Centre Of Excellence-Centre for cArdiometabolic Risk Reduction in South Asia

COE-CARRS:COHORT-2 SURVEILLANCE STUDY

Manual of Procedures

[8th October 2014]

Public Health Foundation of India (PHFI); All India Institute of Medical Sciences (AIIMS); Madras Diabetes Research Foundation (MDRF) ; Aga Khan University (AKU)

Overview of the field manual

This manual is a part of the CARRS-SURVEILLANCE STUDY- Cohort II documents and is designed for the field staff who will be involved in household listing, participant recruitment and data collection. Apart from them the internal and external monitors / evaluators should also follow this manual during monitoring and process evaluation.

Structure

The manual is structured in the following manner –

There are thirteen chapters each starting with a short introduction, followed by learning objectives, description of the study tools specific to the chapter and ending with few points to remember.

Uses

- This manual is an operational guide for the CARRS-SURVEILLANCE STUDY- Cohort 2
- It includes description of all the study tools for CARRS-SURVEILLANCE STUDY- Cohort 2
- The manual describes the sampling methods of the study in details and should be used by site coordinators and project manager to select households and participants
- The manual describes the methods for assigning unique identifications codes
- The manual should be used for training of field staff
- This is a guide book for the monitors and evaluators
- It is intended to serve as an operational guide to anyone who is directly or indirectly involved with the CARRS-SURVEILLANCE STUDY- Cohort 2

Contents

List of Abbreviations

AIIMS	All India Institute of Medical Sciences
AKU	Aga Khan University
BC	Buffycoat
BMI	Body Mass Index
BP	Blood Pressure
COE-CARRS	Center of excellence- Center for Cardiometabolic Risk Reduction in South Asia
CEB	Census Enumeration Blocks
CFR	Code of Federal Regulation
CMD	Cardiometabolic Diseases
DEO	Data Entry Operator
DM	Diabetes Mellitus
DMC	Delhi Municipal Corporation
EP	EDTA Plasma
EQ-5D	European Quality of Life 5
FI	Filed Interviewer
FS	Field Supervisor
FPG	Fasting Plasma Glucose
GTT	Glucose Tolerance Test
HbA1c	Glycated Hemoglobin
HDL	High Density Lipoprotein
HH	Household
HHID	Household Identification Code
HINTS	Health Information National Trends Study
HRT	Hormone Replacement Therapy
ICF	Informed Consent Form
ICMR	Indian Council of Medical Research
ID	Identification Code
KAP	Knowledge, Attitude and Practices
LDL	Low Density Lipoprotein
LMP	Last Menstrual Period
MDRF	Madras Diabetes Research Foundation
ml	Mililitre
mm	Milimetre
MOP	Manual Of Procedures
NCD	Non Communicable Diseases
NHANES	National Health and Nutrition Examination Survey

NS	Not Straight
NDMC	New Delhi Municipal Corporation
OCP	Oral Contraceptive Pills
PHQ	Patient Health Questionnaire
P	Plasma (Fluoride Plasma)
PIS	Participant Information Sheet
PP	Post Prandial
PR	Permanent Resident
PHFI	Public Health Foundation of India
PI	Principal Investigators
PID	Participant Identification Code
PIS	Participant Information Sheet
PM	Project Manager
PVD	Peripheral Vascular Disease
QC	Quality Control
QME	Quality Monitoring and Evaluation
RBC	Red Blood Cells
RIQAS	Randox International Quality Assessment Scheme
RCC	Regional Coordinating Center
S	Serum (Processed serum)
SID	Sample ID
SM	Site Manager
SOP	Standard Operating Procedures
TG	Triglycerides
U	Urine samples (processed)
UC	Union Council
USA	United States of America
VLDL	Very Low Density Lipoprotein
WBC	White Blood Cell
WHO	World Health Organization
µl	Micro Liter

Chapter 1: Study Overview

Introduction

Centre for Cardiometabolic Risk Reduction in South Asia (CARRS) surveillance study is a hybrid cohort- modelled cross-sectional multicentre surveillance study for cardio-metabolic diseases (CMD) and its risk factors in three metropolitan cities in South Asia. This) is a collaborative effort between Public Health Foundation of India (PHFI), New Delhi (India); Emory University, Atlanta (USA); All India Institute of Medical Sciences (AIIMS), New Delhi (India); Aga Khan University, Karachi (Pakistan) and Madras Diabetes Research Foundation (MDRF), Chennai (India).

The study aims to develop a model surveillance system for Cardio-metabolic Diseases (CMD) and its risk factors which can be adopted for continuing surveillance by countries in South Asia. The secondary aim is to measure the incidence of CMD, morbidity and mortality associated with CMD and prevalence of risk factors for CMD among adults aged 20 years and above, permanently residing in well-defined urban communities.

The study consist of two cross-sectional representative population surveys four years apart [2010-11 and 2014-15] in Delhi, Chennai (India) and Karachi (Pakistan). Participants from both surveys are followed up as cohort. The cross sectional surveys measures in the trend and follow up surveys incidence of cardio-metabolic diseases and illness.

This document is the manual of procedures to be used in second cross-sectional survey (Cohort -2) of the CARRS Surveillance study.

It is designed for the field staff who will be involved in household listing, participant recruitment and data collection. Apart from them the internal and external monitors / evaluators should also follow this manual during monitoring and process evaluation.

Learning objectives

After completing this chapter the field staff will be able to

1. Understand the purpose and importance of this study
2. Identify the objectives of the study
3. Get an overview of the study organization
4. Get an overview of the study design and its operations

Objectives of the Study

Primary objectives

a) To implement and evaluate a model sentinel surveillance system in two study sites in India: Delhi and Chennai and one at Karachi, Pakistan

b) To assess the prevalence of CMD and their risk factors among adults aged 20 years and above, permanently residing in well-defined urban communities in the study sites

c) Ascertain factors that influence knowledge, attitudes and practices (KAP) of population on CMD and their risk factors

Secondary objectives

a) Determine the incidence of intermediate risk factors (such as hypertension, obesity and dyslipidemia in initially healthy individuals), and morbidity and mortality associated with CMD

b) To derive cost-effectiveness indices which can be used to model projected burden of CMD in order to execute effective and timely interventions

Study organization

Regional Coordinating Centers (RCC): **C**enter **o**f **E**xcellence – **C**enter for C**A**rdio-metabolic **R**isk **R**eduction in **S**outh Asia (**COE-CARRS**) at Public Health Foundation of India (PHFI), New Delhi, India

Study Centres: Delhi, Chennai & Karachi

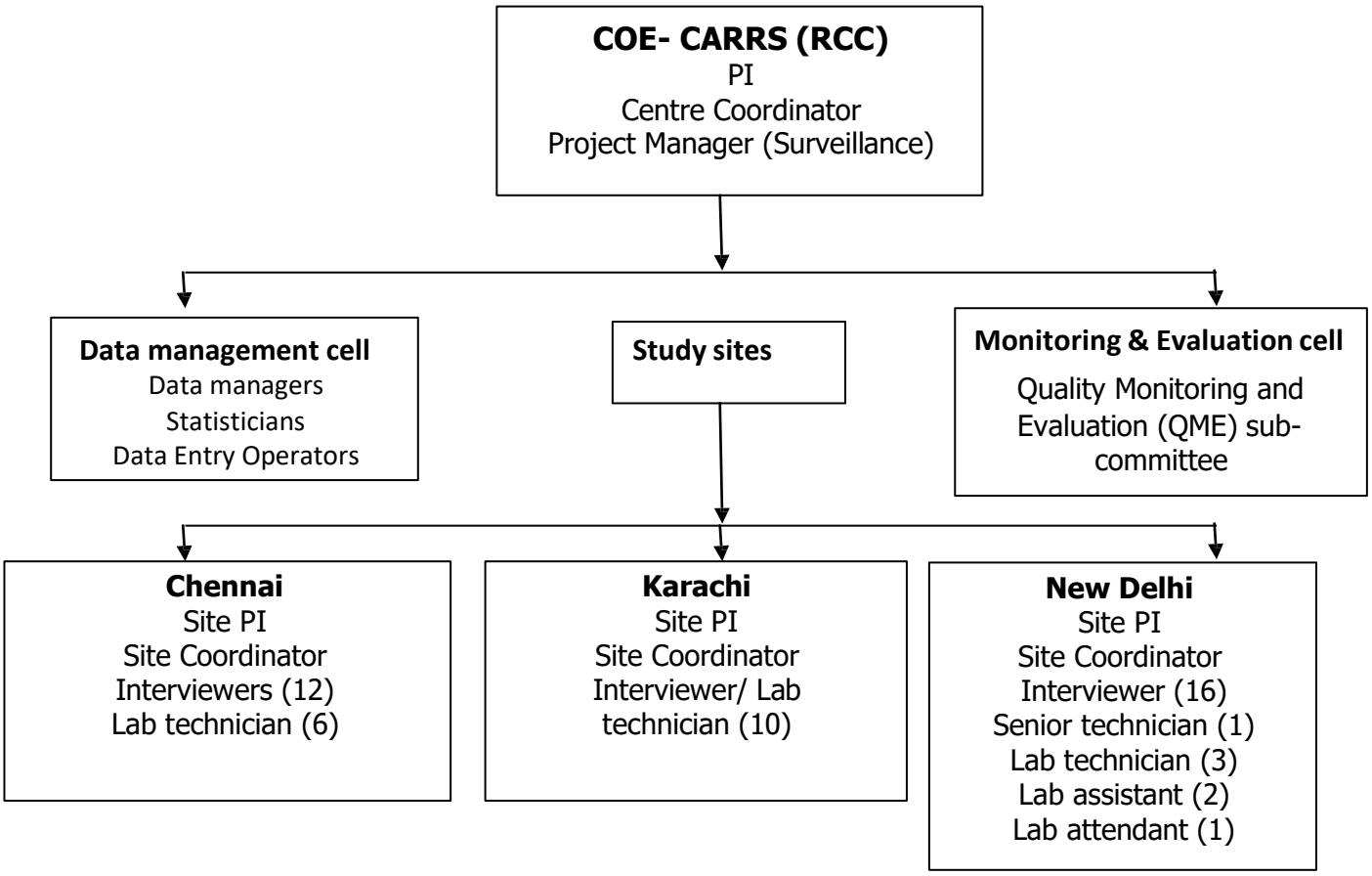
Principal Investigators: Prof. D. Prabhakaran (PHFI) and Prof. K. M. V. Narayan (Emory University)

Principal Investigators for study sites: Prof. D. Prabhakaran (New Delhi); Dr. Masood Kadir (Karachi); Dr. V. Mohan (Chennai)

Co – Investigators: Prof. K. S. Reddy (PHFI); Dr. Nikhil Tandon (AIIMS); Dr. M. K. Ali (Emory University); Dr. R. Guha Pradeepa (MDRF) and Dr. Syed Zafar Ahmed Fatmi (Aga Khan University).

Study Team: Each of the three study sites has a team who is involved in all phases of the study starting from study design to implementation, data collection, data entry, data processing, and monitoring and evaluation of the study to ensure quality control and smooth operation. In addition to this the regional coordinating center (RCC) at COE-CARRS (PHFI, New Delhi) will coordinate with the three study sites and is the focal point for the study. The final data processing, analysis and reporting will be done at the COE-CARRS.

Organogram of Study Organization



Overview of the study design and operations

While the primary study design for the surveillance model is cross- sectional, a cohort study design will be used to follow-up the participants The cross-sectional study will assess the prevalence of CMD and their risk factors while the pilot cohort study will estimate the incidence of morbidity and mortality associated with CMD.

Cross-sectional Study (2014-2015): This is the primary study and will be conducted over a period of twelve months. This will also form the baseline for the cohort study conducted in the subsequent years.

The study will be implemented through questionnaires and instruments for anthropometry, and bio-chemical measurements and will comprise of three visits to each participant (Visit-1, Intermediate visit and Visit-2).

During Visit-1, details of the household selected through a random method will be collected and the selected individuals will be informed about the study. Consenting individuals will be enrolled as participants and interviewed for demographic and social characteristics, risk factors for CMD, reproductive history (females only), quality of life, medical history, health service utilization and expenditures. Apart from these body circumferences, blood pressure, pulse rate will be measured.

During Intermediate visit, the participants will be informed about the camp. They will be provided with the information sheet and container for collecting urine. Also, they will be informed verbally as well and all their queries will be answered.

During Visit-2, height and body composition measurements using bio-impedence will be taken and samples of blood and urine will be collected in a local camp/clinic (participant's house- Karachi).

Cohort Follow-up- Participants enrolled into the cross- sectional study who provide consent will be followed every year as part of a cohort to measure the outcomes of interest (incidence of CMD, incidence of intermediate risk factors such as hypertension, diabetes and dyslipidemia, incidence of mortality and morbidity associated with CMD and anthropometric changes – Body Mass Index (BMI), body fat percentage, etc.).

Points to remember

1) CARRS-SURVEILLANCE STUDY is a cohort modelled surveillance study
2) It will be conducted over a period of two years
3) Goal is to establish a model surveillance system for CMD which can be operational in South Asia
4) Objective of the study is to estimate the prevalence and incidence of CMD and their risk factors

Chapter 2: Study Methodology

Introduction

A multi-stage cluster random sampling technique will be used to capture a sample representative of the urban population at the three sites. Each of the cities has its own distinctive municipal sub-divisions, encompassing municipal corporations, wards and Census Enumeration Blocks (CEB) from which households will be randomly selected. Ward/Union Council will be the primary sampling unit for Chennai, Delhi and Karachi. Site specific sampling methods are given below.

Learning objectives

After completing this chapter the field staff will be able to

1) Understand the sampling scheme for each study site – Chennai, Delhi and Karachi.

2) Understand how to capture a sample representative of the urban population in the study sites using a multi-stage cluster random sampling technique in 4 stages.

Sampling scheme

Delhi

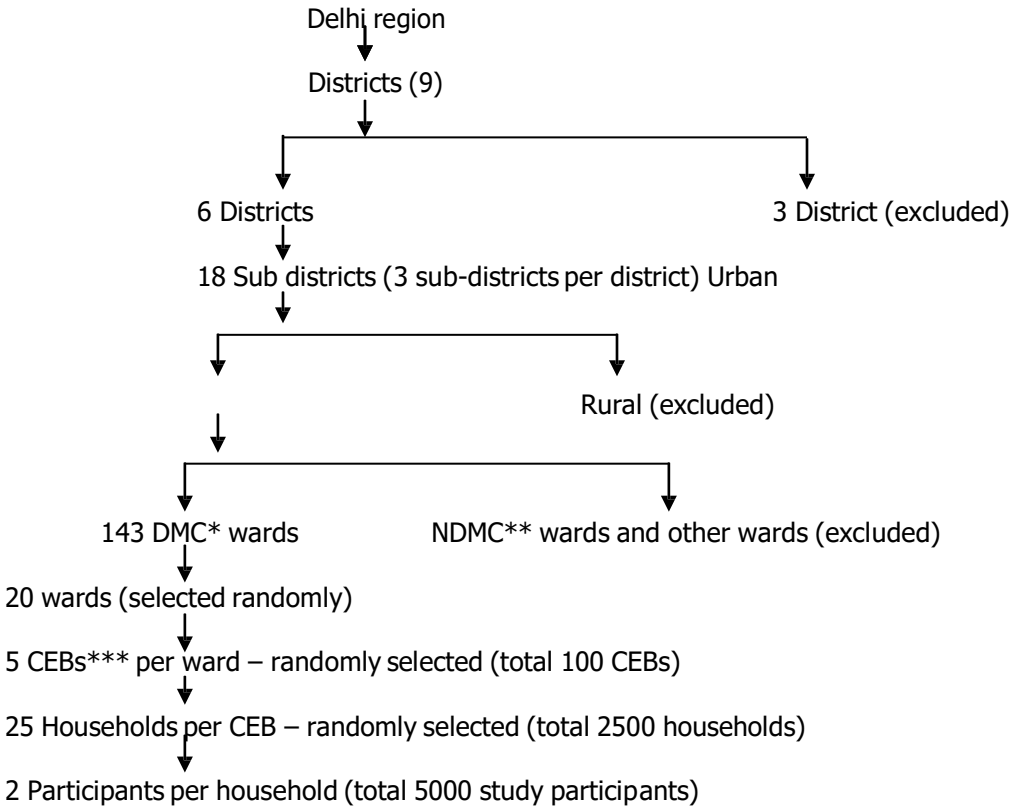
Delhi is divided into 9 districts. Each district in Delhi is divided into 3 sub-divisions (except for New Delhi). Each sub-division is further sub-divided into urban and rural areas. Rural areas will not be included in this study. The urban areas (towns) are further sub-divided into wards of varying sizes. Wards comprise of census enumeration blocks (CEB).

Districts in Delhi Region

For the Delhi site, random selection at the sub-district level was not done to avoid a sample of sub-districts unrepresentative of the Delhi region. Instead 20 wards were randomly selected from the 18 sub districts falling into 6 districts in Delhi. From each of these 20 wards, 5 CEBs were selected at random giving a total of 100 CEBs. Maps of all selected CEBs from Delhi were obtained from the Directorate of Census Operations, Delhi and were used for household listing. From each CEB, 20 households will be selected giving a total of 2500 households in the region of Delhi. Further 2 participants from each household will give us the required sample of 5000 participants.

For the purposes of this study, we have excluded 3 districts; namely New Delhi, North and South West. The first two are predominantly commercial establishments whereas South West Delhi's Cantonment area includes defence personnel who may be transferred elsewhere and Vasant Vihar is inhabited by expatriates who may leave the country during our study period.

Delhi sampling scheme



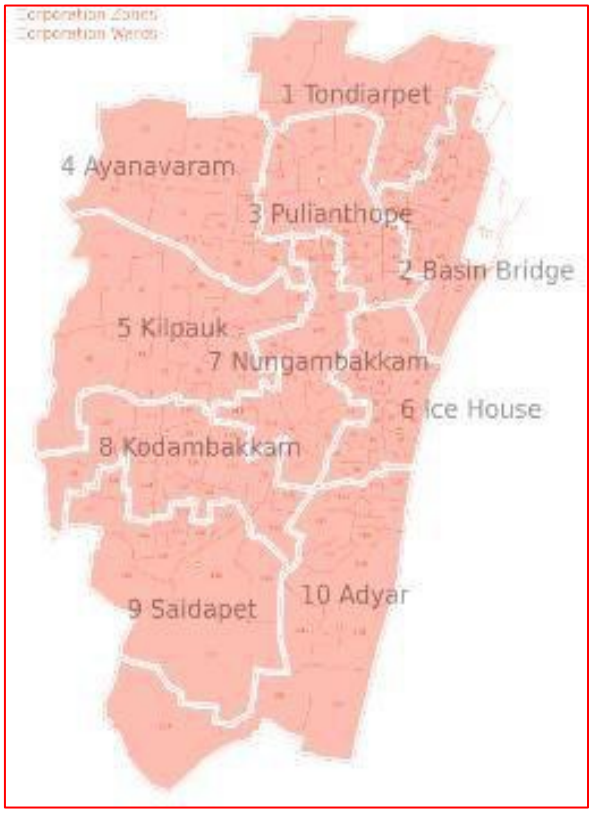
*Delhi Municipal Corporation; **New-Delhi Municipal Corporation, ***Census Enumeration Blocks

Chennai

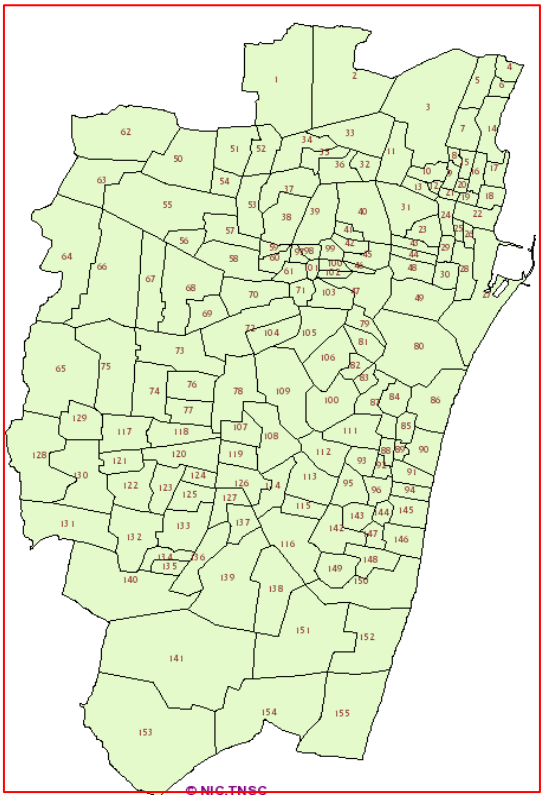
Chennai is divided into 10 Zones and 155 wards by the Chennai Corporation. Each ward comprises of CEBs.

From the list of wards, 20 were randomly selected to represent the 10 zones of Chennai. From each of these 20 wards, 5 CEBs were selected at random giving a total of 100 CEBs. From each CEB, 25 households will be selected leading to a total of 2500 households. Two participants from each of the 2500 households will provide the required sample of 5000 participants.

Zones of Chennai City



Wards of Chennai City



Chennai sampling scheme

Chennai Municipal Corporation

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155 Corporation wards

↓

20 wards (randomly selected)

↓

5 census blocks per ward -randomly selected (total of 100 CEBs)

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25 Households per CEB randomly selected (total 2500 households)

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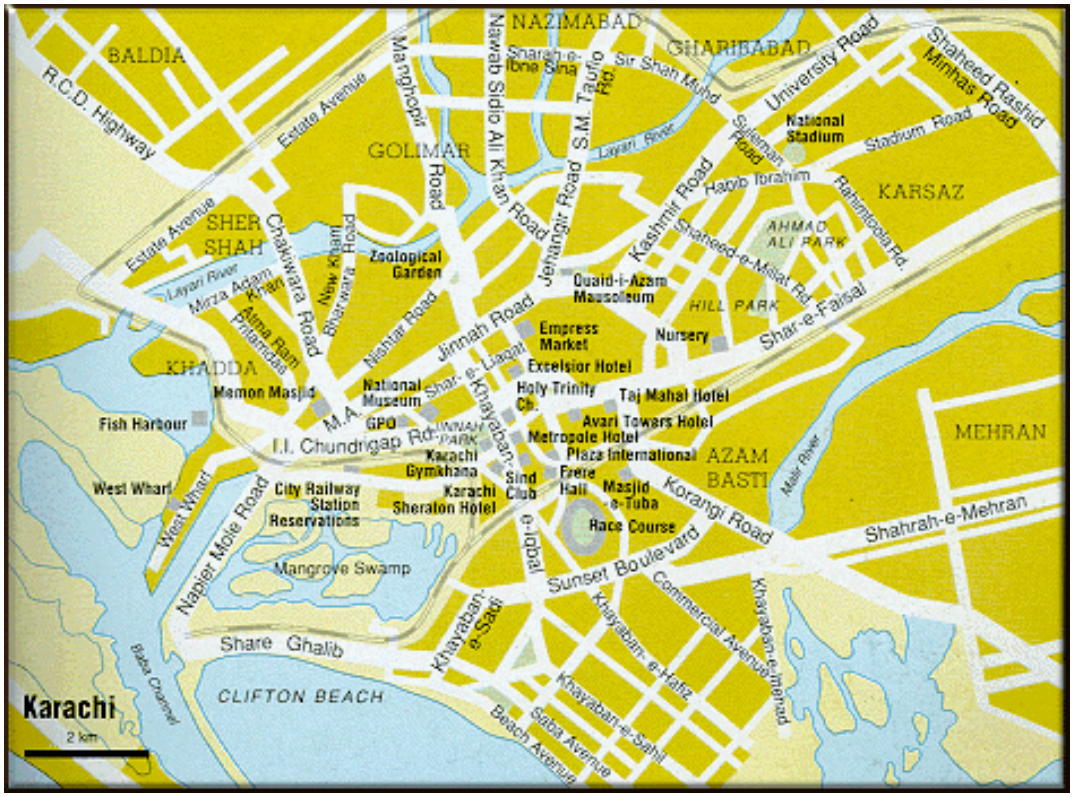
2 Participants per household (total 5000 study participants)

Karachi



Karachi sampling scheme

City District Government of Karachi

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18 towns

↓

178 union councils

↓

7500 Clusters / Census blocks (250 household per cluster)

↓

80 random clusters

↓

32 Households per cluster – randomly selected (total 2500 households)

↓

2 Participants per household (total 5000 study participants)

Multistage Cluster Random Sampling

To capture a sample representative of the urban population in the three study sites a multi-stage cluster random sampling technique will be adopted in 4 stages.

Stage-1: Selection of Wards/clusters	▪ 20 wards were randomly selected for each study centre from a total of 143 wards for Delhi; and 155 wards for Chennai; in Karachi the survey will be done in same 80 clusters of Cohort-1.
Stage-2: Selection of CEBs (For Delhi & Chennai)	▪ On an average each ward comprises of 120 CEBs. ▪ 5 CEBs were selected at random from each of the 20 randomly selected wards to get a total of 100 CEBs at each site (300 for all sites) ▪ CEBs which are occupied predominantly by Jhuggi Jhophri clusters and commercial establishments were excluded from this pool. ▪ Selection of wards and CEBs was done at COE-CARRS and a list has been provided to the study sites. ▪ Subsequent process of selection of households will be done at the respective sites from the ward-wise list of CEBs.
Stage-3: Selection of Households (For Delhi & Chennai)	▪ Each CEB or cluster on an average consists of 100-150 households (HH). ▪ A house to house survey will be conducted to get the list of all HH in randomly selected CEBs. ▪ Mapping of all HHs and important landmarks will be done for each selected CEB. ▪ From this list a random sample of 25 HH would be selected for each CEB. This will give a total of 2500 HH for each site. In Karachi 32 household will be selected after excluding the HHs participating in Cohort-1.
Stage-4: Selection of Participant within Households	▪ The average family size of each HH is approximately 5 ▪ We will be selecting 2 eligible participants (one male and one female) from each HH. ▪ "Kish method" used in the WHOs STEPwise surveillance will be adopted.

The final sample for the study will be composed of equal proportions of males and females who have provided consent to participate in the study (both cross- sectional and three years of follow-up) leading to a sample of 5000 participants in Delhi and Chennai and 4000 in Karachi.

Central random sampling

For Delhi and Chennai: List of wards and CEBs for Delhi and Chennai were reviewed from Census Data dissemination centres. 20 wards and 100 CEBs were selected and coded and sent to the sites. This list will be used by the sites for enlisting and mapping of HHs and to finally select the required number of HHs.

Secondary list of 2 CEBs/ward for replacement in case of need i.e. high refusal, ineligible CEBs (commercial), security threat etc.

Points to remember

1) Wards / union councils (UCs) are the primary sampling units
2) 20 wards / UCs were selected randomly from the districts
3) 5 CEBs were selected from each ward / UC
4) 25 households (32 for Karachi) per CEB will give a total of 2500 HH per site
5) Average 2 participants (1 male and 1 female) will be selected from each HH using within HH sampling methods

Chapter 3: Coding procedures for the Surveillance Study

Introduction

A common coding procedure will be followed by all the participating sites. Unique identification codes (ID) will be assigned to the study sites, sub districts/Zones/Towns, Wards, Census enumeration Blocks (CEBs). All these codes combined will constitute the cluster ID. Households will be assigned household ID. ID numbers will also be assigned to the interviewers and laboratory technician who will be involved in collection of data. After the participant signs the informed consent and is formally included in the survey, s/he will be assigned a unique participant ID.

Learning objectives

After completing this chapter the field staff will be able to

1) Understand the procedure for assigning unique identification codes: interviewer ID, Household ID and Participant ID

2) Able to assign the unique identification codes

Description of the Codes

The table in the next page provides further instruction for assigning these ID numbers: Coding procedures for the study.

Type of ID	Description	Value Range
Staff ID	Every interviewer should be assigned a unique ID number. 1) 1st digit will be the city code. Chennai (Code:1) and Delhi (Code:2) and Karachi (Code:3) 2) 2nd digit will be the code for staff involved in the process of data collection. Field Interviewer (Code:1), laboratory technician (Code: 2), field supervisor (Code: 3) 3) 3rd and 4th digit will be the serial number for the Interviewers, laboratory technicians and field supervisor (range 01-99)	4 digits 1 2 3 4 **1** Site **2** Staff **3-4** Interviewer code (Serial number)
Household ID (HHID)	All households in a CEB will be assigned a unique ID following their random selection. This will be a 6 digit number. 1) 1st, digit will be city code 2) 2nd, 3rd and 4th digits will be the CEB code (201, 202, ...300) 3) 5th and 6th digit will be the serial number of the household selected in each CEB (01, 02, ……., 25)	6 digits 1 2 3 4 5 6 **1** City code **2-4** CEB code **5-6** Household selected (Serial number)

Type of ID	Description	Value Range
Participant ID (PID)	All participants should be assigned a unique ID. 1) 1st digit will be the city code mentioned above 2) 2nd to 6th digit will be the serial number of enrolment of the participant and should start from 0001	6 digits 1 2 3 4 5 6 **1** City code **2-6** Enrolment of participant (Serial number)

Assigning Codes Centrally

District code: Delhi the code will range from **1 – 9**
District code: Karachi and Chennai the code will be **"0"**
Sub-District code: Delhi the code will range from **01-18**

Sub-District / Zone code: Chennai the code will range from **01-10**

Sub-District / Towns code: Karachi the code will range from **01-15**
CEBs / clusters code: All sites the code will range from **201 – 400**
Ward code (For Delhi & Chennai) will range from **21-40**

The list of wards from each study site will be sent to COE-CARRS (PHFI) where the wards will be coded and random selection will be done. The list of wards randomly selected will be sent back to the respective sites that will be responsible for obtaining the list of CEBs from the Census data. The ward-wise CEB lists will be once again sent to COE-CARRS where random selection of 5 CEBs per ward will be done. Coding of CEB will be done centrally at COE- CARRS. The code list for each study site is included in Annexure-1.

Points to remember

1) Unique identifying (ID) codes should be assigned to all clusters, households and participants
2) Field staff will be assigned ID codes
3) Correct IDs should be written in all forms
4) Field staff will assign only the participant ID, rest will be assigned at the regional coordinating centre and sent to the respective sites for maintaining uniformity

Chapter 4: Household Selection

Introduction

A total of 25 households are planned to be surveyed in each Census Enumeration Block (CEB). To give each household an equal chance for being selected for the study, listing of households (HHs) in each CEB is a prerequisite before randomly selecting the HHs for the survey.

A household is defined as **"a group of people who live together, usually pool their income and eat at least one meal together a day when they are at home. This doesn't include people who've migrated permanently or are considered visitors"**

Learning objectives

After completing this chapter the field staff will be able to

1) List all households of the selected CEBs
2) Fill the household listing form (Form-2)
3) Map all structures / constructions in a CEB

Enlisting Households and Mapping

The first step in the field survey will be to enlist the households in all selected CEBs in each study site (except Karachi) along with mapping. The objective is to enumerate and identify all constructions / structures and HHs, especially the newly constructed households that have come up after the last census survey. This list will then be used to randomly select 25 households from each CEB to have a total of 2500 households in each study site. Basic maps of CEBs will be provided to the field team. In case of major changes in the CEB, they need to make a new map. Finally the selected HHs will be marked on the same map to understand the geographical distribution of the HHs in the study sites.

Listing of Households

Once the pool of CEBs has been decided and the list sent to the study site, the order in which the CEBs are selected for the survey is up to the site project manager. After choosing a particular CEB, at least 2-3 field staff is expected to list all constructions (residential, medical facility and other) / structures in the CEBs, list the number of floors in each structure and number of HHs in each floor using the "Household Listing Form", Form-1 (Annexure-2). With the help of local residents and the details given in the census data an approximate boundary for each CEB will be demarcated so that there is no overlap with other CEBs during selection of HH. The field staff will have to list all structures in each CEB, all floors in each structure and all HHs in each floor.

Once the list has been prepared by the field staff, all information will be entered in an excel sheet so that a comprehensive list of HHs is available. The serial number of the HH will be in the same order in which they were recorded in the HH listing form. The study statistician will select 25 HH from this list using computer generated random numbers. The number of HHs selected will be fixed (25 HH per CEB) irrespective of the size of the CEB. This will be the "Primary HH list". A second list, "Supplementary HH list" will contain 25 more randomly selected HHs which should be used in case if (i) there is problem in identifying the HHs listed in the "Primary HH list", (ii) field staff is unable to contact an adult member of the HH even after three attempts, (iii) in case of refusal (after three attempts). Both lists of selected households will be handed over to the field team to start the visits.

Frequently Asked Questions

What is a **Designated area:**

A designated area is a geographical area allotted to a single team for survey and household listing.

What is a **Structure?**

A structure is a building, room or any dwelling unit (jhuggi- jhopri, hut) whether residential or commercial (shop, office, hospital, clinic, nursing home) or other (administrative, recreational, religious, abandoned or damaged)

What is a **Household?**

A household consists of a person or a group of related or unrelated persons, who live together in the same dwelling unit, who acknowledge one adult male or female as the head of the household, who share the same housekeeping arrangements, and who are considered to constitute one unit. In some cases one may find a group of people living together in the same house, but each person has separate eating arrangements; they should be counted as separate one-person households. Collective living arrangements (e.g., army camps, boarding schools, or prisons) will not be considered as households.

Examples of households are:

A man with his wife or his wives with or without children

A man with his wife or his wives, his children, and his parents

A man with his wife or his wives and his married children living together for some social or economic reasons (e.g., the group recognizes one person as the household head)

An unmarried man or woman with his or her children who provides their living essentials and foods

A widowed or divorced man or woman with or without children

On the map provided below, mark each structure using the serial number assigned to the household in the first column of the table (HH listing).

Sample map

Random selection of households

Once field listing of households is complete, CEB-wise data will be entered in excel workbook. The title of each of this list should have the ward number, CEB name and number. The columns will be the same as the format (Form-1). From this excel list only the residences will be selected by filtering the residence column. This will be the final household (HH) list from where 50 HHs will be selected randomly using STATA. The first 25 HHs will be included in the "primary HH list" and the remaining 25 in the "secondary HH list". Two columns should be added at the end of each list, "Recruited" (Status of recruitment of the HH) and a comment section. In the "Recruited" column, the field interviewers will enter "1" or "2" depending on whether the HH has been included in the study or not. In the comment section the interviewer can write the reason for refusal, phone numbers or any other information. Example is shown in the next page.

PRIMARY LIST									
S No	HHID	Address	Floor no	Name of head of hh	Interviewer ID	Visit 1 Recruited (Yes=1 No=2)	Visit 2 Recruited (Yes=1 No=2)	Visit 3 Recruited (Yes=1 No=2)	Comments
1	06401	CN 1473	GF to 3rd	Babu Ali					
2	06402	CN 1438	GF to 1st	Moh. Yusuf					
3	06403	CN 1477	2nd	Beg					
4	06404	CN 1422	GF	Motti Ullah					
5	06405	CN 1456-57	GF to 1st	Sultan Mahmood					
6	06406	CN 1459-60	3rd	Abdul Gafoor					
7	06407	CN 1429	GF to 1st	Naseem Begam					
8	06408	CN 1458	3rd	Asad Absari					
9	06409	CN 1439-1440	2nd	Tausit					
10	06410	CN 1415	1st	Door Locked					
11	06411	CN 1472	GF to 2nd	Hazi Shamsuddin					
12	06412	CN 1437	GF	Molana Rabbali					
13	06413	CN 1420	GF to 1st	Noor Aalam					
14	06414	CN 1413	GF	Mh. Hasan					
15	06415	CN 1430	Gf to 1st	Basir Ahmad					
16	06416	CN 1451	2nd	Md Ahmad					
17	06417	CN 1470	GF to 2nd	Door Locked					
18	06418	CN 1492	1st	Heena					
19	06419	CN 1492	3rd	Sardar Bhai					
20	06420	CN 1429	2nd	Naruddin					
SECONDARY LIST									
S No	HHID	Address	Floor no	Name of head of HH	Interviewer ID	Visit 1 Recruited (Yes=1 No=2)	Visit 2 Recruited (Yes=1 No=2)	Visit 3 Recruited (Yes=1 No=2)	Comments
21	06421	CN 1445	1st	Shabnam					
22	06422	CN 1446	1st	Samir Khan					
23	06423	CN 1422	1st	Mh. Ashraf					
24	06424	CN 1458	2nd	Tarikh Siddiqi					
25	06425	CN 1413	1st	Humayu Akbar					
26	06426	CN 1409	2nd	Door Locked					
27	06427	CN 1453	2nd	Wazid Ali					
28	06428	CN 1462	4th	Subudh Nadeem					
29	06429	CN 1466	GF	Higar Sultana					
30	06430	CN 1462	3rd	Bilal Ahmad					
31	06431	CN 1435	2nd to 3rd	Abrar					
32	06432	CN 1478	GF	Imran Khan					
33	06433	CN 1446	GF	Neyaz Ahmad					
34	06434	CN 1436	GF to 2nd	Musarai Jahan					
35	06435	CN 1451	GF	Door Locked					
36	06436	CN 1444	Gf to 1st	Ashraf Rizivi					
37	06437	CN 1458	2nd	Shakib					
38	06438	CN 1459-60	GF	Shajav Ahmad					
39	06439	CN 1485	GF to 1st	Md Tarik					
40	06440	CN 1483	GF to 1st	Syed Ahmad onzzaim					

Role and responsibilities of Field interviewers during HH listing

1) Inform the local administration and leaders about the household listing operation and request for their cooperation
2) Identify the boundaries of the designated area.
3) Draw a sketch map of the area showing boundaries of the designated area with all the structures; residential, non-residential, abandoned or damaged.
4) Systematic listing of all the structures/ households.

The household listing will be conducted by two FIs in each designated area. The two FIs will identify the boundaries of the designated area.

The two FIs in each team should work at the same time in the same area. They identify the cluster boundaries together, and then one FI prepares the location and sketch map, while the other does the household listing. The sketch map and the household listing form must be prepared in tandem. During household listing each worker will carry the following;

1) Rough map of the designated area
2) Household listing forms
3) Markers for numbering of structures.

To avoid duplications or omissions of the households, the FIs should be careful and move in a systematic manner. Within each block or street in the designated area, FI will start from one corner and move clockwise.

Drawing map of the designated area

One of the team members will act as a mapper and draw the map of the designated area.

Mapper will locate and highlight the designated area including the instruction to reach to the area. The mapper will draw all the structures in the designated area. The structure number should correspond to the structure number given in the household listing form.

Mark the starting point of the map with **large X** and draw a small square representing each structure in the designated area. For non- residential structure identify the type of structure (shop, office, temple etc).

Numbering of the structure should begin with '1' and move forward in the sequence. Show arrow in the map to indicate the break in the number (moving from one set of structures to another. Add all the landmarks (park, public buildings, temple, streets, roads, canals etc) present in the designated area as they are helpful in identifying other structures in the area.

Use the marker or chalk provided to write the assigned structure number (from the household listing form) on the entrance. Write 'CARRS' in front of the number to distinguish it from the other numbers eg CARRS- 32.

Listing the Households

The lister will fill in the household listing form (Form- 1)

Study Site :								
Sub-district/Zone/ Town:								
Ward number :								
CEB name :								
CEB number								
Total number of structures								
Interviewer ID :								
List if Dwellings: List all structures/constructions, provide a detailed address, mention the floor number (G,1,2,3,4), write whether the floor has residences, list the HHs(Households) in the floor if it has residences, write the name of the head of HH (wherever possible) followed by comments if any.								
S. No of Structure	Address/Location/ Description structure	Floor No	Residence Yes/No	S No Of HH in the floor	Name of head of HH	How long have been staying		Comments
						Year	Month	
001	C1/52; Safdarjung development area	G	Y	1	Mr Ramdas	4	0	No floors
			Y	2	Mr Ajay	5	0	
			Y	3	Mr Kaushik	4	6	
002	C1/53; Safdarjung development area	G	Y	1	Mr Roy	3	0	No floors
				2	Mr Raj	11	0	
				3	Mrs Singh	10	0	

After filling the date, interviewer's ID, lister will fill up the information about study site, subdistrict/ zone/ town, ward, CEB number and name before starting the listing on the field.

Complete the rest of the form as follows:

1) **Column (1)** [Serial Number of Structure]: For each structure, record the same serial number that the mapper enters on the sketch map.
2) **Column (2)** [Address/location/Description]: Record the address of the structure. Where structures do not have visible street addresses (e.g., often in rural areas), give a description of the structure and any details that help in locating it (e.g., in front of the school or next to the store).
3) **Column (3)** [Floor No]: If the structure has more than one floor then designate number to floors from `ground floor`, first floor and so on.
4) **Column (4)** [Residential Y/N]: Indicate whether the structure is used for residential purposes (e.g., eating and sleeping) by writing Y for "Yes." In cases where a structure is used for commercial or other purposes, write N for "No." Structures used both for residential and commercial purposes (e.g., a combination of a store and a home) should be classified as residential (i.e., mark Y in Column 3). Make sure to list any household unit found in a non-residential structure (e.g., a guard living inside a factory or in a house).
5) **Column (5)** [Serial Number of Household in Structure]: This is the serial number assigned to each household found in the structure; there can be more than one household in a structure. The first household in the structure will always have number "1." If there is a second household in the structure, then this household should be recorded on the next line (a "2" is recorded in Column (5), and Columns (1) to (4) are left blank).
6) **Column (6)** [Name of Head of Household]: Write the name of the head of the household. There can only be one head per household. If no one is home, ask neighbours for the name of the head of the household. If a name cannot be determined, leave this column blank. Note that it is not the name of the landlord or owner of the structure that is needed, but the name of the head of the household that lives there. (Annexure-2)
7) **Column (7)** [Duration of stay]: In this column, the FI need to write the duration of their stay in that HH.
8) **Column (8)** [Comments]: This space is provided for any special remarks that might help the interviewing team locate the structure or identify the household during the main survey fieldwork.

If the structure is an apartment building, assign one serial number to the entire structure (e.g., only one square with one number appears on the sketch map), but complete Columns (2) through (7) for

each apartment in the building individually. Each apartment should have its own address, which is the apartment number.

The listing team should be careful to locate hidden structures. In some areas, structures have been built so haphazardly that they can easily be missed. If there is a pathway leading from the listed structure, check to see if the pathway goes to another structure. People living in the area may help in identifying the hidden structures.

Quality Control

Training: All FIs will be trained for house- listing. They will also be provided with the field training for actual mapping and household listing.

A regular data quality monitoring system will be implemented to ensure that the information collected by the field staff is correct. The field supervisor (FS) will daily supervise and monitor the FIs working in household listing data collection and check for the completion of the forms. He will also randomly check some of the houses. Field supervisor will carry with him the following things during **field supervision:**

1) Map of the areas
2) Household listing forms
3) List of FIs teams and their designated areas
4) Markers

The information for daily HH listing will be given by the FS to the person assigned by the study coordinator.

Job responsibilities of supervisory team during house listing

Team members:

1) Field Supervisor (FS)
2) Research Associate (RA)
3) Project Coordinator (PO)

Job responsibility:

Field Supervisor

a) Daily distribution of work and other logistic supply to FIs.

b) Daily supervision of the FIs while they are in the field in the morning.

c) Checking of forms for completeness and correctness.

d) If found incomplete and/or incorrect, review the forms then and there with the FIs.

e) Reporting to PO/ person assigned by the PO regarding the supervision.

f) Discuss the issues arising during house listing

g) Interacting with community leaders and other key stakeholders to solicit support for house listing.

h) Maintain the attendance of all FIs and review their work diary.

i) Providing constant motivation and support to the FIs.

Research Assistant:

a) Field monitoring.

b) Train and solve the problems of field interviewers.

c) Monitor the data entry of house listing forms on regular basis.

d) Review the performance of field interviewers along with Project Coordinator and suggest measures to improve performance.

e) Provide training to the field interviewers.

Points to remember

1) List all structures / constructions in the selected CEBs
2) Write the detailed address for each structure
3) List the number of floors in each structure
4) Mention whether the floor has residences (Y/N)
5) If it is a floor with residence – list all HHs in the floor
6) Write the name of the HH head (if possible to contact any HH member)
7) Write the duration of the stay of the family living in the particular HH.
8) Write in the comment section if you notice something different eg. Bachelor living in a house, demolished place, person living alone in a house etc.
9) Primary and Secondary Household lists each with 25 HHs should be prepared and the selected HHs should be assigned HH IDs
10) The same HH ID allocated for the selected HHs should be entered in the interview forms / questionnaire.

Chapter 5: Approaching households

Introduction

Once the randomly selected list of households (HHs) is provided by the project manager to the field team the next step would be to approach the HHs. The team should have the lists of the selected household with detailed addresses and the "household proforma" and copies of "Notification of the surveillance study".

The "Household Proforma" Form-2 (Annexure - 3) will be used to gather information on the dwelling type (temporary / permanent), HH size, number of eligible participants living in the house, selection of participants using the Kish table, documenting number of attempts and refusals and to verify the postal address of the HH.

Learning objectives

After completing this chapter the field staff will be able to

1) Approach the households in an appropriate manner
2) Plan their activities and make pre-visit preparations
3) Handle refusals at the household level

Approaching the Households

The field staff is required to carry their photo identity cards, prominently displayed. Before approaching the household, information about the dwelling type should be recorded. If it is a Jhuggi (temporary dwelling) then document this in Form-2 and do not make further attempts to contact the HH. This HH is dropped, therefore take the first HH from the "Supplementary HH list" instead and fill Form-2.

If it is a Pucca house (concrete permanent dwelling) then the household should be approached by knocking on the door or ringing the doorbell. Do not attempt to enter

the HH just because the door is left open. And do not simply walk away by thinking that no one is at home if the door is closed.

If	Then
Someone is at home	Speak to the first adult you encounter in the household.
Nobody answers the door	Look around the side of the house to see if someone is nearby.
Nobody is at home	Leave a notification of the surveillance study- Form-A (Annexure-4) and record the attempt in Form-2.
Household members are not available at the time of the first visit	Make at least 3 different visits to be able to recruit the HH members. Choose alternate timings and if required consult the neighbours.

Handling Refusals at Household Level

The field staff should be prepared for varying kinds of responses from the community.

1) If the household member refuses to open the door due to security reasons, do not give up at the first attempt; leave the "Surveillance Notification Form", Form-A (Annexure-4) at their door step and revisit the household at a different time.
2) If the household member gives you the details of the "HH Performa" but requests you not to bother them anymore, politely leave the **"Participant Information Sheet"**, Form-B (Annexure-5) and request them to contact you if they change their mind.
3) If the informant is a minor, enquire which would be the best time to come back to meet an adult member of the HH and leave the "Surveillance Notification Form" with him/her.
4) If the informant is a housekeeper/servant, enquire which would be the best time to come back and meet a member of the HH and leave the "Surveillance Notification Form" with him/her.

Instructions

You are allowed to discard the household only after 3 unsuccessful attempts. But if the refusal was very hostile (refer to the codes for strength of refusal on the Non-Interview Report Form), do not go back to the household after the first attempt

Note: All refusals need to be documented in the "non-Interview report form", Form- 3 (household refusal) (Annexure-6) or 4 (individual refusal) (Annexure-7).

Points to remember

1) Approach the households in a cordial manner
2) Respect the privacy of people, do not enter the HH without permission
3) Inform about the study and share the "Surveillance Notification Form"
4) Complete Form-2 (Household Proforma) and provide the participant information sheet and consent form to selected participants
5) Document all the attempts in Form-2 and refusal in Form-3 or 4

Annexure

Forms

1) Household Proforma (Form-2)- Annexure -3
2) Surveillance Notification form (Form-A)- Annexure -4
3) Non-Interview report form (Form-3 & 4)- Annexure -6 & 7

Instructions for filling the Household Proforma [Form-2]

A list of randomly selected households per CEB for each ward will be provided to the Field Interviewer (FI).

1) Date – The day, month and year of the household visit should be entered
2) Household ID- Enter the six digit HHID
3) Interviewer ID - Enter the four digit unique interviewer ID
4) Dwelling type – The FI should observe the household which s/he is visiting from outside and record the following –
    a) Is the house Kutcha?
    Definition of a **"Kutcha house"** – A temporary dwelling whose roof, floor and walls are all made of make shift materials (polythene, thatch, bamboo, mud, other materials that are not concrete).
    If the answer to the above question is "yes" then answer question b to d
    b) Is the Roof made of Plastic/Polythene/thatch/Bamboo/Mud?
    If the roof is made of any of these materials answer the question as yes (use code 1)
    c) Is the Wall made of Plastic/Polythene/thatch/Bamboo/Mud?
    If the wall is made of any of these materials answer the question as yes (use code 1)
    d) If the floor made of mud?
    Observe the house and answer the question

Frequently Asked Questions

What is a permanent dwelling or pucca house?

A pucca house is one, which has walls and roof made of the following material.Wall material: Burnt bricks, stones (packed with lime or cement), cement concrete, timber, ekra etc. Roof Material: Tiles, GCI (Galvanized Corrugated Iron) sheets, asbestos cement sheet, RBC, (Reinforced Brick Concrete), RCC (Reinforced Cement Concrete) and timber etc.

What is a temporary dwelling or kutcha house?

A house is treated as a temporary dwelling or a **kutcha house** if the walls and roof of which are made of material other than those mentioned above, such as un-burnt bricks, bamboos, mud, grass, reeds, thatch, polythene, plastic and loosely packed stones etc and the floor of mud.

What is a semi pucca house?

A house that has fixed walls made up of pucca material but roof is made up of the material other than those used for pucca house.

If the answers for all questions from "**a**" **to** "**d**" are **"Yes"** then **do not approach the HH,** go the next HH in the "Primary List". Use a new form and repeat the process.

After completing visits to all HHs in the "Primary List" go to the HHs in the "Secondary List" to complete the recruitment of 25 HHs.

Example:

If there is a group of labours staying at one place (in kutcha house) due to some on-going construction work and in few months they will move to someplace else. These would be counted as a temporary dwelling. We would not take those houses in our HH listing and if by chance this kind of houses got included in the HH listing and got selected then we would not include those household in the study.

When to reject a household or not to approach the household?

If the house is a kutcha house and all the three parts of the house i.e. the roof, wall made of shift materials (polythene, thatch, bamboo, mud, other materials that are not concrete) and the floor of mud.

Instructions for filling the Household Proforma [Form-2]- Contd..

1. Name of the informant

   Write the name of the household member who volunteers to answer the questions.

2. Name of the HH head

   Ask the informant if s/he is the head of the HH. If not, then request the informant to provide the name of the HH head.

Who is a **head of the Household?**

The head of household is the person who is acknowledged as such by members of the household and who is usually responsible for the upkeep and maintenance of the household.

3. Relationship with HH head

   Politely ask the informant about her/his relationship with the HH head.

4. Postal address

   Note the full postal address along with CN number, important landmark and PIN code.

5. For how long have you been staying in the current residence?

   Ask the above question only to a permanent resident of the HH. If the informant is not the permanent resident of the house, then request her/him to introduce you to a permanent resident of the HH.

Definition of permanent resident

"For the purpose of this study a permanent resident is one who lives in this household, is related to the household head and eats at least **3 meals in a week with the family."**

6. Are you planning to move out to a new house in the next one year?

   Ask this question only to a permanent resident of the HH.

7. List of all HH members

7. List of all household members (Sex: Males=M, Females=F; Age in completed years)										
S No	Name	Age (Years)	Sex (M/F)	Bed ridden (1=Yes 2=No)	Reason for being bed ridden **	For other reasons	Pregnant (1=Yes 2=No)	PR* (1=Yes 2=No)	Selected (1=Yes 2=No)	Consented to participate (1=Yes 2=No)

*** Permanent resident (PR)-:** For the purpose of this study a permanent resident is one who lives in this household, is related to the household head and eats at least 3 meals in a week with the family.

****** Ask for the medical diagnoses of this person and select one or more from the below mentioned options

1=Diabetes, 2= Stroke, 3=Amputation, 4=Heart failure, 5=Kidney disease, 6=Hypertension, 7=Obesity, 8=Psychiatric illness, 9=Other. If others, specify the reason in the next column

Explain the study to the household members and leave a copy of Participant Information Sheet for them to read it. Proceed to the next section for selection of participant

a) **Name and age:** Serially write the names of all the members who live in the HH. Note the age in years for each member

b) **Sex:** write "M" for males and "F" for females

c) **Bed ridden:** If the a member of the HH is confined to bed and is unable to perform the day to day activities, note the member as bed-ridden

d) **Reasons for being bed-ridden:** ask the informant about the medical diagnosis of the bed-ridden member and note one or more options from the list provided. If the reason given by the informant is not included in the list, then select option "9" (Others) and specify the reason in the space provided.

e) **Pregnant:** For female members judiciously ask if anyone is pregnant in the HH.

f) **Selected:** Is the participant selected by using Kish method (explained in details in chapter 6) - write "1" for yes and "2" for no.

g) **Consented to participate:** Does the participant consent to participate- If the participant is selected by using Kish and he/she consented to participate then write "1" for yes and "2" for no. If the selected participant didn't give his/her consent to participate then select another participant using Kish method (explained in details in chapter 6)

8. The method of selection of participants is described in details in chapter – 6.

Completion form for HH Proforma

1) **Interviewer ID** - Enter the four digit unique interviewer ID.
2) **Attempts** – Fill the attempt form serially. Example: if this is your 1st visit to the HH, then note the information in the "Attempt – 1" column. If the attempt is not successful, return to the address for the 2nd attempt and note the details in the same form in the "attempt-2 column". If the visit is still unsuccessful, note in the same form in the "Attempt-3" column.

> At least three attempts should be made to visit the selected HH for recruitment of participant. The FI should judiciously select a day and time for the 2nd and 3rd visit such that they are able to meet the members of the HH in case the house is found locked. The HH may be dropped and further attempts aborted only if the HH members request no further visits by the FI even after being explained the purpose of the visit.

Example:

If a field worker visited a house and the house is locked. What should a field worker do?

In the above scenario a field worker can

- leave the notification form with their contact no, time and date of their next visit.
- talk to the neighbours and can get the information about them.
- go in different time (especially in case of daily wagers who go early to work).
- go on different days especially on a holiday i.e. weekend or a weekday (in some cases people get weekday off).

3) **Date** – write the date of visit to the HH for each attempt.
4) **Is the HH form complete?**

Write "1" if the form is complete and there is no information missing. If there is even one question that has been left unanswered then make a repeat visit to the HH to complete the form.

5) If "NO" give reason for not completing the form. Refer to the reasons given in

the question and enter the appropriate code.

6) If the reason is something for which the option is not provided, then select "7" (Others) and specify the reason in the space provided.
7) Please follow the instructions for re-visit given at the end of the form.
8) **End result** – For each attempt write the end result, whether the HH was included or not. If the HH was included in the first attempt and Form-2 was complete, no other visit is required for this purpose.

Explain the study to the household members and leave a copy of Participant Information Sheet and consent form [Form-B; Annexure-5] for them to read. Provide further information in the Surveillance Study Notification Form [Form-A]. Request a date and time to collect the signed copy of the consent form from the participant.

Instructions for the Surveillance Study Notification Form [Form – A]

Name of the study coordinating site and the study centre is printed on the form.

1) **Date of visit** – note the date of visit to the HH.
2) **HH address** – write the HH address from the list provided.
3) **Next visit** – Write the date and time of your next visit by consulting with a member of the house (if available), otherwise note a date on your own (use your judgement). You could ask the neighbours (if no one is available) about the weekly off of the HH members.

Note this information in your records so that you are able to keep the appointment.

4) Provide information about yourself and the study centre in the rows provided and assure the participant and HH members that you will be available to take their call and answer all queries. Request them to either call in the phone number or visit the study centre at the address provided if they need any further information.

Instructions for filling the Non Interview Report Form (Cross-sectional survey) [Form – 3: Household refusal]

1) **Interviewer ID** - Enter the four digit unique interviewer ID assigned to you.
2) **Household ID** – The interviewer should enter the household ID from the given list of codes.
3) **Household visits** – record the information for each visit in a single column and use the same form for all three visits (if three visits are required).
4) **Date of visit** – note the date when you visited the HH.
5) **Reasons for refusal** – If the participant refuses to participate in the study after reading the PIS then indicate the reason for refusal. Options are provided along with a box for each option. In each box write "1", "2" or "9" depending on the reason for the refusal.
6) If the reason is not specified, describe the reason for refusal in the space provided.
7) **Reasons for not responding** – The participant may not be willing to respond when you re-visit her/him to collect the consent form. In such a case fill the boxes provided with the options in the question by using codes write "1", "2" or "9" depending on the reason.
8) If the reason is not specified, describe the reason for not responding in the space provided.
9) Number of persons ≥20 years of age: Ask the number of males and females whose age is ≥20 years.

None of the boxes should be left empty

Instructions for filling the Non Interview Report Form (Cross-sectional survey) [Form – 4: Individual refusal]

1) **Interviewer ID** - Enter the four digit unique interviewer ID assigned to you.
2) **Household ID** – The interviewer should enter the household ID from the given list of codes.
3) **Gender** – For male select 1 and for female select 2.
4) **Age** – note the age (in years) of the member who has refused to participate.
5) **Education status:** Choose from the options
6) **Occupation:** Ask the member about his/her occupation
7) **Have you EVER been told by a doctor that you have any of the following diseases?:** Ask the individual has s/he ever been told by a doctor that they have high blood pressure/ high blood sugar/ high blood cholesterol/ heart disease/ stroke/ kidney problem or cancer?
8) **Reasons for refusal** – Describe the reason for refusal in the space provided.
9) **Interviewer's comment**: Write any other comment in the provided space.

Chapter 6: Selection of Participants (Visit-1)

Introduction

As the field interviewer (FI) is completing the Household Performa (Form-2), they will also be selecting participants from the pool of eligible members of the household (HH) during the same visit. In urban areas there is a possibility that a fair proportion of households will have two or fewer adults, therefore the within HH sampling strategy is based on the method used in the 2002 Health Information National Trends Study (HINTS) in the US. According to this method if a household has one to two adults (≥20 years), they will be selected and enrolled into the study based on eligibility criteria and informed consent. For HHs with more than two eligible adults (≥20 years) "Kish method" used in the WHOs STEPwise approach to chronic disease risk factor surveillance will be applied.

Learning Objectives

After completing this chapter the field staff will be able to

1) Understand the inclusion and exclusion criteria for selection of participants
2) Select participants from the households
3) Use the **"Kish method"** for the selection of participants

Inclusion and Exclusion Criteria for Selection of Participants

Inclusion criteria: Any individual who is more than 20 years of age and is permanently residing in the HH is eligible to participate in this study.

Exclusion criteria: Following are the exclusion criteria:

1) Pregnant women will not be included in the study since their biochemical parameters will vary from the normal physiology due to pregnancy, further their patterns of diet and physical activity will also be different from usual.
2) Bed-ridden individuals will be excluded because of the difficulty in taking

3) anthropometric measurements in these individuals.
4) People who are unable to comprehend the interview questionnaire. However, reasons for exclusion will be documented in Form-2.

Selection of Participants from the Households

The following steps should be used to select eligible individuals from the HHs by using Form-2 (Annexure - 3):

After listing all the household members in the HH performa; an adult member should be asked to enumerate the number of adults (≥20 years) in the household which should be denoted as "N".

1) If N=1, then the respondent should be selected based on inclusion and exclusion criteria and the selection process ends.
2) If N=2, where one member is male and the other female, then select both individuals based on inclusion and exclusion criteria and end the selection process.
3) If N=2 and both members are of the same sex, then select the eligible participant (based on inclusion and exclusion criteria). However if both are eligible, then apply the Kish method to select one individual
4) If N>2, then apply the Kish Method to select eligible individuals from the HH.

Selection of Participants by Kish method

The KISH method will be used for selection of participants from those HH where point numbers **3** and **4** listed above are true. The detailed directions on how to implement the Kish method in each household are as follows:

Step-1: Complete the table shown below in Form-2 (Q-8) based on the information noted in Q-7 of the same form.

Example: List of all members aged ≥20 years in household

Sex	Age	Rank	Selected respondent
F	45		
M	45		
F	29		
M	30		

Step-2: Assign a rank to each adult in the above table. The ranks should be consecutive and begin with 1. Assign the ranks according to the following rules-

- First assign ranks to males in order of decreasing age (oldest to youngest)
- Next assign ranks to females in order of decreasing age.

Example: Participant ranking table

Sex	Age	Rank	Selected respondent
F	45	3	
M	45	1	
F	29	4	
M	30	2	

Step-3: Use the Kish Selection Table to randomly select one participant from the total number of eligible HH members. The columns in the Kish selection table is labeled with the last number of the household ID (horizontally) ranging from 0-9 and the rows are labeled by the number of eligible HH members (vertically). Within the table each row has a randomly placed number depending on a probable number of eligible HH members.

Kish Selection Table

Number of eligible members in household	Last Digit of Household ID number									
	0	1	2	3	4	5	6	7	8	9
1	1	1	1	1	1	1	1	1	1	1
2	1	2	1	2	1	2	1	2	1	2
3	3	1	2	3	1	2	3	1	2	3
4	1	2	3	4	1	2	3	4	1	2
5	1	2	3	4	5	1	2	3	4	5
6	6	1	2	3	4	5	6	1	2	3
7	5	6	7	1	2	3	4	5	6	7
8	1	2	3	4	5	6	7	8	1	2
9	8	9	1	2	3	4	5	6	7	8
10	9	10	1	2	3	4	5	6	7	8

Step-4: Find the square (or box) on the Kish table whose column heading matches the last digit of the HH number (that you are visiting) and whose row heading matches the total number of eligible members in the HH. The person whose rank matches this number (refer to the ranking table) is the selected participant for this household.

Example

We have to select two participants from a HH whose last digit of the HH ID number is 3 and the total number of eligible people in the HH is 4.

- **Selection of 1st participant:** Applying the last digit of HH ID (3) to the column and number of eligible members (4) in the Kish selection table (shown below), we have selected a square which is at the intersection of the above two numbers. The number in this square is "4", which should then be matched with the rank assigned to participants in the ranking table (given above). In the above example of the ranking table, number 4 from the Kish table coincides with rank "4" i.e. female of 29 years old (see the illustrations below).

Number of eligible members in household	Last Digit of Household ID number									
	0	1	2	3	4	5	6	7	8	9
1	1	1	1	1	1	1	1	1	1	1
2	1	2	1	2	1	2	1	2	1	2
3	3	1	2	3	1	2	3	1	2	3
4	1	2	3	4	1	2	3	4	1	2
5	1	2	3	4	5	1	2	3	4	5
6	6	1	2	3	4	5	6	1	2	3
7	5	6	7	1	2	3	4	5	6	7
8	1	2	3	4	5	6	7	8	1	2
9	8	9	1	2	3	4	5	6	7	8
10	9	10	1	2	3	4	5	6	7	8

1st participant ranked 4 on the participant ranking table

Example: Participant ranking table

Sex	Age	Rank	Selected respondent
F	45	3	
M	45	1	
F	29	4	SELECTED
M	30	2	

- **Selection of 2nd participant:** Once the first participant is selected, re-rank the remaining eligible members of the sex opposite to that of the selected participant in a second participant ranking table.

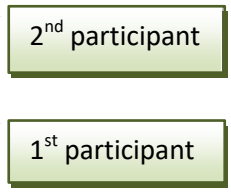
- **2nd participating ranking table**: Since the 29 years old female was selected in this example, remove the selected female and also all other female members and re-rank the remaining male members of the HH.

Example: Participant ranking table

Sex	Age	Rank	Selected respondent
M	45	1	
M	30	2	

The last digit of the household ID number will be the same (3), but now the total number of eligible people in the household is 2 (instead of 4). Repeating the above mentioned process, square with number "2" is selected on the Kish selection table. Thus, the participant ranked "2" i.e. male of 30 years of age will be the second participant selected for the study.

Number of eligible members in household	Kish Selection Table: (Example) Last Digit of Household ID number									
	0	1	2	3	4	5	6	7	8	9
1	1	1	1	1	1	1	1	1	1	1
2	1	2	1	2	1	2	1	2	1	2
3	3	1	2	3	1	2	3	1	2	3
4	1	2	3	4	1	2	3	4	1	2
5	1	2	3	4	5	1	2	3	4	5
6	6	1	2	3	4	5	6	1	2	3
7	5	6	7	1	2	3	4	5	6	7
8	1	2	3	4	5	6	7	8	1	2
9	8	9	1	2	3	4	5	6	7	8
10	9	10	1	2	3	4	5	6	7	8



Example: Participant ranking table

Sex	Age	Rank	Selected respondent
M	45	1	
M	30	2	SELECTED

Other probabilities for selection of the second participant

- If there is only one eligible member of the sex opposite to that of the selected participant then select this member and Kish method will not be required.
- If all eligible members are of the same sex then use the Kish methodology for selection of one participant only. If there are only two eligible HH members and one of them refuses to participate then recruit the other member from that HH.
- If the HH has 2 eligible members of the same sex and the selected member refuses to participate the other person who was not selected is automatically recruited and has to be approached.
- If there are more than 3 members of the same sex in the HH and if one of the members selected using the Kish method refuses to participate then repeat the Kish method for the remaining two people (excluding the member who is selected and the member who refused)

- All refusals should be documented in the Non- Interview report form (Form- 3: household refusal or Form-4: Individual refusal).

Points to remember

1) Participant selection will be done using two methods – HINT and KISH
2) Second section of Form-2 is for participant selection
3) Follow accurate guidelines for selection of participants
4) Do not select more than one participant of the same sex from one HH

Chapter 7: Participant Information Sheet and Consent Procedures

Introduction

All study participants in the surveillance study must give their informed consent to take part in the study. This is a requirement of the Office for Human Research Protection of the United States Department of Health and Human Services and the regulations published in the Code of Federal Regulations (45 CFR 46).This is also a requirement of the Indian Council of Medical Research (ICMR). The consent process provides the mechanism by which an individual can make an informed decision regarding participation in the study and also provides for the protection of a participant's rights as a subject in human research.

The consent form, Form-B (Annexure -5) 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.

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

Consent for the Cross - Sectional Survey and Follow-up Study

During Visit-1, the field staff has to explain about the purpose of his/her visit, the objectives of the study. After that Form-2 has been completed and 2 eligible participants are selected using the Kish method, the field staff. They share the copy of the Participant Information Sheet (PIS) in the language of their preference (Hindi/English/Tamil / Urdu) with them. They will explain the contents of the consent document and its purpose, and answer any questions which the potential participant may have regarding the study or her/his involvement in the study.

Field Interviewer (FI) will present Form-B with an explanation about its purpose. The potential 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 potential 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:

i. The purpose of the study
ii. What constitutes participation in the study including the interview and bio- specimen collection procedures
iii. The potential risks and benefits associated with the study
iv. Their rights and responsibilities as a study participant
v. 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-B), it is important to invite questions from the potential participant. The FI should offer to explain any words or phrases that may be unclear.

Once it is established that the potential 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-B).The interviewer will also sign and date both copies. One copy of the consent form will be given to the participant for their records.

Handling refusals

If the participant refuses to participate, 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 Non-Interview Report Form (Form-3 in case of household refusal and Form-4 in case of individual refusal). The interviewer should thank the participant for her/his time, and leave the house.

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 in Form-3 or 4

Chapter 8: Interviewer's task and Responsibilities

Importance of the Interviewer's Role

Field Interviewers (FI) play a key role in the study. The FI presents the human face of the scientists conducting this study. The success of the study is dependent upon the FI's observance of study procedures and protocols, as well as her/his understanding of the use of the study instruments. The FI should use interviewing techniques known to build rapport with study participants and enhance response rates to data collection activities.

Learning Objectives

After completing this chapter the field staff will

1) Understand the importance of adequate behaviour and communication skills
2) Understand their activities before the field visit, during the visit and after the visits
3) Learn about the procedure to conduct in-home interview
4) Address the participants with disability
5) Learn about the follow up study visits

Behaviour and Communication Skills

1) The FI should project a pleasant personality and should be cordial to all participants and their family members.
2) S/he should be well educated about the study to be able to answer queries.
3) The FI should spend enough time in each HH and with each selected participant to complete the questionnaire and to administer the clinical and anthropometric tests.
4) Body and anthropometric measurements should be taken by gender specific FI (female FI should attend to female participants and male FI should attend to male participants).
5) Confidentiality and privacy of participants should be the prime concern for the FIs.
6) If a participant is not cooperative, the FI should politely address her/his concerns and motivate / encourage the participant.

Remember
The FI's behaviour should portray the study organization's reputation

Recording Information

1) The FI should fill the questionnaire neatly and clearly. Remember that the study outcomes will depend on what is recorded in the study tools.
2) The records should be cross-checked several times so that they are complete and the information recorded is correct.
3) These should be legible to the data entry personnel.
4) Before taking anthropometric measurements, s/he should ensure that the instruments are calibrated and set at null.
5) The readings should be recorded clearly in Form-6 (Annexure-8).
6) The FI should understand that if any information is incomplete or an error is found s/he may have to repeat the interview

Enlisting Households and Mapping

It's described in Chapter- 4.

Study visits

The study will incorporate two epidemiological study designs (Cross- sectional survey and follow-up study) and will be conducted over a period of two years.

Visits for the cross-sectional survey: There will be three visits for the cross-sectional survey

Visit – 1	Participant recruitment and consent; Questionnaire based interview, blood pressure and pulse rate, and anthropometric measurements (body circumferences)
Intermediate visit	Distribution of containers for collecting urine samples and provide information/ instruction regarding camp
Visit – 2	Biological sample collection, height and body composition in the blood collection camps (House visit for Karachi)

Visits for the follow-up study: One follow-up visit will be conducted after the cross-sectional ends. The interval between the visits will be one calendar year.

Cross-sectional Survey

1) **Visit – 1:** This is the visit to 2500 selected households for recruitment of participants. During this visit the interviewer will select participants from each selected HH using the HINT and Kish methods. S/he will then explain the aims, objective and conduct of the study to the selected participant/s and their family members and complete the Household Proforma (Form-2). The FI would provide the Participant Information Sheet (PIS) and the consent forms to the selected participants and if they agreed to be interviewed at that time, interview them otherwise leave the PIS with the participant decide (with the participant) on a date and time to collect the consent form. Three visits should be attempted in each selected HH before coding the household as a non-response. In case of refusal, the final outcome should be documented in Form-3 in case of HH refusal and Form-4 in case of individual refusal.

   After obtaining consent, the selected participants will be interviewed and the information will be recorded in the study questionnaire.

- **Pre-visit activities:** It is the FIs responsibility to make sure that s/he has a complete interview pack prior to arriving at the participant's home. It is recommended that the FI should verify the contents of each interview pack. Before going to the participant's house to conduct the household visit, the FI should make sure that s/he has a packet for each household that contains the following documents:

  - **Photo ID proof of the FI**
  - **Household proforma with the Kish tables [Form-2]**
  - **Surveillance study notification letter [Form-A]**
  - **Participant information sheet and informed consent form (both English and regional language) [Form-B]**
  - **Non-interview report form (Cross-sectional survey)- Household refusal [Form-3]**
  - **Non-interview report form (Cross-sectional survey)- Individual refusal [Form-3]**
  - **Questionnaire booklet-[Form-5]**
  - **Blood pressure instrument**
  - **Seca, non-stretch measuring tape**
  - **Wax-based cosmetic pencils**

  It may not always be possible to check each interview package prior to leaving the field Office; therefore, the FI should keep extra copies of each of the documents listed above.

- **Activities during the visit 1:** During this visit the interviewer will complete the following tasks:

  - **Explain the study and PIS**
  - **Complete the Household Proforma- Form 2**
  - **Select the eligible participants by HINT / Kish methods**
  - **Provide a copy of the Surveillance study notification letter [Form-A]**
  - **PIS+ ICF [Form-B]**
  - **If they consented to participate, take interview, conduct anthropometric measurements (body circumference), record blood pressure and pulse rate; review activities to be completed in Visit 1; request participant to bring medical records during visit 2 if these were not available during the current visit OTHERWISE schedule an appointment to know their willingness to take part or not, and complete the consent form process**
  - **Schedule the next visit if the participant tells the FI to come some other time to collect the consent form and to fill the questionnaire**
  - **Complete the Non-Interview (Form-3) in case of HH refusal and in case of individual refusal complete Form-4.**
  - **Thank the participants and other family members for their valuable time**

- **Post visit activities:** The interviewer should verify that all the questions have been administered and the form is complete. The interviewer will thank the participant for their time and participation in the study.

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

  - **Review all forms for legibility and completeness**
  - **Check that all materials have been picked up**
  - **Return completed forms to the field office**

Once the FI has left the house, s/he should review the forms and questionnaire again and note any other omissions or inconsistencies s/he remembers. The answers should never be changed. The interviewer will also review previous comments to ensure that they are understandable. If the interviewer believes that a response has been incorrectly entered, s/he should explain the circumstances to the Field Supervisor. The participant should be contacted to verify the response.

2) **Intermediate Visit:** During this visit the 2nd visit will be scheduled by providing the date and time for the participant's visit to the blood collection camp (FIs and lab teams visit to the participant's house- Karachi) and the address where the blood collection camp will be organized. During this visit, they will be provided with the container for collecting urine, information and instructions to visit the camp. They would be requested to bring medical records during visit 2, if these were not available during the current visit.

- **Pre-visit check list:** It is the FIs responsibility to make sure that s/he has properly labelled specimen collection container prior to leaving the field office.

  - **Specimen collecting containers**
  - **Instructions for blood collection [Form-D], Annexure -9 and instruction for performing GTT (Only for Chennai and Delhi) [Form-D1], Annexure -10**
  - **Urine collection instructions [Form-D], Annexure -9 and sterile containers**

The FI should keep extra copies of each of the documents listed above and extra specimen collection containers.

- **Activities during Intermediate Visit-:** The FI should complete the following activities during this visit:

  - **Provide and explain the instructions for blood collection- for GTT (Delhi & Chennai)**
  - **Provide the urine collection container with instructions**
  - **Review activities to be completed in Visit 2**
  - **Schedule Visit 2 by providing the date and time for the participant's visit to the blood collection camp (FIs and lab teams visit to the participant's house- Karachi)**
  - **Provide the address where the blood collection camp will be organized**
  - **Request participant to bring medical records during visit 2 if these were not available during the current visit**

- **Post Visit Activities**

  - **Check if the participants have received the containers.**
  - **Call them to remind about the camp** (See in the next page- appointment reminder calls)

The interviewer will explain that Visit 2 will take place at a place (camp) which will be near to their home. If the participant does not want to travel to that place, then arrangements should be made to conduct Visit 2 at the participant's home. The FI will schedule an appointment that accommodates the participant's schedule. The interviewer will provide the participant with instructions and kits for collecting their early morning void (preferably second morning void). The participant will be asked to not eat or drink anything ten to twelve hours before their next appointment. If the participant was not able to show the records of treatment and/or hospitalization during the visit, the FI should ask her/him to bring them to the camp.

Appointment Reminder Calls

The day before a scheduled appointment, the FI should call the participant to confirm the appointment. Occasionally, the participant may not remember, so the 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. The FI should also remind that s/he will require to review the participant's medical records, prescriptions and other related documents, and request the participant to keep them at a place where these can be readily accessed.

3) **Activities during Visit-2:** Local camps for blood collection will be organized in the neighbourhood of selected CEBs on a pre-fixed date, usually on a weekend. The participants will be invited to come to the camps in fasting state during the early hours of the day. The date and time will be communicated to the participants during intermediate visit and a reminder call will be made a day or two before the scheduled day to ensure 100% response rate. The participant should also be reminded to collect the early morning void (preferably second morning void). The specimens should be brought to the camp for submitting to the laboratory technician.

- **Check List for the Local Camp**

  It is recommended that the FI and the laboratory technicians set-up the camp at least one hour before the scheduled appointment of the participants. The laboratory technician and the FI should ensure that the following are available in the camp in sufficient quantity:

  - **Blood collection supplies (Vacutainer tubes, cooler, needles and other blood collection supplies)**
  - **Biological specimen collection forms**
  - **Seca Brand-214 Portable Stadiometer**
  - **Body Composition Analyzer BC 601 (Delhi & Chennai) and BC 601F (Karachi) (Bio-impedance measuring instrument)**

- **Activities during Visit-2 in the Blood Collection Camps (Home visit for Karachi):** The following activities should be completed:

- **Collect the urine sample container brought by the participant**
- **Complete specimen collection forms for urine [BS-1]- Annexure-11**
- **Collect blood specimens in the camp**
- **Centrifuge the blood samples within 20-30 minutes of collection and store in separate aliquots maintaining adequate temperature**
- **Complete blood collection [BS-1] & processing forms [BS-2]- Annexure-12.**
- **Measure height and body composition**
- **Check the medical records of those participants whose records were not available during visit-1**
- **Perform all activities pertaining to blood collection, storage and transport**
- **If any participant doesn't come to the camp, visit the person's house to remind and request her/him again**
- **In case a participant wants to re-schedule the visit, s/he should be invited to a follow-up camp (or during mopping) and also remind the participant to follow the specimen collection instructions and collect the urine before coming for blood collection**

➢ **Post-Visit Activities**: The following tasks should be completed following each visit:

- **Review all forms for legibility and completeness**
- **Return completed forms to the field office**
- **Transport all bio-specimens to the laboratory or field office**

- **Returning Reports to Study Participants**

  Within a week's period the lab team should be able to provide the reports of the biological specimens. The reports duly signed by the head of the biochemistry department should be given to the participant. While giving that report to the participant, please take signature of the participant in the photocopy of the report. The readings of the BP and anthropometric measurements should be provided to the participant at the time of taking the measurements. It is preferable that the FI gives the reports to the concerned person or to the next of kin if the FI is unable to meet her/him. In case of abnormal findings, s/he is advised to consult her/his physician.

Follow-up of Participants

Three follow-up visits will be conducted for all participants at an interval of 365 calendar days (1 year). During these visits participants will be interviewed to elicit their medical history, quality of life, status of disability due to CMD, history and costs of treatment. In case of death of a participant, verbal autopsy forms will be used to ascertain the cause of death.

Participant Confidentiality

All information obtained while conducting the study will be kept confidential as specified by the Indian law. The 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 absolutely necessary. The FI must not discuss data collected or observed with anyone within and outside the project. This includes discussions with other FIs or at home with family members or friends. Unless a special exception is made by project managers, the FI should never interview anyone they know or anyone known to them through mutual acquaintances.

Points to remember

1) **Make a phone call to the participant a day prior to the visit 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) **Check for completion of forms, questionnaire and checklist before leaving the participant's house**
5) **Reports of anthropometry and blood pressure should be provided to the participant at the time of taking the measurements.**
6) **Reports of bio-specimen should be handed over to the participant alone.**
7) **It is very important to maintain confidentiality of all information**

Chapter – 9: 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 90 minute conversation").
3) 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, as long as it is within the range of expected answers.
4) Question responses that are outside of expected answers. Note the reason for deviation from the normal response.
5) Signal the respondent when you move to another section (e.g., "We are now turning to the next section of the interview").
6) 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 data instrument. Answer interviewee questions, but try to stick to the topic. Limit participation from third parties.
7) 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.
8) Paraphrase to check for understanding if the individual's response is unclear.
9) Express appreciation at the closure of the interview; explain briefly again what happens with the data collected.
10) Inform the participant about the bio-specimen collection camp.
11) Explain the purpose of the camp.
12) Hand over the instruction cards for fasting, urine collection and saliva collection.
13) Read the instructions aloud and clarify queries of the participant.
14) Hand over the sterile container for urine and saliva collection.
15) Request the participant to keep the containers in a clean, dry place.
16) Request the participant to store urine and saliva as per instructions provided in the instruction card.
17) If the participant has any problem, try your best to resolve it.

18) If you are unable to resolve, tell her/him that you will return with appropriate answers within a day or two.

Conducting the In-home Interview

There are certain guidelines the FI should follow when conducting an in- home interview:

1) 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.
2) Although the 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.
3) As a general 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.
4) 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.
5) The 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, the FI should schedule another appointment within a few days. The FI must document the situation fully and indicate if the participant will continue with the interview or not.

Participants with Disability

The eligibility of the participants for the interview will depend on the type and severity of the disability or impairment. In some cases the participant may need assistance from a household member to complete certain components of the in-home interview. Again the type and level of assistance that is allowed depends on the type and severity of the impairment. The FI should adhere to the following guidelines:

1) **Hearing Loss:** If the participant has some hearing loss, but is not totally deaf, the interview can be conducted. If the participant is totally deaf, but is able to read lips and to speak, the interview can be conducted. If the participant is totally deaf and cannot read lips or cannot speak, the interview is **not** conducted. It is not acceptable for live participants to use a proxy for the interview, even if one is offered.
2) **Limitations in Vision/Blindness:** A blind participant or one with visual impairment can participate and be interviewed. The FI reads the Consent Form and PIS to the participant. The participant may receive assistance from a household member, however, only the participant can give answers directly to the FI.
3) **Language Impairment:** A participant with language impairment, such as that from an episode of stroke, can still be interviewed directly. A participant who cannot communicate verbally can be interviewed as long as s/he can understand questions and communicate a response in writing. Assistance is allowed as long as the responses are given to the FI directly by the participant.
4) **Mental or Memory Impairment:** If a participant has a mild developmental disability, s/he may still be able to participate. If the mental impairment or memory impairment is not too severe, the FI can obtain consent and conduct the interview. Assistance is allowed as long as the responses are given to the FI directly by the participant. If a participant seems too confused or disoriented to provide informed consent and to be interviewed in the FI's judgement, then the interview should be terminated and the situation documented.

Chapter 10: Instructions for using the Questionnaire for Cross-sectional survey

Overview

This chapter provides instructions for filling the questionnaire and forms related to the cross-sectional survey. The list of forms and sections of the questionnaire is provided below. Questionnaire (Form-5) is included in Annexure -13.

List of Forms and Sections of the Questionnaire

Forms/Questionnaires	Description
Visit-1: Questionnaire	
CONTACT DETAILS	
PARTA	RESEDENTIAL DETAILS (PARTICIPANT DETAILS)
PART-B	CONTACT INFORMATION
PART -C	HOMETOWN CONTACT DETAILS
SECTION – 1	DEMOGRAPHIC AND SOCIO-ECONOMIC DETAILS
SECTION – 2	DETAILS OF TOBACCO AND ALCOHOL CONSUMPTION, DIETARY HABITS, PHYSICAL ACTIVITY AND SLEEP
PART-2A	TOBACCO USE
PART-2B	ALCOHOL USE
PART-2C	PHYSICAL ACTIVITY
PART-2D	SLEEP HISTORY
PART-2E	DIET
SECTION - 3	MEDICAL HISTORY (CARDIOMETABOLIC DISEASES AND THEIR RISK FACTORS)
PART 3A	DISEASE SPECIFIC QUESTIONS
3A-I	HYPERTENSION (High Blood Pressure)/ DIABETES/ HYPERLIPIDEMIA (High Blood Cholesterol)
3A-II	HEART DISEASE
3A-III	STROKE (Paralytic attack)
3A-IV	KIDNEY PROBLEM
3A-V	CANCER

PART-3B	PERIPHERAL VASCULAR DISEASE
PART-3C	FRACTURES
PART-3D	COMPLICATIONS
3D-1	FOOT ULCERS AND AMPUTATION
3D-2	EYES
SECTION 4	DRUG INFORMATION
SECTION-5	TREATMENT HISTORY AND EXPENDITURES
PART-5A	OUTPATIENT
PART-5B I	INPATIENT
PART-5B II	HOSPITALISATION COST
SECTION-6	FAMILY HISTORY
SECTION-7	PATIENT HEALTH QUESTIONNAIRE
SECTION-8	QUALITY OF LIFE
SECTION-9	FEMALE REPRODUCTIVE HISTORY

Remember to fill the following:

Household ID	Enter the unique 6 digit household ID provided.
CEB code	Enter the CEB code assigned
Interviewer ID	Enter the four digit unique interviewer ID.
Participant ID	This is the unique identification ID provided to each participant who has consented to participate in the study.
Date of interview	Write the date of interview
Start time	Note the time in the space provided in hrs: min before starting the interview.

General instructions

- Note the HHID and other information correctly.
- Before starting the interview make sure that you have the signed consent form from the participant.
- The interviewer should assure the participant that s/he has the right to refuse to answer any question.
- The FI must read all questions **EXACTLY** as they are written and in the proper order.
- Explain each section of the questionnaire thoroughly to the participant and answer any question the participant may have.
- Clarify all doubts and concerns regarding the confidentiality and the purpose of the interview.
- Thank the participant for her/his valuable time.
- Write the start and end time of the interview on the form clearly.
- Note all answers clearly in the form and re-check to avoid errors and missing fields.

PART A: RESIDENTIAL DETAILS
Spouse's name Ask only if the participant is married.
Address detail Write the detailed address to which one can send posts (Postal address).
Telephone numbers Request the participant for multiple phone numbers including the workplace phone number. He may change his residence or place where he lives or sim but it's less probable that he will change his/her work place.
PART B: CONTACT INFORMATION
Whom should we contact to obtain your new contact address or telephone numbers, if required? [Take details of two different contacts] 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. From the codes provided, select the appropriate code for each contact person. If participant's response is not on the list, select the code for "Others" and record her/his answer in the space provided. 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 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 them to contact them if they would go out due to some reason. If the participant don'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

Phone number of the 1st / 2nd contact person Mobile phone number should be of 10 digits. Check the number of digits in phone number (For example for Delhi and Chennai, landline number should be of 8 digits).
PART C: HOME TOWN CONTACT DETAILS
Home town contact information In the case participants home town 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 the participant changes the city and how to get in touch with her/him. **Note:** Include landmarks in the address.

Note: Please write all the information i.e. household ID, participant ID, CEB code, date of interview and other details in the 3rd page, again.

Collect **Global Positioning System (GPS) coordinates** of the household after getting consent from the participant and fill the details in the provided space. Fill that information in both the forms (female and male participant from the same household).

SECTION-1: DEMOGRAPHIC AND SOCIO- ECONOMIC DETAILS

The purpose of these questions is to gather basic information about the participant. This section consists of 22 questions. Below are specifications for questions requiring additional clarification.

PART-1A: DEMOGRAPHIC DETAILS

1.1 For men, relationship with the female participant

This question should be asked ONLY to the male participant. If a female participant is not selected then write "00" in the space provided.

We are collecting this information just to know the relationship between the 2 participants selected from all the households

Note: This question shall be asked ONLY to male participant.

1.2 Age (in completed years)

Age should be recorded as age of the person in total years completed on last birthday. To get the accurate age, ask other questions related to life histories such as age at which s/he was married, first child and age of first child. If participant says that he/she does not remember the age, help him/her to remember the age, ask them to relate it to some major event of their life like marriage, first child birth etc. Ask regarding her/his son/daughter's age and try to estimate age from that information. Also, relate to other events such as independence, death of Indira Gandhi etc.

Note: If the participant doesn't remember or doesn't know his/her age, suspecting their age can give inaccurate information, so the field interviewer must probe:

In case of married person- ask them in what year they got married; what is the birth year of his/her first born; what is the age of their first born, what was the gap between the marriage and birth of their first child (in years). You can calculate his/her age by this. **OR**

You can ask them to relate this with some major events like during some particular famine, 2-3 years after or before independence, during partition etc. try to estimate

age from that information.

1.3 Date of Birth (DOB) (If available):

Interviewer needs to ask the date of birth of the participant. Information on DOB is mainly collected to cross verify the age. Verification of age is needed because mostly age is reported in digit preference of '0' or '5'.

Example: People tend to report their age in the multiples of 5. Like if you will ask somebody whose age is 63 years then there is a high chance, that person will report his age as "65 years". Therefore, verify the date of birth of the participant with the valid document e.g. voter id card, Xth certificate, ration card etc.

1.4 Sex

This information has to be filled in by the interviewer through observation. Enter the sex as "Male", "Female" or "transgender".

"A **transgender** is defined as a gender identity which includes transsexuals, cross dressers, intersexed persons, gender variant persons and others."

1.7 Marital Status

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.

1.8 What is your mother tongue? (State of origin)

This information is just to obtain the information about their **"state of origin"**.

Note: If the person is Bengali but could not speak the language then also you need to write the code given for "Bengali" language. It is not necessary that the person needs to speak/proficient in that particular language.

1.9 What religion do you follow (optional)?

Field interviewers need to ask about which religion is followed by respondent and write the options accordingly. If in case, the answer do not fall under any of the given option then they should report it under "other" category and clearly mention the response given by respondent in the provided space.

The answer provided by the participant should not be contested.

1.10 What is your caste or tribe?

Caste can be a sensitive issue for some participants. The interviewers should use their discretion and judgment while asking this question. Ask this question politely. Choose the options wisely.

If the participant is not comfortable in answering then skip the question.

PART-1B: SOCIOECONOMIC STATUS

1.11 Number of years of formal education

This should provide information on the number of years the participant spent in any educational institution. This includes the total years spent in schools, colleges, religious schools, etc.

1.12 Educational status (highest attained degree)

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:

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

2) 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 (Q.24) write the code for 12.

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 that 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 Q24 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.

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

1.13 What is your employment status?

Respondent is asked about his/her work status in this question where one option need to be selected for each respondent as per their status. If the participant is employed select the "Employed" as response, and ask Q1.14. If the participant is Student/ Housewife/ Retired/ Unemployed then Q1.14. will be skipped.

1.14 If employed, what is your current occupation?

Occupation has been classified into five broad categories to simplify the classification. Field interviewer should ask the type of employment to the respondent if they are currently employed. According to the type of employment field interviewer can select the occupation category from the given options:

-Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer

-Trained, clerical, medium business owner, middle level farmer, teacher, maintenance (in charge), personnel manager.

-Skilled manual labourer, small business owner, small farmer, army jawan.

-Semi-skilled manual labourer, marginal landowner, rickshaw driver, carpenter, fitter.

-Unskilled manual labourer, landless labourer

Also, note the occupation in the paper questionnaire.

1.17 What is your total household income per month?

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 and choose from the income ranges. If the participant refuses to answer the question or doesn't know the answer to the question, select the appropriate response.

1.18 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, and further whether cooking is done under a chimney or under proper ventilation.

1.19 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, note the source that is most commonly used

1.20 What is the source of drinking water used at home?

Access to basic amenities such as safe drinking water and sanitation is not only important to study the socioeconomic status of the household but also fundamental to the health of its members. Therefore, major source of drinking water used by household is collected through this question.

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

1.21 What is the toilet facility you use?

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

1.22 Which of the following do you own?

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 need 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. Don't copy. If the information obtained from the same house is different, confirm with the participants.

SECTION-2: DETAILS OF TOBACCO AND ALCOHOL CONSUMPTION, PHYSICAL ACTIVITY, SLEEP AND DIETARY HABITS

This section of the questionnaire is to elicit details of life-style and eating habits.

PART-2A: TOBACCO USE

The purpose of this section is to gather information about tobacco consumption. Below are specifications for questions requiring additional clarification.

2.1 Have you EVER used tobacco in any form (smoking, chewing, snuff, etc)?

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 (toothpaste, 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 Q.8.

2.2 In what forms have you consumed tobacco?

Here we are interested in different forms of tobacco. If participant uses cigarette, bidi, cigar 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 toothpaste and snuff.

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

Note: Do not leave any box empty

2.3 Do you currently consume tobacco?

"Currently" means tobacco consumed within the past six months.

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.

2.4 In which form?

Here we are interested in different forms of tobacco that is consumed by the participant CURRENTLY. If participant uses cigarette, bidi, cigar 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 toothpaste and snuff.. If you've written "Yes" for any of the forms (smoked, chewed, any other form), the next question will be "if yes, how often".

You need to answer the "how often" question only for the forms for which you have written "Yes" in Q2.4. For each form of tobacco that the participant uses, write the frequency of consumption using the appropriate code provided.

Example: If the participant consumes only gutkha then write "Yes" in the corresponding column for chewed form and for smoking form and any other form write "No". After that, write the frequency of consumption of the gutkha using the appropriate code (given below).

Codes: Daily =1; 1-6 days a week=2; <once a week=3; Not applicable= 9

Example: If the participant chooses "2" for any of the options (a-c; in a smoking form; chewed form and in any other form –snuff, toothpaste etc) i.e currently not using that particular product then write "9" in the boxes provided for how often column.

2.5 Quantity and duration of use (for both current and past users)

This table should be filled for both **CURRENT AND PAST USERS** of tobacco. The different forms of tobacco are listed in the second column. Then for the products selected, note the additional information in the corresponding rows. For example if the participant currently chews tobacco, then note the details in the 4th row.

Ever Consumed:. Note "Yes" or "No" against the tobacco items listed in Q.2.5.

Example: If a participant is not using tobacco currently but used it in past, then, the answer to this question should be "Yes". Then, the answer to this question (for tobacco) should be "Yes" in 3rd column.

Duration of use: Here, we need to write duration of use i.e. for how long the participant is consuming the product for which he/she has said "yes" for in the 3rd column. Write the duration in the appropriate column months / years.

Example: If the participant has been consuming beedi for 10 years and also started smoking cigarette from past 6 months, write "Yes" in the 3rd column for cigarette and beedi and in the 4th column write 10 in years column (for cigarette) and 6 in months column (for beedi).

Usage: For tobacco products, ask him/her to indicate the approximate amount/number consumed per day. Most people, who consume tobacco products, use it every day. Therefore, we'll note the numbers/weight (in grams) in "per day" column. However, if any of the participants consumes tobacco less than once a day ask them how much they consume in a week or month and write in the appropriate column.

Example: If the participant smokes/ chewed tobacco/ consumed tobacco in any other form then write its frequency of usage per day **or** per week **or** per month (in column 5). Choose wisely.

Note: Fill **ONE** column only

Note: One participant may select several products; note the details for each product.

a) For cigarette, beedi and cigar – usage hould be in numbers.

b) For Hukka/Chelum and snuff – the usage should be in number of times the product is used.
c) For Tobacco, pan with zarda and pan-masala with zarda and pipe – usage should be indicated in approximate grams of the product consumed. If available, request the participant to show you the pack.

If participant's response is not on the list, select the code for "Others" and record her/his answer in the space provided.

If stopped, for how long (months / years)

If the participant **stopped using any of the following products, time in months/years since you have stopped (NOT THE AGE)**: note the above details and in the 6th column, write the time period in the appropriate column (months / years) since when the participant has given up using that product.

Note: Fill this, if Q2.1 is filled with "1" AND Q2.3 with "2".

Example: When asked in year 2014, another participant used to consume pan with zarda (started consuming it in 1970) and has left consuming in year 1990. Then, write code for yes in the 3rd column (for pan with zarda). Write 20 (1990-1970) in 4th column for pan with zarda in years column and in the 6th column write 24 (2014-1990) in years column (for pan with zarda).

2.6 At what age did you first start smoking regularly?

Please note that in this question, we need to write the **AGE (NOT DURATION)** at which the participant started smoking.

Note the age when the participant started smoking. Note down the age as told by the participant in completed years. For example, if the participant started smoking at the age of 18, note down 18 in the given space. 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 age of initiation then write "00" 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, age at initiation would be 30 years (70-40).

NOTE: While answering Q2 (in what forms have you consumed tobacco), if the participant has replied **"NO"** for part a. (in smoking form) and **"Yes"** for part b (in a chewed form) and c (in other form). Then, please enter code for **NOT APPLICABLE** (99) in the provided box.

2.7 At what age did you first start consuming smokeless tobacco product regularly?

Please note that in this question, we need to write the **AGE** (NOT DURATION) at which the participant started consuming smokeless tobacco products.

EXAMPLE: This can be ascertained if the participant is 70 years old and says he started consuming tobacco 50 years ago, age at initiation would be 20 years (70-50).

NOTE: While answering Q2 (in what forms have you consumed tobacco), if the participant has replied **"YES"** for part a. (in smoking form) and **"NO"** for part b (in a chewed form) and c (in other form) that are examples of smokeless tobacco. Then, please enter code for "**NOT APPLICABLE"** (99) in the provided box.

2.8 Are you exposed to tobacco smoke (from others) at home or at workplace regularly*? (e.g. at home, at work place regularly, while travelling, any other place)

* Regularly means at least once a day in a week

If "Yes", move to the next question. Otherwise, go to Part 2B, alcohol use.

What is Second hand smoke?

Second hand smoke includes smoke from the burning end of a cigarette, beedi, chutta or cigar and the smoke breathed out by the person or people smoking. It includes 7000 chemical substances out of which 50 can cause cancer.

Second hand smoke causes a range of diseases in those are exposed to it and who do not themselves smoke. It causes cancer of lung, heart diseases, respiratory diseases/infections, ear infections (in children).

If Yes (exposed to tobacco smoke from others) in Q2.8.

2.8a. How many days a week?

Ask the participant to give the approximate number of days in a week that s/he is

exposed to tobacco smoke.

2.8b. How much time during a day?

Note the duration in hours and minutes.

Part-2B: ALCOHOL USE

The purpose of this section of the questionnaire is to gather information pertaining to the participant's use of alcoholic beverages.

2.9 Have you ever consumed alcohol?

Here, the most important thing is to note that we are asking the participant "has he **EVER CONSUMED** alcohol in any form (beer, wine, spirits and/or local spirits. Select an appropriate response. If "Yes" is selected for Q.2.9, move to Q.2.10. Otherwise, skip the whole part and move to Part 2C: Physical Activity.

EXAMPLE: If a participant don't consume alcohol currently but used to consume it earlier. Then, the answer to this question should be "Yes".

2.10 How often do you use alcoholic beverages?

Select one of the four options given in the box below and write the appropriate code in the provided space:

1) Consuming alcohol regularly means at least once a day in a week
2) Consuming alcohol Occasionally* means less than once a week
3) Used alcohol in the past means stopped more than 6 months ago
4) Recently stopped alcohol means less than 6 months ago

2.11 History of alcohol use (for both present and past users)

Type of alcohol used

Examples:

A) Local spirits e.g. desi arrack, toddy etc.
B) Spirits e.g. whisky, rum, brandy, gin, vodka
C) Beers e.g. Castle Lager, Macopolo, Haywards 2000 and 5000, Zingaro, Kings, Kingfisher, Pint, and Sand piper.
D) Wine includes red, white, rose and champagne.

Note: A participant may use more than one type of alcohol. Write the details for each type used.

Have you ever consumed following items

Ever consumed: Here, the most important thing is to note that we are asking the participant "has he **EVER CONSUMED** alcohol in any form (beer, wine, spirits (whiskey, brandy, gin) and/or local spirits (toddy, desi arak). Please write code for yes/no (ever consumed) in the 2nd column.
Note: If a participant has left consuming beer currently but used to consume it. Then, the answer to this question should be "Yes" (for beer) in 2nd column.

Duration of use (in years/months)- For how long

Here, we need to write duration of use i.e. **for how long** the participant is consuming the product for which he/she has said "yes" for in the 2nd column.

Ask the participant to recall the duration of use of alcoholic beverages in months or years and write the number in the appropriate column (months / years).

Example:

If the participant has been consuming alcohol for months only then write the number of months (e.g. 5) in the month's column.

Example1: If the participant has been consuming beer for 10 years and with this, also started consuming whiskey from past 9 months. Write Yes in the 2nd column (Ever consumed) for spirits and beer. In the 3rd column write 10 in year's column (for beer) and 9 in months column (for spirits).

Example 2: When asked in year 2014, another participant used to consume beer (started consuming it in 1980) and has left consuming in year 2010. Then, write code for yes in the 2ndcolumn (for beer). Write 30 (2010-1980) in 3rdcolumn for beer in year's column and in the 6th column write 4 (2014-2010) in year's column (for beer).

Usage: Frequency per use

Write the average number of occasions per week **or** per month **or** per year that the participant drinks alcohol (note that there could be celebrations or occasions in certain weeks when the participant must have drunk more or less than average). Here, we need to collect information about how frequently he/she drinks **USUALLY** or in **a normal day**. Do not collect information about a special day (special occasion, celebrations, festivals, marriage etc).
Example: If the participant drinks brandy then write its frequency of usage per day **or** per week **or** per month **or** per year (in column 4). Choose wisely.
Note: Fill one column ONLY

Quantity/occasion (in ml only)**

For alcohol, ask him/her to indicate the approximate amount consumed per occasion. Enter the quantity of alcohol consumes/ consumed (in ml only). Use the code book for conversion, given below this question.

Conversion: Please use local measures in calculating the total consumption (in ml per occasion)	
For A & B: 1 small peg=30ml; 1 large peg=60ml; 1 extra-large peg=90ml; 1 quarter =180ml; a half bottle =375 ml; full bottle=750ml	
For C: 1glass of beer =approx.325ml; Beer Can= 500ml; Bottle of Beer= 650 ml	**For D:** 1glass of wine=100ml

In South Asia, not many people consume alcohol every day. For those who consume it everyday, enter the amount (in ml) in "per day" column (alcohol consumed every day). Many drinks only during weekends and for them enter the amount in "per week" column. For those who drink less frequently than a week, enter the amount in "per month" column.

Note: One participant may select several products; note the details for each product.
If participant's response is not on the list, select the code for "Others" and record her/his answer in the space provided.
Enter the quantity in "ml".
Refer to the table for conversion from "pegs/glass/can/bottle to ml.

If stopped, for how long (months / years)

Ask the participant to recall the duration since s/he has given up the specific type of alcoholic beverage. Write the duration in the appropriate column (months / years).

If the participant **stopped using any of the following products, time in months/years since you have stopped**: note the above details and in the 6th column, write the time period in the appropriate column (months / years) since when the participant has given up using that product.

Example: When asked in year 2014, another participant used to consume beer (started consuming it in 1970) and has left consuming in year 1990 then, write code for yes in the 2nd column (ever consumed-for beer). Write 20 (1990-1970) in 3rd column (duration of use- for beer) in year's column and in the 6th (if stopped, since how long) column write 24 (2014-1990) in year's column (for beer).
Note: If Q.2.10 is filled with option "3" and "4" then this question should be filled.

Part-2C: PHYSICAL ACTIVITY- Global Physical Activity Questionnaire (GPAQ)

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 different types of physical activity in a **typical week**. Ask the participant these questions even if they do not consider them to be a physically active person.

Field interviewers should carry the Physical Activity Showcard listed in annexure-19

The **Global Physical Activity Questionnaire (GPAQ)** was developed by WHO for physical activity surveillance in countries. It collects information on physical activity participation in three settings (or domains) and sedentary behavior.

These domains are:

- Activity at work
- Travel to and from places
- Recreational activities

"Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing, seeking employment.

In answering the following questions **'vigorous-intensity activities'** are activities that require hard physical effort and cause large increases in breathing or heart rate, **'moderate-intensity activities'** are activities that require moderate physical effort and cause small increases in breathing or heart rate."

You have to explain to the participant that you will be going to ask him/her the questions related to various types of physical activities taken by the participant in a **"Typical week"**.

2C-I:- ACTIVITY AT WORK

2.12 Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?

Activities are regarded as vigorous intensity if they cause a large increase in breathing and/or heart rate. For examples, sawing hardwood, forestry (cutting, chopping, carrying wood], ploughing, cutting crops (sugarcane), digging, grinding (with pestle), laboring [shoveling sand, loading furniture (stoves, fridge), instructing sports aerobics, cycle rickshaw driving]

Write "Yes" if the participant is involved in a "Vigorous intensity activity" in a **typical week** for **at least 10 minutes** continuously otherwise write "No".

Note: If "No" skip to Q2.15 (Moderate intensity activities)

2.13 In a typical week, on how many days do you do vigorous intensity activities as part of your work?

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

Valid responses range from 1-7

Enter here the number of days in a week the participant is involved in Vigorous intensity activity (1 to 7 days) and go to Q2.14

2.14 How much time do you spend doing vigorous-intensity activities at work on a typical day?

Ask the participant to think of a typical day he/she can recall easily in which he/she engaged in vigorous-intensity activities at work.
Consider only those activities undertaken continuously for 10 minutes or more.

Probe very high responses (over 4 hrs) to verify

Enter the time the participant spends doing "vigorous intensity activity" on a typical day in "Hours" and "Minutes".

2.15 Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? (USE SHOWCARD)

Ask the participant to think about moderate-intensity activities at work only. 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 at least 10 minutes continuously otherwise select "No".

Note: If selected "No" skip to Q2.18 (Travel to and from places).

2.16 In a typical week, on how many days do you do moderate intensity activities as part of your work?

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

Valid responses range from 1-7

Enter here the number of days in a week the participant is involved in Moderate intensity activity (1 to 7 days) and go to Q 2.17.

2.17 How much time do you spend doing moderate-intensity activities at work on a typical day?

Ask the participant to think of one day s/he can recall easily. Consider only those activities undertaken continuously for 10 minutes or more.

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

Probe very high responses (over 4 hrs) to verify

Enter the time the participant spends doing "moderate intensity activity" on a typical day in "Hours" and "Minutes".

2C-II:- Travel to and from places

The next questions exclude the physical activities at work that you have already mentioned.

Speak out the introductory statement

"Now I would like to ask you about the usual way you travel to and from places. For example: to work, for shopping, to market, to place of worship."

The introductory statement to the following questions on transport-related physical activity is very important. It asks and helps the participant to now think about how they travel around getting from place-to-place. This statement should not be omitted.'

2.18 Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?

Select the appropriate response.

Note: Here write "yes" only if the participant "walks" or "pedals cycle" for at least 10 minutes continuously to get and from places.

If the answer is "No", go to Q2.21.

2.19 In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?

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

Valid responses range from 1-7

2.20 How much time do you spend walking or bicycling for travel on a typical day?

Think of one day you can recall easily. Consider the total amount of time walking or bicycling for trips of 10 minutes or more.

"Typical day" means a day when the participant is engaged in his/her usual activities. Probe very high responses (over 4 hrs) to verify.

Enter the time the participant spends "**walking or bicycling for travel**" on a typical day in "Hours" and "Minutes".

2C-III:- Recreational activities

Introductory statement: "The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (leisure)".

This introductory statement directs the participant to think about recreational activities. This can also be called discretionary or leisure time. It includes sports and exercise but is not limited to participation or competitions. Activities reported should be done regularly and not just occasionally.

It is important to focus on only recreational activities and not to include any activities already mentioned. This statement should not be omitted.

2.21 Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously? (USE SHOWCARD)

Activities are regarded as vigorous intensity if they cause a large increase in breathing and/or heart rate. Example: playing badminton, tennis, high-impact aerobics, aqua aerobic, fast swimming etc

Note: If the response is "No" then move to Q2.24

2.22 In a typical week, on how many days do you do vigorous intensity sports, fitness or recreational (leisure) activities?

"Typical week" means a week when the participant is engaged in his/her usual activities. Valid response range from 1 to 7

2.23 How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?

Think of one day you can recall easily. Consider the total amount of time doing vigorous recreational activities for periods of 10 minutes or more.

Probe very high responses (over 4 hrs).

Enter the time the participant spends doing **"vigorous intensity sports, fitness or recreational activities"** on a typical day in "Hours" and "Minutes".

2.24 Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that causes a small increase in breathing or heart rate such as brisk walking,(cycling, swimming, volleyball)for at least 10 minutes continuously? (USE SHOWCARD)

Activities are regarded as **moderate intensity** if they cause a small increase in breathing and/or heart rate. Examples are cycling, jogging, dancing, horse-riding, yoga, low-impact aerobics, cricket.

2.25 In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?

"Typical week" means a week when the participant is engaged in his/her usual activities. Valid response range from 1 to 7

2.26 How much time do you spend doing moderate-intensity sports, fitness or recreational activities on a typical day?

Think of one day you can recall easily. Consider the total amount of time doing moderate recreational activities for periods of 10 minutes or more.

Probe very high responses (over 4 hrs).

Enter the time the participant spends doing **"moderate intensity sports, fitness or recreational activities"** on a typical day in "Hours" and "Minutes".

2C-IV:- Sedentary Behavior

The following 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. (USE SHOWCARD)**

2.27 How much time do you usually spend sitting or reclining on a typical day?

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.

2.28 How many hours/ minutes do you spend sitting/reclining in each of the following on a typical day? 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).
2.29 For how long you stand in a typical day (calculate only if the standing is more than 10 minutes continuously) Consider total time (in hours and minutes) spent standing in a normal day for more than 10 minutes continuously.
Additional Comments Note down any additional comments about the physical activity not covered in the previous questions.

Frequently Asked Questions

Some definitions:

- **Physical activity and exercise**: Any body movement produced by skeletal muscles that result in energy expenditure beyond resting expenditure.
- **Exercise**: Physical activity that is planned, structured, repetitive, and purposeful, usually aimed at improving or maintaining physical fitness.

~ Richard C Pasternak, Braunwald's Heart Disease, A textbook of cardiovascular medicine, 7th Edition 2005'

What are the components of exercise?

- Aerobic exercise
- Resistance training
- Flexibility

What are types of exercise?

- **Aerobic means** "using oxygen for energy". Aerobic Exercises use large muscles (legs, shoulders, chest, and arms) and can be performed continuously. This type of exercise burns calories and is critical to losing fat and keeping it off.
- **Strength Training** helps in increasing the number of Insulin receptors and their sensitivity as skeletal muscle is major site of insulin resistance. It also maintain muscle while losing fat.
- **Flexibility exercise** helps a person to do above mentioned activities (aerobic and strength training)

What are the benefits of exercise?

- Decrease total cholesterol and LDL- Cholesterol
- Increase HDL- Cholesterol and decrease Triglyceride
- Decrease blood pressure
- Decrease weight, body fat and increase muscle mass
- Alleviates stress
- Strengthen your bones and prevents osteoporosis
- Improves quality of life and sense of well being
- Reduces your risk of dying prematurely

What are the benefits of exercise in diabetes?

- Prevention of type-2 diabetes
- Maintenance of glycaemic control
- Prevention of diabetes complications
- Additional benefits

What type of exercise to do?

Combination of aerobic activity and resistance training

How much exercise to do?

- At least 150 min/week of moderate intensity aerobic physical activity
- In the absence of contraindications, resistance training three times a week is to be encouraged

How often should exercise be done?

- Resistance training
  - 2 to 3 times a week
  - 8 to 10 major muscle groups
  - 10 to 15 repetitions
  - 2 to 3 sets

What are the examples of leisure /spare time related physical activity/ moderate intensity activities

- Cycling
- Jogging
- Dancing
- Horse-Riding
- Low-impact aerobics
- Fast Walking
- Swimming
- Cricket
- Volley Ball

What does Intensity of physical activity mean?

Intensity refers to the rate at which the activity is being performed or the magnitude of effort required to perform an activity or exercise. It can be thought of "How hard a person works to do the activity?"

The intensity of different forms of physical activity varies between people. The intensity of physical activity depends on an individual's previous exercise experience and their relative level of fitness.

Types – moderate intensity and vigorous intensity

Moderate intensity physical activity	**Vigorous intensity physical activity**
Requires a moderate amount of effort and noticeably increases the heart rate	Requires a large amount of effort and causes rapid breathing and a substantial increase in heart rate
Examples: **1. Brisk walking** **2. Housework and domestic chores** **3. Active involvement in games and sports with children** **4. Walking domestic animals** **5. Roofing, thatching, painting** **6. Carrying/moving moderate loads (<20 kg)**	**Examples:** 1. Running 2. Walking/climbing up a hill 3. Fast cycling 4. Aerobics 5. Fast swimming 6. Competitive sports and games 7. Carrying/moving heavy loads (>20 kg)

How to answer the participant about physical activity?

Answer the patient's questions using the **FITT principle!!**

Frequency- at least 5 days/week

Intensity- moderate

Type- aerobic+ resistance

Time- for 30-45 minutes at a stretch

Some important points to remember:

- **Probe** whenever you have some concern with the answers provided by the participants. Don't hesitate to ask questions.

- **Probe** when a housewife says that I work all the time. It is also not possible. Please probe. Also, a housewife's activity can't come under vigorous activity. Normal household work normally comes under moderate activity unless she is a maid and mops other people's home

PART-2D: SLEEP HISTORY

In this part we will ask questions to assess the sleep habits (snoring and breathing during sleep) of the participant. The questions are self- explanatory, but it is important that the FI follows the skip patterns. Below are specifications for questions requiring additional clarification.

2.30 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. Enquire for the average hours of sleep separately for weekdays and weekends.

Note: Don't include naps

2.31 During a usual week, how many times do you nap for 5 minutes or more?
(Write **"00"** if the participant does not take any naps)

For this question, write the number of times the participant take nap for 5 minutes or more.

> **"Nap"** means a brief period of sleep usually during the day.

2.32 Please indicate how often you experience each of the following (refer to codes below)

This question is self-explanatory. Here, you need to ask how often the participant experience the following:
Have trouble falling asleep; Wake up during the night and have difficulty getting back to sleep; Wake up too early in the morning and be unable to get back to sleep; Feel unrested during the day, no matter how many hours of sleep you had; Do not get enough sleep and Take sleeping pills or other medication to help you sleep
Use these codes: Never = 1; Rarely (1/month or less) = 2; Sometimes (2-4/month) = 3; Often (5-15/month) = 4; Almost always (16-30/month) = 5

Important point to remember:

- **Probe** when old people say that they can't sleep or sleep for only 1-2 hours. Ask them exactly what time they sleep and wake up. Also, probe the nap periods.
- Please probe to get the correct answer.

PART- E: DIET HISTORY

In this part of the questionnaire we will elicit the dietary history of the participant. All questions are self-explanatory. Below are some specifications about certain words/phrases or questions for additional clarification.

2.33 Are you a vegetarian?

If the participant is a "vegetarian" then select "1" otherwise select "2". Please confirm the person is vegetarian not 'just the family'. Also, if a participant doesn't eat meat but eat egg; give that participant a code for vegetarian i.e. "1".

2.34 Do you take eggs?

If the participant eats egg then select "1" otherwise select "2".

2.35 Have you been advised a special diet?

Ask the participant if they have been **advised** by a doctor/ dietician to follow a special diet.

Note: If the answer to this question is "No" skip to Q2.36 otherwise move to the next question.

2.35a If YES, what diets are you currently following?

Please note, what diet the person is on, as suggested to him/her by his/her doctor or dietician. Please fill appropriate codes in the provided space. Please specify, if they chose a diet not given in options.

Since how many years are you on this special diet?

In this question, please write the number of years participant is following the special diet (if entered "1" in Q2.35a). If the participant is following more than one special diet then write the duration of all the diets followed by the participant.

2.36 How frequently do you use reheated oil?

Reheating of oil (even of the finest quality) again and again transforms it into trans-fatty acid, which is one of the main risk factors behind heart diseases and stroke. Please select down the frequency of reheated oil used for cooking in the household from the given options.

Reheated oil While frying food in hot oil the proteins and carbohydrates react with the oil. At high temperatures oil releases some harmful chemicals (Tran's fats, aldehydes).

It's health implications: Repeated use of the heated oil releases more of these chemicals. These chemicals cause cardio vascular diseases and cancers.

2.37 Which oil or fat do you commonly use for cooking?

Please write "1" for "Yes" and "2" for "No" for the type of oil/fat consumed by the participant and write the quantity (in ml/ gram) of the oil/fat to which they've said yes to. Next ask about the monthly consumption of the type of oil/fat (in ml/gram) the participant have said "yes" for, to measure the quantity (in ml/gram). Example is given below:

Type of oil	**Use (Yes=1; No=2)**	**Monthly consumption (in ml)**
Unsaturated fat		
Mustard oil	1	1000
Sunflower oil	2	
Soyabean oil	1	1000
Groundnut oil	2	
Ricebran oil	2	
Palm oil	2	
Sesame/til oil	2	
Cocount oil	2	
Olive oil	1	500
Other, please specify	2	
Saturated fat	**Use (Yes=1; No=2)**	**Monthly consumption (in grams)**
Butter	1	500
Ghee	2	
Vanaspati	2	
Other, please specify	2	

2.38 Usually what type of milk do you consume?

Please choose the appropriate option. If the participant is not able to tell you milk's type then just ask them the price and brand of milk that they purchase and colour of the packet. Use the local information to categorise it appropriately (Discuss with project coordinator/team leader). If the participant does not know please choose the option don't know.

2.39 How often is the meat you eat usually trimmed of fat?

Trimming of fat means removal of unwanted fat from meat. Choose the appropriate option.

Note: Some people ask the butcher to remove the fat (white layer) from meat while some prefer to remove it themselves. Please ask them the methods by which they remove fat from the meat.

Don't ask this question to vegetarians. For them, write "1" in the provided box.

2.40 In the past one year how often have you consumed foods from the following food groups? (FI should be sensitive to vegetarians while asking about non- vegetarian foods)

This section aims to obtain information about frequency of consumption of food groups and approximate amount eaten at one time by the participant.

Field interviewers should refer to the standard utensils showcard (page 108-115).

The table appended below illustrates the following example:

Example:

Meat: Participant consumes 1 large bowl of mutton once in a month

Poultry: Participant consumes chicken two times a week; 2 medium bowls/day; 1 bowl eaten at one time

Organ meat, fish, shell fish and crustaceans: Participant does not consume it

Fishes: Participant consumes fish curry weekly; thrice in a week; 2 times/day; 1/2 small bowl each time

Eggs: Once a day

Column 1: Food items are listed and named. Ensure that participant has understood what each food item means, otherwise elaborate by reading the examples mentioned within brackets with each food items.

2.40 In the **PAST ONE YEAR**, how often have you consumed foods from the following food groups? **[Write in the appropriate column]**

Food items	**Daily-1; eekly-2; onthly-3, Never or less han once a onth-4**	**Frequency**		**Approx. amount eaten at one time (refer to show cards)**	
		No. of days per month/ week	**No. of times/ day**		**Encircle one**
Meats [lamb, mutton, goat, veal, rabbit, beef, pork; their curries]	3	1	1	1PC3(A)	(Bowl) /Pcs
Poultry [chicken, turkey, duck, pheasant, quail; their curries]	2	2	2	1PC2(B)	(Bowl) /Pcs
Organ meats [liver, kidney, brain, spleen, heart and sausages nihari, paya]	4				Bowl/Pcs
Fish [fresh-water and sea-water fish; preserved fish such as salted fish, canned fish, dried fish]	2	3	2	1/2 PC1 (C)	(Bowl) /Pcs
Shell fish and crustaceans [crab, squid, prawns, molluscs]	4				Bowl/Pcs
Eggs [Includes preserved eggs, duck eggs]	1	30	1	1	(Pcs)

Column 2: Ask the participant how often (Daily=1; Weekly=2; Monthly=3; Never or less than once a month=4) s/he consumed that particular food items (given in column 1) in the past 1 year. Ask him/her to provide a response that is most applicable. This column would tell us the frequency of consumption-daily, weekly,monthly, less than a year or never of the food items mentioned in column 1.

Column 3: Column 3 has 2 sub-columns (number of days per month/week and number of times/day i.e serving size). This column would give us the information on how many **days** the participant consumed the particular food and on those days, how many **times** the food was consumed.

Sub column 1: For each food item note the number of days (fill if code is 1, 2 or 3 in column 1) Ex: In the above example fish curry is eaten by the participant weekly and he was eating fish thrice in a week.

Sub column 2: For each food item note the number of times a food item has been eaten by the participant per day. As per the above example, our participant is eating half servings of fish curry in a day.

Column 4: For each food item note the approximate amount eaten at one time (serving size) (refer to food model booklet) . In the example the participant has eaten 1/2 bowl of fish curry at one time. Show them the food model booklet and make them understand about the sizes

and write the appropriate code (PC1-PC5, B1-B4, C1-C5) with approximate level of food consumed (A-D). So, in the **Sub column 2** the FIs need to encircle "bowl".

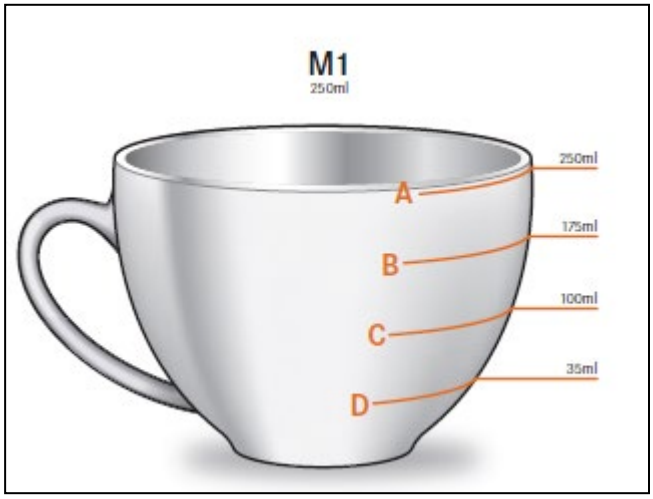
For each food item, ask the participant to select correct measure of spoon/bowl/glasses/mugs using food model booklet. For example in the food model booklet different sizes of spoons (S1-S5), mugs (M1-M3), Glasses (G1-G10) & Bowls (B1-B4, PC1-PC3) with different levels (A-D) is given for the participant to see and recall the correct size/amount consumed.

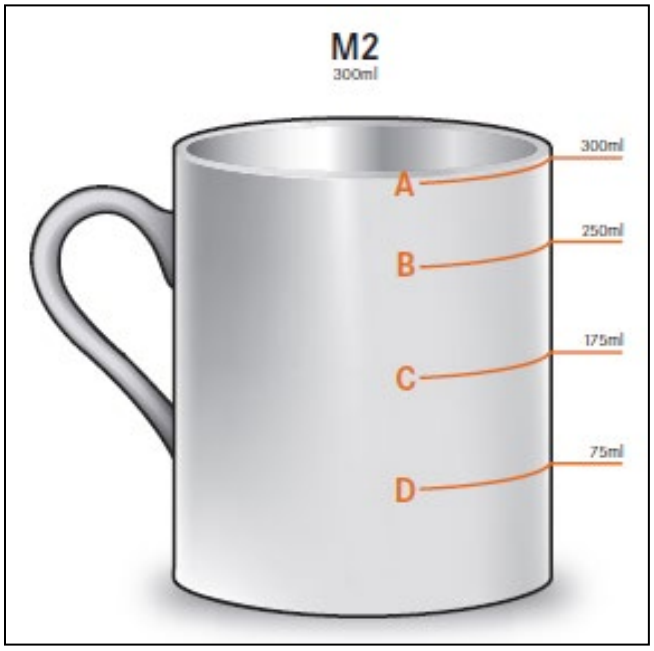
Note: Interviewers should be sensitive to vegetarians/vegans and restrict from asking about non-vegetarian foods. Being sensitive to cultural norms, for example, while interviewing people with special food preferences, caution should be exercised.

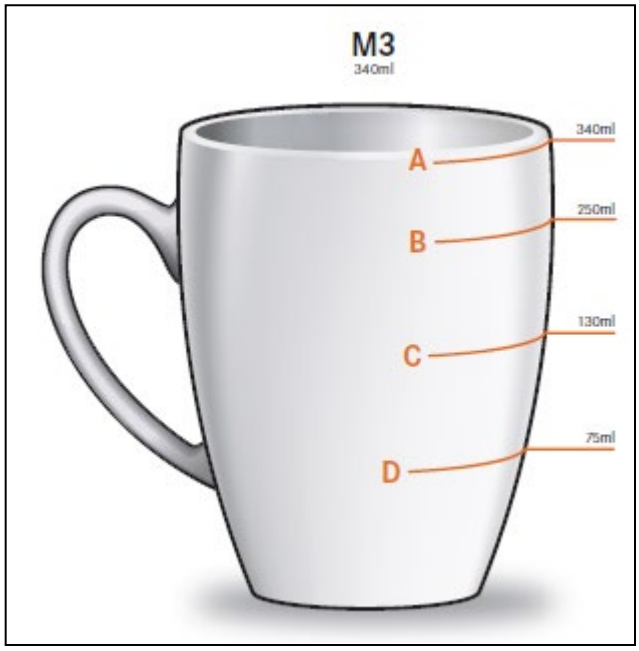
Standard Utensils Show card

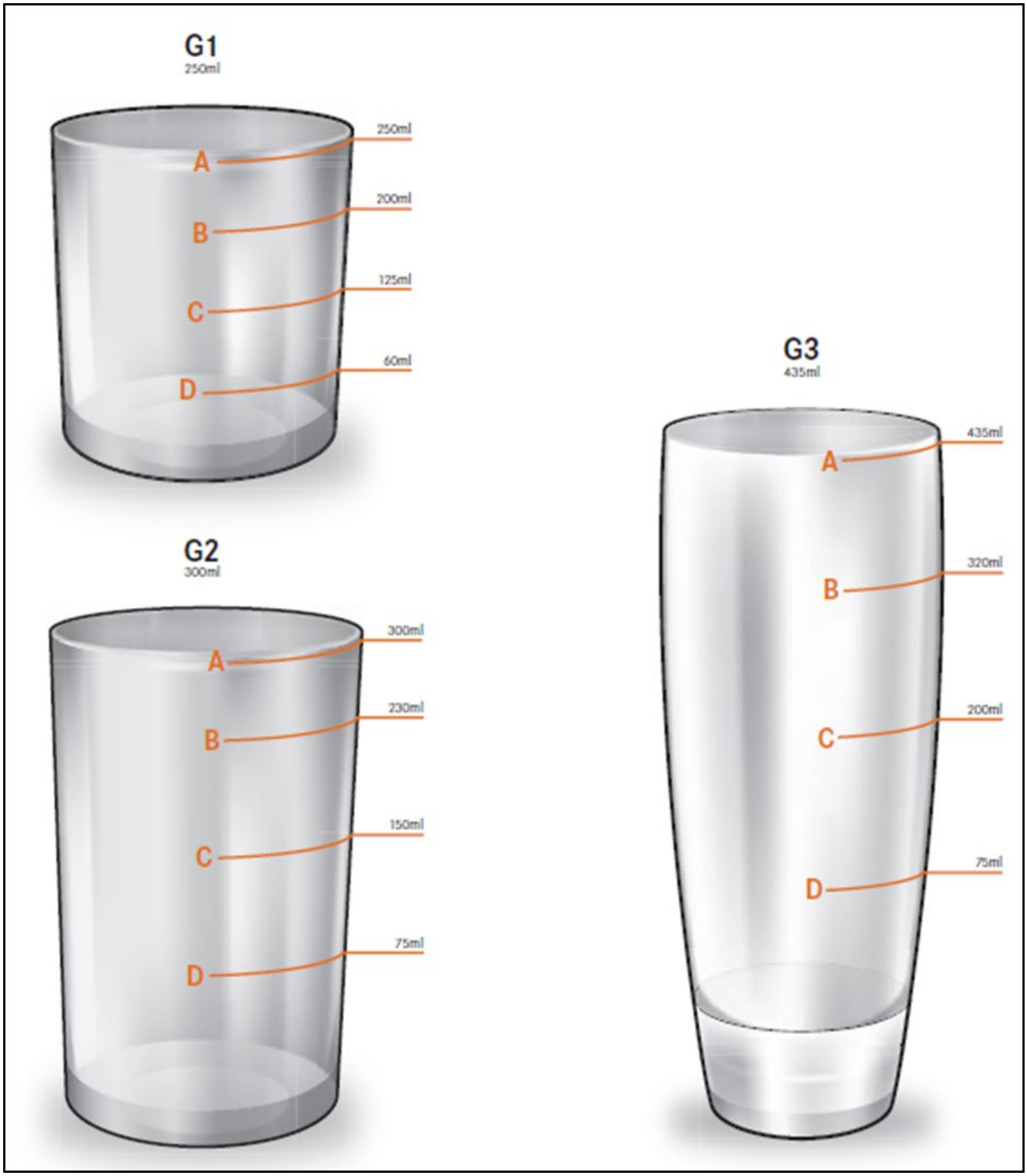
SPOONS

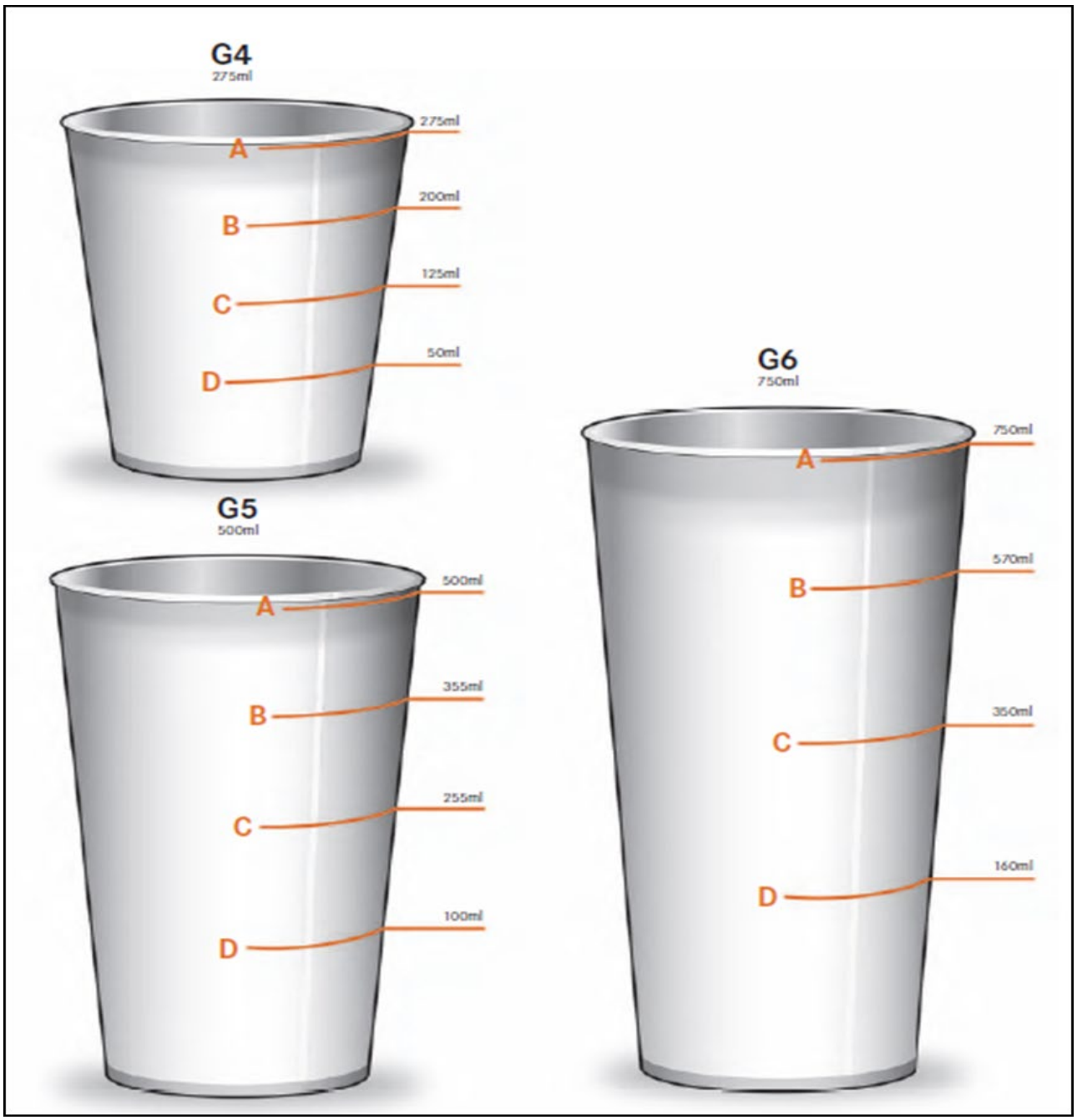
BEVERAGE CONTAINER

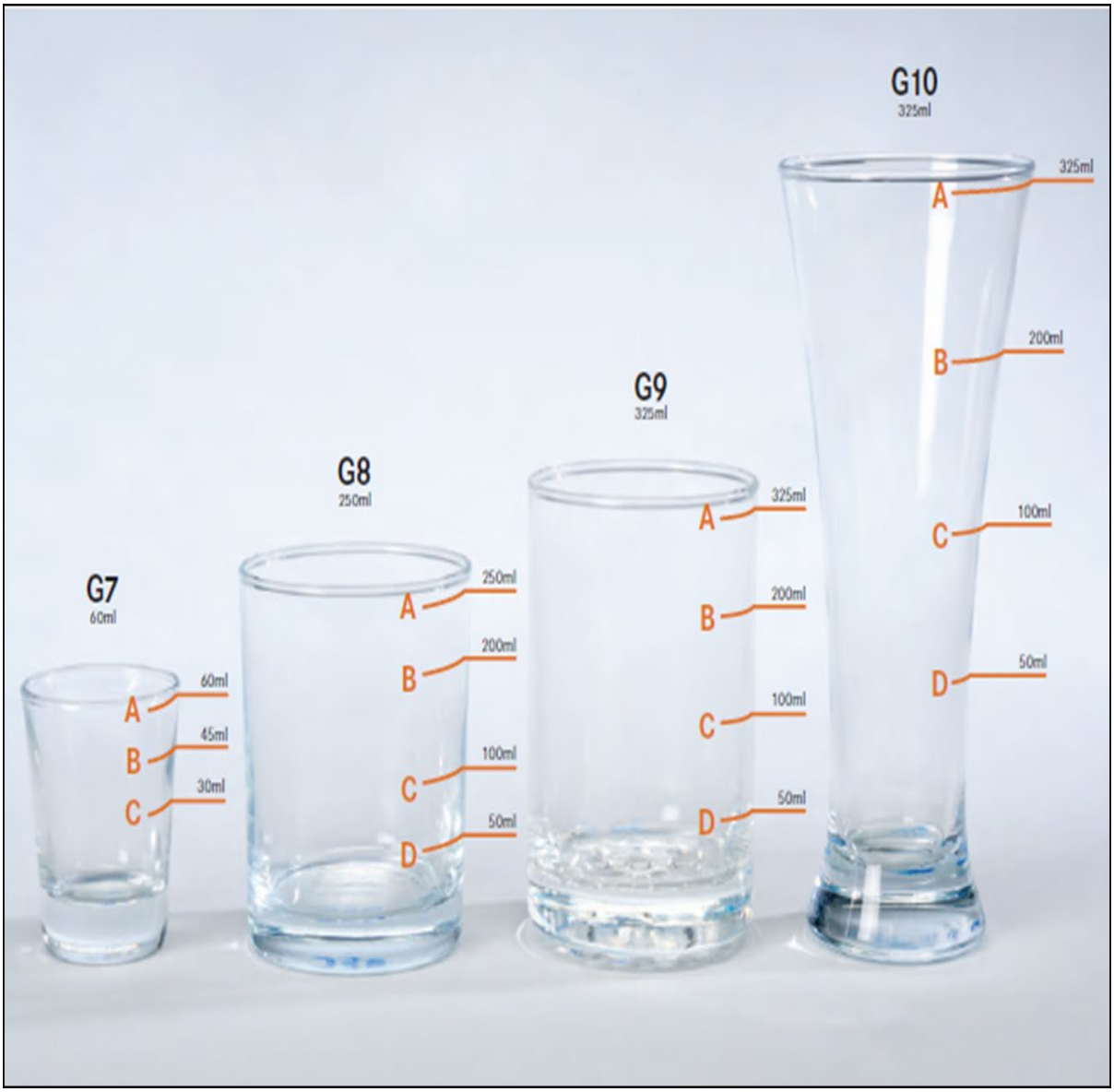







G1
250ml
A
250ml
B
200ml
C
125ml
D
60ml
G2
300ml
A
300ml
B
230ml
C
150ml
D
75ml
G3
435ml
A
435ml
B
320ml
C
200ml
D
75ml


G4
275ml
A
275ml
B
200ml
C
125ml
D
50ml
G5
500ml
A
500ml
B
355ml
C
255ml
D
100ml
G6
750ml
A
750ml
B
570ml
C
350ml
D
160ml


G10
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325ml
A
200ml
B
100ml
C
50ml
D
G9
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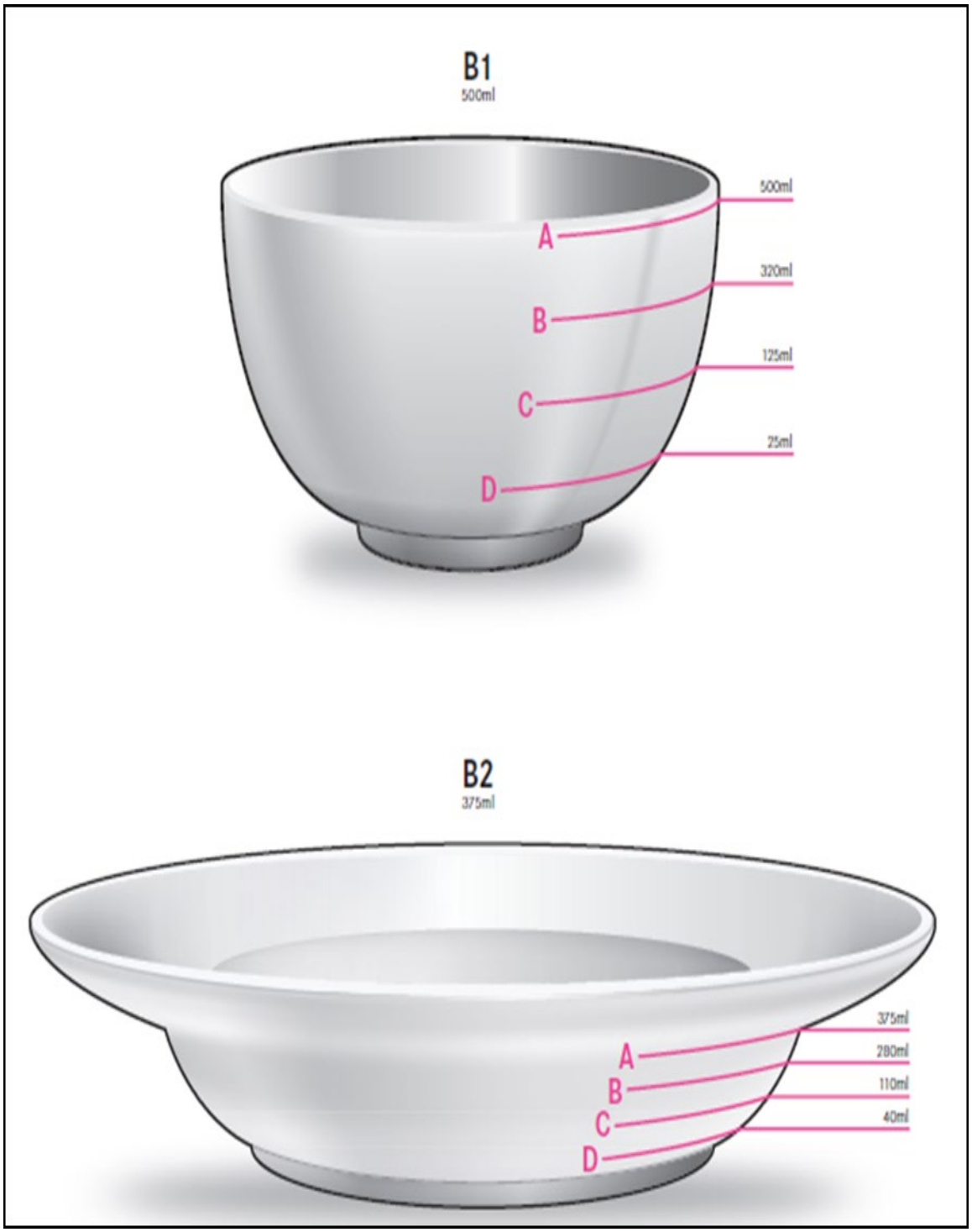
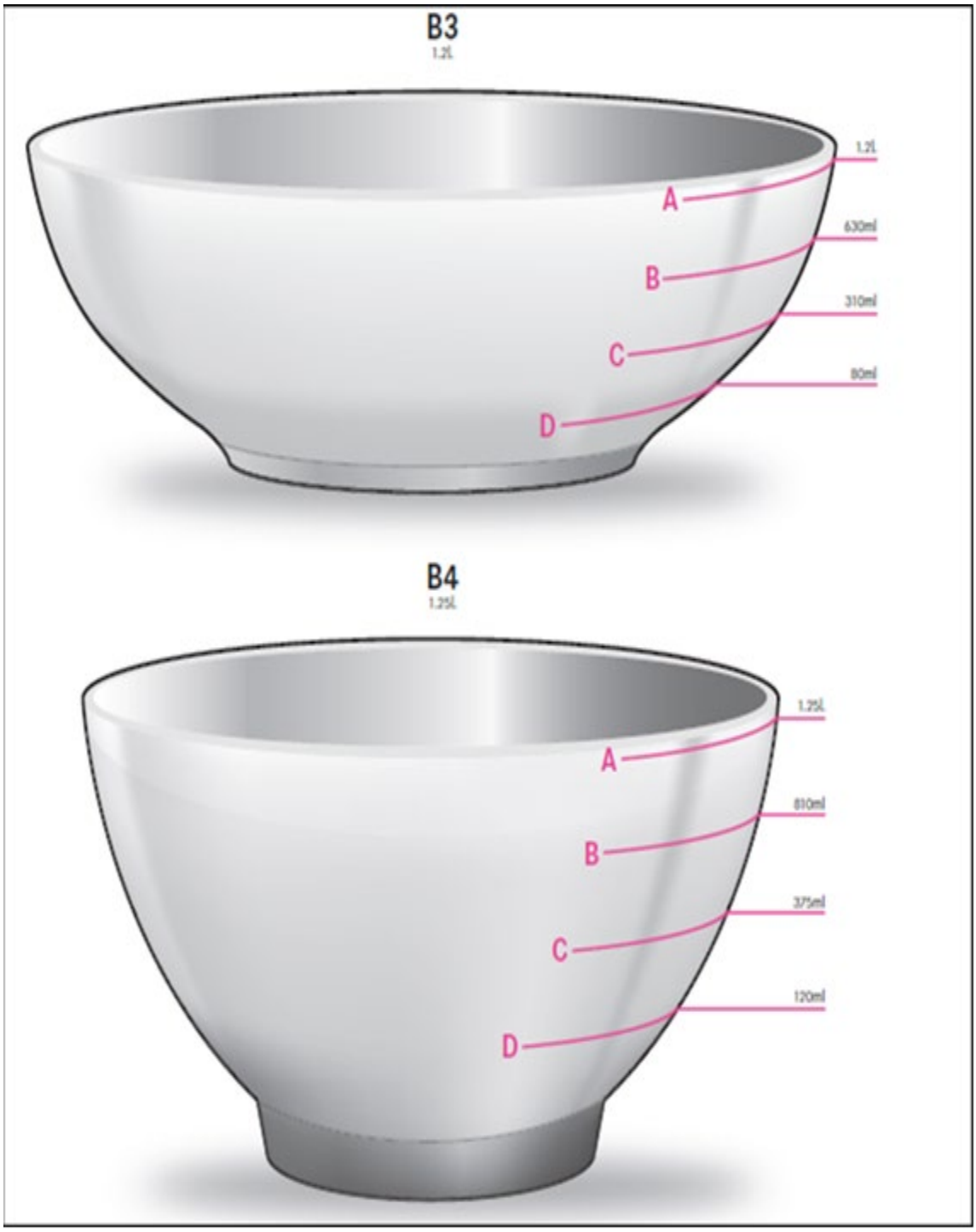
325ml
A
200ml
B
100ml
C
50ml
D
G8
250ml
250ml
A
200ml
B
100ml
C
50ml
D
G7
60ml
60ml
A
45ml
B
30ml
C

FOOD CONTAINERS




B3
1.2L
A
B
C
D
1.2L
630ml
310ml
80ml
B4
1.25L
A
B
C
D
1.25L
810ml
375ml
120ml

SECTION-3: MEDICAL HISTORY (CARDIO-METABOLIC DISEASES AND THEIR RISK FACTORS)

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- 3A: DISEASE SPECIFIC QUESTIONS

3A-I: HYPERTENSION (High Blood Pressure)/DIABETES (High Blood Sugar)/ HYPERLIPIDEMIA (High Blood Cholesterol)

*Exclude pregnancy induced Hypertension and High Blood Sugar

3.1 Have you EVER been told by a doctor that you have any of the following diseases: hypertension (high blood pressure)/diabetes (high blood sugar)/hyperlipidemia (high blood cholesterol)? (Yes-1, No- 2, Don't know- 3)

This question refers to the past history of patients regarding the diagnosis of any of the conditions [diabetes (high Blood Sugar)*, hypertension (High blood pressure)*, hyperlipidemia (high blood cholesterol) 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 questionnaire and write the code of the response as either "Yes" or "No" or "Don't know". The FI needs to ask Q3.2 (Part 3A-I) of only those conditions to which the participant says "Yes" in Q3.1.

If the answer is "Yes" to any of the choices in Q3.1, then go **Q3.2** otherwise **skip** t**o Part 3A-II**.

NOTE: If the answer is "YES" for any of the options provided in the Q3.1 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 '3' 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 has to be a confirmed diagnosis by a doctor.
3) If the answer is "YES" to any of the choices in Q3.1, then go to Q3.2 otherwise go to Part-3A—II.

What is Diabetes?

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

Diagnostic criteria:

Fasting plasma glucose ≥ 126 mg/dl or 2 hour post prandial glucose ≥ 200 mg/dl or HbA1C ≥ 6.5%.

What is 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.

Normal blood pressure is <120/80. If the blood pressure is ≥140/90 then it is considered as raised.

Classification of Blood Pressure for Adults*

BP Classification	SBP mm Hg		DBP mm Hg
Normal	<120	and	and <80
Prehypertension	120–139	or	or 80–89
Stage 1 hypertension	140–159	or	or 90–99
Stage 2 hypertension	≥160	or	or ≥100

* American Heart Association

What is blood pressure? What does "Systolic" and "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 units used to measure blood pressure.)

3.2 For how many years have you had high blood pressure/Hypertension; Diabetes; Hyperlipidemia/High Blood Cholesterol?

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.

EXAMPLES:

Example 1: If a 60 years old women had diagnosed with high BP at 40 years. Then for this, the answer would be 60-40= **20 years.**

Example 2: If a 60 years old women had diagnosed with diabetes at 45 years. Then for this, the answer would be 60-45= **15 years.**

Example 3: 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.

3.3 What treatment are you taking for it?

This question tries to know regarding different treatment strategies being followed by the 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:

Prescribed dietary modifications
Prescribed physical exercise
Traditional medicine/ therapy*
Allopathic drugs (English/modern)

*Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy and meditation.

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

3.4 When was the last time you consulted your doctor?

This question asks participants to report the last time they visited their doctor. The visit should be related to the condition for which these questions have been asked (E.g. If the participant suffers from high blood pressure – ask the participant, "When was the last time you consulted your doctor for the problem of high blood pressure?" The participant should choose the most accurate time frame from the options provided in the questionnaire **(less than 1 month=1, 1-3 months=2, 4-6 months=3, more than 6 months=4).**

3A-II: HEART DISEASE

3.5 Have you EVER been told by a doctor that you have heart disease?

Here, the most important thing is to note that we are asking the participant "have you **EVER been told** by a doctor that you have heart disease.

This question refers to the past history of patients regarding the diagnosis of heart disease. 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 3A-III** (stroke).

3.6 When did you first come to know that you have heart disease?

In this question ask the patient when he was diagnosed with heart diseases by consulting a doctor and choose the appropriate options **(<1 year=1; 1-5 years=2; >5 years=3).**

3.7 What did the doctor say it was?

Ask the participant to specify the cause for heart trouble and select an appropriate code from the options provided. If the reason is not included in the list then select "Others" and specify the cause in the space provided.

a) Heart attack

b) Angina

c) Heart failure

d) Valve disease

e) Hole in the heart

f) Not informed about the nature of the problem

g) Others

Note: If the answer to the above question is "heart attack" then move to next question (Q3.8) Otherwise go to Q3.12 OR don't move to Q3.8 if it is angina or other heart condition.

What is Heart attack, angina, heart failure, hole in the heart?

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.

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.

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.

Hole in the Heart: Heart problems present from birth.

Select one or more heart diseases which the patient has been diagnosed with. Select "Not informed about the nature of the heart problem" if the patient has been told by the doctor that he has a heart disease but not the exact diagnosis.

If the patient states that he has had a "Heart attack" which is the first option, you will write "1" and then move to next question (Q3.8) Otherwise go to Q3.12.

Q3.8 At what AGE did you have your first heart attack?

Remember this is AGE (not duration).

Specifically ask this question if the reason for the above question is "Heart attack". This should be the age at which the participant had her / his first heart attack.

EXAMPLE: If a 60 year old participant had his 1st heart attack 20 years ago. Then the answer to this question would be (60-20)= 40 years.

3.9 Were you hospitalized for treatment?

In this question we need to ask whether he/she was hospitalized for the treatment.

3.10 Did you have any repeat attacks?

In this question ask the participant if she/he had any other attacks after the first attack; choose the appropriate answer form options.

Note: If the answer to this question is "No" then skip to Q3.12.

3.11 Were you hospitalized for the subsequent attacks?

Participant may have more than 1 such subsequent attack. If they are hospitalized even once in subsequent attacks then opt "yes".

3.12 What treatments are you taking for heart diseases?

Ask the patient on what treatment is he/she currently on. He/she might be following different modalities like dietary modification, exercises, traditional medicine, and allopathic medicine. He/she might not be taking any treatment currently at all.

3.13 Ask the participant to show the medical records (if any) and note the diagnosis below.

Ask the participant if s/he has medical records or prescription related to the disease. If the participant does not have or does not know whether s/he has such records then skip to the next question. If the participant says that s/he has the records then politely request her/him to show you the records. Look through the medical records and prescriptions and note the diagnosis from them in the space provided in the questionnaire.

3A-III: STROKE (Paralytic Attack)

3.14 Have you EVER been told by a doctor that you have stroke (paralytic attack)?

This question refers to the past history of patients regarding the diagnosis of stroke (paralytic attack). 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 3A-IV** (Kidney).

What is 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.

3.15 What was your age when you had stroke (Paralytic attack)?

Remember this is **AGE not DURATION.**

Please note that this question tries to know at what age he/she had 1st attack of stroke. Record the response in years. If they don't remember exactly, then encourage them to recollect and ask them to give an approximate answer. Write the response in years.

EXAMPLE: If a participant is 80 years old and he had stroke at 50 years then the answer to this question would be 50. If he says that he had stroke 30 years ago then just calculate 80-30= 50 years.

3.16 Is there any residual disability in any part of the body?

Ask the participant if s/he has any residual disability in any part of the body that means any non- functional or semi-functional part in the body which was previously affected by episode of paralytic attack / stroke. If present mark as "Yes", and if absent mark as "No".

3.17 If yes, does it involve the following?

If answer was yes to the previous question, ask her/him to indicate the type of residual disability. Write "Yes" or "No" for appropriate answer.

- Paralysis of leg/foot
- Paralysis of arm/hand
- Weakness of leg/foot
- Weakness of arm/hand
- Defect of speech
- Defect of vision
- Urinary incontinence
- Any other weakness (specify)

Some definitions:

- **Paralysis** – Unable to move the affected body part/s due to stroke
- **Weakness** – Able to move, but unable to function the affected body part/s normally due to stroke
- **Defect of speech** – unable to speak normally due to stroke
- **Defect of vision** – Problem with eye sight due to stroke
- **Urinary incontinence** – Patient is unable to hold urine / flow of urine without the knowledge of patient as a result of paralytic attack.

If there is any other disability that the participant suffers from and is not listed in the questionnaire, then write "1" in the box against the option "**Any other weakness**" and specify the type of disability.

3.19 Ask the participant to show the medical records and note the diagnosis below.

Ask the participant if s/he has medical records or prescription related to the disease. If the participant does not have or does not know whether s/he has such records then skip to the next section. If the participant says that s/he has the records then politely request her/him to show you the records. Look through the medical records and prescriptions and note the diagnosis from them in the space provided in the questionnaire. From the most recent medical records / prescriptions / diagnostic test reports of paralytic stroke.

3A-VI: KIDNEY

3.20 Have you EVER been told by a doctor that you have kidney stone/kidney disease/kidney failure?

This question refers to the past history of patients regarding the diagnosis 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". Write "1" if you **EVER** been told by a doctor that you have developed or suffered from kidney stone, kidney disease or kidney failure in front of that option and for NO, write "2". If "1", ask the patient since **how long (duration)** has he/she been diagnosed with kidney disease/kidney problem in years or months except for kidney stones, where you need to write when you had its most recent episode.

Note: If the answer to any of the diseases is "YES" then continue the question in this part, otherwise **skip** to **Part 3A-V** (Cancer).

If "yes" for kidney stone, go to Q 3.21 and if yes for kidney disease or kidney failure go to Q3.22.

3.21 If YES, for kidney stones, what treatment was received

Depending on the response from the participant enter the code in the boxes against the list of the treatment provided in the question. If the response is not listed in the form, select "others" and specify the type of treatment in the provided space.

3.22 If YES, for Kidney disease or kidney failure

If the participant has undergone dialysis or kidney transplant for kidney disease or kidney failure, write "1" for YES and "2" for NO.

3A-V: CANCER

3.23 Have you EVER been told by a doctor that you have cancer?

This question refers to the past history of patients regarding the diagnosis 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 3B** (Peripheral Vascular disease).

3.24 The site for cancer was?

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

3.25 At which stage the cancer was diagnosed?

Write the appropriate code in the provided space.

Note: If multiple site in Q3.24., fill the 2nd box as well

3.26 Since how many years have you been suffering from cancer? (in years)

Please note, here you need to write duration (in years). Please write the number of years or months you have been suffering from cancer.

Note: If the participant have been suffering from more than one kind of cancer then write the duration of the oldest cancer (longest duration).

Write the duration in months/years

3.27 What was the primary treatment?

Write the appropriate code in the provided space.

Note: Primary treatment- First treatment that has been provided to the participant.

If others is selected, please specify in the provided space.

PART- 3B: PERIPHERAL VASCULAR DISEASE (PVD)

What is 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.

Q3.28 Do you get pain in either leg on walking?

Pain here means a strong, painful contraction or tightening of a muscle that comes on suddenly and lasts from a few seconds to several minutes. This question is put forward to assess the condition of peripheral vascular disease, where due to disturbance in blood supply, pain appears in the legs. If they reply **"Yes"**, move to **Q3.29**.

Note: If the answer is "2", skip to **Part-3C**

3.29 If YES, in which part of your leg do you feel it?

This question is asked to know the region where the pain experienced by the patient. Write the appropriate code (Pain including calf/calves=1; Pain doesn't include calf/calves=2) for the response.

Note: If the answer is "2", skip to **Part-3C**

3.30 Do you get it if you climb stairs or walking fast?

Through this question we want to know whether participant gets pain when walking fast or climbing stairs. Enter the response as either "Yes" or "No". Write code "3", if the participant doesn't climb stairs or walk fast.

Note: If participant says "No", skip to **Part-3C.**

3.31 Do you get it if you walk at an ordinary pace on the level ground?

This question tries to assess whether pain appears when walking at ordinary pace on the level ground. Write the response as either "Yes" or "No".

Note: If participant says "No", skip to **Part-3C.**

3.32 Does the pain ever disappear while you are still walking?

Through this question we were trying to assess the severity of the condition, whether the pain recedes or aggravate during walking.

Note: If participant says "Yes", skip to **Part-3C.**

3.33 What do you do if you get it when you are walking?

This question is put forward to know whether participant stops/slackens pace or continues to walk on appearance of pain on walking.

Note: If the answer is "2", skip to **Part-3C.**

3.34 What happens to it if you stand still?

This question is to know, what happens to pain if participant stands still. Select the response as either "Relieved" or "Not relieved".

Note: If the answer is "2" i.e. not relieved, skip to **Part-3C.**

3.35 If relieved, how soon?

This question tries to know how soon the pain gets relieved on standing still. Record the appropriate response in the box.

PART-3C: FRACTURES

3.36 Have you ever had a broken bone or fracture?

Ask the participant if s/he had a broken bone or fracture. Please include small fractures and hairline fractures as well. Write appropriate codes accordingly.

Note: if the answer to this question is yes then go to Q3.37 otherwise skip to Q3.38.

3.37

3.37 If yes	did that involve (Yes=1, No=2)	Age at fracture*	Was this due to fall from standing height (example, falling in bathroom, fall while walking) (Yes=1, No=2)	If no, what was the cause?
Hip				
Wrist				
Spine/ Vertebra				
Others		Specify :-		

If the answer to the above question is "yes" then ask this question. For this question, please ask the site of fracture (is it hip/wrist/spine or vertebra/any other bone) and write yes or no in the corresponding column (2nd column). If others is selected then specify (which bone).

If the participant has said yes for any of the site given in the 1st column (Hip, wrist, spine/vertebra) then write the age of the participant at which he had fractured that bone (in the 3rd column).

Ask the participant whether that fracture was due to fall from standing height (example, falling in bathroom, fall while walking). Write "1" or "2" depending upon participant's response.

If the participant has said that the fracture was not due to fall from standing height then ask the reason for that fracture (in the 5th column).

* *If they had multiple fracture note the age of most recent fracture*

3.38 Has either of your parents or siblings had a fracture of the hip, wrist or spine?

Please ask the participant if either of his/her parents or siblings had fractured their hip, wrist or spine in their lifetime.

PART- 3D: COMPLICATIONS (This section will be applied to all participants not just for diabetes)

This part of the questionnaire should be filled for all the participants.

3D-I:- FOOT ULCERS AND AMPUTATION

3.39 Have you ever had a non-healing ulcer/sore in the foot that took more than 4 weeks to heal?

This question put forward to know whether patients have had any non-healing ulcers or sores. A non-healing ulcer can be defined as any wound or ulcer on skin that has been present for 3-4 weeks duration, without healing.

3.40 Do you walk around bare foot?

If the participant walks around bare foot answer the question as "Yes".

3.41 Have you had an amputation?

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 part (3D-II) on complication of eyes.

3.42 If 'YES', When?

Record the response in years and months when he/she underwent the amputation.

3.43 What was the level of amputation?

If answer was "Yes" to Q3.42, ask her/him to indicate the level of the amputation. Write the appropriate code in the box.

3.44 What was the cause for 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; Others=4**). If the reason for amputation is "others" then specify the reason in the provided space.

If participant was unable to give the exact information refer to her past medical history or diagnostic reports.

3.45 Do you have medical records or prescriptions?

If the answer is "Yes", ask the participant to show the medical records and note the diagnosis below.

3.46 Ask the participant if s/he has medical records or prescription related to the disease. If the participant does not have or does not know whether s/he has such records then skip to the next part-3D-II. If the participant says that s/he has the records then politely request her/him to show you the records. Look through the medical records and prescriptions and note the diagnosis from them in the space provided in the questionnaire.

This finishes with the "foot ulcers and amputation" part and move to next part 3D-II "Eyes".

3D-II:- EYES

3.47 Do you have 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 eye sight for which spectacles have been prescribed.

Note: If the answer is "**No**" then **skip** to **Part 4- Drug information**.

3.48 If 'YES', what was the diagnosis?

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 **(Physician-diagnosed cataract=1; Physician diagnosed retinopathy=2; Both, Physician-diagnosed cataract and retinopathy=3; Others=4)** for the stated response.

If others then specify the reason in the provided space.

3.49 Have you undergone laser therapy (Photocoagulation) at any time?

Laser therapy / photocoagulation is a surgical procedure on the eye to treat a number of eye diseases such as diabetic retinopathy, age related macular degeneration, glaucoma, etc.

3.50 & 3.51 Do you have medical records or prescriptions? If the answer is 'YES', ask the participant to show the medical records and note the diagnosis below.

Ask the participant if s/he has medical records or prescription related to the disease. If the participant does not have or does not know whether s/he has such records then **skip** to the **section 4 (drug information)**. If the participant says that s/he has the records then politely request her/him to show you the records. Look through the medical records and prescriptions and note the diagnosis from them in the space provided in the questionnaire. From the most recent medical records / prescriptions / diagnostic test reports of Eyesight.

What are diabetic complications – retinopathy, neuropathy, nephropathy?

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).

Diabetic neuropathy: High blood sugar can injure nerve fibers 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.

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-4: DRUG INFORMATION

4.1 In the past one week, have you taken any Allopathic drugs (English / modern) for any disease?

In the past week if the participant had taken any allopathic drugs write "1" for YES and "2" for NO. If "1" go to Q4.2 and if "**2" skip** to **Section 5**.

NOTE: We are noting about the medicines that the participant had consumed in the **past 1 week**. We will note the duration of consumption in appropriate time-frame (Years/ months/ week/days).

4.2 If yes, provide details of all the medication that the participant is taking at the time of survey in the below columns.

Write the names of all the allopathic drugs that the participant has taken in the past 1 week, Since when they are taking that particular drug, select the code (Years=1; months=2; week=3; days=4) for the appropriate time measures.

WRITE THE NAME OF THE DRUG IN "CAPITAL LETTERS"

EXAMPLES:

Example 1: If a patient of high BP is not consuming/ skipping his medicines for part 1 week then the answer to Q4.1 would be NO and go to section 5. But if that person is has consumed any other medicine (pain killer etc) then the answer to Q4.1 would be yes and include that painkiller's name in Q4.2 (don't write the name of his BP medicine in Q4.2- as he is didn't take his medicine for last 1 week).

Example 2: if a participant is diabetic and has been consuming medicines for past 3 years then write the name of the drug in CAPITAL LETTERS and write 03 in the adjacent column and write the code "1" for years (to know the appropriate time measure). Same participant has also started taking medicines for his high BP from past 7 days then write 07 in the adjacent column and write the code "4" for days.

SECTION-5: TREATMENT HISTORY AND EXPENDITURES

The purpose of this section is to gain knowledge about the treatment history of participants and also to know the expenditure incurred by participants for treatment of diseases over a period of 6 months (for outpatient) and one year (for inpatient). This section is divided into three parts (outpatient, inpatient and hospitalisation cost) to capture the details of treatment and expenditure related to outpatient and hospitalization. Below are specifications for questions that require additional clarification.

PART- 5A: OUTPATIENT

This part of the section is to elicit the outpatient treatment history and its related expenditure for participants.

5.1 Are you undergoing treatment as an out-patient for any of the following reasons?

Show the participant the questionnaire 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

Ask the participant to select the disease/s from the list for which s/he had been undergoing treatment as an outpatient. 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.

Since in this study we are interested to know about the treatment expenditure for limited non-communicable diseases so restricted options are given for this particular question. If respondent has under gone treatment for other than mentioned diseases then it is not taken into account as it is beyond our study interest

Note: If the answer to any of the above is "Yes" go to the next question **OTHERWISE** skip to **PART-5B: 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.

In the following questions ask the details of treatment and cost only for the LAST 6 MONTHS

5.2 List the expenditure incurred towards above mentioned conditions in the last 6 months (Q5.1) in the given table

Name: Write the name of the clinics/ labs/ physical and occupation rehabilitation centre the participant was/is going to in the past 6 months due to his/her above mentioned conditions (in Q5.1). It will help you to ask further questions like instead of "that lab from which you get your blood test done" you can ask them the same question by that lab's name and this makes easier for you to ask rest of the questions.

Type of setting: 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 Q5.1) in past 6 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 care free 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.

Note: For "home nurse/carer", please leave it empty.

No. of visits/No of days*: Write the number of times respondent visited a health

clinic/doctor/therapist/lab/rehabilitation centre etc in past 6 months for treatment of above mentioned diseases (Q5.1).

* Include all the investigations examples blood tests, urine tests, ECG, echocardiogram, X ray, CT scan/MRI, dialysis, ultrasound etc

Note: For home nurse/carer write the number of days, he/she took care of you. For physical and occupation rehabilitation, it can be number of days a participant spent in the rehabilitation centre or number of visits a participant make to the centre.

Total amount spent (in rupees): Request the participant to provide information about the total amount of money that s/he has spent in the past 6 months to meet the expenses on treatment and visits.

Mode of payment: Ask the respondent about all the sources through which they paid for the treatment. Depending on the response, enter the appropriate code [Own savings/family member paid=1; Employer paid=2; borrowed from friend/relative/employer=3; borrowed from bank=4; sold house/land or other assets=5; health insurance=6; Free medical treatment (govt hospital, CGHS, ECHS, ESI etc)=7] in the boxes provided against the options.

- Own savings/family member paid: If the participant and/or his family pay the money and s/he does not have to return it.
- Employer paid: If the employer pays the money and s/he does not have to return it.
- Borrowed from friend/relative/employer: If the money is borrowed from friend/relative/employer i.e. in some point of time, the participant has to return the money.
- Borrowed from bank: If the money is borrowed from a bank i.e. in some point of time, the participant has to return the money
- Sold house/land or other assets: If the participant had to sell his/her house or any other asset in order to pay for the expenses incurred due to the above mentioned conditions (Q5.1) OR at first the money is borrowed from a friend and in order to pay him; the participant sells his/her asset.
- Health insurance: If the participant has health insurance and s/he pays his/her medical

bills by using that. Health insurance is of two types i.e. cashless and claim-cash.

- **Direct Payment or Cashless Facility:** Under this facility, the person does not need to pay the hospital as the insurer pays directly to the hospital. Under the cashless scheme, the policyholder and all those who are mentioned in the policy can undertake treatment from those hospitals approved by the insurer.
- **Cash-Claim**: After staying for the duration of the treatment, the patient can take a reimbursement from the insurer for the treatment that is covered under the policy undertaken.

- Free medical treatment (govt hospital, CGHS, ECHS, ESI etc): If the participant didn't pay any money or get free medical treatment i.e. got treated in government hospital or are the members of government health schemes like Central Government Health Scheme (CGHS), Ex-Servicemen Contributory Health Schemes (ECHS), Employee's State Insurance Corporation (ESI) or any other scheme.

Note: Note the source from which >50% of money was paid. For example, if to meet the expenses on treatment and visits the participant spends money from his own savings (40%) and 60% of that expense is paid by selling one of his asset. Please select the option from which higher percentage of money is coming from i.e selling his assets (option 5).

Distance from home: This question is to elicit the approximate distance from home to the places the participant was visiting due to his/her above mentioned conditions (in Q5.1) in past 6 months i.e. clinics (setting 1,2,3 or 4), labs (setting 1 to 4), physical and occupation rehabilitation (setting 1 & 2).

Note: For "home nurse/carer", please leave it empty.

If the participant visited clinic 1 consultation and on the same visit he got his blood work done. In that case please write the number of visits and distance from home in the corresponding column of clinic 1 and leave the same columns empty for lab setting 1. Please specify the same detail in "others" column.

Also, if the participant spends money on his/her due to the diseases mentioned in Q5.1 and is not covered in Q5.2, please write its detail in others column.

Example: In the past 6 months, a participant visited Kapoor's clinic twice and AIIMS once and total amount spent is Rs 2000 (own saving) and 20. Besides this, he also got some test done at Kapoor's clinic for Rs 1000 in same visit. The tests performed at Lal Path Labs which costs him Rs 5000 (which he borrowed from his friend). He was rehabilitated at Avantika rehabilitation centre for a month due to amputation of a leg, which costs him Rs 70,000 (for which he had to sell a piece of his land). In addition, he bought glucose strips for himself (costs him Rs 1500- own saving) from the place which was near to his home.

In the following questions ask the details of treatment and cost only for the LAST 6 MONTHS

5.2 List the expenditures incurred towards above mentioned conditions in the last 6 months (Q.5.1) in the given table

		Names	Type of setting (govt=1, pvt=2, charity=3 others =4)	If others, specify	Number of visits/No. of days *	Total amount spent (in Rs)	Mode of payment^	Distance from home (km)
A	**Consultation**							
	Clinic -1	Kapoor's clinic	2		2	2000	1	3
	Clinic -2	AIIMS	1		1	20	7	5
	Clinic -3							
	Clinic-4							
B	**Laboratory/other investigations**							
	Setting-1	Kapoor's clinic	2		1	1000	1	
	Setting-2	Lal Path	2		3	5000	3	2
	Setting-3							
	Setting-4							
C	**Home nurse/carer**							
D	**Physical and occupation rehabilitation**							
	setting-1	Avantika	2		30	70,000	5	10
	Setting-2							
E	**Others #-specify**	Glucose strips	4	Mehra Medicos	1	1500	1	0
	Others #-specify							

*** Include all the investigations examples blood tests, urine tests, ECG, Echocardiogram, X-ray, CT/MRI scans, dialysis, ultrasound etc.**

 # Example- self monitoring of blood glucose

^ Mode of payment – options

Own savings/family member paid=1	**Borrowed from friend/relative/ employer =3**	**Sold house/land or other assets=5**	**Free medical treatment (government hospital, CGHS, ECHS, ESI etc)=7**
Employer paid=2	**Borrowed from bank=4**	**Health insurance=6**	

5.3 Total amount of money spent in rupees on MEDICATIONS for the diseases mentioned in Q5.1 in the last 6 months.

Write the total amount of money (in rupees) spent on medications for which the participant has said yes to Q5.1 in the past 6 months ONLY.

PART 5B-I: INPATIENT

This part of the section is to elicit the inpatient treatment history and its related expenditure for participants. Below are specifications of questions that require additional clarification.

5.4 Were you hospitalised for any illness in the past 12 months?

This question is to know whether respondent has been hospitalized for any reason in past 12 months/1 year. If respondent has been hospitalised then write "1" otherwise "2" but incase individual is unable to recall the event of hospitalisation then write "3".

Note: If options "2" or "3" is filled in the box, go to Q.5.7.

5.5 If yes, how many times?

If respondent has been hospitalised then ask the number of times been hospitalised in past 12 months.

Note: This is "number of times" not "day".

5.6 Were you admitted for any of the following reasons?

Ask the reason for hospitalisation. Write "1", if any of the mentioned disease has been the reason for hospitalisation otherwise write "2".

5.7 Have you undergone any surgical procedure in the past 12 months?

Ask the respondent whether they have under gone any surgical procedure in the past 12 months. Record the answer as "Yes" even if it is minor or major surgery.

5.8 If yes, what was the procedure?

Depending on the response from the participant enter the code in the boxes against the list of the procedures provided in the question. If the response is not listed in the form, select "others" and specify the type of procedure.

5.9 Do you have medical records related to hospitalization /surgical procedure?

If the response is "Yes", request the participant to show the medical records and note the diagnosis in a chronological order separately for hospitalisation due to any illness and surgical procedures in the space provided. If there are any additional comments please note in the space provided for comments.

PART 5B-II: HOSPITALISATION COST

Fill this section only if the participant has undergone hospitalization due to illness or procedure mentioned in Q5.6 and Q5.8 of PART 5B-I, otherwise go to "section 6".

For each hospitalisation note the following details, starting the first hospitalisation in **past 12 months.** If the number of hospitalisation is more than three then use a second form to complete the history.

5.10 When were you hospitalised?

For each hospitalization, ask the respondent when were you hospitalised? Write the exact date, month and year. In case the participant didn't remember check with the medical records.

5.11 How many days did you stay in the hospital?

Ask the number of days respondent stayed in the hospital and then write in the box provided.

5.12 Type of hospital

Select the type of hospital in which they were admitted whether it was a private or Government facility or charity hospital or any other facility. If the option is not available in the list then write "1" for "others" and write the type of hospital used.

5.13 Name of hospital (Address)

Write the complete name and postal address of the hospital along with pin code.

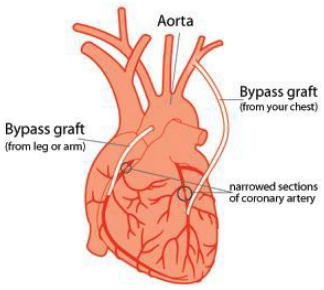
5.14 What type of treatment/procedure/surgery did you undergo?

Appropriately write "Yes" against the treatment/procedure/surgery from the list of options provided.

Note: Cross-check with the medical records and information in Part-5A

What is bypass surgery?

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.



What is valve repair?

Valve repair is a procedure done on heart valves which have become diseased or damaged. Valves are an important part of the heart. They regulate the flow of blood from one chamber of the heart to another. When the valves are damaged, the regulation of flow is disturbed, resulting in severe strain on the heart. Sometimes the damage is so severe that valve needs to be replaced instead of being repaired.

What is amputation?

Amputation 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.

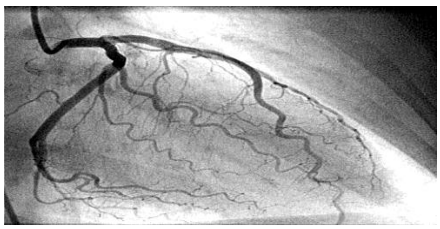
What is transplantation?

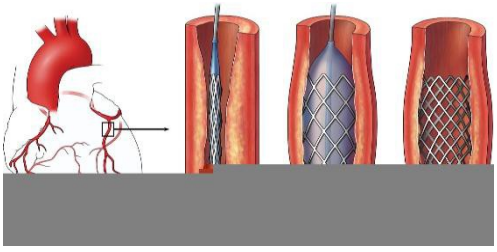
Transplantation is a surgical procedure where a new organ is placed inside the body of a person in place of a damaged organ. Common organs which are transplanted are heart, kidney, cornea etc. transplantation surgeries are the final modality of treatment in most cases and cost a lot. After transplantation, the person has to take lot of medication for long duration so that the transplanted organ works correctly.

What is 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.

Angioplasty is a therapeutic procedure carried out to clear blockages present in the blood vessels supplying the heart.





What is echocardiography?

Echocardiography 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.

What is dialysis?

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.

What is a pacemaker?

A pacemaker is a small device that's placed in the chest or abdomen to help control abnormal heart rhythms. This device uses electrical pulses to prompt the heart to beat at a normal rate. The electrical impulses are of low strength to correct less dangerous abnormal heart rhythm.

5.15 Total amount spent on treatment (hospitalisation expenses + medicines purchased during the stay)

This should be the total of all expenses related to treatment of the participant.

5.16 Number of days attendant stayed with you in the hospital

Ask respondent about the number of days attendant stayed with them in the hospital. Write the exact number in the box.

5.17 Distance from home to hospital?

Write the distance in km from home to hospital in the box provided. This is only one side distance.

5.18 Cost of travel from home to hospital (excluding ambulance cost, if any)

This should be the cost incurred per person for travelling from home to the hospital. If private vehicle is used then cost of fuel to be reported and if public transport is used then report the total travel cost.

5.19 How do you pay for your hospitalisation costs? Ask respondent about how the he/she will pay for their hospitalisation costs.
5.20 If used, which type of insurance have you used? If the participant has answered "yes" for health insurance in Q5.19 then ask the respondent about the type of insurance [govt health insurance, social health insurance, commercial health insurance (employer paid), commercial health insurance (self-paid)] used to pay his/her hospitalisation cost. If the answer to this question is others then specify in the provided space.

SECTION-6: FAMILY HISTORY

This section of the questionnaire captures the family history of the participant. Please note that the "Family" refers to respondent's blood relatives i.e. father, mother, son, daughter, sister and /or brother. It does not include respondent's spouse.

6.1 Has anyone in your family suffered from any of the following diseases, before the age of 60 years?

Family history about four diseases: Diabetes Mellitus (high blood sugar), Hypertension (high blood pressure), Heart disease (All these conditions- Angina/heart attack/ heart failure grouped in heart disease) Stroke (Paralytic attack) and cancer.

The answer would be either "Yes", "No" or "Don't know" for the above mentioned diseases. Answer should be recorded in the questionnaire.

If the answer is "Yes" for any of it, then the next question **(Q6.2)** would be who has suffered from that disease. Write appropriate options (Yes=1; No=2; Don't know=3; Not applicable=9). For heart disease and stroke, write the age (in years) when the respondent's relative had suffered from 1st attack.

If a participant has 3 brothers A, B and C and "A" is diabetic and hypertensive then, write code for yes in the column adjacent to Brother A only. In addition to this if his brother "B" has heart disease then write code for yes in the column adjacent to brother B (**NOT for brother A)**

Example:

If the participant has 2 brothers, a son and a daughter. His father has suffered from a stroke. Then for stroke write "1" in Q6.1. In Q6.2, write the code "1" adjacent to father under stroke and write "9" or not applicable for brother 3 and sister 1,2 and 3 and code "2" for his son, daughter, mother, brother 1 and 2.

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 he/she said "Not at all" write "1" OTHERWISE write the code for any one 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.

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.

What is PHQ?

PHQ stands for Patient Health Questionnaire. It is a multiple choice questionnaire for screening and diagnosing mental health disorders like depression, anxiety etc. This questionnaire is used in primary care settings.

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".***

Q.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.

Q.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.

Q.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.

Q.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.

Q.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.

The **scale** is described in the next page.

To help 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.

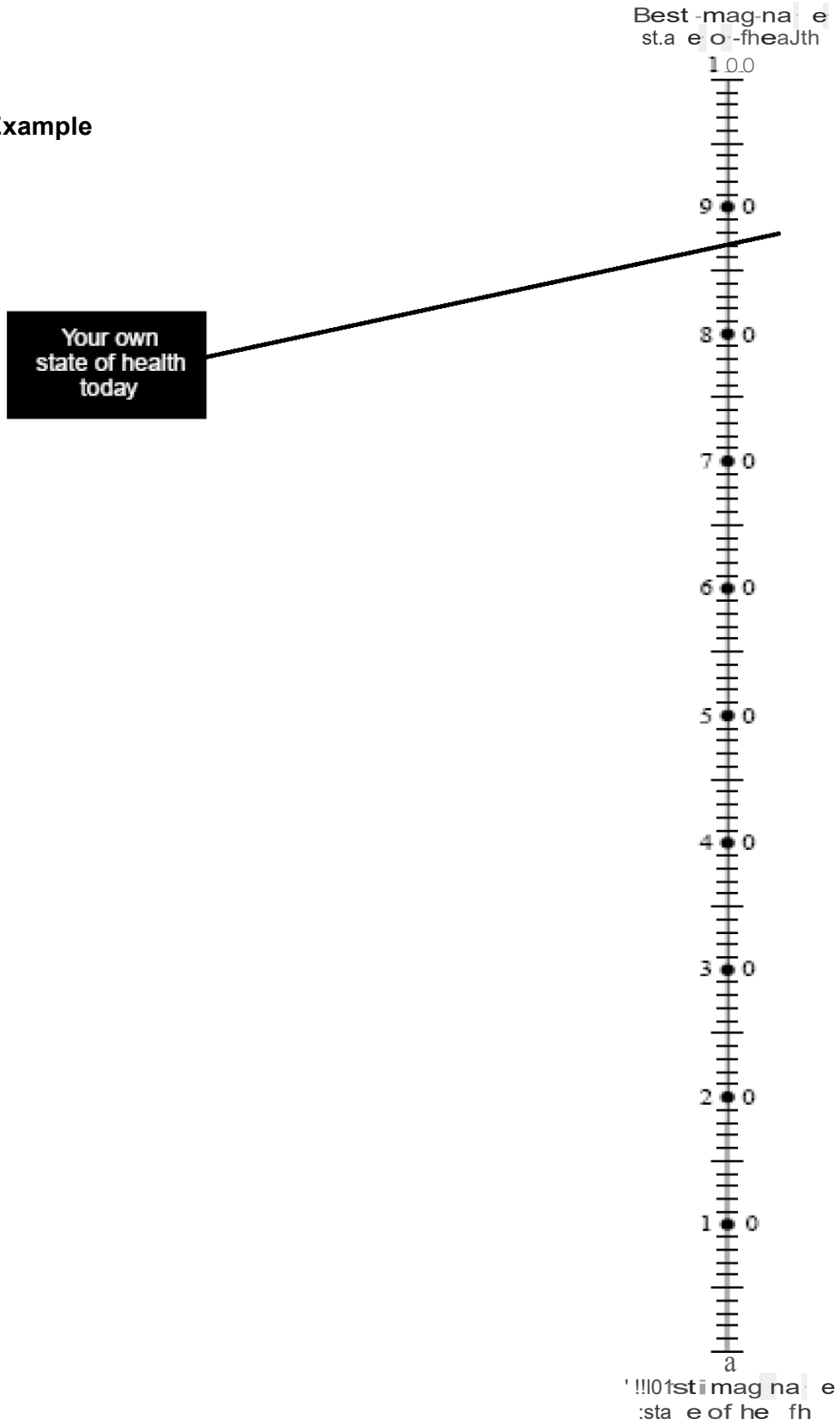
Ask the participant to indicate on this scale how good or bad her/his own health is on the day of interview. This should completely be the subjective feeling of the participant

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 bad her/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.

Example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a
Your own state of health today

SECTION-9: 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.

9.1 At what AGE did you start menstruating?

The question tries to know about the AGE **NOT** number of years ago at which respondent started having her menstrual cycle. The answer would be the age in years and enter the same in the box.

EXAMPLE: If a 20 years old girl started to menstruate at 12 years. Then answer to this question would be **12 years.**

9.2 Are you currently having menstrual cycles?

It should be answered as "Yes" or "No". If "No" then ask Q. 9.3. If the answer is "Yes", skip to Q. 9.5.

What is menstrual cycle?

Menstrual cycle is the monthly series of changes that takes place in a woman's body. Every month an egg is released from the ovary and hormonal changes take place. If the pregnancy does not happen then the lining of uterus is shed as blood. This is known as menstrual period. The normal cycle is of 3 – 5 days every. Periods happen 21 to 35 days apart. Periods are not the same every month and varies between one female to another.

9.3 If 'No' what is the reason?

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

What is menopause?

Menopause is a natural phenomenon where a women stops having her periods, permanently, due to lack of hormone secretion by the ovary. It can be **natural** (due to ageing) or **surgical** (removal of ovaries and/or uterus through surgery/radiotherapy). After menopause, the risk of cardio vascular diseases and osteoporosis (weakening of bones) increase.

9.4 If menopausal, since how long?

Remember in this question we'll ask since **HOW LONG (duration) NOT** age. If the participant is postmenopausal (natural or surgical menopause-not having menstrual cycle). Ask her since HOW LONG (years and month) she is menopausal.

Note: Ask this question if Q.9.3 is filled with option 3 or 4.

EXAMPLE: If a 60 years old women had her menopause at 45 years. Then for this, the answer would be 60-45= **15 years.**

9.5 When was your last menstrual period?

In Q.9.5, ask the participant when she had her last menstrual period and if the participant is unable to recall the exact date, ask her to remember how many years/months/days ago she had her last menstruation period (for **Q.9.5a**).

NOTE: Note the exact date and move to Q9.6. If the participant can't recall the exact date move to Q9.5a

9.5a If the participant can't recall the date

Ask this question, if Q9.5 is not filled.

In this, ask the participant to remember how many years/months/days **AGO** she had her last menstruation period.

If she is unable to tell this (mostly in case of older women), ask them to relate it with some major event in her life e.g. birth of her grandchild, marriage of her children etc.

9.6 Have you used hormonal drugs or oral contraceptive pills?

Ask the participant if she ever used hormonal drugs/OCPs in the past or using it currently. If the answer to any one of the option is "YES" then write the time period for which she took/taking the drugs/OCPs.

Have you ever used hormonal drugs/ oral contraceptive pills (not including current use)?

If the participant says "Yes" then ask duration of its use and if the answer is "No" then ask "are you currently using it?"

Duration of use (since how long)?

If the answer for "ever used hormonal drugs/OCPs" is "Yes" then then note down the duration of usage in years and months.

Are you currently using?

Ask the participant whether she is "currently using any hormonal drugs/OCPs" if the answer is "Yes" then ask its duration of use" and if "No" move to Q9.7 ((Ask this question discreetly/ don't ask for unmarried woman unless there is strong reason to do so).

Duration of use (since how long)?

If the answer for "currently using hormonal drugs/OCPs" is "Yes" then then note down the duration of usage in years and months.

What are Hormonal Drugs/Oral Contraceptive pills?

These are medicines containing hormones (oestrogen &/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.

What is Hormone replacement therapy?

After menopause the risk of some disorders like cardiovascular diseases, osteoporosis increases. Women also experience symptoms like hot flushes. In order to decrease that, hormones needs to be supplemented for the lack of it. This is known as hormone replacement therapy

9.7 Number of pregnancies so far? (Ask this question discreetly/ don't ask for unmarried woman unless there is strong reason to do so)

This question includes all pregnancies, regardless of the outcome. The participant should include live births, multiple birth (twins, triplets etc.), stillbirths (death after five months in utero), miscarriages (death before five months in utero), induced abortion, and ectopic/tubal.

9.8 In the last pregnancy was the delivery:

Ask the participant about the mode of delivery of her last child. Choose the appropriate option.

Note: If the participant only had abortions/ectopic/not married (not pregnancy ever) use code "9" and specify the reason in the provided space.

9.9 Were you diagnosed to have gestational diabetes in any of the pregnancies?

Please write "1" if the participant has been diagnosed 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

Similarly for 9.10, ask whether the participant has been diagnosed with hypertension in any pregnancy.

Remember

The **last menstrual period** (LMP) refers to the first day (onset of bleeding) of your last menstrual period.

Chapter 11: Anthropometric Measurements

Introduction

There will be a total of three anthropometric measurements taken during both visit-1 and visit-2. Blood pressure and pulse rate will be measured during visit after implementing the questionnaire and before taking the anthropometric measurements. Body composition analysis via Tanita would be done in the visit-2. This chapter is based on the third National Health And Nutrition Examination Survey (NHANES-III) methods for anthropometry.

Visit – 1

1) Blood pressure (BP)
2) Pulse rate
3) Waist circumference
4) Hip circumference

Visit - 2

5) Height (Standing)
6) Bio-impedance/body composition analysis

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, bio-impedance and blood pressure recording

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 Gulick II/ 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)
   - Pulse rate – 2 recordings
   - Body circumferences – 1 reading
   - Body Weight – 1 reading
   - Height (standing) - 1 reading
   - Body composition analysis- 1 reading
   -

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

Equipment and Supplies

The following equipment will be used to conduct the BP and anthropometric measurement:

- Electronic Sphygmomanometer – Omron HEM-7080
- Seca Brand-214 Portable Stadiometer
- Seca, non-stretch measuring tape
- Body Composition Analyzer - Tanita BC-601 (Delhi & Chennai) and BC-601F (For Karachi)

Step-by-Step Procedures

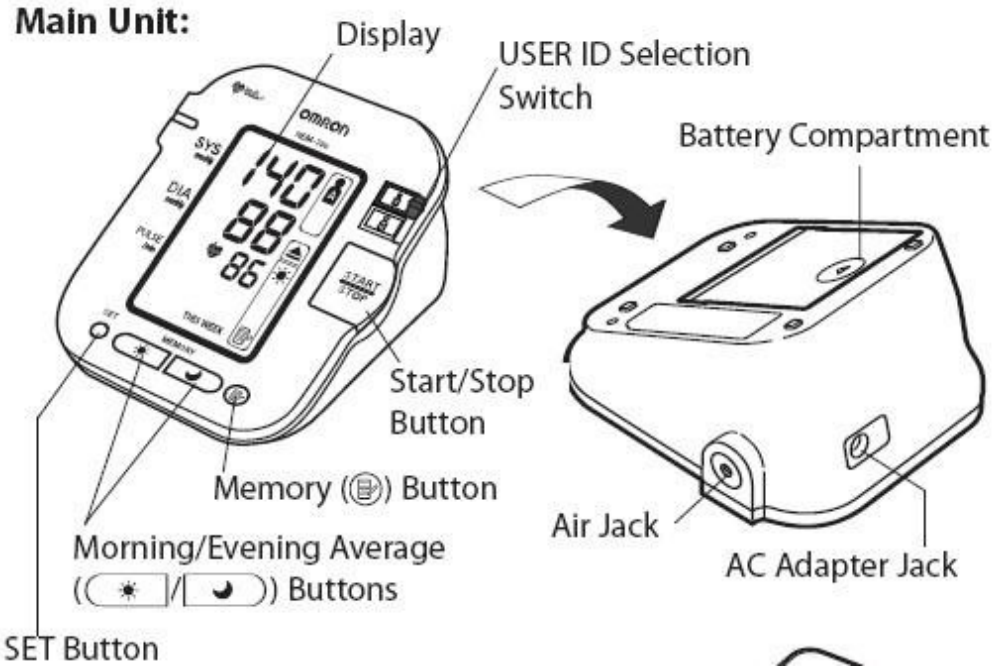
Blood Pressure and Pulse Rate

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, drugs that affect the blood pressure; a full bladder affects the blood pressure and patients 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 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 exactly 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-6.

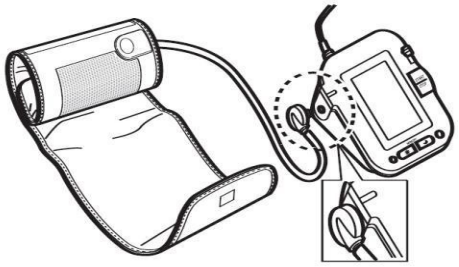
The BP Apparatus [Omron HEM-7080]



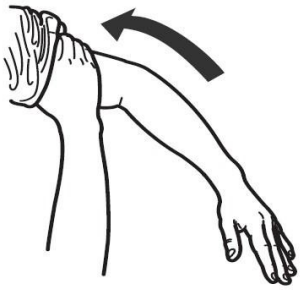
Applying the Arm Cuff

Applying the Cuff on the Left Arm

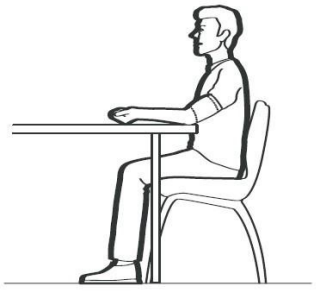
1. Make sure the air plug is securely inserted in the main unit

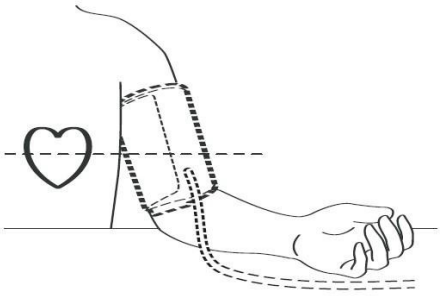


2. Remove tight-fitting clothing from the upper left arm of the participant



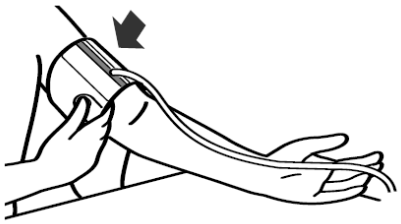
3. The participant should sit in a chair with her/his feet flat on the floor. Place the participant's left arm on a table so that the cuff is level with the heart



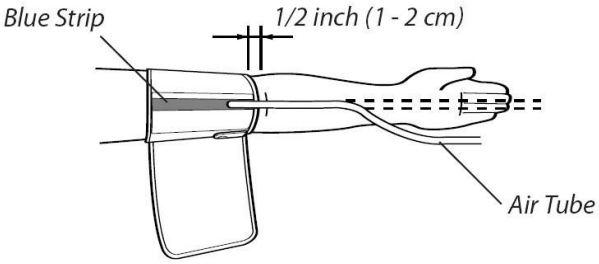


4. Hold the grip on the cuff securely with your right hand, placing your thumb on the thumb grip

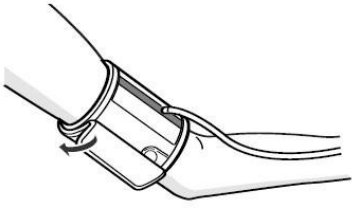
5. Turn the palm of your left hand upward



6. 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



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

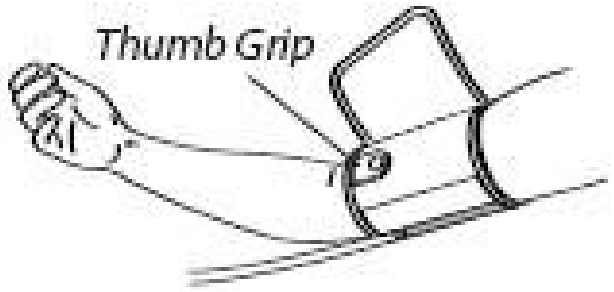


Applying the Cuff on the Right Arm

To apply the cuff on the right arm, follow the steps from 1 to 4 given for the left arm.

5. Turn the palm of your right hand upward

6. Apply the cuff to the participant's right upper arm so the thumb grip is centered on the inside of the inner arm. The bottom of the cuff should be approximately 1/2" above the elbow.



7. 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

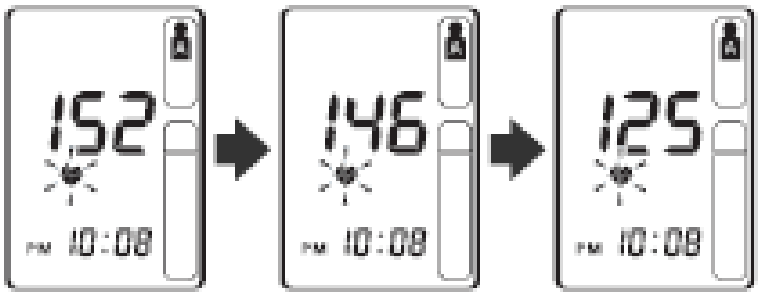
1. Press and hold the START/STOP button. The A and B symbols disappear from the display.

2. Release the START/STOP button. The cuff starts to inflate automatically.

> To stop the inflation, press the **START/STOP** button. The monitor will stop inflating, start deflation and turn off

3. Inflation stops and the measurement starts. When the measurement is complete, the blood pressure and pulse rate appear on the display.

4. As the cuff deflates, decreasing numbers appear on the display. The heartbeat Symbol ( ) flashes at every heartbeat.



5. When the measurement is complete, the arm cuff completely deflates. BP and pulse rate is displayed

6. Press the START/STOP button to turn the monitor off.

Error Indicators and Troubleshooting Tips

ERROR INDICATORS

SYMBOL	CAUSE	CORRECTION
	Cuff under-inflated. Cuff not applied correctly.	**Single Mode** Remove the arm cuff. Read, "Taking a Measurement". Take another measurement.
	Cuff over-inflated	**TruRead™ Mode** The monitor will repeat the process up to 5 times.
	Monitor could not detect pulse wave. Air plug is not connected.	Take another measurement and remain still until the measurement is complete.
	Batteries are worn	Replace the four batteries. Refer to "Battery Installation."

TROUBLESHOOTING TIPS

PROBLEM	CAUSES AND SOLUTIONS
No power. No display appears on the unit.	Replace all four batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and how you wrap the cuff, may affect your blood pressure. Review the sections "Before Taking a Measurement" and "Taking a Measurement."

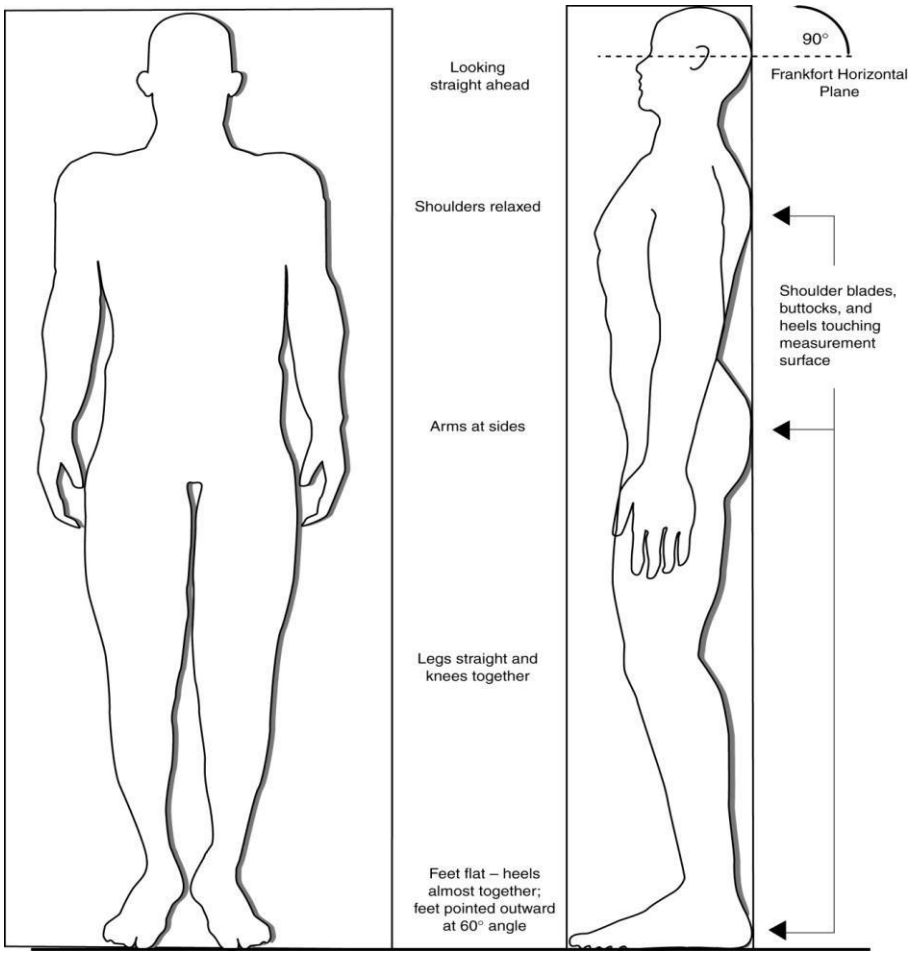
Procedure for Measuring Height

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 head board.

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.

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.



Procedures for 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.

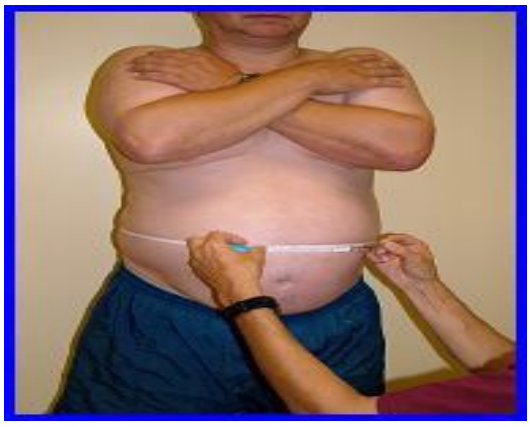
3) For the arm circumference there may be gaps between the tape and the skin in some individuals. If the gap is large, a note should be made on the data form, but in most instances, this gap is small and of little concern.

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 (illiac crest). The measurement should be taken on bare skin.

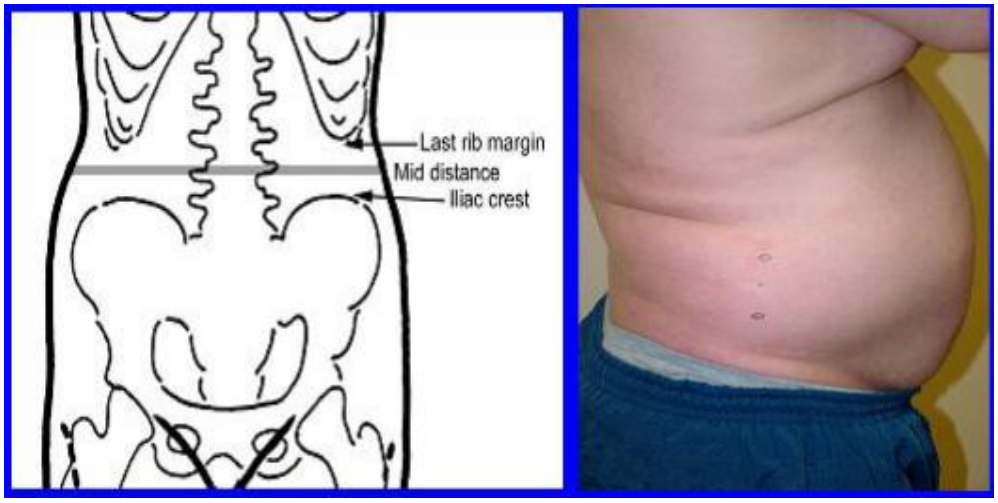
1) To define the level at which the waist or abdominal circumference is measured, you must first locate and mark the iliac crest and the lowest rib.
2) Have the participant stand with feet close together and the abdomen relaxed.
3) Request the participant to lower his/her pants and underclothing slightly, 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.



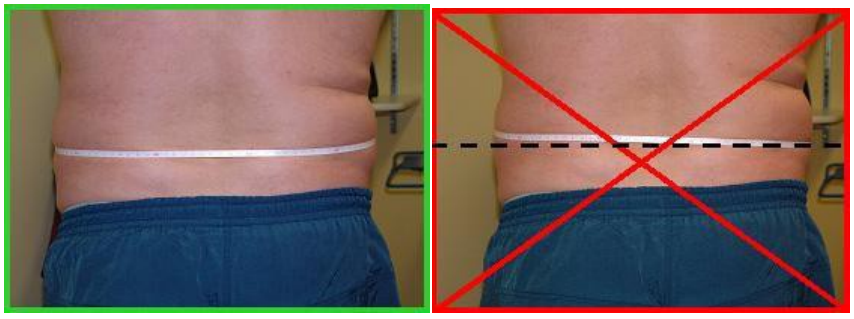
Arms crossed

Detailed instructions

1) Request the participant to stand with her / his arms crossed as shown above.
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**

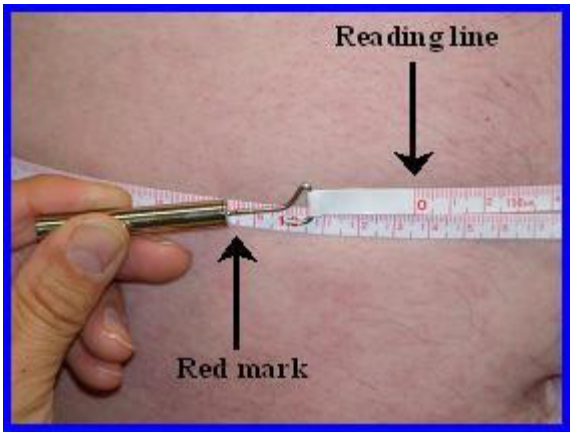
Note: A mirror could be used to facilitate this procedure.

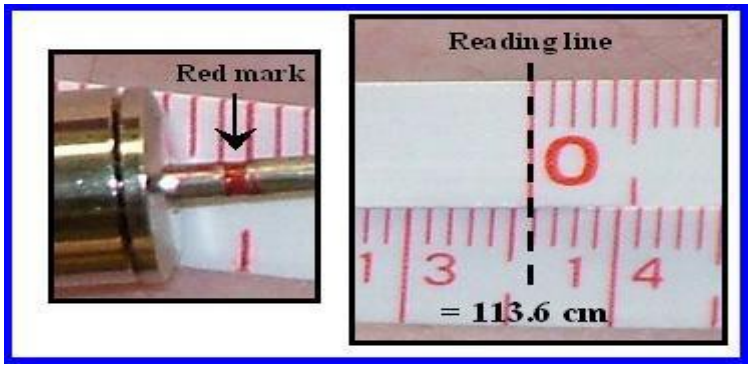
Hip Circumference

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 removed.
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 – 6 [Annexure-8].





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.

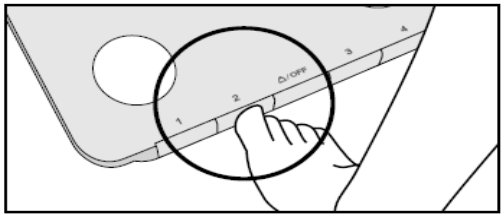
Body Composition/Bio – Impedance

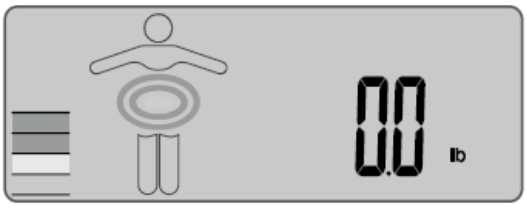
Equipment for measuring bio-impedance sends out a very weak electric current to measure impedance (electrical resistance) of the body. Therefore, in principle, users need to use this equipment with bare feet. Moreover, since impedance fluctuates in accordance with the distribution of body fluid, please observe the following instructions for accurate measurement -

1) To prevent a possible discrepancy in measured values, "avoid taking measurement of participants after vigorous exercise" until sufficiently rested.
2) To prevent inaccurately low body fat percentage measurements and other measurement errors, always hold both arms straight down when taking measurements.
3) Ask the participant to urinate before taking measurements to get a more accurate picture of the measurements over time.
4) 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; if necessary, place a dry towel between the participant's arm and side and/or between the thighs.
5) Also, make sure the soles of feet are free of excess dirt, as this may also act as a barrier to the mild current.
6) False results may be reported after excessive food/fluid intake, or after periods of intense exercise.
7) Measurement is sometimes impossible on a surface that is strongly vibrating. In this case, please move the equipment onto a surface with little vibration.
8) Do not take measurements while using transmitters, such as mobile phones, which may affect readings.
9) Do not take measurements on people with an implanted cardiac device (such as pacemaker, etc.)

Operating guidelines

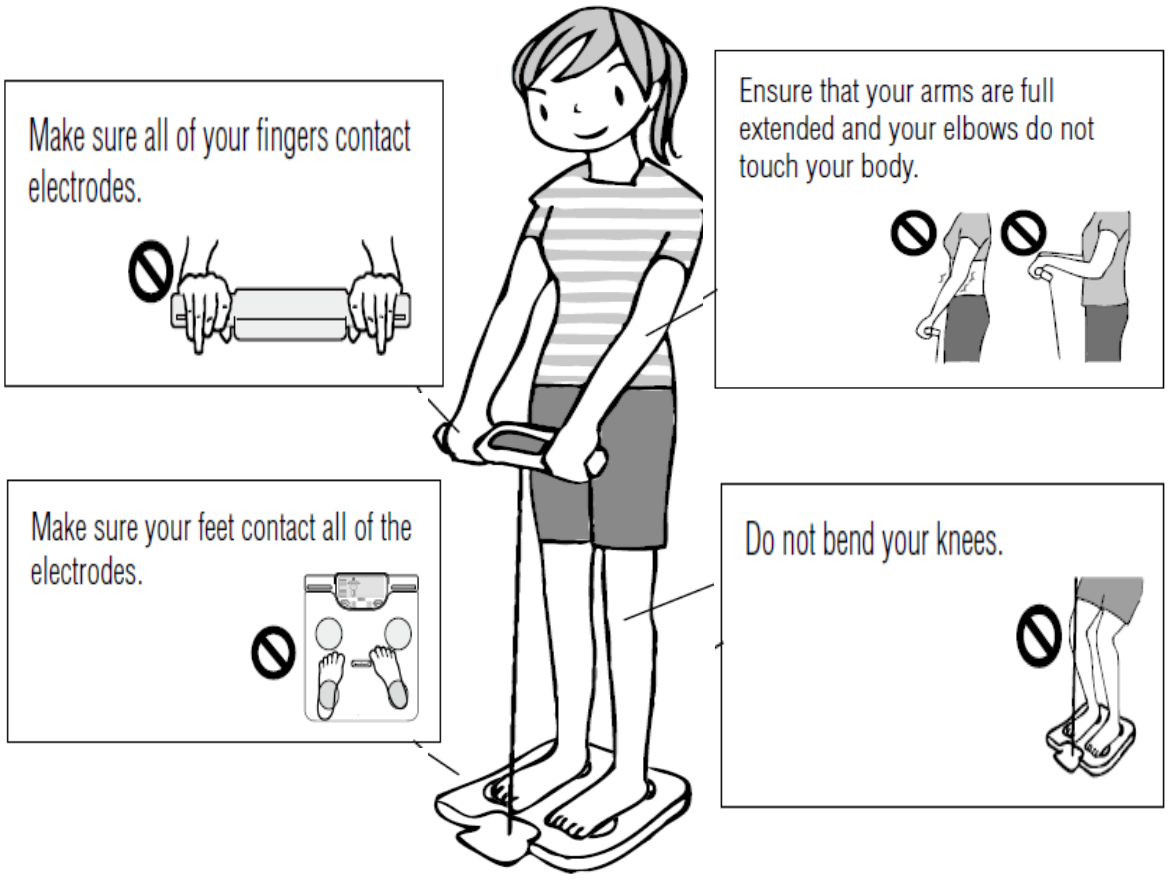
1) Turn on the Power: Press the ON/OFF key, display will show "0.0".





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-7), Annexure-14.

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.

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.

Calibration of Equipment

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.

Monthly Calibration

a) Body composition analyzer: Two FI need to measure their body composition two times and note and print out the readings.

b) Stadiometer: Two FI need to measure each other's height three times.

See Annexure-15 for the Monthly Calibration Forms (E1).

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 sphygmomanometer.
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) 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.

4) 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.

5) Body composition/ body impedance

i. Now I am going to measure your body composition which will give your weight and fat distribution in the body along with your BMI.
ii. Refer to the instructions in procedure guidelines
iii. We have finished all measurements. Thank you for your cooperation and patience.
iv. 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 – 6: Blood pressure and anthropometric measurement recording form (Annexure-8)

Monthly calibration form (E1 and E2)-Annexure-15

Quality Control/Assurance Procedures

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 the scanned copy of the certificate (Annexure-16) should be sent to CCC. Their measurement performance would be evaluated bimonthly by the trainer and they would provide their feedback and send the scanned copies of the certificates to CCC. 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 CCC.

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

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

Chapter 12: Biological specimens

Introduction

Biological specimens for the study:

18 ml of blood

40 ml of urine (early morning void)

After the specimens are collected, the lab technician will complete a specimen collection form (Form-BS1), Annexure-7 and transport the specimens to the laboratory for processing. The blood tubes will be processed for serum (S), plasma (P), EDTA-Plasma (EP), buffycoat (BC) and red blood cells (RBC). Analysis for plasma glucose and lipid profile and urea, creatinine will take place same day of collection. Serum, whole blood (WB) and other aliquots will be stored in deep freezer. Urine samples will be tested for protein & sugar by dip sticks on the same day. Remaining urine will be aliquot into vials and will be stored.

Labelling of bio-specimens

Assigning codes: Each specimen collected during the study will be identified with a unique sample ID (SID) number. This will be X 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.

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.

Pre-labelling of collection materials: All collection materials for blood-Vacutainer tubes (three red top, three grey top and one lavender top) 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 "0000." Only these specific labels should be used to label replacement collection materials.

Blood collection

Collection kit: One specimen collection kit is used for each blood sample. Each specimen collection kit contains the key items required for blood collection. As much as possible, protect tubes from extreme temperatures by storing the kits in a cool place.

The following items for blood collection are included in the specimen collection kit:

- One 6.0 ml lavender-top vacutainer tube
- One 6.0 ml red-top/yellow top vacutainer tube
- Two 4.0 ml red-top/ yellow top vacutainer tubes
- Three 2.0 ml Grey top tubes
- Cryo-label sheet to paste on the tubes
- Three Standard 22 gauge blood collection needle with holder
- Alcohol wipes
- Cotton pads
- Band-Aids
- Holding rack for Vacutainers
- Sharps needle disposal units(sharps container)
- Drape sheets to cover work surface (Chux)
- Laboratory coat and gloves
- Tourniquet

For Glucose Tolerance Test (GTT) Sample Collection (Delhi & Chennai)

Collection of blood will be done at three time points on the same day:

1) First blood sample will be collected from the participants when they arrive. This is their fasting sample in 2 ml grey tube & 6 ml red tube/yellow tube. It provides a baseline for comparing with other glucose values.

2) 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 slip carried by the participant. This will be considered as zero time.

3) Collect blood sample after 30 minutes (half-an hour) in 2 ml grey top & 4 ml red top/yellow top from the drink and another sample after 120 minutes (two hours) in 2 ml

grey top & 4 ml red top/yellow top). Try to stick to the time schedule as much as possible. Mark the time of each collection.

Procedures for blood collection:

Steps to be followed for sample collection-

1) Ask the participant when s/he last ate a meal and record the time on the Blood Collection Form.
2) 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.
3) Record the time of the blood collection on the Blood Collection Form.
4) Clothing should not restrict the arm. Ask the participant to adjust her/his clothing to expose the middle portion of her/his arm.
5) Explain the procedure and position the participant with the arm in a dependent position.
6) Prepare the appropriate blood collection tubes, placing them in a test tube rack in the order in which they will be drawn.
7) Wash your hands and put on protective gloves.
8) 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.
9) 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.
10) Apply a tourniquet four to five inches above the site with enough pressure to impede venous blood flow. Select a vein that is palpable and well-fixed to surrounding tissue.
11) 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.
12) Perform the blood draw by inserting an appropriate needle into the arm, then attaching the Vacutainer tube.
13) Immediately after the venipuncture, press clean gauze square over the

venipuncturesite. 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.

14) After the blood draw is complete, fill in the appropriate items in the Blood Collection Form.

15) 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.

Venipuncture complications

1) 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.

2) 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 venipucture. 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.

3) **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).

4) **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.

5) **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.

Packing instructions for samples following blood collection

Samples should be placed in the racks inside ice buckets to **minimize exposure to sun light and maintain an even temperature**. Open the buckets as little as possible. The ice buckets should have ice packs at the bottom and on the sides.

Recommendation

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.

Specimen Processing

After the blood specimens have been collected place the pre-labelled vacutainers inside the ice buckets. The specimen should be processed within 20-30minutes of collection in the blood camp itself (Transfer the ice buckets with samples to the laboratory for processing as soon as possible)

Labeling of cryovials

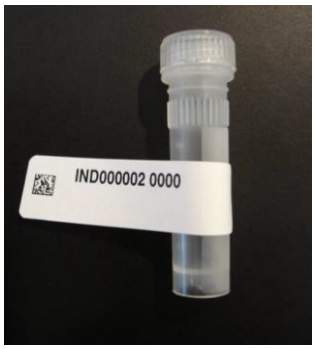
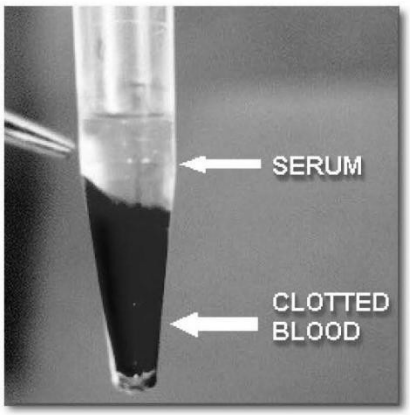


Table: Overview of aliquots to be prepared

Tubes and their aliquots	No. of aliquots
Fasting	
Red top- Serum	**3 + 1***
Lavender Top – Whole blood (for HbA1c analysis & dried blood spots)	**1***
Lavender Top – EDTA Plasma	**3**
Lavender Top – Buffy Coat	**1**
Lavender Top – RBC	**2**
Grey Top-Plasma	**2 + 1***
Urine samples	**2 + 1***
30 min after glucose load	
Grey top-plasma	**1 + 1***
Red top-serum	**2**
120 min after glucose load	
Grey top-plasma	**1 + 1***
Red top-serum	**2**

***to be analyzed same day**

Processing for Red top tube (Fasting)



1) Allow the tubes to remain upright at room temperature for complete blood coagulation. Once clot retraction is complete, maintain the red-top tube at 2°to 8°C by placing the tube upright in a test tube rack stored in either a refrigerator or an ice water bath if needed until it can be centrifuged.
2) Label the cryovials (four 2.0 ml vials for serum) with participant ID.
3) Centrifuge the red top tubes for 10 minutes at 3,500 rpm.
4) After the blood has been centrifuged, reserve 250µl for clinical tests in one cryovial (**S4**).
5) Aliquot the remaining serum from the red-top tube into three pre- labelled cryovials (**S1, S2**&**S3**). Aspirate all the serum generated into the tube.

Prepare an additional aliquot of serum for every tenth sample collected for blinded duplicate analysis. The person processing the sample will be provided with an additional sequence of numbering which would be generated by the Biochemistry in-charge. The technician analysing the samples will be blinded for these numbers.

6) Discard the clot.
7) Store the vials **S1** into **Box A, S2** into **Box B, S3** into **Box C** and **S4** into **Analysis Box**.
8) Store the boxes in deep freezer at -80° C.

Preparation of blood spots

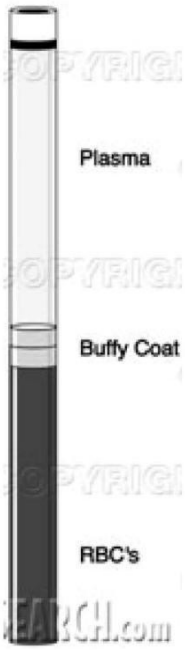
Prior to centrifugation of the lavender top tube, 200 µl of whole blood should be extracted and preserved for spot preparation and HbA1c analysis on a Whatman's filter paper No # 3.

Procedure is as follows -

1) Place the Whatman filter paper on a clean, non-absorbent surface. Using a pipette, gently mix the contents of the tube. If the spots are being prepared from the vacutainer directly, mix by gentle inversion 7-8 times.
2) Pipette out 10 µl of blood using a micropipette. Allow blood drop to touch the filter paper without touching the tip to the filter paper. Let the paper soak the blood. Prepare 10-15 such spots for each sample. Keep enough spacing between the spots so that they do not overlap. **Do not drop blood second time on the same spot.**
3) Allow the blood spots on the paper to air dry for one hour. Do not stack, heat, or allow touching other surfaces during the drying process.
4) Label a zip-lock bag with the sample ID label. Apply a cello-tape on the label. Place the paper in the pre-labelled zip-lock bag with a desiccant pouch. Remove air from the bag and seal it.
5) The zip-lock bags with blood spots on Whatman filter paper No #3 should be stored at 4^0C but preferably at -20° C.

Processing for Lavender top tube (Fasting)

1) Label the cryovials (three vials for plasma, one vial for whole blood, one vial for buffy coat (BC) and two vials for RBC with specimen ID labels.
2) Mix the content of the tube by inverting it 6-7 times. Remove 100µl of whole blood from the lavender top tube in a separate cryovial (**WB**) for HbA1c analysis.
3) Take out 200ul of whole blood for Dried blood spots.
4) Centrifuge lavender top tube for10minutes at 3,500 rpm.
5) Aliquot plasma into three cryovials (**EP1, EP2**&**EP3**).
6) Transfer the buffy coat into one cryovial (**BC**).
7) Wash RBCs three times with Phosphate Buffer Saline (PBS)/Normal Saline (NS).
8) For this add same amount of PBS)/Normal Saline (NS) into the tube. Mix gently by inversion. Centrifuge. Discard the supernatant.



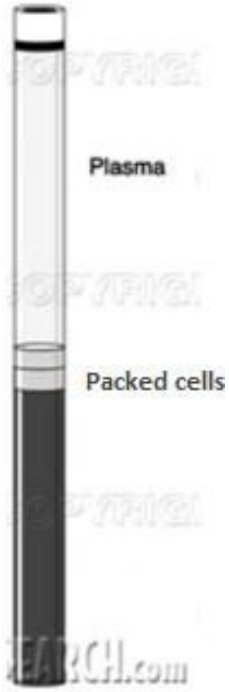
Repeat two more times using PBS/NS. The final supernatant should be clear with no colour. DO NOT USE DISTILLED WATER FOR WASHING AS IT WILL HEMOLYZE RED BLOOD CELLS.

9) Transfer RBCs into labelled cryovials (**RBC1 & RBC2**).
10) In order to maximize the buffycoat yield, when removing plasma leave a small amount of plasma above the buffy coat and when aspirating buffycoat include a small amount of RBC in the sample.
11) Transfer all the plasma into the cryovials. Do not discard any component of lavender top tube.
12) Divide the participant's plasma, RBC, and buffycoat vials between labelled and numbered freezer boxes. Place the **EP1** into **Box-F**, **EP2** into **Box G**, **EP3 into Box H,** cryovials with buffy coat (**BC**) in **Box-I**, RBC vials**RBC1**into **Box J& RBC2** into **Box-K**.
13) Store the boxes in a deep-freezer at -80° C.

Processing for Grey top tube (Fasting)

1) Label the cryovials (three vials for plasma)with specimen ID labels.
2) Centrifuge grey top tube for 10 minutes at 3,500 rpm.
3) Transfer 100 µl of plasma in one cryovials (**P3**) and the rest of the plasma into two cryovials (**P1 & P2**). Use cryovial (**P3**) for clinical tests and store cryovial **P1** into **Box D & P2** into **Box E.**

   Prepare an additional aliquot of plasma for every tenth sample collected for blinded duplicate analysis. The person processing the sample will be provided with an additional sequence of numbering which would be generated by the Biochemistry in-charge. The technician analysing the samples will be blinded for these numbers.



4) Discard the packed cells.
5) Store the boxes in a deep freezer at -80° C.

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

1) Label the cryovials (two vials for plasma) with specimen ID labels.
2) Centrifuge grey top tube for 10 minutes at 3,500 rpm.
3) Transfer 100 µl of plasma in one cryovial **PP2(30 min**) and the rest of the plasma into cryovial **PP1(30 min)**. Use cryovial **PP2(30min)** for clinical tests and store cryovial **PP1(30 min) i**nto **Box D.**

Processing for Grey top tube after 120 minutes of glucose load

1) Label the cryovials (two vials for plasma) with specimen ID labels.
2) Centrifuge grey top tube for 10 minutes at 3,500 rpm.
3) Transfer 100 µl of plasma in one cryovial **PP2 (120 min**) and the rest of the plasma into cryovial **PP1(120 min)**. Use cryovial **PP2(120min)** for clinical tests and store cryovial **PP1(120 min)** into **Box D.**

Processing for Red top tube (30 minutes after glucose load)

1) Label the cryovials (two vials for serum) with specimen ID labels.
2) Centrifuge red top tube for 10 minutes at 3,500 rpm.
3) Transfer serum into two cryovials **SP1(30 min**) and **SP2(30 min)**. Store cryovial **SP1 (30 min) i**nto **Box A and SP2 (30 min) in Box B.**

Processing for Red top tube (120 minutes after glucose load)

1) Label the cryovials (two vials for serum) with specimen ID labels.
2) Centrifuge red top tube for 10 minutes at 3,500 rpm.
3) Transfer serum into two cryovials **SP1(120 min**) and **SP2(120 min)**. Store cryovial **SP1(120 min) i**nto **Box A and SP2 (120 min) in Box B.**

Urine specimen

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.

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.

Processing of urine

Label three cyovials with participant ID. Transfer urine into 2.0 ml of urine into the cryovials (**U1, U2 & U3**). Use the remaining urine in the container to test for protein and sugar content using dipsticks. Store U1, U2 in **Box-L and place into the** deep - freezer at -80°C. Store U3 into analysis box.

Storage of Specimens

Table: Storage of Aliquots has to be done as per details given in the table

Box A	S1, SP1(30min), SP1(120 min)
Box B	S2, SP2(30,in), SP2(120 min)
Box C	S3
Box D	P1, PP1(30 min), PP1(120min)
Box E	P2
Box F	EP1
Box G	EP2
Box H	EP3
Box I	BC
Box J	RBC1
Box K	RBC2
Box L	U1,U2
Analysis Box	S4, WB, U3, P3, PP2(30 min), PP2 (120 min)

Labeling the cryoboxes:

Arranging the cryovials: The cryovials are arranged in the cryoboxes (A,B,C,D, E & F) 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 cryoboxA-2-00 is shown below.

Example: Layout of Cryovials in cryobox A-001

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

Repeat collection of urine specimen

The urine sample would be tested for albumin and creatinine if the albumin creatinine ratio comes out positive (> 17 mg/g for men and >25 mg/g for women) then we need to recollect the early morning void from the participants within 6-12 weeks of the 1st collection.

Collection procedure

One early morning void mid-stream urine will be collected from all participants at visit 2. 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 2 (mention the day/date of visit 2) and the container has to be at least three-fourth filled. During visit 2 confirm whether the sample collected in the container by the participant is the morning void of the same day. If the sample is the morning void of the same day, collect the container and fill the Urine and fill the urine column in the "sample collection sheet". If the sample is not the morning void of the same day or there is any other problem, then provide another sterile container labelled with a different sample ID and repeat the instructions. Re-visit the participant on the following day to collect the sample and give your comments in the "sample collection sheet".

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.

Processing of urine

Label three cryovials with participant ID. Transfer 2.0 ml of urine into the cryovials (**U1, U2 & U3**). Use the remaining urine in the container to test for protein and sugar content using dipsticks. Store **U1, U2** in **Box L** and place into the deep - freezer at -80° C. Store **U3** into **Analysis box**.

Laboratory Quality Control (QC)

Quality assurance for laboratory procedures will be ensured through internal and external quality control measures. All laboratory methods, such as test kits, procedures for bio-specimen collection, processing and storage as well as methods of analysis across the three sites have been standardised. Apart from this QC methods will involve laboratory procedures assessments at two levels:

Level-1: Internal Quality control

Local laboratories attached with the study centre will follow their own internal quality control Standard Operating Procedures (SOPs). Further a copy of Lab SOP and references ranges will be filed in the study site file. The greatest emphasis at every local study site laboratory should be given to ensure accuracy, precision, reproducibility and speedy reporting.

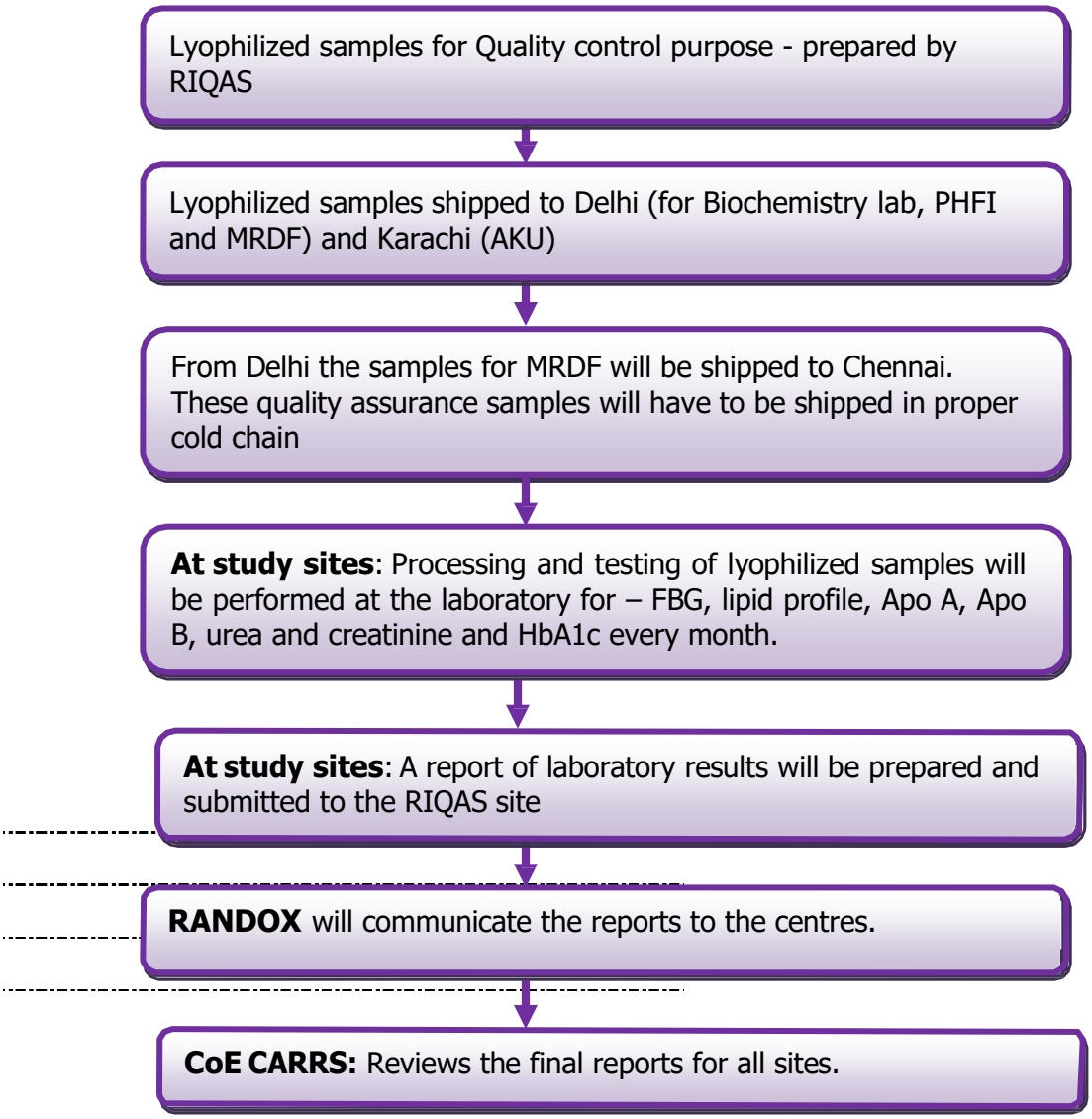
To control for pre-analytic variations resulting from problems of phlebotomy, centrifugation, aliquoting of samples, storage and transportation; a training session detailing these issues will be organized for the participating laboratories before the start of the study.

Level-2: External Quality control

To ensure the quality of laboratory investigation at each study site, irrespective of the nature of existing laboratory involvement with accreditions board and/or SOPs, all local laboratories at the study sites will be asked to participate / enroll into an External Quality Assessment program for laboratory investigations done specifically for the purpose of this study. This will be implemented with support from Randox International Quality Assessment Scheme (RIQAS).

The process of external quality assessment will be performed once a year for all the participating sites using lyophilized samples from the reference laboratory. Please find below a flow chart as an overview for the external quality assessment program that will operate at each study site.

Fig: Schematic flowchart - External Quality Control System



Chapter 13: Roles and Responsibilities of Study Staff

Introduction

In order to ensure high standard and quality of the study all members involved in the study will have to fulfill the following roles and responsibilities. Apart from this other roles and responsibilities may be assigned to team members by their supervisor as and when required for the proper execution of the study.

Centre of Excellence – Centre for cArdiometabolic Risk Reduction in South Asia (COE-CARRS)
The COE-CARRS at PHFI; New Delhi will be acting as the regional coordinating centre for the Surveillance study.

Roles and responsibilities

1) Designing study tools, software.
2) Providing training to study staff
3) Supporting the site coordinators and managers, providing guidance and advice on all aspects of planning, implementation and dissemination of data.
4) Regular communication with the site coordinators.
5) Monitoring of recruitment rates of participants, progress reports and error rates for quality assurance

Data Management Cell

Statistician

The statistician at the regional coordinating centre plays a key role in sampling and data analysis procedures.

Roles and responsibilities:

1) Assisting in the multi stage cluster random sampling for each study site
2) Formulate the statistical analysis plan
3) Management of the data
4) Statistical analysis of the data

Data manager

The data manager will be responsible for overall management of data and will supervise the data entry personnel at each site.

Roles and responsibilities:

1) Cross-checking of data files sent from the field sites
2) Monitoring error rates
3) Running check files
4) Preparing the final data file for analysis
5) Performing the analysis
6) Will conduct regular review meetings to supervise the site operators
7) Flag high error rates and suggest corrections
8) Will coordinate with the project manager to review all process of data collection, entry and analysis

Monitoring and Evaluation Cell

The Quality Monitoring and Evaluation (QME) sub-committee will be responsible for quality assurance of the study, will monitor all phases of the study and will conduct process and outcome evaluation.

Roles and responsibilities

1) Monitor the progress of the study
2) Regular appraisal of the study
3) Monitor the timeline of the study
4) Visit the field sites at least twice a year to monitor the activities
5) Provide on job training to the field staff
6) Provide feedback for corrective action to site PI and manager
7) Provide feedback for corrective action to project PI and project manager (at COE-CARRS)

Site Coordinator / Site manager

The Site coordinator will be the key person to whom the regional coordinating committee will be communicating.

Roles and responsibilities:

1) Active participation in planning the study
2) Oversee the overall implementation of the study
3) Recruiting and training field staff
4) Supervising the data collection and data entry processes
5) Overseeing archiving of files at completion of the project

Field Interviewer

Field Interviewer will play the key role in the study. The success of the study is dependent upon the Interviewer's observance of study procedures and protocols, as well as her/his understanding of the use of the study instruments. The Interviewer should aim to build rapport with study participants and enhance response rates during data collection activities.

Roles and responsibilities have been discussed in details in Chapter-8

Laboratory Technician

Laboratory technician is responsible for collection, processing and analyzing the bio-specimens collected from the study participants.

Roles and responsibilities:

1) Preparation of blood collection kits before visit 2
2) Ensure collection of blood samples from the community with sterile precautions
3) Ensure proper transport of sample from field to the laboratory (proper cold chain)
4) Processing and analysis of blood samples
5) Handing over blood reports to the field staff
6) Recording results and passing records on for data entry
7) Identifying out-of-range results for clinical attention
8) Ordering supplies
9) Quality control measure during analysis

Lab Attendant/Phlebotomist

Roles and Responsibilities:

1) Responsible for biological specimen collection of all enrolled individuals on standard laboratory protocols
2) Ensure all logistic arrangements required for specimen collection before hand
3) Ensure proper labeling of specimen and transport of specimen to the lab iv. Keep record of all results and enter results in database program
4) Maintain log of stored specimen and lab requirements vi. Distribute lab reports to the study participants
5) Any other task as assigned by the investigator

Data Entry Team

The data entry team includes all those who have been recruited to enter, check, and validate the data gathered by the data collection team at the study site.

Data Entry Operator (DEO)

Roles and responsibilities:

1) Logging receipt of completed questionnaire and forms
2) Filing and organizing paper copies of questionnaire and forms iii. Entering survey data
3) Tracking questionnaire and forms during data entry
4) Identifying errors and resolving problems with supervisor vi. Regular back up and archive of data.

Appendix-1

LIST OF ANNEXURES

SNo	Annexure	Forms	Description
1	Annexure-1		Code list of 3 study site
2	Annexure-2	Form 1	Household listing form
3	Annexure-3	Form 2	Household proforma
4	Annexure-4	Form A	Study notification form
5	Annexure-5	Form B	Participant Information Sheet (PIS) and Informed Consent Form (ICF)- English
6	Annexure-6	Form 3	Non interview report form-Household
7	Annexure-7	Form 4	Non interview report form-Individual
8	Annexure-8	Form 6	Blood Pressure and Anthropometry recording Form
9	Annexure-9	Form D	Instruction Sheet- Urine (All site) and Blood collection (Karachi)
10	Annexure-10	Form D1	Instruction Sheet- Oral Glucose Tolerance Test (OGTT)- Chennai & Delhi
11	Annexure-11	Form BS1	Bio-specimen collection sheet
12	Annexure-12	Form BS2	Bio-specimen processing sheet
13	Annexure-13	Form 5	Baseline questionnaire
14	Annexure-14	Form 7	Tanita form
15	Annexure-15	E1	Monthly calibration forms
16	Annexure-16	Certificate 1	Anthropometric measurement certification
17		Certificate 2	BP Monitor observation checklist/ Certification rating form
18		Certificate 3	Interviewer's certification rating form
19		Certificate 4a	Blood collection, processing & storage rating checklist
20		Certificate 4b	Blood collection, processing & storage rating checklist
21	Annexure-17	Form C	List of tests and measurement to be performed (all site)
22	Annexure-18	Form 8	Suggested Lab report proforma (all site)
23	Annexure-19	SC-PA	Show cards for physical Activity
24	Annexure-20	FMB	Food model booklet
25	Annexure-21	SC-T	Show cards for smokeless and smoking tobacco products