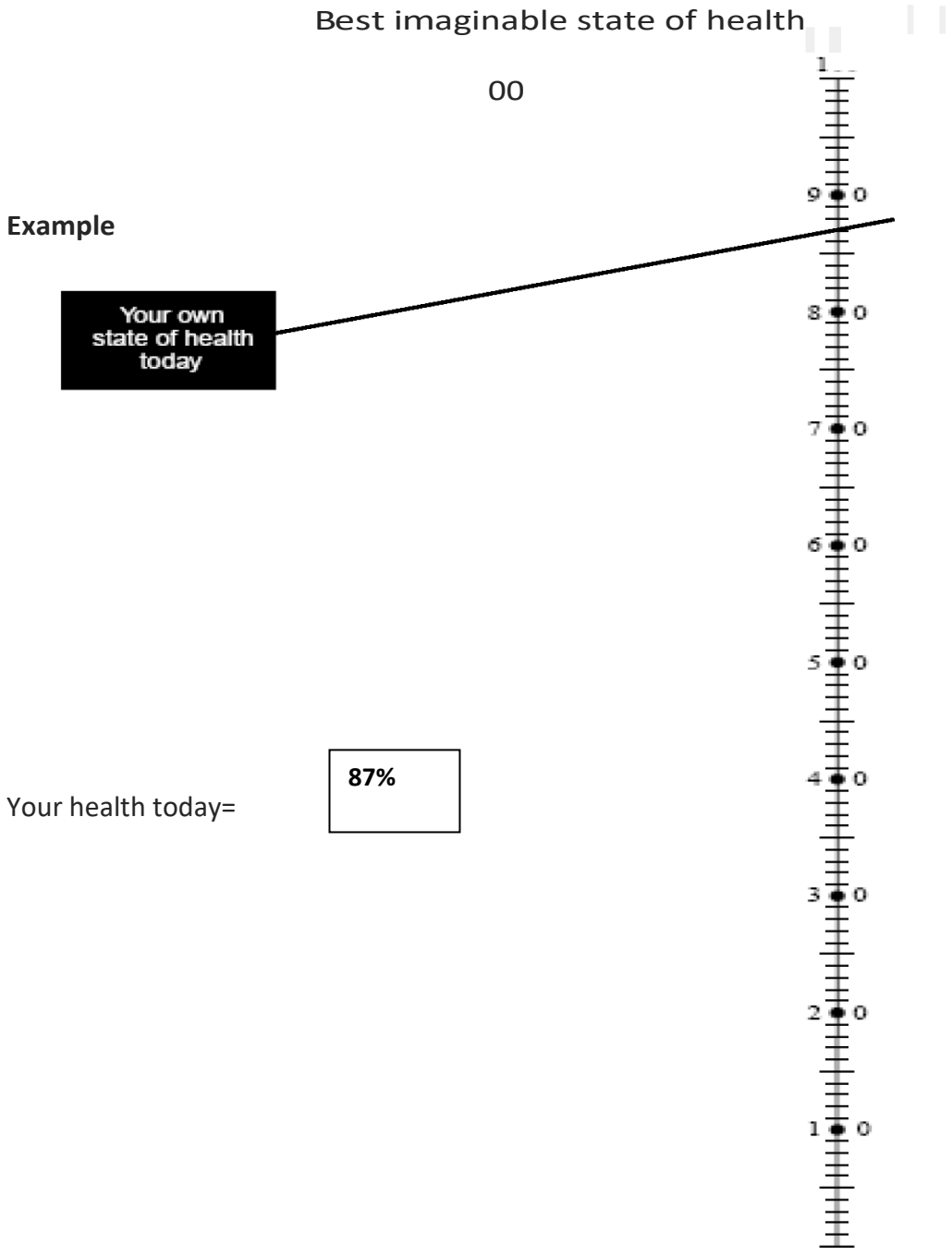
6. The **scale** helps people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state a participant can imagine is marked 100 and the worst state the participant can imagine is marked 0.

   Ask the participant to indicate on this scale how good or bad her/his own health is on the day of interview. This should completely be the subjective feeling of the participant and the FI should

not prompt. Ask the participant to draw a line from the box provided besides the scale to a point on the scale which s/he feels denotes how good or badher/his state of health is on that day. Example is given in the next page.

What is Quality of Life?

In general, quality of life (QoL or QOL) is the perceived quality of an individual's daily life, that is, an assessment of their well-being or lack thereof. This includes all emotional, social, and physical aspects of the individual's life. In health care, health- related quality of life (HRQoL) is an assessment of how the individual's well-being may be affected over time by a disease, disability, or disorder.



SECTION 9: SOCIO DEMOGRAPHIC & SOCIO-ECONOMIC STATUS

This section has a total of twelve questions.

PART 9A: DEMOGRAPHIC DETAILS

1. **What is your current marital status?**
   Marital status could have changed since last time therefore we are collecting this information. Also, it is important to know the marital status of the participant especially for women because some of the questions can be asked only to a married woman. Apart from this, married and not married people have difference in risk factors.

   1a. Spouse name
   Ask the participant the name of his/her spouse.

2. **Is your spouse enrolled in the CARRS study (i.e., the opposite sex participant)?**
   Ask the participant if the spouse (opposite sex participant- husband/wife) is also a part of CARRS study.

PART 9B: SOCIO-ECONOMIC DETAILS

1. **What is your highest level of education attained?**

2. **What is your total number of years of schooling?**
   Education status could have changed since the last visit therefore we are collecting this information. It states the highest educational degree attained by respondent. Ask the participant, "What is the highest level of education that you have completed?" Write the code corresponding to her/his response in the box. If respondent is currently studying, then last completed degree should be reported. If participant's response is not on the list, select the code for "Others" and record her/his answer in the space provided.

   - Literate, no formal education: A person aged 7 years and above who can both read and write with understanding in any language without any formal education or passed any minimum educational standard.
   - Illiterate: A person, who can neither read nor write or can only read but cannot write in any language, is treated as illiterate.

   Examples:
   If the participant A is pursuing graduation. He is in its 3rd year. Then the number of formal education would be 12+2=14.

   If the participant is in 3rd year of graduation and had failed for 2 years. Then also, the number of formal years would be 12+2=14. But for the highest degree obtained (Q1) write the code for 12 i.e.,3.
   If the participant is in 3rd year of graduation and had jumped 1 class (2nd) then the number of formal years would be 11+2= 13 but for the next question, please write the code Secondary school/intermediary i.e., 3.

   NOTE: Please ask the participants about the years of degree/ diploma that they've pursued. For example, some of the degrees are of 4 years (B Tech) some of 3 years (BSc); Same thing follows for diploma.

   Example:

Earlier, in some part of India there used to schooling till 10th after those 2 years graduation and 1 year post graduation programme. For those participants the year of formal education would be 10+2+1=13. But, in Q1 we need to write the code for post-graduation i.e.,"1". If there is any discrepancy, please check and explain the reasons in the provided space.

Notes:
If the participant is in 3rd year of his bachelor's degree, then the highest degree obtained would be class 12th.

3. **What is your total household income per month (INR)?**
   NOTE: Please include income from all members who contribute to the household.

   Total household income per month could have changed since the last visit therefore we are collecting this information. Ask the participant what her/his household income is per month. It is an indicator of the economic condition of an individual and the household. The total income is the combination of the money sent by family living away and incomes of all household members including incomes from sources (shop or house rents, agricultural fields, etc.). The total income also includes money that is contributed on a regular basis by those who live outside the home. Ask the participant what her/his household income per month is. As far as possible encourage the respondent to report the income (Q3a) and choose from the income ranges (Q3b). If the participant refuses to answer the question or does not know the answer to the question, select the appropriate response.

4. **Which of the following best describes your main work status over the past 12 months? Specify Occupation.**
   Employment status could have changed since last visit therefore we are collecting this information. From the options given, ask what his/her main work status (Government employee=1, non-government employee=2; self-employed=3 etc) over the past 12 months. Respondent is asked to select only one option. Specify the occupation if options are 1,2 or 3. Otherwise move to the next question.

5. **Do you have a separate room for cooking (Kitchen)?**
   To study the potential for exposure to cooking smoke from solid fuels, survey collects information on the place where cooking is usually done.

6. **What is the fuel used for cooking?**
   Smoke from solid cooking fuels has a serious health hazard (solid cooking fuels include coal/lignite, charcoal, wood, straw, shrubs, grass, agricultural crop waste and dung cakes). The purpose of this question is to determine the type of fuel used to cook meals at home. Common sources of fuel include gas, kerosene, wood, and electricity. Electrical appliances include a stove, microwave, and toaster. If the participant reports using a gas stove and a microwave, then write code "2" in the box. If participant's response is not on the list, select the code for "Others" and record her/his answer in the space provided.

   ***NOTE**: If more than one source is used then note the source that is most commonly used.*

7. **What is the source of drinking water used at home?**
   Major source of drinking water used by household is collected through this question. Choose from the options, given below:
   Public source, Private source (shared), Private source (own), Bottled water, Purified tap water.

   NOTE: If more than one source is used, note the source that is most commonly used.

8. **What is the toilet facility you use?**

Access to sanitation facility is also one of the basic needs of individual, which has severe effect on their health. Information on type of toilet facility used by the household helps in determine their current health status.

9. **Which of the following do you own?**
   This information could have changed since last visit therefore we are collecting this information. Ownership of household asset is widely used indicator for economic condition of the household. Information on household assets is used to construct wealth index, which is often used as proxy to determine the economic well-being of the individual and their household. A set of items are asked under this where investigator needs to ask all the ownership of all the items mentioned. Against each item need to write "1" or "2" according to the given response.

   NOTE: Obtain this information for both the participant separately. Do not copy. If the information obtained from the same house is different, confirm with the participants.

10. **Do you have any domestic help for house chores, cooking etc?**
    Ask the participant if they are paying some one (domestic help) for doing household chores (cooking, cleaning, washing clothes, washing utensils etc).

SECTION 10: FEMALE REPRODUCTIVE HISTORY

This section should be administered to female participants alone. The purpose of this section is to find information about a female participant's reproductive history particularly menstruation, pregnancy, and use of hormones (oral contraceptives or Hormone Replacement Therapy). Remember to assure the participant that all answers will remain confidential. Below are specifications for questions requiring additional clarification.

1. **Have you EVER been pregnant?**
   Ask this question discreetly/ don't ask for unmarried woman unless there is strong reason to do so.
   Ask the if she has ever been pregnant. If "2" skip to Q10.

2. **How many live births have you had?**
   This question includes only the live births that the participant had. It should not include stillbirths (death after 28 weeks in utero), miscarriages (spontaneous loss of pregnancy before five months in utero), induced abortion, and ectopic/tubal.
   If the participant doesn't know, write 999 or if the participant was pregnant and had a miscarriage and since then did not give live birth to a child select "555" (not applicable).

3. **How old were you at your first live birth?**
   Ask the participant what her age was (how old was she) at the time of first live birth.

4. **What is the date of birth of your youngest biological child?**
   Here, you need to write the date of birth of participant's youngest biological child (alive) and if the participant is unable to remember the exact date of birth, please go to next question (4a) and write the **age** of her youngest biological child (in years and months) otherwise skip to the next question.

   4a. If the participant is unable to recall the exact date of birth of the youngest child, how old is your youngest child (age in completed years)?

5. **For women with a history of diabetes, did you have diabetes prior to any pregnancies?**
   This question will appear for the female participant who had reported that she has diabetes in the earlier surveys, the FI will ask if s/he had diabetes before any pregnancies or not. Choose from the options-

Yes=1, No=2, 999=Don't know, 9= Not applicable.

6. **Were you diagnosed to have gestational diabetes in any of the pregnancies?**
   Please write "1" if the participant has been diagnosed (newly detected) with gestational diabetes in any pregnancy.

> **Gestational Diabetes**: Pregnant women who have never had diabetes before but whose blood glucose is high during pregnancy are said to have gestational diabetes.

7. **Did you receive any drug (insulin/metformin/ glibenclamide) for treatment of diabetes during pregnancy?**
   If the participant had said yes for Q6, please ask if she had received any drug (insulin/ metformin/ glibenclamide) for the treatment of diabetes during pregnancy. If any medical records are available. Please scan the document and save the documents.

8. **For women with a history of hypertension (auto-populate), did you have hypertension prior to any pregnancies?**
   This question will appear for the participant who had reported that she had hypertension in the earlier surveys, the FI will ask if s/he had hypertension before any pregnancies or not. Choose from the options- yes=1, No=2, 999=Don't know, 9= Not applicable.

9. **Were you newly diagnosed to have hypertension in any of the pregnancies?**
   Please write "1" if the participant has been diagnosed with pregnancy induced hypertension in any pregnancy.

10. **How old were you when you had first menstrual period?**
    Ask the age (in completed years) of the participant when she had started menstruating.

11. **Are you currently having menstrual cycles?**
    It should be answered as "Yes" or "No". If "No" then ask Q11a. If the answer is "Yes", skip to Q14.

11a) If 'No' what is the reason?

If the participant is not having the menstrual cycles ("2" for Q11), then this question assesses the cause for it. Select the reason among pregnancy/ lactation/ natural menopause/ hysterectomy/ other as told by the participant. Please specify the reason if it's "others."

***NOTE**: Hysterectomy means removal of the uterus/womb with or without removal of the ovaries*
Natural menopause means no menstrual period for 1 year and no medical intervention.

12. **If Q11a if filled with "natural menopause" or "hysterectomy" or "Other", at what age did you stop menstruating?**
    Ask the participant her age (in completed years) at which she stopped menstruating due to natural menopause or due to removal of uterus/womb or any other reason.

    In Q12, if the participant doesn't know the exact age at which the participant stopped menstruating, ask the participant how many years or months ago (Q12a) she had stopped menstruating.

13. **Have you used hormonal medicines (that is oestrogen or progesterone combinations) for hormonal replacement therapy, to regulate your periods or for birth control?**
    Ask the participant if she had ever used or currently using any hormonal medicine like oestrogen or progesterone combination to regulate periods or for birth control. Write yes for 1 and 2 for No.

SOME DEFINITIONS

1. **What are Hormonal Drugs/Oral Contraceptive pills:** These are medicines containing hormones (oestrogen and progesterone). **Hormonal drugs** or Hormone Replacement Therapy (HRT) is usually prescribed to post-menopausal women and **Oral Contraceptive Pills** (OCPs) are usually prescribed as a birth control drug for women in their reproductive age.
2. The **last menstrual period** (LMP) refers to the first day (onset of bleeding) of your last menstrual period.
3. **Youngest Biological child-** youngest child conceived and delivered by the mother. Please **DON'T** include adopted child.

SECTION 11: MEDICAL DOCUMENTS

1. Has the participant shared any medical documents?
   a. Medicine
   b. Medical documents

   Select "Yes" if it was shared by the participants. Check if all the documents are scanned by the FI.
   If "No", thank the participant and end the questionnaire.

Procedure for writing the medicine prescription in the tablet.

1. Ask participants to get all doctor's prescriptions whose medicines they are currently taking.
2. Ask participants to bring all the medicine they are currently taking including the ayurvedic tonic and syrups and non-prescribed medicines.
3. Click the photograph of all these- doctor's prescription and tablet/capsule/syrup/ inhaler separately.
4. Suppose the strip is broken do the followings:
   a. Ask participants if they have a new unused strip with them, as most NCD patients purchase multiple strips at one go.
   b. Ask participants if they remember the name and write the name on the used strip.
   c. If this is not available ask for a doctor's prescription mentioning this medicine's name

   Note: Even if the strip is broken, please take a photograph

5. After clicking the photos ask participants how they take them and select the options given (same is provided in the table below). if the options are not there, please select others and specify how the medicine is consumed by the participant.
6. Upload the photographs of the medicines in the tablet and sync the data.

Use the following codes:

Codes (for tablet)	Meaning
1-0-0	Once in morning
1-1-0	One in the morning and one in the afternoon
1-1-1	One in the morning, one in the afternoon, and one in the evening
1-W	Once a week

1-M	Once a month
2-0-0	Two in morning
2-2-0	Two in the morning and Two in the afternoon
2-2-2	Two in the morning, Two in the afternoon, and Two in the evening
1-1-1-1	Every 6 hr (write no of tablets they are taking each time)
Others	If any other, please specify
Twice a week	2-W
Taking medicine alternate day	3-W
Taking a medicine 3 times in a day	3 per day
¼ tablet in a morning	0.25-0-0
Codes for syrup	
5-5-5	For syrup write the ml they are taking each time, this means the participant is taking 5ml three times a day
0-0-25	The participant is taking 25ml in the evening and night time

SECTION 12: FRIED FRAILTY PHENOTYPE SCALE (≥50 YEARS)

The Fried frailty phenotype (FP) assesses physical frailty through *five criteria*: unintentional weight loss; weakness or poor handgrip strength; self-reported exhaustion; slow walking speed; and low physical activity. These questions will be asked to the participant **who is 50 years old or older.**

1. **Weight loss:** Self-reported unintentional weight loss ≥5Kg in previous year?
   Ask the participant she s/he has lost weight ≥5Kg unintentionally in previous year.

   NOTE*: Unintentional weight loss is when you lose weight without changing your diet or exercise routine. It can be a sign of stress or a serious illness.*

2. **Do you feel full of energy?**
   Choose yes or no based on their answer.

3. **During the last 4 weeks how often, you rested in bed during day?**
   Ask the participant if how often s/he rested in bed during day in the last 4 weeks. Choose the answer from the options *(Every day$_{=1}$, Every Week=$_2$, Once=$_3$, Not at all=$_4$).*

4. **How often you do mildly energetic physical activity?**
   Ask the participant how often the participant do any mild physical activity. Choose from the options (>3 times per week=$_1$; 1-2 times per week=$_2$; 1-3 time per month=$_3$; Hardly ever/never=$_4$).

   NOTE*: "mild physical activity" is activities which doesn't increase breathing or heart rate.*

5. **How often you do moderately energetic physical activity?**

Ask the participant how often the participant do any moderate physical activity. Choose from the options *(>3 times per week$_1$;1-2 times per week$_2$; 1-3 time per month$_3$; Hardly ever/never$_4$).*

***NOTE**: "moderate-intensity activities" are activities that require moderate physical effort and cause small increases in breathing or heart rate.*

6. **How often you do very energetic physical activity?**
   Ask the participant how often the participant do any vigorous physical activity. Choose from the options *(>3 times per week$_1$; 1-2 times per week$_2$;1-3 time per month$_3$; Hardly ever/never$_4$)*.

   ***NOTE**: "vigorous-intensity activities" are activities that require hard physical effort and cause large increases in breathing or heart rate.*

7. **Do you have any problems from recent surgery, injury, or other health conditions that might prevent you from walking?** (If "1", skip to the next part "MINICOG")
   Ask the participant if s/he has any problem (surgery, injury, amputation or any other health problem) which might prevent them from walking. If the participant said yes, then skip to *"Section-13 Minicog."*

8. **Walking time in seconds (usual pace) over 15 feet.**
   ***NOTE**: Ask the participant to walk over 15 feet and note the time*
   Detailed procedure is given in chapter 7- Measurements.

9. **Was the participant able to complete the walk?**
   Select "yes" if the participant is able to complete the 15 feet walk and no if due to any reason s/he will not be able to complete the walk. If No go to *"Section-13 Minicog."*

10. **Did the participant use any type of aid for walking?**
    Select yes, if the participant had used any aid for completing the 15feet walk and go to the next question.

11. **Record type of aid used.**
    Write the code for the aid the participant used for walking *(Walking stick or cane=1; Elbow crutches=2; Walking frame= 3; Other, please specify=4).* Kindly specify the name of the aid if the answer is others or option 4.

SECTION 13: COGNITIVE FUNCTION: MINICOG (≥50 YEARS)

1. **Have you ever attended a doctor for problems with your memory?**
   Ask the participant if s/he ever attended a doctor for problems with their memory. If yes, move to the next question.

2. **If yes, have you have been diagnosed with dementia, Alzheimer's, or vascular dementia?**
   Ask the participant about the diagnosis made by the doctor- dementia, alzheimers or vascular dementia etc.

   ***NOTE**:* **Dementia** is not a specific disease but is rather a general term for the impaired ability to remember, think, or make decisions that interferes with doing everyday activities. **Alzheimer's disease** is the most common type of dementia. Though dementia mostly affects older adults, it is not a part of normal aging. (CDC.gov)

   Vascular dementia is a decline in thinking skills caused by different conditions that block or reduce blood flow to various regions of the brain, depriving them of oxygen and nutrients.

3. **If yes, have you ever been prescribed medications for your memory?**
   If yes to Q2, ask the participant if s/he has been prescribed medication for their memory.

STEP BY STEP MINICOG INSTRUCTIONS

1. **Three words registration**
   a. Make sure you have the person's attention.
   a. Instruct the person to listen carefully to and remember three unrelated words and then to repeat the words back to you so then you will know they heard the words correctly.
   b. You may want to say something like, "What we're going to do next will take some concentration. Ready?"

   Script*: Look directly at the person and say:* "Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [read out words from below]. Please say them for me now." *If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).*

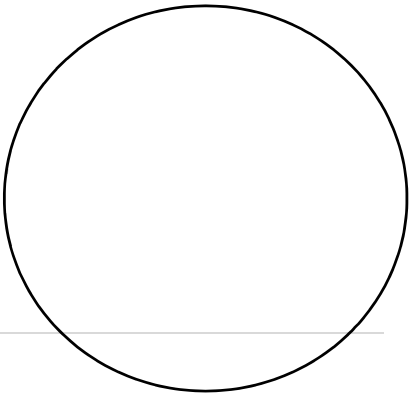
Hindi	Tamil	English
के ला	வாழைப்பழம்	Banana
सुबह	சூரிய உதயம்	Sunrise
कुर्सी	நாற்காலி	Chair

2. **Ask the person to repeat the words to ensure understanding.**
   a. Once you are sure the person is paying attention, say, "I am going to say three words that I want you to remember now and later. The words are banana, sunrise, chair (or the word set you have chosen). Please say them now."
   b. Give the person three tries to repeat the words. You may repeat the words to them for each try.
   c. If they are unable to repeat the words back to you after three tries, go directly to the clock drawing.

3. **Ask person to draw a clock.**
   a. Provide the person with page 2 of the standardised mini-cog instrument with a blank circle.
   b. Say all the following phrases in the order indicated below:
   c. "Please draw a clock in the circle." It is acceptable to provide a sheet of paper with the circle already drawn for the person, as depicted on the standardized Mini-Cog.
   d. "Put all the numbers in the circle".
   e. When step 2 is completed, say, "Now set the hands to show ten past eleven."
   f. If the person has not finished the clock drawing in 3 minutes, discontinue and ask for the word recall items.

   Script: Say: "Next, I want you to draw a clock for me. First, put in all the numbers where they go." When that is completed, say: "Now, set the hands to 10 past 11." *Repeat instructions as needed as this is not a memory test.* Move to Step 3 if the clock is not complete within **three minutes.**

Score the participant based on the following questions:



1. Was the participant unable or refused to draw the clock?
   ☐ Yes ☐ No

2. Are all numbers placed in the correct sequence and approximately the correct position (e.g., 12, 3, 6 and 9 are in no anchor positions) with no missing or duplicate numbers?
   ☐ ☐

Yes No

3. Are all the hands pointing to the 11 and 2 (11:10). Hand length is irrelevant/not scored.

☐ Yes ☐ No **Score: ___/2**

NOTE: Picture Taking on Tablet: *Once participant has completed this step, take a picture on the tablet. It is **very** important that you review the picture you have taken it and ensure the following:*

1. *Participant ID, household ID, Subject Initials are all included in the picture.*
2. *Picture is taken in **Portrait mode** and is **clear** (i.e., ensure the entire clock is visible, and the image is not blurry)*

4. <u>WORD RECALL- Ask person to recall the 3 words.</u>

a. Ask the participant to recall the set of 3 words you gave them at the beginning of the test.
b. Say, "What were the three words I asked you to remember?"
c. Administer this portion of the test even if the person did not accurately repeat the 3 words earlier in step 2 above.
d. Write the participant's answer in the provided space.

Participant's Answers: _____ _____ _____

Score: ___/3

Total Score: ___/5

Scoring	**Points**	
Word recall (0-3 points)	_____	1 point for each word spontaneously recalled without cueing.
Clock draw: 0 or 2 points	_____	**Normal clock** = 2 points. A normal clock has all numbers placed in the correct sequence and approximately correct position (e.g., 12, 3, 6 and 9 are in anchor positions) with no missing or duplicate numbers. Hands are pointing to the 11 and 2 (11:10). Hand length is not scored. Inability or refusal to draw a clock (abnormal) = 0 points
Total score: 0-5 points	_____	**Total score** = Word Recall score + Clock Draw score.

CHAPTER 6 | EVENT MODULES

A. EVENT MODULE- ANGINA

Angina: Ask whether the participant was diagnosed with Angina by a physician. Angina pectoris is defined as symptoms, such as chest pain, chest tightness, or shortness of breath, produced by myocardial ischemia that does not result in infarction.

Please complete an **Angina report** (Annexure B.1) each time a participant has been **newly diagnosed** with Angina or has a **worsening** or **unstable** episode of angina.

For example: If a participant has experienced two episodes of angina since last follow-up, two reports of angina need to be filled in.

Q1. Angina diagnosis: Indicate whether this is a new diagnosis of angina or a recurrent episode of angina. If new diagnosis, provide the NEW diagnosis date in **Q3**. If recurrent episode of angina, indicate whether it is worsening or unstable angina. If worsening or unstable angina, provide two dates: - the original diagnosis date (i.e. when subject was first diagnosed with angina). If both year and month are not known, check 'Unk' box **(Q2)**. Document whether the angina has increased frequency, increased severity, increased duration in the follow-up period.

Q4. Mention whether the subject was hospitalized for the event,
If Yes – mention the date of admission and If No – mention the reason for not admitted in the hospital. (a) Event did not need hospitalization, (b) Visited a clinic/medical professional, (c) Visited a traditional healer, (d) Could not get transportation on time, (e) Could not afford transportation, (f) Could not afford hospital care, (g) Other reasons, specify. (Check all that apply).

Q5. Indicate what are all the following tests that are performed for this event (No/Yes/Unknown) If yes check is there any evidence of ischemia? (No/Yes/Unknown).

Q6. Mention does the subject underwent a coronary angiography? Check appropriately (No/Yes/Unknown).

Q7. Mention does the subject underwent a CABG surgery? Check appropriately (No/Yes/Unknown).

Q8. Mention does the subject underwent a PCI/PTCA? Check appropriately (No/Yes/Unknown).

Q9. Mention what are all the following medication that are used for the treatment of Angina? – Aspirin, Beta-blocker, Clopidogrel, Nitrates, Ticlopidine, Statin Calcium Channel Blockers (Check all that apply). If not used any drugs mention as (No drugs / Unknown) appropriately.

Q10. Record if the subject died – No / Yes.

Q11. The available supporting documents of the subject needs to be photocopied and stored for the adjudication process and mention the available documents – Discharge report, consult notes, prescription, lab report and if

others, specify (check all that apply). If there are no supporting documents available, check as, 'no supporting documents.'

Q12. New ECG changes? This question needs to be filled by only a medically qualified person.

KEY DEFINITIONS

1. **Unstable angina:** Unstable angina is chest pain that is sudden and often gets worse over a short period of time. Unstable angina can develop if the chest pain: (i) Starts to feel different, (ii) is more severe, (iii) comes more often, or (iv) occurs with less activity or while you are at rest. It lasts longer than 15 to 20 minutes.
2. **Worsening or Stable angina:** The angina pain is worsening and occurs with less physical effort. The pain doesn't go away with rest or the usual angina medications.
3. **Stress test**: In an exercise stress test, sensors (electrodes) taped to the chest record the heart's rhythm. A health care provider monitors the heartbeat while the person walks on a treadmill or pedals a stationary bike.
4. **Stress echocardiogram:** A stress echocardiogram is a test done to assess how well the heart works under stress. The 'stress' can be triggered by either exercise on a treadmill or a medicine called dobutamine. A dobutamine stress echocardiogram (DSE) may be used if the person is unable to exercise.
5. **Coronary angiography:** It is a procedure that uses X-ray imaging to see the heart's blood vessels. The test is generally done to see if there's a restriction in blood flow going to the heart. Angiography allows a doctor to take a closer look at the blood vessels and arteries, usually around the heart.
6. **CABG:** A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.
7. **PCI/PTCA:** Percutaneous transluminal coronary angioplasty (PTCA) also called percutaneous coronary intervention (PCI) is a minimally invasive procedure to open blocked or stenosed coronary arteries allowing unobstructed blood flow to the myocardium. PCI include PTCA procedures, commonly known as "angioplasty" or "balloon angioplasty". These procedures treat the narrowed coronary arteries of the heart often found in people with coronary heart disease. Angioplasty procedures use a balloon-tipped catheter to enlarge a narrowing in a coronary artery and, if necessary, a small lattice-shaped metal tube called a stent is inserted permanently into the artery to help hold it open so blood can flow through it more easily.

B. EVENT MODULE- HEART FAILURE

Heart failure: Congestive heart failure (CHF) is defined as a constellation of symptoms and physical signs that occur in a person whose cardiac output cannot match metabolic needs despite adequate filling pressures. In simple words, a condition in which the heart has trouble pumping blood through the body. It may develop over a long period of time. Symptoms include shortness of breath, problem exercising, fatigue, and swelling of the feet, ankles, and abdomen. CHF may be caused by coronary artery disease, a heart attack, or a high blood pressure.

1. Mention the date of the diagnosis of Heart failure (Annexure B.2). If not known, check as "Unknown date of diagnosis."
2. Mention whether the subject was hospitalized for the event,

If Yes – Go to **Q3**, and If No – mention the reason for not admitted in the hospital (a) Event did not need hospitalization, (b) Visited a clinic/medical professional, (c) Visited a traditional healer, (d) Could not get transportation on time, (e) Could not afford transportation, (f) Could not afford hospital care, (g) Other reasons, specify (Check all that apply).

3. Hospital details: (i) Document the date of admission in the hospital, (ii) number of days in hospital, (iii) number of days off work or usual activities (including hospital stay), (iv, v, vi) name of hospital and address, (vii) type of hospital – government or non-government/private, (viii) mode of transportation to hospital – public transportation, taxi, private car, walk, others, specify and (ix) whether the subject was transferred to another hospital for further care.

4. Mention whether the participant experienced any symptoms. If No, Go to **Q7 and** If Yes**,** mention the symptoms – (a) shortness of breath – during exertion or at rest, (b) awaken during sleep by shorten of breath, (c) swelling of feet, (d) wheezing, (e) others, specify. (Check all that apply).

5. How long were the symptoms present before seeking medical attention? – This question needs to capture the duration of the symptoms persist before getting medical attention. (minutes/hours/days/weeks), If not known check "Unknown."

6. How long did it take to see a physician or nurse? – This is to capture the duration, how long have it taken to see/get a medical attention by a physician/nurse. This includes the total waiting time to get an appointment and to get the health care facility and also to meet the physician/nurse.

7. Did the subject have any of the following accompanying this event? This question is to obtain information on any of the following that accompanied this event – (a) pneumonia/respiratory infection, (b) other infection (specify), (c) myocardial infarction, (d) anemia, (e) atrial fibrillation, (f) other precipitating cause (specify), (g) mechanical ventilation, (h) angina.

8. Did the subject have an assessment of LV function. This is to obtain information, whether the subject was assessed with LV function. (a) Document the method used – nuclear studies, echo, angio, others (specify) and (b) was there a documentation of low ejection fraction.

9. The medication details used to treat heart failure have to be captured. Diuretics, Digitalis, ACE-Inhibitor, Nitrates (IV or oral), IV Inotropes (dobutamine, dopamine), Beta blockers, Entresto (Sacubitril/Valsartan), Spironolactone, Angiotensin II Receptor Blocker (ARB), Others (Specify)/ (Check all that apply). If don't know or not using drugs, check "No drugs / Unknown."

10. Has the subject died? – Mention Yes / no, if the subject died.

11. The available supporting documents of the subject needs to be photo copied and stored for the adjudication process and mention the available documents – Discharge report, consult notes, prescription, ECG, lab report, others-specify (check all that apply). If there is unavailable of supporting documents, check, 'no supporting documents.'

KEY DEFINITIONS

1. **Pneumonia:** A severe inflammation of the lungs in which the alveoli (tiny air sacs) are filled with fluid. This may cause a decrease in the amount of oxygen that blood can absorb from air breathed into the lung.

2. **Myocardial infarction:** Heart Attack/Myocardial Infarction – A heart attack medically known as a myocardial infarction, is a deadly medical emergency where the heart muscle begins to die because it is not getting enough blood flow. A blockage in the arteries that supply blood to the heart usually causes this.

3. **Anemia:** A condition in which you lack enough healthy red blood cells to carry adequate oxygen to your body's tissues. Having anemia, also referred to as low hemoglobin, can make you feel tired and weak.

4. **Atrial Fibrillation:** An irregular heartbeat that occurs when the electrical signals in the atria (the two upper chambers of the heart) fire rapidly at the same time. This causes the heart to beat faster than normal.

5. **Mechanical ventilation:** Mechanical ventilation is use of a machine to assist with the work of breathing. Mechanical ventilators are frequently used for conditions that cause either low oxygen levels (such as pneumonia) or high carbon dioxide levels (such as chronic obstructive pulmonary disease) **.**

6. **LV function:** The left ventricle is the heart's main pumping chamber. It pumps oxygen-rich blood up into your body's main artery (aorta) to the rest of the body. Assessment of left ventricular (LV) systolic function is important for diagnosis, management, follow-up, and prognostic evaluation of patients in a variety of clinical settings. Ejection fraction is a measurement of the percentage of blood leaving your heart each time it squeezes (contracts). It is just one of many tests the doctor may use to determine how the heart works.

C. EVENT MODULE- MYOCARDIAL INFARCTION

Myocardial infarction: Heart Attack/Myocardial Infarction – A heart attack medically known as a myocardial infarction, is a deadly medical emergency where the heart muscle begins to die because it is not getting enough blood flow. A blockage in the arteries that supply blood to the heart usually causes this.

1. Mention the date of the diagnosis of Myocardial infarction (Annexure B.3), if not known, check in the "Unknown date of diagnosis."

   Mention whether the subject was hospitalized for the event,
   If Yes – Go to **Q3**, and If No – mention the reason for not admitted in the hospital. (a) Event did not need hospitalization, (b) Visited a clinic/medical professional, (c) Visited a traditional healer, (d) Could not get transportation on time, (e) Could not afford transportation, (f) Could not afford hospital care, (g) Other reasons, specify (Check all that apply).

2. Hospital details: (i) Document the date of admission in the hospital, (ii) number of days in hospital, (iii) number of days off work or usual activities (including hospital stay), (iv, v, vi) name of hospital and address, (vii) type of hospital – government or non-government/private, (viii) mode of transportation to hospital – public transportation, taxi, private car, walk, others, specify and (ix) whether the subject was transferred to another hospital for further care.

3. Did the subject have any of the following symptoms? – Mention if the participant experiences any of the symptoms – (a) chest pain or discomfort >20 minutes, (b) pain radiating to arm, shoulder, or neck, (c) sweating or vomiting, (d) others, specify.

4. How long were the symptoms present before seeking medical attention? This question needs to capture the duration of the symptoms persist before getting medical attention. (minutes/hours/days/weeks), If not known, check 'Unknown.'

5. How long did it take to see a physician/nurse? – This is to capture the duration, how long have it taken to see/get a medical attention by a physician/nurse. This includes the total waiting time to get an appointment and to get the health care facility and also to meet the physician/nurse. (minutes/hours/days/weeks), If not known, check 'Unknown.'

6. The information on blood tests done needs to be checked as No / Yes / Not available.

7. Has the subject died? – Mention Yes / no, if the subject died.

8. Has the participant received, (i) Thrombolytic therapy, (ii) PCI, (iii) CABG surgery. (No / Yes / Unknown).
9. Were any of the following medications used to treat MI? – Mention the medications that are used for the treatment of Myocardial Infarction? – ASA (Acetyl Salicyclic Acid/ Aspirin), Satin, Ace-Inhibitor, Nitrates (IV or oral), Calcium channel blocker, Ticagrelor, Plavix, Prasugrel, Angiotensin II Receptor Blocker (ARB), Beta blockers, Others-Specify (Check all that apply). If not used any drugs mention as (No drugs / Unknown) appropriately.

10. The available supporting documents of the subject needs to be photo copied and stored for the adjudication process and mention the available documents (check all that apply). If there is unavailable of supporting documents, check, 'no supporting documents.'

11. Were cardiac enzymes measured? This question needs to be filled by only a medically qualified person.

12. Was ECG done? This question needs to be filled by only a medically qualified person.

KEY DEFINITIONS

1. **Thrombolytic therapy:** Thrombolytic therapy is the use of drugs to break up or dissolve blood clots, which are the main cause of both heart attacks and stroke.

2. **PCI/PTCA:** Percutaneous transluminal coronary angioplasty (PTCA) also called percutaneous coronary intervention (PCI) is a minimally invasive procedure to open blocked or stenosed coronary arteries allowing unobstructed blood flow to the myocardium. PCI include PTCA procedures, commonly known as "angioplasty" or "balloon angioplasty". These procedures treat the narrowed coronary arteries of the heart often found in people with coronary heart disease. Angioplasty procedures use a balloon-tipped catheter to enlarge a narrowing in a coronary artery and, if necessary, a small lattice-shaped metal tube called a stent is inserted permanently into the artery to help hold it open so blood can flow through it more easily.

3. **CABG:** A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.

D. EVENT MODULE- STROKE

Stroke: A stroke, sometimes called a brain attack, occurs when something blocks blood supply to part of the brain or when a blood vessel in the brain bursts. In either case, parts of the brain become damaged or die. A stroke can cause lasting brain damage, long-term disability, or even death.

1. Mention the date of diagnosis of Stroke (Annexure B.4). If not known, check 'Unknown date of diagnosis.'

2. Mention whether the subject was hospitalized for the event. If Yes – Go to **Q3**, and if No – mention the reason for not admitted in the hospital. (a) Event did not need hospitalization, (b) Visited a clinic/medical professional, (c) Visited a traditional healer, (d) Could not get transportation on time, (e) Could not afford transportation, (f) Could not afford hospital care, (g) Other reasons, specify (Check all that apply).

3. Hospital details: (i) Document the date of admission in the hospital, (ii) number of days in hospital, (iii) number of days off work or usual activities (including hospital stay), (iv, v, vi) name of hospital and address, (vii) type of hospital – government or non-government/private, (viii) mode of transportation to hospital – public transportation, taxi, private car, walk, others, specify and (ix) whether the subject was transferred to another hospital for further care.

4. Did subject receive any of the following therapies as in-patient or out-patient? Mention all the therapies undertaken by the participant – Physiotherapy, Occupational therapy, Speech and language therapy, Others, specify, or no therapy (Check all that apply).

5. Did subject receive any of the following treatments: Aspirin, Anticoagulant (eg: Heparin), Thrombolysis, Statin, ACE-Inhibitor, Angiotensin II Receptor Blocker (ARB), Others-specify, No treatments (Check all that apply).

6. Mention the symptoms present during the event. (a) Did the subject become unconscious or drowsy? (b) Was there loss of vision? (c) Was there weakness in face or limbs? (d) Was there weakness in one limb/half the body? (e) Was there difficulty in speaking? (f) Was there a disturbance of balance or walking? (g) Was there a trauma to the head or neck in the last week? (Check all that apply).

7. Does the duration of the symptoms persists more than 24 hours. (No/ Yes/ Unknown).

8. The duration of the symptom presents before getting the medical attention. (minutes/ hours/ days/ weeks). If the duration was not known, check 'Unknown.'

9. How long did it take to see a physician or nurse? – This is to capture the duration, how long have it taken to see/get a medical attention by a physician/nurse. This includes the total waiting time to get an appointment and to get the health care facility and also to meet the physician/nurse. (minutes/hours/days/weeks), If not known check 'Unknown.'

10. Whether the CT scan or MRI done to confirm the diagnosis. (No/ Yes/ Unknown).

11. Current Modified-Rankin Scale score for this subject? Check the appropriate option.

12. Has the subject died? – Mention Yes / no, if the subject died.

13. The available supporting documents of the subject needs to be photo copied and stored for the adjudication process and mention the available documents – Discharge report, consult notes, prescription, lab report and if others, specify (check all that apply). If there are no supporting documents available, check as, 'no supporting documents.'

KEY DEFINITIONS

1. **Physiotherapy:** The use of exercises and physical activities to help condition muscles and restore strength and movement.

2. **Occupational therapy:** Occupational therapy focuses on enabling people to do the things they want and need to do in their everyday lives. For example, activities to build fine motor skills might include picking things up with tweezers. Exercises to improve gross motor skills might include jumping jacks or running an obstacle course. For someone who struggles with motor planning, therapists might work on daily routines like getting dressed.

3. **Speech and language therapy:** This provides treatment, support and care for people who have difficulties with communication, or with eating, drinking and swallowing.

4. **CT:** A computerized tomography (CT) scan combines a series of X-ray images taken from different angles around your body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside your body. CT scan images provide more-detailed information than plain X-rays do.

5. **MRI:** Magnetic resonance imaging (MRI) is a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in the body.

CHAPTER 7 | MEASUREMENTS

A. INTRODUCTION

There will be a total of four anthropometric measurements taken during Precision-CARRS visit. Blood pressure, pulse rate, body composition analysis via Tanita (Annexure 3) and handgrip strength, timed walk will be measured during visit after implementing the questionnaire and before taking the anthropometric measurements. This chapter is based on the third National Health And Nutrition Examination Survey (NHANES-III) methods for anthropometry.

SNo	Type of measurements	Measurements	Equipment (Model)	Number of readings
1	Anthropometric measurements	Waist circumference (WC) in cm	Non stretchable measuring tape (Seca)	1
		Hip circumference (HC) in cm		1
		Height (Standing) in cm	Portable stadiometer (Seca-213 in Delhi ; Seca 214 in Chennai)	1
		Weight in Kg	BC-601 (Delhi) BC-545 (Chennai)	1
2	Physiological measurements	Bio-impedance/ body composition analysis		1
		Blood pressure (BP) in mmHg Pulse rate	Automated Blood pressure & pulse measuring device (OMRON HEM 7121)	
3	Performance based measurements	Hand grip strength in Kg	Digital Dynamometer (JAMAR)	3 for each hand
		Timed walk in sec	Stop watch Steel Measuring tape	1

Learning objectives:

After completing this chapter the field staff will be able to:

1. Understand the procedures for taking anthropometric measurements and recording blood pressure and pulse rate.
2. Use the instruments for anthropometric measurement, hand grip, timed walk & bio- impedance and blood pressure recording.

B. BEFORE GETTING STARTED

1. Explain to the participant what you will be doing and what they can expect from each measurement procedure. Continue to explain to the participant what you are doing while you are taking the measurements.

   A well-informed participant is more likely to feel at ease.

2. Explain to the participant that the measurements will not be accurate if made over clothing. Ask if they are comfortable removing their outer clothing to their undergarments. If they do not feel comfortable, participants may leave their outer clothing on and lift up their shirts for waist/abdominal measurements and lower their pants/skirt for hip measurements.

3. Be tactful. Try to avoid excessive body contact while arranging the measuring tape and finding sites.

4. Keep all equipment clean. Wipe measuring tape with an alcohol wipe after each interview.

5. Use the non-stretch, pliable Seca tape. This allows for repeatable measurements which are accurate and consistent no matter who is doing the measuring.

6. Number of readings to be taken for each parameter per participants:
   - Blood pressure – 2 recordings (3rd, if required- if the difference between 1st & 2nd systolic or diastolic reading is ≥10mmHg or ≥6 mmHg respectively).
   - Pulse rate – 2 recordings
   - Body circumferences – 1 reading
   - Body Weight – 1 reading
   - *Height (standing) - 1 reading
   - Body composition analysis- 1 reading
   - Handgrip strength- left and right hand (3 readings each)

7. **Remember: Pregnant women should NOT be excluded from anthropometric measurements.**

General Instructions

1. All body measurements should always be taken on the right side of the body. However, if the participant has a cast or amputation, or there is some other reason, and the measurement cannot be taken on the right side then take them on the left side of the body.

2. All measurements should be taken to the nearest 0.1 centimetre (or 1.0 millimetre).

3. Blood pressure and pulse rate will be measured twice (3rd reading if required).

C. STEP-BY-STEP-PROCEDURES

1. Blood Pressure and Pulse Rate

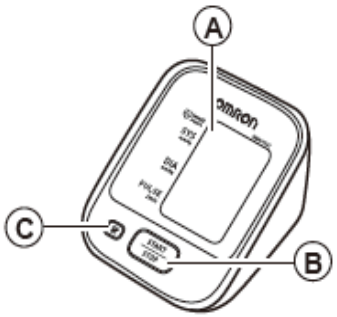
It is important that measurement of Blood Pressure (BP) is as precise as possible. This is essential for valid comparisons to be drawn. Therefore, a strict routine for BP measurement should be adhered to. The measurement should follow the administration of the questionnaire:

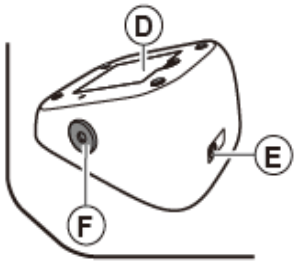
1. The subject should be instructed to avoid the following activities for at least one hour before the BP measurement: strenuous exercise, eating, drinking of anything other than water, smoking, during stressful situations, drugs that affect the blood pressure; a full bladder affects the blood pressure

and patient should be advised accordingly. This is ensured that the measurements are taken at the end of the interview.

2. The participant should have removed outer garments, jackets etc. The sleeve of shirts, blouses, etc. should be rolled up so that the upper right arm is bare for the blood pressure cuff. The garment should not be constrictive and the blood pressure cuff should not be over the garment.
3. The examination should take place in a quiet room with comfortable temperature.
4. The cuff size (bladder-size) should be 12-13 cm wide and sufficiently long (recommended length: width ratio >2:1) to surround at least two thirds of the upper arm. The centre of the inflatable part of the cuff (bladder) must be positioned over the brachial artery of the inner side of the upper arm. The cuff should neither be applied too loosely or too tightly (ensuring that two fingers can be placed under the sleeve without difficulty), in order to avoid over or under estimation of the pressure required to obliterate the artery.
5. The BP should be measured after resting with no change of position for at least 5 minutes, in a sitting position and using the right arm - unless there is a deformity. When seated the subject's arm should be allowed to rest on a desk so that the antecubital fossa is level with the heart. To achieve this either the chair should be adjusted, or the arm may be raised or lowered on a comfortable support. The subject must always be in an upright position and feel comfortable.
6. Then repeat the measurement in the same way that the first one was carried out. Whenever experiencing difficulties, the cuff must be completely deflated and at least 30 seconds must elapse before making the next measurement. Record the value of both measurements in Form-C.2.

The BP Apparatus [Omron HEM-7121]





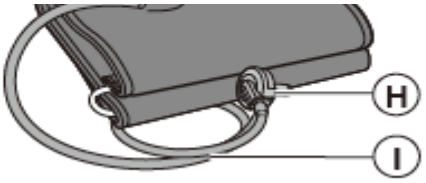
A. Display
B. START/STOP button
C. Memory button

D. Battery compartment
E. AC adapter jack (for optional AC adapter)
F. Air Jack

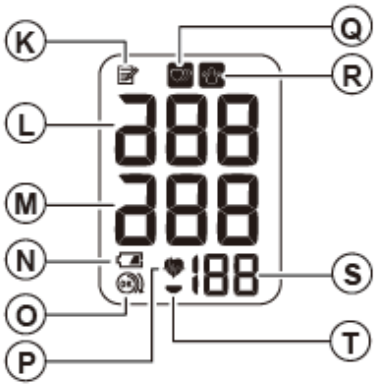
ircumference

22 - 42 cm)

H. Air plug
I. Air tube



Display



K. Memory symbol
L. Systolic blood pressure
M. Diastolic blood pressure
N. Low battery symbol
O. Cuff wrapping guide
P. Heartbeat symbol
   1. Flashes during measurement.
   2. If flashing after measurement completed or when viewing results stored in the memory, indicates blood pressure out of recommended range*.

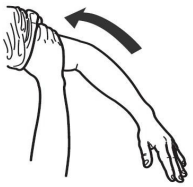
Q. Irregular heartbeat symbol
R. Movement error symbol
S. Pulse display and Memory number
T. Deflation symbol

* Note: If your systolic or diastolic pressure is outside the standard range (above 135/85 mmHg) the Heartbeat symbol (♥) will blink. Please refer to Section 3.3.

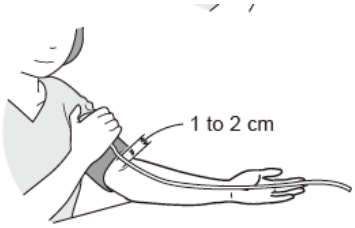
Applying the Cuff on the Left Arm

1. Make sure the air plug is securely inserted in the main unit.

2. Remove tight-fitting clothing from the upper left arm of the participant.

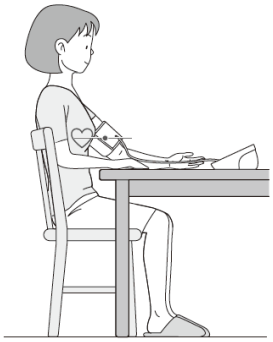


3. Put the arm of the participant through the cuff loop.



4. The bottom edge of the arm cuff should be 1 to 2 cm above the elbow. The air tube is centred on the middle of your inner arm.

5. The participant should sit in a chair with her/his feet flat on the floor. Sit with your back and arm being supported. Place the participant's left arm on a table so that the cuff is level with the heart.

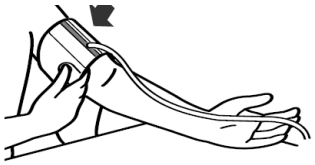


6. Close the fabric fastener FIRMLY.

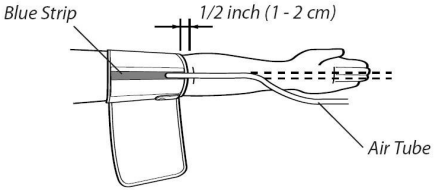
NOTES:

When you take measurement on the right arm, the air tube will be at the side of participant's elbow. Be careful not to rest your arm on the air tube.

7. Turn the palm of your left hand upward.



8. Apply the cuff to the participant's left upper arm so the blue strip is on the inside of her/his arm and aligned with your middle finger. The air tube runs down the inside of the arm. The bottom of the cuff should be approximately 1/2" above the elbow



Applying the Cuff on the Right Arm

To apply the cuff on the right arm, follow the steps from 1 to 3 given for the left arm.

4. Turn the palm of your right hand upward.

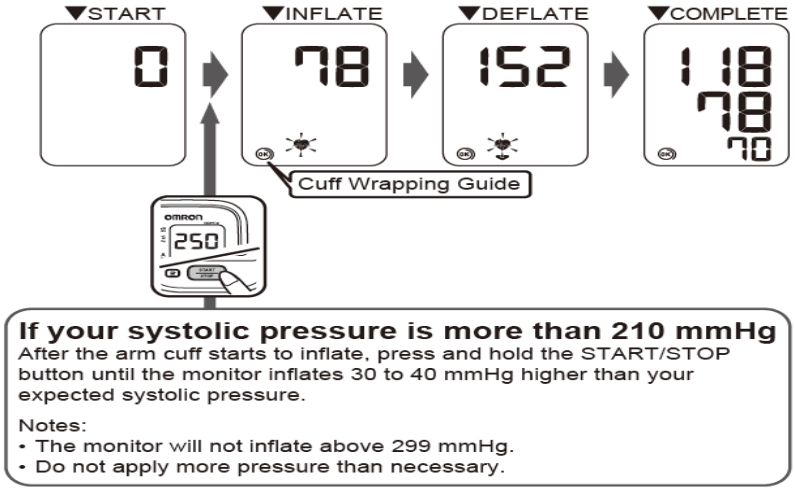
5. Apply the cuff to the participant's right upper arm so the the air tube will be at the side of participant's elbow. Be careful not to rest your arm on the air tube. The bottom of the cuff should be approximately 1/2'' above the elbow.

6. Wrap the cuff firmly in place around the participant's arm using the cloth strip.

Be careful not to rest the participant's arm on the air tube. This will restrict the flow of air to the cuff.

Taking Measurement

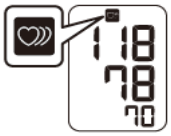
1. Press the START/STOP button. The arm cuff will start to inflate automatically.



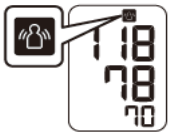
2. Inflation stops, and the measurement starts. When the measurement is complete, the blood pressure and pulse rate appear on the display.
3. As the cuff deflates, decreasing numbers appear on the display.
4. When the measurement is complete, the arm cuff completely deflates. BP and pulse rate is displayed.
5. Press the START/STOP button to turn the monitor off.

*Important

- Your blood pressure monitor includes an irregular heartbeat feature. Irregular heartbeats can influence the results of the measurement. The irregular heartbeat algorithm automatically determines if the measurement is usable or needs to be repeated. If the measurement results are affected by irregular heartbeats but the result is valid, the result is shown together with the irregular heartbeat symbol ( ). If the irregular heartbeats cause the measurement to be invalid, no result is shown. If the irregular heartbeat symbol ( ) is shown after you have taken a measurement, repeat the measurement. If the irregular heartbeat symbol ( ) is shown frequently, please make your doctor aware of it.



- If you move during measurement, the movement error symbol ( ) will appear on the display. Keep still and repeat the measurement.



Error Indicators and Troubleshooting Tips

The icons and error messages.

Error Display	Cause	Remedy
	Irregular heartbeats are detected.	Remove the arm cuff. Wait 2 - 3 minutes and then take another measurement. Repeat the steps in section 3.3. If this error continues to appear, contact your doctor.
	Movement during measurement.	Carefully read and repeat the steps in section 3.3.
	Cuff is not applied correctly.	Apply the arm cuff correctly. Refer to section 3.1.
	The batteries are low.	You should replace them with new ones ahead of time. Refer to section 2.1.
	The batteries are exhausted.	You should replace them with new ones at once. Refer to section 2.1.
E1	Air plug disconnected.	Insert the plug securely. Refer to section 3.1.
	Arm cuff not applied correctly.	Apply the arm cuff correctly. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the cuff with the new one. Refer to Chapter 5.
E2	Movement during measurement and the arm cuff has not been inflated sufficiently.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
		If "E2" appears repeatedly, inflate the cuff manually until it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
E3	The arm cuff was inflated above 299 mmHg when inflating the cuff manually.	Do not inflate the cuff above 299 mmHg. Refer to section 3.3.
E4	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
E5	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
Er	Device error.	Contact your local OMRON representative.

In case of any of the below problems occur during measurement, first check that no other electrical device is within 30cm. If the problem persists, please refer to the table below:

Problem	Cause	Remedy
The reading is extremely low (or high).	Arm cuff not applied correctly.	Apply the arm cuff correctly. Refer to section 3.1.
	Movement or talking during measurement.	Remain still and do not talk during measurement. Refer to section 3.3.
	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
Arm cuff pressure does not rise.	The air tube is not securely connected into the air jack.	Make sure that the air tube is connected securely. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to Chapter 5.
Arm cuff deflates too soon.	The arm cuff is loose.	Apply the cuff correctly so that it is firmly wrapped around the arm. Refer to section 3.1.
Cannot measure or readings are too low or too high.	The arm cuff has not been inflated sufficiently.	Inflate the cuff so that it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
Nothing happens when you press the buttons.	The batteries are empty.	Replace the batteries with new ones. Refer to section 2.1.
	The batteries have been inserted incorrectly.	Insert the batteries with the correct (+/-) polarity. Refer to section 2.1.
Other problems.	• Press the START/STOP button and repeat measurement. • If the problem continues, try replacing the batteries with new ones. If this still does not solve the problem, contact your local OMRON representative.	

Calibration and service

It is generally recommended to have the device inspected every 2 years to ensure correct functioning and accuracy.

Storage

a. Unplug the air plug from the air jack.
b. Gently fold the air tube into the arm cuff

Notes:

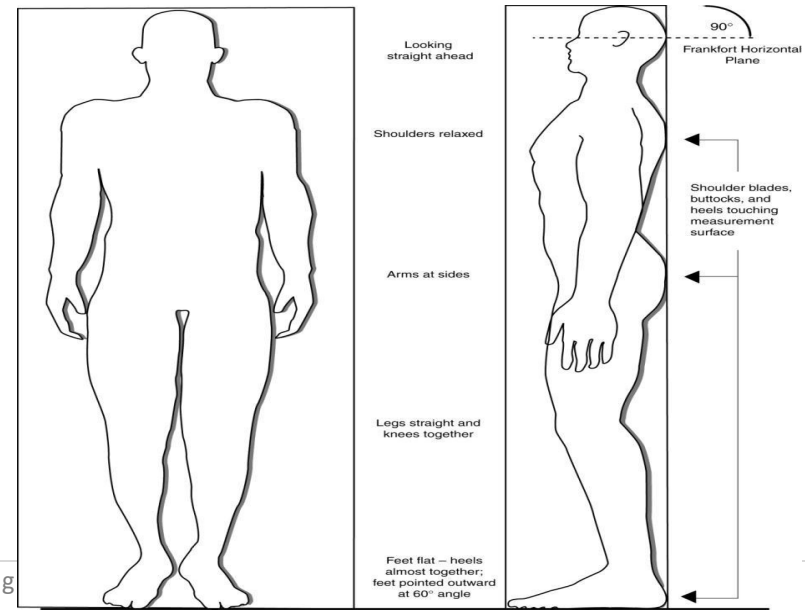
- Don’t bend the air tube excessively.
- Don’t store your monitor in the following situations:
- If your monitor and other components are wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapours.
- Locations exposed to vibrations, shocks or where it will be at an angle.

2. Measuring Height

Standing height is an assessment of maximum vertical size of the participant. It is measured with a fixed stadiometer with a vertical backboard and a moveable headboard.

1. Request the participant to move or remove hair ornaments, jewellery, shoes, and buns in order to measure stature properly.
2. Make the participant stand with the heels of both feet together and the toes pointed slightly outward at approximately 60^{o} angle (Fig in the next page).
3. Make sure the body weight is evenly distributed and both feet are flat on the floor.
4. Check the position of the heels, the buttocks, shoulder blades, and the back of the head for contact with the vertical backboard.
5. Depending on the overall body conformation of the individual, all points may not touch. In such case, make sure the participant's trunk is vertical above the waist, and the arms and shoulders are relaxed.
6. Align the head in the Frankfort horizontal plane (Fig in the next page). The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical back board. Many people will assume this position naturally, but for some it may be necessary to make a minor adjustment. If required, gently tilt the head up or down until proper alignment is achieved with eyes looking straight ahead.
7. Once correctly positioned, lower the headboard and instruct the participant to take a deep breath and stand as tall as possible. A deep breathe will allow the spine to straighten, yielding a more consistent and reproducible stature measurement.
8. Position the headboard firmly on top of the head with sufficient pressure to compress the hair.
9. When the participant is properly positioned, record the height (in form C.2).
10. Make the participant relax and step away from the stadiometer.
11. If the stadiometer is not functioning properly, push the headpiece to the top of the measurement column and obtain participant's height using the tape mounted on the right side of the measurement column.

Some participants may have conditions that interfere with a specific procedure for measuring stature. One of the more common conditions is Kyphosis. Kyphosis is a forward curvature of the spine that appears as a hump or crooked back condition. Kyphosis most frequently occurs in the elderly and in women the condition is commonly referred to as "dowager's hump". In these cases it is important to get the best measure possible according to the protocol. Then record "NS" (not straight) in the comments section.



3. Measuring Circumferences

Circumferences are important measurements that record the size of cross-sectional and circumferential dimensions of the body. Circumferences used alone or in combination with skinfold measurement taken at the same location can provide indices of nutritional status and levels of fat patterning. Measurements should be taken on the right side of the body.

1) Positioning of the tape for each specific circumference is important for an accurate measure. For each circumference, place the plane of the tape around the site perpendicular to the long axis of that part of the body. For those circumferences typically measured with the subject erect (waist, hip), the plane of the tape is also parallel to the floor.

2) The tension applied to the tape by the measurer affects the validity and reliability (correctness) of the measurements. The Seca tape (picture below) applies a consistent amount of tension (4 ounces) each time.

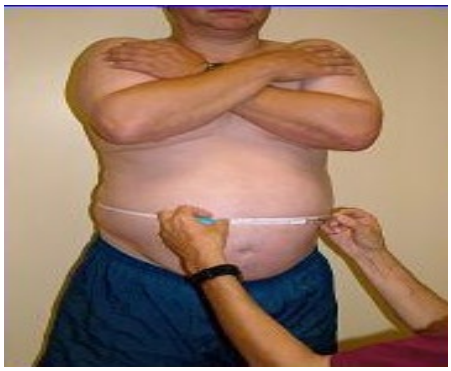
3) For the arm circumference there may be gaps between the tape and the skin in some individuals. If the gap is large, a note should be made on the data form, but in most instances, this gap is small and of little concern.

Attempting to reduce the gap by increasing the tension of the tape is **not** recommended

Waist Circumference

The waist measurement is taken at the midpoint between the lowest rib and the top of the hip bone (iliac crest). The measurement should be taken on bare skin.

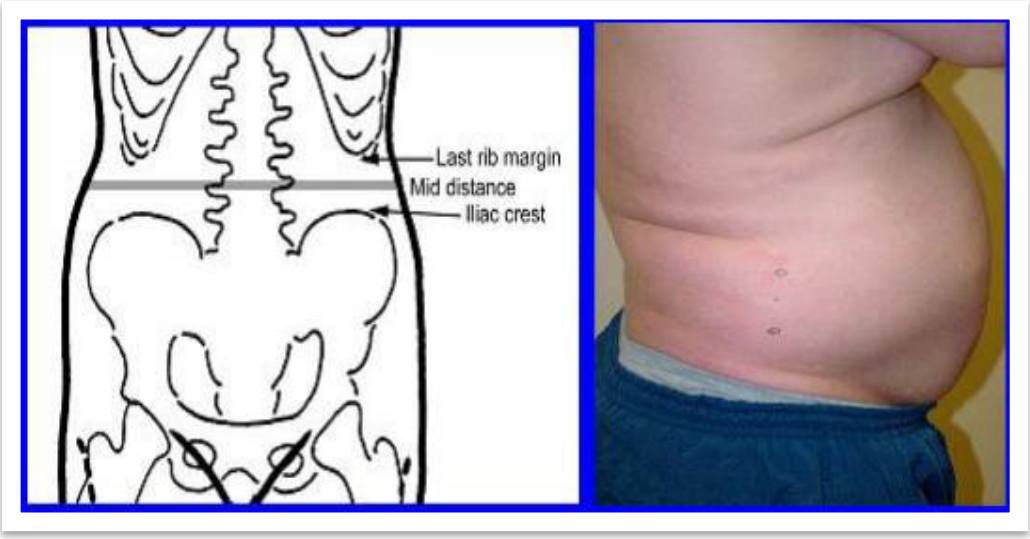
1. To define the level at which the waist or abdominal circumference is measured, you must first locate and mark the iliac crest and the lowest rib.
2. Have the participant stand with feet close together and the abdomen relaxed.
3. Request the participant to lower his/her pants and underclothing slightly, and stand behind and to the right of the participant, palpate the hip area to locate the right ilium.
4. Palpate the lowest rib and measure the distance between the two points. Mark the mid-point between the two points.
5. Place the measuring tape around the participant at the marked point.
6. Make sure that the tape is parallel to the floor and that the tape is snug but does not compress the skin.
7. The zero end is held above the measurement value.
8. Make the measurement at the end of a normal expiration (breathing out) and record it to the nearest 1 mm (in the form C.2).



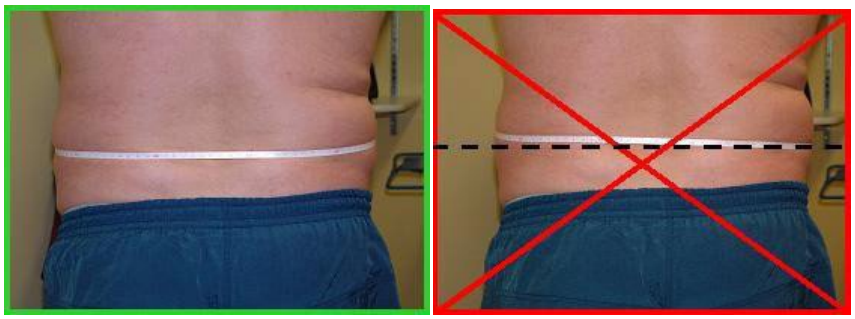
**Arms crossed*

Detailed instructions:

1. Request the participant to stand with her / his arms crossed as shown in the previous page.
2. Mark with a skin pencil the bony landmarks of the right and left last rib margin.
3. Mark with a skin pencil the bony landmarks of the right and left iliac crest.
4. Mark with a pencil the mid-distance between the last rib margin and the top of the iliac crest of the two sides as shown below.



5. Place the tape horizontally directly on the skin with respect to both mid- distance landmarks as shown below.



Tape placed horizontally *Tape not horizontal*

Note: A mirror could be used to facilitate this procedure.

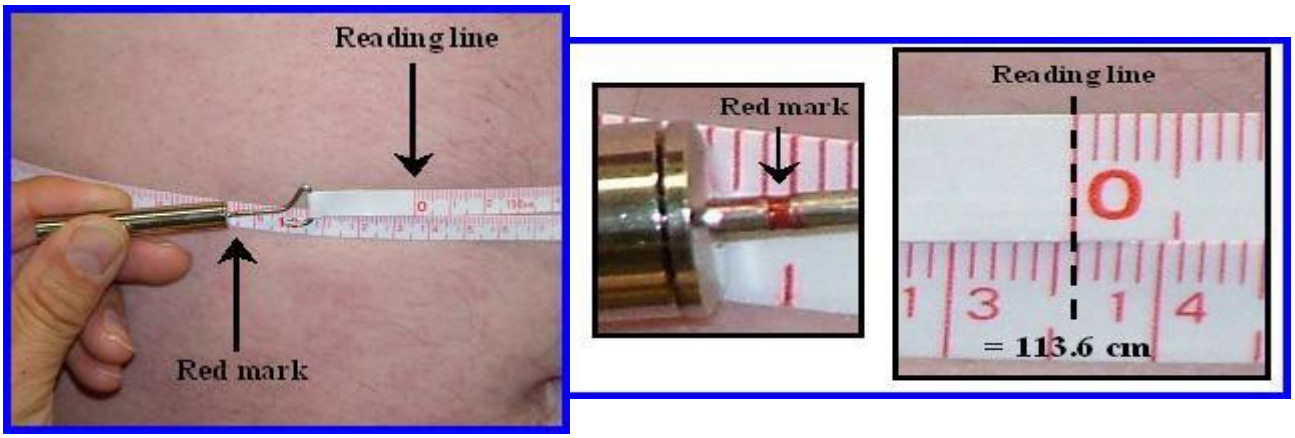
Hip Circumference

1. This measurement should be taken with the participant wearing minimal clothing; it's best to measure directly over the skin. If this is not possible, the measurement may be taken over light clothing. It must not be taken over thick or bulky clothing. This type of clothing must be best avoided.
2. Request the participant to stand with her / his arms crossed as shown in the previous page (waist circumference).

3. The measurement should be taken at the maximum circumference over the buttocks.
4. Stand on the side of the participant; position the measuring tape around the maximum circumference of the buttocks.
5. Ask the participant to:
    a) Stand with their feet together.
    b) Place their arms at crossed position with their side with the palms of their hands facing inwards and breathe out gently.
6. Check that the tape position is horizontal all around the body.
7. Measure hip circumference and record the measurement at the level of the tape to the nearest 1 mm.

Reading the Measurements

A slight tension should be applied to the tape at the moment of the reading. Zero end should be held above the measuring value as shown below. Record the readings in Form
– C.2 [Annexure 3].



http://www.metabolic-syndrome-institute.org/informations/screening-diagnosis/procedures-for-the-measurement-of-the-waist-circumference.php

General Instructions

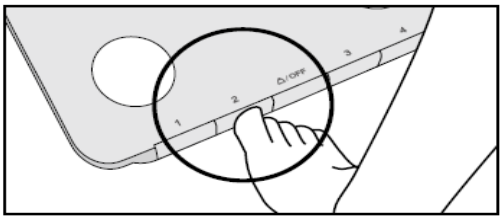
1. Measurements should be taken on the right side of the body.
2. Mark each site with a skin pencil.
3. Record the measurement to the nearest 0.1 millimetre.
4. Practice the measurement procedures until you are completely comfortable with them.
5. It takes practice to become skilful in measuring circumferences consistently.

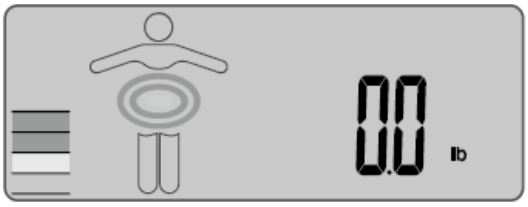
4. Body Composition/Bio-Impedance

1. Equipment for measuring bio-impedance sends out a very weak electric current to measure impedance (electrical resistance) of the body. Therefore, in principle, users need to use this equipment with bare feet. Moreover, since impedance fluctuates in accordance with the distribution of body fluids, please observe the following instructions for accurate measurement.
2. To prevent a possible discrepancy in measured values, "avoid taking measurement of participants after vigorous exercise" until sufficiently rested.
3. To prevent inaccurately low body fat percentage measurements and other measurement errors, always hold both arms straight down when taking measurements.
4. Ask the participant to urinate before taking measurements to get a more accurate picture of the measurements over time.
5. Ensure that the participant's arms are not touching the side of the body and that the inner thighs are not touching each other during measurements.
6. Also, make sure the soles of feet are free of excess dirt, as this may also act as a barrier to the mild current.
7. Excessive food/fluid intake, or intense exercise need to be avoided.
8. Measurement is sometimes impossible on a surface that is strongly vibrating. In this case, please move the equipment onto a surface with little vibration.
9. Do not take measurements while using transmitters, such as mobile phones, which may affect readings.
10. Do not take measurements on people with an implanted cardiac device (such as pacemaker, etc.)

Operating guidelines

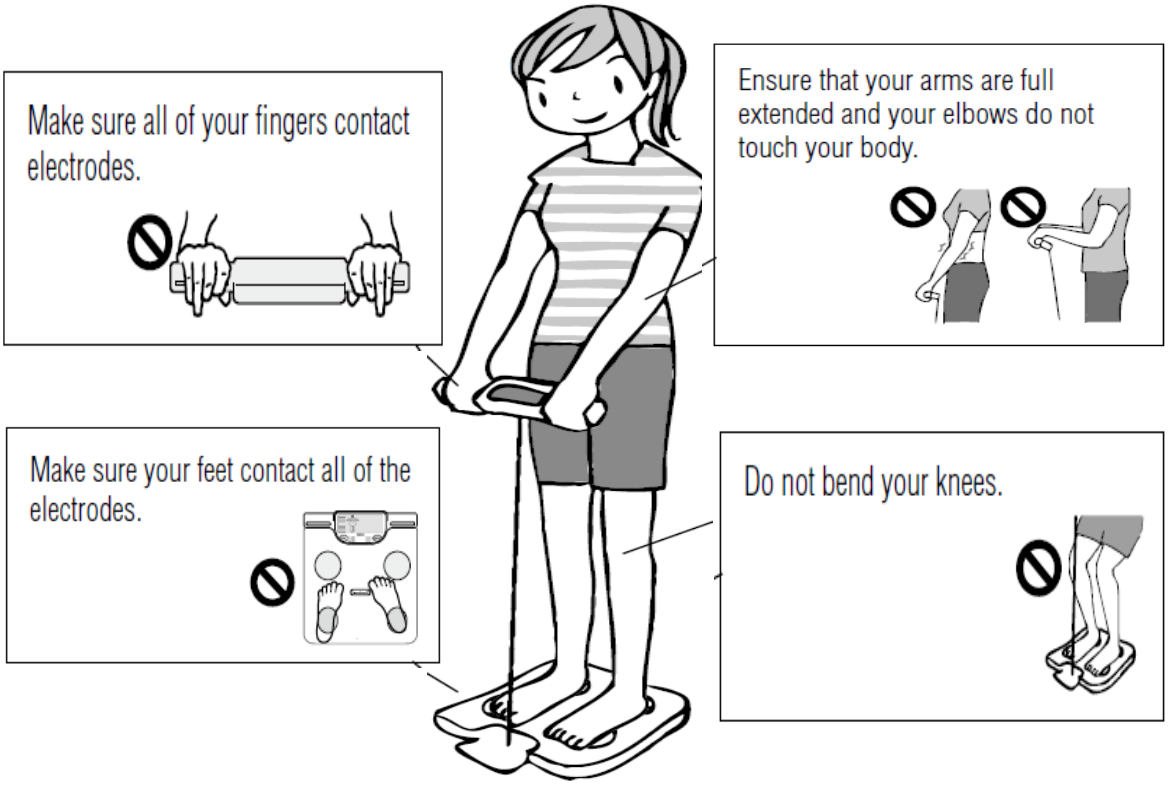
1. Turn on the Power: Press the ON/OFF key, display will show "0.0".





2. **Step on:** When "0.0" is displayed, hold the hand electrode as shown and step onto the platform with bare feet so that they touch the electrodes. Make sure heels are placed on the posterior electrodes, and the front parts of the feet are in contact with the anterior electrodes. The unit will beep twice when the measurement is taken. Please stand still until the unit beeps. S/he should be made to stand in a stable position without bending the knees.

   NOTE: If you step onto the platform before "0.0" appears the display will show "Err" and you will not obtain a reading.



3. **Obtain your weight:** The machine will measure your weight and it got displayed on its screen.
4. **Press "Guest"** and the machine will scan the body.
5. **Enter Age:** Specify your age with ▲ ▼, and press SET to confirm.
6. **Select the Body Type:** Select the body type from Male, Female, Athletic Male and Athletic Female. Specify your body type with ▲ ▼, and press SET to confirm. Please use the Athletic key when the user is 20 years or older and also meets the following definition.
    - Tanita's athlete definition includes "lifetime of fitness" individuals who have been fit for years but currently exercise less than 10 hours per week.
    - Tanita's athlete definition doesn't include "enthusiastic beginners" who are making a real commitment to exercising at least 10 hours per week but whose bodies have not yet changed to require the Athlete mode definition.
7. **Enter height:** Specify your height (in cm) with ▲ ▼, and press SET to confirm.
8. **Press "code 1"** and SET to confirm. After this the machine will start analysing the body.
9. **Obtain your readings:** After the measurement, the unit will display all the readings. The last reading will be of visceral fat and after that the machine will show the reading of weight. A beep sound will come. Ask the participant to step off from the scale and press RESULT to see desired readings and record it in the Tanita Form (Form-C.3), Annexure 3.

NOTE: Ask the participant to step down from the machine calmly.

10. **Press segment to get other body fat readings** e.g., right and left arm, right and left leg, rest of the body and whole body.

    NOTE: Please note all the readings before pressing "SEGMENT", as you won't be able to see those readings after pressing SEGMENT.

11. If the measurements of the body fat ratio or the quantity of fat are abnormally small or the error message is shown on the display, the probable reason is that the soles of the feet and the electrodes are not in full contact. Make sure the participant steps on the Weighing Platform so there is contact between the electrodes and the soles of your feet. If the problem is not solved this way, it is possible that the soles of the participant's feet have calluses and the resistance is too great. Therefore, place about 0.5 ml of water on each of the four electrodes where the feet touch before measurement.

12. Measurement is Complete: Once the body weight and impedance measurements have been completed, the overall body fat percentage will be shown at the bottom of the display and a buzzer will sound.

13. When You Continue to Measure: After you've recorded all the values, follow the same procedure mentioned above.

14. **Finish Measurement:** Press the "ON/OFF" key and turn off the power.

5. Hand-grip

Introduction: Hand-grip strength affects everyday functions such as raising the body weight or holding heavy objects, and usually declines with age. To conduct grip strength tests, you will need JAMAR digital hand dynamometer.

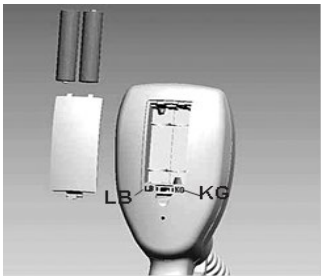
General Instructions:

1. Do not perform this task if the respondent's hands or wrists are swollen or inflamed (possibly due to arthritis); are in severe pain; and have recently been injured or operated (in the last three months).
2. Inform respondent that they will need to squeeze the dynamometer thrice with each hand (starting with the non-dominant hand).
3. Encourage respondent to remove rings as it may hurt to squeeze the device and may damage the jewellery.
4. Explain the test and demonstrate it.
5. Explain that it may not feel like the bar is moving at all.

Installing and Replacing Batteries

Turn the instrument so the Key Pad Operator faces front and the back of the Key Pad Housing faces toward you. Open the compartment cover and install two (2) AAA batteries. (Quality, alkaline or re- chargeable batteries are recommended). Replace the cover after installation. Press the **[ON/OFF]** key on the face of the Jamar Smart Hand Dynamometer to ensure battery installation is correct. As the batteries approach the end of their life cycle, the "BATT" indication will be displayed on the instrumentdisplay. Batteries should be replaced as soon as this is displayed to ensure proper unit function.

Preparing the Hand Grip Dynomometer



1. **[LB/KG]:** The Jamar Smart Hand Dynamometer is originally set to display in LBs. To change to KG, open up the battery compartment and move the frequency switch down to KG.
2. Adjust the grip handle to the 2nd handle position of the dynamometer best suit patient comfort and test requirement.

Push the lower end of the handle so that the slotted portion rotates away from the lower shaft (See diagram). Making sure not to drop the handle, allow it to separate from the topshaft. Replace the top part of the handle on the top shaft. Rotate the lower part of the handle onto the lower shaft until it clicks into place. The special ball detent on the lower part of the handle helps prevent the handle from separating from the shaft during normal use.

Procedure

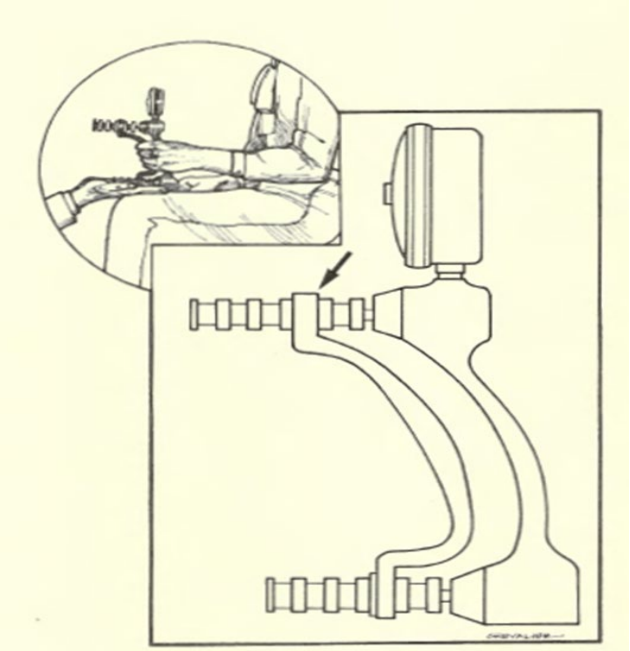
Follow the steps below to take grip strength measurements

1. Check the dynamometer- set to display in Kg and grip handle in 2nd position.
2. Look for a suitable place where the participant can sit comfortable with his/her feet resting comfortably on the floor.
3. The FI will ask the participant to be seated in the chair/bed.

4. Press the **[ON/OFF]** key to start the instrument. It should show 0.0 Kg.
5. We would be using the non-dominating first. Using the **[SELECT TEST]** key, scroll to the "L" (Left) or "R"(Right) icon to select the hand to be tested.
6. To select the number of test repetitions (3) to be recorded for that hand, press the **[# OF TRIALS]** key. Each

of the three numbers (1 through 3) will be displayed on the upper line ofthe display. Stop scrolling on the number which represents the number of tests to be taken.

7. Ask the participant sitting with his shoulder adducted and neutrally rotated, elbow flexed at 90°, and the forearm and wrist in neutral position.



8. Have the participant grasp the Hand Dynamometer gently so that the palm fits comfortably to the rear of the instrument and the fingers curl around the adjustable grip at the front of the instrument.
9. Press the **[TEST]** key to begin the test. Start with the first test trial and the number "1" will appear and flash at the top of the display, indicating that the first test for the chosen hand is ready. Have the participant squeeze the grip and be ready to enter the second trial (after resting for 30sec).
10. When the first test is completed, press the **[TEST]** key one time to scroll to the next test. Repeat the 3 trials to complete the test cycle for the chosen hand.

Example:
The right hand is chosen to perform three tests. Press the **[SELECT TEST]** key and scroll tothe "R" (Right) icon. Press the **[# OF TRIALS]** key until the number "3" is displayed. Press the **[TEST]** key to begin the test. "R" and "1" will be displayed on the upper line. Have the patient perform the first test. Press the **[TEST]** key to move the display to "R2". Have the patient perform the second test.Press the **[TEST]** key after each test until all three tests have been performed.

11. When testing is completed for the chosen hand and the required data is recorded, press the **[RESET]** key to clear the previous test data. Repeat steps 4 through 9 for the remaining hand if de sired.
12. Press the **[ON/OFF]** key to turn the instrument OFF when testing is complete and return it to a safe storage location.

Calibration

The unit should be returned to seller after 12 months of use for recalibration.

Care and Storage

The Jamar Smart Hand Dynamometer is an electronic instrument and should be cared for in a manner suitable for its function and components. Store the instrument when not in use in a safe location to prevent inadvertent damage. Use a clean, damp cloth and mild detergent for cleaning.

When not in use, the instrument should be stored in the black case provided. Care should be taken, however, to prevent undo stress to the grip posts, as this may damage the post mountings or electronic components.

6. Timed Walk

Introduction

Walking speed is predictive of overall health, level of disability, future use of health care and mortality among older people. Walking speed and steadiness declines with age. This decline increases the chances of injury. The timed walk test is a quick, inexpensive, and highly reliable measure of functional capacity that can be easily done in the home interview. It has been shown that gait speed predicts major health outcomes for older people such as self-reported health.

Equipment

To measure timed walk, you will need the following:

- 15- feet length space
- Stopwatch
- Measuring tape (Steel measuring tape)
- Masking tape

Preparation

Find the suitable area that is safe, flat and free of any obstruction to conduct the timed walk. Measure out a distance of 15 feet and mark the start and finish point with a strip of masking tape.

General Guidelines

Follow the general guidelines below to prepare respondents and take the measurements.

1. Tell the participant that she/he will need to walk a 15feet distance, at a normal speed; and the FI will time how long the walk takes with a stopwatch.
2. Make sure respondent is comfortable walking this distance without risking a fall.
3. Do not perform timed walk if the participant:
   a. Cannot walk even with a cane or a walker
   b. Is sitting on a wheelchair
   c. Suffering from dizziness
   d. Has significant pain or swelling of knee or hip
4. Ensure the participant wears appropriate footwear or walk barefoot; low heeled shoes ortrainers or socks are preferred.
5. Explain that you will walk alongside to provide support.
6. If participant uses a cane or another walking aid and would be more comfortable with it, thenshe/he may use it.

Procedure

1. Demonstrate a normal walk first.
2. If the participant t does not understand the instructions, demonstrate once more and explain the instructions verbally.
3. If the participant still does not understand, skip the task.
4. Ask the participant to stand with both feet together touching the starting line.
5. Explain that when you say begin you want them to walk tothe opposite wall or object nearest to the other end of the course at their usual speed, just as if they arewalking down the street to go to the store.
6. Say –Ready, begin.
7. Press the Start/Stop button on the stopwatch ONLY when either foot is waived across the start line.
8. Walk beside the participant for the length of the walk to provide support in case they lose their balance.
9. Press the –Start/Stop button to stop timing when the respondent's whole foot is across the finish line and touches the floor.
10. Record the time from stopwatch.
11. Press the SPLIT/RESET button to reset the stopwatch.

D. GENERAL INSTRUCTIONS

1. Body Circumferences

a. Talk to the participant as you are proceeding through the measurements. Explain why and what you are doing, especially before adjusting the pants down to feel for the hip bone.

b. Remain completely professional and unaffected by tattoos, body piercing, etc. **DO NOT COMMENT** about the participant's body.

c. When you are taking the circumference, remember to stay in one place and move the participant around rather than moving around the participant.

2. Standing Height

a. Make sure the head and heels are against the stadiometer before taking the height, unless this position is anatomically impossible.

b. **DO NOT FORGET** to have the participant take a deep breath and hold it while you position the headboard.

c. If the participant is unable to stand with the head and heels against the stadiometer, make sure the trunk is vertical above the waist, and that the arms and shoulder are relaxed.

E. CALIBRATION OF EQUIPMENTS

1. Monthly Calibration

Standardization (Calibration) of measuring instruments is done by checking the measuring instruments against an accurate standard to determine any deviation and to correct errors.

a. Calibration of the instruments needs to be done on a monthly basis.

b. Readings for the calibrations needs to be taken on the same two field interviewers monthly at the beginning of the day.

c. The monthly calibration readings need to be entered into the form provided and given to the study manager every month for assessment.

d. Each instrument needs to be numbered.

e. Calibration needs to be done only for the instrument which is being used and only on the days it is used.

f. For monthly calibration the first working day of every month is selected, and all the instruments are calibrated on the same day.

2. Additional Calibration (once in 3 months)

a. Body composition analyzer: The FIs need to measure their colleague's body composition on every analyzer and note the readings.

b. Stadiometer: All the FIs need to measure each other's height three times.

See Annexure 10 for the Monthly Calibration Forms (E.1, E.2 & E.3).

Anthropometry Measurement Script

When you provided consent to enrol in the study, you agreed to allow us to measure your blood pressure, pulse rate, body circumferences and skin- fold thickness. Blood pressure, pulse rate and skin-fold thickness will be measured at least twice.

1. **Blood Pressure**
    a. I would like to start by taking your blood pressure.
    b. If necessary, ask the participant to roll up one sleeve as far as possible.
    c. Place the blood pressure cuff on the participant's arm.

d. Activate the BP machine.
e. Record blood pressure and pulse rate.
f. Remove the blood pressure cuff.

2. **Waist Circumference**
   a. This measure should be taken on bare skin if possible.
   b. The purpose of the following instructions is to help the interviewer find the narrowest point on the waist.
      i. Please stand with your feet close together and your stomach relaxed. I am going to touch your right hip.
      ii. Now I need to find the lowest rib on your right side.
      iii. I am going to use the cosmetic pencil to mark the spot on your waist where I will take the measurement.
3. **Hip Circumference**
   a. While taking the circumference and skinfold measures stay in one place and move the participant around.
      i. Now I am going to measure your hip circumference.
      ii. Please stand with your feet together and your arms at your side with palms in.
      iii. I am going to place this measuring tape around your hips and take a measurement.
   b. The measurement should be taken from behind the participant and the tape should be placed at the maximum circumference around the buttocks.
4. **Height**
   a. If the participant is unable to remove head coverings or undo the bun in her/his hair, take the measurement and make a note of it in the comments section.
      i. Please stand with your heels together touching the back board. Your toes should be pointed slightly outward.
      ii. Please stand up straight and look straight ahead.
      iii. The back of your head, shoulder blades, buttocks, and heels should all be touching the back board.
   b. Make sure that the participant's weight is evenly distributed between both feet and that all of the relevant body parts are touching the back board.
   c. If the participant is unable to stand in a position that allows her/his head, shoulder blades, buttocks, and heels to touch the back board, make sure that her/his trunk is vertical above the waist and the arms and shoulders are relaxed.
   d. Make sure that the head is positioned in the Frankfort plane.
   e. If the participant has kyphosis, take the best measurement possible and record "NS" (Not Straight) in the comment section.
   f. Once the participant is positioned correctly, lower the head board to just above the participant's head.
   g. **Take a deep breath.**
      i. Rest the head board on the top of the participant's head with sufficient pressure to compress the hair.

ii. Record the height.

iii. Raise the head board.

h. Thank the participant and ask him/her to step away from the back board.

5. **Body composition/ body impedance**

a. Now I am going to measure your body composition which will give your weight and fat distribution in the body along with your BMI.

b. Refer to the instructions in procedure guidelines.

c. We have finished all measurements. Thank you for your cooperation and patience.

d. I will see you again later.

Points to Remember

1. It is important to make the participant comfortable.
2. Measurements of female participant will be taken by female staff and that of male participants by male staff.
3. Avoid direct contact with body as much as possible.
4. You will have to be efficient in taking measurements and BP, such that the procedure requires minimum possible time.
5. The measurements should be done as per instructions.
6. Body circumferences and skin-fold thickness should be measured on bare skin as far as possible, if not; over very light clothing [mention about the thickness of clothing].
7. Thank the participant for cooperation.

ANNEXURE

Form C.2: Blood pressure and anthropometric measurement recording form (Annexure-3)

Form C.3: Tanita form (Annexure-3)

Form C.4: Handgrip form (Annexure-3)

Form E1: Monthly calibration form (Annexure-10)

F. Quality Control/Assurance Procedures

1. Training and Evaluation

At the beginning of the survey, the site coordinator/ senior lab supervisor would train all the study personnel (field interviewers and lab technicians/ attendants) vis-à-vis how to fill the questionnaire and take the anthropometric measurements of the participants. After that they would be certified by the trainer and store the scanned copy of the certificate (Annexure 11) at the site.

Their measurement performance would be evaluated bimonthly by the trainer, and they would provide their feedback and store the scanned copies of the certificates with them. Likewise, lab technician's performance would be evaluated by the senior lab supervisor after every 3 months and provide their feedback and send the scanned copies of the certificates to the project co-ordinator.

Timeline for training and certification of field interviewers and lab technicians/ attendants

Interviews	Timeline	Responsibilities	Follow up action
Training of the interviewers and certification	At the beginning of the survey	Site coordinators	Scanned copy of the certificate to be saved
Training and certification of measurements and blood pressure measurements: Height/ weight/ bio-impedance/ body measurements	At the beginning of the survey	Site coordinators	Scanned copy of the certificate to be saved
Evaluation of measurement performance	Every bi-monthly	Site coordinator provides feedback/ retraining	Scanned copy of feedback/retraining report saved
Training and certification of lab technicians and attendants	At the beginning of the survey	Senior lab supervisor	Scanned copy of the certificate to be saved
Evaluation of technician's and attendant's performance	Every 3 months	Senior lab supervisor provides feedback/ retraining	Scanned copy of feedback/retraining report saved

**In the certificates, please provide appropriate comments in the provided space.

2. Instructions

At the end of the day the FI will check all the forms thoroughly, sync the data and inform the supervisor. The supervisor will inform the data manager.

1. Select the correct PID in the tab.
2. Explain each section of the questionnaire thoroughly to the participant.
3. Thank the participant for her/his valuable time.
4. Select all answers cautiously in the form and re-check to avoid errors and missing fields.

G. DATA QUALITY ASSURANCE

Field investigator will check the forms for completeness, improper skip pattern/ inconsistencies and after thorough checking they should sync the forms daily (if incomplete- save as incomplete then sync; if the form is complete, save as complete then sync the form) and inform the field supervisor and s/he will inform the data manager.

Remember:
The PIS and consent form will be stores at the collecting site.

1. Interviewer Administered Questionnaire

Interview data is an essential part of the study assisting researchers in the interpretation of clinical examination results. In addition, interview data provides some information not otherwise available. It is important that this self-reported data be as accurate as possible. The integrity of this data is imperative in yielding valid data. For this type of data, there are two major sources of errors: unintentional errors and intentional errors of interviewers, which may or may not be systematic. The unintentional errors could be simple errors like incorrect completion of the questionnaire due to interviewer's inaccuracy and/or lack of interviewing skills. The intentional errors, called falsification errors, could result from deliberate interviewer actions leading to false data.

Certain characteristics of interviewers, characteristics of respondents, and features of the interview task affect the likelihood that falsification will occur. There are several tools for the detection, prevention, and correction of both types of error. Quality control processes, including appropriate checking of the questionnaires and follow-up actions in response to suspected and proven instances of errors, is essential in the detection and correction of errors. To facilitate detection of interviewer's errors, the Precision CARRS study will use two methods: observation and quality checks.

2. Follow-Up Action

Each study coordinator will be notified by the CC when it is necessary to take further actions to correct or re-train an interviewer. Interviewers with high error rates will be monitored more closely until performance is improved sufficiently.

CHAPTER 8 |VERBAL AUTOPSY

The purpose of the verbal autopsy questionnaire is to collect the death details of the deceased, cause of death, history of past medical conditions, symptoms noted during the final illness and narrative summary of the deceased. Verbal autopsy (VA) is an interview with relatives of the deceased using a detailed questionnaire, to obtain information on the symptoms, signs and other relevant events during the illness leading to death.

VA was principally developed to provide information on the cause of death in communities where there was very limited access to healthcare and medical certification of causes of death. In such situations the only viable source of information on the terminal illness is from caregivers of the deceased, most often the family members.

A. PROCEDURE

VA questionnaire (Annexure 6, form C.1) has to be administered to the respondent (usually a close family member, in the absence of whom, a relative or a neighbour) of the deceased participant who died in the period between the baseline and the follow-up. The main criteria for selecting the most appropriate respondent from the family members should be the person who most closely attended to the deceased during the illness. His/her educational status and communication skills may also be considered while identifying the most appropriate respondents. This could likely be the mother in the case of an infant death, the spouse in case of an adult death, and the son/daughter in the case of deaths among the elderly.

In some situations, there may be a need for the primary respondent to consult other household members for specific details (e.g., someone else who accompanied the deceased on a health facility visit). When initiating a VA interview, the introduction is very important. The interviewer should be polite and considerate when making the first introduction. It is useful to maintain eye contact whenever feasible, to build confidence in the respondent. If culturally appropriate, some opening statements about the composition of the household and/or the respondent's occupation could help establish a rapport.

When approaching households to initiate the interview, it would be helpful to adopt an empathetic attitude and start by expressing sympathy or condolences for the death. After consent is obtained from the respondent, the next step is to explain the format of the questionnaire and what type of questions the interview will cover. Given the length of the questionnaire it is helpful for respondents to have an idea of its structure and how long it is to prepare them before beginning the questions. The VA questionnaire includes the detailed information of the deceased, exact cause of death, medical history, signs and symptoms of the final illness preceding death.

Fill the questionnaire in the same order as printed in the form and get the detailed narrative summary of how the person died. Use the symptom list to probe the detailed responses from the respondent. Document all the past medical histories of the deceased and the details of the final illness as reported by the respondent (in the respondent's own words). Ensure the cause of death verbally and by checking the medical records from the respondent. Record and collect the copy of all medical and supporting documents available of the deceased. The interviewer should demonstrate good understanding and patience during the interview. At the end of the interview, whether successfully completed, or terminated or postponed due to any reason, the interview should thank the respondent and household, and offer the potential for them to contact the interviewer or the VA team in case they need any clarification or further information regarding the process.

B. SCENARIOS

(1) If the entire household is shifted, enquire with relatives, neighbours or local authorities and administer the VA questionnaire. (2) If there is confusion with the medical terminology, it is suggested to write in the local or

comfortable language of the interviewer, which can be translated later. (3) If the respondent become overcome with grief / crying on recalling the terminal events or remembrance of the deceased, it is advisable that the interview should be paused, to allow the respondent to recover, and where necessary, be consoled by other members of the household present at the interview. (4) In case it is too distracting, or the pause is prolonged, it may be necessary to postpone the interview to an alternate time point. (5) The responses may be indicative of a disease or condition associated with stigma e.g., suicide; or HIV/AIDS; or TB in some communities; and this may also lead to hesitation or non-committal responses and lack of engagement in the interview beyond a certain point. In such circumstances, it would be necessary for the interviewer, on identifying this potential situation, to reassure the respondent of the strict confidentiality of the information being collected, as well as the importance of the accuracy of information.

How did the person die? (Write an account of final illness in respondent's own word)

This question is to obtain a detailed narrative summary of how the person died. Use the symptom list to probe and obtain the detailed responses from the respondent. Document all the past medical histories of the deceased and the details of the final illness as reported by the respondent (in the respondent's own words). Ensure the cause of death verbally and by checking the medical records from the respondent. Record and collect the copy of all medical and supporting documents available of the deceased.

C. CONTEXT AND HISTORY OF PREVIOUSLY KNOWN MEDICAL CONDITIONS

1. *Did he/she die suddenly?*
   Check whether the subject dies suddenly, if "Yes" – Go to 1a, else check "No."

   1a. *Mention whether the sudden death was witnessed. Check appropriately (No/Yes).*

2. *Was he/she well during the 12 hours prior to death?*
   Mention whether the subject was well during the 12 hours prior to death, if "No" – Go to 2a, else check "Yes/Don't know."

   2a. *How long was he/she ill before he/she died?*
   Mention how long the subject was ill before he/she dies. (<12hours / >12 hours but <24 hours / 2-7 days / >1week / Don't know) Check appropriately.

D. SYMPTOMS NOTED DURING THE FINAL ILLNESS

3. *Did he/she have any breathing problems?*
   Mention whether the subject had any breathing problems, if "Yes" – Go to 3a, else check "No / Don't know".

   3a. *Did he/she have fast breathing?*

   Fast breathing is also called as rapid, shallow breathing (medical term – tachypnea), which occurs when you one takes more breaths than usual in a given minute. This is usually defined as more than 20 breaths per minute in an adult. The average adult typically takes 12 to 20 breaths per minute. Rapid breathing can be the result of anything from anxiety or asthma, to a lung infection or heart failure.

   Mention whether the subject had fast breathing, if "Yes" – Go to 3(i) Mention, how long (No. of days & No. of weeks), else check "No / Don't know."

   3b. *Did he/she have breathlessness?*

   Breathlessness is an unpleasant sensation of uncomfortable, rapid or difficult breathing. People say they feel puffed, short of breath or winded. The medical term is dyspnoea. The chest may feel tight and breathing may hurt. It may come on suddenly (acute) or gradually over a period of time (chronic).

Mention whether the subject had breathlessness, if "Yes" – Go to 3(b) Mention, how long (No. of days & No. of weeks), else check "No / Don't know."

3b(ii). *Was he/she unable to carry out daily routines due to breathlessness?*

Mention whether the subject was unable to carry out daily routines due to breathlessness. Check appropriately (No/Yes).

3b(iii*). Did he/she have breathlessness on exertion?*

Mention whether the subject had breathlessness on exertion, (No/ On vigorous exertion (climbing stairs)/ On moderate exertion (rapid walking0/ On slight exertion / At rest/ Don't know) Check appropriately.

3b(iv). *Was there breathlessness at night causing the person to wake up after?*

Mention whether the subject had any breathless at night causing the person to wake up after that. (No / Yes/ Don't know). Check appropriately.

4. *Did he / she have wheezing/ whistling in the chest?*

Wheezing happens when blockages or inflammation of a person's airways makes their breathing sound like whistling or squeaking. If a person experiences a wheezing sound when breathing out, it typically means they are only exhaling at around half of their usual capacity.

Mention whether the subject has wheezing or whistling sound in the chest. (No / Yes/ Don't know). Check appropriately.

5. *Did he/ she have chronic cough lasting 3 months in the past 2 years?*

Mention whether the subject had chronic cough lasting for 3 months in the past 2 years. (No / Yes/ Don't know). Check appropriately.

6. *Did he/ she have both feet swollen?*

Mention whether the subject had swelling on both the feet. (No / Yes/ Don't know). Check appropriately.

7. *Was he/ she unconscious for more than 24 hours?*

Check whether the subject is unconscious for more than 24 hours. If "Yes" Go to 7a. else check "No/ Don't know".

7a. *Did the unconsciousness start suddenly / quickly (atleast within a single day)?*

Mention whether the unconsciousness starts suddenly or quickly that atleast within a single day. (No / Yes/ Don't know). Check appropriately.

8. *Did he/ she have noticeable weight loss?*

Mention whether the subject had noticeable weight loss. (No / Yes/ Don't know). Check appropriately.

9. *Did he/ she drink a lot more water than usual?*

Mention whether the subject drank a lot more water rather than usual. (No / Yes/ Don't know). Check appropriately.

10. *Did he/ she have urine problems?*

Mention whether the subject had any urine problems. If "Yes" Go to 10a. else check "No/ Don't know" appropriately.

E. SYMPTOMS NOTED DURING THE MONTH PRECEDING DEATH

11. Did he/she have chest pain?

Chest pain appears in many forms, ranging from a sharp stab to a dull ache. Sometimes chest pain feels crushing or burning. In certain cases, the pain travels up the neck, into the jaw, and then spreads to the back or down one or both arms. Many different problems can cause chest pain. The most life-threatening causes involve the heart or lungs.

Mention whether the participant had any chest pain. If "Yes" Go to 11a. else check (No/ Don't know) appropriately.

11a. *How long did the chest pain last?*

Mention how long the chest pain lasts. Check (<24 hours, > 24 hours) appropriately.

11b. *Where was the chest pain located?*

Mention the location, where the chest pain occurred. (Central chest/ Left chest/ Other/ Don't know) Check all that apply.

11c. *Was the chest pain / discomfort accompanied by or followed by.*

Mention whether the chest pain or discomfort accompanied or followed by any of the following symptoms – Sweating / Unconsciousness / Vomiting / Others (No/ Yes/ Don't know) Check all that apply.

11d. *Was there chest pain/ discomfort on exertion?*

Mention whether the subject had chest pain or discomfort on exertion. (No/ On vigorous exertion (climbing stairs)/ On Moderate exertion (rapid walking)/ On slight exertion/ At rest/ Don't know). Check all that apply.

12. Did he / she have paralysis of one or both sides of the body?

Paralysis (medical term – stroke) is a loss of muscle function in part of the body. It can be localized or generalized, partial or complete, and temporary or permanent. Signs and symptoms of stroke include trouble speaking and understanding what others are saying, paralysis or numbness of the face, arm or leg, problems seeing in one or both eyes, headache and trouble walking.

Mention whether the subject had paralysis of one or both sides of the body. (No/ Yes, one side/ Yes, both sides/ Don't know) Check all that apply.

12a. *If yes, was the paralysis accompanied or followed by a sudden loss of consciousness?*

If "Yes", mention whether the paralysis accompanied or followed by a sudden loss of consciousness. (No/ Yes) Check appropriately.

13. Was there a pre-existing heart problem at anytime or was heart disease diagnosed as cause of death?

Check whether the subject had any pre-existing heart problem at anytime or the heart disease was diagnosed as the cause of death. (No/ Yes/ Unknown). Check appropriately.

13a. *If yes, what was the diagnosis (record verbatim)?*

If yes, mention the diagnosis for the cause of death. Record the responses from the respondent precisely.

14. Were any of the following listed as the diagnosis – verbally or on medical certificate?

Is any of the following listed diagnosis is mentioned as the cause of death

verbally or on medical certificates. a. Hearth attack b. Angina c. Heart failure d. Heart beat abnormally (irregular heart beat) e. Heart valve defect f. Birth defect of heart or blood vessels g. Fluid around the heart h. Related to heart surgery i. Other

(No / Yes/ Unknown) Check all that apply.

CHAPTER 9 | BIOLOGICAL SPECIMENS

A. INTRODUCTION

Biological specimens to be collected for the study:

- 29 ml of blood
- 40 ml of urine (early morning void)

After the specimens are collected, the lab technician will complete a specimen collection form (Appendix) and transport the specimens to the laboratory for processing. The blood tubes will be processed for serum (S), plasma (P), EDTA-Plasma (EP), buffy coat (BC) and red blood cells (RBC). Analysis for plasma glucose and lipid profile and creatinine will take place on the same day of collection. Whole blood (WB) will be kept in fridge (4-8^{0}C) and other aliquots will be stored in deep freezer (-80^{0}C) immediately after processing. Urine samples will be tested for protein & sugar by dip sticks on the same day. Urine sample will be aliquoted into vials and test for protein and sugar by dip sticks will be done from the remaining urine. The aliquots will be stored in deep freezer.

1. Assigning a Sample ID

Each participant who enrols into this study will be assigned a Sample ID. These SIDs will be used when a specimen collection kit is assigned to a participant.

2. Labelling of Bio-Specimen

Each specimen collected during the study will be identified with a unique sample ID (SID) number. This will be 6-digit numeric code. Sample ID will be used to identify the unique specimens. The Sample IDs will be printed on labels that are freezer safe.

3. Pre-Labelling of Collection Materials

All vacutainer tubes (Two yellow, one grey and one lavender top) for fasting and one each grey and yellow for 30- and 120- min will be pre-labelled with Sample ID. Extra labels will be provided in the specimen collection kit to be used in case of damage to any of the printed labels. The extra labels to label replacement collection materials have a sample ID of "XXXXX." Only these specific labels should be used to label replacement collection materials.

4. Collection of Blood Will Be Done At Three Time Points On The Same Day

a. First blood sample will be collected from the participants when they arrive. This is their fasting sample. It provides a baseline for comparing with other glucose values.

b. Immediately, participants will be provided with 75 gm (82.5 gm Glucon-D monohydrate) of glucose to drink with water. It is best to drink the liquid quickly. Mark the time on the specimen collection form. This will be considered as zero time.

c. Collect blood sample after 30 minutes (half-an hour) after the drink and another sample after 120 minutes (two hours). Try to stick to the time schedule as much as possible. Mark the time of each collection.

NOTE: DO NOT ADMINISTER GLUCOSE TO THE PARTICIPANTS WHO HAVE DIABETES.

5. Blood Collection Items

5.1. Specimen Collection Kit:

It contains the key common items required for blood collection

a. Tourniquet
b. Vacutainer Holders
c. Holding rack for Vacutainers
d. Sharps needle disposal units (sharps container)
e. Drape sheets to cover work surface (Chux)
f. Laboratory coat and gloves

5.2. The Following Items For Blood Collection Are Required Per Participant:

a. One 6.0 ml lavender-top vacutainer tube
b. Two 5.0 ml yellow top vacutainer tube
c. Two 3.5 ml yellow top vacutainer tubes
d. Three 2.0 ml Grey top tubes
e. Cryo-label sheet to paste on the tubes
f. Three Standard 22G blood collection needles
g. Alcohol wipes
h. Cotton pads
i. Band-Aids

5.3. Items For Glucose Tolerance Test (Gtt): Per Participant

a. 75 gm (82.5 gm Glucon-D monohydrate)
b. Disposable Glass
c. Disposable spoon
d. Drinking water

5.4. Items For Processing Of Samples

a. Storage vials (1.8 ml), TARSONS
b. Whatman filter paper 903
c. Pasteur pipettes
d. Pipette tips (1 ml, 250 ml, 10 ul)
e. Variable Pipettes
f. Storage boxes
g. Labels
h. RNA Later
i. Normal saline
j. Cold centrifuge

6. Procedure for Blood Collection

Ensure that the participant is fasting and have not taken anything to drink or eat in the morning.

6.1. Steps To Be Followed For Sample Collection:

a. Ask the participant when s/he last ate a meal and record the time on the Specimen Collection Form.
b. Before the blood samples are drawn, make the participant sit or recline on a chair for at least five minutes and remain in this position during the venipuncture.

c. Record the time of the blood collection on the Blood Collection Form.
d. Clothing should not restrict the arm. Ask the participant to adjust her/his clothing to expose the middle portion of her/his arm.
e. Explain the procedure and position the participant with the arm in a dependent position.
f. Prepare the appropriate blood collection tubes, placing them in a test tube rack in the order in which they will be drawn.
g. Wash your hands and put on protective gloves.
h. Position the participant's arm so that the veins are readily accessible and you are able to work in a comfortable position. Ensure that the arm is in a downward position with the elbow lower than the heart to prevent backflow. Inspect the arm to be used for the venipuncture. The veins of choice are those located in the antecubital area.
i. Blood should not be drawn from any arm with an arterial access, such as a fistula or shunt, not from any arm which has a rash or open sorceries swollen or oedematous.
j. Apply a tourniquet four to five inches above the site with enough pressure to impede venous blood back flow. Select a vein that is palpable and well-fixed to surrounding tissue.
k. Clean the skin with alcohol in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed. Dry the area completely using a sterile gauze pad before the venipuncture in order to reduce the burning sensation caused by alcohol penetrating the skin.
l. Perform the blood draw by inserting an appropriate needle into the arm, then attaching the vacutainer tubes.
m. Remove the tourniquet
n. Immediately after the venipuncture, press clean gauze square over the venepuncture site. After a few minutes, check the venipuncture site and if clotting has occurred, apply an adhesive bandage over the gauze pad. If bleeding continues, apply direct pressure to the site for five minutes.
o. After the blood draw is complete, fill in the appropriate items in the Specimen Collection Form.
p. If the blood draw is not successfully completed for all tubes (all tubes filled to capacity), another draw should be attempted from the other arm. If attempts from both arms are unsuccessful, no further attempts should be made to collect the specimen.

6.2. Administer Glucose to the Participant For OGTT

Provide the participant with 75 gm (82.5 gm Glucon-D monohydrate) of glucose to drink with water. It is best to drink the liquid quickly. Mark the time on the specimen collection form. This will be considered as zero time.

6.3. Collection of Blood at 30 Min and 120 min after the Glucose Load

a. Collect blood from the participant following the method in 6.1 after 30-minutes and 120-minutes of glucose intake.
b. Use 3.5 ml Yellow vacutainer and 2 ml of Grey vacutainer at each time points for collection.

6.4.Venipuncture Complications

Haematosis

Hematomas are a common complication of venipuncture that is caused by coagulation of extravagated blood in a tissue or cavity. Hematomas most frequently result from failure to apply pressure, insufficient time spent in applying the pressure, or from flexing the arm to stop bleeding. Once the venipuncture is

complete, instruct the participant to apply mild pressure to the puncture site and raise her/his arm straight in the air for about two minutes. Constant pressure should always be maintained until the bleeding stops.

Syncope (Fainting)

Syncope or fainting is a sudden loss of strength or temporary loss of consciousness and is caused by decreased blood flow to the brain. To prevent injury of any participant who might faint, always perform the venipuncture when the participant is in a seated, relaxed position with feet flat on the ground.

The warning signs include becoming pale and beginning to perspire heavily, feeling dizzy and hot, beginning to pant (hyperventilate), and/or feeling nauseated.

The participant should always be instructed not to watch the procedure. If the participant displays any of the above signs, immediately terminate the venipuncture. The seated participant should put her/his head down between her/his knees, and prevent the participant from falling. Talk to the participant in a calm, reassuring manner, instruct the participant to takes low deep breaths and call for a family member, if available. If the participant faints, gently ease the participant to a lying position and elevate her/his feet. Check the radial pulse. After the participant regains consciousness, give her/him some glucose drink or fruit juice. Stay with the participant until she/he has recovered.

Continued bleeding

Some participants may be receiving certain drug therapies or have bleeding disorders that may cause them to continue to bleed after the venipuncture. It may be necessary to apply pressure to the puncture site for an extended period of time. If the participant continues to bleed after ten minutes call the Research Officer (medical doctor).

Thrombosis

Thrombosis is the formation of blood clots (thrombi) inside a blood vessel or inside the chambers of the heart. They can occur as a result of venipuncture when the endothelial lining of the vein is injured. A thrombosis vein should not be used for venipuncture. A thrombosis vein can be detected by palpation prior to the venipuncture. A vein with thrombosis lacks resilience, feels hard and cord like, and rolls easily.

Accidental Needle Stick or Contamination of Open Wound (of Phlebotomist)

Accidental needle sticks or contamination of an open wound can occur as a result of careless technique and improper disposal of used needles and blood drawing equipment. If an accidental needle stick injury occurs, wash the area thoroughly with soap and water, cover it, and report the incident immediately to the field supervisor. Refer to hospital/centre policies for completing the required documentation, instructions, and proper post needle stick injury procedures.

7. Instructions for Sample Collection in Case of Failure

In case of partial failure of collection or difficulty in collection or participant refusal to provide blood in all the tubes, preference of collection tubes should be as follows:

1. Yellow tube-1 in no. (5 ml)
2. Lavender tube-1 in no. (6 ml)

8. Instructions for Samples Following Blood Collection

a. Allow the yellow top tube to stand at room temperature for 15-20 min for clotting. Keep them in ice bucket after the clotting time is over.
b. All other samples should be placed in the racks at room temperature for 10 minutes. After that they

should be shifted inside ice buckets to maintain an even and cool temperature.

- Minimize exposure to sun light and exposure to excessive heat to samples at all-time points.

c. Open the buckets as little as possible. The ice buckets should have ice packs at the bottom and on the sides.
d. Use separate ice-buckets for blood and urine.

Recommendations: Bring extra buckets with extra icepacks. If the ice packs in the first bucket do not maintain a sufficiently cool temperature, move the specimens into the second bucket with frozen packs or add fresh icepacks to the original bucket to maintain the appropriate temperature.

9. Specimen Processing

After the blood specimens have been collected place the vacutainers inside the ice buckets. Transfer the ice buckets with samples to the laboratory for processing as soon as possible.

9.1. Labelling of cryovials:

Start placing the label on the vial from the last end. Superimpose the labels with a cello-tape in a manner that it covers the entire label.

Table 1: Overview of Aliquots to be Prepared from Different Vacutainers

Tubes and their aliquots	**No. of aliquots**
Fasting	
Yellow top [2 x 5 ml]- Serum (S)	**4 + 2***
Lavender Top [1 x 6 ml] – 300 µl Whole blood (for HbA1c + Hb analysis + Spot preparation)	**1***
Lavender Top – EDTA Plasma (EP)	**3+1***
Lavender Top – Buffy Coat (BC)	**1**
Lavender Top – RNA (RNA)	**1**
Lavender Top – RBC (RBC)	**1**

Grey Top [1 x 2ml] -Plasma (FP)	**1 + 1***
Grey top- Fluoride packed cells (FPC)	**1**
Urine samples [20 ml] (U)	**2 + 1***
30 min after glucose load	
Grey top [1 x 2 ml]-plasma (30-FP)	**1 + 1***
Yellow top [1 x 3.5 ml]-serum (30-S)	**1+1***
120 min after glucose load	
Grey top [1 x 2 ml]-plasma (120-FP)	**1 + 1***
Yellow top [1 x 3.5 ml]-serum (120-S)	**1+1***

***for analysis**

9.2. Processing for Yellow top tubes (Fasting) [2 x 5 ml]

1. Allow the tubes to remain upright at room temperature for complete blood coagulation. Once clotting is complete, maintain the yellow-top tube at 2°to 8°C by placing the tube upright in a test tube rack in an ice-bucket.
2. Label the cryovials (Six 1.8 ml vials for serum) with participant ID.
3. Centrifuge the yellow top tubes for 15 minutes at 1100 x g.
4. After the blood has been centrifuged, dispense serum from both the tubes, as per the **table 2** below.
5. Discard the tube with clot in appropriate bio waste disposal bag.
6. Store the samples in vials as suggested in the table 2 below.
7. Store the boxes immediately in deep freezer at -80° C.

Table 2: Volume, Purpose & Storage of Serum

Vials	Volume	Purpose	Storage box
S6	100 µl	Lipid profile	Box-Lipids
S5	700 µl	Insulin, C-peptide, Trop-I, ApoA/B, Lp(a), hsCRP, Cystatin-C, Adiponectin, Leptin	Box- Analysis
S4	650 µl	Thyroid function (sub-study)	Box S4
S3	850 µl	Long-term Storage	Box S3
S2	850 µl	Long-term Storage	Box S2
S1	850 µl	Long-term Storage	Box S1

9.3. Proc essing for Lavender top tube (Fasting)

a. Label the cryovials, one vial for whole blood (WB), four vials for plasma (EP), one vial each for buffy coat (BC), RNA and RBC (RBC) with specimen ID labels.

b. Mix the content of the tube by inverting it 6-7 times. Remove 300µl of whole blood from the lavender top tube in a separate cryovial (**WB**) for HbA1c and Hb analysis and for preparing blood spots.

c. Centrifuge lavender top tube for15minutes at 1100 x g.

d. Aliquot plasma into four cryovials. Follow volume as given in the table 3 below (**EP1, EP2, EP3** & **EP4**).

e. Transfer the buffy coat into one cryovial (**BC**). In order to maximize the buffycoat yield, when removing plasma leave a small amount of plasma above the buffy coat and when aspirating buffy coat include a small amount of RBC in the sample.

f. Pipette out 100 µl of buffy coat into cryovial labelled RNA. Add 500 µl of RNA Later. Mix by inverting the tube.

g. Wash RBCs three times with Phosphate Buffer Saline (PBS)/Normal Saline (NS).

   - For this add same amount of PBS)/Normal Saline (NS). into the tube. Mix gently by inversion. Centrifuge. Discard the supernatant. Repeat two more times using PBS/NS. The final supernatant should be clear with no colour.
   - **NOTE**: do not use distilled water for washing as it will hemolyze red blood cells.

h. Transfer washed RBCs into labelled cryovials (**RBC**).

   - **NOTE**: **Do not discard any component of lavender top tube.**

i. Store EP, BC, RNA & RBC vials in boxes as suggested in the table.

j. Store the boxes immediately into the deep-freezer at -80° C.

Table 3: Volume, Purpose & Storage Of Components From Lavender Tube

Vials	Volume	Purpose	Storage box
WB	300 µl	HbA1c Analysis	Box HbA1c, Hb analysis & spot preparation
EP4	400 µl	BNP, SuPAR, Homocysteine	Box Analysis
EP3	200 µl	Metabolomics	Box Omics
EP2	800 µl	Long-term storage	Box EP2
EP1	800 µl	Long-term storage	Box EP1
RNA	100 µl	RNA extraction	Box RNA
BC	200 µl	DNA extraction	Box BC
RBC	800 µl	Long-term storage	Box RBC

Preparation of Dried Blood spots

a. Label Whatman filter paper no. 903 with participant ID.

b. Place the filter paper on a clean non-absorbent surface.

c. Pipette out 10 µl of whole blood and drop over the filter paper. Allow the blood to soak into the paper.

Prepare 15 such spots and allow the spots to dry at room-temperature (1-2 hours).

d. Place the filter paper with spots in a zip-lock pouch with a desiccant, close the zip carefully to make it air tight and store in a box at -20^{0}C.

NOTE: Do not expose the spots to sun light and excessive heat.

9.4. Processing for Grey top tube (Fasting)

a. Label the cryovials (two vials for plasma) with specimen ID labels.
b. Centrifuge grey top tube for 10 minutes at 3,500 rpm.
c. Transfer 100 µl of plasma into the autoanalyzer cup and the rest of the plasma into cryovial **P**. Use the plasma in the cup for analysis immediately **OR,** use plasma in primary tube for analysis of glucose and store cryovial **P** into **Box-FP** as in table 4.
d. Do Not discard the packed cells.
e. Store the boxes in a deep freezer at -80° C.

9.5. Processing for Grey top tube (30 minutes after glucose load)

a. Label the cryovials (two vials for plasma) with specimen ID labels.
b. Centrifuge grey top tube for 10 minutes at 3,500 rpm.
c. Transfer 100 µl of plasma into the autoanalyzer cup and the rest of the plasma into cryovial **30 min-PP**. Use the plasma in the cup for immediate analysis and store cryovial **30 min-PP i**nto **Box-PP** as described in table 4.
d. Do Not discard the packed cells.
e. Store the boxes in a deep freezer at -80° C.

9.6. Processing for Grey top tube after 120 minutes of glucose load

a. Label the cryovials (two vials for plasma) with specimen ID labels.
b. Centrifuge grey top tube for 10 minutes at 3,500 rpm.
c. Transfer 100 µl of plasma into the autoanalyzer cup and the rest of the plasma into cryovial **120 min-PP**. Use the plasma in the cup for immediate analysis and store cryovial **120 min-PP** into **Box-PP** as described in table 4**.**
d. Do Not discard the packed cells.
e. Pool the upper layer of fluoride packed cells from Fasting, 30-min and 120-min into one cryovial labelled Fluoride Packed cells (FPC) and store.
f. Store the boxes in a deep freezer at -80° C.

Table 4: Volume, Purpose & Storage of Components from Grey Tubes

Vials	**Volume**	**Purpose**	**Storage box**
Fasting			
Analyzer cup/Primary tube	100 µl	Glucose Analysis	-
P	700 µl	Long-term Storage	**Box-FP**
Packed cells	1000 µl	Hold	**-**

30-min			
Analyzer cup/Primary tube	100 µl	Glucose Analysis	-
30min-PP	700 µl	Long-term Storage	**Box-PP**
Packed cells	1000 µl	Hold	**-**
120-min			
Analyzer cup/Primary tube	100 µl	Glucose Analysis	-
120min-PP	700 µl	Long-term Storage	**Box-PP**
Packed cells	Pool from Fasting,30-min & 120-min	Long-term storage	**Box-FPC**

9.7. Processing for Yellow top tube (30 minutes after glucose load)

a. Label the cryovials (two vials for serum) with specimen ID labels.
b. Centrifuge yellow top tube for 10 minutes at 3,500 rpm.
c. Transfer 150 µl serum into two cryovials 30 min-**S2** and the rest of the serum (1250 µl) into **30 min-S1**. Store cryovial 30 min-**S2 i**nto Box Insulin Analysis and **30 min-S1** in **Box- [PP-S]** as described in table 5.
d. Discard the tube with clot in appropriate bio waste disposal bag.

9.8. Processing for Yellow top tube (120 minutes after glucose load)

a. Label the cryovials (two vials for serum) with specimen ID labels.
b. Centrifuge yellow top tube for 10 minutes at 3,500 rpm.
c. Transfer serum into two cryovials 150 µl **120 min-S2** and the rest of the serum (1250 µl) into **120 min-S1**.
d. Store cryovial **120 min-S2** into **Box Insulin Analysis** & **120 min-S1** into **Box- [PP-S]** as described in table 5.
e. Discard the tube with clot in appropriate bio waste disposal bag.

Table 5: Volume, Purpose & Storage of Components from Yellow Tubes (30- & 120-Min)

Vials	Volume	Purpose	Storage box
30-min			
30-min S2	150 µl	Insulin Analysis	Insulin Analysis
30min-S1	1250 µl	Long-term Storage	**Box-PP-S**
120-min			
120-min S2	150 µl	Insulin Analysis	Insulin Analysis
120min-S1	1250 µl	Long-term Storage	**Box-PP-S**

10. Urine Specimen

10.1. Collection Procedure

One early morning void mid-stream urine will be collected from all participants. A sterile container labelled with the participant ID should be provided to all participants during visit one. Explain to the participant that s/he has to collect an early morning void on the day of visit (mention the day/date of visit) and the container has to be at least three-fourth filled. During visit confirm whether the sample collected in the container by the participant is the morning void of the same day. If the sample is not the morning void of the same day or there is any other problem, then provide another sterile container labelled and repeat the instructions. Re-visit the participant on the following day to collect the sample.

10.2. Transportation

The container with sample has to be carried to the lab. in ice-bucket then needs to be deposited at the laboratory for processing.

10.3. Processing of urine

a. Label three cyovials with participant ID. Transfer urine into 1.7 ml of urine into the cryovials (**U1, U2 & U3**).
b. Use the remaining urine in the container to test for protein and sugar content using dipsticks.
c. Store U1, U2 in **Box-U1 & Box U2** respectively and place into the deep - freezer at -80°C.
d. Store U3 into Analysis box for analysis.

11. Storage of Specimens

Table 6: Long-Term Storage of Aliquots as per Given in the Table

	Boxes	**Content**
1	Box-[S1]	S1
2	Box-[S2]	S2
3	Box-[S3]	S3
4	Box-[S4]	S4 (Thyroid function)
5	Box-[EP1]	EP1
6	Box-[EP2]	EP2
7	Box-[Omics]	EP3
8	Box-BC	BC
9	Box-RNA	BC + RNA Later
10	Box-RBC	RBC
11	Box-FP	FP
12	Box-PP	30min-PP, 120min-PP
13	Box-[PP-S]	30min-[PP-S], 120min-[PP-S]
14	Box-FPC	FPC
15	Box-[U1]	U1
16	Box-[U2]	U2

12. LABELLING THE CRYOBOXES:

The lay-out of each cryo box should be prepared in an excel sheet indicating the number of vials stored with the sample ID and the amount of processed material in each vial. Example of lay-out of cryobox-S1-001 is shown below.

Example: Layout of Cryovials in Box-S1-001

	Box S1-001	
Position No.	**Sample no.**	**volume**
1	Participant ID	500
2	Participant ID	500
3	Participant ID	500
4	Participant ID	500
5	Participant ID	500
6	Participant ID	500
-		
81		