STUDY MANUAL

(COE-CARRS)

Center **O**f **E**xcellence

Center for c**A**rdiometabolic **R**isk **R**eduction in **S**outh Asia

SURVEILLANCE STUDY

Supported by:

Study Manual | 2009

Center **O**f **E**xcellence - **C**enter for c**A**rdiometabolic **R**isk **R**eduction in **S**outh Asia

(COE-CARRS)

SURVEILLANCE STUDY

Study Manual

Prepared by

Dr. Manisha Nair, Dr. Niveditha Devasenapathy & Dr. Dimple Kondal

With extensive inputs from

Prof. D. Prabhakaran, Prof. K.M.V. Narayan, Dr. M.K. Ali, Prof. N. Tandon,

Dr. R. Lakshmy, Dr. R. Gupta, Dr. R. Siddiqui, Dr. R.G. Pradeepa, Ms. D. Pillai

Overview of the field manual

This manual is a part of the CARRS-SURVEILLANCE STUDY 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 sixteen chapters each staring 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
- It includes description of all the study tools for CARRS-SURVEILLANCE STUDY
- 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

Contents

List of Abbreviation

AIIMS	All India Institute of Medical Sciences
AKU	Aga Khan University
ApoA/B	Apolipoproteins A & B
BMI	Body Mass Index
BP	Blood Pressure
BRFSS	Behavioral Risk Factor Surveillance System
CAP	College of American Pathologists
COE-CARRS	Center of excellence- Center for Cardiometabolic Risk Reduction in South Asia
CDC	Centers for Disease Control and Prevention
CEB	Census Enumeration Blocks
CHD	Coronary Heart Disease
CHF	Congestive Heart Failure
CKD	Chronic Kidney Failure
CMD	Cardiometabolic Diseases
CUPS	Chennai Urban Population Study
CURES	Chennai Urban Rural Epidemiology Study
CVD	Cardiovascular Disease
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
HbA1c	Glycated Hemoglobin
HDL	High Density Lipoprotein
HH	Household
HINTS	Health Information National Trends Study
HTN	Hypertension
ID	Identification Code
IRB	Institutional Review Board
KAP	Knowledge, Attitudes, and Practices
LDL	Low Density Lipoprotein
LMCI	Low- and Middle-Income Countries
MDRF	Madras Diabetes Research Foundation
MI	Myocardial Infarction

MONICA	Multinational MONItoring of trends and determinants in CArdiovascular disease
MOP	Manual Of Operations
NCCD	National Center for Chronic Diseases
NCD	Non Communicable Diseases
NDMC	New Delhi Municipal Corporation
NHLBI	National Heart, Lung and Blood Institute
NIH	National Institutes of Health
P	Plasma (Fluoride Plasma)
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
RCC	Regional Coordinating Center
S	Serum (Processed serum)
SID	Sample ID
SM	Site Manager
SOP	Standard Operating Procedures
TG	Triglycerides
U	Urine samples (processed)
UA	Unstable Angina
UC	Union Council
UKNEQAS	United Kingdom National External Quality Assessment Scheme
USA	United States of America
VLDL	Very Low Density Lipoprotein
WHO	World Health Organization
µl	Micro Liter

Chapter 1

Study Overview

Introduction

The surveillance study for cardiometabolic disease risk factors in South Asia 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 primary aim of this study is 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.

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 two study sites

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

Secondary objective

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: **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

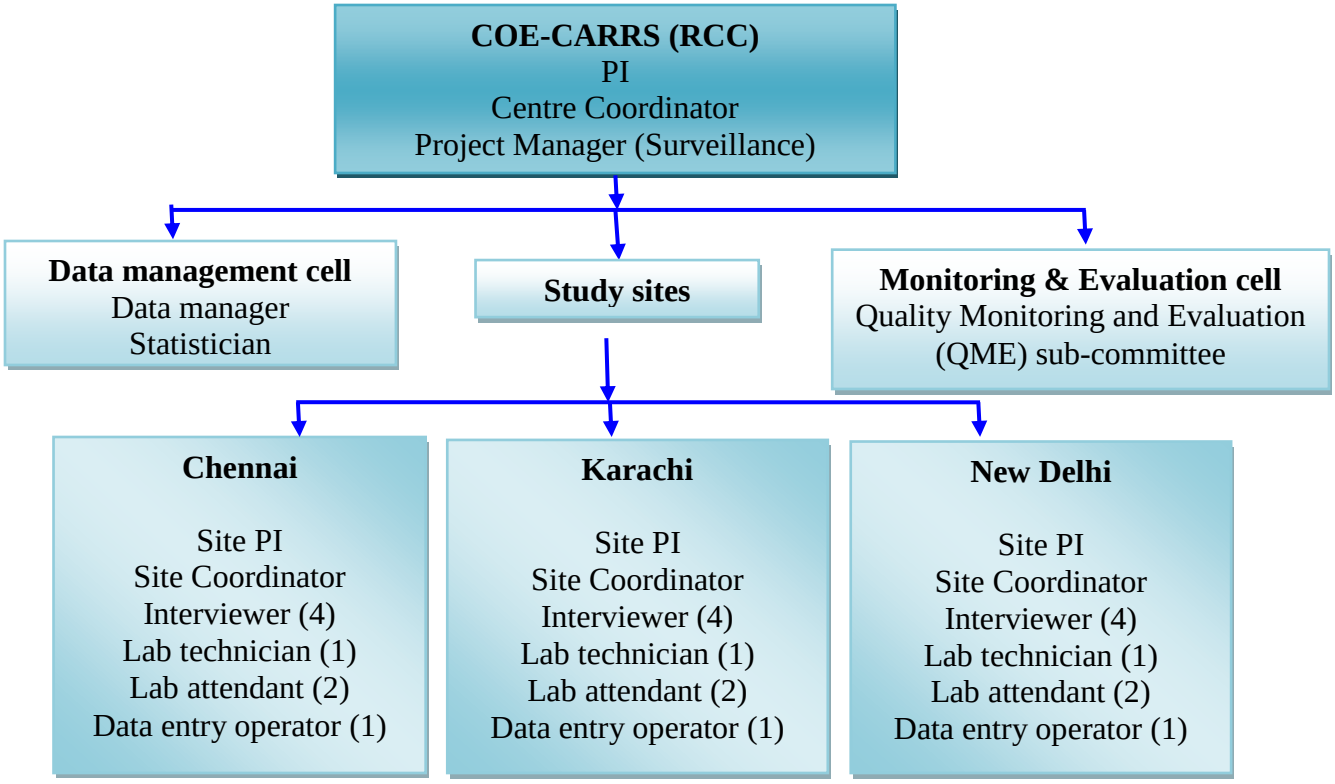
Principal Investigators: Prof. D. Prabhakaran (PHFI) and Prof. K. M. V. Narayan (Emory University)

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 for three years subsequent to the cross-sectional study. 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 (2010-2011): 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. A repeat cross-sectional survey will be conducted in 2013-2014 by recruiting a separate sample in the same study sites to estimate the trend in prevalence of CMD and their risk factors.

The study will be implemented through questionnaires and instruments for anthropometry, spirometry and bio-chemical measurements and will comprise of three visits to each participant (Visit-0, Visit-1 and Visit-2).

During Visit-0, details of the household selected through a random method will be collected and the selected individuals will be informed about the study.

During Visit-1, 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, skin-fold thickness, blood pressure and pulse rate will be measured.

During Visit-2, height and body composition measurements will be taken and samples of blood, urine and saliva will be collected in a local camp/clinic (participant's house-Karachi). Spirometry test will be done on a randomly selected sub-sample.

Cohort Follow-up (2012 to 2014) – Participants enrolled into the cross-sectional study who provide consent will be followed-up for three consecutive years 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, Body fat percentage, etc.). Each year the following parameters would be recorded:

a. Anthropometric Changes (Weight/Waist Circumference/Skinfold Thickness/Body Fat)

b. Development of intermediate risk factors (Hypertension, Diabetes Mellitus, Dyslipidaemia) in individuals who were risk free during the baseline cross-sectional survey

c. Incident morbidity (Stroke/Myocardial Infarction (MI)/Congestive Heart Failure (CHF)/Amputation/Chronic Stable Angina/ Chronic Kidney Disease (CKD)/ Dialysis/ Renal Transplantation/ Procedures, Revascularization, Hospitalization/Outpatient use/Medication history)

d. Mortality (all cause, Cardiovascular Disease (CVD)-specific, diabetes-specific)

Points to remember

1. CARRS-SURVEILLANCE STUDY is a cohort modelled surveillance study
2. It will be conducted over a period of four 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).

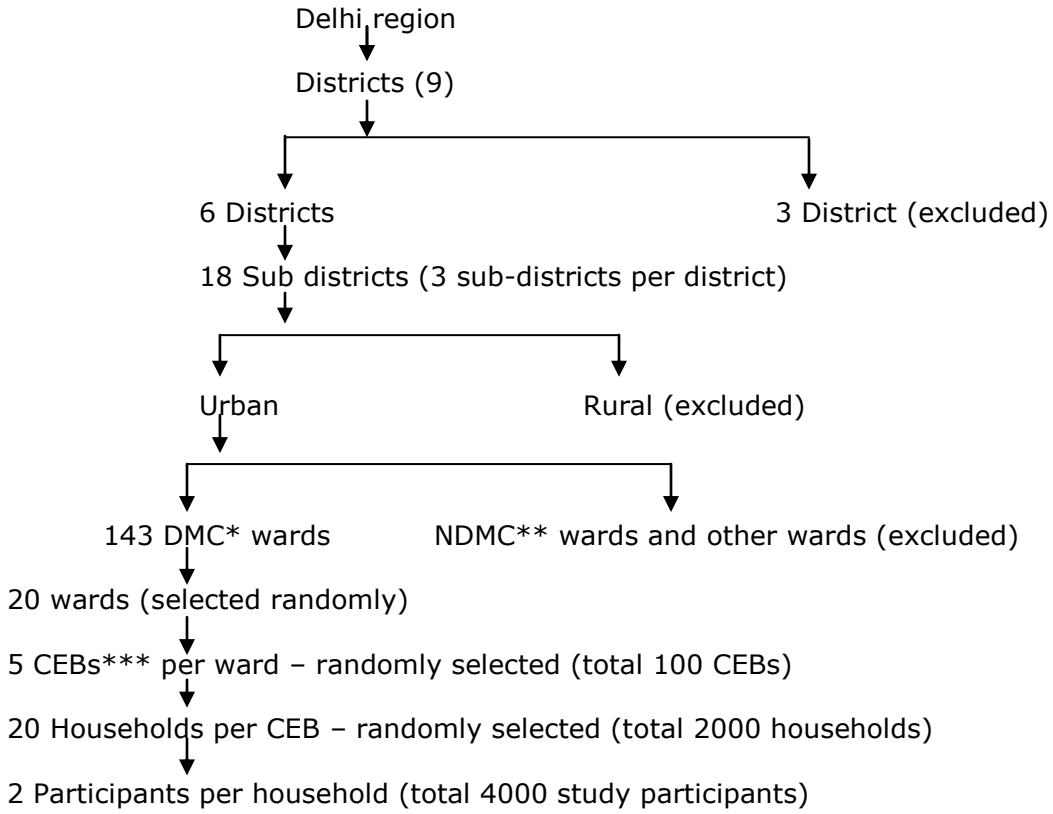
Districts in Delhi Region

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. From each CEB, 20 households will be selected giving a total of 2000 households in the region of Delhi. Further 2 participants from each household will give us the required sample of 4000 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 defense personnel who may be transferred elsewhere, Najafgarh is a marshy agricultural

area and Vasant Vihar is inhabited by expatriates who may leave the country during our study period of five years.

Delhi sampling scheme



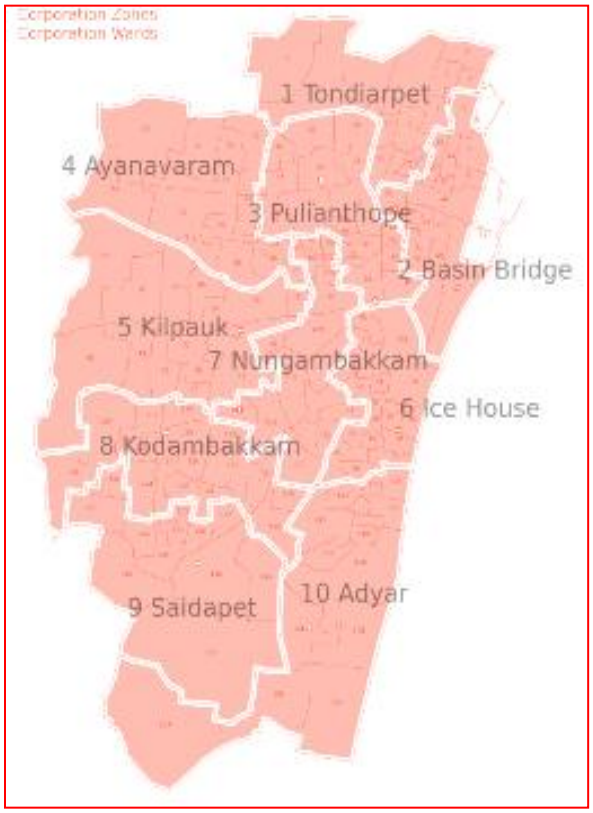
*Delhi Municipal Corporation; **New-Delhi Municipal Corporation, ***Census Enumeration Blocks

Chennai

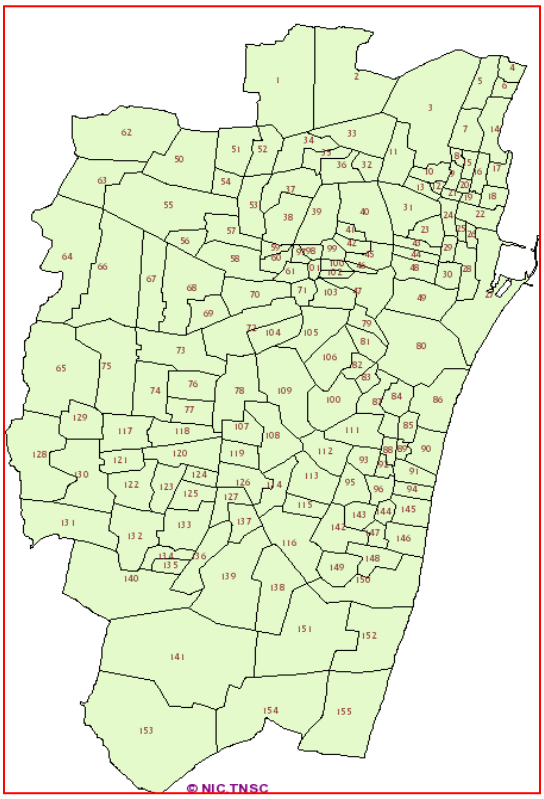
Chennai is divided into 10 Zones and 155 wards by the Chennai Corporation. Each ward comprises of CEBs.

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, 20 households will be selected leading to a total of 2000 households. Two participants from each of the 2000 households will provide the required sample of 4000 participants.

Zones of Chennai City.



Wards of Chennai City.



Chennai sampling scheme

Chennai Municipal Corporation

↓

155 Corporation wards

↓

20 wards (randomly selected)

↓

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

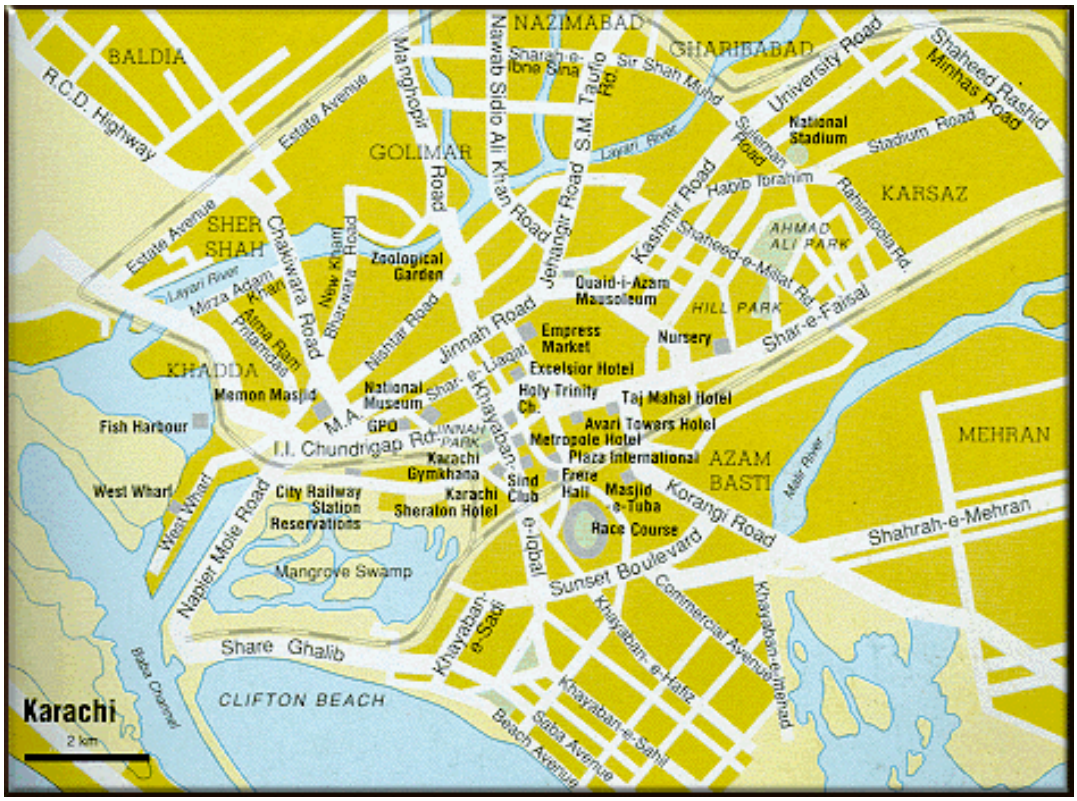
↓

20 Households per CEB randomly selected (total 2000 households)

↓

2 Participants per household (total 4000 study participants)

Karachi



Karachi sampling scheme

City District Government of Karachi
↓
18 towns
↓
178 union councils
↓
7500 Clusters / Census blocks (250 household per cluster)
↓
80 random clusters
↓
25 Households per cluster – randomly selected (total 2000 households)
↓
2 Participants per household (total 4000 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	• 20 wards were randomly selected for each study center from a total of 143 wards for Delhi; 155 wards for Chennai and 178 union councils for Karachi.
Stage-2: Selection of CEBs	• 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 Jhompri 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	• Each CEB 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 the 300 randomly selected CEBs. • Mapping of all HHs and important landmarks will be done for each selected CEB. • From this list a random sample of 20 HH (25 for Karachi) would be selected for each CEB. This will give a total of 2000 HH for each site and a total of 6000 HH for all the three study sites.
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 in each of the three age strata (20-45 years, 45-60 years and >60 years) who have provided consent to participate in the study (both cross-sectional and three years of follow-up) leading to a sample of 4000 participants in each of the three study sites.

Central random sampling

A list of wards from each study site was sent to COE-CARRS (PHFI). From this list 20 wards were randomly select and coded for each site. This list of twenty randomly selected wards was sent back to the respective sites who then obtained a list of CEBs for each of the selected wards from the 2001 Census data. The list of CEBs ward-wise was used to randomly select 5 CEBs per ward giving a total of 100 CEBs per study site. The randomly selected CEBs were coded again. This list will be used by the sites for enlisting and mapping of HHs and to finally select the required number of HHs.

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. 20 households (25 for Karachi)per CEB will give a total of 2000 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.

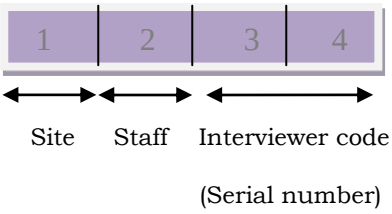
Learning Objectives

After completing this chapter the field staff will be able to

1. Understand the procedure for assigning unique identification codes: interviewer ID, cluster ID, Household ID and Participant ID
2. Able to assign the unique identification codes

Description of the Codes

The table below 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 
Cluster ID	A unique number should be assigned to all selected sampling units from which households will be selected. 1. 1st digit will be for the study (1 for the first cross-sectional survey and follow-up, 2 for the second cross-sectional survey) 2. 2nd digit will be for city code as mentioned above 3. 3rd digit will be the code for district 4. 4th and 5th digits will be for sub-district/Zone/towns (starting with 01, these should be coded in alphabetical order)	Study Code: 1 digit City code: 1 digit District code: 1 digit Sub district/Zone code: 2 digits Ward code: 2 digits CEB Code: 3 digits 

	5. 6th and 7th digit for ward /union council code and it will be as per the list prepared for random selection 6. 8th, 9th and 10th digit will be the CEB / cluster code 7. The codes and cluster ID will be assigned by the regional coordinating center (Appendix 3)	
Household ID	All households in a CEB will be assigned a unique ID following their random selection. This will be a 5 digit number. • 1st, 2nd and 3rd digits will be the CEB code (001, 002, ...100) • 4th and 5th digit will be the serial number of the household selected in each CEB (01, 02, ..., 20)	Household ID: 5 digits
Participant ID	All participants should be assigned a unique ID. • 1st digit will be the city code mentioned above • 2nd to 5th digit will be the serial number of enrollment of the participant and should start from 0001	Participant ID: 5 digits

The Cluster ID number will be of 10 digits

Study Code	City Code	District Code	Sub district/ Zone Code		Ward Code		CEB Code		

The Participant ID will be of 5 digits

City Code	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 01 - 100

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 Appendix-3.

Points to remember

1. Unique identification (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

Appendix - 3

CODE LIST FOR CHENNAI

STUDY SITE: CHENNAI **CITY CODE: 1** **Study code: 1**

ZONES			WARD			CEB		Cluster ID
Number	Name	Code	Number	Name	Code	Number	Code	
ZONE-1	TONDIARPET	01	6	CHERIYAN NAGAR (SOUTH)	01	305	001	1100101001
						322	002	1100101002
						301	003	1100101003
						299	004	1100101004
						315	005	1100101005
			8	KORUKKUPET	02	392	006	1100102006
						361	007	1100102007
						374	008	1100102008
						359	009	1100102009
						381	010	1100102010
ZONE-2	BASIN BRIDGE	02	22	MEENAKSHIAMMANPET	03	222	011	1100203011
						486	012	1100203012
						225	013	1100203013
						484	014	1100203014
						450	015	1100203015
			29	SEVENWELLS (SOUTH)	04	392	016	1100204016
						394	017	1100204017
						388	018	1100204018
						378	019	1100204019
						382	020	1100204020
ZONE-3	PULIANTHOPE	03	34	PERAMBUR (NORTH)	05	102	021	1100305021
						119	022	1100305022
						129	023	1100305023
						133	024	1100305024
						99	025	1100305025
			38	THIRU-VI-KA NAGAR	06	298	026	1100306026
						295	027	1100306027
						265	028	1100306028
						304	029	1100306029
						276	030	1100306030
			40	DR. SATHYAVANIMUTHU NAGAR	07	364	031	1100307031
						353	032	1100307032
						378	033	1100307033
						631	034	1100307034
						381	035	1100307035
ZONE-4	AYANAVARAM	04	51	SEMBIAM	08	66	036	1100408036
						105	037	1100408037
						383	038	1100408038
						65	039	1100408039
						210	040	1100408040
			57	NAGAMMAIAMMAIYAR NAGAR (SOUTH)	09	303	041	1100409041
						315	042	1100409042

						455	043	1100409043
						314	044	1100409044
						306	045	1100409045
ZONE-5	KILPAUK	05	71	GANGADEESWARAR KOIL	10	509	046	1100510046
						494	047	1100510047
						516	048	1100510048
						497	049	1100510049
						503	050	1100510050
			73	AMANJIKARAI (NORTH)	11	576	051	1100511051
						573	052	1100511052
						591	053	1100511053
						566	054	1100511054
						589	055	1100511055
ZONE-6	ICE HOUSE	06	86	CHEPAUK	12	403	056	1100612056
						170	057	1100612057
						177	058	1100612058
						401	059	1100612059
						166	060	1100612060
			91	KRISHNAMPET	13	269	061	1100613061
						273	062	1100613062
						280	063	1100613063
						274	064	1100613064
						275	065	1100613065
ZONE-7	NUNGAMBAKKAM	07	104	CHETPET	14	410	066	1100714066
						400	067	1100714067
						139	068	1100714068
						132	069	1100714069
						148	070	1100714070
			111	AMIR MAHAL	15	333	071	1100715071
						344	072	1100715072
						336	073	1100715073
						326	074	1100715074
						454	075	1100715075
ZONE-8	KODAMBAKKAM	08	114	SATHYAMURTHY NAGAR	16	46	076	1100816076
						55	077	1100816077
						37	078	1100816078
						53	079	1100816079
						35	080	1100816080
			118	VADAPALANI (EAST)	17	184	081	1100817081
						201	082	1100817082
						199	083	1100817083
						654	084	1100817084
						205	085	1100817085
			129	SALIGARMAM	18	608	086	1100818086
						609	087	1100818087
						628	088	1100818088
						605	089	1100818089
						645	090	1100818090

ZONE-9	SAIDAPET	09	137	VOC NAGAR	19	332	091	1100919091
						346	092	1100919092
						341	093	1100919093
						348	094	1100919094
						328	095	1100919095
ZONE-10	ADYAR	10	154	THIRUVANMIYUR (WEST)	20	529	096	1101020096
						500	097	1101020097
						540	098	1101020098
						502	099	1101020099
						556	100	1101020100

CODE LIST FOR DELHI

STUDY SITE: DELHI **CITY CODE: 2** **Study code: 1**

District		Subdividion		Ward (DMC-U)			Census Enumeration Block (CEB)			
Name	Code	Name	Code	Number	Name	Code	Number	Name	Code	Cluster ID
Central	1	Karol Bagh	01	129	Beadon Pura	01	39	Karol Bagh	001	1210101001
							51	Karol Bagh	002	1210101002
							63	Karol Bagh Double Storey Qtrs DCM line	003	1210101003
							81	Poorvi Marg Pusa Road Karol Bagh	004	1210101004
							83	Sarai Rohilla New Rohtak Road	005	1210101005
		Darya Ganj	02	107	Bazar Sita Ram	02	16	Bazar Sita Ram	006	1210202006
							19	Bazar Hindu Wara	007	1210202007
							20	Kali Masjid	008	1210202008
							82	Gali Shahatara (Ajmeri Gate)	009	1210202009
							83	Shardha Nand Marg (Ajmeri Gate)	010	1210202010
East	2	Preet Vihar	03	67	Trilok Puri	03	9	Trilokpuri Resettlement Colony	011	1220303011
							12	Trilokpuri Resettlement Colony	012	1220303012
							20	Trilokpuri Resettlement Colony	013	1220303013
							21	Trilokpuri Resettlement Colony	014	1220303014
							34	Mayur Vihar Phase-I, Pocket-I	015	1220303015
				70	Kondli	04	14	Indira Camp near Block 21	016	1220304016
							25	Kalyan Puri Block-18 (Indira Camp)	017	1220304017
							47	Kalyan Puri Block-12	018	1220304018
							62	Kalyan Puri Block-18	019	1220304019
							101	Khichri Pur Block- 5	020	1220304020

North East	3	Seelam pur	04	91	Seelampur	05	12	Area of Marginal Bandh	021	1230405021
							57	Kaith Wara Village	022	1230405022
							104	Chauhan Banger (Between Jaffrabad and Rishi Qurdam Marg) part-II	023	1230405023
							118	Chauhan Banger (Between Rishi Qurdam Marg & Gali No. 8) part-III	024	1230405024
							137	Chauhan Banger (Between Gali No. 8 & Akhare Wali Gali) part-IV	025	1230405025
		Shahda ra	05	93	Ambedkar Basti	06	79	East Ghonda	026	1230506026
							89	Braham Puri	027	1230506027
							103	Braham Puri	028	1230506028
							125	Braham Puri	029	1230506029
							126	Braham Puri	030	1230506030
		Seema puri	06	88	Bhagwan Pur Khera	07	11	New Modern Shahdara	031	1230607031
							22	Jagat Puri	032	1230607032
							47	Man Sarovar Park	033	1230607033
							59	Khera Bhagwan Pur	034	1230607034
							72	Ashok Nagar Block B	035	1230607035
North West	4	Sarawa ti Vihar	07	27	Tri Nagar	08	56	Tri Nagar	036	1240708036
							58	Tri Nagar	037	1240708037
							78	Tri Nagar	038	1240708038
							87	Lawrence Road Near Madhev Marg	039	1240708039
							103	Indira Colony	040	1240708040
				31	Shalimar Bagh	09	10	Shalimar Bagh	041	1240709041
							67	Shalimar Bagh	042	1240709042
							70	Shalimar Bagh	043	1240709043
							94	Shalimar Bagh	044	1240709044
							98	Shalimar Bagh	045	1240709045
		Model Town	08	116	G.T.B. Nagar	10	6	Tagore Garden	046	1240810046
							22	Parmanand Colony	047	1240810047
							24	Parmanand Colony	048	1240810048
							51	Mukharjee Nagar	049	1240810049
							139	Mukharjee Nagar	050	1240810050
				118	Model Town	11	27	Derewal Nagar BlockA	051	1240811051
							34	GujranwalaTown PartII	052	1240811052
							77	Model Town II	053	1240811053
							101	Rameshwar Nagar and Kewal Park	054	1240811054
							109	M2,M1 Block near Mohan Park & MCD colony & pre-primary s	055	1240811055

South	5	Defence Colony	09	3	Sewa Nagar	12	3	Sewa Nagar (Kasturba Nagar)	056	1250912056
							12	Sewa Nagar (Kasturba Nagar)	057	1250912057
							16	Sewa Nagar (Kasturba Nagar)	058	1250912058
							84	Village Pillanjee	059	1250912059
							102	Tyag Raj Nagar (Prem Nagar)	060	1250912060
				7	Okhla	13	58	Mahboob Nagar	061	1250913061
							101	Johari Farm (Noor Nagar II)	062	1250913062
							130	New Friends Colony	063	1250913063
							133	New Friends Colony	064	1250913064
							150	Abdul Fazal Enclave I and II	065	1250913065
		Hauz Khas	10	64	Sangam Vihar	14	96	Sangam Vihar	066	1251014066
							134	Sangam Vihar	067	1251014067
							166	Sangam Vihar	068	1251014068
							193	Sangam Vihar	069	1251014069
							202	Sangam Vihar	070	1251014070
West	6	Patel Nagar	11	47	Hastsal	15	12	Vikas Puri	071	1261115071
							57	Vikas Puri	072	1261115072
							88	Vikas Puri	073	1261115073
							118	Kali Basti Transit Camp	074	1261115074
							137	DDA flats Hasthal	075	1261115075
				123	Karam Pura	16	3	Rohtak Road (Madan Park)	076	1261116076
							25	Ramchandra Park (Moti Nagar)	077	1261116077
							38	New Sudama Market Moti Nagar	078	1261116078
							47	Moti Nagar	079	1261116079
							58	New Moti Nagar	080	1261117080
				125	East Patel Nagar	17	54	West Patel Nagar	081	1261117081
							55	West Patel Nagar	082	1261117082
							88	Rama Colony	083	1261117083
							97	Rama Colony	084	1261117084
							111	Prem Nagar	085	1261117085
				134	Anand Parbat	18	18	Baljit Nagar	086	1261118086
							75	Baljit Nagar	087	1261118087
							90	Baljit Nagar	088	1261118088
							92	Baljit Nagar	089	1261118089
							106	Punjabi Basti (Bihari Basti at Pahari near Talli Wali Jhuggi)	090	1261118090
		Rajouri Garden	12	45	Khayala	19	3	Vishnu Garden Khayala Road (Block - NM)	091	1261219091
							14	Vishnu Garden (Sham Nagar) Block-S	092	1261219092

							48	Sham Nagar Block-C	093	1261219093
							83	Vishnu Garden (Navyug Block & Vishnu Park)	094	1261219094
							127	Vishnu Garden Shyam Nagar	095	1261219095
				46	Guru Nanak Nagar	20	49	JJ Colony Khyala (F Block)	096	1261220096
							81	Major Bhupender Singh Nagar	097	1261220097
							97	Major Bhupender Singh Nagar	098	1261220098
							151	Vikas Puri Block J (Him Giri Appartments)	099	1261220099
							178	H Block Vikas Puri	100	1261220100

CODE LIST FOR KARACHI

STUDY SITE: KARACHI **CITY CODE: 3** **Study code: 1**

Town		Union council			Cluster			Cluster ID
Name	**Code**	**Number**	**Name**	**Code**	**Name of locality**	**Locality/ street/ road name**	**Code**	
Baldia Town	01	1	Gulshan-e-Ghazi	01	Memon Colony	58	001	1300101001
		5	Data Nagar/Saeedabad	02	Jangle School	44	002	1300102002
		8	Rasheedabad	03	Rasheedabad	77	003	1300103003
Bin Qasim Town	02	1	Ibrahim Hyderi	04	Ibrahim Hyderi	41	004	1300204004
		3	Cattle Colony	05	Juma Goth	45	005	1300205005
Gulberg Town	03	4	Aisha Manzil	06	Musa Colony	62	006	1300306006
		5	Naseerabad	07	Dastagir	20	007	1300307007
					Gulshan-e-Shamim	36	008	1300307008
		6	Yaseenabad	08	F.B. Area Block 15 (Café Javed)	25	009	1300308009
		7	Water Pump	09	F.B. Area Back Power House	23	010	1300309010
					F.B. Area Block # 16	24	011	1300309011
		8	Shafiq Mill Colony	10	F.B. Area Block 18 (Al Noor Society)	26	012	1300310012
Gulshan Town	04	2	Civic Centre	11	Press Qanqer	73	013	1300411013
		3	Pir Illahi Buksh Colony	12	PIB Colony	71	014	1300412014
		4	Essa Nagri	13	Essa Nagri	21	015	1300413015
		6	Gillani Railway Station	14	Gulshan-e-Iqbal 13 G (Madina Colony)	34	016	1300414016
		7	Shanti Nagar	15	Evershine Appartment	22	017	1300415017
					Shanit Nagar	84	018	1300415018
					Gulshan-e-Iqbal Block 10-A	35	019	1300415019

		9	Gulshan-e-Iqbal II	16	Azeem Goth Gulshan-e-Iqbal Block # 9	11	020	1300416020
		10	Pehlwan Goth	17	Hussain Hazara Goth	39	021	1300417021
		11	Matrovil Colony	18	Metrovil 3 Gulazar-e-Hijri	59	022	1300418022
		12	Gulzar-e-Hijri	19	Gulshan-e-Umair	37	023	1300419023
					Ayub Goth	9	024	1300419024
					Pioneer Villas	72	025	1300419025
		13	Safooran Goth	20	Muhammad Khan Goth	60	026	1300420026
					Gulistan-e-Johar (Safoora)	33	027	1300420027
					Rizwan Society	79	028	1300420028
Jamshed Town	05	3	Azam Basti	21	Azam Basti	10	029	1300521029
		4	Chanesar Goth	22	Chaniesr Goth	17	030	1300522030
		6	P.E.C.H.S.	23	P.E.C.H.S Block 02	69	031	1300523031
					Martan Road	56	032	1300523032
		9	Jacob Line	24	Khudadad Colony	49	033	1300524033
		11	Garden East	25	Banethine Colony	13	034	1300525034
					Shan-e-Karim	83	035	1300525035
		12	Soldier Bazar	26	Soldier Bazar	86	036	1300526036
Kiamari Town	06	1	Bhutta Village	27	Massan Road (Bhutta Villlage)	57	037	1300627037
					Jackson Bazar (Gul Center)	42	038	1300627038
		2	Sultanabad	28	Gul Bai	30	039	1300628039
		5	Machar Colony	29	Muhammadi Colony	61	040	1300629040
		6	Maripur	30	Costum Colony	19	041	1300630041
					Fathar Colony (Qrax)	27	042	1300630042
Korangi Town	07	1	Bilal Colony	31	Bilal Colony	14	043	1300731043
		2	Qayyumabad/Nasir Colony	32	Qayyumabad	74	044	1300732044
		3	Chakra Goth	33	Korangi No 2	51	045	1300733045
		4	Mustafa Taj Colony	34	Korangi 5 1/2	50	046	1300734046
Landhi Town	08	6	Bhutto Nagar	35	Landhi 3 1/2	53	047	1300835047
Liaquata-bad Town	09	2	Firdous Colony	36	Gulbahar (Firdous Colony)	32	048	1300936048
		4	Dak Khana	37	Liaquatabad No. 5	54	049	1300937049
		7	Sharifabad	38	Sharfabad	85	050	1300938050
		10	Nazimabad	39	Muslim League Colony	63	051	1300939051
		11	Abbasi Shaheed	40	Chotta Maidan (Nazimabad)	18	052	1300940052
Lyari Town	10	1	Agra Taj Colony	41	Agra Taj	6	053	1301041053
		4	Khada Memon Society	42	Khada Market	48	054	1301042054
Malir Town	11	2	Kala Board	43	Kala Board (A.Area)	46	055	1301143055
		3	Saudabad	44	Saudabad (R.C Ground)	80	056	1301144056
New Karachi	12	3	Fatima Jinnah Colony	45	U.P. Society	89	057	1301245057
		6	Hakim Ahsan	46	11-D New Karachi	1	058	1301246058

Town		8	Faisal Colony	47	Two Minute Stop	88	059	1301247059
		10	Mustafa Colony	48	5-D New Karachi	5	060	1301248060
		11	Khawaja Ajmeer Nagri	49	5C-2 Bilal town	4	061	1301249061
North Nazimabad Town	13	2	Pahar Ganj	50	KDA Flats Nazimabad	47	062	1301350062
		7	Mustafabad/Nusrat Bhutto Colony	51	North Nazimabad (Block 5)	66	063	1301351063
		9	Buffer Zone	52	Buffer Zone	15	064	1301352064
Orangi Town	14	2	Haryana Colony	53	5/E Area Orangi Town	3	065	1301453065
		3	Hanifabad	54	Orangi # 10 (Noor Colony)	67	066	1301454066
		4	Mohammad Nagar	55	Gulashan-e-Zia 11 1/2 Orangi Town	31	067	1301455067
		11	Data Nagar	56	Orangi Town No - 08 / L	68	068	1301456068
		12	Mujahidabad	57	1-C Area Orangi Town No. - 01	2	069	1301457069
					Ali Garh Colony Orangi Town	8	070	1301457070
Saddar Town	15	2	Garden	58	Hasan Lashkani Village	38	071	1301558071
		4	City Railway Colony	59	Railway Colony (City Station)	76	072	1301559072
		5	Nanak Wara	60	Nareen Para (Naran Para)	64	073	1301560073
		7	Millat Nagar	61	Garden	28	074	1301561074
		8	Saddar	62	Ratan taluoo Akber Road	78	075	1301562075
					Jama Cloth	43	076	1301562076
					Naz Plaza	65	077	1301562077
					Gari Khata	29	078	1301562078
					Burns Road	16	079	1301562079
		10	Clifton	63	Shah Rasool Colony (Neelam Colony)	82	080	1301563080

Chapter 4

Household Selection

Introduction

A total of 20 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 does not include people who have 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-1)
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 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 20 households from each CEB to

have a total of 2000 households in each study site. Basic maps of CEBs will be provided to the field team wherein s/he will have to mark all constructions / structures and important landmarks (not already present in the printed 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 / 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 (Appendix-4). 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 project manager will select 20 HH from this list using random number table or computer generated random numbers. The number of HHs selected will be fixed (20 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 20 more randomly selected HHs which should be used in case (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) and (iv) if total of 40 eligible participants could not be recruited from the " Primary HH list". Both lists of selected households will be handed over to the field team to start the visits.

Appendix - 4

FORM-1

COE – CARRS: Surveillance Study

Household Listing

Date: ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Study Site:
Sub-district/Zone / Town:
Ward (Number): ☐☐☐
CEB name :
CEB number ☐☐☐
Total number of structures
Interviewer ID: ☐☐☐☐

List of 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.

Sl.NO of structure	Address/Location/ Description of Structure	Floor No.	Residence Yes/No	Sl.No. of HH in the Floor	Name of head of HH	Comments
001	C1/52; Safdarjung development area	G	Y	A	Mr. Ajay	
				B	Mr. Ram Das	
				C	Mr. V. Sharma	
		1	N	_	_	
		2	Y	A	Mr. Shyam	
				B	Mr. Tripathi	

Sl.NO of structure	Address/Location/ Description of Structure	Floor No.	Residence Yes/No	Sl.No. of HH in the Floor	Name of head of HH	Comments
002	C1/53	_	Y	A	Mr. Roy	No floors
				B	Mr. P. Jain	

On the map provided along with this template, mark each structure using the serial number assigned to the household in the first column of the table.
Symbol to denote a structure on the map that is listed as 23 in the HH listing table – **23**

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 40 HHs will be selected randomly using either STATA, random number tables or web generated random numbers. The first 20 HHs will be included in the "primary HH list" and the remaining 20 in the "secondary HH list". Two columns should be added at the end of each list, "Recruited" (Status of recruitment of the HH) and "Household ID" (Example is shown below). 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. HH IDs will be assigned to only the recruited HHs as described in Chapter-3 (Example is shown below).

Primary HH list						
WARD 023		CEB 011		Rajouri Garden G block		
Sl. No.	SNo. of Structure	Address/Location/Description of Structure	Floor No.	SNo. of HH in Structure	Recruited [1=Yes; 2=No]	HH ID
1	017	G-18/7 Rajouri Garden	2	A	1	01101
2	011	G-18/1 Rajouri Garden	2	A	1	01102
3	023	G-19/2 A Rajouri Garden	1	A	1	01103
4	098	24/6 Rajouri Garden	G	A	2	-
5	033	G-19/11 Rajouri Garden	2	A	1	01104
6	133	G-19/11 Rajouri Garden	1	A	2	-
7	031	G-19/9 Rajouri Garden	1	A	2	-
8	063	22/2 A Rajouri Garden	1	A	2	-
9	076	23/3 Rajouri Garden	G	A	1	01105
10	081	23/1 Rajouri Garden	1	A	1	01106
11	063	22/2 A Rajouri Garden	G	A	1	01107
12	094	24/2 Rajouri Garden	G	A	2	-
13	085	23/5 Rajouri Garden	3	A	1	01108
14	125	G-19/4 A Rajouri Garden	G	B	2	-
15	052	21/4 A Rajouri Garden	1	A	1	01109
16	089	24/3 Rajouri Garden	2	A	1	01110
17	077	23/4 Rajouri Garden	2	A	1	01111
18	088	24/2 Rajouri Garden	G	A	1	01112
19	042	20/1 Rajouri Garden	2	B	1	01113
20	097	24/5 Rajouri Garden	1	B	1	01114

Secondary HH list						
WARD 023		CEB 011		Rajouri Garden G block		
Sl. No.	SNo. of Structure	Address/Location/Description of Structure	Floor No.	SNo. of HH in Structure	Recruited [1=Yes; 2=No]	HH ID
1	005	G-17/5 A Rajouri Garden	G	A	1	01115
2	032	G-19/10 Rajouri Garden	G	A	2	-
3	005	G-17/5 A Rajouri Garden	1	A	1	01116
4	040	20/6 Rajouri Garden	G	A	1	01117
5	040	20/6 Rajouri Garden	2	A	1	01118
6	096	24/4 Rajouri Garden	2	A	2	-
7	064	22/3 A Rajouri Garden	1	A	2	-
8	092	24/6 Rajouri Garden	G	A	2	-
9	088	24/2 Rajouri Garden	3	A	1	01119
10	047	20/6 Rajouri Garden	G	A	2	-
11	003	G-17/3 A Rajouri Garden	G	A	1	01120
12	083	23/3 Rajouri Garden	1	A		
13	028	G-19/7 Rajouri Garden	2	A		
14	034	G-19/12 Rajouri Garden	2	A		
15	082	23/2 Rajouri Garden	2	A		

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. Primary and Secondary Household lists each with 20 HHs should be prepared and the selected HHs should be assigned HH IDs
8. 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 detail addresses and the "Household Performa" and copies of "Notification of the surveillance study"

The "Household Performa" Form-2 (Appendix - 5) 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 in 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 door bell. 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 knock	**Look around the side of the house to see if someone is nearby.**
Nobody is at home	**Leave a notification of the surveillance study 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 neighbors.**

Handling Refusals at Household Level

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

- 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-3 (Appendix-5) at their door step and revisit the household at a different time.
- 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-4 (Appendix-5) and request them to contact you if they change their mind.

- 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.
- 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.

Instruction

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-5 (Appendix-5)

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 attempts in Form-2 and refusal in Form-5

Appendix – 5

Forms

1. Household Proforma (Form-2)
2. Surveillance Notification form (Form-3)
3. Non-Interview report form (Form-5)

Instructions for filling the forms

FORM-2

COE-CARRS: Surveillance Study

Household Proforma

Date ☐☐ ☐☐ ☐☐☐☐
Day Month Year

Household ID: ☐☐☐☐☐	Interviewer ID: ☐☐☐☐	
Cluster ID: ☐☐☐☐☐☐☐☐☐☐		
Dwelling Type ***Instructions: Observe the following and record***		
a. Is the house Kutcha?	1 Yes 2 No	☐
If Yes, then answer(b-d)		
b. Is the Roof made of Plastic/ Polythene/thatch/Bamboo/Mud?	1 Yes 2 No	☐
c. Is the Wall made of Plastic/ Polythene/thatch/Bamboo/Mud?	1 Yes 2 No	☐
d. Is the Floor made of mud?	1 Yes 2 No	☐
Instructions: *If all answers from (a - d) are Yes, then do not approach the household, select a household from the "Supplementary HH List" (in serial order), otherwise go to the next questions*		
1. Name of the Informant		
2. Name of the head of household		
3. Relationship with head of household		
4. Postal Address		
5. For how long you have been staying in the current residence ***(Ask this question only to a permanent resident* of the house)***	Years ☐☐ Months ☐☐	
6. Are you planning to move out to a new house in the next 1 year? ***(Ask this question only to a permanent resident* of the house)***	1 Yes 2 No	☐

7. *List all household members (Sex: Males=M, Females=F; Age in years)*

Name	Age (Years)	Sex (M/F)	Bed Ridden (1=Y 2=N)	Reason for being bed ridden**	For other reasons	Pregnant (1=Y 2=N)	PR* (1=Y 2=N)

**** 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=Chronic 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 participants

8. Selection of participants for the study

Kish Household Coversheet

Do not include bed-ridden members, pregnant women and non-permanent residents in the Kish household cover sheet while ranking

S. No.	Sex	Age	Rank	Selected
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

S. No.	Sex	Age	Rank	Selected
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

Kish Household Table

Number of Eligible persons 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

Completion form for household Proforma			
Household ID:		**Interviewer ID:**	
Attempts	**Attempt - 1**	**Attempt - 2**	**Attempt - 3**
Date	DD/ MM/ YY	DD/ MM/ YY	DD/ MM/ YY
Is the household form complete? ***[1=yes; 2=no]***			
If No, give reason for not completing the form ***(refer to the Code given below)***			
1: Locked; 2: Did not answer; 3: Refused to open; 4: Opened the door but refused to provide information; 5: Provided information but requested no further visits; 6: Incomplete; 7:Others			
If "7" (others), specify the reason			
Instructions for Re-visit: ***If the reason for non completion of the HH form during attempt 1 and 2 are "1", "2", " 3", "4" or "6" then revisit. If the reason for any of the attempt is "5", then abort the household***			
End Result			
Household included ***[1=yes; 2=no]***			

Instructions for filling the Household Proforma [Form-2]

A list of selected households per CEB for each ward will be provided to the Field Interviewer (FI) along with a list of codes for the ward, CEB and household (included in annexure-2).

Date – The day, month and year of the household visit should be entered

Cluster ID – Should be entered from the code list.

Interviewer ID - Enter the four digit unique interviewer ID

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 questions 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

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 20 HHs.

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.

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 important landmark and PIN code

5. For how long have you been staying in the current residence?
   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. Ask the above question only 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 years)

Sl. No.	Name	Age	Sex	Bed Ridden (1=Y 2=N)	Reason for being bedridden **	Pregnant (1=Y 2=N)	PR* (1=Y 2=N)

**** 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 _____

Serially write the names of all the members including children and infants who live in the HH

Note the age in years for each member

Sex – write 'M' for males and 'F' for females

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

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.

For female members judiciously ask if anyone is pregnant in the HH.

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

Completion form for HH Proforma

- Interviewer ID - Enter the four digit unique interviewer ID.
- 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.

- Date – write the date of visit to the HH for each attempt.
- 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.
- If 'NO' give reason for not completing the form
  Refer to the reasons given below the question and enter the appropriate code.
- If the reason is something for which the option is not provided, then select '7' (Others) and specify the reason in the space provided.
- Please follow the instructions for re-visit given at the end of the form.
- 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-4; appendix-6] for them to read. Provide further information in the Surveillance Study Notification Form [Form-3]. Request a date and time to collect the signed copy of the consent form from the participant.

FORM-3

COE-CARRS: Surveillance Study

Surveillance Study Notification Form

Name of study coordinating site:_____

Notification of Surveillance Visit		
Today a research staff from _____ (study center) visited your household to conduct a survey of people aged 20 years and above on disease like hypertension, diabetes, heart and chronic kidney diseases. Since we were not able to contact you, we will return on the date indicated below. If this is not convenient, please contact anyone at the below mentioned phone numbers to provide a suitable time for our visit.		
Date of Visit		
Household address		
Next Visit :	Day/Date:	Time:
Name of the field staff: Phone:		
Contact details of the study site: Address: Phone:		

Instructions for the Surveillance Study Notification Form [Form – 3]

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

- Date of visit – note the date of visit to the HH.
- HH address – write the HH address from the list provided.
- Next visit – Write the date of your next visit by consulting with a member of the house (if available), otherwise note a date on your own (use your judgement).

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

- Provide information about yourself and the study center 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 center at the address provided if they need any further information.

FORM-5

COE-CARRS: Surveillance Study

Non Interview Report Form (cross-sectional survey)

Household ID:	Interviewer ID:
Cluster ID:	

Household visits	**Visit - 1**	**Visit - 2**	**Visit - 3**
Date of visit			
Reasons for refusal **Yes=1; No=2; not applicable=9**	Not interested Do not trust the interviewer Concerned about the study procedure Concerned about privacy No benefit Do not want to give blood sample	Not interested Do not trust the interviewer Concerned about the study procedure Concerned about privacy No benefit Do not want to give blood sample	Not interested Do not trust the interviewer Concerned about the study procedure Concerned about privacy No benefit Do not want to give blood sample
Other reason, specify			
Spirometry			
Reasons for refusal **Yes=1; No=2; not applicable=9**	Do not want to undergo spirometry Do not want to use bronchodilator/ medication	Do not want to undergo spirometry Do not want to use bronchodilator/ medication	Do not want to undergo spirometry Do not want to use bronchodilator/ medication
Other reason, specify			
Reasons for not responding **Yes=1; No=2; not applicable=9**	Too ill No household member at home Entire household absent for an extended period of time House vacant	Too ill No household member at home Entire household absent for an extended period of time House vacant	Too ill No household member at home Entire household absent for an extended period of time House vacant
Other reason, specify			

Instructions for filling the Non Interview Report Form (Cross-sectional survey) [Form – 5]

- Interviewer ID - Enter the four digit unique interviewer ID assigned to you.
- Household ID – The interviewer should enter the household ID from the given list of codes.
- Cluster ID – Should be entered from the given list of codes.
- 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).
- Date of visit – note the date when you visited the HH.
- 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.

None of the boxes should be left empty

- If the reason is not specified, describe the reason for refusal in the space provided.
- 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 '1', '2' or '9' depending on the reason.

None of the boxes should be left empty

- If the reason is not specified, describe the reason for not responding in the space provided.
- The section on spirometry should be filled for participants selected for the test, otherwise enter code "9" (Not applicable) and in the space below "other reasons" – write that the participant has not been selected for spirometry.

Chapter 6

Selection of Participants (Visit-0)

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:

- 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.
- Bed-ridden individuals will be excluded because of the difficulty in taking anthropometric measurements in these individuals.
- 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 (Appendix - 5):

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 illustration below).

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

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.

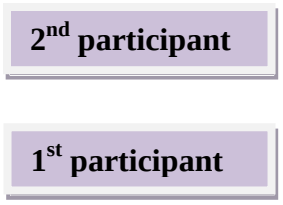
Example: Participant ranking table

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.

Kish Selection Table: (Example)

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



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 two participants from the HH. While selecting the second participant only the member who has been already selected is removed from the table and the rest are re-ranked.
- 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-5).

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
5. The project manager at each site will guide the selection process to ensure that there is equivalent distribution of participants in both sexes and three age strata (20-45 years, 45-60 years and >60 years)

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-4 (Appendix -7) 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-0 once Form-2 has been completed and 2 eligible participants are selected using the Kish method, the field staff has to explain about the purpose of his/her visit, the objectives of the study and leave a copy of the Participant Information Sheet (PIS) in the language of their preference (Hindi/English/Tamil / Urdu).

Interviewer 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-4 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-4), 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-

4). 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-5). 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-5

Appendix-7

FORM-4

COE-CARRS: Surveillance Study
Participant Information Sheet

Name of the study coordinating site: _____

Principle Investigator: Dr. _____(Name of the site PI)

Regional coordinating site: Public Health Foundation of India (PHFI), New Delhi, India

Introduction

You are invited to take part in a community based study. Before you decide to take part, it is important that you understand why the project is being conducted and what it will involve. If you wish to take part you will be asked to sign a consent form. By volunteering for this study or by signing this consent form, you are not giving up any of your rights. Our contact details are included and you are free to contact if you want any further information.

What is the purpose of the study?

Cardio- metabolic diseases (CMD) include diabetes, heart attacks, stroke (paralytic attack), chronic kidney disease and other blood vessel disease (gangrene) . CMD is one of the top ten costly diseases and widely occurs all over the world. People in South Asia are prone to these diseases at a relatively young age compared to other regions of the world. In India/Pakistan these diseases are the cause of early deaths and loss of productivity. The common risk factors for these diseases are obesity (excess body weight), increased blood pressure, increased bad cholesterol and high blood sugar. These risk factors can be controlled through changes in lifestyle particularly through healthy eating habits and regular physical activity.

Currently in our country we do not have reliable data on the burden of the CMD and their risk factors. This study aims to measure the burden of CMD and its risk factors in the South Asian population. This knowledge will help formulate health policy and ultimately help in health promotion and disease prevention in the population.

Why have you been chosen to take part?

You and your household have been chosen randomly from your locality to take part in the study. Individuals 20 years and above will be eligible to take part in this survey.

What does it mean to participate?

To participate in the study means that you have given your consent to be a part of this study for a duration of four years during which the following will be required from you.

First year - Our field staff will contact you at your residence at two time points (Visit 1 and Visit 2). During visit 1 you will be requested to provide us details of your education, occupation, socioeconomic status, diet history, lifestyle behaviours like tobacco, alcohol consumption and physical activity. We will also take details about your present and past illness and request you to share with us your medical records for documenting the diagnosis and prescribed medications. This will be solely for the purpose of this study.

Prior to the day of Visit 2, you will be asked to fast overnight from 10:00 pm onwards. On the day of visit 2 you will be required to collect a 100 ml urine sample of the first morning void in sterile container provided by us during the first visit. A trained laboratory technician will draw a small sample of blood in a safe and sterile manner. Your blood and urine will be used for research purposes only. The blood will be analyzed for sugar, urea, creatinine and cholesterol levels and urine will be analysed for presence of proteins, and the reports will be given to you. Your blood pressure will also be recorded. Trained field staff of the same gender will take your body measurements like height, weight, skin fold thickness, waist and hip circumferences and bioelectrical impedance (for measurement of body fat). You will be requested to provide a sample of saliva in a special sterile container provided by us with instructions during the first visit. This sample will be used to measure exposure to tobacco smoke.

Currently we have limited knowledge about the factors related to increased incidence of CMDs in young people in India/Pakistan. To know these factors we will store your blood sample to enable us to study the risk factors of CMDs that may emerge in future including genetic factors.

To enable us to follow you up for three subsequent years, we will require your contact details including phone numbers and email ID.

Second year – A year after the visit in the first year, with prior appointment our field staff will revisit you at your residence. During this visit we will enquire about your current health status, hospitalisation details (if any) and your diet history. Blood pressure and body measurements as done in the first year will be repeated.

Third year – A year after the visit in the second year, with prior appointment our field staff will revisit you at your residence. During this visit we will enquire about your current health status, hospitalisation details (if any) and your diet history. Blood pressure and body measurements as done in the first year will be repeated.

Fourth year - A year after the visit in the third year, with prior appointment our field staff will revisit you at your residence. During this visit we will enquire about your current health status, hospitalisation details (if any) and your diet history. Blood pressure and body measurements as done in the first year will be repeated. Apart from this a table spoon of blood and 100 ml of urine samples will be requested from you to repeat the tests done during the first year and reports will be provided to you.

Who is organizing this project?

This study is being organized by " _____" (Name of the study site)

Benefits from this study

We will provide the reports of the blood and urine tests, blood pressure and anthropometry along with relevant advice. In case any abnormality is detected, you would be referred to _____(hospital name).

By participating in the study you will be providing us with valuable information regarding burden of Cardiometabolic disease in the community. This information will help the government to formulate policies for preventing the disease at the community level.

What are the risks in participating in the study?

We do not expect that you will incur any risk by participating in this study. Blood drawing might involve some discomfort when the needle is passed into the vein, but does not cause long term pain. After blood is taken sometimes there can be a small bruise or soreness at the site.

Voluntary Participation

It is entirely your decision to participate in the study. If you want to discontinue at any point of time during the four year duration of the study you are free to leave without stating any reason. You are free to refuse to provide us with your blood and or /urine and or/saliva samples and also not disclose your medical records if you are not willing.

You have the right to ask any questions concerning the study any time during the study period.

Dr. _____ (Contact no.- _____) or one of his associates will answer your queries regarding the study or your participation in the study.

What about confidentiality?

Information on your personal and medical record details as well as your blood, saliva and urine reports will be kept confidential and it will not be made available to anybody except for the investigators of this study. Information will be stored in password protected computers in the regional coordinating centre. When the results are published in research journals your names and details will not be disclosed.

Thank you for taking time to read this information sheet. If you wish to take part in this project please sign and date the consent form given to you. You will be given a copy of the information sheet and your signed consent form.

COE-CARRS: Surveillance Study

Participant Consent Form

Study site _____

Please read the following before putting your signature below.

I am free to participate or not to participate in this study and also leave the study at any point of time.

I have been given the opportunity to ask questions and reply was given for all the questions to my satisfaction.

I have been informed by the investigators about the process including the nature, objective and known and likely inconveniences related to this study and I have understood them.

My medical data are strictly confidential and I only authorise the persons, involved in the research, identified by the sponsor or health authorities to consult about the same.

By signing this form, I give my free and informed consent to take part in this study as outlined in the information sheet and this consent form. Specifically, I agree to being interviewed, examined and having blood drawn. I also agree my information, including results of blood, saliva and urine tests, to be used in research.

I give permission for any blood that is left over after the tests to be stored and used for further laboratory tests for medical research

I understand that future research using the sample I give may include genetic research aimed at understanding genetic influences on diseases but the results of these investigations are unlikely to have any implications for me personally

I have been given a copy of the information sheet and consent form to keep. By signing this form I have not given up my legal rights.

Printed name of the Participant_____

Signature of the Participant_____Date_____

Printed name of the Study officer_____

Signature of the Study officer _____Date_____

Participant ID 

Appointment for interview: Date _____ Time _____

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 behavior 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

Behavior 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 behavior 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-A (Appendix-11).

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

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 four years.

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

Visit – 0 Participant recruitment and consent

Visit – 1 Questionnaire based interview, blood pressure and pulse rate, and anthropometric measurements (body circumference and skin-fold thickness)

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 each year for a period of three years. The interval between the visits will be one calendar year.

Cross-sectional Survey

Visit – 0: This is the visit to 2000 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 should leave

the Participant Information Sheet (PIS) and the consent forms with the selected participants and with the participant decide 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. The visits and their final outcome should be documented in Form-5.

Pre-visit activities: 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 form with the Kish tables [Form-2]**
- **Surveillance study notification letter [Form-3]**
- **Participant information sheet (both English and regional language) [Form-4]**
- **Non-interview report form (Cross-sectional survey) [Form-5]**

Activities during the visit: During the visit the interviewer will complete the following tasks:

- **Explain the study**
- **Complete the Household Form-2**
- **Select the eligible participants by HINT / Kish methods**
- **Provide a copy of the Surveillance study notification letter [Form-3]**
- **PIS [Form-4]**
- **Schedule an appointment to know their willingness to take part or not, and complete the consent form process**
- **Schedule the first visit (visit-1) if the participant provides consent**
- **Complete the Non-Interview Form-5 in case of refusal**
- **Thank the participants and other family members for their valuable time**

Visit 1: This visit will be made only to selected participants who have provided consent to participate in the study. During this visit the participants will be interviewed and the information will be recorded in the study questionnaire.

Pre-visit check list: 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 and ensure the specimen collection containers are properly labeled prior to leaving the field office. Each interview pack should contain the following materials:

- **Questionnaire booklet**
- **Blood pressure instrument**
- **Holtain skinfold calipers**
- **Gulick-II, non-stretch measuring tape**
- **Wax-based cosmetic pencils**
- **Fasting instructions for blood collection**
- **Saliva collection instructions**
- **Saliva collection tube**
- **Urine collection instructions and sterile container**

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 and extra specimen collection containers.

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 reviewing 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.

Conducting the In-home Interview

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

- 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.
- 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.
- 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.
- 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.
- 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:

- **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.
- **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.
- **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, or with the help of "Show Cards". Assistance is allowed as long as the responses are given to the FI directly by the participant.
- **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 judgment, then the interview should be terminated and the situation documented.

Activities during Visit-1: The FI should complete the following activities during Visit 1:

- **Complete the questionnaire**
- **Conduct anthropometric measurements – body circumferences and skin-fold thickness**
- **Record blood pressure and pulse rate**
- **Provide and explain the fasting instructions for blood collection**
- **Provide the saliva collection tube with instructions**
- **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

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.

The Interview Checklist [Form-6; appendix-10] should be used to document the completion of the first home visit activities. On this form, the field team will indicate which components were completed. One form will be completed for each participant within the household.

The interviewer will explain that Visit 2 will take place at a local clinic. If the participant does not want to travel to the local clinic, 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) and saliva. 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 clinic.

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

- **Complete a home visit checklist**
- **Check the questionnaires for completeness**
- **Check that all materials have been picked up**

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.

Visit 2: Local clinics for blood collection will be organized in the neighborhood of selected CEBs on a pre-fixed date, usually on a weekend. The participants will be invited to come to the local clinics in fasting state during the early hours of the day. The date and time will be communicated to the participants during visit-1 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) and the sample of saliva before brushing her/his teeth in the morning of the scheduled visit. The specimens should be brought to the clinic for submitting to the laboratory technician.

Check List for the Local Clinic

It is recommended that the FI and the laboratory technicians set-up the clinic 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 clinic 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 418 (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 saliva sample tube brought by the participant**
- **Collect the urine sample container brought by the participant**
- **Complete specimen collection forms for urine [BS-2] and saliva [BS-3]**
- **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] and processing forms [BS-4]**
- **Measure height and body composition**
- **Check the medical records of those participants whose records were not available during visit-1**

(Activities continued from the previous page)

- **Perform all activities pertaining to blood collection, storage and transport**
- **If any participant does not come to the local clinic, 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 clinic and also remind the participant to follow the specimen collection instructions and collect the saliva and urine before coming for blood collection**
- **If a participant refuses to participate, fill the non-response form**

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 along with the BP and anthropometric measurements should be given to the participant. 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 Study

It is very crucial for the FI to build rapport with the participants. This will help in reducing the number of loss to follow up and refusals. Since the FI will interview the participant only once in a year, it is advisable that the FI contacts her/him at least once in 3 months for a general discussion. This will help to track the participants and again minimize loss to follow-up. The FI should request the participants to inform if s/he changes her/his place of residence.

Follow-up of Participants

Three follow-up visits will be conducted between 2011 and 2014 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. The first and second follow-up visits will be questionnaire based along with blood pressure recording and anthropometric measurements. However, in the third follow-up visit blood samples will also be collected.

First and Second Follow-up Visits: During visit 1 and also after blood collection the interviewer should explain to the participant about the three subsequent follow-up visits and provide the date of the first visit. The interviewer should call the participant at least one week before the visit to confirm the date and time.

Pre-visit Checklist

- **The questionnaire booklet**
- **Electronic Sphygmomanometer**
- **Holtain skinfold caliper**
- **Seca Brand-214 Portable Stadiometer**
- **Gulick-II, non-stretch measuring tape**
- **Wax-based cosmetic pencils**
- **Body Composition Analyzer BC 418 (bio-impedance measuring instrument)**

Activities

- **Complete the questionnaire**
- **Check all available medical records. If the relevant records are not available request the participant for another appointment to review the records**
- **Schedule the next follow-up visit**
- **Measure height and body composition**
- **Conduct body circumference and skin fold measures**
- **Complete the Non-Interview Form-C1(in the event of refusal)**

Third Follow-up Visit

The third follow-up visit will be conducted on two days -

Day - 1: The FI will visit the participant's house and interview the participant, take blood pressure and anthropometric measurements (as discussed above) and provide the fasting and urine collection instructions. S/he

should then invite the participant to the blood collection camp and inform the date and time.

Day - 2: Blood collection camps will be organized and all activities described in the visit 2 of cross-sectional survey should be repeated.

Post-visit Activities

The following tasks should be completed following each visit:

- **Review the questionnaire and all forms for legibility and completeness**
- **Return completed forms to the field office and all bio-specimens to the laboratory (third follow-up)**

Returning Reports to Study Participants

Reports of BP and anthropometric measurements should be given to the participant after the first and second follow-up visits. It is preferable that the FI gives the reports to the concerned person or to the next of kin if the participant is not available. In case of abnormal findings, s/he is advised to consult her/ his physician.

Within a week of bio-specimen collection during third follow-up visit the lab team should be able to provide the reports of the blood specimens. The reports duly signed by the head of the biochemistry department along with the BP and anthropometry reports should be delivered to the participant.

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. All study team members will be asked to sign a confidentiality agreement.

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 bio-specimen, anthropometry and blood pressure should be handed over to the participant alone
6. 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.

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. These forms and questionnaire are included in Appendix - 10.

List of Forms and Sections of the Questionnaire

Forms/Questionnaires	**Description**
Pre-visit: Described in chapter - 4	
Form-1	Household listing form
Visit – 0: Described in chapter – 5,6 and 7	
Form-2	Household Proforma
Form-3	Surveillance study notification form
Form-4	Participant Information Sheet and consent form
Form-5	Non-interview report form (Cross-sectional survey)
Visit-1: Questionnaire	
SECTION – 1	DEMOGRAPHIC,SOCIO-ECONOMIC AND RESIDENTIAL 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 HISTORY*
SECTION – 3	FEMALE REPRODUCTIVE HISTORY
SECTION – 4	QUALITY OF LIFE (EQ-5D)
SECTION – 5	MEDICAL HISTORY

PART-5A	*CARDIOMETABOLIC DISEASES AND THEIR RISK FACTORS*
PART-5B	*DISEASE SPECIFIC QUESTIONS*
5B-1	*HYPERTENSION (High Blood Pressure)*
5B-2	*DIABETES*
5B-3	*HYPERLIPIDEMIA*
5B-4	*HEART TROUBLE*
5B-5	*STROKE (Paralytic attack)*
5B-6	*CHRONIC KIDNEY DISEASE*
PART-5C	*COMORBIDITIES*
5C-1	*ANGINA*
5C-2	*PERIPHERAL VASCULAR DISEASE*
5C-3	*HEART FAILURE*
PART-5D	*COMPLICATIONS*
5D-1	*FOOT ULCERS AND AMPUTATION*
5D-2	*EYES*
PART-5E	*RESPIRATORY DISEASE*
PART-5F	*FAMILY HISTORY*
SECTION – 6	TREATMENT HISTORY AND EXPENDITURES
PART-6A	*OUTPATIENT*
PART-6B	*INPATIENT*
PART-6C	*HOSPITALISATION COST*
Form A	Anthropometric measurement and blood pressure recording form
Visit-2: Instructions are provided in chapter-13	
Biological specimen collection and processing forms	
BS-1	Blood collection form
BS-2	Urine collection form
BS-3	Saliva collection form
BS-4	Blood processing form
Spirometry form	To record the test results of the spirometry test
Form-6	Interview Checklist

Questionnaire for the Cross-sectional Survey

Household ID Enter the unique 5 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.

Instructions

1. The FI should explain each question to the participant and answer any question the participant may have.
2. The interviewer should assure the participant that s/he has the right to refuse to answer any question.
3. The FI must read all questions **EXACTLY** as they are written and in the proper order.

Section -1: Demographic, Socio-economic and Residential Details

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

Q.12. What is your mother tongue? (State of origin)

The purpose of this question is to determine what language the participant spoke growing up. For example, as a child did her/his parents first teach her/him to speak English or Hindi or something else? Show her/him the card containing the list of different languages. If participant's response is not on the list, check "Others" and record her/his answer in the space provided.

Q.14. Do you belong to a particular caste or tribe?

Caste can be a sensitive issue for some participants. The interviewers should use their discretion and judgment while asking this question. Is the participant is not comfortable in answering then skip the question.

The same instructions apply for Q.12 and Q.13 a.

Q. 15. Number of years of formal education

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

Q.16. Educational status (highest attained degree)

Ask the participant, "What is the highest level of education that you have completed?" Show her/him the card containing a list of different levels of education. Write the code corresponding to her/his response 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.

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.

Q. 19. What is your total household income per month?

Ask the participant what her/his household income is per month. Read all the income ranges and show them the card with the ranges. The total income is the combination of the incomes of all household members including income from assets (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. If the participant refuses to answer the question or doesn't know the answer to the question, select the appropriate code.

Q. 21. What is the fuel used for cooking?

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

Q. 22. What is the source of drinking water used at home?

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

Q.26. In case you move from current residence, whom can we contact to obtain your new contact address or telephone numbers? (Select two 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. 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.

Section -2: Details of Tobacco and Alcohol Consumption, Dietary Habits, Physical Activity and Sleep

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

Part-A: Tobacco use

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

Q.1. Have you ever used tobacco in any form (smoking, chewing, snuff, etc)?

*If '**NO**', go to Q. 8*

Q.2. In what forms have you consumed tobacco?

Compulsory to write **'1'** for **'YES'** for each form in the box given & '**2**' for '**NO**'. Do not leave any box empty

Q.3. Do you currently* consume tobacco?

Currently refers to 'in the past 6 months'

Q.4. If Yes, how often? Regularly (≥ once a week)= 1; Occasionally (<once a week)= 2; No=3; Not applicable=9	Smoking form	Chewed form	Any other form

For each form of tobacco that the participant uses, write the frequency of consumption using the appropriate code provided. Write "9" if not applicable.

Q.5. Quantity and duration of use

This table should be filled for both current and past users of tobacco. The different forms of tobacco are listed in the first column. Show the card that includes this list to the participant and ask her/him to indicate the type/s of tobacco products consumed presently or in the past. 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 5th row.

Brand name: Request the participant to either show you the product or tell you the brand name of the product (Complete commercial name of the product should be

noted)

Duration of use: For how long has the participant been using the product? Write the duration in the appropriate column months / years.

Usage per day: For tobacco, ask him/her to indicate the approximate amount consumed per day in grams. If he/she is able to show you the pack, note the weight mentioned in the pack and then multiply the weight by the number of packs consumed per day.

If the same participant smoked cigarette in the past – note the above details and in the 4th column write the time period in the appropriate column (months / years) since when the participant has given up smoking.

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

For cigarette, beedi and cigar – usage per day should be in numbers.

For Hukka/Chelum and snuff – the usage should be in number of times the product is used per day.

For Tobacco, pan with zarda and pan-masala with zarda and pipe – usage should be indicated in approximate grams of the product consumed per day. 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.

Q.6 and 7. At what age did you first start smoking / start consuming smokeless tobacco product regularly?

Note the age when the participant started using the particular tobacco product **regularly. Write "99" in the box if not applicable.**

Q.8. Are you exposed to tobacco smoke (from others) at home or at workplace regularly?

If '**NO'**, go to **Part B**

Q.9. If Yes (exposed to tobacco smoke)

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.

How much time during a day?

Note the duration in hours and minutes.

Smokeless tobacco products

Kimam

Mawa

Mishri

Handmade

Manufactured

Snuff

Tooth Powder

Part-B: Alcohol use

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

Q.2. How often do you use alcoholic beverages?

Regularly means at least once a day in a week

Occasionally means less than once a week

Past means stopped more than 6 months ago

Recently stopped means less than 6 months ago

Q.3. History of alcohol use for both present and past users

Type of alcohol used

Examples of beers include Castle Lager, Macopolo, Haywards 2000 and 5000, Zingaro, Kings, Kingfisher, Pint, and Sand piper. Wine includes red, white, rose and champagne.

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

Duration of use

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).

Frequency per week

Write the average number of occasions per week 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).

Quantity

Enter the number of bottles, pegs, or glasses that the participant drinks/drank in the space provided.

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).

Part-C: Physical activity

(International Physical Activity Questionnaire (IPAQ)-short)

This form will be used to obtain physical activity information from the participant for the study.

Note: Usual seven days refers to a week in which the participant had spent a normal day to day life (did not have any special events, disease, injury etc which may increase or limit the participant's daily activities)

Now, think about all the vigorous activities that you did in a usual 7 days. Vigorous activities makes you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least ten minutes at a time. During a usual 7 days, on how many days did you do vigorous physical activities? Think only about those physical activities that you do for at least ten minutes at a time.

If the participant's response to this question is "0," "Don't know," or "Refuse," go to the next set of questions about physical activity.

How much time did you usually spend doing vigorous physical activities on one of those days? Think only about those physical activities you do for at least ten minutes at a time.

If the participant can't answer because the pattern of time spent varies widely from day to day, then rephrase the question as: "Can you tell me how much time in total you spent **over a usual 7 days** doing vigorous physical activities?"

If the participant is able to provide a response, confirm that it is the total time spent doing vigorous physical activity over **a usual 7 days**. Record the response in the space provided for hours or minutes per week.

During a usual 7 days, on how many days did you do moderate physical activities for at least ten minutes? Examples include: carrying loads, bicycling at a regular pace, tennis, badminton, cricket, washing clothes, sweeping the floor, gardening, taking care of children less then three years old, washing cars,

motorcycles or scooters, walking home while carrying vegetables & groceries from market, climbing stairs (three floors or more) and grinding chutney on stone.

If the participant's response to this question is "0," "Don't know," or "Refuse," go to the next set of questions about walking.

How much time did you usually spend doing moderate physical activities on one of those days? Think only about those physical activities that you do for at least ten minutes at a time.

If the participant can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, then rephrase the question as: "Can you tell me what is the total amount of time you spent **over a usual 7 days** doing moderate physical activities?"

If the participant is able to provide a response, confirm that it is the total time spent over **a usual 7 days** doing moderate physical activity. Record the response in the space provided for hours or minutes per week.

During a usual 7 days, on how many days did you walk for at least ten minutes at a time? Think only about the walking that you do for at least ten minutes at a time.

If the participant's response to this question is "0," "Don't know," or "Refuse," go to the next set of questions about sitting.

Explain the participant that you are interested in the average time for one of the days on which s/he walks. "Can you tell me what is the total amount of time you spent walking over a usual 7 days?"

If the participant can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, then rephrase the question as: "Can you tell me what is the total amount of time you spent walking **over a usual 7 days**?"

If the participant is able to provide a response, confirm that it is the total time spent walking over **a usual 7 days**. Record the response in the space provided for hours or minutes per week.

Now think about the time that you spend sitting on week days during a usual 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down watching television.

If the participant can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, then rephrase the question as: "Can you tell me what is the total amount of time you spent sitting last Wednesday?"

If the participant is able to provide a response, confirm that it is the total time spent sitting last Wednesday. Record the response in the space provided for hours or minutes on Wednesday.

Additional Comments

The interviewer should use this section to record anything that s/he observed or was told that may affect the quality of the data.

Part-D: Sleep History

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

1. **How many hours of sleep do you usually get at night (or your main sleep period)?**

   Explain the participant that you are referring to average hours of sleep per night. Enquire for the average hours of sleep separately for weekdays and weekends.

2. **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)**

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

9. **Have you ever been told by a doctor that you had sleep apnoea (a condition in which breathing stops briefly during sleep)?**

   Sleep Apnoea is a condition in which a person stops breathing for a brief period of time during sleep.

13. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (refer to the codes below)

No chance=1; Slight chance=2; Moderate chance=3; High chance=4

The answer is based on subjective feeling of the participant. Request the participant to think for sometime before giving an answer. If the participant is never or rarely in such a situation, request her/him to give the best **guess** for the situation.

Part E: Diet History

In this part of the questionnaire we will elicit the dietary history of the participant. All questions are self explanatory. Only the food group table will be discussed here.

Q5. 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)***

For each food group note the frequency of consumption in the columns provided. Items in each food group are described in the Annexure below the table in the questionnaire.

Example:

Food group-Meat/poultry: Participant consumes chicken two times a week and mutton once a month

Food group-Organ meat, fish, shell fish and crustaceans: Participant does not consume

Food group – Eggs: Once a day

Food group-Milk and milk products: Milk is consumed twice daily, curd once daily, lassi once a week and cheese three times a week (add the frequencies for each column)

Sl. No.	Food groups	Consumed never / less than once / month [√]	Consumed monthly	Consumed weekly	Consumed daily
1	Meat	√			
2	Poultry		1	2	
3	Organ meats	√			
4	Fish	√			
5	Shell fish and crustaceans	√			
6	Eggs				1
7	Milk and milk products			4 (1+3)	3 (2+1)

Note: Please be cautious while asking questions about frequency of intake of non-vegetarian food items to participants who are strictly vegetarian. Assure them that this is only for the purpose of the study and that you do not have any intention to disrespect their customs and culture. The same applies for tobacco and alcohol.

Section – 3: Female Reproductive History

This section will 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.

Q.2. Number of pregnancies so far?

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.

Q.6. Hormonal drugs or 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 (OCP) are usually prescribed as a birth control drug for women in their reproductive age.

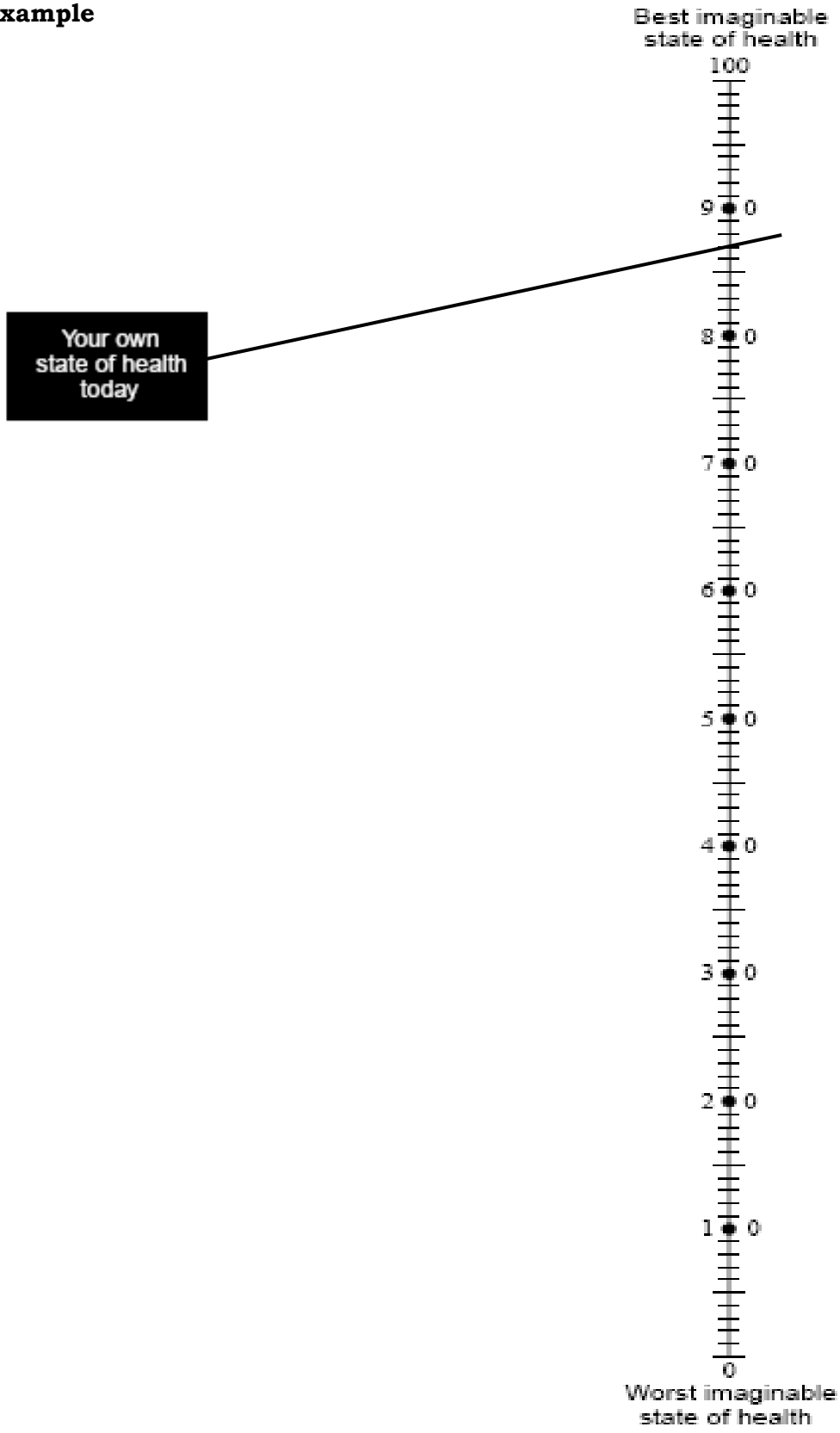
Section – 4: Quality of Life (EQ-5D)

This section of the questionnaire is self explanatory and is used to understand the quality of life of the participant. The scale is described below.

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 below.

Example


Best imaginable state of health
100
90
80
70
60
50
40
30
20
10
0
Worst imaginable state of health
Your own state of health today

Section – 5: Medical History

The purpose of these questions is to gain knowledge of the participant's medical history. Below are specifications for questions that require additional clarification.

Part-A: Cardio-metabolic diseases and their risk factors

Q.1. Have you ever been told by a doctor that you have any of the following diseases? (Yes-1, No- 2, Don't know- 3)

High blood pressure (hypertension)

Diabetes (high Blood Sugar)

Hyperlipidemia (high cholesterol)

Heart trouble

Stroke (Paralytic attack)

Chronic Kidney disease

Show the participant the card with the list of the above mentioned diseases and ask the participant if s/he has been told by a doctor that s/he suffers or suffered from these diseases.

Instructions

- Write '1', '2' or '3' depending on the response of the participant in the box provided for each disease.
- Do not write the subjective feeling of the participant; it has to be a confirmed diagnosis by a doctor.

If the answer is **'YES'** to any of the choices in Q. 1, then go to **Part – B** otherwise go to Part-C.

Part - B: Disease Specific Questions

If the answer is "**YES**" for any of the options provided in the above question then fills 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 all the diseases.

Hypertension/High Blood Pressure; Diabetes; Hyperlipidemia/High Blood Cholesterol

Q.b. What treatment are you taking for it?

Show the participant the card with the following options and ask her/him to indicate the type of treatment that s/he is undergoing.

Prescribed dietary modifications
Prescribed physical exercise
Traditional medicine / therapy*
Allopathic drugs

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

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

Q.h. 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 card (less than 1 month=1, more than 1 month=2, more than 3 months=3, less than 6 months=4, more than 6 months=5).

Q.j. If the answer to the above question is no, then skip to the next section. 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 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.

Q.k. Note the recorded blood pressure/fasting blood sugar/total cholesterol/ from the most recent medical record / prescription

From the most recent medical records / prescriptions / diagnostic test reports note the blood pressure for people with hypertension, fasting blood sugar for people having diabetes and total cholesterol level for participants with hyperlipidemia.

Heart Trouble

This section should be filled if the answer for heart trouble is "**YES**" in Part-A, Q.1.

Q.b. 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.

Q.c. At what age did you have your first heart attack?

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.

Q.e. Did you have any repeat attacks?

Ask the participant if s/he had any other attacks after the first one.

Stroke (Paralytic attack)

Q.a. What was your age when you had stroke (Paralytic attack)?

Ask the participant her/his age when s/he had the paralytic attack.

Q.b. Is there a residual disability?

Ask the participant if s/he has any residual disability following the episode of paralytic attack / stroke.

Q.c. If 'yes', does it involve the following? (Yes-1, No-2)

Show the participant the card that has the following options ask her/him to indicate the type of residual disability.

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) _____

- 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 card, then write '1' in the box against the option "Any other weakness" and specify the type of disability

Part - C: Co-morbidities

This section of the questionnaire should be administered to all participants. These questions are intended to elicit history of Angina, Peripheral vascular disease and heart failure. Below are specifications for questions that require additional clarification.

Ask this question if the answer to any of the options in Q.2. is "yes". Ask the participant if s/he has any of the following symptoms:

Pain

Heaviness

Discomfort

Numbness

Write '1' or '2' in the boxes provided under "symptoms" depending on the response. If the response is '1' for any of the above mentioned options then ask the participant to indicate the area in the chest or back where s/he has the selected symptom. Write the code from the diagram in the boxes provided below the "location" in the third column of the question. If the participant indicates positions on the back of the chest write '11' and if it is on the back of the neck write '12'. If the participant indicates more than one site for each symptom, note the code on the margin of the questionnaire.

Heart Failure

a. Are you unable to walk due to physical disability?

Yes =1

No = 2

Code "1" should be selected if the participant is unable to walk due to physical disability (Physical deformity since birth or disability since young age or due to injury/accident).

i. Do you have a cardiac device? Cardiac device is an instrument that is implanted in the heart to help it function normally in certain cardiac patients.

Part-D: Complications

This section of the questionnaire should be filled only if the diabetes section II of the questionnaire has been filled. The purpose of this section is to elicit complications related to diabetes. Request the participant to show you the medical records related to these complications and note the diagnosis / procedures for treatment of the complications at the end of each section. Below are specifications for questions that require additional clarification.

I. Foot Ulcer and Amputations

b. Do you walk around bare foot?

Irrespective of the time, if the participant walks around bare foot answer the question as "yes".

c. Have you had an amputation? 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 life saving procedure in certain disease conditions.

II. Eyes

d.Have you undergone laser therapy (Photocoagulation) at anytime? 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.

Part-E: Respiratory Disease

This section of the questionnaire should be filled for all participants. Below are specifications for questions that require additional clarification.

1. In the past 12 months, have you had chronic **cough** and chronic mucous production on **most** days or nights of the week (during at least three months in a row)? [Yes=1, No=2]

Cough means cough even when you are not suffering from cold

Most means at least 4 days or nights per week

3. Have you ever been hospitalized for a chest infection / pneumonia in the past 12 months?

Chest infection includes all infection of the chest other than tuberculosis.

3.a. If 'yes' length of stay

Write the length of stay in the appropriate box (days, weeks, months)

4.a.ii. Have you suffered from any infections that required medical attention in the past 12 months? ***[Yes=1, No=2]***

This question is particularly aimed at eliciting history of infection in asthmatics.

Part-E: Family History

This section of the questionnaire captures the family history of the participant. Below are specifications for questions that require additional clarification.

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

[Yes-1; No-2; Don't know-3] Show the participant the card that lists the cardio-metabolic diseases and ask if any of his family members suffered from any of these diseases before the age of 60 years.

High blood pressure

Heart disease (Angina/ heart attack/heart failure – all these conditions are grouped under heart problem)

Diabetes mellitus (High Blood Sugar)

Stroke (paralytic attack)

Fill the table below: This table should be filled with details of history of disease conditions, age at diagnosis (any age) and age of death for the family members

Relationship to the family member	Disease condition (refer to the codes below)*	Age at diagnosis (in years)	If dead, age at which the family member died
Father	1	64	
Mother			
Son			
Daughter			
Paternal Grandfather	3		83
Paternal Grandmother			
Maternal Grandfather			
Maternal Grandmother			
Brother	3	48	
Sister			
Paternal uncle			
Paternal aunt			
Maternal uncle			
Maternal aunt			
For others, please write the relationship to the participant and provide the required details below			
2nd Brother	1	52	

Disease condition: Diabetes = 1, heart disease = 2, high blood pressure = 3, Stroke = 4

Section-6: 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 one year/ 12 months. This section is divided into three parts to capture the details of treatment and expenditure related to outpatient and hospitalization. Below are specifications for questions that require additional clarification.

Part A: Outpatient

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

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

Show the participant the card that lists the cardio-metabolic disease, their risk factors and their complication –

Heart trouble
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 diseases mentioned.

Instruction

If the answer to any of the diseases is "YES" then continue the questions in this part, otherwise skip to PART B.

Q.4. List the expenditures incurred towards the above mentioned conditions (Q.1) separately in each table.

In the tables provided for Q.4., specify the disease and note the expenditure incurred for the items listed in the table. If the participant is unable to segregate information for different diseases, request her/him to provide an overall estimate and note in table 4.i.

In the space provided for disease note all diseases that the participant has selected from Q.1.

Note: As far as possible try to ascertain separate expenditure records for diseases if the participant suffers / suffered from more than one disease (listed in Q.1) in past 12 months

Example of how to fill the table is provided below.

Q.4. List the expenditures incurred towards the above mentioned conditions (Q.1) separately in each table

4.i. Disease: <u>Diabetes</u>

Nature of expenditure	**Frequency**	**Amount spent in Rupees per visit/test/remuneration to home nurse or carer**
Visit to Doctor (fees)	6	200
No. of months home nurse / career was hired	4	1500
Tests	8	1400
Physical or occupational rehabilitation	-	-
Others (Specify)		
Medications ***(average amount spent in last 12 months for the above mentioned condition)***		10,000
Total expenditure in past 12 months		**28,400**

Q.5. Did you get any reimbursement from insurance?

Ask the participant if s/he has received the reimbursements for this outpatient expenditure from any insurance company. Select the appropriate code from the options provided.

Q.6. If yes, of the above mentioned expenditure how much was reimbursed?

Calculate the total expenditure incurred by the participant in the past year for all treatment received as outpatient and request the participant to tell you the amount that s/he has been reimbursed from the insurance company, if s/he has an insurance cover. If the participant is unable to tell the exact amount request her/him to tell you the percentage reimbursed and note the answer as % instead of "Rs". If the participant is in the process of receiving the reimbursement, record the amount promised. In certain cases the participant might have not incurred any expenditure because either the insurance company pays directly or the employer pays for the expenses directly. In that case request the participant to provide you the information of the billed amounts even if s/he has not paid them. If no information can be elicited note the problem in the space provided for Q.6 or at the bottom of the page.

Q.8. Transport cost to visit the above mentioned health facility/doctor/therapist.

This question is to elicit the approximate transport cost per visit. If the participant travels by her/his own vehicle request the participant to provide the distance to the health facility (to and fro) and calculate the cost of fuel required to travel the distance.

If the participant has a private vehicle, ask him to give you an estimate of the amount spent on fuel to travel to the particular facility /doctor/therapist

Q.9. Average time spent at health facility

This should include waiting time, time required to undergo tests, etc along with the time for consultation and prescription.

Q.10. What has prevented you from getting medical attention?

Depending on the response, select the appropriate code/s from the list provided. If there is more than one reason, enter the codes for each reason in a separate box. If the reason is not listed, select "others" and specify the reason.

Q.11. How do you pay for your treatment and visits?

Depending on the response, enter the appropriate code ***(Yes=1; No=2)*** in the boxes provided against the options. If the source is not listed, select "others" and specify the source.

Q.12. On an average what proportion of money in percentage (%) did you spent from the above mentioned source for your treatment and visits?

Request the participant to provide information on the approximate proportion of money (in percentage) that s/he has raised in the past 12 months from each of the source selected for treatment as an outpatient.

Part B: 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.

Q.4. Have you undergone any surgical procedure in the past 12 months?

Irrespective of whether the surgery was major or minor, record the answer as "yes" if the participant has undergone a surgical procedure in the past 12 months.

Q.5. If yes, what was the procedure?

Depending on the response from the participant enter code 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.

Q.6. 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 hospitalization 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 C: Hospitalization Cost

Fill this section only if the participant has undergone hospitalization due to illness or procedure mentioned in Q.3 and Q.5 of PART B, otherwise end the interview and thank the participant.

For each hospitalization note the required details, starting with the first hospitalization in past 12 months. Use one column for one hospitalization history. If the number of hospitalization is more than three then use a second form to complete the history.

Instruction: Do not forget to write the participant ID in the new form and attach it with the original form.

Q.1. When were you hospitalized?

For each hospitalization, ask the participant how long ago was s/he hospitalized. E.g. If the participant says six months ago, write '06' in the box for months.

Q.3. Type of hospital?

Ask the participant the type of hospital where they were admitted whether it was a private or Government facility or charity hospital or any other facility.

Q.4. Name of hospital (Address)

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

Q.5. What type of treatment/procedure/surgery did you undergo? (*Cross-check with the medical records and information in PART-A*)

Depending on the response, appropriately check the box/es against the list provided. If the response is not included in the list, check the box for "others" and specify the type.

Q.6. Total amount spent on treatment (hospitalization expenses + medicines purchased during the stay).

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

Q.10. Cost of travel from home to hospital (excluding ambulance cost, if any).

This should be the cost incurred by the patient for traveling to the hospital.

For questions 12, 13 and 14 refer to the instructions provided in page 112 and 113

Visit – 2

During visit – 2 blood samples will be collected, height and body composition will be measured, and spirometry will be conducted on randomly selected participants. The blood, urine and saliva collection procedures and their respective collection and processing forms are discussed in details in chapter-13. The methods for measuring blood pressure and anthropometry and the related forms are explained in chapter-11. The methods for spirometry and related form are explained in Chapter-12.

Interview Checklist [Form 6]

At the end of the interview the FI will fill the interview checklist (Appendix-10) and attach it with the questionnaire. At the end of the day the FI will submit all filled forms to the Field Supervisor (FS) who will check the questionnaire for completion and put her/his remarks on the interview checklist. The checklist will be signed by both the FI and FS to confirm the completion of the interview forms.

General instructions

- Note the participant ID correctly on each page of the form.
- Before starting the interview make sure that you have the signed consent form from the participant.
- Explain each section of the questionnaire thoroughly to the participant.
- 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.

Appendix – 10

CARRS: Surveillance Study

Instruction to the interviewer: HAS THE PARTICIPANT SIGNED THE INFORMED CONSENT? DO NOT PROCEED UNTIL THE CONSENT FORM HAS BEEN SIGNED.

Household ID	Participant ID
CEB Code	Interviewer ID
Date of interview: DD/ MM/ YY	Start Time [Hr:min] HR : MIN

SECTION – 1: DEMOGRAPHIC, SOCIO-ECONOMIC AND RESIDENTIAL DETAILS

1. Name of the Participant: First name: Middle Name: Surname:	 _____ _____ _____
2. Father's/Spouse's name: First name: Middle Name: Surname:	 _____ _____ _____
3. Address/Details: Street: District: State: Postal Code:	
5.Telephone Number Residence Office Mobile	 _____ _____ _____
6.Email ID	(1) (2)
7.Place of Birth District: State:	
8.Age (in completed years)	

9.Date of birth (if available)	DD / MM / YYYY	
10.Sex	Male 1 Female 2 Trans-gender 3	
11.What is your marital status?	Single 1 Married 2 Widow/Widower 3 Separated/Divorced 4 Others 5	Others, specify _____
12.What is your mother tongue? (State of origin)	Assamese 1, Balochi 2, Bengali 3, Gujarati 4, Hindi 5, Hindko 6, Kannada 7, Kashmiri 8, Maithili 9, Malayalam 10, Marathi 11, Memoni 12, Pashto 13, Punjabi 14, Sindhi 15, Telegu 16, Tamil 17, Urdu 18, Others 19	Others, specify _____
13.What religion do you follow? (Optional)	Hindu 1 Muslim 2 Sikh 3 Christian 4 Jain 5 Buddhism 6 No religion 7 Others (specify) 8 No response 9	Others, specify _____
14.Do you belong to a particular caste or tribe? (Optional)	Yes 1 No 2 Don't know 3 Don't want to answer 4 Not applicable 5	
14.a. If "Yes" What is your caste or tribe? (Optional)	Schedule caste 1 Schedule tribe 2 Other backward caste 3 Most backward 4 Others 5	Others (specify) _____

15. Number of years of formal education* * The total number of years the participant spent in any educational institution (schools, colleges, religious schools, etc.)		☐☐ **years**
16. Educational status (highest attained degree) ** A person who can both read and write with understanding in any language without any formal education or passed any minimum educational standard.* *** A person, who can neither read nor write or can only read but cannot write in any language.*	Professional degree/post graduate 1 Graduate (B.A/B.Sc/B.Com/Diploma) 2 Secondary School / Intermediary (ITI course, class XII/X or Intermediate) 3 High school (class V to IX) 4 Primary School (upto Class IV) 5 *Literate, no formal education 6 **Illiterate 7 Others 8	☐ Others, specify _____ _____
17. Your employment status?	Employed 1 Student 2 Housewife 3 Retired 4 Un-employed 5	☐ **"1" go to 17.a Otherwise go to Q18**
17.a. If ***"Employed",*** what is your current occupation? ***[Use nearest applicable employment codes given below]***		☐
18. Have you been involved in any other occupation during past ten years?	Yes 1 No 2	☐ **"2" go to Q. 19**
18.a. If ***'YES'***, name the occupation? ***[Use nearest applicable employment codes given below]***		☐
Coding list for employment (for Q.18.a and Q.19.a)- refer to annexure for definition of skilled, semi-skilled, un-skilled		
Professional, big business, landlord, university teacher, class 1 IAS/services officer, lawyer		1
Trained, clerical, medium business owner, middle level farmer, teacher, maintenance (in charge), personnel manager		2
Skilled manual labourer, small business owner, small farmer		3
Semi-skilled manual labourer, marginal landowner, rickshaw driver, army jawan, carpenter, fitter		4
Unskilled manual labourer, landless labourer		5
19. What is your total household income per month? ***Please include income from all members who contribute to the household***	<3000 1 3000-10,000 2 10,001-20,000 3 20,001-30,000 4 30,001-40,000 5 40,001-50,000 6 >50,000 7 Refuse 8 Don't know 9	☐

20. Do you have a separate room for cooking (Kitchen)?	Yes 1 No 2	☐
21. What is the fuel used for cooking? ***If more than one source is used then note the source that is most commonly used***	Coal/charcoal/kerosene 1 Electricity/gas (LPG)/solar/CNG (IGL) 2 Wood/dung 3 Others 4	☐ Others (specify) _____
22. What is the source of drinking water used at home? ***If more than one source is used then note the source that is most commonly used***	Public source 1 Private source (Shared) 2 Private source (Own) 3 Bottled water 4 Purified tap water 5 Others 6	☐ Others (specify) _____
23. What is the toilet facility you use?	Public toilet 1 Shared toilet 2 Own flush toilet 3 Others 4	☐ Others (specify) _____
24. Which of the following do you own? ***[Yes=1; No=2]***	a. Television b. Refrigerator c. Washing machine d. Microwave / OTG e. Mixer-grinder f. Mobile phone g. DVD player h. Computer i. Car j. Motor Cycle /Scooter k. Bicycle	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
25. Are you likely to move from your current residence within a year or two?	Yes 1 No 2 Don't know 3	☐
26. In case you move from current residence, whom can we contact to obtain your new contact address or telephone numbers? ***Take details of two different contacts***	Neighbour 1 Relative 2 Friend 3 Employer 4 No one to contact 5 Others 6 Specify _____	1st ☐ 2nd ☐

27.Name of the 1st contact person First Name: Middle name: Last Name:	
28.Address of the 1st contact person	
29.Phone number (home, office, mobile) of 1st contact person	Home _____(area code)_____(number) Office _____(area code)_____(number) Mobile_____(number)
30.Name of the 2nd contact person First Name: Middle Name: Last Name:	
31.Address of the 2nd contact person	
32.Phone number (home, office, mobile) of 2nd contact person	Home _____(area code)_____(number) Office _____(area code)_____(number) Mobile_____(number)

SECTION – 2: TOBACCO AND ALCOHOL CONSUMPTION, DIETARY HABITS, PHYSICAL ACTIVITY AND SLEEP

PART – A: TOBACCO USE

1. Have you ever used tobacco in any form (smoking, chewing, snuff, etc)?	Yes 1 No 2	☐ **"2" go to Q. 8**
2. In what forms have you consumed tobacco? ***[Yes=1; No=2]***	a. In a smoking form b. In a chewed form c. In any other form (snuff, toothpaste etc)	☐ ☐ ☐
3. Do you currently* consume tobacco? * within past 6 months	Yes 1 No 2	☐ **"2" go to Q. 5**

4. If Yes, how often? ***[Regularly (≥ once a week)= 1; Occasionally (<once a week)= 2; No=3; Not applicable=9]***	Smoking form	Chewed form	Any other form

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

Type of tobacco use / used	***Brand name***	***Duration of use***		***Usage per month*** ****Number smoked*** *****Number of times*** ******Approximate amount in gms***	***If you have stopped using any of the following products, time in months/years since you have stopped***	
		Years	***Months***		***Years***	***Months***
1. Cigarette*						
2. Beedi*						
3. Cigar*						
4. Hukka/Chelum/Pipe **						
5. Tobacco chewing***						
6. Pan with Zarda***						
7. Pan masala with zarda***						
8. Snuff**						
9. Gutkha***						
10. Others: Specify _____						

6. At what age did you first start smoking regularly? ***[Not applicable – write '99' in the box]***	**years**	
7. At what age did you first start consuming smokeless tobacco product regularly? ***[Not applicable – write '99' in the box]***	**years**	
8. Are you exposed to tobacco smoke from others regularly*? (e.g. at home, at workplace regularly, while travelling, any other place) * At least once a day in a week	Yes 1 No 2	**"2" go to PART B**
9. **If Yes**: How many days a week*? How much time during a day*?	HR : MIN (Please provide approximate time)	

PART – B: ALCOHOL USE

1. Have you ever used alcohol?	Yes 1 No 2	☐ **"2" go to PART C**
2. How often do you use alcoholic beverages? ***Occasionally means less than once a week***	Currently using alcohol regularly 1 Currently using alcohol occasionally* 2 Used alcohol in the past (stopped more than 6 months ago) 3 Recently stopped alcohol (less than 6 months ago) 4 Never used alcohol 5	☐ **"5" go to PART C**

3. History of alcohol use for both present and past users

Type of alcohol used	***Duration of use***		***Frequency of use per week***	***Quantity**** *in ml/peg per occasion*	**If stopped, since how long**	
	Months	**Years**			**Months**	**Years**
a) Local spirits eg. Desi, arrack, toddy etc						
b) Spirits eg. whisky, rum, brandy, gin, vodka						
c) Beer						
d) Wine						

** Conversion

1 small peg = 30 ml; 1 large peg = 60 ml; 1 extra large peg = 90 ml

1 glass of beer = approx. 325 ml

1 glass of wine = 100 ml

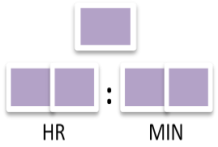
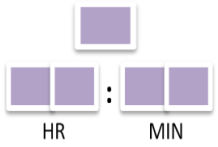
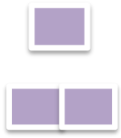
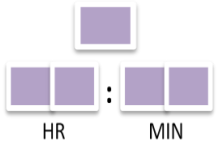
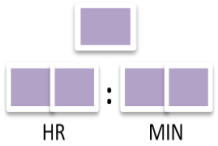
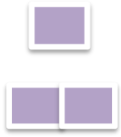
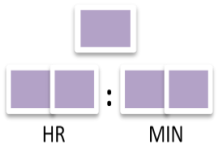
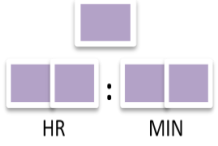
Please use local measures in calculating the total consumption (in ml per occasion)

PART – C: PHYSICAL ACTIVITY (International Physical Activity Questionnaire – short)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. I am going to ask you about the time you spent being physically active in the usual 7 days of a week. Please answer each question even if you do not consider yourself to be an active person. Think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Now, think about all the *vigorous* activities that you did in a usual 7 days. Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you do for at least 10 minutes at a time.

1. During **a usual 7 days**, on how many days did you do **vigorous** physical activities?	Days per week (If 0, go to 3) = 1 Refused (go to Q.3) = 2 Don't Know/Not Sure (go to 3) = 3 Don't do any activity = 4	☐ ☐☐

2. How much time did you usually spend doing **vigorous** physical activities on one of those days? Think only about those physical activities you do for at least 10 minutes at a time.	Hours/ Minutes per day = 1 Refused (go to Q.2a) = 2 Don't Know/Not Sure (go to 2a) = 3	
2a. **Interviewer probe:** If the respondent can't answer because the pattern of time spent varies widely from day to day, say, "I am interested in the average time for one of the days on which you do vigorous activity. Can you tell me how much time in total would you spend **over a usual 7 days** doing vigorous physical activities?"	Hours/ Minutes per day = 1 Refused = 2 Don't Know/Not Sure = 3	
Now think about activities which take *moderate physical effort* that you did in a usual 7 days. Moderate physical activities make you breathe somewhat harder than normal. Do not include walking. Again, think about only those physical activities that you did for at least 10 minutes at a time.		
3. During a **usual 7 days**, on how many days did you do **moderate** physical activities for at least 10 minutes? Examples: carrying loads, bicycling at a regular pace, tennis, badminton, cricket, hand washing clothes, sweeping the floor, gardening, taking care of children less than three years old, washing cars, motorcycles, or scooters, walking home while carrying vegetables and groceries from market, climbing stairs (three floors or more), and grinding chutney on stone.	Days per week (If 0, go to Q.5) =1 Refused (go to Q.5) = 2 Don't Know/Not Sure (go to Q.5) = 3 Don't do any activity = 4	
4. How much time did you usually spend doing **moderate** physical activities on one of those days? Think only about those physical activities that you do for at least 10 minutes at a time.	Hours/ Minutes per day=1 Refused (Go To Q.4a) = 2 Don't Know/Not Sure (Go To Q.4a)=3	
4a. **Interviewer probe**: If the respondent can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, say, "I am interested in the average time for one of the days on which you do moderate activity. Can you tell me what is the total amount of time you spent over a **usual 7 days** doing moderate physical activities?"	Hours/ Minutes per day=1 Refused = 2 Don't Know/Not Sure = 3	
Now think about the time you spent walking in a usual 7 days. This includes at work and at home, walking to travel from place to place. Also include any walking that you do solely for recreation, sport, exercise, or leisure, for example, walking to the bus stop, to workplace, to the market for at least 10 minutes.		
5. During a **usual 7 days**, on how many days did you **walk** for at least 10 minutes at a time? Think only about the walking that you do for at least 10 minutes at a time.	Days per week (If 0, go to Q. 7)=1 Refused (go to Q. 7) = 2 Don't Know/Not Sure (go to Q. 7) =3 Don't do any activity = 4	
6. How much time did you usually spend **walking** on one of those days?	Hours/ Minutes per day (go to Q. 7) =1 Refused (go to Q.6a) = 2 Don't Know/Not Sure (go to Q6a) =3	
6a. **Interviewer probe**: If the respondent can't answer because the pattern of time spent varies widely from day to day say, "I am interested in the average time for one of the days on which you walk. Can you tell me what is the total amount of time you spent walking over **a usual 7 days**?"	Hours/ Minutes per week =1 Refused =2 Don't Know/Not Sure =3	

Now think about the time you spent sitting on week days during a usual 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television, cutting vegetables, sewing and knitting, or time spent in teaching children, performing religious prayers, chatting with friends, talking on the phone, or working in front of the computer.

7. During a usual 7 days, how much time did you usually spend ***sitting*** on a **weekday**? Include time spent lying down (awake) as well as sitting. *(*Exclude sleeping at night)*	Hours/ Minutes per week day (go to Q. 8)=1 Refused (go to Q. 7a) = 2 Don't Know/Not Sure(go to Q7a) = 3	HR : MIN
7a**. Interviewer probe**: If the respondent can't answer because the pattern of time spent varies widely from day to day, say "I am interested in the average time per day spent sitting. Can you tell me what is the total amount of time you spent *sitting* last **Wednesday**?"	Hours/ Minutes on Wednesday [1] Refused =2 Don't Know/Not Sure =3	HR : MIN
8. Additional comments		

PART – D: SLEEP (Sleep Heart Health Study; NHLBI)

3. How many hours of sleep do you usually get at night (or your main sleep period)? **Average hours of sleep per night**	On weekdays / workdays No. of hrs	On weekends No. of hrs
4. 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)	No. of times	

5. Please indicate how often you experience each of the following **(refer to codes below)**
[Never=1; Rarely (1/month or less)=2; Sometimes (2-4/month)=3; Often (5-15/month)=4; Almost always (16-30/month)=5]

a. Have trouble falling asleep
b. Wake up during the night and have difficulty getting back to sleep
c. Wake up too early in the morning and be unable to get back to sleep
d. Feel unrested during the day, no matter how many hours of sleep you had
e. Do not get enough sleep
f. Take sleeping pills or other medication to help you sleep

Questions 4 to 10 are about snoring and breathing during sleep. To answer these questions please consider what other have told you <u>and</u> what you know about yourself

6. Have you ever snored (now or any time in the past)?	Yes No Don't know	1 2 8	**"2", "8" go to Q.7**
7. How often do you snore now?	Do not snore anymore Rarely (<1 night/week) Sometimes (1-2 nights/week) Frequently (3-5 nights/week) Always or almost always(6-7nights/week) Don't know	0 1 2 3 4 8	**"0" go to Q.7**

8. How loud is your snoring?	Only slightly louder than heavy breathing 1 About as loud as mumbling or talking 2 Louder than talking 3 Extremely loud-can be heard through a closed door 4 Don't know 8	
9. Based on what you have noticed or household members have told you, are there times when you stop breathing during your sleep?	Yes 1 No 2 Don't know 8	**"2", "8" go to Q.9**
10. How often do you have times when you stop breathing during your sleep?	Rarely (<1 night/week) 1 Sometimes (1-2 nights/week) 2 Frequently (3-5 nights/week) 3 Always or almost always(6-7nights/week) 4 Don't know 8	
11. Have you ever been told by a doctor that you had sleep apnoea (a condition in which breathing stops briefly during sleep)?	Yes 1 No 2 Don't know 8	**"1" go to Q.11** **"2", "8" go to Q.10**
12. Have you ever been told by a doctor that you had some other sleep disorder?	Yes 1 No 2 Don't know 8	**"2", "8" go to Q.11**
10.A. If response is "yes" to the above question, please specify the disorder _____ _____		
13. Do you usually use oxygen therapy (oxygen delivered by a mask or nasal cannula) during your sleep?	Yes 1 No 2	
14. During the past year how often have one or more members of your household been in or near the room where you have slept?	Never 1 Sometimes 2 Usually 3	

15. **What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (refer to the codes below)**

[No chance=1; Slight chance=2; Moderate chance=3; High chance=4]

*If you are never or rarely in the situation, please give your **best guess** for the situation*

A. Sitting and reading

B. Watching TV

C. Sitting inactive in a public place (such as a theatre or a meeting)

D. Riding as a passenger in a car for an hour without a break

E. Lying down to rest in the afternoon when circumstances permit

F. Sitting and talking to someone

G. Sitting quietly after a lunch

H. In a car, while stopped for a few minutes in traffic

I. At the dinner table

J. While driving

16. How often do you take aspirin or aspirin-containing medicines?	Never 1 Less often than once a week 2 Once or twice a week 3 Every other day (one day out of two) 4 Every day 5 Don't know 8	
17. Do you drive?	Yes 1 No 2	

18. **If the response to the above question is "yes" please answer the following questions, else go to Part-E (Diet)**

A. No. of years of driving

B. How often do you drive?
[everyday=1; sometimes=2; rarely/never=3]

C. Since you began driving, how many accidents have you had while you were the driver?

D. How many accidents have you had in the last year while you were the driver?

PART – E: DIET

1. Are you a vegetarian?	Yes 1 No 2	
2. Do you take eggs?	Yes 1 No 2	
3. Are you on any special diet?	Yes 1 No 2	**"2" go to Q.4**
4. If ***YES***, what diets are you currently following ***[Yes = 1; No = 2]***	Diabetic diet Low fat diet High fibre diet Low salt diet Weight reducing diet Others (Specify) _____	

5. Since how many years are you on this special diet? Yrs ____ Mnts ____ [Enter the the longest duration]

6. How frequently do you use reheated oil?	Every day 1 Every other day (one day out of two) 2 Once or twice a week 3 Less often than once a week 4 Never 5	

5. In the past one year, how often have you consumed foods from the following food groups? **[write the frequency of consumption in the appropriate column]**

Sl. No.	Food groups	Consumed never/less than once /month [√]	Consumed monthly	Consumed weekly	Consumed daily
1	**Meats**				
2	**Poultry**				
3	**Organ meats**				
4	**Fish**				
5	**Shell fish and crustaceans**				
6	**Eggs**				
7	**Milk and milk products**				
8	**Milk based desserts**				
9	**Deep fried foods: western style**				
10	**Deep fried foods: desi style**				
11	**Western style desserts/sweet snacks**				
12	**Mithai**				
13	**cold beverages**				
14	**Fruits (1)**				
15	**Fruits (2)**				
16	**Fruit juices**				
17	**Nuts/seeds**				
18	**Leafy greens**				
19	**Other raw vegetables**				
20	**Legumes and pulses**				
21	**Use of pickles, pickled foods**				
22	**Other cooked vegetables**				
23	**Refined cereals with less fibre**				
24	**Whole grain**				
25	**Tea consumption**				
26	**Coffee consumption**				

Annex for food groups [showing items in each group]

Meat [lamb, mutton, goat, veal, rabbit, beef, pork; their curries]
Poultry [chicken, turkey, duck, pheasant, quail; their curries]
Organ meats [liver, kidney, brain, spleen, heart and sausages nihari, paya]
Fish [fresh-water and sea-water fish; preserved fish such as salted fish, canned fish, dried fish]
Shell fish and crustaceans [crab, squid, prawns, molluscs, caviar]
Eggs [Includes preserved eggs, duck eggs]
Milk and milk products: [milk, yogurt, cheese, curd, raita, lassi, milk based drinks]
Milk based desserts [custard, khoya, firni, kheer, milk puddings, rasgullah/rasmalai, ice creams]all milk based desserts
Deep fried foods: western style [french fries, potato chips, onion rings, chicken nuggets]
Deep fried foods: desi style [samosas, papad, pakoras, sev, namak paray, egg rolls, poori, kachori]
Western style desserts/sweet snacks [cakes; pies; chocolate; candy; biscuits]
Mithai [burfi/ladoo; gulab jamun; halwa; shameia, mohalabeia]
Cold beverages [carbonated beverages, sherbets, and other soft drinks]
Fruits (1) [strawberries, pine apples, jumbo berries (jamuns), apples]
Fruits (2) all seasonal fruits except the ones above
Fruit juices [any type, homemade, purchased, fresh, frozen]
Nuts/seeds [Includes peanuts, almonds, sunflower seeds, cashews, walnuts]
Leafy greens [all fresh leafy green vegetables: spinach, mustard or turnip greens; asparagus either raw or cooked]
Other raw vegetables [any raw vegetables not included in the preceding categories]
Legumes and pulses [includes all daals, chickpeas, lentils]
Use of pickles, pickled foods [achar, chutneys, pickled vegetables etc]
Other cooked vegetables [any cooked vegetables not included in the preceding categories]
Refined cereals with less fibre [boiled rice, fried rice, biryani, pulao, idli, dosa, semolina,sago, pearl barley, pasta, sheermal, taftan, white bread slice]
Whole grain (cereal dished with more fibre) [Roti made with whole meal flour, brown rusk, whole wheat porridge, bread slice whole meal/brown]
Tea consumption [black tea, coffee with and without milk and sugar and any other tea]
Coffee consumption [coffee with and without milk and/sugar]

SECTION – 3: FEMALE REPRODUCTIVE HISTORY

THIS SECTION IS TO BE FILLED ONLY FOR THE FEMALE PARTICIPANTS, FOR MALE PARTICIPANTS SKIP THIS SECTION AND GO TO SECTION – 4.

1. Number of pregnancies so far?		
2. At what age did you start menstruating?	Years	
3. Are you having menstrual cycles?	Yes 1 No 2	**"1" go to Q. 6**
4. If '**No'** what is the reason?	Pregnancy 1 Lactation 2 Natural menopause 3 Surgical menopause 4 Other reasons(specify) 5	***Others, specify***_____
5. If postmenopausal, since how long?	Years Months	
6. Hormonal drugs or oral contraceptive pills? ***[Yes = 1; No = 2]***	Ever used in the past	If Yes, duration in years/month Yrs Mnts
	Currently using	If Yes, duration in years/month Yrs Mnts

SECTION – 4: QUALITY OF LIFE (EQ-5D) © 1990 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group.

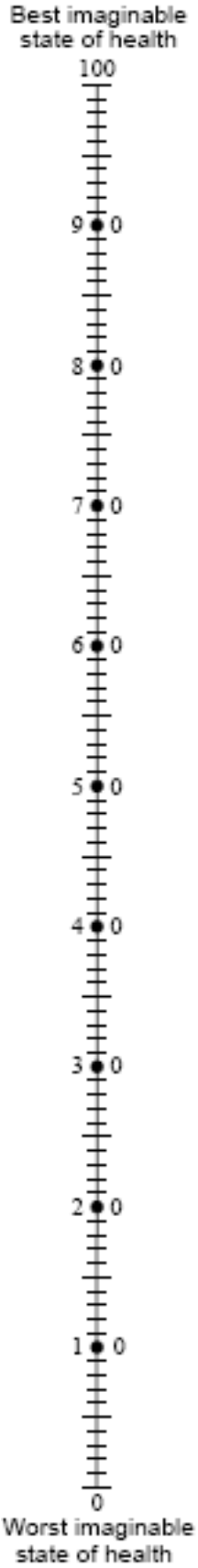
By writing a code from the options in the box, please indicate which statements best describe your own state of health today.

1. Mobility	I have no problems in walking about=1 I have some problems in walking about=2 I am confined to bed=3	
2. Self-Care	I have no problems with self-care=1 I have some problems washing or dressing myself=2 I am unable to wash or dress myself=3	
3. Usual Activities *(e.g. work, study, housework, family or leisure activities)*	I have no problems with performing my usual activities=1 I have some problems with performing my usual activities=2 I am unable to perform my usual activities=3	
4. Pain/ Discomfort	I have no pain or discomfort=1 I have moderate pain or discomfort=2 I have extreme pain or discomfort=3	
5. Anxiety/ Depression	I am not anxious or depressed=1 I am moderately anxious or depressed=2 I am extremely anxious or depressed=3	

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 you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today



SECTION – 5: MEDICAL HISTORY

PART-A: CARDIOMETABOLIC DISEASES AND THEIR RISK FACTORS

1. Have you ever been told by a doctor that you have any of the following diseases? ***[Yes =1; No =2; Don't know=3]***	Hypertension (High blood pressure) Diabetes (High Blood Sugar) Hyperlipidemia (High Cholesterol) Heart Disease Stroke (Paralytic Attack) Chronic Kidney Disease	☐ ☐ ☐ ☐ ☐ ☐

**Exclude pregnancy induced Hypertension and High Blood Sugar*

*If the answer is **'YES'** to any of the choices in Q. 1, then go to PART – B **'OTHERWISE'** skip the entire section and go to PART-C.*

PART - B: DISEASE SPECIFIC QUESTIONS

I. HYPERTENSION (High Blood Pressure)

Fill this section if the answer for high blood pressure is "YES" in PART - A, Q.1.

a. Since how many years have you had high blood pressure?		Duration in years/month Yrs ☐☐ Mnts ☐☐
b. What treatment are you taking for it currently? ***[Yes=1; No=2]*** ****Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy, meditation***	Prescribed dietary modifications Prescribed physical exercise Traditional medicine / therapy* Allopathic drugs (English / modern) None	☐ ☐ ☐ ☐ ☐
c. How regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel the blood pressure is high 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" go Q.d otherwise go to Q.e.		
d. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
e. Do you think your blood pressure is under good control?	Yes 1 No 2 Don't Know 3	☐

f. Does your doctor say that your blood pressure is under good control?	Yes 1 No 2 Don't Know 3	☐
g. What was your last blood pressure recording (when your doctor checked you)? = 1 Don't know = 2 Can't remember = 3	☐ _____(systolic) / _____(diastolic) mmHg	
h. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐
i. Do you have medical records or prescriptions related to high blood pressure?	Yes 1 No 2 Don't Know 3	☐
*j. If the answer is **YES,** ask the participant to show the medical records and note the diagnosis below*		
k. Note the recorded blood pressure from the most recent medical record / prescription _____(systolic) / _____(diastolic) mmHg		
II. DIABETES Fill this section if the answer for high blood sugar is **"YES"** in PART-A, Q.1		
a. For how long have you had high blood sugar / diabetes?	Duration in years/month Yrs ☐☐ Mnts ☐☐	
b. What treatment are you taking for it currently? ***[Yes=1; No=2]*** ****Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy, meditation***	Prescribed dietary modifications Prescribed physical exercise Traditional medicine / therapy* Allopathic drugs (English / modern) None	☐ ☐ ☐ ☐ ☐
c. How regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel the blood sugar is high 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" go Q.d otherwise go to Q.e.		

d. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
e. Do you think your diabetes/high blood sugar is under good control?	Yes 1 No 2 Don't Know 3	☐
f. Does your doctor say that your diabetes /high blood sugar is under good control?	Yes 1 No 2 Don't Know 3	☐
g. What was your fasting blood sugar and after meal blood sugar when you got it checked last time?	Fasting _____mg/dl After meal _____mg/dl	
h. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐
i. Do you have medical records or prescriptions related to diabetes/high blood sugar?	Yes 1 No 2 Don't Know 3	☐

j. *If the answer is **YES,** ask the participant to show the medical records and note the diagnosis below*

k. ***Note the recorded fasting blood sugar and after meal blood sugar level from the most recent medical record / prescription***

Fasting_____mg/dl

After meal_____mg/dl

Also complete PART – D

III. HYPERLIPIDEMIA or High Blood Cholesterol **Fill this section if the answer for high blood cholesterol is "yes" in PART-A, Q.1**		
a. For how long have you had high blood cholesterol?	Duration in years/month Yrs ☐☐ Mnts ☐☐	
b. What treatment are you taking for it currently? ***[Yes=1; No=2]*** ****Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy, meditation***	Prescribed dietary modifications Prescribed physical exercise Traditional medicine / therapy* Allopathic drugs (English / modern) None	☐ ☐ ☐ ☐ ☐
c. How regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel the blood cholesterol is high 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" Q.d otherwise go to Q.e		
d. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
e. Do you think your cholesterol is under good control?	Yes 1 No 2 Don't Know 3	☐
f. Does your doctor say that your cholesterol is under good control?	Yes 1 No 2 Don't Know 3	☐
g. What was total cholesterol level when you last checked it?	_____ mg/dl	
h. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐

i. Do you have medical records or prescriptions related to high blood cholesterol?	Yes 1 No 2 Don't Know 3	
*j. If the answer is **YES,** ask the participant to show the medical records and note the diagnosis below*		
k. Note the recorded total cholesterol from the most recent medical record / prescription		
IV. HEART DISEASE **Fill this section if the answer for heart trouble is "YES" in PART-A, Q.1**		
a. When did you first come to know that you have heart disease?	**<**1 year 1 1-5 years 2 >5 years 3	
b. What did the doctor say it was?	Heart attack 1 Angina 2 Heart failure 3 Valve disease 4 Hole in the heart 5 Others* 6 Not informed about the nature of the problem 7	Use separate boxes for more than one option ***Others, specify*** _____
If "1" go to Q.c otherwise go to Q. g.		
c. At what age did you have your 1st heart attack?	Years	
d. Were you hospitalized for treatment?	Yes 1 No 2	
e. Did you have any repeat attacks	Yes 1 No 2	
f. Were you hospitalized for the subsequent attacks	Yes 1 No 2	

g. What treatment are you taking for heart disease currently? ***[Yes=1; No=2]*** ****Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy, meditation***	Prescribed dietary modifications Prescribed physical exercise Traditional medicine / therapy* Allopathic drugs (English / modern) None	☐ ☐ ☐ ☐ ☐
h. How regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel unwell 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" go to Q.i question otherwise go to Q.j.		
i. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
j. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐
k. Do you have medical records or prescriptions related to heart trouble?	Yes 1 No 2 Don't Know 3	☐
l. ***If the answer is 'YES', ask the participant to show the medical records and note the diagnosis below***		

V. STROKE (Paralytic attack) **Fill this section if the answer for stroke (paralytic attack) is "yes" in PART-A, Q.1**		
a. What was your age when you had stroke (Paralytic attack)?	Years ☐☐	
b. Is there a residual disability in any part of the body?	Yes 1 No 2	☐
c. If **'YES'**, does it involve the following? ***[Yes=1; No=2]***	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)_____	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
d. Are you advised to continue any medication after your paralytic attack?	Yes 1 No 2	☐
e. If **YES**, how regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel unwell 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" go to Q.f otherwise go to Q.g.		
f. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
g. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐
h. Do you have medical records or prescriptions related to Stroke?	Yes 1 No 2 Don't Know 3	☐

i. *If the answer is **YES**, ask the participant to show the medical records and note the diagnosis below*

VI. CHRONIC KIDNEY DISEASE

Fill this section if the answer for chronic kidney disease is "YES" in PART-A, Q.1

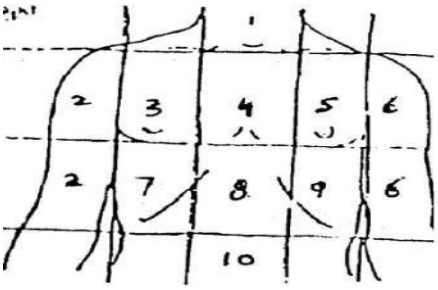
a. At what age were you diagnosed with chronic kidney disease?	Years ☐☐	
b. What treatment are you taking for it currently? ***[Yes=1; No=2]*** ****Traditional medicine / therapy include yoga, ayurveda, unani, homeopathy, Tibetan, naturopathy, meditation***	Prescribed dietary modifications Prescribed physical exercise Traditional medicine / therapy* Allopathic drugs (English / modern) None	☐ ☐ ☐ ☐ ☐
c. How regular are you in taking your medicines?	Taking Regularly 1 Forget to take occasionally 2 Take medicines only when I feel unwell 3 Discontinued for more than a month at a time 4 Never taken any medication 5	☐
If "4" go Q.d otherwise go to Q. e.		
d. What is the reason for discontinuation?	Cannot afford 1 Cannot tolerate 2 I have recovered 3 No reason 4 Don't remember 5 Others (specify) 6	☐ ***Others, specify*** _____
e. When was the last time you consulted your doctor?	Less than 1 month 1 More than 1 month 2 More than 3 months 3 Less than 6 months 4 More than 6 months 5	☐
f. Do you have medical records or prescriptions related to chronic kidney disease?	Yes 1 No 2 Don't Know 3	☐

g. *If the answer is **YES,** ask the participant to show the medical records and note the diagnosis below*

PART - C: ANGINA, PERIPHERAL VASCULAR DISEASE AND HEART FAILURE

I. ANGINA

a. Do you have any of the following symptoms? ***[Yes=1; No=2]***	Palpitation Chest pain Breathlessness Fatigue/weakness Chest discomfort/heaviness/pressure	**"2" for all, skip to Q. m**
b. With exertion*, have you ever had any of the following symptoms in and around the chest, arms, shoulders, neck, lower jaw, abdomen or upper back? *walking fast, climbing stairs, lifting weights, etc ***[Yes=1; No=2]***	Pain Heaviness Pressure Discomfort Numbness	**"2" for all, skip to Q. d**
c. Where did you mostly feel the (symptoms noted in Q.b)? ***[Yes=1; No=2]*** (Please specify the location from the numbered diagram below) ***Additional numbers: back of chest = 11, back of neck = 12)***		***Symptom*** ***Location***
	Pain Heaviness Discomfort Numbness	

Right  Left

d. Do you feel any of the above symptoms anywhere else?	Yes 1 No 2 *If **'YES'**, specify:* Symptom:_____ Location:_____	

Fill Q.e to Q.l only if you have noted "1" for any of the symptoms in Q.b and Q.c, OTHERWISE GO TO Q.m

e. Do you get the above symptoms, or breathlessness, or palpitation when you walk uphill or climb steps or walking fast?	Yes 1 No 2 Never walk uphill/hurry 3	
f. Do you get it when you walk at an ordinary pace on the level ground?	Yes 1 No 2	
g. Do you get a similar symptoms while you are resting or after a meal?	Yes 1 No 2	
h. What do you usually do if you get it while you are exerting?	Stop 1 Slow down 2 Carry on at the same pace 3	
i. Does it go away if you slow down or stand still?	Yes 1 No 2	**"2" go to Q.k**
j. If `***YES'*** to Q. i, how soon does it usually go away?	< 3 mins 1 3-20 mts 2 >20 mts 3	
k. Do you take usually a pill under the tongue to get relief?	Yes 1 No 2	**"2" go to Q.m**
l. If `***YES'***, how soon does it go away?	< 2mts 1 2-5 mts 2 6-10 mts 3 >10 mts 4	
m. Have you ever had a severe pain or discomfort in the front of your chest lasting for half an hour or more?	Yes 1 No 2	**"2", go to the next section**
n. If ***'YES',*** was the pain or discomfort accompanied by - ***[Yes=1; No=2]***	Cold clammy skin Breathing difficulty Sweating	
o. How old were you when you had such a severe pain in the chest?	Years	
p. How many of these attacks have you had?		
q. Have you ever had an ECG done?	Yes 1 No 2	
r. Did you see a doctor because of the pain?	Yes 1 No 2	

II. PERIPHERAL VASCULAR DISEASE		
a. Do you get pain in either leg on walking?	Yes 1 No 2	**"2" go to the Part III**
b. If **YES**, in what part of your leg do you feel it?	Pain includes calf / calves 1 Pain does not include calf/claves 2	**"2" go to the Part III**
c. Do you get it if you climb stairs or walking fast?	Yes 1 No 2 Not Applicable 3	**"2" go to the Part III**
d. Do you get it if you walk at an ordinary pace on the level ground?	Yes 1 No 2	
e. Does the pain ever disappear while you are still walking?	Yes 1 No 2	**"1" go to the Part III**
f. What do you do if you get it when you are walking?	Stop or slacken pace 1 carry on 2	**"2" go to the Part III**
g. What happens to it if you stand still?	Relieved 1 Not Relieved 2	**"2" go to the Part III**
h. If relieved, how soon?	10 minutes or less 1 more than 10 minutes 2	
III. HEART FAILURE		
a. Are you unable to walk due to physical disability?	Yes 1 No 2	**"1" skip to Q. e**
b. Do you ever get short of breath while walking with other people of your own age on level ground?	Yes 1 No 2	
c. On walking uphill or upstairs, do you get more breathless than people of your own age?	Yes 1 No 2	**"2" go to Q. e**
d. Do you ever have to stop walking because of breathlessness?	Yes 1 No 2	
e. In the past years have you at any time awoken at night by an attack of shortness of breath?	Yes 1 No 2	**"2" go to Q. g**

f.	For how long have you had this problem?	Less than one year 1 More than one year 2	☐
g.	Do you have swelling in your ankles?	Yes 1 No 2	☐
h.	Have you been told by your doctor at any time that you are suffering from any lung disease (COPD, Asthma,etc)?	Yes 1 No 2	☐
i.	Do you have a cardiac device?	Yes 1 No 2	☐
j.	If "**YES**", name the device	Standard pacemaker 1 Implantable Cardioverter defibrillator (ICD) 2 Cardiac resynchronisation therapy device with defibrillator (CRT-D) 3	☐

PART - D: COMPLICATIONS

Complete the following sections only if you have filled the "diabetes section" (2) in PART-B

I. FOOT ULCERS AND AMPUTATION

a.	Have you ever had a non healing ulcer/sore in the foot that took more than 4 weeks to heal?	Yes 1 No 2	☐
b.	Do you walk around bare foot?	Yes 1 No 2	☐
c.	Have you had an amputation?	Yes 1 No 2	☐ **"2" go to Part II**
d.	If '**YES'** When?	years before ☐☐ (or) months before ☐☐	
e.	Level of amputation	Toe 1 Below ankle 2 Below knee 3 Above Knee 4	☐
f.	What was the cause for amputation?	Injury 1 Diabetes 2 Infection 3 Other 4	☐☐ Others specify _____
g.	Do you have medical records or prescriptions?	Yes 1 No 2 Don't Know 3	☐

h. If the answer is '**YES'**, ask the participant to show the medical records and note the *diagnosis below*

II. EYES		
a. Do you have difficulty with your eyesight other than your ordinary power glasses (spectacles)?	Yes 1 No 2	☐ **"2" skip the section**
b. If '**YES'**, were you told that your poor eyesight is due to complications of diabetes?	Yes 1 No 2	☐ **"2" skip the section**
c. If '**YES'**, what was the diagnosis?		
d. Have you undergone laser therapy (Photocoagulation) at anytime	Yes 1 No 2	☐
e. Do you have medical records or prescriptions?	Yes 1 No 2 Don't know 3	☐
f. If the answer is **YES**, ask the participant to show the medical records and note the diagnosis below		

PART – E: RESPIRATORY DISEASE	
2. In the past 12 months, have you had chronic **cough** and chronic mucous production on **most** days or nights of the week (during at least three months in a row)? ***[Yes=1; No=2]*** **Cough** means cough even when you are not suffering from cold **Most** means at least 4 days or nights per week	☐
a. If '**YES'** *i.* How many episodes of such cough have you had in the past 12 months? ii. Have you suffered from any infections that required medical attention in the past 12 months? ***[Yes=1; No=2]*** iii. How many times did you seek medical attention in the past 12 months?	☐☐ ☐ ☐☐
3. Have you seen a doctor or health practitioner for a chest infection (excluding TB) in the past 12 months? ***[Yes=1; No=2]***	☐
a. If '**YES'** i. How many episodes in the past 12 months? ii. How many were doctor-diagnosed? iii. For how long have you had such infection? iv. Did you take antibiotics for these infections? ***[Yes=1; No=2; Don't know=3]***	☐☐ ☐☐ Yrs ☐☐ Mnts ☐☐ ☐
3. Have you been hospitalized for a chest infection/pneumonia in the past 12 months? ***[Yes=1; No=2]***	☐
a. If '**YES',** Length of stay	☐☐ days ☐☐ weeks ☐☐ months

4. Do you currently suffer from asthma? ***[Yes=1; No=2]***	
a. IF '**YES**' i. How many attacks of asthma have you had in the past 12 months? ii. Have you suffered from any infections that required medical attention in the past 12 months? ***[Yes=1; No=2]*** iii. How many times did you seek medical attention in the past 12 months?	
5. Have you ever been diagnosed with TB in past 5 years? ***[Yes=1; No=2; Don't remember=3]***	

PART – F: FAMILY HISTORY

1. Has anyone in your family suffered from any of the following diseases, **before the age of 60 years**? ***[Yes=1; No=2; Don't know=3]***	High blood pressure Heart disease* Diabetes mellitus (High Blood Sugar) Stroke (paralytic attack) ****Angina/ heart attack/heart failure***	

2. Fill the table below

Relationship to the family member	**Disease condition (refer to the codes below)***	**Age at diagnosis (in years)**	**If dead, age at which the family member died**
Father			
Mother			
Son			
Daughter			
Paternal Grandfather			
Paternal Grandmother			
Maternal Grandfather			
Maternal Grandmother			
Brother			
Sister			
Paternal uncle			
Paternal aunt			
Maternal uncle			
Maternal aunt			
For others, please write the relationship to the participant and provide the required details below			

Disease condition: Diabetes = 1, heart disease = 2, high blood pressure = 3, Stroke = 4

SECTION – 6: TREATMENT HISTORY AND EXPENDITURES

PART A: OUTPATIENT

1. Are you undergoing treatment as an out-patient for any of the following reasons? ***[Yes=1; No=2]***	Heart disease Stroke Diabetes Diabetic complications (infections, retinopathy, nephropathy, etc.) High blood pressure Chronic Kidney disease	☐ ☐ ☐ ☐ ☐ ☐

*If the answer to any of the above is **"YES"** go to the next section **OTHERWISE** skip to PART B*

In the following questions ask the details of treatment and cost only for the last 12 months

2. How many times did do you visit a health facility/doctor/therapist in past 12 month?	☐☐	
3. Type of health facility/doctor/therapist	Government 1 Private 2 Charity 3 Others 4	☐ ***Others, specify*** _____

4. List the expenditures incurred towards the above mentioned conditions (Q.1) separately in each table

4.i. Disease _____

Nature of expenditure	**Frequency**	**Amount spent in Rs per visit/ test/remuneration to home nurse or carer**
Visit to Doctor (fees)		
No. of months home nurse / carer was hired		
Tests		
Physical or occupational rehabilitation		
Others (Specify)_____		
Medications ***(average amount spent in last 12 months for the above mentioned condition)***		
Total expenditure in past 12 months		

4.ii. Disease _____

Nature of expenditure	Frequency	Amount spent in RS per visit / test/remuneration to home nurse or carer
Visit to Doctor (fees)		
No. of months home nurse / career was hired		
Tests		
Physical or occupational rehabilitation		
Others (Specify)_____		
Medications ***(average amount spent in last 12 months for the above mentioned condition)***		
Total expenditure in past 12 months		

4.iii. Disease _____

Nature of expenditure	Frequency	Amount spent in RS per visit/ test/remuneration to home nurse or carer
Visit to Doctor (fees)		
No. of months home nurse / career was hired		
Tests		
Physical or occupational rehabilitation		
Others (Specify)_____		
Medications ***(average amount spent in last 12 months for the above mentioned condition)***		
Total expenditure in past 12 months		

4.iv. Disease _____

Nature of expenditure	Frequency	Amount spent in RS per visit/ test/remuneration to home nurse or carer
Visit to Doctor (fees)		
No. of months home nurse / career was hired		
Tests		
Physical or occupational rehabilitation		
Others (Specify)_____		
Medications ***(average amount spent in last 12 months for the above mentioned condition)***		
Total expenditure in past 12 months		

5. Did you get any reimbursement from insurance?	Yes 1 No 2 Don't know 3 Don't have any insurance 4	☐
6. If **YES**, of the above mentioned expenditure how much was reimbursed (in RS)?	RS _____	
7. Time taken to reach the health facility/doctor/therapist?	☐☐ : ☐☐ HR MIN	
8. Transport cost to visit the above mentioned health facility/doctor/therapist*	RS _____	
If the participant has a private vehicle, ask him to give you an estimate of the amount spent on fuel to travel		
9. Average time spent at health facility	☐☐ : ☐☐ HR MIN	
10. Are you getting proper medical attention? ***[Yes=1; No=2]***	☐	
10.a. If **"No"** What has prevented you from getting medical attention?	Not available 1 No one to help me get there 2 Too far 3 Too expensive 4 Don't want to spend money 5 Complicated procedures for care seeking 6 Too long a wait 7 Too sick to make the trip 8 Do not trust medical care 9 Do not know where to go 10 Others (Specify) 11	☐ ☐ ☐ ☐ If other, specify _____
11. How did you pay for your treatment and visits? ***[Yes=1; No=2]***	Own saving 1 Family members paid 2 Employer paid 3 Borrowed from friend, relatives & employer 4 Borrowed from bank 5 Sold house, land or other assets 6 Health insurance 7 Others (specify)_____ 8	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
12. On an average what proportion of money in percentage (%) did you spent from the above mentioned source for your treatment and visits?	Own saving Family members paid Employer paid Borrowed from friend, relatives & employer Borrowed from bank Sold house, land or other assets Health insurance Others (Specify)_____	_____% _____% _____% _____% _____% _____% _____% _____%

PART B: INPATIENT		
1. Were you hospitalized for any illness in the **past 12 months**?	Yes 1 No 2 Don't remember 3	☐ **"2" go to Q.4**
2. If **YES**, how many times?	☐☐	
3. Were you admitted for any of the following reasons? ***[Yes=1; No=2]***	Heart disease Stroke Diabetes Diabetic complications (infections, retinopathy, nephropathy, etc.) High blood pressure Chronic Kidney disease	☐ ☐ ☐ ☐ ☐ ☐
4. Have you undergone any surgical procedure in the **past 12 months**?	Yes 1 No 2 Don't remember 3	☐ **"2" go to Q.6**
5. If yes, what was the procedure? ***[Yes=1; No=2]***	Revascularisation / bypass Valve repair/replacement Pacemaker Amputation Abscess Renal transplantation Heart transplant Retinal photocoagulation Others (Specify_____)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
6. Do you have medical records related to hospitalization / surgical procedure?	Yes 1 No 2	☐

*If the answer is **YES,** ask 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 below*

Hospitalisation

Surgical procedure

Comments

PART C: HOSPITALISATION COST

Fill this section only if the participant has undergone hospitalisation due to illness or procedure mentioned in question 3 and 5 of part B, otherwise end the interview and thank the participant.

For each hospitalisation note the following details, starting with 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.

Sl. No	Questions	1	2	3
1	When were you hospitalized?	Month ☐☐	Month ☐☐	Month ☐☐
2	How many days did you stay in the hospital?	Days ☐☐	Days ☐☐	Days ☐☐
3	Type of hospital? ***[Yes=1; No=2]***	Government ☐ Private ☐ Charity ☐ Other ☐	Government ☐ Private ☐ Charity ☐ Other ☐	Government ☐ Private ☐ Charity ☐ Other ☐
4	Name of hospital (Address)			

5	What type of treatment/procedure/ surgery did you undergo? ***(Cross-check with the medical records and information in PART-A)*** ***[Yes=1; No=2]***	Medicines ☐ Thrombolysis ☐ Angiogram ☐ Angioplasty ☐ Bypass surgery ☐ Brachytherapy ☐ Pacemaker ☐ Heart transplant ☐ Amputation ☐ Echocardiography ☐ Neuro-imaging ☐ Dialysis ☐ Kidney-transplant ☐ For observation ☐ Other procedure ☐ Specify ___________	Medicines ☐ Thrombolysis ☐ Angiogram ☐ Angioplasty ☐ Bypass surgery ☐ Brachytherapy ☐ Pacemaker ☐ Heart transplant ☐ Amputation ☐ Echocardiography ☐ Neuro-imaging ☐ Dialysis ☐ Kidney-transplant ☐ For observation ☐ Other procedure ☐ Specify ___________	Medicines ☐ Thrombolysis ☐ Angiogram ☐ Angioplasty ☐ Bypass surgery ☐ Brachytherapy ☐ Pacemaker ☐ Heart transplant ☐ Amputation ☐ Echocardiography ☐ Neuro-imaging ☐ Dialysis ☐ Kidney-transplant ☐ For observation ☐ Other procedure ☐ Specify _________
6	Total amount spent on treatment (hospitalisation expenses + medicines purchased during the stay)	Rs ________________	Rs ________________	Rs ________________
7	Number of days attendant stayed with you in the hospital	Days ☐☐	Days ☐☐	Days ☐☐
8	Cost of attendant's stay (include food accommodation and travel)	Rs _______________	Rs ____________	Rs ____________
9	Distance from home to hospital?	Kms ☐☐☐	Kms ☐☐☐	Kms ☐☐☐

10	Cost of travel from home to hospital (excluding ambulance cost, if any)	Rs __________________	Rs __________________	Rs __________________
11	What type of medical insurance do you have? ***[Yes=1; No=2]***	Free medical treatment ☐ Commercial Insurance ☐ None ☐ Self-pay ☐ Other ☐ (________________) Specify	Free medical treatment ☐ Commercial Insurance ☐ None ☐ Self-pay ☐ Other ☐ (________________) Specify	Free medical treatment ☐ Commercial Insurance ☐ None ☐ Self-pay ☐ Other ☐ (____________) Specify
12	Amount reimbursed from health insurance, if any?	Rs ___________________	Rs ___________________	Rs ___________________
13	How do you pay for your hospitalisation costs? ***[Yes=1; No=2]***	Own saving ☐ Family members paid ☐ Employer paid ☐ Borrowed from friends, relatives, employer ☐ Borrowed from bank ☐ Sold house, land, or other assets ☐ Health insurance ☐ Other ☐ (Specify___________) ☐	Own saving ☐ Family members paid ☐ Employer paid ☐ Borrowed from friends, relatives, employer ☐ Borrowed from bank ☐ Sold house, land, or other assets ☐ Health insurance ☐ Other ☐ (Specify___________) ☐	Own saving ☐ Family members paid ☐ Employer paid ☐ Borrowed from friends, relatives, employer ☐ Borrowed from bank ☐ Sold house, land, or other assets ☐ Health insurance ☐ Other ☐ (Specify___________) ☐
14	Proportion of money in percentage (%) did you spent from the above mentioned source for your hospitalisation?	Own savings____________% Family members paid__________________% Employer paid___________% Borrowed from friends, relatives, employer ______% Borrowed from bank _____% Sold house, land, or other assets ________________% Health insurance_________% Other ________________% (Specify ____________)	Own savings____________% Family members paid__________________% Employer paid___________% Borrowed from friends, relatives, employer ______% Borrowed from bank _____% Sold house, land, or other assets ________________% Health insurance_________% Other ________________% (Specify ____________)	Own savings____________% Family members paid__________________% Employer paid__________% Borrowed from friends, relatives, employer _____% Borrowed from bank ____% Sold house, land, or other assets _______________% Health insurance________% Other ________________% (Specify ____________)

15. Time interview ended: ☐☐ : ☐☐
HR MIN

Form - 6

CARRS - Surveillance Study

Interview Checklist

Participant ID

Visit details	**Visit - 0**	**Date:** **Time:**
	Visit - 1	**Date:** **Time:**
	Visit - 2	**Date:** **Time:**

Checklist		**Completed**		
		YES	**NO**	**NA***
Visit - 0				
Form-2	Household Proforma			
Form-3	Surveillance study notification form			
Form-4	Participant Information Sheet and consent form			
Form-5	Non-interview report form (Cross-sectional survey)			
Visit-1: Questionnaire				
Section-1	Demographic, Socio-economic and residential detail			
Section-2	Details of tobacco and alcohol consumption, dietary habits, physical activity and sleep			
Part - A	Tobacco			
Part – B	Alcohol			
Part – C	Physical activity			
Part – D	Sleep			
Part - E	Diet			
Section-3	Female reproductive history			
Section-4	Quality of Life			
Section-5	Medical history			
Part - A	Cardiometabolic diseases and their risk factors			
Part - B	Disease specific questions			
B-1	Hypertension (High blood pressure)			
B-2	Diabetes			
B-3	Hyperlipidemia			
B-4	Heart trouble			
B-5	Stroke (Paralytic attack)			
B-6	Chronic Kidney disease			
Part - C	Co-morbidities			
C-1	Angina			
C-2	Peripheral vascular disease			
C-3	Heart failure			

Part - D	Complications			
D-1	Foot ulcers and amputations			
D-1	Eyes			
Part - E	Respiratory disease			
Part - F	Family history			
Section-6	Treatment history and expenditures			
Part – A	Outpatient			
Part – B	Inpatient			
Part - C	Hospitalization cost			
Form - A	BP and anthropometric measurement recording form			
Form - 5	Non-interview report form			
Specimen collection kits and instructions				
Urine collection container and instructions				
Saliva collection tube and instructions				
Fasting instructions				
General instructions				
Date and time of second visit				
Address of the blood collection camp				
Medicines / medical records / prescriptions to be brought during visit-2 (if these could not be provided during visit-1)				
Visit-2				
Biological specimen collection and processing forms				
BS-1	Blood collection form			
BS-2	Urine collection form			
BS-3	Saliva collection form			
BS-4	Blood processing form			
Spirometry form	Spirometry form			

*__NA__ – Not applicable

Signature of Field Interviewer

Verified
Name and Signature of Field Supervisor

Chapter – 11

Anthropometric Measurements

Introduction

There will be a total of ten 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. 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. Mid-arm circumference
4. Waist circumference
5. Hip circumference
6. Triceps skinfold
7. Sub-scapular skinfold
8. Supra-patellar skinfold

Visit - 2

9. Height (Standing)
10. 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

- 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

- 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 a sleeve for the triceps measurements, their shirts for sub-scapula and waist/abdominal measurements, and lower their pants/skirt for hip and thigh measurements.
- Be tactful. Try to avoid excessive body contact while arranging the measuring tape, finding sites and using the calipers.
- ***Keep all equipment clean.*** Wipe skinfold caliper heads and measuring tape with an alcohol wipe after each interview.
- Use gloves in the presence of obvious contamination with blood or secretions.
- Use the non-stretch, pliable Gulick II tape which has a tensioning device attached to the measuring tape. This allows for repeatable measurements which are accurate and consistent no matter who is doing the measuring.
- Number of readings to be taken for each parameter per participants:
  - Blood pressure – 2 recordings
  - Pulse rate – 2 recordings

  } If the difference between the first two readings is more than the acceptable limit, a third one should be taken

  - Height (standing) – 1 reading
  - Body circumferences – 1 reading
  - Skin-fold thicknesses – 2 readings. If the difference between the first two readings is more than the acceptable limit, a third one should be taken

General instructions

- If possible, 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.
- All measurements should be taken to the nearest 0.1 centimeter (or 1.0 millimeter).
- Skin-fold measurement should be taken to the nearest 0.1 millimeter.
- Skin-fold, blood pressure and pulse rate will be measured twice
- For skin-fold thickness, if the measurements are not within the specified tolerance a third measurement will be taken [Skin-fold measurement tend to be variable even when taken by the same observer[1]]
- If subject is too large or too muscular to get a measurement, you need to indicate this on your data entry form. For example, "***exceeds caliper scale"*** can be indicated for very large measurements, or ***"measurement unreliable"*** can be indicated for difficult measurements.

Equipment and Supplies

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

- Electronic Sphygmomanometer – Omron HEM-7080
- Holtain Skinfold Caliper
- Seca Brand-213 Portable Stadiometer
- Gulick II, non-stretch measuring tape
- Body Composition Analyzer - Tanita BC-418 (body-impedance)
- Wax-based cosmetic pencils

[1] Stanley JU, Kerr DA. Anthropometric measurement error and the assessment of nutrition status. British Journal of Nutrition. [Review article]. 1999;82:165-77.

Step-by-Step Procedures

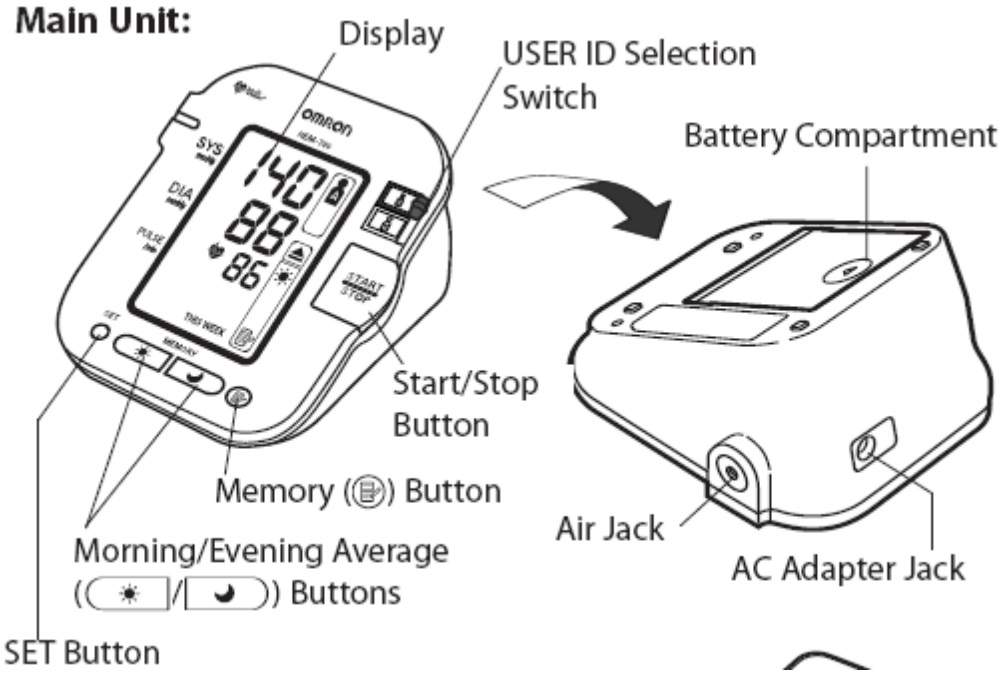
Blood Pressure and Pulse Rate

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; ideally before starting the medical history section 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.
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. The room temperature should be recorded routinely.
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-A.
7. If the difference between the two readings is greater than the accepted tolerance limit (systolic 10 mmHg and diastolic 6mmHg), another measurement should be taken.

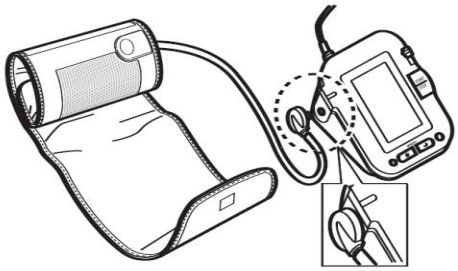
The BP Apparatus [Omron HEM-7080]



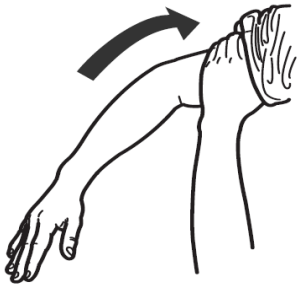
Applying the Arm Cuff

Applying the Cuff on the Right Arm

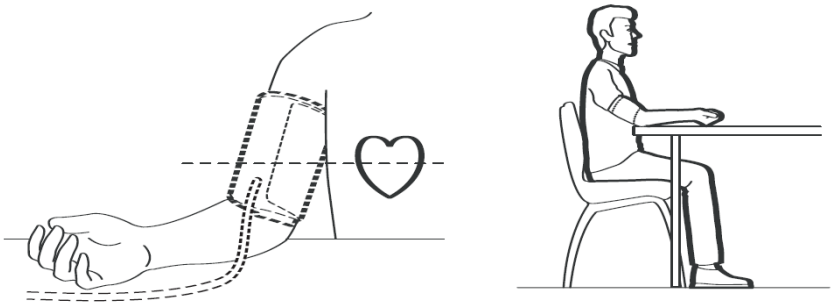
1. Make sure the air plug is securely inserted in the main unit



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

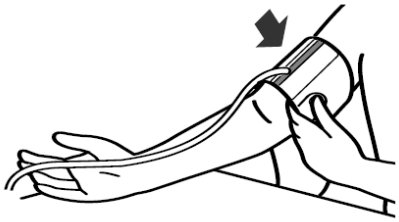


3. The participant should sit in a chair with her/his feet flat on the floor. Place the participant's right arm on a table so that the cuff is level with the heart

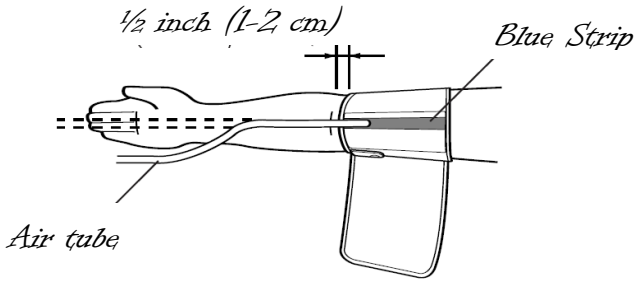


4. Hold the grip on the cuff securely with your right hand, placing your thumb on the thumb grip

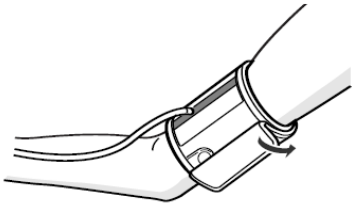
5. Turn the palm of your left hand upward



6. Apply the cuff to the participant's right upper arm so that the blue strip is on the inside of her/his arm and aligned with the participant's 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



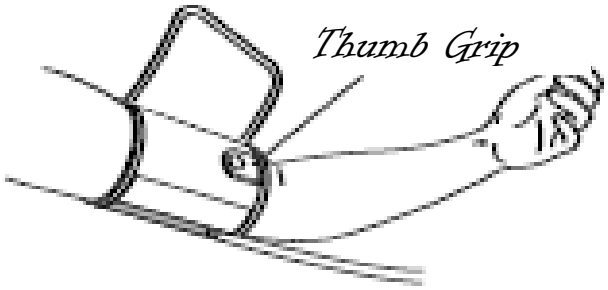
7. Wrap the cuff firmly in place around the participant's arm using the cloth strip



Applying the Cuff on the Left Arm

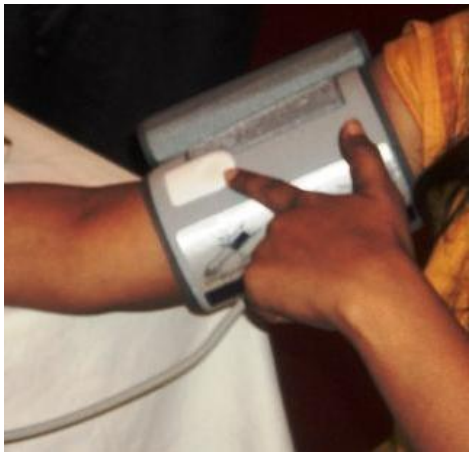
To apply the cuff on the left arm, follow the steps from 1 to 5 given for the right arm.

6. Apply the cuff to the participant's left upper arm so that 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.



The **"White thumb grip"** should be 1/2" inches above the ante-cubital fossa as shown in the figure

Taking Measurement

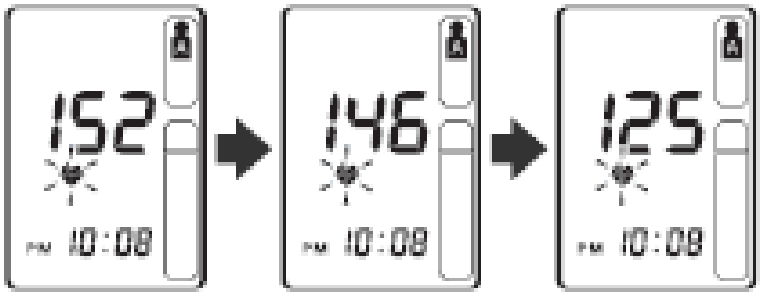
1. Press and hold the START/STOP button. The A and B symbols disappear from the display.

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

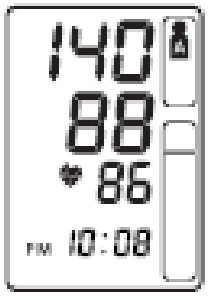
> To stop the inflation press the START/STOP button
> The monitor will stop inflating, start deflation and turn off

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 are 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."

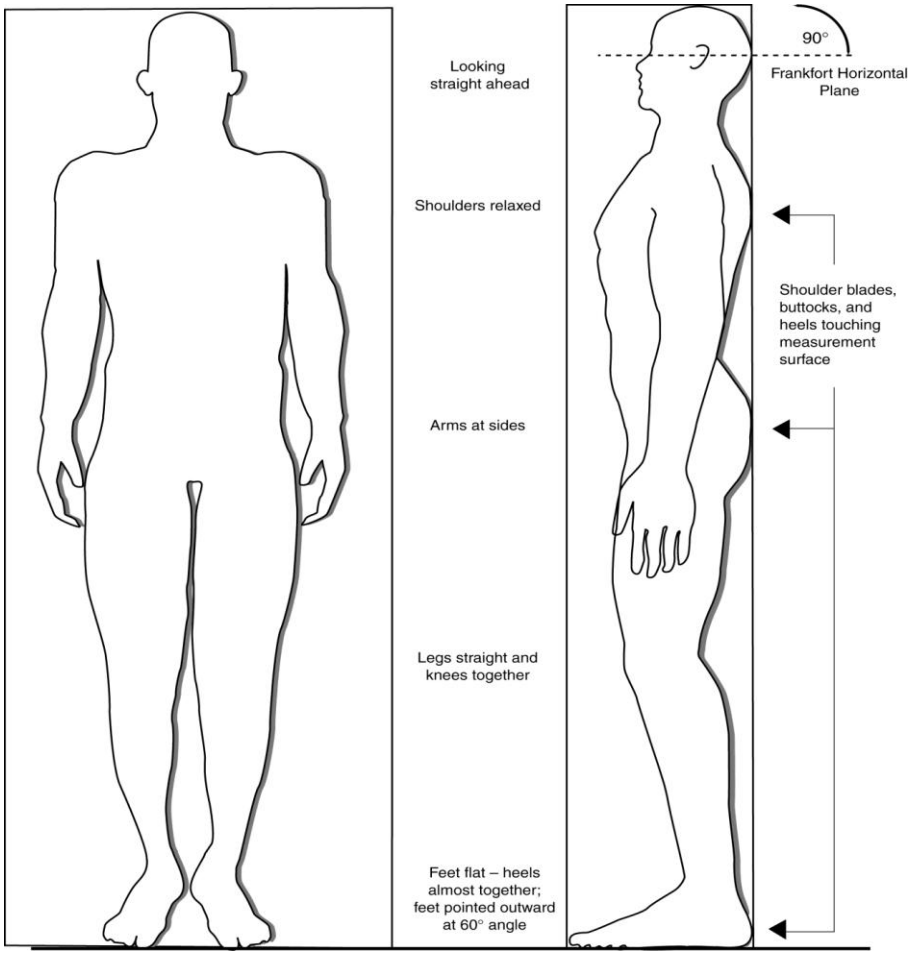
Procedure for Measuring Height

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 below).
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 below). 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 the participant's height using the tape measure 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. Circumferences of the limbs, together with skinfold measure of subcutaneous adipose tissue thicknesses at corresponding levels, can provide cross-sectional areas of adipose tissue or areas of the underlying "muscle plus bone".

- Measurements should be taken on the right side of the body.
- 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.
- The tension applied to the tape by the measurer affects the validity and reliability (correctness) of the measurements. The Gulick II tape (picture below) applies a consistent amount of tension (4 ounces) each time.

- 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.

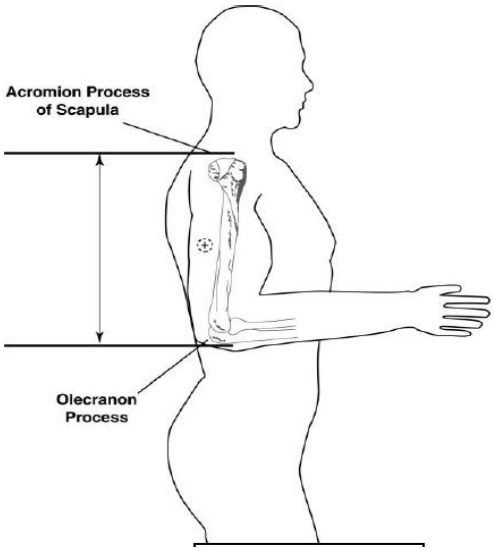
Attempting to reduce the gap by increasing the tension of the tape is not recommended

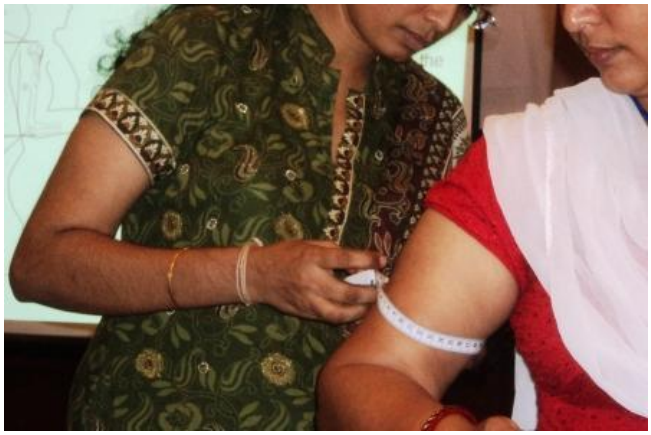
Mid-arm Circumference

The arm circumference is measured with the subject standing upright, shoulders relaxed, and the right arm hanging loosely. It is important to be certain that the muscle of the arm is not flexed or tightened, which could yield a larger and inaccurate reading.

To locate the mid-arm:

1. Locate and mark the tip of the *acromium* process (the point of the shoulder), refer to the figure given below.
2. Then with the participant's arm flexed at 90 degrees, feel the *olecranon* (tip of the elbow).
3. Place the tape measure on the mark on the shoulder and drop it down to the tip of the elbow by the side of the arm.
4. Put a (+) mark mid-way between the shoulder and the elbow. Stand facing the participant's right side and place the measuring tape around the upper arm at the crossed point (+), perpendicular to the long axis of the upper-arm.
5. Hold the measuring tape gently on the skin's surface. Pull the two ends of the overlapping tape together so that the zero end is held below. The measurement is taken on the lateral aspect of the arm.
6. Be careful not to compress the skin and the underlying subcutaneous tissue.
7. Record the measurement to the nearest millimeter.

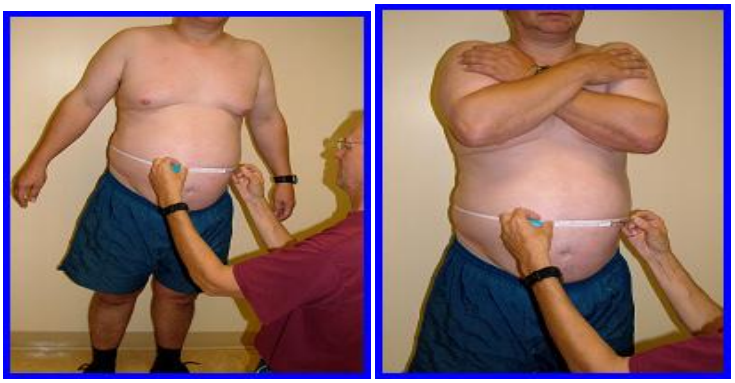




Waist Circumference:

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.

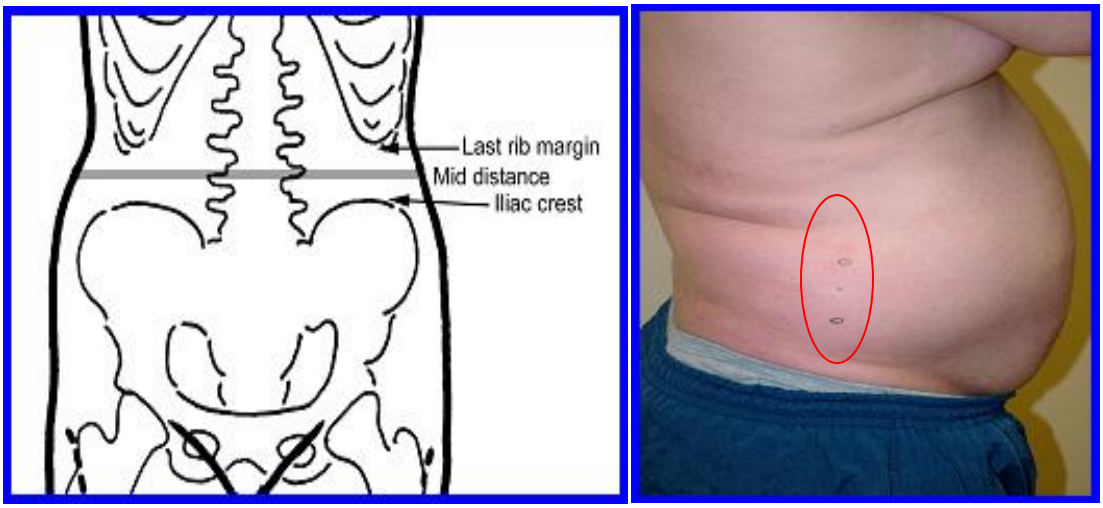
1. To define the level at which the waist or abdominal circumference is measured, you must first locate and mark the iliac crest and the lowest rib.
2. Have the participant stand with feet close together and the abdomen relaxed.
3. Lower the pants and underclothing of the participant slightly, and standing 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.



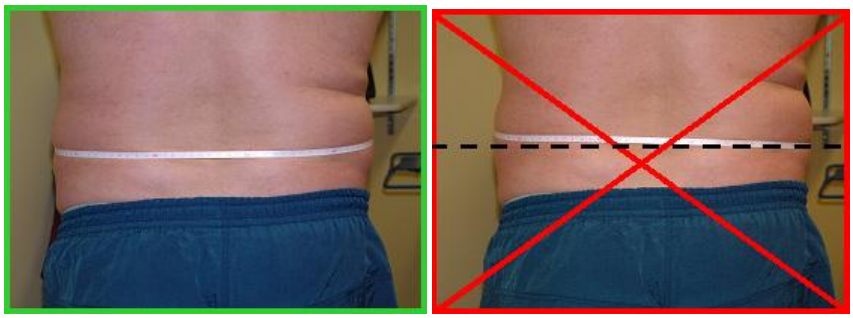
Arms at 30 degrees **Arms crossed**

Detailed instructions

1. Request the participant to stand with her / his arms at 30 degrees or crossed as shown above [crossed arm is a better position to take body circumferences]
2. Mark with a skin pencil the bony landmarks of the right and left last rib margin.
3. Mark with a skin pencil 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. Note: A mirror could be used to facilitate this procedure.



Tape placed horizontally Tape not horizontal

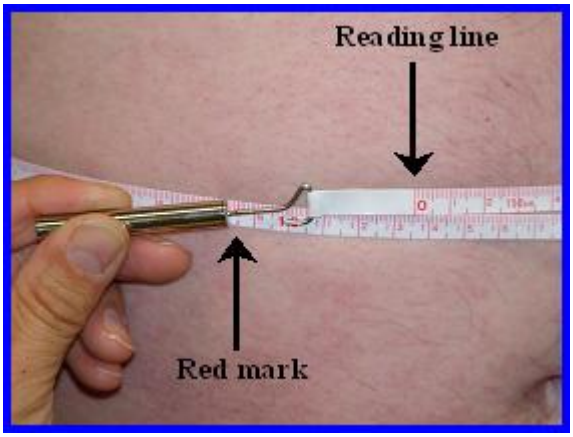
Hip Circumference

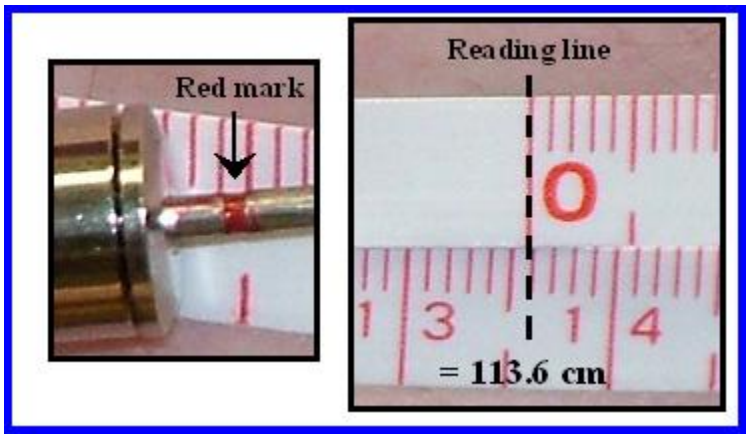
This measurement should be taken with the participant wearing minimal clothing; it's best to measure directly over the skin. If this is not possible, the measurement may be taken over light clothing. It must not be taken over thick or bulky clothing. This type of clothing must be removed.

1. Make the participant relax their arms to the side.
2. The measurement should be taken at the maximum circumference over the buttocks.
3. Stand on the side of the participant; position the measuring tape around the maximum circumference of the buttocks.
4. Ask the participant to:
   a. Stand with their feet together.
   b. Place their arms at their side with the palms of their hands facing inwards, and breathe out gently.
5. Check that the tape position is horizontal all around the body.
6. 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 (until the red mark appears if you use a tape with a spring handle) at the moment of the reading. Zero end should be held above the measuring value as shown below. Record the readings in Form – A [Appendix-11].





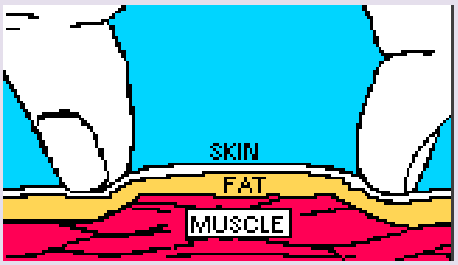
http://www.metabolic-syndrome-institute.org/informations/screening-diagnosis/procedures-for-the-measurement-of-the-waist-circumference.php

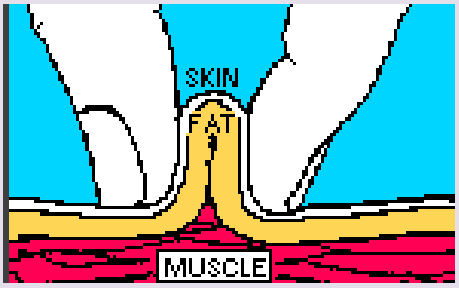
Procedures for Measuring Skinfold Thickness

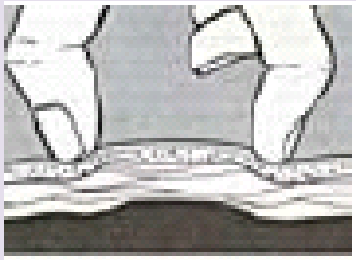
Skinfold thicknesses, sometimes called "fatfold" thicknesses, are actually the thicknesses of double folds of skin and subcutaneous adipose tissue at specific sites on the body. They provide a relatively simple estimation of general fatness, and can help provide valuable information on the distribution of subcutaneous body fat.

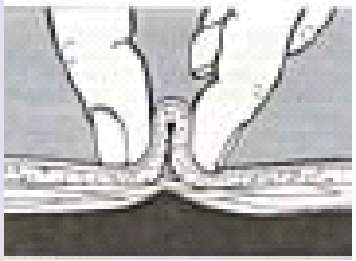
Measuring body fat with skinfold caliper is challenging. It is particularly important to standardize site selection and location because small differences in location can make significant differences in measurement. In addition, the compressibility of both skin and adipose tissue varies with the state of hydration, age, size, and individual. Very lean and very obese individuals pose special measurement problems. In general, the thicker the skinfold the more difficult it is to achieve a reproducible measure.

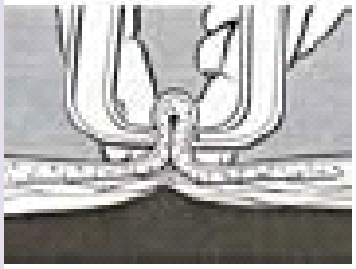
1. Start by explaining what you will be doing and show the participant the calipers you will be using.
2. Tell the participant that it may hurt a little, but you will be try to be quick and gentle.
3. You must mark each site carefully. Make all marks on the right side of the body.
4. All skinfold measurements must be taken directly on the skin, not over any clothing.
5. Use either a bony landmark on the trunk of the body or midpoints between two well defined bones on the limbs.
6. Take all measurements with the Holtain skinfold caliper.











7. Gently grasp the fold of skin and adipose tissue to form a distinct fold that separates from the underlying muscle.
8. The sides of the fold should be roughly parallel.
9. The skinfold should be grasped 2.0 cm above the place where the measurement is to be taken, and gently held with the thumb and forefinger.
10. Place the jaws of the calipers at the mark, perpendicular to the length of the fold.
11. Measure the skinfold thickness to the nearest 0.1 mm while the fingers continue to hold the skinfold.
12. Read the actual measurement from the caliper about three seconds after the caliper tension is released.

General Instructions

- Measurements should be taken on the right side of the body.
- Mark each site with a skin pencil.
- **Grasp the skinfold firmly with the thumb and index finger of your left hand and pull the skinfold away from the body**. The skinfold should have parallel sides. The more fat under the skin, the thicker or wider the fold will be.
- Pulling the skinfold away from the body is usually easier in thin persons compared to obese persons. It can also be somewhat uncomfortable for the participant.
- **Hold the caliper in your right hand**, perpendicular to the skinfold, and with the dial face up. Place the caliper heads on the skinfold *⅓ to ½ inch (1 cm) away from your fingers holding the skinfold*. This is important to prevent pressure from the fingers effecting pressure of the caliper heads. During each measurement maintain the pressure of the fingers.
- Take care not to place the caliper too far into the skinfold. The caliper heads should be placed on the actual double fold of the skin's thickness.
- Release the lever of the caliper and read the dial after approximately 4 seconds. Waiting longer than 4 seconds will result in inaccurate smaller readings.
- Record the measurement to the nearest 0.1 millimeter.
- Repeat the measurements in the same order for the subsequent readings. Make sure at least 15 seconds have passed before repeating the measurement at the

same site so that the skinfold is allowed to "flatten" or return to normal between readings.

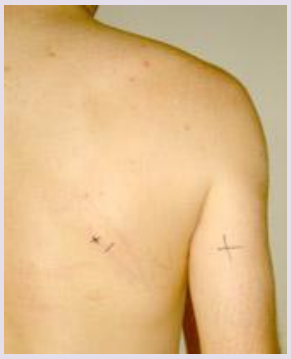
- If the difference between the first two recordings is greater than 1mm, then take a third measurement.
- Practice the measurement procedures until you are completely comfortable with them.
- It takes practice to become skillful in measuring skinfolds consistently.

For obese participants

- Attempt the measurement and if unsuccessful, note as "unreliable" on the data form.
- If the skinfold is above the measurable limits of the calipers (i.e., greater than 67 mm), then note "exceeds caliper" in the recording space for that skinfold.

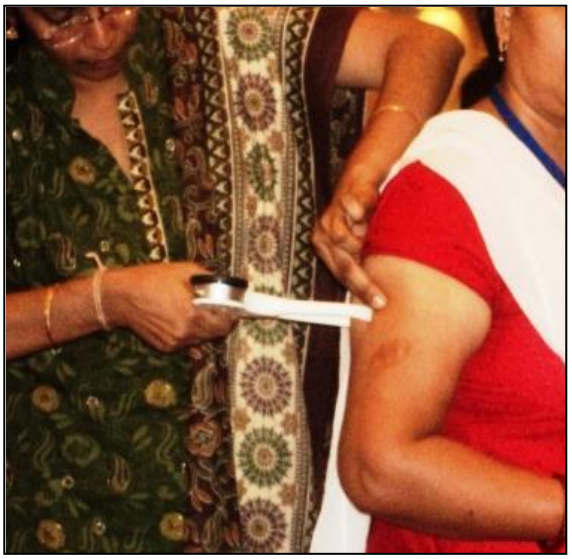
Triceps Skinfold:

Measure the triceps skinfold on the posterior surface of the right upper arm (fig below), at the point previously marked for the mid-upper arm circumference.

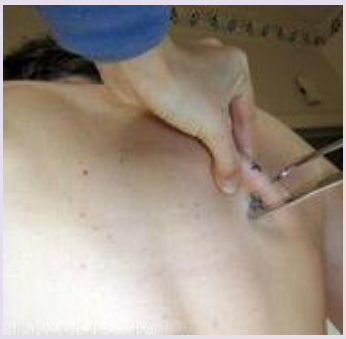


Have the participant stand upright with weight evenly distributed and feet together, shoulders relaxed, and the arms hanging freely at the sides. Stand behind the participant's right side and gently grasp a fold of skin and subcutaneous adipose tissue with thumb and index finger, approximately 2.0 cm above the marked point. The skinfold should be parallel to the long axis of the arm. Place the tips of the caliper jaws over the marked point, perpendicular to the length of the fold (Fig below). Measure the skinfold thickness to the nearest 0.1 mm while the fingers continue to hold the skinfold.

- Make sure the participant's right arm is hanging loosely.
- Stand behind the participant and pull a vertical skinfold about half an inch above the previously marked site, with the thumb and index finger pointing downward, centering the mark (+).
- Place the calipers perpendicular to the length of the fold, centering the mark.
- Release the caliper and read the dial after approximately 4 seconds while the fingers continue to hold the skinfold.
- Record the measurement to the nearest millimeter.



Sub-scapula Skinfold:



Measure the sub-scapular skinfold with the participant standing straight with shoulders relaxed and arms hanging loosely at the side. Palpate for the inferior angle (or triangle portion) of the right scapula. Make a cross (+) on the inferior angle of the scapula with the cosmetic pencil marker. Gently grasp a fold of skin and subcutaneous adipose tissue with the index finger directly above (1.0 cm) and medial to the inferior angle of the scapula, with the thumb reaching toward the

spine. The skinfold should form a line about 45 degrees below horizontal extending diagonally toward the right elbow. Place the tips of the caliper jaws perpendicular to the length of the fold about 2.0 cm lateral to the fingers with the top jaw of the caliper on the mark over the inferior angle of the scapula (Refer to figure). Measure the skinfold thickness to the nearest 0.1 mm while the fingers continue to hold the skinfold.

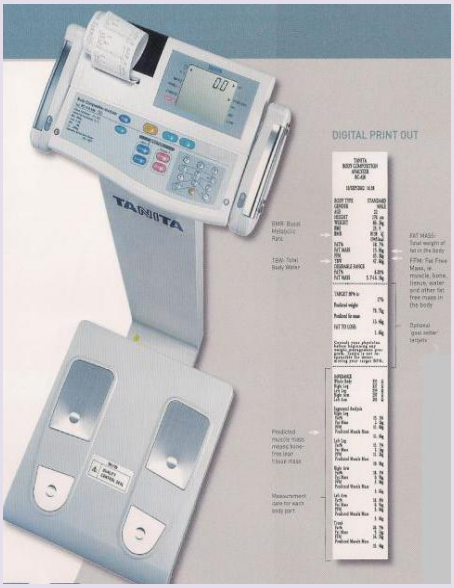
If there is difficulty finding this landmark, get the subject to reach behind their back with their right arm, while feeling for the movement of the scapula.

On female subjects it is sometimes difficult to take this measure and maintain modesty, and also the bra-strap may often obstruct this site. Therefore you should be very careful in explaining the method and make the participant comfortable.

Supra-patellar (front thigh) Skinfold

A vertical pinch is made at the mid-point of the anterior surface of the thigh, midway between patella (knee cap) and inguinal fold (crease at top of thigh). Measure the skinfold thickness to the nearest 0.1 mm while the fingers continue to hold the skinfold (Refer to figure). Same caution has to be maintained for female participants as described above.

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 - "0.0" will appear on the upper portion of the display.

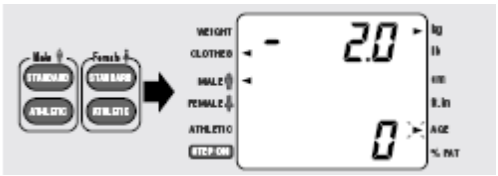
2. **Enter Clothes Weight:** Enter the approximate weight of clothes worn by the participant using the numerical keys. Example: if the clothes weight is 2.0 kg, press [2], [.] and then [0]. Ask the participant to remove the heavy outer clothing like coat, shawl, pull-over etc, and keep away all electronic devices during the process of measurement.

   When the data input is completed, the data will be displayed as a minus number.

3. **Select the Body Type:** Select the Body Type from Standard Male, Standard Female, Athletic Male and Athletic Female. Please use the Athletic key when the user is 17 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 does not 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.



4. Enter Age:

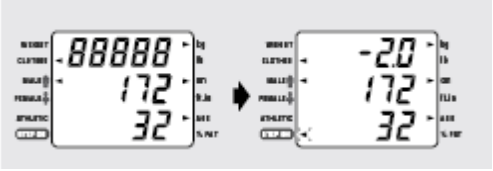
Example: If the user is 32 years old or younger Press [3] and [2].

5. Enter Height

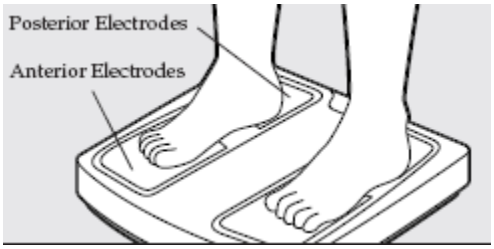
Example: If the user's height is 172 cm, please press [1], [7] and then [2].

Do not make the participant step on the Weighing Platform until the target body fat ratio setting has been completed because the power may be automatically turned off or the measurement may be inaccurate.

6. After **"88888"** is displayed on the upper portion of the display, a flashing arrow will appear next to "STEP ON"

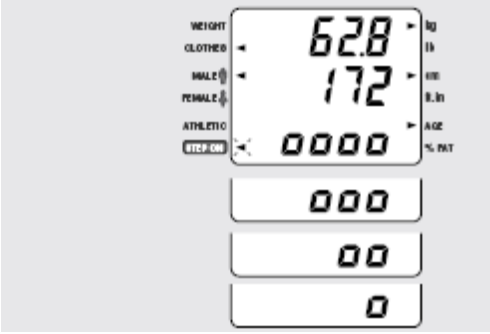


7. Start Measurement: Now ask the participant to step on the Weighing Platform with bare feet so they touch the electrodes. S/he should be made to stand in a stable position without bending the knees.



Do not use the hand grips, as you will only be measuring the body weight.

8. **Taking Measurement:** The participant should be made to step on the weighing platform in bare feet. Make sure heels are placed on the posterior electrodes, and the front parts of the feet are in contact with the anterior electrodes.



9. **Measure the Impedance:** When the grips are grasped with both hands, "***0000***" will appear at the bottom of the display and the impedance measurement will begin. The "***0000***" marks will disappear one by one during the measurement; after five full cycles, the measurement will be complete.

- **Ask the participant to hold the grips only after the body weight figure on the display has stabilized.**
- **The participant should not step off the Weighting Platform until the "*0000*" symbols disappear completely.**

If the measurements of the body fat ratio or the quantity of fat are abnormally small or the error message (E01) 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.

10. **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. The printer should be ON such that the measurement results are printed out.

11. **When You Continue to Measure:** After printing is completed, go back to step 3. Follow the same procedure mentioned above.

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

General instructions

Body circumferences

- Talk to the participant as you are proceeding through the measurements. Explain why and what you are doing, especially when locating the leg tendon in the groin area, and before adjusting the pants down to feel for the hip bone.
- Remain completely professional and unaffected by tattoos, body piercing, etc. DO NOT COMMENT about the participant's body.
- When you are taking the circumference and skinfold measurement, remember to stay in one place and move the participant around rather than moving around the participant.

Standing height

Make sure the head and heels are against the stadiometer before taking the height, unless this position is anatomically impossible. DO NOT FORGET to have the participant take a deep breath and hold it while you position the headboard. 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.

Skinfolds

- Take the measurements at eye level.
- If the triceps skinfold is hard to separate, start at the elbow (where the skin/fat is looser), and work up to the mark.
- If skinfolds are tight, take the measurement closer than ¾ inch to your fingers.
- For the subscapular skinfold, place the fingers ¾ inch above the (X) mark; only the top jaw of the caliper needs to be on the mark.

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.

- Calibration of the instruments needs to be done on a weekly and monthly basis.
- Readings for the calibrations needs to be taken on the same two field interviewers weekly at the beginning of the day.
- The weekly and monthly calibration readings need to be entered into the form provided and given to the study manager every month for assessment.
- Each instrument needs to be numbered.
- Calibration needs to be done only for the instrument which is being used and only on the days it is used.
- For monthly calibration the first working day of every month is selected and all the instruments are calibrated on the same day.

Weekly Calibration

- **Body composition analyzer:** Two FI need to measure their body composition and take a print out of the readings.
- **Stadiometer:** Assemble the portable stadiometer. The height of same FIs need to be measured and entered.
- **Skin fold caliper:** The thickness of two, wooden/plastic blocks of varying but known thickness should be measured every day.
- **Blood pressure apparatus:** Blood pressure recordings of the same FIs need to be measured.

Monthly Calibration

- **Body composition analyzer:** Two FI need to measure their body composition and print out the readings.
- **Stadiometer:** A metallic tape can be used for this and readings to be taken at 75 and 150 cms on the stadiometer.

- **Skin fold caliper:** The thickness of two, wooden/plastic blocks of varying but known thickness should be measured every day.
- **Blood pressure apparatus:** The blood pressure of two FIs are measured and compared with the BP recording of the same two individuals using a mercury sphygmomanometer. The same mercury sphygmomanometer to be used for comparison throughout the study.

See Appendix-11 for the Weekly and Monthly Calibration Forms (A1, A2, A3 and A4).

Anthropometry Measurement Script

When you provided consent to enroll 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.

I would like to start by taking your blood pressure.

1. If necessary, ask the participant to roll up one sleeve as far as possible.
2. Place the blood pressure cuff on the participant's arm.
3. Activate the sphygmomanometer.
4. Record blood pressure and pulse rate.
5. Remove the blood pressure cuff.

Height

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.

Please stand with your heels together touching the back board.

Your toes should be pointed slightly outward.

Please stand up straight and look straight ahead.

The back of your head, shoulder blades, buttocks, and heels should all be touching the back board.

1. 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.
2. 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.
3. Make sure that the head is positioned in the Frankfort plane.
4. If the participant has kyphosis, take the best measurement possible and record "NS" (Not Straight) in the comment section.
5. Once the participant is positioned correctly, lower the head board to just above the participant's head.

Take a deep breath.

1. Rest the head board on the top of the participant's head with sufficient pressure to compress the hair.
2. Record the height.
3. Raise the head board.

Thank you.

Please step away from the back board.

<u>Mid-arm Circumference</u>

While taking the circumference and skinfold measures stay in one place and move the participant around.

Now I am going to measure the circumference of your upper arm, waist, and hips.

Please stand up straight and relax your shoulders.

I am going to put a pencil mark on the tip of your shoulder.

Please hold your right arm at a 90 degree angle.

I am going to place a pencil mark on the tip of your elbow.

Now I am going to use the tape measure to measure the length of your upper arm and mark the midpoint with the pencil.

Make a "+" mark at the midpoint of the arm perpendicular to the long axis of the upper arm.

I am going to wrap this measuring tape around your arm and record the measurement.

1. Take the measurement. 2. Be careful not to compress the skin and underlying subcutaneous tissue.

Thank you.

<u>Waist circumference</u>

1. This measure should be taken on bare skin if possible. 2. The purpose of the following instructions is to help the interviewer find the narrowest point on the waist.

Please stand with your feet close together and your stomach relaxed.

I am going to touch your right hip.

Now I need to find the lowest rib on your right side.

I am going to use the cosmetic pencil to mark the spot on your waist where I will take the measurement.

Now I am going to put the measuring tape around your waist and take the measurement.

Take the measurement

Thank you.

Hip Circumference

Now I am going to measure your hip circumference.

Please stand with your feet together and your arms at your side with palms in.

I am going to place this measuring tape around your hips and take a measurement.

The measurement should be taken from behind the participant and the tape should be placed at the maximum circumference around the buttocks.

Thank you.

Triceps Skinfold

Take skinfold measurement at eye level. If skinfolds are tight, grasp skin with fingers less than ¾ of an inch from the "+" mark.

Now I am going to take the skin fold measure on your arm.

Please stand with your feet together, shoulders relaxed, and your arms hanging freely at your sides.

I am going to pinch the skin on your arm and then use the caliber to measure the thickness.

Stand behind the participant's right side and gently grasp a fold of skin and subcutaneous adipose tissue with your thumb and index finger, approximately 2.0 cm above the marked point. The skin fold should be parallel to the long axis of the arm. Place the tip of the caliper jaws over the marked point, perpendicular to the length of the fold. Record the measurement.

Thank you. Now I am going to do it again.

If the difference between the two measures is not within the specified tolerance range a third measurement must be taken.

Sub-scapular Skinfold

Now I am going to do a skin fold measure on your right shoulder blade.

I am going to have (name of FI) hold your shirt/blouse up in the back so that I can take the measurement on your skin.

First I am going to mark the place where the measurement will be taken and then I will pinch the skin on your back and take the measurement just as I did on your arm.

1. Make a "+" on the inferior angle of the right scapula with the cosmetic pencil.
2. Grasp a fold of skin and subcutaneous adipose tissue with the index finger 1.0 cm above and medial to the inferior angle of the scapula, with the thumb reaching toward the spine.
3. The skinfold should form a line about 45 degrees below the horizontal extending diagonally toward the right elbow.
4. Place the tips of the caliper jaws on the mark, perpendicular to the length of the fold and take the measure.

Thank you.

Now I am going to measure it again.

If the difference between the two measures is not within the specified tolerance range a third measurement must be taken.

Supra-patellar (Front Thigh) Skinfold

Now I am going to measure the skinfold on your upper thigh.

I am going to put a mark on your skin on the anterior surface of the thigh mid-way between the knee cap and the crease between your hip and the thigh.

After finding the point, request the participant to pull up the clothing about an inch above the point.

Now I am going to pinch the skin just above the mark.

Grasp the skin and adipose tissue approximately 2cm above the mark. While holding the skin, place the jaws of the caliper over the mark and take the measure.

Thank you.

Now I am going to take the second skinfold measure on your thigh.

If the difference between the two measures is not within the specified tolerance range a third measurement must be taken.

Body composition / body impedance

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

Refer to the instructions in procedure guidelines

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

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

APPENDIX - 11

Form – A: Blood pressure and anthropometric measurement recording form

Weekly calibration form (A1 and A2)

Monthly calibration form (A3 and A4)

FORM - A

CARRS: SURVEILLANCE STUDY

BLOOD PRESSURE AND ANTHROPOMETRY

Participant ID ☐☐☐☐☐ Interviewer ID ☐☐☐☐

Date Completed: ☐☐☐☐☐☐ DD/ MM/ YY

I. BLOOD PRESSURE AND PULSE RATE

Instrument ID ☐☐

Type of Measurement	1st Reading	2nd Reading	Difference between 1st and 2nd	Tolerance	3rd Reading (if necessary)
Systolic BP	☐☐☐	☐☐☐	☐☐☐	10 mm Hg	
Diastolic BP	☐☐☐	☐☐☐	☐☐☐	6 mm Hg	
Pulse rate	☐☐☐	☐☐☐			

II. ANTHROPOMETRIC MEASUREMENTS

1. Height (cm) — **Instrument ID** ☐☐

Standing Height	|__|__|__|.|__|	Comments:

2. Body circumferences (cm) — **Instrument ID** ☐☐

Mid-arm	Clothing(√) None ☐ Light ☐ Heavy ☐	Waist	Clothing(√) None ☐ Light ☐ Heavy ☐	Hip	Clothing(√) None ☐ Light ☐ Heavy ☐
|__|__|__|.|__|		|__|__|__|.|__|		|__|__|__|.|__|	

3. Skinfold Thickness (mm) — **Instrument ID** ☐☐

Type of Measurement	1st Reading	2nd Reading	Difference between 1st and 2nd	Tolerance	3rd Reading (if necessary)
Triceps	|__|__|.|__|	|__|__|.|__|	|__|.|__|	1 mm	|__|__|.|__|
Supra-scapular	|__|__|.|__|	|__|__|.|__|	|__|.|__|	1 mm	|__|__|.|__|
Supra-patellar	|__|__|.|__|	|__|__|.|__|	|__|.|__|	1 mm	|__|__|.|__|

Attach the print-out of body composition / bio-impedance measurement of the participant along with this form. Note any specific comments on the back of this form.

Form – A1

Weekly Calibration Form

Date	BP Apparatus 1		BP Apparatus 2		BP Apparatus 3		BP Apparatus 4	
	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2

Form - A2

Weekly Calibration Form

Date	Caliper 1		Caliper 1		Stadiometer 1		Stadiometer 2	
	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2

Attach the print – out of the body-composition measurement for the two FIs

<u>Form - A3</u>

Monthly Calibration Form

Date	BP Apparatus 1		BP Apparatus 2		BP Apparatus 3		BP Apparatus 4	
	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2

Form - A4

Monthly Calibration Form

Date	Caliper 1		Caliper 2		Stadiometer 1		Stadiometer 2	
	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2	FI 1	FI 2

Attach the print – out of the body-composition measurement for the two FIs

Chapter 12
Spirometry

Introduction

The procedure manual for this study is based on the "Spirometry procedure manual" of the National Health And Nutrition Examination Survey III (NHANES III) and the present standards of the American Thoracic Society (ATS).

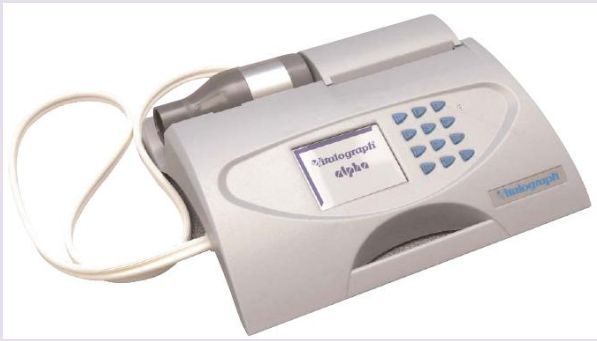
Study objective

The objective of performing spirometry is to validate the self-reported history of participants captured in the respiratory section of the questionnaire (Section-5; PART-E).

Study sample

Twenty percent of the total participants will be selected randomly at each of the three study sites for undergoing the spirometry test. The participant codes will range from 0001 to 4000 at each site, 800 codes will be selected prior to recruitment of the participants to form the "Code list for spirometry" (Provided in Annexure-12). During general recruitment of the participants, those who will be assigned participant codes listed in the code list for spirometry will be provided with an additional "Participant Information Sheet and consent form". The field interviewer will explain the participant about the test and the objectives for performing it. Only those who provide informed consent for both participating in the study as well as to undergo spirometry test will be recruited to undergo spirometry. If the participant provides consent for the study, but not for undergoing spirometry, the interviewer should not compel her/him. Such participants should be recruited for the study and the interviewer should document refusal in Form-5.

Equipment and supplies



- Vitalograph ALPHA; Model No: 6000
- Calibration syringe
- Noseclips
- Pens
- Stop watch
- Log sheets
- Chart papers
- Barometer
- Ammonia inhalants
- 4 X 4 sponges
- Isopropyl alcohol
- Room thermometer

Study setting

One room in the bio-specimen collection camp is dedicated to spirometry examinations. The room should have the Vitalograph ALPHA, a computer system and other supplies listed above. All spirometry examinations will be done by a trained technician under the supervision of a medical doctor.

Exclusion criteria for spirometry examination (Spirometry form)

Participants who are positive for the below mentioned criteria should be excluded from the study (Spirometry form; Annexure-12):

1. Eye, heart, lung, chest or abdominal surgery in the past 3 months
2. Heart attack in the past 3 months
3. Pulse greater than 120 beats per minute
4. Blood pressure greater than 180 (systolic) / 100 (diastolic)
5. Obvious major defect of chest (scoliosis)

Participants who are negative for the above mentioned criteria, should be reviewed on the following criteria (Spirometry form; Annexure-12):

1. Respiratory infection in the past 2 weeks
2. Medication (Long acting bronchodilators)for breathing trouble in the past 12 hours

3. Medication (Short acting bronchodilators) for breathing trouble in the past 4 hours
4. Smoked in the previous hour

If the participant responds positively for any of the above mentioned criteria, re-schedule the appointment for another day and ask the participant to avoid using bronchodilators (last dose) and / or smoke.

Pre-Examination Procedures

1. Calibration Procedures

Perform syringe calibration check. A spirometer calibration check and a "pressure" calibration check should be performed before each testing session when the spirometer is dry and at ambient temperature. All calibration checks are performed using a standard three litre calibrating syringe.

Using a three litre syringe, two different syringe calibration procedures are used:

i. With the spirometer at its zero position, the three litre calibrating syringe will be emptied into the spirometer. This procedure will be repeated three times, with the spirometer piston returning to the zero position after each syringe check. The spirometer should read within ± three percent of the syringe volume. However, the spirometer chart volume will read approximately 50 mililiters lower than the syringe volume (intercept term or offset volume) of the spirometer. After the calibration check, the technician should perform five maneuvers on himself. At the end of the testing sessions, a calibration check without the "pressure" calibration check will be done.

ii. A "pressure" calibration check procedure should be performed in addition to above. Two to three litres of air will be pulled into the spirometer by pulling on the spirometer pen shaft. Once this volume of air has been entered, a full three liter calibrating syringe will be connected to the spirometer hose. The technician will answer the computer prompt and enter and extract three liters of air three times

without disconnecting the syringe. The technician will then wait for the computer to indicate that 20 seconds has elapsed (completion of lead test). The manual chart drive should displace and record three litres of volume, unlike procedure #1. No intercept coefficient is present during the "pressure" calibration check since a volume change is being measured.

2. Read barometric pressure from barometer and record in daily log
3. Study Participant (SP) instruction and preparation

i. Check for eligibility of the SP by noting the responses to the questions in the “Spirometry Form”.

ii. Explain the purpose of the examination and the need for extra effort from the SP to get maximal results. Instructions such as "I want to measure how hard and fast you can breathe" are helpful and may be sufficient.

iii. Explain the procedure in simple language and demonstrate a deep inspiration, proper placement of the mouthpiece, and blasting of air into tube. Blow for at least four seconds to make the demonstration as realistic as possible.

iv. Ask the SP to loosen any tight clothing and remove dentures (if not secure).

v. Install a new spirotube (mouthpiece) into the spirometer hose.

vi. The SP should be seated comfortably in a bench.

vii. Have SP elevate the chin and extend neck slightly.

viii. Place noseclip on nose. Clips may be removed between trials.

ix. Have the SP do a trial exhalation. The following instructions may be helpful:

(a) "Take a great big deep breath of air as far as you can inhale." (Have the examinee inhale from room air).

(b) "Put the mouthpiece into your mouth and seal your lips tightly around it." (Demonstrate the right way.)

(c) "Blast your air into the tube as hard and fast as you can." (The exhalation should be made with the lips tight around the mouthpiece with maximal force and speed.)

(d) "Keep on blowing out the same breath of air, until I tell you to stop."

x. Review the procedure and correct any problems from the trial.

Examination Procedures

1. Pre-bronchodilator

i. Follow prompts from Spirometry System to begin exam.

ii. Tell SP to take a deep breath.

iii. Press return key on Spirometry System to start chart drive.

iv. After chart drive starts rolling, tell the SP to put the tube in their mouth and start blowing out hard and fast.

v. Encourage SP to keep blowing for at least the six second minimum required by ATS. The terminal screen will expand at the six second mark as a cue, but look at the spirogram before terminating the test.

vi. Tell SP to stop blowing and remove the mouth tube.

vii. Continue to follow prompts from the Spirometry System for repetition of trials. Note error messages. Enter responses (yes=1, no=2) to the tech codes as needed to explain or comment on results (Spirometry form).

viii. End the exam for the SP when five acceptable/reproducible trials are obtained to obtain three American Thoracic Society (ATS)13 acceptable manoeuvres, with forced vital capacity (FVC) and forced expiratory volume in the first second (FEV1) reproducible within 150 mL (the ATS-recommended margin of error is up to 200 mL).

ix. Do not obtain more than eight trials on one SP.

x. After the procedure is over, note the reasons for stopping from the codes provided in the spirometry form - ATS OK=1, Dizziness=2, 8 tests

conducted=3, machine not working=4, Participant refused=5, others =6 (specify_____).

xi. Select a quality control score (QC score) according to the machine results

2. Post-bronchodilator

i. Post-bronchodilator test will be done to assess irreversible airway obstruction for only those participants whose a ratio of the pre-bronchodilator FEV1 over FVC was below 0·70.

ii. A bronchodilator (salbutamol 200 μg) will be administered by the doctor present in the examination room by inhalation through a 500-mL spacer, and the test will be repeated 15 min later (average four or five manoeuvres). Two puffs of bronchodilator will be given. SP will be asked to inhale deeply when the bronchodilator is given.

Definition of COPD

Any participant with a ratio of the post-bronchodilator FEV1 over FVC below 0·70 has an obstructive pattern. If the post-bronchodilator volume increases to ≥200 ml or FEV1 ≥12% of the pre-bronchodilator value, then participant can be diagnosed as asthmatic according to guidelines of Global Initiative for Asthma (GINA criteria). If not reversible then consider as COPD, according to the definition proposed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD). This definition is consistent with recent European Respiratory Society and ATS recommendations.

List of spirometric parameters *(Both absolute values and predicted percentages will be recorded in the spirometry form)*	
FVC	Forced Vital capacity (ml)
FEV1	Forced expiratory volume in 1.0 seconds (ml)
FEV1/FVC ratio	Forced expiratory volume in 1.0 seconds (ml) over Forced Vital capacity (ml)

Appendix - 12

CARRS: SURVEILLANCE STUDY
Spirometry form

Instruction to the interviewer: HAS THE PARTICIPANT SIGNED THE INFORMED CONSENT? DO NOT PROCEED UNTIL THE CONSENT FORM HAS BEEN SIGNED

Questions to screen for eligibility of participants to undergo the spirometry test: Response codes **[1=Yes, 2=No]**	
1. Did you undergo eye, heart, lung, chest or abdominal surgery in the past 3 months?	
2. Have you had a heart attack in the past 3 months?	
3. Pulse rate greater than 120 beats per minute?	
4. Blood pressure greater than 180 (systolic) / 100 (diastolic)?	
*If the participant answers **"Yes"** to any of the above questions, then s/he is not eligible for spirometry:* ***Exclude***	
If the response is **"No"** to all questions from 1 to 4, then ask the following questions: Response codes **[1=Yes, 2=No]**	
1. Did you have a respiratory infection in the past 2 weeks?	
2. Have you taken any medication for your lungs or for breathing trouble in the past 12 hours? (Long acting bronchodilators)	
3. Have you taken any medication for your lungs or for breathing trouble in the past 4 hours? (Short acting bronchodilators)	
4. Have you smoked in the previous hour?	
*If the participant answers **"Yes"** to any of the above questions, then re-schedule the appointment for another day and ask the participant to avoid using bronchodilators and / or smoke:* ***Re-schedule***	

Spirometry Test Report Form: Pre-Bronchodilator Test

Date of examination: DD/ MM/ YY | Participant ID | Examiner ID

Spirometer number | Barometric pressure | Temperature (°C) . | Humidity (%)

Pre-bronchodilator tests | **Tech codes: Response [1=Yes, 2=No]**

Test	FVC [L]	Predicted value [%]	FEV1 [L]	Predicted value [%]	FEV1 / FVC ratio	Predicted value [%]	Didn't hesitate	Blew out longer	Waited for buzzer	Deeper breath	Cough detected	Repeatability within 150 ml
1	.	.	.	.	.	.						
2	.	.	.	.	.	.						
3	.	.	.	.	.	.						
4	.	.	.	.	.	.						
5	.	.	.	.	.	.						
6	.	.	.	.	.	.						
7	.	.	.	.	.	.						
8	.	.	.	.	.	.						

Reason for stopping

Response codes
ATS OK=1
Dizziness=2
8 tests conducted=3
Machine not working=4
Participant refused=5
Other=6 (specify_____)

QC score

Select one according to machine result
A; B; C; D; E

Spirometry interpretation

Normal = 1
Mild obstruction = 2
Moderate obstruction=3
Severe obstruction = 4
Mild restriction = 5
Moderate restriction= 6
Severe restriction=7

Spirometry Test Report Form: Post-Bronchodilator Test

Date of examination: DD/ MM/ YY | Participant ID | Examiner ID

Spirometer number | Barometric pressure | Temperature (°C) . | Humidity (%)

Post-bronchodilator tests | **Tech codes: Response [1=Yes, 2=No]**

Test	FVC [L]	Predicted value [%]	FEV1 [L]	Predicted value [%]	FEV1 / FVC ratio	Predicted value [%]	Didn't hesitate	Blew out longer	Waited for buzzer	Deeper breath	Cough detected	Repeatability within 150 ml
1	.	.	.	.	.	.						
2	.	.	.	.	.	.						
3	.	.	.	.	.	.						
4	.	.	.	.	.	.						
5	.	.	.	.	.	.						
6	.	.	.	.	.	.						
7	.	.	.	.	.	.						
8	.	.	.	.	.	.						

Reason for stopping

Response codes
ATS OK=1
Dizziness=2
8 tests conducted=3
Machine not working=4
Participant refused=5
Other=6 (specify_____)

QC score

Select one according to machine result
A; B; C; D; E

Spirometry interpretation

Normal = 1
Mild obstruction = 2
Moderate obstruction=3
Severe obstruction = 4
Mild restriction = 5
Moderate restriction= 6
Severe restriction=7

Code list for Spirometry sub-sample: Random participant IDs											
Chennai				**Delhi**				**Karachi**			
10001	10958	11982	13052	20006	20948	21945	23001	30004	31041	32034	33041
10006	10961	11992	13053	20009	20959	21947	23018	30021	31047	32048	33046
10008	10967	11997	13054	20024	20971	21963	23019	30023	31052	32058	33053
10012	10969	12002	13055	20027	20972	21974	23034	30032	31053	32066	33069
10022	10976	12003	13056	20032	20980	21978	23048	30034	31054	32070	33077
10029	10994	12006	13059	20039	20984	21989	23056	30036	31060	32072	33082
10034	10996	12014	13062	20043	20985	21992	23059	30039	31061	32074	33084
10038	11007	12016	13064	20044	20994	21995	23060	30049	31074	32083	33087
10040	11008	12023	13068	20045	20997	21998	23061	30056	31080	32085	33094
10044	11009	12026	13075	20046	21000	22003	23067	30060	31083	32087	33095
10051	11012	12029	13080	20049	21003	22004	23081	30068	31084	32090	33098
10055	11016	12030	13086	20054	21006	22016	23098	30074	31085	32091	33106
10057	11017	12035	13087	20062	21007	22028	23107	30080	31086	32092	33109
10058	11023	12039	13090	20067	21008	22030	23120	30084	31089	32098	33112
10067	11028	12040	13091	20068	21015	22033	23123	30085	31092	32099	33114
10071	11041	12045	13097	20074	21017	22039	23129	30089	31098	32104	33119
10073	11044	12047	13106	20079	21021	22044	23137	30092	31102	32116	33124
10080	11052	12059	13122	20085	21022	22048	23139	30097	31108	32119	33130
10082	11060	12065	13132	20090	21030	22053	23141	30105	31114	32132	33142
10086	11068	12070	13136	20092	21031	22058	23143	30108	31115	32135	33144
10093	11073	12072	13145	20099	21035	22062	23146	30112	31119	32136	33157
10104	11076	12073	13146	20109	21036	22066	23157	30118	31123	32139	33161
10107	11078	12074	13149	20116	21043	22076	23164	30120	31129	32146	33162
10113	11080	12075	13158	20119	21046	22080	23165	30122	31131	32152	33171
10114	11082	12076	13159	20120	21047	22081	23172	30123	31136	32158	33177
10118	11085	12077	13169	20129	21052	22084	23175	30130	31147	32168	33212
10124	11086	12078	13171	20133	21061	22091	23181	30145	31152	32176	33225
10129	11097	12086	13181	20137	21063	22094	23184	30152	31159	32178	33226
10135	11100	12087	13187	20140	21068	22097	23189	30164	31164	32181	33231
10137	11101	12089	13192	20155	21076	22100	23197	30177	31170	32186	33232
10154	11104	12102	13194	20167	21079	22103	23200	30179	31172	32193	33233
10156	11113	12103	13197	20185	21083	22105	23204	30180	31187	32194	33235
10158	11114	12104	13198	20188	21084	22110	23224	30185	31198	32198	33239
10159	11117	12112	13203	20192	21088	22118	23237	30188	31199	32223	33253
10161	11121	12115	13204	20204	21098	22122	23251	30189	31201	32226	33255
10164	11123	12116	13207	20205	21101	22128	23259	30190	31204	32227	33256
10165	11125	12118	13214	20213	21102	22129	23266	30193	31213	32233	33258
10167	11129	12122	13217	20216	21103	22141	23268	30201	31216	32235	33263
10173	11131	12123	13228	20222	21105	22147	23286	30209	31231	32238	33265
10174	11132	12125	13238	20223	21106	22164	23287	30211	31232	32239	33266

Chennai				Delhi				Karachi			
10180	11137	12139	13241	20224	21120	22167	23288	30213	31233	32247	33272
10181	11139	12142	13244	20228	21131	22168	23289	30229	31248	32248	33274
10182	11143	12151	13254	20231	21132	22173	23293	30241	31258	32255	33275
10188	11144	12162	13266	20237	21134	22177	23294	30243	31271	32259	33277
10207	11148	12184	13269	20251	21135	22179	23295	30254	31273	32263	33280
10213	11153	12188	13270	20258	21137	22181	23304	30258	31277	32265	33284
10218	11156	12194	13272	20262	21149	22185	23306	30261	31278	32283	33288
10226	11167	12197	13279	20266	21151	22186	23310	30274	31291	32291	33292
10230	11172	12198	13280	20269	21153	22197	23318	30276	31298	32293	33296
10236	11178	12201	13281	20277	21162	22203	23319	30288	31302	32295	33298
10240	11191	12209	13292	20281	21168	22204	23336	30291	31308	32303	33302
10242	11196	12210	13298	20282	21172	22211	23337	30299	31310	32308	33311
10248	11206	12213	13301	20283	21176	22213	23338	30303	31311	32315	33316
10252	11213	12218	13308	20291	21180	22217	23348	30304	31312	32316	33321
10255	11216	12240	13316	20293	21186	22219	23352	30305	31315	32318	33324
10258	11221	12242	13318	20294	21187	22227	23354	30324	31318	32319	33334
10264	11228	12246	13320	20296	21191	22229	23364	30325	31320	32322	33339
10267	11229	12247	13321	20304	21196	22238	23369	30328	31322	32326	33340
10270	11230	12252	13330	20307	21197	22239	23370	30332	31323	32333	33342
10275	11232	12257	13332	20315	21223	22242	23372	30335	31329	32347	33344
10287	11233	12258	13348	20319	21232	22245	23375	30341	31341	32349	33346
10289	11234	12262	13351	20320	21233	22250	23381	30366	31342	32353	33347
10297	11242	12263	13354	20322	21234	22253	23384	30369	31343	32356	33351
10301	11244	12274	13355	20333	21235	22254	23386	30385	31345	32357	33356
10303	11251	12277	13358	20335	21236	22257	23391	30393	31356	32367	33366
10327	11259	12292	13364	20337	21239	22260	23393	30406	31365	32383	33372
10335	11264	12296	13368	20348	21245	22270	23395	30410	31366	32386	33375
10340	11274	12297	13369	20353	21249	22271	23399	30415	31375	32393	33387
10346	11280	12300	13386	20355	21252	22284	23400	30418	31388	32399	33391
10350	11285	12302	13392	20363	21255	22287	23407	30425	31391	32402	33400
10356	11300	12304	13394	20365	21269	22293	23409	30435	31392	32416	33404
10357	11308	12305	13412	20367	21271	22299	23413	30437	31406	32417	33406
10360	11311	12308	13418	20372	21272	22305	23416	30439	31409	32424	33421
10361	11312	12315	13419	20376	21281	22319	23423	30442	31410	32430	33424
10367	11331	12326	13428	20377	21282	22322	23433	30443	31414	32433	33426
10373	11348	12329	13436	20379	21283	22324	23435	30445	31418	32442	33428
10374	11352	12338	13438	20384	21289	22325	23437	30446	31428	32450	33440
10375	11364	12339	13440	20386	21290	22326	23439	30447	31430	32451	33442
10376	11366	12348	13442	20390	21295	22328	23442	30449	31435	32453	33445
10384	11370	12352	13447	20393	21296	22335	23444	30450	31438	32461	33455
10393	11372	12353	13451	20397	21311	22336	23445	30459	31439	32472	33457

Chennai				Delhi				Karachi			
10403	11373	12359	13456	20401	21314	22355	23446	30471	31443	32474	33461
10406	11374	12367	13464	20407	21323	22385	23453	30488	31445	32482	33462
10412	11377	12377	13468	20410	21324	22391	23465	30491	31456	32485	33470
10416	11378	12384	13471	20412	21325	22394	23466	30500	31464	32490	33475
10428	11387	12390	13477	20422	21334	22395	23471	30507	31469	32499	33478
10429	11390	12399	13478	20424	21335	22398	23473	30514	31480	32508	33479
10442	11393	12411	13480	20429	21338	22400	23477	30515	31482	32510	33500
10452	11395	12419	13483	20431	21340	22402	23478	30516	31494	32516	33509
10458	11397	12420	13485	20433	21359	22409	23482	30517	31502	32517	33514
10459	11407	12438	13489	20435	21363	22410	23485	30521	31503	32519	33515
10465	11411	12447	13501	20437	21374	22411	23496	30523	31504	32520	33518
10470	11443	12453	13522	20442	21392	22414	23499	30531	31506	32523	33520
10481	11450	12460	13534	20445	21396	22418	23500	30535	31507	32524	33521
10482	11453	12461	13536	20447	21398	22423	23501	30536	31510	32527	33522
10491	11457	12464	13537	20449	21403	22424	23505	30537	31512	32545	33527
10495	11460	12469	13541	20451	21418	22426	23506	30539	31517	32547	33528
10498	11466	12474	13546	20452	21420	22440	23508	30541	31521	32550	33531
10506	11472	12481	13549	20456	21427	22443	23509	30547	31525	32551	33532
10514	11474	12482	13551	20462	21436	22454	23510	30548	31527	32554	33533
10515	11482	12486	13552	20464	21439	22462	23513	30551	31531	32555	33534
10516	11489	12491	13553	20468	21442	22468	23520	30557	31545	32556	33536
10517	11495	12495	13575	20483	21454	22469	23523	30561	31548	32563	33549
10518	11498	12497	13581	20493	21469	22474	23532	30564	31559	32565	33558
10520	11501	12505	13583	20501	21484	22480	23536	30574	31560	32571	33571
10521	11512	12509	13588	20506	21485	22483	23543	30584	31563	32588	33583
10522	11516	12514	13589	20507	21500	22485	23544	30586	31564	32594	33587
10526	11523	12515	13598	20509	21508	22489	23553	30593	31565	32597	33588
10530	11524	12518	13600	20513	21512	22492	23554	30599	31574	32603	33595
10534	11528	12522	13610	20518	21522	22501	23556	30603	31577	32609	33596
10536	11541	12529	13614	20520	21527	22515	23562	30606	31582	32611	33599
10538	11546	12533	13626	20521	21538	22517	23563	30610	31590	32623	33604
10550	11548	12534	13633	20526	21540	22520	23564	30616	31596	32624	33605
10562	11550	12545	13636	20527	21546	22523	23567	30635	31603	32627	33608
10564	11556	12546	13639	20529	21553	22528	23571	30639	31606	32629	33622
10578	11563	12552	13644	20535	21569	22533	23572	30643	31607	32637	33626
10579	11567	12559	13645	20536	21571	22539	23575	30644	31608	32646	33630
10580	11568	12563	13652	20545	21580	22546	23584	30648	31611	32649	33631
10581	11572	12566	13658	20546	21586	22553	23586	30650	31612	32651	33637
10584	11574	12576	13659	20547	21598	22559	23587	30651	31618	32653	33640
10594	11581	12605	13663	20552	21600	22567	23589	30654	31632	32661	33642
10597	11592	12606	13664	20554	21606	22571	23590	30664	31642	32666	33644

Chennai				Delhi				Karachi			
10605	11599	12612	13665	20561	21609	22576	23591	30665	31645	32669	33649
10614	11615	12616	13673	20562	21614	22579	23592	30667	31646	32673	33655
10615	11616	12637	13674	20565	21626	22595	23602	30669	31648	32690	33659
10618	11619	12646	13682	20574	21627	22597	23604	30677	31649	32691	33661
10624	11627	12647	13683	20582	21633	22599	23611	30679	31656	32696	33665
10627	11629	12655	13685	20583	21637	22610	23614	30688	31661	32697	33668
10629	11632	12657	13687	20587	21639	22626	23617	30689	31665	32700	33670
10631	11639	12662	13697	20588	21643	22629	23628	30701	31668	32703	33673
10637	11642	12663	13700	20593	21646	22631	23650	30706	31685	32707	33687
10642	11659	12665	13709	20596	21647	22633	23652	30712	31687	32711	33693
10645	11662	12666	13710	20598	21652	22637	23654	30715	31691	32712	33695
10648	11668	12672	13715	20602	21657	22642	23667	30717	31692	32715	33708
10651	11672	12679	13719	20609	21658	22648	23668	30718	31703	32726	33710
10657	11678	12682	13721	20613	21661	22673	23671	30719	31715	32743	33713
10661	11683	12684	13728	20620	21662	22682	23672	30723	31724	32744	33727
10668	11685	12687	13733	20627	21669	22686	23674	30730	31737	32749	33731
10670	11686	12699	13737	20630	21671	22691	23675	30732	31741	32755	33734
10672	11691	12703	13738	20631	21682	22694	23677	30749	31745	32756	33739
10680	11692	12704	13748	20634	21685	22696	23683	30754	31749	32761	33745
10697	11695	12710	13752	20635	21689	22704	23687	30760	31763	32768	33751
10700	11701	12730	13754	20638	21691	22713	23691	30761	31764	32770	33754
10703	11707	12731	13758	20639	21692	22717	23692	30770	31767	32776	33755
10704	11709	12735	13761	20640	21695	22720	23695	30779	31772	32778	33756
10708	11710	12737	13770	20641	21701	22725	23706	30782	31773	32780	33759
10709	11711	12742	13771	20650	21704	22726	23717	30786	31780	32789	33760
10722	11717	12750	13780	20651	21706	22728	23718	30787	31790	32794	33776
10725	11720	12753	13793	20658	21709	22731	23720	30789	31794	32799	33778
10726	11721	12765	13797	20664	21726	22736	23721	30792	31805	32800	33779
10727	11722	12771	13798	20670	21732	22745	23733	30795	31815	32805	33780
10729	11725	12772	13804	20677	21734	22748	23741	30796	31820	32807	33787
10730	11727	12773	13808	20678	21741	22749	23744	30799	31824	32813	33791
10732	11729	12782	13809	20681	21742	22750	23747	30801	31825	32816	33797
10734	11735	12788	13810	20683	21767	22754	23760	30806	31828	32820	33801
10735	11752	12794	13823	20685	21772	22758	23762	30810	31835	32821	33807
10738	11755	12802	13827	20690	21773	22761	23776	30823	31836	32826	33834
10743	11756	12803	13830	20691	21782	22768	23777	30828	31838	32832	33837
10755	11760	12804	13838	20701	21784	22778	23782	30833	31839	32841	33838
10758	11761	12812	13839	20709	21787	22781	23785	30835	31842	32846	33840
10764	11765	12821	13840	20711	21791	22786	23788	30840	31843	32849	33841
10770	11768	12825	13842	20715	21794	22789	23790	30841	31844	32855	33848
10777	11776	12832	13845	20717	21801	22813	23794	30845	31850	32860	33856

Chennai				Delhi				Karachi			
10783	11777	12837	13847	20719	21804	22816	23801	30846	31859	32862	33858
10785	11778	12840	13858	20722	21806	22819	23807	30857	31872	32888	33859
10787	11785	12844	13865	20723	21816	22825	23808	30858	31875	32894	33861
10796	11788	12845	13866	20731	21818	22829	23831	30861	31878	32896	33862
10798	11803	12851	13867	20742	21819	22830	23833	30867	31885	32900	33868
10801	11804	12868	13871	20752	21822	22841	23839	30874	31894	32918	33876
10807	11805	12872	13872	20756	21825	22845	23840	30875	31905	32920	33881
10814	11808	12873	13876	20770	21830	22846	23841	30876	31909	32927	33883
10817	11817	12875	13878	20775	21831	22849	23849	30880	31912	32932	33884
10832	11819	12878	13880	20779	21835	22852	23851	30885	31917	32937	33886
10838	11837	12885	13883	20780	21841	22854	23859	30886	31920	32942	33896
10849	11845	12886	13885	20781	21846	22856	23891	30890	31921	32943	33898
10852	11851	12893	13888	20791	21848	22862	23892	30896	31926	32946	33899
10855	11853	12897	13892	20794	21853	22863	23897	30898	31934	32949	33906
10857	11855	12907	13900	20795	21855	22867	23909	30903	31940	32951	33915
10862	11860	12908	13901	20798	21856	22882	23913	30904	31941	32956	33917
10863	11876	12911	13903	20802	21867	22887	23917	30906	31944	32957	33920
10880	11877	12917	13904	20807	21886	22888	23929	30911	31948	32962	33921
10893	11883	12919	13906	20816	21889	22892	23931	30914	31950	32965	33924
10896	11886	12925	13913	20820	21890	22898	23940	30916	31952	32967	33932
10897	11891	12930	13914	20832	21891	22910	23941	30918	31954	32972	33934
10904	11902	12943	13915	20834	21895	22912	23946	30919	31955	32973	33939
10910	11905	12947	13923	20843	21900	22913	23949	30925	31956	32974	33942
10912	11914	12955	13927	20849	21911	22915	23950	30936	31958	32975	33949
10913	11929	12966	13930	20852	21913	22919	23954	30949	31959	32980	33957
10914	11934	12973	13934	20859	21914	22922	23956	30956	31964	32981	33970
10918	11938	12976	13935	20870	21917	22924	23969	30958	31968	32982	33971
10922	11939	12984	13937	20877	21918	22929	23974	30973	31976	32991	33974
10923	11941	13000	13940	20880	21919	22933	23976	30974	31980	32992	33975
10924	11945	13008	13941	20895	21924	22953	23977	30979	31987	32997	33979
10927	11952	13010	13949	20896	21928	22968	23979	31005	31991	32999	33984
10929	11961	13013	13952	20902	21933	22970	23986	31008	31997	33001	33985
10945	11966	13019	13966	20914	21934	22972	23989	31009	31998	33013	33987
10952	11972	13022	13971	20917	21939	22984	23992	31015	32006	33025	33990
10953	11973	13023	13979	20919	21940	22986	23994	31017	32008	33026	33993
10954	11976	13036	13985	20921	21941	22987	23998	31035	32022	33031	33997
10957	11977	13046	13999	20933	21943	22990	24000	31037	32025	33032	33999

Chapter 13
Biological specimens

Introduction

Biological specimens for the study:

- 15 ml of blood
- 100 ml of urine (early morning void)
- 10 ml of saliva

These specimens will be collected at Visit 2 of the cross-sectional study. While blood and urine samples will be collected from all participants, the sample of saliva will be collected from 600 (15% of total sample) randomly selected subset of participants (Participant IDs for each site is provided in Annexure-13). Of the three follow-up visits, blood samples will be collected only during the third visit.

Table: Bio-specimen collection for the surveillance study

Bio-specimen collection for the surveillance study		
	Cross-sectional survey: Visit 2	**Follow-up: Visit -3**
Red Top Tube (8 ml)	✓	✓
Lavender Top (5 ml)	✓	
Grey Top Tube (2 ml)	✓	✓
Saliva*	✓	
Urine	✓	✓

* Only on 15% of the 4000 participants (n=600)

Specimen processing

After the specimens are collected, the Field Interviewer (FI) will complete a specimen collection form and transport the specimens to the laboratory for processing. The blood tubes will be processed for serum, plasma, buffy coat, and red blood cells (RBC). On the same day plasma will be analyzed for glucose, serum for lipid profile and whole blood for HbA1c. Urine samples will be tested for microalbuminuria. The saliva will be stored after centrifuging and analyzed for cotinine content within 7-10 days.

Labeling of bio-specimens

Assigning codes: Each specimen collected during the study will be identified with a unique sample ID (SID) number. This will be 8 digit numeric code. The first number indicating the city code (1= Chennai, 2= Delhi, 3= Karachi). The second 4 digits will be the participant ID and the last 3 digits will be the specimen ID. Note that the Participant ID allotted during Visit 1 will be different from the Participant ID allocated for the bio-specimens. The link between the PID and the SID will be maintained for all the participants (to maintain confidentiality). The last three digits of the Sample ID will be used to identify the unique specimens. The Sample IDs will be printed on labels that are freezer safe.

SAMPLE ID- 8 digit numeric code

City Code	Participant ID				Specimen ID		

Assigning a Sample ID

Each participant who enrolls into this study will be assigned a Participant ID during visit-1. Sample IDs will be assigned when a specimen

collection kit is assigned to a participant. A new Sample ID will be assigned during each visit that includes specimen collection. For example if a participant is enrolled in both the cross sectional survey and the subsequent cohort study, s/he will have two unique Sample IDs. A spread sheet will be maintained to link the Sample ID with the Participant ID.

Pre-labeling of collection materials: All collection materials for blood , urine and saliva will be pre-labeled with Sample ID and included in the specimen collection kit. 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. If it becomes necessary to use these labels, the field interviewer (FI) should strike through the "0000" sample ID on the label and write the correct procedure ID on the label. Example of a table showing the materials to be collected and processed for the study and their assigned Sample IDs is provided below.

Specimen collection kits and placement of labels: Study staff will assemble the bio-specimen kits that will contain all the collection materials required for a study visit. Prior to this, s/he will pre-label (example of labeling sheet for a participant is shown in a figure below) the following components of the bio-specimen kit:

- Collection kit bag
- Vacutainer tubes (one red top, one grey top and two lavender top)
- Saliva collection tube
- Sterile container for urine collection
- Whatman filter paper No # 3 with zip-lock pouch
- 18 Cryovial(2ml)

Table: Instructions for specimen labelling

Surveillance study-Specimen Labeling		
Specimen To Be Labeled	**Numbers**	**Specimen IDs**
Pre-labeled Specimens collection materials		
Kit	1	001
Red top tube	1	002
Lavender top tube no. 1	1	003
Grey top tube	1	004
Sterile vial for urine	1	005
Saliva tube (Salivette)	1	006
Processed Specimens		
Serum	4	201-204
Plasma-Lavender Top (EP-1, EP-2, EP-3)	3	301-303
Buffy Coat	1	300
Whatman filter paper (No#3)	1	304
Whole blood	1	305
RBC (RBC1, RBC2)	2	306-307
Plasma-Grey Top (P-1, P-2, P-3)	3	401-403
Packed cells	1	400
Urine samples (U1, U2)	2	501-502
Extra Labels	3	0000

Figure: Example of label sheet for a participant whose SID is 15001

15001 001 Kit	15001 002* Red top	15001 003* Lavender 1	15001 004* Grey top	15001 005* Urine
15001 006* Saliva	15001 201 Serum 1	15001 202 Serum 2	15001 203 Serum 3	15001 204 Serum 4
15001 300 Buffy coat	15001 301 EP 1	15001 302 EP 2	15001 303 EP 3	15001 304 Whatman
15001 305 Whole blood	15001 306 RBC 1	15001 307 RBC 2	15001 400 Packed cells	15001 401 P 1
15001 402 P 2	15001 403 P 3	15001 501 U 1	15001 502 U 2	15001 0000 Extra label
15001 0000 Extra label	15001 0000 Extra label			

*Three labels each

Blood collection

Collection kit: A specimen collection kit is provided 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 5.0 ml lavender-top Vacutainer tubes
- One 8.0 ml red-top Vacutainer tube
- One 2.0 ml Grey top tube
- Cryo-label sheet to paste on the tubes
- Standard 22 gauge blood collection needle with holder
- Alcohol wipes
- 2” x 2” gauze pads
- Bandaids
- Holding rack for Vacutainers
- Sharps needle disposal units (sharps container)

- Drape sheets to cover work surface (Chux)
- Personal protective equipment [Laboratory coat and gloves]
- Tourniquet

The three primary blood tubes (one lavender top, one grey top and one red top) included in the collection kits are pre-labeled with sample ID labels. Additional tubes should be included in the collection kit, but should not be pre-labeled. These additional tubes will be used only in the event of breakage, vacuum failure, or other damage to the pre-labeled tubes. If these back-up tubes are used, they will need to be labeled. Additional sample ID labels are included in the specimen collection kit.

Procedures for blood collection:

Steps to be followed for sample collection -

i. Ask the participant when s/he last ate a meal and record the time on the Blood Collection Form.

ii. 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.

iii. Record the time of the blood collection on the Blood Collection Form.

iv. Clothing should not restrict the arm.

v. Ask the participant to adjust her/his clothing to expose the middle portion of her/his arm.

vi. Explain the procedure and position the participant with the arm in a dependent position.

vii. Prepare the appropriate blood collection tubes, placing them in a test tube rack in the order in which they will be drawn.

viii. Wash your hands and put on protective gloves.

ix. 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.

x. Blood should not be drawn from any arm with an arterial access, such as a fistula or shunt, nor from any arm which has a rash or open sore or is swollen or edematous.

xi. 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.

xii. 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.

xiii. Perform the blood draw by inserting an appropriate needle into the arm, then attaching the Vacutainer tube.

xiv. Immediately after the venipuncture, press a clean gauze square over the venipuncture site. After a few minutes, check the venipuncture site and if clotting has occurred, apply an adhesive bandage over the gauze pad. If bleeding continues, apply direct pressure to the site for five minutes.

xv. After the blood draw is complete, fill in the appropriate items in the Blood Collection form.

xvi. 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

Hematosis

Hematomas are a common complication of venipuncture that is caused by coagulation of extravasated blood in a tissue or cavity. Hematomas most frequently result from failure to apply pressure, insufficient time spent in applying the pressure, or from flexing the arm to stop bleeding. Once the venipuncture is complete, instruct the participant to apply mild pressure to the puncture site and raise her/his arm straight in the air for about two minutes. Constant pressure should always be maintained until the bleeding stops.

Syncope (Fainting)

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

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

The participant should always be instructed not to watch the procedure. If the participant displays any of the above signs, immediately terminate the venipuncture. The seated participant should put her/his head down between her/his knees, and prevent the participant from falling. Talk to the participant in a calm, reassuring manner, instruct the participant to take slow 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 s/he has recovered.

Continued bleeding

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

Thrombosis

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

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

Accidental needle sticks or contamination of an open wound can occur as a result of careless technique and improper disposal of used needles and blood drawing equipment. If an accidental needle stick injury occurs, wash the area thoroughly with soap and water, cover it, and report the incident immediately to the field supervisor. Refer to hospital/center 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 sunlight and maintain an even temperature. Open the buckets as little as possible. The ice buckets should have icepacks at the bottom and on the sides.

Recommendation: Bring extra buckets with extra ice packs. 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 ice packs to the original bucket to maintain the appropriate temperature.

Specimen Processing

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

Table: Specimen processing overview

Tube	Serum	Plasma	RBC	Buffy Coat	Packed cells	Whole Blood	Urine
Red Top	• 3 aliquots • One 100 µl for clinical tests						
Lavender top # 1 (K2-EDTA)		• 3 aliquots	• 2 aliquot	• 1 aliquot		• 200 µl for Whatman filter paper(#3) One 100 µl clinical tests	
Grey top (Flouride)		• 2 aliquots • One 100 µl for clinical tests			• 1 aliquot		
Sterile container Urine							• 2 aliquots

Labeling of cryovials

Processing for lavender top tube

i. Label the cryovials (three vials for plasma, one vial for whole blood, one vial for buffy coat and two vials for RBC) with specimen ID labels.

ii. Remove 300 µl of whole blood from the lavender top tube in a separate cryovial before centrifuging.

iii. Centrifuge lavender top tube for 10 minutes at 3,500 rpm.

iv. Aliquot plasma into three 2.0 ml cryovials.

v. Transfer the buffy coat into one 2.0 ml cryovial. Transfer RBC into two 2.0 ml cryovial.

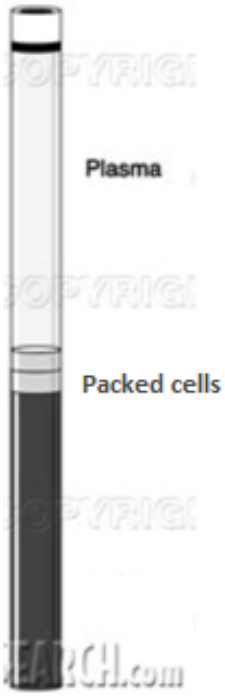
vi. In order to maximize the buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when removing buffy coat include a small amount of RBC in the sample.

vii. **For the plasma and RBC, after the initial aliquot is made into the cryovials, aliquot the remaining material across each of the five vials up to the fill line.**

viii. Divide the participant's plasma, RBC, and buffy coat vials between four labeled and numbered freezer boxes. Place the plasma (EP) vials in box-C, RBC vials in box-B and box-C and cryovials with buffy coat in box-D.

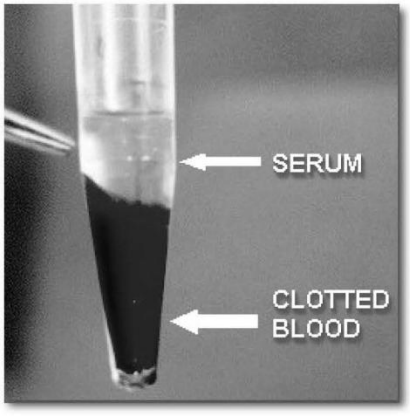
ix. Store the boxes in a deep-freezer at -80° C.

Processing for grey top tube



i. Label the cryovials (two vials for plasma and one vial for packed cells) with specimen ID labels.
ii. Centrifuge lavender top tube for 10 minutes at 3,500 rpm.
iii. Aliquot plasma into two 2.0 ml cryovials.
iv. Transfer the packed cells into one 2.0 ml cryovial.
v. For the plasma and packed cells after the initial aliquot is made into the cryovials, aliquot the remaining materials across each of the three vials up to the fill line.
vi. Place the participant's plasma (P1, P2) vials in box-B and packed cell vial in box-D.
vii. Store the boxes in a deep freezer at -80° C.

Processing for red top tube



i. 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.
ii. Label the cryovials (four 2.0 ml vials for serum) with sample IDs.
iii. Centrifuge the red top tubes for 10 minutes at 3,500 rpm.
iv. After the blood has been centrifuged, reserve 100 µl for clinical tests in one cryovial.

v. Aliquot the remaining serum from the red-top tube into three pre-labeled cryovials. Aliquot any remaining material across each of the three vials, up to the fill lines.

vi. Place the serum vials in box-A.

vii. Store the box in a deep freezer at -80° C.

Whatman filter paper No # 3

Prior to centrifugation of the lavender top tube, 200 µl of whole blood should be extracted to preserve as spots on a Whatman filter paper No # 3.

Procedure is as follows -

i. Label a zip-lock bag with the sample ID label ending in sample ID 305. This bag is for storage of the Whatman filter paper No # 3.

ii. Place the Whatman filter paper on a clean, non-absorbent surface.

iii. Using a pipette, gently mix the contents of the tube.

iv. Insert a pipette or capillary tube into the center of the tube contents and allow it to fill with approximately 200 µl of blood. Make 10-20 spots on the Whatman filter paper, each of 10 µl. Allow the blood spot on the paper to air dry for one hour.

v. Place the paper in the pre-labeled zip-lock bag with a desiccant pouch. Remove the air from the bag and seal it.

vi. The Whatman filter paper No #3 with blood spot should be stored at temperatures of 4° to 8° C.

Storage of Specimens

Labeling the cryoboxes: Each storage box will be labeled using a unique code. The box number will consist of five characters (**B-C-NNN**). The first letter (B) indicates the storage **B**ox. The letter (C) indicates the **C**ity code (1 = Chennai, 2 = Delhi, 3 = Karachi), and the last three (NNN) indicates the box **N**umber (001 to 999). Example: In Chennai, the first box A will be labeled as **A-1-001**. Table below provides a description of how the vials are divided into the

different boxes. The box label should be written on the top, bottom, and on a side that is visible in the freezer.

Table: Aliquots for Boxes

Box A	4 Serum
Box B	2 Plasma (P) 1 RBC
Box C	3 Plasma (EP) 1 RBC
Box D	1 Buffy 1 Packed cell 2 Urine vials

Arranging the cryovials: The cryovials are arranged in the cryoboxes (A,B,C & D) in such a way that cryobox A has samples of serum, cryobox B has plasma (P) and RBC-1 vials from grey top tube and lavender top tube respectively, cryobox C has plasma (EP) and RBC-2 vials from lavender top tube, and cryobox D has vials with buffy coat, packed cells and processed urine samples. The lay-out of each cryobox should be prepared in a spread sheet indicating the number of vials stored with the sample ID and the amount of processed material in each vial. Example of lay-out of cryobox **A-1-001** is shown below.

Example: Layout of Cryovials in cryobox A-1-001

25001201 S=450µl	25001202 S=400µl	25001203 S=450µl	25001204 S=470µl	25002201 S=455µl	25002202 S=380µl	25002203 S=390µl	25002204 S=450µl
25003201 S=420µl	25003202 S=450µl	25003203 S=450µl	25003204 S=550µl	25004201 S=400µl	25004202 S=475µl	25004203 S=460µl	25004204 S=450µl
25005201 S=450µl	25005202 S=450µl	25005203 S=450µl	25005204 S=450µl	25006201 S=450µl	25006202 S=450µl	25006203 S=450µl	25006204 S=450µl
25007201 S=450µl	25007202 S=450µl	25007203 S=450µl	25007204 S=450µl	25008201 S=450µl	25008202 S=450µl	25008203 S=450µl	25008204 S=450µl
25009201 S=450µl	25009202 S=450µl	25009203 S=450µl	25009204 S=450µl	25010201 S=450µl	25010202 S=450µl	25010203 S=450µl	25010204 S=450µl
25011201 S=450µl	25011202 S=450µl	25011203 S=450µl	25011204 S=450µl	25012201 S=450µl	25012202 S=450µl	25012203 S=450µl	25012204 S=450µl
25013201 S=450µl	25013202 S=450µl	25013203 S=450µl	25013204 S=450µl	25014201 S=450µl	25014202 S=450µl	25014203 S=450µl	25014204 S=450µl
25015201 S=450µl	25015202 S=450µl	25015203 S=450µl	25015204 S=450µl	25016201 S=450µl	25016202 S=450µl	25016203 S=450µl	25016204 S=450µl
25017201 S=450µl	25017202 S=450µl	25017203 S=450µl	25017204 S=450µl	25018201 S=450µl	25018202 S=450µl	25018203 S=450µl	25018204 S=450µl
25019201 S=450µl	25019202 S=450µl	25019203 S=450µl	25019204 S=450µl	25020201 S=450µl	25020202 S=450µl	25020203 S=450µl	

Urine specimen

Collection procedure: One early morning void will be collected from all participants at visit 2. A sterile container labeled with the sample 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 atleast 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 collection form (BS-2). If the sample is not the morning void of the same day or there is any other problem, then provide another sterile container labeled with a different sample ID and repeat the instructions. Re-visit the participant on the following day to collect the sample and fill the BS-2 form.

Transporting: The container with sample then needs to be deposited at the laboratory.

Processing of urine: Centrifuge the tube for 10 minutes at 3,500 rpm. A small amount (about 100 ml) of the processed sample will be analyzed immediately for presence of albumin and the remaining should be aliquoted into two 2.0 ml cryovials and stored in Box-D in a deep freezer at -80° C

Analysis: All urine samples will be tested for the presence of albumin using immune-turbidimetric method and results will be recorded on a standard proforma along with the sample ID.

Saliva specimen

Collection procedure

Saliva collection will be carried out by chewing a cotton wool swab. Recovery of the saliva sample is achieved by returning the swab to the Salivette and centrifuging the container. A clear fluid sample is obtained which is then used for analysis.

i. The saliva specimen should be collected on the day of visit-2.

ii. Label the Salivette with the specimen ID number prior to handing over to the participant.

iii. As soon as the participant wakes up, BEFORE BRUSHING TEETH, EATING OR DRINKING, advise her/him to collect the specimen.

iv. Advice the subject to take off the cap of the Salivette and drop the cotton provided in the Salivette directly into the mouth.
The participant should not touch the cotton with hand.

v. The participant should chew the cotton roll for 2 min or count to 120

vi. Instruct the participant to be put the cotton directly back into the tube. **The participant should not touch the saliva soaked cotton with hand.**

vii. The small tube with the cotton roll should be put into the outer tube.

viii. The participant should take the tube to the blood collection camp as soon as possible.

ix. Place the tube in ice.

x. Document any medication taken by the participant during his visit to the camp.

Processing and storage

i. Place the salivettes into a clinical centrifuge.

ii. Ensure that the tubes are balanced properly.

iii. Centrifuge for 10 min at 1500 rpm to collect the clear saliva fluid into the centrifuge tube.

iv. Aliquot and store the saliva at -70^{0}C

v. On the day of the assay, thaw completely, vortex and centrifuge at 1500 g for 15 min to precipitate the mucins.

Analysis

Salivary cotinine will be measured by the Elisa method

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.

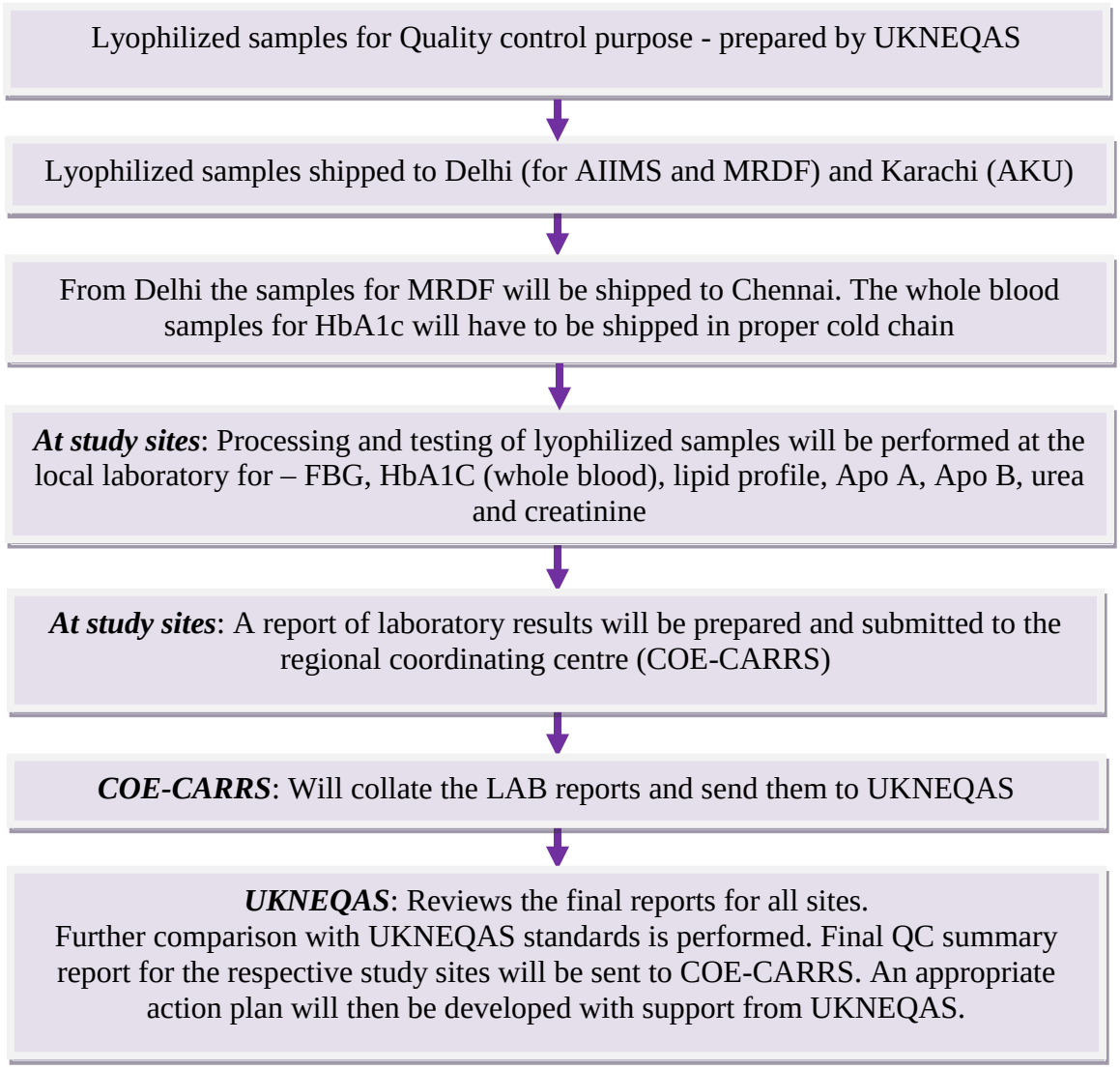
To control for pre-analytic variations resulting from problems of phlebotomy, centrifugation, aliquoting of samples, storage and transportation; a training session detailing these issues will be organized for the participating laboratories before the start of the trial.

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 accreditations board and / or SOP's, 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 UK NEQAS (United Kingdom National External Quality Assessment Scheme).

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



Appendix – 13

CARRS-SURVEILLANCE STUDY
BLOOD COLLECTION FORM (BS-1)

Participant ID

1. Date of Collection: |__|__|/|__|__|/20|__|__| Day Month Year	**2. Collected by:** _____ |__|__|__|__|__| INITIALS ID NUMBER

3. Date of last Meal: |__|__|/|__|__|/20|__|__| **Time of Last Meal** |__|__|:|__|__| Military time (24 hrs.)
Day Month Year

BLOOD COLLECTION PROCEDURES

1. Time of Collection: |__|__|:|__|__| Military time (24 hrs.)

2. Medical Complications: *(MARK ALL THAT APPLY)*

- ☐ None
- ☐ Fainting
- ☐ Light-headedness
- ☐ Hematoma
- ☐ Bruising
- ☐ Other *(SPECIFY)* _____
  _____

Comments

.....

.....

.....

.....

3. Tubes Collected

10a. Lavender Top 1☐ Yes 1☐ No

Sample ID label

10b. Red Top 2☐ Yes 2☐ No

Sample ID label

10c. Grey Top 3☐ Yes 3☐ No

Sample ID label

4.Collection Problems: *(MARK ALL THAT APPLY)*

4a. Lavender Top	**4b. Red Top**	**4c. Grey Top**
1☐ Not drawn	1☐ Not drawn	1☐ Not drawn
2☐ None	2☐ None	2☐ None
3☐ Short draw	3☐ Short draw	3☐ Short draw
4☐ Damaged	4☐ Damaged	4☐ Damaged
5☐ Multiple attempts required	5☐ Multiple attempts required	5☐ Multiple attempts required
6☐ Other *(SPECIFY)*	6☐ Other *(SPECIFY)*	6☐ Other *(SPECIFY)*
_____	_____	_____

CARRS-SURVEILLANCE STUDY
URINE COLLECTION FORM (BS-2)

Sample ID label

Participant ID

Is this the first morning void [Yes=1; No=2]

1. Date of Collection: |__|__|/|__|__|/20|__|__| Day Month Year	**2. Collected by:** _____ |__|__|__|__| INITIALS ID NUMBER

2. Collection Problems: *(MARK ALL THAT APPLY)*

- ☐ None
- ☐ Spillage
- ☐ Damaged
- ☐ Contamination
- ☐ Other *(SPECIFY)* _____

Comments

CARRS-SURVEILLANCE STUDY
SALIVA COLLECTION FORM (BS-3)

Sample ID label

Participant ID

Did you brush your teeth before collecting the sample? [Yes=1; No=2]

Did you eat or drink anything (including water) before collecting the sample? [Yes=1; No=2]

1. Date of Collection: |__|__|/|__|__|/20|__|__| Day Month Year	**2. Collected by:** _____ INITIALS |__|__|__|__| ID NUMBER

SALIVA COLLECTION AND STORAGE

2. Collection Problems: *(MARK ALL THAT APPLY)*

- ☐ None
- ☐ Spillage
- ☐ Damaged
- ☐ Unable to chew the gum
- ☐ Contamination
- ☐ Other *(SPECIFY)* _____

3. Time specimen frozen \|__\|__\|:\|__\|__\| Military time (24 hrs.)

Write the details of smoking history for the participant below from the history provided in the questionnaire during the interview:

Is the participant a smoker? [Yes=1; No=2] \|__\|

If "No"; is the participant passively exposed to smoking? [Yes=1; No=2] \|__\|

Comments

CARRS-SURVEILLANCE STUDY
BLOOD PROCESSING FORM (BS-4)

Participant ID

1. Date of Collection:
|__|__|/|__|__|/20|__|__|
Day Month Year

2. Collected by:
_____ |__|__|__|__|
INITIALS ID NUMBER

A. PROCESSING FOR RED TOP TUBE

Sample ID label

1. Date Processed:
|__|__|/|__|__|/20|__|__|
Day Month Year

2. Time Centrifuged: |__|__|:|__|__|
(Military Time 24 hrs.)

3. Processed by:
_____ |__|__|__|__|
INITIALS ID NUMBER

4. Problems with condition of the serum (Red Top):
(MARK ALL THAT APPLY)

☐ No problem

Hemolyzed serum

☐ Slight
☐ Moderate
☐ Gross

☐ Icteric serum
☐ Turbid serum
☐ Insufficient serum

5. Serum Vials Filled:

☐ Yes – all vials filled
☐ No – partial number of vials filled *(GO TO 5a)*
☐ No – no vials filled (Specify in comments section at the end of the form)

5a. Number of Vials Filled: ☐

6. Indicate Filled Vials:
(MARK ALL THAT APPLY)

MAX 4 VIALS FOR SERUM

☐ 201
☐ 202
☐ 203
☐ 204

B. PROCESSING FOR LAVENDER TOP TUBES

1. Date Processed:
|__|__|/|__|__|/20|__|__|
Day Month Year

2. Time Centrifuged: |__|__|:|__|__|
(Military Time 24 hrs.)

3. Processed by:
_____ |__|__|__|__|
INITIALS ID NUMBER

4. Whole Blood Obtained:
☐ Yes ☐ No (Specify in comments section at the end)

Whatman filter paper No # 3
☐ Yes ☐ No (Specify in comments section at the end)

4a. Time processed: |__|__|:|__|__| (Military Time 24 hrs.)

4b. Time stored: |__|__|:|__|__| (Military Time 24 hrs.)

Lavender Top

Sample ID label

5. Problems with condition of the plasma (lavender top):
(MARK ALL THAT APPLY)

☐ No problem

Hemolyzed plasma

☐ Slight
☐ Moderate
☐ Gross

☐ Icteric plasma
☐ Turbid plasma
☐ Insufficient plasm
☐ Blood clotted

6. Plasma Vials Filled:

☐ Yes – all vials filled
☐ No – partial number of vials filled *(GO TO 6a)*
☐ No – no vials filled (Specify in comments section at the end)

6a. Number of Vials Filled: |__|

7. Problems with condition of the buffy coat (lavender top):
(MARK ALL THAT APPLY)

☐ No problem
☐ Clot formed
☐ Quantity Not Sufficient

7a. Buffy Coat Obtained

☐ Yes
☐ No (Specify in comments section at the end)

Lavender Top (continued)

8. Problems with condition of the RBC (lavender top): *(MARK ALL THAT APPLY)*

☐ No problem

☐ Quantity Not Sufficient

8a. RBC Obtained

☐ Yes

☐ No (Specify in comments sectiion at the end)

9. Indicate Filled Vials:

PLASMA - 3 VIALS MAX, BUFFY COAT 1 VIAL, AND RBC 2 VIALS MAX.

☐ 300 ☐ 303

☐ 301 ☐ 306

☐ 302 ☐ 307

Grey Top

Sample ID label

15. Problems with condition of the plasma (grey top tube): *(MARK ALL THAT APPLY)*

☐ No problem

Hemolyzed plasma

☐ Slight

☐ Moderate

☐ Gross

☐ Icteric plasma

☐ Turbid plasma

☐ Insufficient plasma

☐ Blood clotted

16. Plasma Vials Filled:

☐ Yes – all vials filled

☐ No – partial number of vials filled *(GO TO 16a)*

☐ No – no vials filled (Specify in comments section at the end)

16a. Number of Vials Filled:

|__|

17. Packed cells Obtained

☐ Yes

☐ No (Specify in comments sectiion at the end)

18. Indicate Filled Vials:

PLASMA - 2 VIALS MAX; AND PACKED CELLS ONE VIAL

☐ 400 ☐ 401 ☐ 402 ☐ 403

19. **Storage Box #** |__| - |__| - |__|__|__| (Serum)

Storage Box # |__| - |__| - |__|__|__| (EP)

Storage Box # |__| - |__| - |__|__|__| (P)

Storage Box # |__| - |__| - |__|__|__| (RBC)

Storage Box # |__| - |__| - |__|__|__| (Buffy coat)

Storage Box # |__| - |__| - |__|__|__| (Packed cells)

(SEE ADDENDUM)

20. **Time frozen:** |__|__|:|__|__| (Military Time 24 hrs.)

Time frozen: |__|__|:|__|__| (Military Time 24 hrs.)

Time frozen: |__|__|:|__|__| (Military Time 24 hrs.)

Time frozen: |__|__|:|__|__| (Military Time 24 hrs.)

Time frozen: |__|__|:|__|__| (Military Time 24 hrs.)

Time frozen: |__|__|:|__|__| (Military Time 24 hrs.)

16. Reason for Partial Processing: *(MARK ALL THAT APPLY)*

☐ Red-top tube damaged, lost stolen
☐ Lavender-top tube damaged, lost or stolen
☐ Grey-top tube damaged, lost or stolen
☐ Equipment problem
☐ Quantity Not Sufficient
☐ Vial damaged, lost or stolen
☐ Other *(SPECIFY)* _____

17. Comments: ☐ No ☐ Yes *(SPECIFY)*

Comments: _____

_____

_____

ADDENDUM TO
BLOOD PROCESSING FORM
BOX STORAGE

Serum		
	Vial 201	Box # |__|-|__|-|__|__|__|
	Vial 202	Box # |__|-|__|-|__|__|__|
	Vial 203	Box # |__|-|__|-|__|__|__|
	Vial 204	Box # |__|-|__|-|__|__|__|
Plasma (EP)		
	Vial 301	Box # |__|-|__|-|__|__|__|
	Vial 302	Box # |__|-|__|-|__|__|__|
	Vial 303	Box # |__|-|__|-|__|__|__|
Plasma (P)		
	Vial 401	Box # |__|-|__|-|__|__|__|
	Vial 402	Box # |__|-|__|-|__|__|__|
	Vial 403	Box # |__|-|__|-|__|__|__|
Buffy		
	Vial 300	Box # |__|-|__|-|__|__|__|
RBC		
	Vial 306	Box # |__|-|__|-|__|__|__|
	Vial 307	Box # |__|-|__|-|__|__|__|
Packed cells		
	Vial 400	Box # |__|-|__|-|__|__|__|
Urine (processed samples)		
	Vial 501	Box # |__|-|__|-|__|__|__|
	Vial 502	Box # |__|-|__|-|__|__|__|

Code list for Salivary Cotinine sub-sample: Random participant IDs								
Chennai			Delhi			Karachi		
10001	11315	12576	20012	21293	22690	30002	31481	32811
10010	11316	12586	20014	21295	22697	30004	31483	32812
10012	11326	12587	20015	21301	22700	30011	31487	32823
10013	11332	12595	20019	21307	22701	30019	31502	32826
10015	11339	12597	20020	21309	22703	30031	31503	32830
10025	11340	12600	20022	21315	22707	30032	31507	32843
10028	11343	12606	20024	21322	22709	30047	31533	32844
10032	11353	12616	20032	21333	22719	30059	31534	32849
10039	11356	12625	20034	21349	22722	30060	31543	32853
10057	11362	12639	20038	21354	22732	30065	31558	32869
10062	11366	12647	20041	21357	22741	30074	31572	32873
10070	11380	12648	20047	21358	22754	30083	31573	32877
10076	11382	12649	20050	21374	22762	30091	31578	32883
10082	11396	12654	20051	21383	22782	30094	31580	32891
10094	11398	12672	20056	21388	22787	30109	31584	32898
10097	11408	12677	20058	21389	22793	30111	31588	32901
10099	11412	12684	20059	21392	22794	30114	31605	32921
10103	11414	12688	20080	21393	22797	30117	31611	32932
10108	11415	12699	20081	21394	22801	30127	31616	32938
10109	11416	12700	20102	21399	22807	30130	31627	32939
10111	11417	12712	20106	21406	22808	30137	31628	32941
10113	11418	12718	20114	21408	22811	30149	31635	32942
10114	11426	12719	20120	21415	22836	30158	31640	32943
10115	11428	12725	20127	21416	22837	30163	31642	32948
10123	11429	12730	20131	21430	22840	30178	31646	32951
10129	11431	12736	20135	21439	22860	30180	31654	32961
10131	11436	12737	20147	21453	22862	30182	31686	32963
10141	11439	12741	20149	21463	22868	30184	31690	32973
10144	11445	12747	20152	21475	22870	30189	31701	32980
10158	11449	12755	20154	21482	22897	30190	31705	32984
10159	11453	12765	20172	21484	22906	30204	31717	32985
10163	11478	12767	20180	21486	22907	30206	31730	33009
10167	11482	12776	20196	21489	22910	30228	31732	33012
10174	11485	12784	20205	21495	22928	30235	31733	33015
10182	11496	12786	20211	21497	22929	30242	31744	33021
10186	11502	12801	20215	21499	22936	30245	31750	33029
10190	11503	12807	20216	21508	22950	30246	31760	33033
10192	11505	12809	20219	21511	22961	30248	31774	33037
10200	11509	12811	20227	21512	22966	30249	31775	33047
10203	11561	12824	20280	21519	22980	30250	31776	33049

Chennai			Delhi			Karachi		
10204	11581	12825	20281	21524	22984	30265	31780	33060
10219	11593	12826	20285	21530	22989	30269	31793	33065
10225	11599	12827	20307	21540	22992	30277	31804	33068
10249	11611	12831	20308	21542	22998	30288	31820	33085
10250	11617	12833	20312	21558	23005	30306	31823	33088
10252	11623	12847	20337	21561	23007	30321	31825	33090
10255	11628	12848	20369	21569	23017	30324	31826	33091
10259	11636	12860	20370	21587	23025	30326	31852	33096
10260	11653	12871	20371	21588	23029	30338	31854	33097
10277	11657	12873	20372	21594	23030	30339	31859	33102
10282	11668	12889	20387	21596	23031	30372	31874	33105
10283	11673	12892	20392	21597	23032	30391	31886	33111
10290	11675	12905	20407	21598	23043	30401	31899	33124
10291	11677	12910	20409	21601	23046	30406	31911	33128
10292	11678	12916	20419	21620	23068	30409	31920	33131
10317	11688	12920	20420	21629	23075	30419	31926	33138
10318	11691	12927	20425	21643	23081	30422	31939	33140
10327	11692	12931	20430	21646	23083	30427	31948	33150
10335	11699	12934	20439	21648	23091	30432	31950	33151
10338	11700	12938	20441	21649	23093	30438	31952	33161
10354	11704	12941	20457	21653	23107	30439	31956	33169
10358	11708	12942	20461	21661	23108	30440	31979	33171
10359	11726	12946	20464	21662	23116	30449	31990	33183
10366	11730	12948	20468	21664	23136	30457	31991	33185
10372	11751	12951	20471	21682	23138	30474	31995	33189
10376	11775	12952	20472	21699	23144	30476	31998	33195
10388	11782	12956	20478	21711	23166	30486	32017	33215
10400	11786	12961	20489	21714	23168	30489	32020	33220
10407	11795	12966	20493	21718	23169	30498	32021	33221
10416	11797	12979	20496	21728	23181	30511	32022	33233
10419	11799	12992	20497	21729	23189	30517	32023	33236
10421	11804	13004	20500	21733	23205	30525	32032	33243
10432	11815	13020	20506	21740	23206	30534	32057	33248
10452	11820	13027	20507	21743	23207	30542	32066	33250
10455	11825	13033	20511	21744	23213	30551	32081	33252
10462	11833	13072	20515	21752	23220	30552	32087	33253
10469	11839	13074	20519	21759	23241	30556	32088	33254
10476	11841	13077	20521	21760	23245	30574	32091	33270
10485	11850	13078	20528	21764	23256	30578	32096	33271
10490	11854	13087	20534	21765	23266	30580	32100	33275
10491	11858	13089	20539	21767	23270	30581	32101	33284

Chennai			Delhi			Karachi		
10495	11884	13095	20546	21769	23271	30582	32109	33295
10500	11891	13101	20550	21775	23272	30585	32110	33302
10509	11894	13105	20551	21809	23286	30592	32115	33303
10516	11896	13109	20555	21810	23289	30595	32142	33306
10519	11897	13112	20569	21814	23294	30597	32143	33312
10528	11898	13117	20570	21816	23300	30599	32157	33317
10548	11900	13129	20575	21822	23303	30600	32160	33323
10549	11902	13133	20576	21835	23305	30604	32162	33324
10562	11907	13136	20591	21839	23314	30606	32171	33334
10571	11908	13142	20599	21845	23316	30654	32173	33335
10584	11911	13153	20600	21846	23318	30662	32184	33339
10585	11912	13158	20607	21847	23329	30665	32193	33351
10594	11922	13165	20622	21851	23331	30676	32194	33356
10598	11925	13167	20624	21866	23336	30677	32201	33359
10601	11926	13200	20650	21870	23348	30683	32202	33361
10604	11929	13201	20655	21874	23350	30688	32205	33370
10607	11935	13206	20656	21882	23355	30693	32223	33375
10644	11943	13212	20661	21910	23361	30739	32230	33380
10648	11963	13217	20663	21925	23362	30748	32237	33386
10654	11976	13229	20666	21926	23364	30753	32238	33403
10663	11978	13231	20672	21983	23365	30776	32241	33409
10670	11985	13236	20686	22013	23381	30780	32245	33412
10672	11986	13249	20690	22014	23384	30785	32251	33419
10675	11994	13264	20700	22016	23401	30789	32255	33425
10683	11995	13265	20705	22025	23425	30790	32260	33426
10724	11997	13271	20708	22039	23434	30802	32267	33430
10729	12006	13280	20710	22040	23436	30806	32268	33433
10732	12018	13282	20712	22041	23442	30814	32271	33435
10738	12019	13284	20713	22043	23451	30819	32277	33450
10745	12041	13285	20716	22068	23453	30831	32289	33453
10747	12054	13288	20721	22069	23454	30841	32301	33461
10764	12060	13290	20723	22070	23455	30843	32303	33463
10783	12065	13308	20724	22076	23456	30856	32311	33472
10785	12069	13309	20733	22081	23468	30866	32330	33473
10788	12074	13312	20744	22090	23477	30869	32338	33482
10792	12076	13331	20771	22092	23485	30870	32341	33484
10794	12079	13338	20772	22094	23487	30876	32357	33487
10795	12081	13345	20779	22099	23489	30880	32360	33489
10801	12089	13359	20783	22114	23505	30892	32364	33490
10802	12099	13360	20788	22120	23507	30897	32382	33498
10803	12105	13365	20791	22124	23508	30904	32383	33506

Chennai			Delhi			Karachi		
10815	12114	13367	20793	22131	23509	30905	32385	33536
10816	12115	13368	20795	22145	23520	30917	32386	33543
10818	12116	13378	20821	22148	23539	30920	32387	33545
10819	12125	13381	20822	22150	23542	30921	32390	33550
10824	12135	13382	20836	22156	23544	30939	32406	33551
10834	12141	13387	20841	22160	23545	30945	32407	33558
10835	12146	13393	20843	22177	23551	30946	32416	33562
10843	12148	13402	20848	22188	23552	30950	32419	33564
10850	12153	13409	20852	22191	23556	30951	32428	33570
10853	12154	13412	20857	22194	23565	30962	32438	33577
10854	12158	13419	20862	22205	23566	30976	32447	33581
10862	12162	13422	20870	22206	23568	30979	32448	33595
10875	12163	13431	20871	22211	23569	30985	32450	33598
10897	12164	13435	20882	22232	23584	30992	32459	33607
10917	12165	13445	20883	22239	23590	30999	32463	33610
10918	12166	13450	20884	22240	23591	31011	32464	33622
10930	12171	13461	20889	22243	23597	31017	32465	33626
10936	12177	13463	20890	22246	23601	31029	32471	33628
10945	12178	13465	20899	22260	23607	31034	32474	33629
10951	12197	13479	20900	22266	23608	31038	32477	33648
10952	12198	13505	20901	22269	23624	31040	32481	33651
10955	12204	13524	20903	22281	23626	31042	32496	33660
10958	12212	13534	20910	22294	23627	31054	32498	33680
10960	12217	13551	20920	22300	23643	31058	32507	33681
10966	12220	13554	20922	22345	23653	31066	32511	33682
10968	12221	13569	20927	22349	23671	31071	32513	33685
10970	12225	13579	20930	22352	23674	31084	32515	33689
10976	12227	13601	20935	22361	23681	31098	32522	33697
10977	12230	13606	20937	22369	23684	31103	32529	33699
10985	12232	13608	20940	22384	23693	31112	32539	33703
10993	12234	13617	20958	22388	23705	31117	32542	33704
10997	12239	13622	20962	22390	23707	31121	32545	33711
10999	12248	13626	20966	22395	23711	31134	32549	33714
11010	12262	13629	20985	22405	23716	31141	32555	33716
11022	12273	13634	20988	22408	23726	31144	32562	33732
11031	12274	13642	20990	22419	23730	31147	32577	33733
11040	12280	13658	20991	22425	23733	31150	32578	33734
11043	12281	13659	21009	22427	23740	31155	32581	33755
11052	12291	13667	21011	22438	23741	31159	32593	33757
11060	12292	13668	21019	22454	23742	31164	32606	33760
11069	12305	13675	21031	22469	23747	31166	32618	33762

Chennai			Delhi			Karachi		
11090	12308	13691	21039	22475	23761	31172	32631	33763
11097	12319	13697	21046	22479	23762	31181	32636	33773
11098	12320	13702	21065	22490	23764	31182	32641	33776
11099	12324	13703	21068	22491	23767	31186	32655	33785
11102	12330	13722	21090	22498	23782	31198	32656	33786
11106	12333	13729	21114	22499	23787	31244	32661	33800
11113	12336	13731	21122	22505	23795	31252	32665	33817
11120	12344	13733	21135	22513	23797	31253	32666	33818
11121	12348	13747	21137	22516	23800	31255	32669	33844
11125	12351	13758	21140	22519	23810	31258	32676	33847
11128	12361	13777	21141	22523	23818	31273	32685	33848
11131	12362	13779	21144	22532	23827	31274	32691	33864
11141	12366	13788	21155	22541	23832	31287	32692	33866
11145	12392	13797	21156	22545	23834	31288	32699	33872
11157	12393	13820	21160	22546	23868	31289	32720	33879
11158	12402	13834	21164	22557	23875	31299	32722	33881
11170	12406	13842	21166	22566	23878	31311	32728	33884
11171	12415	13846	21168	22575	23881	31314	32730	33886
11173	12419	13859	21189	22578	23885	31317	32732	33891
11182	12423	13881	21191	22584	23902	31321	32737	33895
11187	12428	13883	21209	22587	23906	31329	32738	33902
11194	12438	13884	21224	22588	23908	31332	32746	33914
11200	12441	13891	21225	22596	23911	31347	32757	33922
11203	12446	13892	21229	22606	23916	31349	32764	33932
11205	12460	13903	21241	22622	23920	31352	32766	33934
11235	12468	13910	21242	22630	23922	31369	32774	33935
11251	12481	13915	21253	22633	23926	31376	32776	33937
11263	12483	13917	21260	22640	23931	31385	32780	33942
11265	12498	13943	21268	22644	23939	31387	32783	33964
11267	12530	13949	21269	22663	23944	31394	32785	33966
11268	12531	13950	21270	22669	23948	31401	32786	33968
11279	12543	13957	21272	22677	23957	31404	32790	33972
11282	12550	13959	21274	22681	23966	31428	32794	33975
11288	12551	13964	21277	22682	23975	31441	32798	33977
11291	12563	13981	21280	22685	23976	31452	32799	33981
11303	12565	13990	21284	22687	23988	31465	32802	33989
11308	12574	13994	21291	22688	23998	31474	32809	33999

Chapter - 14
Data Management

Introduction

Data quality is a reflection of study quality. The data management process involves the conversion of paper forms / questionnaires and other data collection tools into electronic data which are ready for statistical analysis. It also involves setting up an appropriate data collection system as well as designing the database, coding, entering, cleaning and editing the data. In this chapter we will deal only with collection, entry and editing of data. At every step details of who does it, what is to be done, how to document the process will be listed.

Overview

The data from the households will be collected through interviewer administered paper questionnaire. The paper questionnaire will be available in four languages – Hindi, Tamil, Urdu and English, but the formatting will be same such that it can be entered into a single database.

An ONLINE (Internet/web based) system will be developed in an OPENSOURCE platform such as PHP (for front-end) and MySQL (for database). The advantage of the online system is,

- It takes no special software. Because it's all done online, all you need is a computer with internet access and a web browser.
- All you have to do is log in to your account. There's nothing to install or upgrade, and you can access your data from anywhere.
- The data is stored on secure, protected centralized database, so that this can be accessed and downloaded easily.

- Remote bug fixing: If the Data entry operators (DEOs) face any errors/bug in the system, the bug can be fixed at one place. This will save time.

Training

The project manager should ensure that all the study staff has undergone training before starting their field activities. The DEO needs to be oriented with the study protocol, questionnaires and other tools, methods to deal with problems encountered during data entry, maintaining logs and filing of the forms.

Data recording and visual editing

The interviewer will keep check on the consistency of the answers from the participants during the interview, while the study participant is available to clarify any immediate discrepancies, errors, or out-of-range characteristics. The questionnaires will have to be submitted at the field office on a daily basis. Site managers (SM) at the field sites should perform routine review of forms to ascertain completion of forms and questionnaire, skip patterns followed, and the data values appear reasonable. If the routine review of the form does not identify any unusual data, the form can be processed for data entry.

Data Entry

Single data entry will be done at each study site. While creating the database, entry checks (logic checks, missing data checks and range checks) have been implemented at all the key points so that the quality of data is ensured. The DEO will enter only the forms provided by the SM and will ensure that data collected and recorded in the questionnaire / forms is accurately entered into the study database.

DEO is supposed to maintain a log of all the forms s/he enters.

Data Entry Rules and Guidelines

To ensure consistently high-quality data and to minimize delays, some general rules need to be observed during the data entry process to handle any difficulties that may be encountered in a given questionnaire.

i. **Questionnaire not correctly filled:** The data entry protocols and guidelines will not work if the instrument is not filled correctly by the data collection team. If you come across a questionnaire that is not correctly filled, immediately consult your SM. (For example: The participant replies that s/he does not currently smoke but then provides values for how many cigarettes s/he smokes each day)

ii. **Duplicate data**

If the DEO encounters two forms with the same Participant ID, inform the PM.

iii. **Missing data**

Missing data in a section of the questionnaire or whole of the questionnaire may be found. It could be expected (like refusal, not applicable or loss to follow up) or unexpected. CARRS-SURVEILLANCE STUDY questionnaire is designed in such a way that there should not be any missing value; all sections should be filled with a specific code. All unexpected missing data should be listed and given to the field supervisor (FS). Mark the missing fields and continue with the rest of the questionnaire of the participant.

iv. **Problem data**

Illegible fields: The DEO is allowed to make an educated guess, but in case of any doubt seek help from the FS or the PM to decipher. If not resolved the concerned FI can be queried.

Notations in margins: When comments are written in non field areas or margins of the form they are generally not entered in the database, but such comments should be scrutinized by the FS/PM during the review of the questionnaire.

Modifications of data: after the queries are resolved the DEO is allowed to go back to the database and correct/ modify the data. But after the database

has been checked by the data manager and PM, the DEO is not supposed to make any changes without the supervision of the PM.

Dates: If the dates are incomplete, do the following:

Birth date – if date is not available – enter 15

-If date and month not available – enter 15 June

-If year is not available, mark as missing (dot) and consult your data manager / PM

Event dates – month and year fields are essential for the incidence rates to be calculated, if any of these are missing, consult PM. PM will review with interviewer and if possible instruct to revisit the participant.

v. **Anthropometric and laboratory values:**

Missing and out of range values are expected in such fields. The DEO should also keep the units in mind while entering the data. If the values are out of range, but on cross checking the value is proved to be correct it should be entered as long as they are not improbable or biologically implausible values.

vi. **Participant ID crossed out**

If you come across any questionnaire where the Participant ID has been crossed out and not verified by the FI's signature and date and another has been written, then:

- Do not enter the form and start entering a new one
- Record both Participant ID in the Household proforma data entry sheet and note if you have entered data on either one of them
- Note the interviewer ID and contact your SM who should verify the entire questionnaire with the interviewer

vii. **Other problems**

You may come across other situations that are not easy to resolve. If your site manager is not immediately available for consultation, follow the guidelines below:

- Do not process the form
- Skip and go on to the next section
- Record the PID number and nature of the problem
- Consult the data manager
- Consult the site manager when s/he becomes available

Coding

The questionnaire will have the codes associated with each of the field (MedDRA / ICD codes will be used for classification of diseases). Unlisted codes will not be allowed to be used in the database.

Consistency Report

At the end of each week, the data manager should run a consistency report on their computer to check the data for:

- missing data for Participant ID
- missing data for date of interview
- missing data for sex
- missing data for age

Storing and filing the Questionnaire and forms

At the end of each day the DEO should store all the paper booklets in a secure location. All study tools / forms that has been entered needs to be returned to the data manager to be stored in the hard copy storage boxes. Log

book of all data management tasks and files should be kept. This can be part of the overall study diary.

Reporting

The DEO should regularly liaise with and report progress and issues to the:

- Data Manager at COE-CARRS, New Delhi, India
- Site Manager
- Site Coordinator/ Principal Investigator
- Data Coordinating Committee

What to report	To Whom	When
• Errors on completed questionnaire & forms	Data Manager / Site Manager	Daily
• Progress • Issues that need resolving • Timeline	Project Manager / Data Manager, COE-CARRS	Weekly
• Progress • Timeline	Data Coordinating Committee	Monthly

Handling queries

- Queries that arise when the forms are being checked by the FI - it is appropriate to get the queries resolved by discussing with the study participant.
- Queries that arise when FS is doing the first review - minor self-evident errors can be corrected by the FS; otherwise s/he should ask the FI to question the participant again.
- Queries that arise at the data entry level or during the second review of entered data by the SM - the query is resolved by the FS/FI who in turn follows the above step.

- Queries that arise when the database is reviewed at COE-CARRS - the project officer at COE-CARRS will send a query form to the SM, who will then resolve the query and mail back the resolution with explanation. The data will be modified or corrected at the COE-CARRS and not at the site.

Data Analysis

The data manager and statistician at COE-CARRS are responsible for downloading the master data from the online system, cleaning and weighting the data, producing the completed fact sheet and data book. Once the "Study Master File" is created, the data needs to be prepared for cleaning and analysis

It is important to create a backup file. During the analysis process you will be writing and saving different data in your file. If something happens to your working copy of the file you will need a backup copy.

The dataset will be cleaned by the data manager prior to data analysis. This includes:

- Checking ranges and combinations of variables
- Detecting and handling missing data
- Detecting and handling outliers
- Checking age and sex variables - The variables Age and Sex should be checked first, prior to checking the data of any other variable. Age and Sex are needed in order to analyze the survey data by age-sex groups and can also be useful in cleaning the remaining variables.
- Checking variables needed for weighting - If data is weighted for probability of selection, variables indicating the location of each record (e.g. Cluster Number) must be checked for missing or outlying values. As the name and value of these variables vary from country to country, no automated program exists for this cleaning.

Automated Cleaning

There are some basic cleaning codes embedded within analysis programs which will clean the data for:

- Basic outliers
- Completeness
- Consistency (e.g. if a participant said 'No' to currently smoking and then 'Yes' to smoking daily).

For each program, records with outlying data or incomplete or inconsistent responses (where more than one question is needed for analysis) are temporarily removed during the analysis.

Even though this basic cleaning is incorporated in most of the available programs, it is highly recommended that each variable and set of variables be checked for outliers, completeness, and consistency prior to any analysis.

Missing data

While most problems related to missing data should be handled during the data entry process, it is still very likely that the final dataset will contain records with missing data. Thus, the data manager will need to explore the missing data in greater depth so that the data analysis is properly completed with attention to this missing data.

Guidelines for handling missing data

- If a record is missing for age, sex, or any location variable or a variable that needs to be weighted, then review the completed study tool and discuss with the site manager to try to recover the missing data either by cross checking with the paper forms or the interviewer or the participant (if possible). If the data cannot be recovered, the record should be dropped and counted as a non-responder for weighting purposes.
- If a record is missing for a variable other than age, sex or location, then exclude the record from all analyzes relating to this variable. For analyzes in which records are excluded, clearly document the number of such records omitted due to missing data in the data book.

Outliers

An outlier is a value of a variable that appears to deviate significantly from the observed values in other participants. It may be correct, and the person

truly has an unusual value, or it may be incorrectly recorded or entered. In any case, it is good practice to investigate the outliers before analysis in order to avoid having those extreme values unduly influencing the results being reported. Range checks provide one such way to examine whether the data seems reasonable.

Quality Control Measures

- **Direct and indirect observation of data collection** by the field supervisor can identify errors in a timely manner.
- **Periodic audits of the database against source documents:** A random sample of data fields can be selected to check for keying errors.
- **Regular review of computer generated queries and summary reports of data quality** will alert the investigators to a variety of data errors, including participant ineligibility, data outside the expected range, and variation in data quality by data field, site, or technician.
- **Site Visit:** Site Visit should be done by the project and site managers to observe operations which will allow greater understanding of site-specific data collection issues, and provide an opportunity to recognize and correct faulty systems.

Chapter 15

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.

Center of Excellence – Center for cArdiometabolic Risk Reduction in South Asia (COE-CARRS)

The COE-CARRS at PHFI; New Delhi will be acting as the regional coordinating center for the Surveillance study.

Roles and responsibilities:

i. Designing study tools, software.

ii. Providing training to study staff

iii. Supporting the site coordinators and managers, and providing guidance and advice on all aspects of planning, implementation and dissemination of data.

iv. Regular communication with the site coordinators.

v. Monitoring of recruitment rates of participants, progress reports and error rates for quality assurance

Data Management Cell

Statistician

The statistician at the regional coordinating center plays a key role in sampling and data analysis procedures.

Roles and responsibilities:

i. Assisting in the multi stage cluster random sampling for each study site
ii. Formulate the statistical analysis plan
iii. Management of the data
iv. 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:

i. Cross-checking of data files sent from the field sites
ii. Monitoring error rates
iii. Running check files
iv. Preparing the final data file for analysis
v. Performing the analysis
vi. Will conduct regular review meetings to supervise the site operators
vii. Flag high error rates and suggest corrections
viii. 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

i. Monitor the progress of the study
ii. Regular appraisal of the study
iii. Monitor the timeline of the study
iv. Visit the field sites at least twice a year to monitor the activities
v. Provide on job training to the field staff
vi. Provide feedback for corrective action to site PI and manager
vii. 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:

i. Active participation in planning the study
ii. Oversee the overall implementation of the study
iii. Recruiting and training field staff
iv. Supervising the data collection and data entry processes
v. 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:

i. Preparation of blood collection kits before visit 2
ii. Ensure collection of blood samples from the community with sterile precautions
iii. Ensure proper transport of sample from field to the laboratory (proper cold chain)
iv. Processing and analysis of blood samples
v. Handing over blood reports to the field staff
vi. Recording results and passing records on for data entry
vii. Identifying out-of-range results for clinical attention
viii. Ordering supplies
ix. Quality control measure during analysis

Lab Attendant/Phlebotomist

Roles and Responsibilities:

i. Responsible for biological specimen collection of all enrolled individuals on standard laboratory protocols

ii. Ensure all logistic arrangements required for specimen collection before hand

iii. Ensure proper labeling of specimen and transport of specimen to the lab

iv. Keep record of all results and enter results in database program

v. Maintain log of stored specimen and lab requirements

vi. Distribute lab reports to the study participants

vii. 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:

i. Logging receipt of completed questionnaire and forms

ii. Filing and organizing paper copies of questionnaire and forms

iii. Entering survey data

iv. Tracking questionnaire and forms during data entry

v. Identifying errors and resolving problems with supervisor

vi. Regular back up and archive of data

Chapter – 16
Monitoring and evaluation

Introduction

A 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. The QME sub-committee will include the principal investigators, senior field personnel, project manager, site coordinators and external evaluators. Progress of the study will be monitored through regular appraisal by the QME sub-committee. Each site will be visited by an external evaluator twice in a year.

Procedures for evaluating the process of the study

Sampling*:*

a. After the list of households is prepared, random checks will be done especially for areas that have been undergoing continuous development to ensure that all households are enlisted.

b. Cross-check the random household number generated with the number of the household in which participants were interviewed.

Data collection:

a. Initial shadow monitoring of all interviewers will be done for practical training and to resolve issues immediately. This will also help to identify weak personnel who may require intermittent supervision.

b. As the study progresses, random checks for about 5-10% of the participants will be done every three months by site managers and the project manager who will verify some of the answers in the filled questionnaire and the anthropometric measurements (visit-1).

c. Random checks will be done during visit-2 (body composition analysis and biological sample collection). There will be regular visits by evaluators to the clinics/camps/households (Karachi) where body

composition measurements and biological sample collection is being done. The monitors will check for instrument calibration (as was done in the MONICA study) and also assess the collection, handling and storage of biological specimen. Temperature of specimen storage equipment will be monitored to check the maintenance of log books and temperature charts. Faulty instruments will be replaced and technicians will be re-trained to correct any immediate issue. Any sample whose quality is compromised will be discarded and if possible a second sample will be collected from the participant. However, minimal technical problems are anticipated as all technicians selected will be thoroughly trained.

d. Laboratory monitoring: Internal quality control checks will be done regularly. About 10% of the samples will be re-analysed at a reference laboratory from each site. Inter-site quality checks will also be done through exchange of 5% of the samples. Inter and intra laboratory coefficient variation will be conducted to standardise results across all the study sites and control bias (Further details have been provided in Chapter – 13).

e. There will be regular documentation of the response rates from participants especially for the follow-up of cohort to minimise loss to follow-up. The QME will also be responsible to audit these rates and other documented field activity indicators such that immediate corrective measure can be taken.

Data entry:

At site:

a. Site managers will be responsible for checking all forms for completion or for any obvious errors before data entry.

b. Inbuilt checks in the software such as logic checks, context checks and ranges will be incorporated.

c. The outcomes of cohort study for all participants will be validated by physicians and intra and inter observer variability will be checked by the site managers and / or an external evaluator before data is entered.

d. Expected error rates: Every time an error is located it will be given a mark of one, once all participants' and field data are checked (all fields, all rows, all columns), the error marks will be summed and using denominators of total fields, context fields and outcome fields, error rates for all fields, context fields and outcome will be respectively generated. The error rates are usually expressed as errors per 10,000 fields. Error rates vary for studies and different studies use different rates as acceptable limits. Since it is a large study with a very large number of data fields, we are using the error rates suggested by Neaton et al., 10 errors per 10,000 fields or 0.001. However, for context or participant identification / demographic fields and for outcome fields "zero tolerance" will be used (acceptable error rate=zero).

   Error rate – all fields (0.001)

   Error rate – context fields (Zero)

   Error rate – outcome of cohort study (Zero)

e. Any errors found will be corrected by referring to the filled questionnaire or if required by a revisit to the participant.

At COE-CARRS:

a. The data manager and statistician will re-check all data entered at the sites for outliers, coding errors and missing values. The data will be run through inbuilt checks in the software.

b. Expected error rates: Every time an error is located it will be given a mark of one, once all data are checked (all fields, all rows, all columns) for all sites, the error marks will be summed and using denominators of total fields per site, total fields per interviewer per site and total outcome fields per site, error rates for site, interviewer and outcome will be respectively generated. As described above, the acceptable error rate for this study will be 0.001 for site and interviewer and zero for outcome fields.

   Error rate – Site (0.001)

   Error rate – interviewer (0.001)

Error rate – outcome for cohort study (zero)

c. Measures to be taken if the error rate is higher than the pre-decided rate:

   High error rate for site - all data for the site will be checked against paper forms.

   High error rate for interviewer – all data for the particular interviewer will be checked against paper forms.

   If there is any error in the outcome for the cohort study, first the data will be cross-checked against paper forms and if required the site will be informed to re-visit the participant. If none of these can correct the error, the error field will be dropped as missing.

d. Once re-checking of the data at COE-CARRS is complete it will be freezed and if the site requires any updating, the data will be sent with proper reasoning to COE-CARRS who will review and make the necessary changes.

e. Decision log will be used to document issues in case of error (using spread sheets and emails).

f. Monitoring data storage and confidentiality procedures: This will be done by the Principal Investigators and external evaluators at the COE-CARRS after the complete collation of data and before using the data for analysis.

Procedures for evaluating the outcome of the study

1. After the study is complete an independent evaluation will be done by the Principal Investigators and the external evaluators to ascertain if the aims and objectives of the study are fulfilled. This will be done through review of all the preceding evaluation processes, and also through review of the findings and results of the study.
2. The report will be presented to the Steering Committee for final comments.