# The Hyderabad DXA Study

STUDY PROTOCOL v2 Dated 22.1.2009

#### **Overview of the study**

*Background:* India is experiencing an epidemic of obesity, diabetes and coronary disease. This epidemic is largely attributable to increasing urbanisation.

People in India may be more vulnerable to obesity than people from other countries. One theory for this is that this is because they faced a lack of nutrition when their mother was pregnant with them or in early childhood. This lack of nutrition may have caused long-term changes in the body, such as a tendency towards obesity and central-body fat. Indian people are also at higher risk of developing diabetes and heart disease, which may be due to their higher levels of central-body fat.

We will examine whether nutritional supplementation in pregnancy and childhood reduces the chances of developing adult central-body fat. We also will investigate the effects of migration from nutritionally deprived rural to urban areas on the development of central-body fat, diabetes and heart disease.

We will examine these questions in two established studies: a long-term follow up of a randomised trial of pregnancy and childhood supplementation; and the Hyderabad arm of the Indian Migration Study. High-technology X-ray scanning (DXA scan) will be used to measure the amount and distribution of body fat. We will also measure coronary disease risk using non-invasive methods.

Understanding how exposure to nutritional shortage and excess at different ages leads to obesity, diabetes and heart disease will help us find better ways of preventing some of the consequences of modernisation and urbanisation in India.

# *Aims and objectives*: The scientific aim of the study is to examine the effect of nutritional supplementation in early life and the effect of within-country migration on obesity, diabetes and heart disease in India.

Our objectives are:

- *1.* To identify predictors of total body fat and central-body fat, including nutritional supplementation in early life and rural-urban migration.
- 2. To assess the association between nutritional supplementation in early life with the development of diabetes and heart disease
- 3. To assess the association between rural-urban migration with the development of diabetes and heart disease
- 4. To assess the association between total body fat and central-body fat with diabetes, precursors of diabetes and heart disease.

#### Methods:

**Study subjects:** We will examine these questions in two established studies. The first is the "Hyderabad Nutrition Trial". In this study, over 2000 women were randomised to receive supplementation during pregnancy and the first five years of their child's life, or to no supplementation. These children were examined at the age of 14-16, and they are now aged 18-21. The second study is the Hyderabad arm of the "Indian Migration Study". This study was conducted includes 820 urban factory workers matched to their siblings who still live in the rural area. Their average age is 44 years.

**Examination:** All participants will be invited to a screening examination at NIN. DXA scanning will be used to measure body fat and central-body fat. Non-invasive measures of coronary disease risk will be made. Blood samples will be taken and analysed to measure insulin, glucose, cholesterol, triglycerides and liver function. Anthropometric variables will be measured and participants will be interviewed in depth about diet, exercise and other health behaviour.

*Timetable:* The fieldwork is expected to take 18 months to complete (Jan 2009 to June 2010), with a further 3 months to analyse the data and write-up the results (study end date October 2006).

*Source of funding:* The study is funded by the Wellcome Trust, UK, and coordinated jointly by the National Institute of Nutrition, India, and London School of Hygiene & Tropical Medicine, UK.

#### Table 1. Main outcome measures and study instruments

Outcome	Instrument/method	Comments
Diet & physical activity		
Diet	Food frequency quest. (single recoding)	Recall over last year
Physical activity	Activity frequency quest. (single recording)	Recall over last week
Physical activity	Triaxial accelerometers (single reading)	Genea Model
Anthropometry		
Standing height	Portable stadiometer (single reading)	Leicester height measure; at end expiration
Sitting height	Above, seated on a stool (single reading)	Local stool; above with feet dangling
Weight	Digital weighing machine (single reading)	Secca scales; minimal clothing, no shoes
Waist circumference	Metallic tape (two readings)	Narrowest part of waist observed from the front
Hip circumference	Metallic tape (two readings)	Maximum extension of the buttock observed from the side
Mid-arm circumference	Metallic tape (two readings)	Mid-upper arm on the left arm
Calf circumference	Metallic tape (two readings)	Maximum calf circumference on the left leg
Head circumference	Metallic tape (two readings)	Maximum head circumference
Triceps skinfold	Holtain skinfold caliper (three readings)	Same level as MAC; Left arm; 5 seconds delay for all skinfolds
Biceps skinfold	Holtain skinfold caliper (three readings)	1 cm superior to line marked for MAC, Left arm
Subscapular skinfold	Holtain skinfold caliper (three readings)	Just below inferior angle of scapula, 45 degree angle, Left side
Suprailiac skinfold	Holtain skinfold caliper (three readings)	Midaxillary line superior to iliac crest, 45 degree angle, Left side
Medial calf skinfold	Holtain skinfold caliper (three readings)	Medial side of left calf viewed from front, same level as calf circ.
Grip Strength	Takei Grip D (four readings)	Right and left arm separately. Provides average of two top scores.
Vascular physiology		
Blood pressure	Systolic & diastolic (three readings)	Omron M5-I; Sitting, right upper arm; small/medium/large cuffs
Pulse rate	Beats per minute (three readings)	Omron M5-I; Sitting, right upper arm; small/medium/large cuffs
Carotid Intima Media Thickness	Ultrasound	Supine measures taken of carotid artery
Arterial Stiffness	Sphygmacor (three readings)	Supine measures taken of radial pulse
Pulse Wave Velocity	Vicorder (three readings)	Supine
Forced vital capacity	Micromedical MicroPlus (min three readings)	Three acceptable blows – maximum five blows
Forced expiratory volume <sub>1</sub>	Micromedical MicroPlus (min three readings)	Three acceptable blows – maximum five blows
Room temperature	Digital thermometer (single reading)	Taiwan model

Table 1. Main outcome measures and study	y instruments (continued)
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Outcome	Instrument/method	Comments
Biochemistry		
Haemoglobin	Calorimetry	At NIN
Fasting sugar	Randox kit/Autoanalyser	At NIN
Fasting triglycerides	Randox kit/Autoanalyser	At AIIMS
Total cholesterol	Randox kit/Autoanalyser	At AIIMS
HDL-cholesterol	Randox kit/Autoanalyser	At AIIMS
Fasting insulin	Radioimmunoassay	At AIIMS
Liver function tests	Randox kit/Autoanalyser	At AIIMS
2 hour glucose	Randox kit/Autoanalyser	At NIN, on participants from IMS only

#### Study staff and their responsibilities

The team will consist of team leader, medical officer, five research assistants, three fieldworkers, biochemist, DXA technician (NIN staff member), data entry operator, and two clinic helpers.

#### **Team leader**

- Overall responsibility for the performance of the team
- Deliver recruitment targets
- Assist with training of staff
- Ensure data quality and completeness
- Coordinate day-to-day running of the study (plan activities of other staff, surveys, and clinics)
- Supervise data entry, data back-up, data storage (electronic and paper), data validation and verification
- Supervise record keeping
- Procure equipment and consumables on time, and ensure their maintenance (except for DXA scanner)
- Contribute to questionnaire completion and anthropometry measurement
- Develop links with the factory management and village leaders
- Report to the local PI at NIN and overseas PI at LSHTM

#### Medical officer (Scientific research fellow)

- Measure carotid intima media thickness, augmentation index and pulse wave velocity
- Collect blood samples in case biochemist has difficulty or is unavailable
- Communicate results of medical examination (blood pressure, BMI) and offer advice to the participants
- Manage any medical emergencies or referrals that may be required

#### Research assistants (X5)

- Involved in all aspects of the fieldwork including questionnaire completion, anthropometry, and blood pressure measurement
- Organise clinics, maintain equipment and records
- Report to the Team Leader

#### Field investigators (X3)

- Arrange appointments for participants
- Explain nature of study to participants
- Provide information sheets to participants
- Send reminders to participants
- Collect participants and transport to NIN and back.
- Assist in the running of the clinic, ensuring adequate participant flow between measurement stations
- Contribute to questionnaire completion and anthropometry measurement if required

#### Biochemist

- Collect blood samples and ensure timely and accurate processing/analyses of samples
- Analyse for glucose and haemoglobin
- Maintain equipment and necessary supplies of consumables
- Arrange transport of samples and quality control with the coordinating laboratory in Delhi
- Report to the Team Leader and Dr Lakshmy in Delhi

#### DXA technician (NIN staff)

- Conduct whole body, lumbar spine, and hip scan
- Conduct analyses to estimate adiposity and abdominal adiposity from whole body scan
- Report to the Team Leader and local PI

#### Data entry operator

- Data entry and check data completion, maintain databases
- Enter data from DXA printouts into database
- Enter census codes on the questionnaires using special software
- Generate and print labels and lists for fieldwork and help with phone calls
- Maintain records and paperwork, progress spreadsheets, electronically transmit the required files at timely intervals
- Report to the Team Leader

#### Clinic helpers (X2)

- Help and support the activities of the team
- Set up clinics and organise the flow of participants and arrange refreshments

#### Collection of participants for examination clinics

12 participants will be invited to attend the clinic per day. 8 will be invited from the Indian Migrant Study, and the remainder from the Hyderabad Nutrition Trial. For instance, if 4 have agreed to attend from the Indian Migrant Study then a further 8 will be invited from the Hyderabad Nutrition Trial. If 8 have agreed to attend from the Indian Migrant Study then a further 4 will be invited from the Hyderabad Nutrition Trial. The Team Leader is responsible for co-ordinating how many people need to be invited from the Hyderabad Nutrition Trial.

To assist with arranging appointments, one fieldworker will be based at BHEL (for Indian Migrant Study), one fieldworker in the intervention villages and one in the control villages.

#### Protocol for participant tracking: Indian Migrant Study

- 1. Team Leader gives fieldworker complete list of participants from IMS (participant book).
- 2. Team Leader or DEO prints labels for all participants from IMS
- 3. Team Leader or DEO puts labels on participant tracking form for all participants from IMS, and gives to fieldworker.
- 4. Fieldworker starts at top of list, and identifies 8 participants (i.e. two factory workers, their spouses, siblings and spouse of sibling) for invitation to examination on scheduled day which is one month later.
- 5. Fieldworker identifies phone number for factory worker from participant book.
- 6. Fieldworker phones index factory worker and invites factory worker and spouse, sibling and spouse of sibling to examination. He explains what happens during the examination and meets index worker to show the participant the information sheet.
- 7. Fieldworker fills in participant tracking form for each participant invited. Makes note in participant book that participant has been invited (places tick in pencil next to name). Fieldworker also fills in log book each day, entering how many people he has contacted and whether they have agreed to attend.
- 8. Fieldworker informs Team Leader of how many people have agreed to attend on particular day.
- 9. Fieldworker makes reminder phonecall to participants two weeks before the appointment to remind about the examination day, and again one day before examination day (remind to come fasting with appropriate id).
- On examination day, fieldworker meets the participants at designated place and accompanies them to NIN. He spends day at NIN with participants and accompanies them back to the factory in the evening.
- 11. Once participant has attended the examination day, he makes a note in the participant book, striking through the name in pencil.
- 12. Fieldworker revisits people not available at previous visits to schedule appointment. Fieldworker continues down the list until everyone who is eligible has been visited, and has either been examined or refused or cannot be identified.

#### Protocol for participant tracking: Hyderabad Nutrition Trial

- 1. Appointments will be made for intervention and control villages on alternate days.
- 2. Team Leader gives fieldworker complete list of participants in village cluster for which he is responsible (participant book).
- 3. Team leader or DEO prints labels for all participants from village
- 4. Team leader or DEO puts labels on participant tracking form for all participants from village, and gives to fieldworker.
- 5. Fieldworker visits village: Team Leader accompanies fieldworker to village on first visit for introduction.
- 6. Fieldworker starts at top of list, and identifies participants for invitation to examination after two weeks. Exact number to be invited for that day determined in advance by Team Leader.
- 7. Fieldworker uses participant tracking form for participant to get address, phone number and waypoint number for participant.
- 8. Fieldworker visits participant at house or phones participant and invites participant to examination. He explains what happens during the examination and shows the participant the information sheet.
- 9. Fieldworker fills in participant tracking form for each participant invited. He makes note in participant book that participant has been invited (places tick in pencil next to name). Fieldworker also fills in log book each day, entering how many people he has contacted and whether they have agreed to attend.
- 10. Fieldworker informs Team Leader of how many people have agreed to attend on day.
- 11. Fieldworker revisits participants one day before the appointment to remind about the examination day, and that participants must come fasting and with suitable id.
- 12. On examination day, fieldworker meets the participants at designated place and accompanies them to NIN. He spends day at NIN with participants and accompanies them back to the village in the evening.
- 13. Once participant has attended the examination day, he makes a note in the participant book, striking through the name in pencil.
- 14. Fieldworker revisits people not available at previous visits to schedule appointment.
- 15. Fieldworker continues down the list until everyone in the village who is eligible has been visited, and has either been examined or refused or cannot be identified.

#### **Participant Information Sheet**

The fieldworker reads the participant information sheet (translated into telugu) to the participant and answers any questions (In appendix).

The fieldworker makes sure he has covered all the points in the checklist for participation.

Benefits of study.

Tests will be conducted for the following, free of cost:

- Blood pressure
- DXA scan to measure body fat
- Heart and blood vessel function (Augmentation Index, Pulse Wave Velocity, Carotid Intima Media thickness)
- Lung function
- Blood tests, including glucose

You will be told if a problem is detected and will be given your blood tests

For examination please remember the following:

- Be on time for pick up
- You will be picked up in morning, dropped back by end of afternoon
- You will be reimbursed for your time and food is provided
- Come fasting overnight, <u>unless you are pregnant or diabetic</u>
- Avoid metal on clothes. Preferably do not wear gold or silver jewellery
- No calcium for 2 days before hand
- Avoid alcohol and fatty food one day before
- Do not smoke from the evening before the examination
- For women, come within 10 days of last menstrual period unless ceased childbearing
- Bring proof of ID
- Bring any medication that you use

#### Exclusion of pregnant women from DXA scanning

People are exposed to a very low dose of radiation when they undergo a DXA scan. This means that we must ensure that pregnant women do not undergo DXA scanning.

Steps to ensure pregnant women are not screened using DXA from Indian Migrant Study

- 1) Team Leader identifies all women aged <35 years from the database.
- 2) She phones them and organises the appointment within 10 days of menstrual period, unless they have undergone tubal ligation.
- 3) For women aged ≥35 years or those who have undergone tubal ligation they are scheduled in the same way as the men.
- 4) At the clinic, women <35 years who have not undergone tubal ligation are asked to take a pregnancy test. If they refuse or are pregnant then they are not given a DXA scan. This is coordinated by the Team Leader.
- 5) At the clinic, women <35 years who have not undergone tubal ligation and are not in the first 10 days after their last menstrual period are asked to reschedule their visit. If they refuse then they are not given a DXA scan but undergo all other examinations.

#### Steps to ensure pregnant women are not screened using DXA from the Hyderabad Nutrition Trial

- 1) Fieldworker visits female together with angwadi worker two weeks before planned appointment.
- 2) Angwadi worker asks female about last menstrual period and regularity of period and estimate start of next menstrual period.
- 3) Female is given tentative appointment for 1-10 days after next menstrual period
- 4) One day before the appointment the female is visited by fieldworker and Angwadi worker to ask about the start of the last menstrual period. If last menstrual period was not in the last 9 days they are given a new appointment.
- 5) Women who are pregnant are given appointments in the same ways as the men, but are not given DXA scans.

#### **Examination clinics**

The clinics will be held at NIN. Participants will be asked to come fasting. As a result, clinics will have to start early, from 8:30 AM. The clinic team will have to arrive half an hour before the time given to the first participant to make arrangements. The following steps provide a guide.

- 1) Step 1. Team arrive half an hour before time given to the first participant. Peon arranges for the breakfast. Fieldworkers set up the equipment and conduct daily calibrations. Biochemist ensures kits are in place. Team Leader ensures folders with questionnaire, consent form and feedback form are ready.
- 2) Step 2. Participants arrive and are received by the Peon. Peon arranges for them to wait in the waiting area and takes them to the Team Leader who checks their identity. Photocopy of proof of identity is saved in the folder. In case the participant has brought only the originals but not the photocopy, the participant or the Team Leader may have to go and get photocopies made (best done in batches rather than for each individual). Following this, the participant moves between different stations with the folder that has all the relevant questionnaires.
- 3) Step 3. **Station 1:** Research Assistants explains the study using the prepared information sheet and takes consent. After consent, the participant is directed towards the laboratory technician.
- 4) Step 4. **Station 2:** The Biochemist collects the blood samples, seeking help from the Doctor in difficult cases. After collecting all the blood samples, the laboratory technician heads back to the laboratory to carry on with processing and analyses of the samples.
- 5) Step 5. *For subjects from Indian Migrant Study only*: Participant is given the glucose drink by the peon after the blood sampling.
- 6) Step 6. Participant moves through the following stations:
  - a. Station 3: Questionnaire Participant is interviewed by fieldworker using questionnaire
  - b. **Station 4:** Anthropometry Anthropometric measures are taken of participant by fieldworker.
  - c. Station 5: DXA scanning Participant undergoes DXA scanning, supervised by technician.
  - d. **Station 6:** Medical examination– Participant undergoes medical interview and examination by doctor. At this station, a report and general health advice is given to the participant and any queries answered.
- 7) Step 7. *For subjects from Indian Migrant Study only*: Two hours after the glucose load, the Biochemist collects the second blood sample. After collecting all the blood samples, the Biochemist heads back to the laboratory to carry on with processing and analyses of the samples.
- 8) Step 8. **Station 7:** Team Leader collects the folder and checks for missing data items, recalling the patient if necessary. After this, the patient is thanked for his/her participation and reimbursed after collecting any receipts if relevant and signatures of the participant that he/she has been reimbursed.
- 9) Step 9. Participants are taken back to factory or village by transport.
- 10) Step 11. After the participants have left, the equipment is stored away as necessary and the paperwork for the day filed away.
- 11) Step 12. The Fieldworkers with the help of the Team Leader/Database person prepare list of participants and folders for the next day. The Laboratory Technician prepares the venepuncture material, labels and transport box for the next day.
- 12) Step 13. The Team Leader may have to spend much of the day planning and organising fieldwork, and in activities related to participant requirement (phone calls, letters etc).
- 13) Step 14. The Database person will support the Team Leader, manage database, generate labels and letters, and enter questionnaires.

#### **STATION 1: Informed Consent**

#### Station 1: Informed consent. Completed by research assistants

The Research assistant explains the study using the prepared information sheet and takes consent. He/she must make sure that the participants have been able to ask any questions or address any concerns.

#### **Consent form:**

#### Nutritional challenges, abdominal adiposity and type 2 diabetes in Indians

#### **Participant:**

Shri/Smt/Kum (First & Last Name)

Address (Lane, Town, State, Pin Code)

I, \_\_\_\_\_\_\_exercising my free power of choice, hereby give my consent to be included as a subject in the clinical study "Nutritional challenges, abdominal adiposity and type 2 diabetes in Indians".

- For the examination today we will ask you to undertake the following: interview, measurement of body size, DXA scan and a visit with the doctor. We will also ask you to give up to two blood samples. The examination will last until the afternoon.
- I am free to participate or not to participate in this study.
- The purpose of this study was explained to me in my own language.
- 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 agree to my information, including results of blood 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 you personally
- I understand that for all practical purposes I may not gain anything by participating in the study though in the long run it may be beneficial to the community.
- I understand that I can withdraw from the study at any point without giving any reasons and withdrawing from the study will not affect me in any way.
- 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 Investigator		
Signature of the Investigator	Date	

#### **STATION 2: BLOOD TAKING**

Blood samples will be taken by the biochemist. For all subjects a fasting sample will be taken. For the Indian Migrant Study participants, a glucose solution will be given to drink and a second blood sample will be taken 2 hours after drinking the glucose solution. **Pregnant women and people with diabetes will not be asked to fast, but blood samples will still be taken**.

	Blood sampling			
2.1	Any illness within the last week?		[1=Yes; 2=No]	
2.2	If yes, specify what illness:			
2.3	Was this illness or some other reason responsible for reduction in food intake over the last week?	2	=No reduction =Minor reduction =Major reduction	
	Do you have diabetes?		1=Yes; 2=No] [IF YES, DO N COSE LOAD OR TAKE SEC	
2.4	Day of last meal		1=Today; 2=Yesterday]	
2.5	Time of last meal		: [Hours: minutes	s; 24-hour clock]
2.6	Time blood taken: sample 1	[Hours: minutes; 24-hour clock]		
2.7	Glucose load given	[1=Yes; 2=No]		
2.8	Time glucose load		: [Hours: minutes	s; 24-hour clock]
2.9	Time blood taken: sample 2		: [Hours: minutes	s; 24-hour clock]
	Success in blood sampling	(a) Vo	lume	(b) Clot formation
2.10	Red capped tube		=No; 2=Partial; 3=Complete]	[1=Yes; 2=No]
2.11	Purple capped tube 1	[1	=No; 2=Partial; 3=Complete]	[1=Yes; 2=No]
2.12	Grey capped tube	[1	=No; 2=Partial; 3=Complete]	[1=Yes; 2=No]
2.13	Purple capped tube 2	[1=No; 2=Partial; 3=Complete] [1=Yes; 2=No]		
2.14	Grey capped tube 2	[1=No; 2=Partial; 3=Complete] [1=Yes; 2=No]		
2.15	(a) Any other comments on blood sample		1=Yes; 2=No]	
	(b) If yes, specify			

# GLUCOSE LOAD GIVEN AND SECOND GREY CAPPED TUBE IS ONLY TAKEN FOR PARTICIPANTS FROM THE INDIAN MIGRANT STUDY

#### **STATION 3: CLINIC QUESTIONNAIRE**

Clinic questionnaire completed by fieldworker

- Filled in biro
- It is only permissible to leave a section blank if it is in a shaded region
- If a section is blank then cross through section

#### Guide for conducting structured interviews

Structured interviews capture vital information. The aim of a structured interview is to measure facts and people's attitudes accurately and in such a way that if one were to repeat it at another time one would get the same answer.

It is, therefore, very important to get the structured interview right. Respondents need to be able to provide truthful answers which reflect their lives. Careful and precise interviewing techniques are essential to ensure the collection of complete, standardised unbiased and accurate data. Much research has been undertaken to identify what works in getting the best from a structured interview and what does not. For example:

- Interviewers who adopt a business like manner (wearing a dark suit) are less likely to gain trust-responders tend not to give truthful answers.
- Young interviewers obtain less reliable results than older interviewers.
- Male interviewers obtain less full information form male respondents than female interviewers and vice versa.

Response and accuracy is likely to be increased if the interviewer looks happy, appears positive. It is likely to be decreased if the interviewer looks tense. Matching up respondents with interviewers is particularly difficult. It is, therefore, vital that the questions in a structured interview are asked in the same way and that the responses are recorded in the same way by the interviewer.

The following provide essential steps and aids to help conduct the structured interview.

#### The interviewer

Foremost the interviewer needs to:

- Know and understand what the study is about- inside out.
- Understand the questionnaire
- Be familiar with the pre- coded questions and those which are open
- To be able to conduct the questionnaire in a uniform manner

#### Good interviewers

- Are sensitive and trustworthy
- Have an ability to establish a rapport with a wide range of people
- Are friendly and positive
- Are good listener and do not interrupt people before they have finished speaking
- Are committed and persevering
- Have the ability to adopt a neutral manner (showing neither approval or disapproval

- Have legible handwriting
- Are adept at leaving the respondent happy
- Are good planners
- Are able to ensure and maintain confidentiality
- dress neutrally- suitable for any kind of home
- Have good intuition about when it is appropriate to approach respondents or not.

#### The interview

The interviewer must approach potential respondents in a positive manner in order to encourage them to participate. The critical moment is when the interviewer introduces themselves.

Always present your ID Card. Be honest about the study's aims and let them know how long the interview will take. Always provide respondents with details about the study and information on who to contact if should they want to.

Find a place where the interview can be conducted in private without interruptions.

Most respondent want to be seen in the best possible light and will want to give answers that reflect this. They will want to answer in such a way as to please the interviewer. The reliability of the information collected will be dependent on the rapport and satisfactory relationship established during the introduction. If a respondent feels anxious or uneasy they may be less likely to want to provide personal information.

When asking questions, the interviewer must always

- be sensitive to the needs of the respondent; e.g. not sitting in sunlight, comfortable seats etc.
- be encouraging
- use the exact words printed in the a questionnaire, and in the exact order: changing words or sentence orders will introduce serious bias to the study
- speak in a non-judgmental manner
- express polite interest
- read the questions and pre- coded answers out in reasonable volume and speed ensuring the respondent has heard and understood the question
- look at the respondent after each question to pick up on any visual clues of embarrassment or unease
- <u>accurately</u> record the answer on the questionnaire

#### NEVER

- appear surprised or disapproving
- express opinions or beliefs
- make assumptions about respondents likely answers
- hurry the respondent for answers
- ask questions in a biased or leading way
- ring a category that comes nearest to the respondent's reply. If the code does not exist, record the exact words used by the respondent in their response
- allow long silences to become embarrassing
- apologise for asking personal or embarrassing questions

If the interviewer appears hesitant, reluctant, unconfident negative or thinks a question is too personal, then the respondent will be influenced and will decline to give accurate answers. In fact they will encourage negative responses. It is important to maintain the respondent's interest and motivation throughout the interview.

It is common for respondents to go off the topic and talk about other issues not relevant in the questionnaire. The interviewer has to be skilled to bring respondents back to the point. If this is done firmly from the onset, further problems are less likely to recur. The following phrases may be helpful:

"This is important information that we can cover a little later-can we now focus on"

"What you say is most interesting but could I just ask you now on"

Another problem with respondents who go off the topic is that may have imparted some information that is useful in the questionnaire. Asking them again may give rise to irritability. BUT, it is very important never to assume the answer. To avoid potential irritability-prefix the question with:

"I know you have already mentioned this, but can I just check"

"Now you have already said something about this, but I would like to ask you this question".

It is never a good idea to break off the interview- it compromises the rapport and relationship already established. It is important to ensure that the respondent is fully aware of how long they are committing themselves to the interview.

If interviewers are seriously worried about a respondent (e.g. someone admitting suicidal thoughts or an elderly person being abused), the interviewer should offer to put the respondent in contact with a suitable professional. If accepted, ensure that this is put in writing and signed by the respondent. If the respondent refuses, only contact a professional if it is seen as a case of emergency.

#### **Probing and Prompts**

A probe is a stimulus which is used to obtain information form respondents who experience discomfort, hesitation, or feel unhappy to reveal information about themselves. Directive probing techniques are acceptable if one is eliciting factual information. Here it is important to motivate respondents in an undemanding and understanding tone. The aim is to encourage respondents to give accurate information. Probes listed below may help.

"Can you tell me more about" "In what way" "Can you describe" "what sort of (office do you do)" "Before, writing your answer down, can I just check"

#### **Third Parties**

Caution would be exercised when other people want to sit in on the interview. The presence of a third party will always influence the respondent and will lead to biased answers. This is best avoided.

#### Hesitancy, misunderstanding and non-response

Some respondents may seem hesitant in answering questions and the interviewer could affirm this with "there is no right or wrong answer on this- we just trying to get your ideas. Some will ask the interviewer for their opinion and here it is important not go give opinions but no explain that it is the respondent's opinion that matters. Some may want to answer with a "don't know" and this can have many different meaning E.g. It may mask misunderstanding of the question, (see next paragraph), may not want to impart the information (use probes), or may genuinely not know. It is important to record such information on the questionnaire.

When respondents genuinely do not and may ask the interviewer to explain it. In this case, the interviewer should repeat the question and if no answer is forthcoming make a note of it on the questionnaire. It is

important not to succumb explaining the question. Interviewers will give different explanations evoking different answers.

If a respondent is very reluctant to answer a question, it may help if the interviewer

- Confirms the information given is confidential
- That replies will be aggregated in tables so that individual responses cannot be identified.

If the respondent still feels unwilling to respond, a note should be made of it and the next question pursued.

Ultimately, if respondents refuse to take part or answer any question, their wishes must be respected. The interviewer should apologise for the inconvenience. Most interviewers achieve 8/10 response rate.

Often a respondent will change their minds and a follow-up letter may help

#### End of the interview

Interviewers must leave their respondents in a positive frame of mind. After the interview, interviewers must:

- Check the questionnaire to ensure all parts are completed
- Must be prepared to spend time explaining the study further
- Emphasise how the information obtained is vital to the study
- Ensure complete confidentiality
- Thank respondents for their willingness to share their experiences
- Ensure the respondent has information and a contact point about the study should they require further information

QUESTIONNAIRE

<u> </u>			
	Interview details		COMMENTS
3.1	Date of quest. Completion	//	
		[DD/MM/YY]	
3.2	Time of quest. Completion		Must be entered; use 24 hour
			clock
2.2		[Hours:minutes; 24-hour clock]	
3.3	Interviewer code		Each interviewer given codes starting from '1' to each of the
			team members
3.4	Interviewer initials		These should decided at the start
			of the study and used consistently (e.g. don't flip between 2/3
			alphabets
	First of all I would like to coll	ect some details about you and where	
	you live at present	-	
	Contact details		
4.1	Family name	[Surname]	
4.2	First name/middle name	[Forename/other name]	Forename followed by middle
			name if any
4.3	Current house address (if any)		This relates to person's current residence defined as place where
	[House No./Street/Locality]		the person spent most nights in
			the 12 months preceding the interview
			Interview
4.4	Place name		
-		[Name of Village/Town/City]	
4.5	PIN Code		6 digit postal information code; first digit can be 1-8
4.6	Sub-district		
4.0	Sub-district	[Tehsil/Taluk/Mandal//Municipality]	Names of sub-district vary according to state; these three
			cover the four states in the study,
			for other states prompt the subject by appropriate name (see list at
			the back)
4.7	District		
4.8	Nearest railway station		Railway station closest to the
	-		place and not the main junction.
4.9	Nearest big town		
		[In case of village only]	
4.10	State		Total 35, see list at the back if
		[Name of country if abroad]	unsure

4.11	Type of place	[1=Village; 2=Town; 3=Small city; 4=Large city]		Ask the subject; if unsure, negotiate on the basis of the definition provided; for large city, confirm from the list at the back if unsure (35 large cities); include urban outgrowths
4.12	2 Travelling by road or rail, total average journey time between this place and NIN [In completed hours]			One way total journey time
4.13	Census code			To be completed at base, leave blank
4.14	Home telephone number (landline)	(Area code] [Phone number]		Leave blank if no landline
4.15	Mobile number			Leave blank if no mobile number

	Now I would like to collect some personal inform		
	Personal details		
5.1	Age last birthday	[In completed years]	
5.2	Day of birth	[DD]	Put as 01 if unknown
5.3	Month of birth	[MM]	Put as 07 if unknown
5.4	Year of birth		Check that year of birth corresponds to age at last birthday
5.5	Sex	[1=Male; 2=Female]	
5.6	(a) How many brothers (alive) do you have?	[Enter 00 if None]	Only for alive brothers
	(b) How many sisters (alive) do you have?	[Enter 00 if None]	Only for alive sisters
	(c) What was your birth order in your family?	[Enter 00 if None]	Only for alive siblings
	(d) Do you have a twin brother or sister?	[1=Yes; 2=No]	
5.7	Current marital status	1=Never married 2=Married 3=Widow/widower 4=Separated/divorced	
5.8	If ever married:		
	(a) How old were you when you first started living with your spouse after your marriage?	[Age in completed years]	Do not ask for those with marital status 3 or 4 – leave blank
	(b) Does your spouse normally live with you now?	[1=Yes; 2=No]	Do not ask for those with marital status 3 or 4 – leave blank
5.9	How many (live) sons do you have?	[Enter 00 if None]	Only alive sons

5.10	How many (live) daughter	s do you have	e?		[Enter 00 if None]	Only alive brothers
	Primary occupation					
5.11	(a) Respondent:			(b) Spouse (if married):		Do not ask (b) if person unmarried
	1=At home doing housework	4= Student/ tra	aining		8=Skilled non-manual	If unsure, check with
	2=Unemployed, not seeking work: retired/ disabled	5=Unskilled manual 6=Se skilled manual		lemi-	9=Semi-Professional	job descriptions in table.
	3=Unemployed, seeking work	7=Skilled mar	nual		10=Professional	
5.12	Briefly describe your job:					Enter short description of person's job
	Highest educational level	attained				
5.13	(a) Respondent:			(b) S	pouse (if married):	Do not ask (b) if person unmarried
				econdary school (ITI course, class X/XII, rmediate)		
	2=Literate, no formal education 5=G		5=Gradu	Graduate (BA, BSc, BCom, Diploma)		
			6=Professional degree/postgraduate (MA, MSc, MBBS, MSW, BTech, PhD)			

	Now I am going to ask you some questions a	bout your household	COMMENTS
	Current household circumstances		Questions below refer to a
6.1	What kind of household do you currently live in?		household. It is important to define the household before proceeding with the following questions. A household is a group of people (related or unrelated) who live together and take their meals together from a common kitchen unless the exigencies of work prevent them from doing so. The key element is kitchen.
	<ul> <li>1=Single</li> <li>2=Hostel/shared accommodation</li> <li>3=Nuclear family (married couple &amp; offspring)</li> <li>4=Extended family (2 related married couples of different generations i.e. married couple with one of the parents)</li> </ul>	5=Joint family (two related married couples from same generation (i.e. two married siblings) 6=Joint-extended 7=Any other	A hostel here refers to any institutional household (group of unrelated persons taking their meal from a common kitchen). Persons living in a common building but not taking their meals from a common kitchen are classed as single/family type as appropriate. Common kitchen refers to joint cooking, not just sharing of a room used as kitchen).
6.2	What is the material used in the construction of the house?	1=Kutcha 2=Semi-pucca 3=Pucca	Kutcha (made from mud, thatch, or other low quality material); Semi-pucca (partly low quality and high quality material); Pucca (high quality material used throughout including roof, walls, floor)

6.3	What is the main source of lighting for your household?	1=Electricity 2=Kerosene 3=Gas 4=Oil 5=Other	For multiple sources, record the predominant one
6.4	What is the main source of drinking water for members of your household?	1=Pipe, hand pump, well (in residence/ plot) 2=Pipe, hand pump or well (public) 3=Other	For multiple sources, record the predominant one
6.5	What kind of toilet facility does the household have?	1=Own flush toilet 2=Own pit toilet/latrine 3=No facility/field/bush 4=Other	
6.6	Do you collect rations from a ration card?	[1=Yes; 2=No]	
	SKIP QUESTIONS 6.7-6.10 IF LIVING	IN HOSTEL/SHARED AC	COMMODATION
6.7	Including yourself, how many people normally live in your household?	[Number of People]	
6.8	How many rooms are there in your household? (count all rooms including kitchen, bathroom, etc)	[Number of Rooms]	Include rooms normally available for use to the person. In case of person living in a hostel with access to a shared kitchen, common room and bathroom, this number would be three.
6.9	Does this household own any agricultural land?	[1=Yes; 2=No]	In case of institutional household (hostel), complete only for that individual
6.10	Does the household own any of the following:		Availability for use (e.g. provided by the employer)
	(a) Clock/Watch	[1=Yes; 2=No]	should be regarded as yes.
	(b) Radio/Transistor/Tape recorder	[1=Yes; 2=No]	
	(c) Television	[1=Yes; 2=No]	
	(d) Bicycle	[1=Yes; 2=No]	
	(e) Motorcycle/scooter/moped	[1=Yes; 2=No]	
	(f) Car	[1=Yes; 2=No]	
	(g) Refrigerator	[1=Yes; 2=No]	
	(h) Telephone	[1=Yes; 2=No]	

## THE FOLLOWING SECTION IS ONLY FOR NUTRITION TRIAL PARTICIPANTS – the participants of the Indian Migrant Study were asked these questions at the previous phase

	Now thinking back to when yo answer the following question time ( <b>Only for nutrition trial</b> )	COMMENTS			
	Household circumstances in	childhood (at age	10-12 years)		
7.1	What was your father's occup	ation at the time?			
	1=At home doing housework				If unsure, check with job descriptions in table.
	2=Unemployed, not seeking work: retired/ disabled	5=Unskilled manual 6=Semi-skilled manual	9=Semi-Professiona 10=Professional	al	
	3=Unemployed, seeking work	7=Skilled manual	11=Died, left family	у	
7.2	What was the highest education	onal level attained by	y your mother?		
	1=Illiterate	4=Secondary school Intermediate)			
	2=Literate, no formal education	5=Graduate (BA, BS			
	3=Up to primary school (class IV)	6=Professional degree MBBS, MSW, BTec	ee/postgraduate (MA, 1 h, PhD)	MSc,	

## **ALL PARTICIPANTS**

	Now	I will ask you a few questions	about your health	and lifestyle			COMMENTS
	Heal						
8.1		(i) Have your ever used tobacco on a REGULAR basis (at least weekly)?	(ii)Age at starting	(iii) Duration of use	(iv) Number of days per week	(v) Number of use or smoked per day	Leave ii, iii, iv and v blank if answer to i is never
(a) Sm	oked	1=Never 2=Former (stopped ⊃6 months) 3=Current (in last 6 months)	[Yrs]	[Yrs]	[Days]		
(b) Ch	ewed	1=Never 2=Former (stopped ⊃6 months) 3=Current (in last 6 months)	[Yrs]	[Yrs]	[Days]		Ask specifically about paan masala and zarda as the subject may not be aware that it contains tobacco.
(c) Sn	uffed	1=Never 2=Former (stopped ⊃6 months) 3=Current (in last 6 months)	[Yrs]	[Yrs]	[Days]		

8.2	(a) Is there someone in your household who smokes tobacco at home? [If no, skip to 8.3]	[1=Yes; 2=No]		
	If yes, (b) How many cigarettes or bedis does this person smoke per day?	cigarettes per day	Do not include chewed or snuffed	
8.3	(a) Has an indoor open fire with wood, crop residues or dung been used in your home as a primary means of cooking for more than 6 months in your life? <b>[If no, skip to 8.4]</b>	[1=Yes; 2=No]		
	<i>If yes,</i> (b) For how many years has wood, crop residues or dung been used for cooking in your home?	[Years]	Leave blank if answer to a is no	
	(c) On average for how many hours a day have you personally spent cooking using wood, crop residues or dung?	[Hours] [00 if none]		
	(d) Is wood, crop residues or dung still used for cooking in your home?	[1=Yes; 2=No]		
	(e) Was your stove or fire vented to the outside?	[1=Yes; 2=No]		
8.4	Would you describe your present alcohol intake as?	□1=Daily/most days 2=Weekends only		
		3=1-2 times/month		

	Now I will ask you of read out a list of stor today.	<i>v 1</i>	COMMENTS	
	Quality of life			
9.1	Mobility		<ul> <li>1= I have no problems in walking around;</li> <li>2= I have some problems in walking around;</li> <li>3=I am confined to bed</li> </ul>	These questions refer to the subjects general health
9.2	Self care		<ul><li>1= I have no problems with washing and dressing myself;</li><li>2= I have some problems with washing or dressing myself;</li><li>3=I am unable to wash and dress myself</li></ul>	state. For each question read out each of the statements
9.3	Usual activities		<ul> <li>(e.g. work, study, housework, family or leisure activities)</li> <li>1= I have no problems with performing my usual activities;</li> <li>2= I have some problems with performing my usual activities;</li> <li>3=I am unable to perform my usual activities</li> </ul>	<u>exactly as they</u> <u>are written.</u>
9.4	Pain/discomfort		<ul> <li>1= I have no pain or discomfort;</li> <li>2= I have moderate pain or discomfort;</li> <li>3=I have extreme pain or discomfort</li> </ul>	
9.5	Anxiety/Depression		<ul> <li>1= I am not anxious or depressed;</li> <li>2= I am moderately anxious or depressed;</li> <li>3= I am extremely anxious or depressed</li> </ul>	
9.6	100 and the worst sta	te you ca	ich the best state you can imagine is marked un imagine is marked 0. Please indicate on this wn health is today, in your opinion 9/0	Show them the scale. We want to know how they rate their own health

	Now I will ask you questions relatin	g to y	our usual sle	ep patteri	ns.		COMMENTS
10.1	How many hours do you usually sleep per day (including sleep at night and during the day) on a typical day when you have school or work the next day?				half h	. [Completed ours]	Total hours slept at night with during day
10.2	How many hours do you usually sleep per day (including sleep at night and during the day) on a typical day when you <b>do not</b> have school or work the next day?				half hours]		Total hours slept at night with during day
10.3	(a) Do you undertake shift work tha sleep patterns?	undertake shift work that interrupts your usual			[1=Yes; 2=No]		
	(b) <i>If yes</i> , how often is the shift work (over the last month)?		1=Daily 2=5-6 times/week	3=2-4 times/we 4=Once a	•	5=2-3 times/month 6=Once a month	Leave blank is answer to a is no. Ask to recall over last month
10.4	In the past month, how often have you experienced difficulties in getting to sleep?		1=Daily 2=5-6 times/week	3=2-4 times/week 4=Once a week		5=2-3 times/month 6=Once a month 7=Never	Ask to recall over last month
10.5	In the past month, how often have you been bothered by awakening during night?		1=Daily 2=5-6 times/week	3=2-4 times/we 4=Once a			Ask to recall over last month

#### Physical activity questionnaire INSTRUCTIONS FOR COMPLETION OF PAQ

The physical activity questionnaire aims to assess the habitual physical activity of the individual, by ascertaining recall over the one week. For the rural participants for the Indian Migrant Study who have had to travel to Hyderabad, you should ask for recall from the day before travel to Hyderabad commenced.

#### PHYSICAL ACTIVITY QUESTIONNAIRE

Ask the subject, how many hours he/she spends working (Q1). This will be easy to ascertain if the person has regular working hours, as is the case with a factory worker on the shop floor. On the other hand executives may tend to work irregular hours and you may have to resort to asking them "On average, how many hours do you work?".

Once you have determined how many hours they spend at work, ask them how many hours they spend in 'standing', 'sitting', and 'walking'. Please use prompt by listing the sample activities provided under these headings in the questionnaire. The distribution of time spent, will depend on the occupation of the individual. Executives for instance may spend a substantial amount of their time sitting. Manual workers in a factory may spend substantial times 'walking' or on activities more strenuous than walking.

Ask whether the participant they participated in each activity listed under the category "more strenuous than walking". If they participated in the activity, record frequency and duration.

Now I am going to ask you questions about the time you spent doing different types of physical activity. Please recall the activities that you did in the **LAST WEEK**.

In case you travelled for a long duration to reach this place, or stayed back in this city for a few days, please recall the activities of the week before you left to this city.

The first questions are about your work/college. This includes paid jobs, working in your farm, study/training, any volunteer work or college activities.

Do not include unpaid work you might do around your home, like housework, garden work, and caring for your family. I will ask you about these later.

	Work related activity		
11.1	Do you currently have a job or do any not include household work, we will a	[1=Yes; 2=No] [ <b>IF NO, SKIP TO 11.8</b> ]	
11.2	How many days did you work at the j	[In completed days]	
11.3	In the last week, how many hours per		
			[In completed half hours]
	<b>v i</b>	a day during the last week I am going , walking and other strenuous activiti	2
	(a) <b>Standing:</b> E.g. talk, lab work, supervise, mild cleaning, cattle grazing done standing.	(b) <b>Sitting:</b> E.g. typing, computer work, cleaning grains, eating lunch, driving for your work, etc	(c) <b>Walking</b> : E.g. walking around, strolling, walking with light loads

	[hours]		[hours]	[hours]	
11.4	If you spend any time at work	on activities more strenu			
		(i) Took part in this activity	(ii) Days per week	(iii) Total duration per day	
	(a) Carrying/walking with loads (30-50 kgs)	[1=Yes; 2=No]	days	[mts]	
	(b) Carrying/walking with heavy load (>50 kgs)	[1=Yes; 2=No]	days	[mts]	
	(c) Lifting / loading of weights	[1=Yes; 2=No]	days	[mts]	
	(d) Pushing cart with a load	[1=Yes; 2=No]	days	[mts]	
	(e) Ploughing	[1=Yes; 2=No]	days	[mts]	
	(f)Digging	[1=Yes; 2=No]	days	[mts]	
	(g) Watering / weeding fields	[1=Yes; 2=No]	days	[mts]	
	(h) Cut / chop wood or stones	[1=Yes; 2=No]	days	[mts]	
	(i) Harvesting	[1=Yes; 2=No]	days	[mts]	
	(j) Any others?	[1=Yes; 2=No]			
	(k)		days	[mts]	
	(1)		days	[mts]	
	(m)		days	[mts]	
	<b>Travel to and from work</b> Now think about how you travel travelling activities if you have	v			
			(a) Days per week	(b) Total duration per day	
11.5	During the last week, how many vehicle, like a car, bus, auto-rick work?			[mts]	
11.6	During the last week, on how m work?	any days did you cycle to a	and from days	[mts]	
11.7	During the last week, on how m work?	any days did you walk to a	nd from days	[mts]	

	<b>Travel apart from to and from work</b> Now think about how you travelled from place to place over the LAST WEEK, including places like stores, movies, visiting relatives etc but excluding to and from work. Please do not include travelling activities if you have already mentioned.								
				(a) Days per week	(b) Total duration per day				
11.8	During the last week, how many of motorised vehicle, like a car, bus, except to and from work?			days	[mts]				
11.9	During the last week, on how man a bicycle except to and from work		laces on	days	[mts]				
11.10	During the last week, on how man places by walking except to and f		ivel to	days	[mts]				
			4	diana and fact					
	Now I am going to ask you some of home over the LAST WEEK	questions about now you sp	pent your	time, apart froi	m work outside of the				
11.11	<b>Sports / games / exercise</b> Now think about all the physical of leisure. Please do not include any	•			port, exercise of				
	Name of activity	(i) Took part in this (ii) Da activity		s per week	(iii) Total duration per day				
	(a) Walking normal speed for leisure	[1=Yes; 2=No]	da:	ys	[mts]				
	(b) Walking brisk speed for leisure	[1=Yes; 2=No]		ys	[mts]				
	(c) Jogging/Running	[1=Yes; 2=No]	day	ys	[mts]				
	(d) Badminton	[1=Yes; 2=No]		ys	[mts]				
	(e) Cricket	[1=Yes; 2=No]		ys	[mts]				
	(f) Yoga	[1=Yes; 2=No] da		ys	[mts]				
	(g) Swimming	[1=Yes; 2=No] da		ys	[mts]				
	(h) Football	[1=Yes; 2=No]	da <u>y</u>	ys	[mts]				
	(i) Volleyball	[1=Yes; 2=No]	day	ys	[mts]				
	(j) Any others?	[1=Yes; 2=No]							

(k)	days	[mts]
(1)	days	[mts]
(m)	days	[mts]

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11.12	2 Household activities								
	Now think about activities you a include any activities already m		ork, gardening and	d hobbies. Please do not					
	Name of activity	(i) Took part in this activity	(ii) Days per week	(iii) Total duration per day					
	(a) Cooking	[1=Yes; 2=No]	days	[mts]					
	(b) Washing vessels	[1=Yes; 2=No]	days	[mts]					
	(c) Mopping	[1=Yes; 2=No]	days	[mts]					
	(d) Sweeping	[1=Yes; 2=No]	days	[mts]					
	(e) Wash clothes manually	[1=Yes; 2=No]	days	[mts]					
	(f) Dusting / cleaning	[1=Yes; 2=No]	days	[mts]					
	(g) Ironing and folding clothes	[1=Yes; 2=No]	days	[mts]					
	(h) Child care	[1=Yes; 2=No]	days	[mts]					
	(i) Collecting fuel/fodder/water	[1=Yes; 2=No]	days	[mts]					
	(j) Animal care	[1=Yes; 2=No]	days	[mts]					
	(k) Gardening	[1=Yes; 2=No]	days	[mts]					
	(1) Any others?	[1=Yes; 2=No							
	(m)		days	[mts]					
	(n)		days	[mts]					
	(0)		days	[mts]					

11.13	Sedentary activities								
	The last question is about time spe Please do not include any activitie	e	ys. Do not includ	e time spent sitting at work					
	Name of activity	(i) Took part in this activity	(ii) Days per week	(iii) Total duration per day					
	(a) Reading for leisure	[1=Yes; 2=No]	days	[mts]					
	(b) Computer/computer games/internet for leisure	[1=Yes; 2=No]	days	[mts]					
	(c) Watching TV/ movies	[1=Yes; 2=No]	days	[mts]					
	(d) Indoor games (e.g. chess, carom, playing cards)	[1=Yes; 2=No]	days	[mts]					
	(e) Prayer/meditation	[1=Yes; 2=No]	days	[mts]					
	(f) Listening to music/radio	[1=Yes; 2=No]	days	[mts]					
	(g) Sewing/embroidery/knitting	[1=Yes; 2=No]	days	[mts]					
	(h) Socialising (talking outside working hours or on phone)	[1=Yes; 2=No]	days	[mts]					
	(i) Any others?	[1=Yes; 2=No]							
	(j)		days	[mts]					
	(k)		days	[mts]					
	(1)		days	[mts]					

## FOOD FREQUENCY QUESTIONNAIRE

### **INSTRUCTION TO SUBJECT:**

I am now going to ask you about the food that you have eaten over the last year. If you have not heard of an item please answer "No".

	CEREALS	Portion Size	(a) Average consumption	(b) Per Day <sup>1</sup>	(b) Per Week <sup>2</sup>	(b) Per Month <sup>3</sup>	(b) Per Year/ Never <sup>4</sup>
12.1	Chapathis / roti	No					
12.2	Parathas / naan	No					
12.3	Jowar roti	No					
12.4	Poori, bhatura	No					
12.5	Plain rice	Bowl					
12.6	Mutton, chicken biriyani	Bowl					
12.7	Lime rice, puliogare, veg biriyani	Bowl					
12.8	Bhagar	Bowl					
12.9	Upma	Bowl					
12.10	Idlis	No					
12.11	Dosa / uthappam	No					
12.12	Pesarattu	No					
12.13	Attakalu	Bowl					
12.14	Rice, ragi porridge	Bowl					
12.15	Corn flakes	Bowl					
12.16	Bread, Toast, Rolls, Buns	No					
12.17	Noodles, pasta etc	Bowl					
	LENTILS / DHALS / GRAVIES						
13.1	Plain dhal sambar	Ladle					
13.2	Dhal sambar with vegetables	Ladle					
13.3	Channa, rajma, dry peas etc. curry	Ladle					
13.4	Green leafy vegetable curry	Ladle					
13.5	Rasam, all types	Ladle					

	CHUTNEYS / SALAD / PAPAD				
14.1	Raw vegetable salad	Tbsp			
14.2	Vegetable Raitha	Tbsp			
14.3	Pickle	Tsp			

		Portion Size	(a) Average consumption	(b) Per Day1	(b) Per Week2	(b) Per Month3	(b) Per Year/ Never4
14.4	Papad	No					
14.5	Coconut chutney	Tbsp					
14.6	Groundnut chutney	Tbsp					
14.7	Tomato chutney	Tbsp					
	NON – VEGETARIAN						
15.1	Chicken curry	Bowl					
15.2	Chicken fry/grilled	No					
15.3	Mutton/ pork/beef curry or fry	Bowl					
15.4	Fish curry	Bowl					
15.5	Fish fry	No					
15.6	Organ meats (Liver, brain, kidney etc.)	Tbsp					
15.7	Prawn, crab, shell fish etc.	Bowl					
15.8	Egg (boiled, poached, omelettes)	No					
	MILK & BEVERAGES						
16.1	Tea	Glass					
16.2	Coffee	Glass					
16.3	Plain milk	Glass					
16.4	Flavored milk (horlicks, bournvita etc)	Glass					
16.5	Curds	Bowl					
16.6	Buttermilk/Lassi	Glass					
16.7	Lime/ orange/ other fresh fruit juice	Glass					

16.8	Fanta, pepsi, coca cola etc.	250ml bottle			
16.9	Beer	Bottle			
16.10	Spirits (whiskey, gin, rum, arrack)	30ml peg			
16.11	Other local alcoholic drinks	30ml peg			
	MISCELLANEOUS				
17.1	Ghee/ butter	Tsp			
17.2	Jam	Tsp			

		Portion Size	(a) Average consumption	(b) Per Day1	(b) Per Week2	(b) Per Month3	(b) Per Year/ Never4
17.3	Sugar	Tsp					
17.4	Cheese	Cube					
	SNACKS/ SWEETS/DESSERTS						
18.1	Mixture, namkeen, chiwda, khara boondi, dalmoth	Tbsp					
18.2	Vada, all types	No					
18.3	Nuts (grounduts, cashewnuts etc.)	Tbsp					
18.4	Chips/salted packed snacks (bingo, kurkure etc)	Bowl					
18.5	Samosa,bajji ,bonda, cutlet, patties	No					
18.6	Salted biscuits (krackjack, bakery biscuits)	No					
18.7	Sweet biscuits (Marie/goodday/cream biscuits)	No					
18.8	Murukku , chakli, sakinalu	No					
18.9	Cakes or sweet pastries	No					
18.10	Payasam, kheer	Bowl					
18.11	Ice cream	Bowl					
18.12	Jamoon, Jilebi, Jangir etc.	No					
18.13	Mysore pak, ladoo, barfis	No					

18.14	Baksham	No			
18.15	Dried fruits (dates, figs, raisins etc)	Tbsp			
18.16	Chocolates	Small Bar			

	FRUITS	Portion size	(a) Average consumption	(b) Per Day <sup>1</sup>	(b) Per Week <sup>2</sup>	(b) Per Month <sup>3</sup>	(b) Per Year/ Never <sup>4</sup>	(c) Seasonal (cross if seasonal)
19.1	Banana	No						
19.2	Apple	No						
19.3	Orange	No						
19.4	Mango	No						
19.5	Guava (amrood)	No						
19.6	Grapes (angoor)	Bowl						
19.7	Pineapple	Slice						
19.8	Papaya ( papita)	Slice						
19.9	Pomegranate ( anar)	No						
19.10	Sapota ( Chikoo)	No						
19.11	Watermelon (tarbooj)	Bowl						
19.12	Musk melon ( kharbooj)	Bowl						
19.13	Custard apple	No						
19.14	Zizyphus (ber)	No						
19.15	Sugarcane (ganaa)	Pieces						
19.16	Palmyra	No						
	VEGETABLES							
20.1	Palak, methi, other leafy vegetables	Tbsp						
20.2	Potato, sweet potato	Tbsp						
20.3	Beetroot/ radish	Tbsp						
20.4	Cabbage	Tbsp						
20.5	Beans, cluster beans	Tbsp						
20.6	Ladies finger	Tbsp						
20.7	Cauliflower	Tbsp						

20.8	Bottlegourd (lauki), ashgourd, Ridgegourd (turai), snakegourds, etc.	Tbsp											
20.9	Brinjal	Tbsp											
20.10	Kovai	Tbsp											
20.11	Capsicum/ green pepper	Tbsp											
20.12	Drumstick	Pieces											
20.13	Raw plantain	Tbsp											
20.14	Colacasia (arvi)	Tbsp											
21.1	Which type of oil is consumed most by your family?			4=Palı 7=But		5=Mus 8=Ghe	undnut oil tard oil e ce bran oil	3=Cocon 6=Dalda/ 9=Olive o 12=Soya	vanaspathi oil				
21.2	How many coconuts do you use for cooking in a month?			[No	/ month]	[00 i	f none]						
21.3	(a) What type of mirregularly consume?	a) What type of milk do you egularly consume?			1=Whole milk4=Skimmed milk per2=Skimmed milk5=Whole and toned3=Toned milk6=Other								
	(b) If other, then specify_												
21.4	(a) Do you consume any v	vitamin or r	nineral su	ppleme	nt at leas	st once a v	veek?	[1=Yes; 2	2=No]				
	<i>If Yes</i> , (b) <b>Brand name</b> /			(c) Dosage(mg)			(d) No. / week						
					<u> </u>								
21.5	Are you vegetarian?			[1=Yes]	; 2=No]								
21.6	Are you on any of the foll	owing spec	ial diets?	Il diets?									
	(a) Diabetic diet			[1=Yes; 2=No]									
	(b) Low fat diet			[1=Yes]	; 2=No]								
	(c) High fiber diet			[1=Yes]	; 2=No]								
	(d) Low salt diet			[1=Yes; 2=No]									
	(e) Weight reducing diet			[1=Yes; 2=No]									
	(f) Other			[1=Yes; 2=No]									
	(g) If other, please specify	7											
	(g) if other, preuse speens	·	(h) <i>If yes</i> , Since how many years are you on this special [completed years]										

#### **INSTRUCTIONS FOR COMPLETION OF FFQ**

The aim of the questionnaire is to obtain the average food intake of an individual over a one year period.

The questionnaire, after entry into a computer, will provide details of consumption of various nutrients – energy, carbohydrates, fat, proteins, vitamins and minerals. Entry of each food item correctly is essential as different foods provide different nutrients. Please use the portion size provided as they guide the subject in reporting the quantity he / she consumes.

#### COMPONENTS OF THE QUESTIONNAIRE:

The questionnaire comprises two components:

- 1. A food list of 98 food items
- 2. A set of questions about diet.

#### FOOD LIST

The food items are grouped under the following headings to help the subject recall the foods better:

- Cereals
- Lentils/Dhals/Gravies
- Chutneys / salad/ papad
- Non-vegetarian
- Milk and Beverages
- Miscellaneous
- Snacks / sweets/ desserts
- Fruits
- Vegetables

#### **DIET RELATED QUESTIONS:**

This comprises a set of questions aimed at eliciting further information on the food pattern of an individual. Information on the type of oil used for cooking of food, coconuts used for cooking, type of milk used, usage of vitamins and mineral tablets/capsules and any special diet adhered to are recorded in this section.

#### **ADMINISTERING THE QUESTIONNAIRE:**

Please familiarise yourself with the food frequency questionnaire before administering it.

#### **INTERVIEWING THE SUBJECT:**

# Some of the food items may not be familiar to the subject. If the subject is not aware of the food item, please proceed to the next item in the list.

Please place the standard serving sizes e.g. katori etc. in front of the subject before you start the food frequency questionnaire. This will help the subject to estimate the food quantities that he/she is reporting.

#### **PORTION SIZES:**

Standard serving measure with volumes

Bowl = 220ml Glass = 125 ml Teaspoon = 5 ml Tablespoon - 10 ml Ladle = 56 ml

Inform the subject before beginning the questionnaire:

"We are doing this study at a national level and there may be several food items in the list that you may not have heard of but are eaten in other places .If we name an item you have not heard please answer'no'so that we proceed to the next question.

Then proceed to ask the questions and make entries in the method specified below to obtain and document information in the **food frequency** questionnaire:

- Ask the subject if they consume each of the food items listed in the questionnaire. For instance, "Do you consume chapathis?" If yes,
- Ask the subject "During the past one year, how often have you consumed this? Daily, weekly or monthly?" ...... If daily,
- Ask "On average how many times would you consume chapathis each day?" If the answer is two times (twice), enter '2' under the "Per Day" column.
   This provides the 'frequency of consumption' of the food item.
- 4. Then ask, "How many chapathis on average do you eat each time?" .... If the answer is '3', enter '3' under the "Average consumption" column. This example is illustrated below:

CEREALS	Portion size	(a) Average consumption	(b) Per Day	(c) Per Week	(d) Per Month	(e) Per Year / Never
Chapathis/parath as/naan	No	3	2			

This is the 'average intake' of the food item.

# 5. If there are any foods that a subject does not consume, enter, '0' under the "average consumption" column and '0' in the "Per Year/ Never" column (two entries).

For example if a person never eats Pizza's or Burgers, the entry would be as shown below:

CEREALS	Portion size	(a) Average consumption	(b) Per Day	(c) Per Week	(d) Per Month	(e) Per Year / Never
Pizza, Burger	No	0				0

## PLEASE NOTE, THEREFORE, THAT EVERY LINE MUST HAVE AN ENTRY

6. When the subjects reports an average portion size as:

2 to 3 chapathis

Record as  $2\frac{1}{2}$  chapathis and NOT 2-3 or 2.5

If for example an individual reports that they have 2-3 chapathis twice a day, your entry will be:

CEREALS	Portion size	(a) Average consumption	(b) Per Day	(c) Per Week	(d) Per Month	(e) Per Year / Never
Chapathis	No	21/2	2			

- 7. For Miscellaneous foods, ask the subject if they add these foods on the table. For instance,
  - Butter, jam, cheese added to bread or toast would come under this category as would tomato sauce added to food on the table
  - Ghee added to rice or other food at the table would come under this category. However, ghee added during preparation/cooking as for instance during the preparation of sweets would not come under this category.
  - For sugar, the amount of additional sugar added to a glass of tea/ coffee or milk at the table is considered. If the subject reports that no sugar is added enter '0'.
    - a. For this reason ask "Do you add additional sugar to tea and coffee. If the answer is YES,
    - b. Ask "How much for each glass?" If the answer is "2 teaspoons"
    - c. enter '2' under the "Average consumption" column,
    - d. *if a person has 1 glass of tea twice a day, and 1 glass of coffee twice a day, enter '4' for the total number of times sugar is added to beverages per day under the "Per day" column.* Enter this information as indicated below:

e.

MISCELLANEOUS	Portion size	(a) Average consumption	(b) Per Day	(c) Per Week	(d) Per Month	(e) Per Year / Never
			-			Never

Sugar	Tsp	2	4			
N	1 1		1 1	1 1	1	

8. For foods where multiple items are listed, ask the individual how often they consume all these foods *For example,* "Lime rice, puliogare, curd rice, veg biriyani".

If the subject reports that he eats one bowl of lime rice once a week and one bowl of veg biriyani once a week

record as '2' under the 'Per Week' column (i.e. both Lime rice and veg biriyani together)

CEREALS	Portion Size	(a) Average consumption	(b) Per Day	(c) Per Week	(d) Per Month	(e) Per Year / Never
Lime rice, puliogare, veg biriyani.	Bowl	1		2		

- 9. Use general items where ever specific foods are not mentioned. For instance, coconut biscuits, cream biscuits will be entered under "sweet biscuits". Similarly, groundnuts, cashew nuts and other type of nuts will be entered under "nuts".
- 10. If individuals consume a combination of preparations eg. paneer mutter masala OR mixed groundnut and coconut chutney, enter the food under that item which is in greater proportion.
- 11. For fruits and vegetables ask the subject if they consume that food only in season or year round. If seasonal put a cross for the item in the appropriate column.

For example if a person eats one banana a day throughout the year and 1 apple a day when apples are in

season, your entry will be:

FRUIT	Portion size	(a)Average consumption	(b)Per Day	(c) <b>Per</b> Week	(d)Per Month	(e)Per Year / Never	(f) Seasonal ( cross if seasonal)
Banana	No	1	1				
Apple	No	1	1				

## AVERAGE PORTION SIZES OF FOODS NOT LISTED IN THE QUESTIONNAIRE:

## If individuals report consumption of foods below regularly, use the measure provided below.

1 big (hotel) idli = 1 ½ servings of medium size idli
1 set dosa = 1 ¼ servings of dosa
1 bhatura = 1 ½ servings of medium size poori
1 small ragi ball = ½ serving of a medium size ball
1 bun = 4 servings of bread slices
50 gms mixture/ namkeen = 3 servings of 1 tbsp mixture
1 bakery sweet / salt biscuit OR Cream Biscuit OR Cookie = 1 ½ serving of sweet/salt biscuits
1 small banana = ½ serving of medium banana
1 cup vegetables = 8 servings of vegetables in tablespoons
1 peg = 30 ml (made up to 1 glass with water or soda)
1 large peg = 45 ml (made up to 1 glass with water or soda) = 1 ½ 30 ml peg

## FOOD LIST DESCRIPTIONS:

All the food items listed in the food list in the FFQ have been described in the following section, so that the interviewers understand the foods items listed. All food items have been listed and described in the same order listed in the questionnaire.

#### **CEREALS:**

- 12.1 <u>Chapathis/roti:</u> Refers to those Indian breads made of wheat flour prepared on a tawa without oil.
- 12.2 <u>Parathas/naan:</u> Refers to all types of Indian breads and parathas with added oil, prepared on a tawa.
- 12.3 Jowar roti: Indian rotis made with jowar flour
- 12.4 <u>Poori, bhatura</u>: Refers to Indian breads fried in oil.
- 12.5 <u>Plain rice:</u> Cooked raw/parboiled rice.
- 12.6 <u>Mutton, chicken pulao/ biriyani</u>: Includes all non-vegetarian fried rice.
- 12.7 <u>Lime rice, puliogare, veg biriyani</u>: refers to rice based preparations that are seasoned and/or flavored in oil. Included are foods such as vangi bath, tamarind rice, coconut rice, fried rice with vegetables (veg biriyani) etc.
- 12.8 <u>Bhagar</u> : Recipe containing rice cooked with potato and tomato.
- 12.9 <u>Upma</u>: Prepared with rava (sooji)/vermicelli/rice cooked with seasonings with or without vegetables.
- 12.10 Idlis: Steamed preparation made with batter of rice/ vermicelli/rava and black gram (urad) dhal.
- 12.11 <u>Dosa, uthappam</u>: Indian pancake made with the batter of rice/rava/wheat flour/rice flour with or without dhal (mainly black gram dhal). Includes rava dosa, set dosa, dosa with filling etc.
- 12.12 <u>Pesarattu</u>: Indian pancakes made on tawa with a batter of green gram (moong) dhal and spices.
- 12.13 Attakalu: Prepared with beaten rice seasoned with a little oil.
- 12.14 <u>Rice, ragi porridge</u>: Porridge (kanji) made with rice or ragi, without milk
- 12.15 <u>Corn flakes</u>: Includes cornflakes consumed with milk.

- 12.16 <u>Bread, Toast, Rolls, Buns</u>: Refers to all types of breads, buns, rolls etc. plain, toasted, sandwiched, or grilled.
- 12.17 <u>Noodles, pasta etc</u>: Includes the ready-to-use (e.g. Top Ramen, Maggi, Pasta Treat etc) and prepared vegetarian and non-vegetarian noodles and macaroni and other pastas.

## LENTILS / DHALS / GRAVIES

13.1 <u>Plain dhal sambar</u>: Refers to sambar or dhal prepared with red gram dhal (tur dhal) **without** any vegetables.

- 13.2 <u>Dhal with vegetables</u>: Refers to sambar or dhal prepared with red gram dhal (tur dhal) with vegetables.
- 13.3 Channa, rajma, dry peas etc. curry: Refers to curry prepared with any whole gram/pulses.
- 13.4 <u>Green leafy vegetable curry</u>: Refers to any gravy preparation that includes any green leafy vegetable such as amaranth, palak, etc., with or without dhal.
- 13.5 <u>Rasam, all types</u>: Refers to all types of rasam e.g. tamarind and tomato rasam.

## CHUTNEYS / SALAD / PAPAD

- 14.1 Raw vegetable salad: All types of fresh salad prepared with one or more vegetables (e.g. cucumber, carrots, lettuce, onions, tomato etc)
- 14.2 Vegetable Raitha: Prepared with vegetables (e.g. onions, tomatoes, cucumber etc) and fresh curds.
- 14.3 Pickle: Includes all types of pickles used.
- 14.4 Papad: Refers to papads fried in oil. Papads are thin crisp sun-dried disc shaped wafers of dhal or cereal flour.
- 14.5 Coconut chutney: Refers to chutneys prepared with mainly coconut.
- 14.6 Groundnut chutney: Refers to chutney prepared with mainly groundnut.
- 14.7 Tomato chutney: Refers to chutney prepared with mainly tomato.

## NON – VEGETARIAN

- 15.1 <u>Chicken curry</u>: Refers to chicken prepared in gravy from.
- 15.2 <u>Chicken fry/grilled</u>: Chicken fried or grilled form.
- 15.3 <u>Mutton/ pork/beef curry or fry</u>: Refers to all red meats in gravy form, fried or grilled form.
- 15.4 Fish curry: Refers to fish prepared in gravy from
- 15.5 Fish fry: Fish fried or grilled form
- 15.6 <u>Organ meats (Liver, brain, kidney etc.</u>): Refers to preparations containing these organs.
- 15.7 <u>Prawn, crab, shell fish etc.</u>: Preparations made with prawn, crab, shrimp or any shell fish.

15.8 <u>Egg (boiled, poached, omelettes</u>): Eggs prepared in any form – boiled, fried, poached, omelette, egg gravy, scrambled.

## MILK & BEVERAGES

- 16.1 <u>Tea</u>: Refers to tea prepared with milk.
- 16.2 <u>Coffee</u>: Refers to coffee prepared with milk.
- 16.3 <u>Plain milk</u>: Refers to plain milk with sugar without any other additions.
- 16.4 <u>Flavored milk (horlicks, bournvita etc</u>): Refers to milk with additions/supplements such as bournvita, milo, cocoa, horlicks, badam milk, milk shake etc.
- 16.5 <u>Curds</u>: Fermented milk

- 16.6 <u>Buttermilk/Lassi</u>: Diluted beaten curds with or without seasonings.
- 16.7 <u>Lime/ orange/ other fresh fruit juice:</u> Refers to any fresh fruit juice.
- 16.8 <u>Fanta, pepsi, coca cola etc.</u>: Refers to all aerated soft drinks available in bottles or cans.
- 16.9 <u>Beer</u>: Includes all forms of beer such as draught beer, etc.
- 16.10 Spirits (whiskey, gin, rum): Includes all other alcoholic beverages such as rum, whisky, vodka etc.
- 16.11 <u>Other local alcoholic drinks</u>: Refers toddy/arrack or any other locally available fermented alcohol taken from palm tree or any other source.

## MISCELLANEOUS

- 17.1 <u>Ghee/ butter</u>: Refers to the addition of ghee or butter to any foods while eating (e.g. bread with butter, ghee with rice, idly etc.)
- 17.2 Jam: Includes all jams and marmalades (e.g. Kissan)
- 17.3 <u>Sugar</u>: Refers to additional sugar added to tea or coffee regularly.
- 17.4 <u>Cheese</u>: Refers to any cheese taken (Amul, Britannia etc.)

## SNACKS/ SWEETS/DESSERTS

- 18.1 <u>Mixture, namkeen, chiwda, khara boondi, dalmoth</u>: Refers to all deep-fried salted snacks prepared from besan and cereal flour.
- 18.2 <u>Vada, all types</u>
- 18.3 <u>Nuts (grounduts, cashewnuts etc.)</u>: Includes all nuts such as groundnuts (moongphali, kadalekayi), badam, cashewnuts, pista, walnut (akrut) etc.
- 18.4 <u>Chips/ salted packed snacks (bingo, kurkure etc)</u>: Includes all types of chips and French fries.
- 18.5 <u>Samosa, bajji</u>, <u>bonda</u>, <u>cutlet</u>, <u>patties</u>: Includes all deep-fried items with potatoes and/or vegetables dipped in batter or filled in a dough.
- 18.6 <u>Salted biscuits (krackjack, bakery biscuits)</u>: Refers to all forms of salted biscuits such as krackjack, monaco, bakery salt biscuits etc.
- 18.7 <u>Sweet biscuits (Marie/goodday/cream biscuits)</u>: Refers to all forms of sweet biscuits such glucose biscuits, marie, coconut, cookies, cream biscuits etc.
- 18.8 <u>Murukku, chakli, sakinalu</u>: Refers to deep fried savories prepared with any dhal and/or cereal flour made into a dough and fried in different shapes (usually rounds or circles)
- 18.9 <u>Cakes or sweet pastries</u>: Includes all cakes plain or cream- and pastries like Black Forest etc.
- 18.10 <u>Payasam, kheer</u>: A sweet dish with cereal (sometimes with or without dhal) cooked in milk.
- 18.11 Ice cream: Refers to all ice creams
- 18.12 Jamoon, Jilebi, Jangir etc.: Refers to all fried sweet preparations dipped in sugar syrup.
- 18.13 <u>Mysore pak, ladoo, barfis</u>: Refers to all Indian besan and/or cereal based sweet preparations shaped into small squares/rectangles or round balls.
- 18.14 <u>Baksham</u>: Sweets prepared using cereal and/or dhal flour.
- 18.15 Dried fruits (dates, figs, raisins etc): Refers to all dried fruit
- 18.16 <u>Chocolates</u>: Includes all chocolates available in the market.

## FRUITS

- 19.1 Banana
- 19.2 <u>Apple</u>
- 19.3 <u>Orange</u>
- 19.4 <u>Mango</u>
- 19.5 Guava (amrood): Amrood, Seebe, Peru, Jami pandu

- 19.6 Grapes (angoor): Angoor, draksha
- 19.7 <u>Pineapple</u>: Ananas
- 19.8 Papaya (papita)
- 19.9 <u>Pomegranate (anar)</u>: Anar, Dalimbari, Danimma pandu
- 19.10 Sapato (chikoo)
- 19.11 <u>Watermelon (tarbooj)</u> : Tarbooj, Kallangadi, Puchakayi
- 19.12 Musk melon (kharbooj) : Kharbooj
- 19.13 Custard apple: Seethaphal
- 19.14 Zizyphus (ber): Bor, Ber, Regu pandu
- 19.15 <u>Sugarcane (ganaa)</u>
- 19.16 Palmyra: Tar, Thati nungu, Thati pandu

#### VEGETABLES

20.1 <u>Palak, methi, other leafy vegetables</u>: Sag/ soppu. green leafy vegetables.

Includes all types of locally available

- 20.2 Potato, sweet potato
- 20.3 <u>Beetroot/ radish/ knol-khol</u>: Includes beetroot, radish/turnip/mooli/shaljam, knol-khol
- 20.4 <u>Cabbage</u>
- 20.5 Beans, cluster beans: Includes French beans/semifalli, cluster beans/gowarfalli, broad beans/avarakkai
- 20.6 Ladies finger: Okra/ bhendi/ benda kayi/ bende kayi.
- 20.7 Cauliflower
- 20.8 <u>Bottlegourd(lauki),ashgourd,Ridgegourd(turai), snakegourds, etc</u>.: Includes all gourds like bottle gourd/dudhi/sorekai/kaddu/ sorekayi, ashgourd/petha/budagumbala kayi, ridge gourd/turai/heeraikayi, beera kayi, snake gourd/padavala, bitter gourd/karela/hagal kayi/kakara kayi.
- 20.9 <u>Brinjal</u>
- 20.10 <u>Kovai</u>
- 20.11 Capsicum or green pepper
- 20.12 Drumstick: Mungana phalli
- 20.13 Raw plantain
- 20.14 Colacasia (arvi): Colacasia/arvi/samagadde/chama dumpa

#### ENTRY OF RESPONSES FOR THE QUESTIONS (QUESTIONS 21.1 to 21.8):

- 21.1. Record the type used most often for the whole family.
- 21.2. Only number of coconuts used for the family per month is to be entered.
- 21.3. Definition of the different milks available:

Whole Milk

Includes all fresh milk given by vendors and supplied by milk booths. Whole milk can be only cow's milk OR milk with a combination of cow's milk and buffalo milk OR buffalo milk. It also includes whole milk powders and long life milk available in the market.

Products available:

Red packet government dairy milk Heritage Jersey Nestle, Amul and Vijaya liquid whole milk and whole milk powder

Skimmed milk

Includes whole milk from which cream has been removed at home and the liquid skimmed milk available in the market.

Products available:

Nestle and Amul skimmed milk Blue packet government milk

#### Toned milk

Includes dried skim milk added to a high –fat milk such as buffalo milk ,to reduce the fat content but maintain the total solids.

Products available:

Green packet government dairy milk

#### <u>Skim milk powder</u>:

## Products available:

Sagar non fat milk powder . Anikspray Milk man dairy whitener (Britannia)-18% fat Milkana –19% fat Amulya dairy whitener – 20 g fat

- 21.4 Vitamins and mineral tablets or capsules if taken should be documented. 1=yes and 2=no. If yes, details of the tablet/capsule taken should be documented.
- 21.5 Record if the subject perceives himself/herself to be a vegetarian.
- 21.6 This question is for people who have consciously adopted a diet that is different from their normal household diets for health or personal reasons.

a-e: If any special diets are taken, for example low fat diet, diabetic diet etc, then it should be documented as '1'=yes and '2' = no.

f: Any other diet apart from that listed in question12.10 is entered here.

h: The number of years the subject is on this type of diet is documented.

## **MEDICAL HISTORY**

	Now I am going to ask you history	COMMENTS		
	Medical history			
22.16	Is your father still alive?	(a) [1=Yes; 2=No] (b) <i>If no, his a</i> [years]	ge at death	Leave b blank if a is no.
22.17	(a) <i>If no</i> , what was the cause of his death?	disease pressure	=stroke 4=lung =other 8=don't know	Leave blank is father still alive
	(b) If "other" specify:			
	Did/does your father suffe	r from any of the following?		
22.18	Diabetes	[1=Yes; 2=No; 3=Don't know]		
22.19	High blood pressure	[1=Yes; 2=No; 3=Don't know]		
22.20	Heart disease	[1=Yes; 2=No; 3=Don't know]		
22.21	Overweight/obesity	[1=Yes; 2=No; 3=Don't know]		
22.22	Lung disease	[1=Yes; 2=No; 3=Don't know]		
22.23	Is your mother still alive?	(a) [1=Yes; 2=No] (b) <i>If no</i> , her a [years]	age at death	Leave b blank if a is no.
22.24	(a) <i>If no</i> , what was the cause of his death?	disease pressure	=stroke 4=lung =other 8=don't know	Leave blank is mother still alive
	(b) If "other" specify:			
	Did/does your mother suff	er from any of the following?		
22.25	Diabetes	[1=Yes; 2=No; 3=Don't know]		
22.26	High blood pressure	[1=Yes; 2=No; 3=Don't know]		
22.27	Heart disease	[1=Yes; 2=No; 3=Don't know]		
22.28	Overweight/obesity	[1=Yes; 2=No; 3=Don't know]		
22.29	Lung disease	[1=Yes; 2=No; 3=Don't know]		
	Did/do any of your brother	rs or sisters suffer from any of the following?		Answer for any
22.30	Diabetes	[1=Yes; 2=No; 3=Don't know; 4=no br	others]	brothers or sisters.
22.31	High blood pressure	[1=Yes; 2=No; 3=Don't know; 4=no br	others]	-
22.32	Heart disease	[1=Yes; 2=No; 3=Don't know; 4=no br		-
22.33	Overweight/obesity	[1=Yes; 2=No; 3=Don't know; 4=no br		
22.34	Lung disease	[1=Yes; 2=No; 3=Don't know; 4=no br	others]	
23.1	(a) Have you had wheezin the last year?	g or whistling in your chest at any time in	[1=Yes; 2=No]	These questions try to assess whether
	<i>If yes,</i> (b) In the last year have yo you have a cold?	ou had this wheezing or whistling only when	[1=Yes; 2=No]	the participant has asthma.

(c) In the last year have you ever had an attack of wheezing or whistling that has made you feel short of breath?

[1=Yes; 2=No]

# **INDIAN MIGRANT STUDY PARTICIPANTS ONLY.** The participants from the Hyderabad Nutrition Trial are too young to have these conditions.

24.1	(a) Do you usually cough when you don't have a cold? [If no, skip to 24.2]	[1=Yes; 2=No]	COMMENTS
	If yes	[] [1=Yes; 2=No]	Skip if answer to a is no
	(b) Are there months when you cough most days		a 15 110
	(c) Do you have a cough on most days for as much as three months each year?	[1=Yes; 2=No]	
	(d) For how many years have you had this cough?	[Years]	
24.2	(a) Do you usually bring up phlegm from your chest, or do you usually have phlegm in your chest that is difficult to bring up when you don't have a cold? <b>[If no, skip to 24.3]</b>	[1=Yes; 2=No]	
	<i>If yes,</i> (b) Are there months in which you have this phlegm on most days?	[1=Yes; 2=No]	Skip if answer to a is no
	(c) Do you bring up this phlegm on most days for as much as 3 months per year?	[1=Yes; 2=No]	
	(d) For how many years have you had this phlegm?	[Years]	
24.3	(a) Are you unable to walk due to a condition other than shortness of breath? [ <b>If no, skip to 24.4</b> ]	[1=Yes; 2=No]	Examples include paralysis,
	(b) <i>If yes</i> , name of condition		amputations
24.4	<b>If able to walk:</b> (a) Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill? <b>[If no, skip to 24.5]</b>	[1=Yes; 2=No]	
	<i>If yes,</i> (b) Do have to walk slower than most people of your age on level ground because of shortness of breath?	[1=Yes; 2=No]	Skip if answer to a is no
	(c) Do you have to stop for breath when walking at your own pace on level ground?	[1=Yes; 2=No]	
	(d) Do you ever have to stop for breath after walking about 100 yards on level ground?	[1=Yes; 2=No]	
	(e) Are you too short of breath to leave the house or short of breath on dressing of undressing?	[1=Yes; 2=No]	
24.5	(a) Have you ever had any pain or discomfort in your chest? [If no, end section]	[1=Yes; 2=No]	
	If yes,	[1=Yes; 2=No]	
	(b) Do you get it when you walk uphill or hurry?		
	(c) Do you get it when you walk at an ordinary pace on the level?	[1=Yes; 2=No]	
	If no pain on walking, end section. Otherwise ask d-g	1-Stop/slow	
	(d) What do you do if you get it while you are walking?	l=Stop/slow down; 2=Carry on	
	(e) If you are standing still, what happens to it?	1=Relieved     2=Not relieved	
	(f) How soon?	1=10 minutes or less; 2=Over 10 minutes	

	(g) Will you show me where it is (record all places)? [SHOW PICTURE]		Mark all the points where pain is felt
--	--	--	--

## STATION 4: ANTHROPOMETRY MEASUREMENT

	Weight and height	a) First reading		b) Secon	d reading	
25.1	Weight	[kg]			• [kg]	To 0.1 kg (100 g)
25.2	Scale number					
25.3	Standing height		[mm]		[mm]	To 1 mm (0.1 cm)
25.4	Sitting height		[mm]		[mm]	To 1 mm (0.1 cm)
25.5	Stool height		[mm]		[mm]	To 1 mm (0.1 cm)
25.6	Stadiometer number					
	Circumferences	a) First reading		b) Secon	d reading	
25.7	Waist circumference		[mm]		[mm]	To 1 mm (0.1 cm)
25.8	Hip circumference		[mm]		[mm]	To 1 mm (0.1 cm)
25.9	Mid-arm circumference		[mm]		[mm]	To 1 mm (0.1 cm)
25.10	Calf circumference		[mm]		[mm]	To 1 mm (0.1 cm)
25.11	Head circumference		[mm]		[mm]	To 1 mm (0.1 cm)
	Skinfold measurements	a) First reading	b) Sec readin		c) Third reading	
25.12	Triceps skinfold	[mm]		[mm]	[mm]	To 0.2 mm
25.13	Biceps skinfold	[][[mm]		. [mm]	[mm]	To 0.2 mm
25.14	Subscapular skinfold	[] [mm]		[mm]	[mm]	To 0.2 mm
25.15	Suprailiac skinfold	[mm]		. [mm]	[mm]	To 0.2 mm

25.16	Calf skinfold	[][ [mm]	[][[mm]	[][[mm]	To 0.2 mm
25.17	Caliper number				
	Muscle strength	Reading			
25.17	Right hand		[kg]		To 1 kg
25.18	Left hand		[kg]		To 1 kg
25.19	Dominant hand	[1=Right, 2	2=Left]		Hand usually used, e.g. for writing
25.20	Grip strength machine				
	General information: antl	propometry measu	irements		
25.22	Researcher code				Each interviewer given codes starting from '1' to each of the team members
25.23	Researcher initials				These should decided at the start of the study and used consistently (e.g. don't flip between 2/3 alphabets
25.24	Left sided measurements		[1=Yes; 2=No	)]	
25.25	If not, specify				
25.26	All measurements adequa	ıte	[1=Yes; 2=No	•]	Adequacy refers to any problems in taking the reading that could affect their validity e.g. bandage or any obvious deformity. Where problems arise, every effort should be made it overcome them (i.e. remove bandage if possible) rather than simply proceeding with recording as such measurements are largely useless.
25.27	If not, specify				

## Anthropometry protocol

The methodology for anthropometrical assessments was adapted from standard reference texts on the subject.

General principles

- A digital weighing machine with an accuracy of 100 gms will be used to measure weight.
- Height will be measured by a portable plastic stadiometer with a base plate, accurate to 1 mm (Leicester height measure; Chasmors Ltd, Camden, London, UK).
- For sitting height, a standard table (of known height) high enough for the legs of the participant to dangle over the edge when seated will be used.
- A skinfold caliper accurate to 0.2 mm (Holtain skinfold caliper; supplied by Chasmors Ltd, Camden, London, UK) will be used to measure the thickness of the skinfolds.
- Lengths and circumferences will be measured with a non-stretch metallic tape with a narrow blade and a blank lead-in (Chasmors metallic tape; Chasmors Ltd, Camden, London, UK).
- The measurements (where relevant) will be made on the **left side**. If for some reason this is not possible, measurements should be taken on the opposite side and this change recorded.
- Measurements should be conducted in normal indoor clothing (basic clothes minus shoes, sweaters, socks, etc).
- Weight and height will be recorded once, circumferences twice and skinfolds readings will be taken three times.

## Notes:

(a) Extreme care should be taken to avoid digit preference when taking the recordings

(b) Any problems at the time of measurement that can affect their accuracy (such as those due to physical deformities, postural problems or bandages on the limbs) are recorded. However, in many cases the problem may be partially rectifiable e.g. removal of bandage in case of one. A common problem is that of hunching in case of older subjects. If so, check if maximum of the back is in contact with the wall. As the inadequate measurements cannot be used, it is strongly advisable to try and address the problem rather than record inadequate measurements.

## <u>Weight</u>

The weighing machine should be placed on the most level part of the floor and calibrated at the start of every clinic. At the time of each reading, the scale should be turned again to ensure that the monitor reads 'zero'. The participant should be asked to stand on the scale reasonably straight and looking ahead. Weight should be recorded only when the reading on the monitor had settled. Avoid taking the reading as the participant is coming off the weighing machine.

## Height and sitting height

The stadiometer should be set up on the most level part of the floor and calibrated at the start of every clinic. The participant should be asked to stand on the stadiometer, while the observer checks the following points:

(a) feet flat on the centre of the base plate, ankles together, heels resting on the bar at the back, and the inner borders of the feet at an angle of 60 degrees;

(b) back as straight as possible, preferably against the rod but not leaning on it;

(c) arms resting by sides, not behind or in front; and

(d) head in the Frankfort plane (eyes looking straight ahead such that the lower edge of orbit was in line with external auditory meatus i.e. ear hole).

The participant should be instructed to keep his/her eyes focused on a point straight ahead and to breathe easily. The headrest should be lowered while checking at the same time that the participant does not stand on tiptoe. The observer should be level with the scale at the time of reading to avoid errors due to parallax. To ensure this, the observer may have to stand on a stool or a thick book.

The table should be set up on a firm flat surface ensuring that it is stable and horizontal. The participant should be asked to sit on the table, and the measurement of height repeated using the same procedure as described for height above: head in the Frankfort plane, the back straight, and the thighs horizontal so that the hollow of the knee is approximately 1 cm clear of the table. The participant should be sitting on the table with the legs hanging unsupported over the edge, hands resting on the thighs with the buttocks and shoulders relaxed. The participant should be asked to sit up tall and headpiece slid down until it touches the head.

#### Waist circumference

The participant should be asked to stand straight with feet close together and abdomen relaxed, weight evenly balanced on both feet, and the arms hanging loosely at the sides. The measurement should be carried out on the bare skin. The observer should face the participant and place the tape around the participant, in a horizontal plane, at the level of the natural waist, which is the narrowest part of the abdomen between the ribs and the iliac crest (top of the hip bone), as seen from the anterior aspect. With the participant breathing out gently looking straight ahead, the reading should be taken at the end of a normal expiration.

#### General notes for measuring circumferences:

Circumferences should be recorded with the zero end of the tape held in the left hand above the remaining part of the tape held by the right hand. The plane of the tape should be perpendicular to the long axis of that part of the body, and parallel to the floor. For all circumference measurements, the tape should not be pulled too loose or too tight, held snugly around the body part but not indenting it. In some individuals there may be gaps between the tape measure and the skin, in such cases attempting to reduce the gap by increasing the tension of the tape is not recommended.

#### Hip (buttock) circumference

The measurement is carried out with the participant wearing normal indoor clothing. The tape measure is applied to the widest part of the buttock. This is ensured by the observer squatting at the side of the participant so that the level of the maximum extension of the buttocks can be seen. Attention should be paid that the hip muscles of the participant are not contracted, and the tape is horizontal and not compressing the skin.

#### Mid-arm circumference

The participant should stand with his/her back to the observer with the arm flexed at 90 degrees. The tip of the acromion (the point of the shoulder) is palpated and marked. Then with the participant's arm flexed at 90 degree, the olecranon (tip of the elbow) is palpated. The tape measure should be put on the mark on the shoulder and dropped down to the tip of the elbow by the side of the arm. The exact distance is read as if an imaginary horizontal line had been drawn from the bottom most point of the elbow to the tape measure, and a point halfway between the acromion and the olecranon marked. One way of doing this to measure the length as above and then fold the tape on to itself to identify the mid-point. The participant is then asked to relax, with the arm hanging by the side. The tape is placed around the upper arm such that its upper border was at the level of the marking. The tape should be horizontal all round, resting firmly on the skin but not indenting it.

#### Calf circumference

The calf circumference is measured with the participant standing, evenly balanced, with the feet shoulder width apart. The measurement should be taken on bare skin. The tape is positioned horizontally around the calf and moved up and down to locate the maximum circumference in a plane perpendicular to the long axis the calf. The observer should bend down at the time of the reading to avoid errors due to parallax. The level at which the measurement is taken should be marked at the medial aspect of the calf (inner border).

#### Head circumference

The head circumference is measured with the subject standing. Added objects, for example, pins are removed from the hair. The measurer stands facing the left side of the adult. The tape is passed around the head and positioned so that large amounts of cranial hair (braids) are excluded. Anteriorily, the tape is placed just

superior to the eyebrows and posteriorily it is placed so that the maximum circumference is measured. The tape is pulled tightly to compress hair. The measurement is recorded to the nearest 0.1 cm.

*General notes for measuring skinfolds:* The sites should be marked before taking these readings. Palpation of the site prior to measurements helps familiarise the participant with contact in the area. The calipers should be held in the right hand, while the thumb and the index finger of the left hand are used to elevate a double fold of skin and subcutaneous adipose tissue about 1 cm proximal to the site at which the skinfold will be measured. Place the thumb and the index finger on the skin about 3 inches apart on a line perpendicular to the long axis of the skinfold, and gently pull the skinfold away from the body by drawing the thumb and index finder towards each other. The fold needs to be grasped firmly, and the amount of tissue must be sufficient to form a fold with approximately parallel sides. Care must be taken so that only skin and adipose tissue are elevated (but not the muscle). The caliper head should perpendicular to the skinfold (with the dial facing), placed halfway between the crest and base of the fold. Gently and fully release the caliper pressure (the release of the pressure should be gradual to avoid discomfort). The pinch should be maintained for 5 seconds before taking the measurement. It is important to keep this timing accurate as otherwise the reading will vary. Errors due to parallax should be avoided by correct positioning over the dial (this may involve standing on something to be at the right height).

#### Triceps skinfold thickness

The triceps skinfold is measured in the midline of the posterior aspect of the arm, over the triceps muscle, at a point midway between the lateral projection of the acromion process of the scapula and the inferior margin of the olecranon process of the ulna (identified as for the mid-arm circumference). A cross is marked with a vertical line drawn on the most dorsal part of the arm determined by 'eyeballing' the midpoint (the part that sticks out furthest posteriorly), and the horizontal line the same as that drawn for the mid-arm circumference. The skinfold is measured with the participant standing and the arm hanging loosely and comfortably at the side. With the caliper held in the right hand, the observer stands behind the subject and places the palm of his/her left hand on the subject's arm proximal to the marked level, with the thumb and index finger directed inferiorly. The triceps skinfold is picked up with the left thumb and the index finger, approximately 1 cm proximal to the marked level, and the tips of the callipers are applied to the skinfold at the marked level. The readings should be taken 5 seconds after the application of the calipers jaws.

#### **Biceps skinfold thickness**

Biceps skinfold thickness is measured as the thickness of a vertical fold raised on the anterior aspect of the arm, over the belly of the biceps muscle. The skinfold is raised 1 cm superior to the line marked for the measurement of triceps skinfold thickness and arm circumference, on a vertical line joining the anterior border of the acromion and the center of the antecubital fossa. The subject stands, facing the measurer, with the upper extremity relaxed at the side and the palm directed anteriorly. The caliper jaws are applied at the marked level. The thickness of the skinfold is recorded to the nearest 0.1 cm.

#### Subscapular skinfold thickness

The lowermost tip of the scapula is identified. If it is difficult to appreciate this, the participant should be asked to place the back of his/her hand on the lumbar region. The medial border of the scapula is followed downwards until the inferior angle is felt. Once it is identified, the participant was asked to relax with arms hanging by the side before a mark is applied to the skin immediately below the lower most tip (angle) of the scapula. The skinfold is picked up obliquely above the mark with the fold slightly inclined downward and laterally (at about 45 degree to horizontal), in the natural cleavage of the skin. The caliper jaws are applied below the fingers, such that the marked cross is at the apex of the fold. Readings should be taken after 5 seconds.

#### Suprailiac skinfold thickness

The suprailiac skinfold is measured in the midaxillary line immediately superior to the iliac crest. The subject stands with feet together and in an erect position. The arms hang by the sides. An oblique skin fold is grasped just posterior to the midaxillary line following the natural cleavage lines of the skin. It is aligned

inferomedically at 45 ° to the horizontal. The caliper jaws are applied about 1 cm from the fingers holding the skinfold, and the thickness is recorded to the nearest 0.1 cm.

## Calf medial skinfold thickness

The participant stands with the foot of the side being measured on a platform, so that the knee and hip are flexed to about 90 degrees. The skinfold is measured at the level of the maximum calf circumference, already marked as before. From a position in front of the participant, the observer raises a skinfold parallel to the long axis of the calf on its medial aspect, when viewed from the front, at a level slightly proximal to the marked site. The caliper head should be perpendicular to the skinfold with the dial facing up at the marked point on the medial border of the calf.

#### Grip strength

- 1) Step 1. Press ON button.
- 2) Step 2. Demonstrate grip strength measurement to participant. Show that it is important to stand upright, with arm by side. When clasping grip do not allow grip meter to swing.
- 3) Step 3. The participant stands upright. Participant holds device so that grip meter indicator faces outwards. Turn the knob to adjust the grip width so that the second joint of pointing finger makes a right angle.
- 4) Step 4. Start measurement with right hand. Participant stands with arm naturally by side. Participant clasps grip with full force. Make sure participant does not swing grip meter at this time. Rest for 10 seconds. Repeat three times. The mean of the highest two values of the forces is indicated by flashing after about three seconds. Record the measurement.
- 5) Step 5. Repeat as above with left hand.
- 6) Step 6. Press OFF button.

If batteries are low or dead, either "LOBAT" will flash on the screen or the screen will be blank. Replace with two A4 size batteries.

#### **Blood pressure**

	Blood pressure	Blood pressure							
26.1	Room temperature	. [degree 0	Celsius]						
		a) First measure	b) Second measure	b) Third measure					
26.2	Systolic BP (brachial)	[mmHg]	[mmHg]	[mmHg]					
26.3	Diastolic BP (brachial)	[mmHg]	[mmHg]	[mmHg]					
26.4	Pulse rate	[bpm]	[bpm]	[bpm]					
26.5	Cuff size used	[1=Small; 2=Mediu	m; 3=Large]						
26.6	BP apparatus number								
26.7	Right arm measurements	[1=Yes; 2=No]							
26.8	Measurements adequate	[1=Yes; 2=No]							
26.9	If not, specify								

#### **Blood pressure measurement**

Blood pressure (BP) will be measured with OMRON M5-I (Omron, Matsusaka Co., Japan). This instrument meets the AAMI and International Protocol accuracy criteria. Three sized cuffs are available: (a) small cuffs (arm circumference 15-22 cm), (b) normal cuff (arm circumference 22-32 cm); and extra large cuff (arm circumference 32-42 cm). A digital thermometer (model name, company, country) will be used to measure room temperature. BP will be measured in right upper arm in sitting position.

*Note:* All those expected to be involved in the BP measurements should go through the instruction manual beforehand to familiarise themselves with the issues, possible problems and care of the equipment.

Steps in blood measurement

- Check the subject has not undertaken following activities for at least 30 minutes preceding the examination: strenuous exercise, eating, drinking of anything other than water, smoking or drugs that affect the BP. Ask the subject to sit on the chair with right arm on the table. *Important:* Upper arm (cuff when applied) should be at the level of the heart, neither too high nor low. If required use a pillow or some other support to ensure this.
- 2) Apply the correct size cuff. This should be determined by the arm circumference (see above), which should be read from the anthropometry section. You should also keep a measuring tape handy to check in case the subject has not been to the anthropometry section (in case you do measure the arm circumference for assessment of the cuff size, avoid the temptation to note it in the anthropometry datasheet at this stage). The green coloured band (indicating the centre of the bladder) should be positioned 1-2 cm above the elbow joint on the inside of the arm. Close the cuff with the fabric fastener. The green area of the cuff must cover the brachial artery. The cuff should not be too tight or too loose; it should fit snugly so that it is just possible to fit two fingers between the arm and the cuff. Do not place the cuff on thick clothes or roll up the sleeve if it is too tight. *Important:* The sleeve of the dress should

not constrict the blood flow in the arm. If so (either because of tight fitting shirt/blouse or rolling up of tight sleeve), take steps to address this (e.g. asking the subject to take off shirt over that arm or in case of female subject provide them with a loose gown to change into).

- 3) After the cuff is applied, wait for five minutes before taking the first reading. The subject should be made to relax during this time by making them sit comfortably, asking them to breathe easily and to relax the body and arm, and explaining the procedure. Stress that they should not move, talk or touch the device during measurement. This period should also be used to note down information in the datasheet: researcher code and initials, BP apparatus number, cuff size used, and arm side on which the measurement is being made. *Important:* The BP apparatus will give accurate readings at temperature range of 10 40 degree Celsius. If room temperature is outside this range, take steps to address this (use room heater if too cold or cooler or table fan with cloth soaked in water if cooler not available if too warm).
- 4) Press the START button on the machine. Wait for the machine to complete the measurement. This is confirmed by the flashing of a single downward arrow symbol. When all the air has been released the 'heart' symbol on the display panel and the readings are displayed for the next five minutes. Note down the systolic and diastolic blood pressure and the pulse rate. *Important:* If the subject moves or talks during the measurement or the measurements appear inaccurate or the symbol 'E' (indicating error) is displayed on the screen, repeat the measurement.
- 5) Wait for 2-3 minutes before taking the second reading so that blood circulation can resume. This can be ensured by presence of 'heart' symbol on display panel. If you need to interrupt a measurement for any reason, you can do so by pressing the ON/OFF button. Record the second set of readings on the datasheet. Note down any problems (such as subject appearing too anxious despite reassurance or if the readings had to be taken on the left arm for some reason). Switch off after measurement to conserve batteries. The monitor will also switch off automatically after five minutes.

## **Respiratory function**

	Respira	atory function							
27.1	In the past three months have you had any surgery on your chest or abdomen?							1=Yes; 2=No]	
27.2	Have you had a heart attack within the past three months?							1=Yes; 2=No]	
27.3	Do you have a detached retina or have you had eye surgery within the past three months?							1=Yes; 2=No]	
27.4	Have you been hospitalized with any other heart problem within the past [1=Yes;							1=Yes; 2=No]	
27.5	Are you in the last trimester of pregnancy?							1=Yes; 2=No]	
27.6	Are you currently taking medication for TB?							1=Yes; 2=No]	
27.7	Have you coughed up blood within the past month?							1=Yes; 2=No]	
27.8	Does the participant have a resting pulse of greater than 120 beats per minute? [1=Yes; 2=No]							1=Yes; 2=No]	
	If any of the questions 27.1 to 27.8 is "yes", do NOT proceed with the test								
27.9	(a) Have you taken medication for breathing in last 6 hours?								
	If yes, name of medication:								
27.10	Have you had a respiratory infection (cold) in the last three weeks?						1=Yes; 2=No]		
	TAKE VERBAL CONSENT TO DO THE TEST								
		a) Blow 1	b) Blow 2		c) Blow 3	d) Blow 4		e) Blow 5	
27.11	$FEV_1$	• [1]	•	[1]	•		[1]	<b></b> [1]	
27.12	FVC	•	•	[1]	• <b>[</b> ]	•			
27.13	If unable to obtain satisfactory spirometry (check one):				1 = Participant did not understand instructions2 = Participant medically excluded3 = Participant unable to physically cooperate4 = Participant refused				

## Spirometry test

Verbal consent

1. Step 1. Before administering the test, explain to the participant that you are going to ask them to do a breathing test, which involves them breathing into a tube. Ask if they are happy with this. If they say yes, then proceed with the questionnaire. If they say no, then explain test further and attempt to persuade them.

Respiratory function questionnaire

2. Step 2. Administer respiratory function questionnaire (below). If any of questions 23.1 to 23.8 is "yes" do not proceed with test.

Preliminary checks

- 3. Step 3. Check person has passed urine before test.
- 4. Step 4. Check weight and height without shoes are recorded.
- 5. Step 5. Wash hands.
- 6. Step 6. Check participant is sitting upright on chair with both feet flat on floor.

Describe spirometry test

- 7. Step 7. Describe spirometry test to participant. Say to the participant:
  "After breathing normally, slowly blow out until your lungs are empty. Then take a big deep breath in filling your lungs completely. Place the mouthpiece inside mouth and close lips tightly around the mouthpiece Blow out as hard and as fast as you can. Keep going until you cannot push anymore air out."
- 8. Step 8. Fieldworker demonstrates test with own mouthpiece.
  - a) Move the switch to 'BLOW'
  - b) Attach nose clip with new piece of plastic
  - c) Demonstrate the test
- 9. Step 9. Check that participant understands test

Participant performs spirometry test.

10. Step 10. Participant performs spirometry test with new mouthpiece and new piece of plastic on noseclip. Fieldworker talks to them as they do test:

"Feet flat on the floor, sit upright.... Breathe out..... Deep breath in.... Mouthpiece inside mouth... Breath out as hard and as fast as you can.... Keep going, keep going, keep going etc.....(encourage vigorously for 6 seconds) And stop. Relax Well done"

Record test results

11. Step 11. Check if blow is acceptable. If any of the following happens the blow is **not** acceptable, so do not record, and repeat the blow.

Unacceptable blow conditions

- The mouthpiece is blocked
- There is a leak around the mouthpiece

- The mouthpiece does not go inside the mouth
- The participant coughs during the blow
- The effort is not maximal
- The participant blows twice
- The participant stops before 6 seconds
- 12. Step 12. If blow is acceptable then record results for Blow 1 on questionnaire
  - a)  $FEV_1$  will be shown on the display. Write this down.
  - b) Move switch to the 'VIEW' position, FVC will be displayed. Write this down. Do not write down PEF and PER.

Repeat test for Blows 2 and 3

13. Step 13. Switch off unit and then back on again.Repeat test at least 2 more times and write down the FEV1 and FVC for blows 1, 2 and 3. Check if test is acceptable after each blow.

Criteria for stopping the test.

- 14. Step 14. After three acceptable sets of results have been obtained, check that the:
  - two largest values of FVC are within 0.15 L of each other
  - two largest values of FEV1 are within 0.15 L of each other
  - (Note these don't need to be from the same blows)

## If both of these criteria are met, stop the test.

# If both of these criteria are not met, perform a further two blows and write these down as Blows 4 and 5.

Repeat blows until

- Both of the above criteria are met
- Or, a total of five tests have been performed
- Or, the subject cannot continue
- 15. Step 15. Discard mouthpiece at end of test.

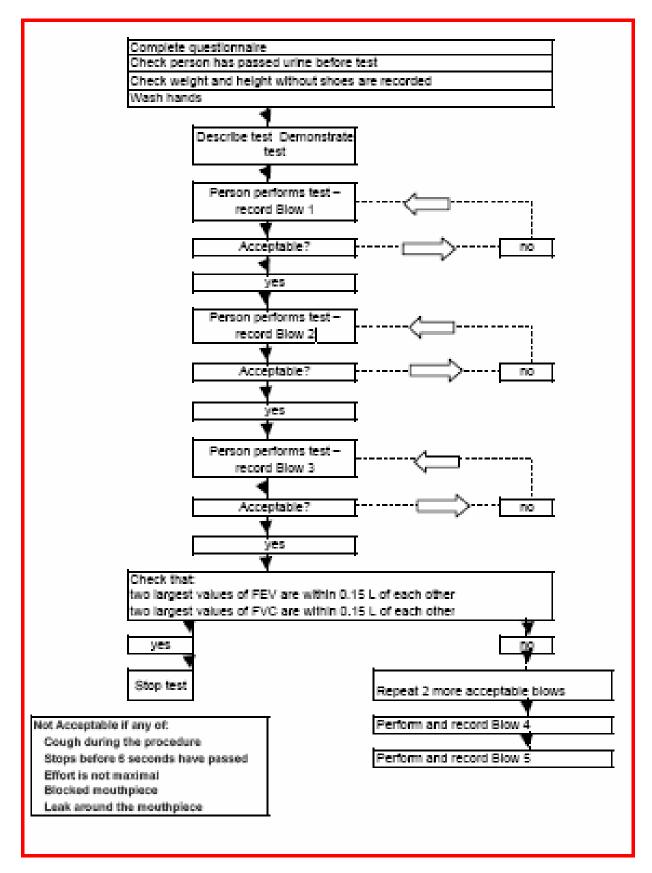
## Potential problems which may affect test:

- Not putting mouthpiece inside mouth (needs to go between the teeth but not so they bite on it)
- Embarrassment and laughing during test which makes effort not be maximal
- Oral phobia so refuses to put it in their mouth or cannot open mouth wide enough to do the test
- Stress incontinence in women so effort will not be maximal. Make sure people pass urine before the test to try and stop this happening.

Other important points:

- Fieldworkers must write their name on their mouthpiece and keep it for the duration of the day.
- Fieldworkers must write down only the FEV and FVC (do not record PEF and PER when they move the switch to VIEW position)
- Check spare batteries are available

## Spirometry flow chart



## ONLY FOR WOMEN

	Now I will ask you a few questions about your reprodu		
	Reproductive history		
28.1	At what age did your periods start?	[Age in completed years]	Record age at first period
28.2	(a) Do you still menstruate?	[1=Yes; 2=No]	
	(b) If no, at what age did your periods stop?	[Age in completed years]	If (a) is yes, leave blank
	(c) <i>If yes</i> , do you have irregular/infrequent menstrual cycles?	[1=Yes; 2=No]	If (a) is no, leave blank
	(d) <i>If yes</i> , how many periods do you have in a year?	[Number]	If (a) is no, leave blank
28.3	Do you have excess hair growth on your upper lip, chin, lower abdomen or inner thighs?	[1=Yes; 2=No]	Self-report by woman only
28.4	(a) Have you ever taken the oral contraceptive pill?	[1=Yes; 2=No]	
	(b) <i>If yes</i> , Which type of pill did you take	□ 1=Combined pill 2=Progestogen only (mini pill) 3=Don't know	If (a) is no, leave blank
	(c) <i>If yes</i> , for how long did you take it?	[Age in completed years]	If (a) is no, leave blank
28.5	(a) Have you ever been pregnant?	[1=Yes; 2=No]	
	(b) If yes, at what age was your first pregnancy?	[Age in completed years]	If (a) is no, leave blank
	(c) If yes, how many pregnancies have you had?	[Total number, 00 if none]	If (a) is no, leave blank
	(d) If yes, how many live births have you had?	[Total number, 00 if none]	If (a) is no, leave blank
	(e) If yes, how many miscarriages have you had?	[Total number, 00 if none]	If (a) is no, leave blank
	(f) If yes, how many abortions have you had?	[Total number, 00 if none]	If (a) is no, leave blank
		[Check that $c = d + e + f$ ]	Add d, e, and f to ensure it equals c
28.6	Have you ever tried to become pregnant during a period of one year or more without success?	[1=Yes; 2=No]	
28.7	(a) Are you pregnant at the moment?	[] [1=Yes; 2=No]	
			1=1-3 months
	(b) <i>If yes</i> , which trimester of pregnancy are you in?	[1, 2 or 3]	2=4-6 months 3=7-9 months

## **Station 5: DXA Measurements**

	DXA Scan	
29.1	DXA machine	[1=New; 2=Old]
29.2	Researcher initials	
29.3	Whole scan taken	[1=Yes; 2=No]
29.4	Spine scan taken	[1=Yes; 2=No]
29.5	Hip scan taken	[1=Yes; 2=No]
29.6	If not, specify reason	
29.7	First L1-L4 measure taken	[1=Yes; 2=No]
29.8	Second L1-L4 measure taken	[1=Yes; 2=No]
29.9	First L2-L4 measure taken	[1=Yes; 2=No]
29.10	Second L2-L4 measure taken	[1=Yes; 2=No]
29.11	If not, specify reason	

## DXA protocol

DXA machine: Hologic Discovery A Phantom: Hologic spine phantom 14855

- 1. The DXA machine should be calibrated at the start of each day using the spine phantom.
- 2. If the participant is a woman, please check that the "DXA needed" box has been filled with a "1". If there is a "2" DO NOT PERFORM THE DXA SCAN.
- 3. If the woman is below 35 ask her if she is pregnant. If the answer is yes, DO NOT PERFORM THE DXA SCAN.
- 4. Ask the participant to take any mobile phones off their person and remove any metallic items eg jewellery, watches, clothing with metal buttons
- 5. Ask the participant to change into light clothing. Pyjama trousers are provided for men. For women, full-length gowns are available if necessary but the scan can generally be performed with sari or salwar kameez.
- 6. In the Hologic programme, click on the PERFORM EXAM icon.
- 7. Click on NEW PATIENT.
- 8. Enter Last Name, First Name, subject ID number (from their questionnaire ID) Sex, DoB and name of study.

- 9. Ask the participant to lie supine on their back on the bed of the DXA machine, so that their left hand side is on the outer edge of the DXA scanner. Ask them to bend their feet inwards so that their big toes are touching. Arms should be by their sides with palms flat on the bed. Check the participant is comfortable and then ask them to remain still until the scan is complete.
- 10. Click on NEW SCAN.
- 11. Select TOTAL BODY from the drop down menu.
- 12. Click on START scan.
- 13. Once the total body scan is complete, ask the participant to lift their legs up and rest their calves on the purple support box with their knees bent so that their spine is flat on the bed. Check the participant is comfortable and then ask them to remain still until the scan is complete
- 14. Click on NEW scan.
- 15. For scan type, select LUMBAR SPINE from the drop down menu.
- 16. Under type of scan select FAST ARRAY option and untick the "use default settings" box.
- 17. Using the controls on the side of the DXA scanner, ask the scanner to show a red laser cross over the area it is about to scan. The participant's position can be adjusted using the controls on the DXA scanner to move the bed so that the cross is over the lumbar spine area
- 18. Click on START SCAN.
- 19. It may be necessary to reposition the scan if the image is not in the correct location. To do this click on REPOSITION SCAN. It is then possible to drag the image into the required position. To resume scanning, click on RESTART SCAN.
- 20. Once the scan is complete, remove the purple box from under the participant's legs. Ask the participant to rest their left foot against the triangular support and strap it in place using the velcro strap. Check the participant is comfortable and then ask them to remain still until the scan is complete
- 21. Click on NEW SCAN.
- 22. For scan type, select LEFT HIP from the drop down menu. Make sure the "use default settings" box is ticked.
- 23. Using the controls on the side of the DXA scanner, get the scanner to show the red laser cross over the area it is about to scan. The participant's position can be adjusted so that the cross is over the left hip area using the controls on the DXA scanner.
- 24. Click on START SCAN.
- 25. It may be necessary to reposition the scan if the image is not in the correct location. To do this click on REPOSITION SCAN. It is then possible to drag the image into the required position. To resume scanning, click on RESTART SCAN.
- 26. Complete the first part of section E of questionnaire, indicating whether each DXA scan has been completed.
- 27. Enter a "1" into the DXA box on front of questionnaire.
- 28. Once all the participants for the day have been scanned, print out the results of the total body, lumbar spine and hip scans for each participant. These will be collected by the data entry officer each day.
- 29. On Monday, Wednesday and Friday afternoons, carry out the L1-L4 and L2-L4 calculations twice for each participant. Print the forms for each participant and staple together. These forms will be collected and entered into the database by the Data Entry Operator.
- 30. At the end of each week, save all the study files for that week to CD. This will be collected by the Data Entry Operator.

## **Station 6: Coronary Measures and Medical History**

	Medical history.						
30.1	(a) Have you been diagnosed wi conditions?	th any of the following(b) If yes, age when diagnosed					
30.2	High blood pressure	(a) [1=Yes; 2=No] (b) [Age in completed years]					
	(c) Are you on regular medication	on for your high blood pressure? [1=Yes; 2=No]					
	(d) Name of medicine:						
	(e) Who diagnosed condition	[1=allopathic doctor; 2=homeopath; 3=ayurvedic doctor 4=RMP – registered medical practitioner; 5=Other]					
30.3	Diabetes (high blood sugar)	(a) [1=Yes; 2=No] (b) [Age in completed years]					
	(c) Are you on a regular diet for	your diabetes? [1=Yes; 2=No]					
	(d) Are you on regular tablets for	r your diabetes? [1=Yes; 2=No]					
	(e) Name of medicine:						
	(f) Are you on a regular treatme	nt with insulin? [1=Yes; 2=No]					
	(g) Do you attend a hospital or (	GP diabetic clinic? [1=Yes; 2=No]					
	(h) Who diagnosed condition	[1=allopathic doctor; 2=homeopath; 3=ayurvedic doctor 4=RMP – registered medical practitioner; 5=Other]					
30.4	Heart disease	(a) [1=Yes; 2=No] (b) [Age in completed years]					
	(c) Are you on regular medication	on for your heart disease? [1=Yes; 2=No]					
	(d) Name of medicine:						
	(e) Who diagnosed condition	[1=allopathic doctor; 2=homeopath; 3=ayurvedic doctor 4=RMP – registered medical practitioner; 5=Other]					
	(f) Type of heart disease	[1=angina; 2=heart attack; 3=heart failure 4=don't know; 5=Other]					
30.5	Stroke (paralytic attack)	(a) [1=Yes; 2=No] (b) [Age in completed years]					
	(c) Who diagnosed condition	[1=allopathic doctor; 2=homeopath; 3=ayurvedic doctor 4=RMP – registered medical practitioner; 5=Other]					

30.6	Asthma, asthmatic bronchitis or allergic bronchitis?	(a)	[1=Yes; 2=No]			(b)	(b) [Age in completed years]		
	(c) Have you had an attac	k of ast	thma in tl	he last year?		[1=Yes; 2=No]			
	(d) If you have asthma, at	re you c	on regular	r medication f	ma? (tal	blets/inhaler) [1=Yes; 2=No]			
	(e) Name of medicine:								
	(f) Who diagnosed condit	tion [1=allopathic doctor; 2=homeopath; 3=ayurvedic doctor 4=RMP – registered medical practitioner; 5=Other]							
30.7	Thyroid problem	(a)	[1=Yes; 2=]	No]	(b)	[Age in completed years]			
	(c) Are you on regular me	on for you	ır thyroid proł	olem?		[1=Yes; 2=No]			
	(d) Name of medicine:								
						<b></b>			
30.8	Tuberculosis	(a)	[1=Y	es; 2=No]	(b)		[Age in completed years]		
	(c) Are you on regular me	edication for your thyroid problem?					[1=Yes; 2=No]		
	Name of medicine:								
30.9	Depression	(a) [1=Yes; 2=No] (b)					Age in completed years]		
	(c) Are you on regular me	ion for your depression?			[1=Yes; 2=No]				
	Name of medicine:								
30.10	Peptic ulcer		(a)	[1=Yes; 2=]	No] (1	b)	[Age in completed years]		
30.11	COPD		(a)	[1=Yes; 2=]	No] (1	b)	[Age in completed years]		
30.12	Emphysema		(a)	[1=Yes; 2=]	No] (1	b)	[Age in completed years]		
30.13	Chronic bronchitis		(a)	[1=Yes; 2=]	No] (1	b)	[Age in completed years]		
30.14	Cancer		(a)	[1=Yes; 2=]	No] (1	b)	[Age in completed years]		
	(c) <i>If yes</i> , what type of cancer:								
						T			

	MEDICAL EXAMINATION							
	Carotid IMT		(a) Far wall	(b) Near wall				
31.1	Right common carotid a	artery image taken	[1=Yes; 2=No]	[1=Yes; 2=No]				
31.2	Right Bulb image taken	l	[1=Yes; 2=No]	[1=Yes; 2=No]				
31.3	Right internal carotid an	rtery image taken	[1=Yes; 2=No]	[1=Yes; 2=No]				
31.4	Any problems taking in	nages	[1=Yes; 2=No]	[1=Yes; 2=No]				
31.5	If yes, specify reason							
	Pulse Wave Velocity							
32.1	Room temperature		. [degree	Celsius]				
32.1	Have you had a meal in	last 2 hours?	[1=Yes; 2=No]					
32.2	Proximal distance (caro	tid to notch)	. [cm]					
32.3	Distal distance (notch to	o upper thigh)	• [cm]					
		(a) First meas	ure (b) Second measur	re (c) Third measure				
32.4	Systolic BP (supine)	[][n	nmHg] [mmH	Ig] [mmHg]				
32.5	Diastolic BP (supine)		ımHg]	Ig] [mmHg]				
32.6	Pulse rate (supine)		opm]	[ [bpm]				
32.7	Pulse wave velocity		[m/s] [m/s	] [m/s]				
32.8	Transit time		ms]	[ms]				
	Arterial Stiffness							
		(a) First measure	(b) Second measure	(c) Third measure				
33.1	Radial augmentation		g] (()) [mmHg					
33.2	Radial augmentation index (Aix)							
33.4	Central SBP	[mmHg]	[mmHg]	[mmHg]				
33.5	Central DBP	[mmHg]	[mmHg]	[mmHg]				
33.6	Any problems taking readings	[1=Yes; 2=No]	[1=Yes; 2=No]	[1=Yes; 2=No]				
33.7	If yes, specify reason							

## **Carotid measures**

- Please make sure that no drinks are placed on the table with the carotid IMT, Arterial stiffness or PWV equipment
- Please ensure that there are no mobile phones switched on near the equipment when taking the measures. Please ask the subject to remove any phones from their person.

## **Protocol for Carotid IMT**

- 1) Connect ultrasound box to Wipro laptop using the white USB cable (not bifurcated cable).
- 2) Turn ultrasound machine on.
- 3) Turn laptop on. The password is lapt0p#.
- 4) Go to C:\Documents and Settings\DOCTOR\My Documents\real study imt
- 5) Create a new folder for the day labelled with the date eg Jan 20
- 6) Click on the Ethiroli icon on the desktop to open the ultrasound programme. Ensure that the Vicorder programme is also open.
- 7) Ask the subject to lie down on the bed.Explain what you are going to do. Say that if it is causing any discomfort they should let you know.
- 8) Put gel on probe.
- 9) Place probe on participant with marked side pointing downwards and unmarked side pointing upwards.
- 10) Working only on right side, scan the whole carotid area, first transversally to view the trachea, thyroid, jugular vein and carotid artery. Then turn probe to view carotid artery only.
- 11) Place probe to get clear image of the near wall of the distal common carotid artery (10 mm). Make sure that the white arrow on the left hand side of the screen (focal point) is at the same level as the wall you are taking the image of. The focal point can be adjusted using the keys with the up and down arrows on the ultrasound keypad. Make sure that the carotid artery appears horizontally on the screen.
- 12) When you have a clear view of the intima, press the button at the bottom right of the ultrasound keypad to freeze image.
- 13) On the top toolbar, go to IMAGE, then SAVE AS.
- 14) Browse to find the date folder you have created in the real study imt folder.
- 15) Save the image as a jpeg file with the name in the following format: ID number-name-cca-nw (see below for abbreviations)
- 16) Press the button at the bottom right of the ultrasound keypad to unfreeze the image.
- 17) Repeat steps 11-15 for far wall of distal common carotid artery.

NOTE: if it is possible to capture both near and far walls of the common carotid in the same image, save the same image twice, naming it first as a near wall image and second as a far wall image.

18) Give participant tissue to wipe off gel.

Storage

- 19) At end of day, wipe any gel off the probe and store in bubble wrap.
- 20) Every Friday, the images for the week should be sent as a zip file by email to Dr Ravi Kumar and saved on to a CD.

Problem spotting

- If you do not have a clear image try putting on more gel
- Do not press too hard (e.g. if participant coughs or complains)
- Make sure not to take videos by accident as these cannot be processed
- Do not clean probe with spirits or other agents. Gently wipe with soft cotton.

- Make sure probe is dry when it is stored.

- If the ultrasound machine loses power and you cannot get the laptop to recognise it, unconnect all the cables and restart the laptop. Reconnect the cables- you may need to use a different USB port on the laptop for the connection.

- If machine does not work call Haneef on 094-4000-2622

Abbreviations for naming the files

nw: near wall

fw: far wall

cca: common carotid artery

To Save:

Go to IMAGE on the top menu, then SAVE. A window will appear allowing you to choose the site that you have captured the image of. Tick the appropriate box. A label should then appear on the top right of the image with the study ID, name and site of the picture.

At the end of the day, go into the patient file and click on ARCHIVE. A "Save as" box will appear. Browse to find the *real study IMT* file and save as a zip file. Name the file with the date eg 21 Jan 2009

## Protocol for Arterial Stiffness

- 1. Plug computer and sphygmoCor box to the mains
- 2. Switch laptop on. Password is lapt0p#
- 3. Double click on sphygmoCor icon.
- 4. Ask the subject to lie down and remain as still as possible.
- 5. Select SYSTEM from the menu bar
  - a. Then select DATABASE MANAGER
  - b. Select REALSTUDY
  - c. Press OK. This will bring up the "Patients window"
- 6. In the patients window, select the "Create New" tab on the right hand side of the screen.
  - a. Enter all the details: patient ID, Name, DoB, sex, other details etc
  - b. Once completed and checked, press the "Update tab". This will bring up a confirmation window which you must select "Yes" to.
- 7. Select the study tab at the top of the screen
  - a. Enter SBP, DBP and operator name
- 8. Press "Capture Data" tab on the right hand side of the screen.
- 9. Find the radial artery on the right inside wrist of the subject by feeling for the pulse.
- 10. Place the probe firmly over the artery. Be careful not too apply too much pressure.
- 11. Once a few screens of uniform wave patterns have been seen (at least 2), press the SPACEBAR to capture the data.

- 12. In the quality control panel, check to see if the 2<sup>nd</sup> and 3<sup>rd</sup> values are under 5. If this is not the case, do not record the values in the questionnaire and take another reading.
- 13. Record in questionnaire:
  - a. Radial Augmentation pressure (mmHg)
  - b. Radial Augmentation Index (%)
  - c. Central SBP
  - d. Central DBP
- 14. Press F3 or the "study tab" to return to the subject's anthropometry page.
- 15. Repeat steps 8-13 for the subsequent readings.
- 16. If the Augmentation index values for two good quality readings are within 5% of each other, no further measurements are needed. If not, take and record a final reading.
- 17. Once you finish, close the programme and shut computer

Problem Spotting

- If the waves move off the top of the screen or are flat along the top, apply less pressure.
- If it is not possible to get all the readings with the quality control under 5, take readings with quality control under 7.

## Protocol for Pulse Wave Velocity

- 1. Connect vicorder USB cable to Wipro laptop.
  - a. Bifurcation ends into 2 USB ports of the laptop
  - b. Other end should be connected to the circular port (8 way socket) at the rear of the vicorder box with the red dots lined up
- 2. Connect the red and blue leads to the press 1 and press 2 ports on the vicorder box. The red lead goes into the red port and the blue lead into the blue port.
- 3. Switch on laptop. The blue light should light up on the Vicorder.
- 4. Double click Vicorder icon on desktop.
- 5. Get the subject to lie down in the supine position. Explain to the subject about the two cuffs (neck and thigh). Check that the subject is comfortable with the cuffs.
- 6. Place 10cm blue cuff as high as possible on the thigh, making sure it is not too tight or too loose. The tube on the thigh cuff should be pointing towards the head and should be in line with the femoral artery.
- 7. Feel the carotid pulse and place the 2.5cm cuff (white) attached to the black velcro neck band on to the neck (right carotid), making sure it is not too tight and not too loose (you should be able to fit 1-2 fingers inside the band). The white pressure pad should be on the inside of the cuff with one end starting in the middle of the neck and the other (end with the tube) over the carotid area. Make sure that the tube is pointing downwards.
- 8. Connect the red lead to the proximal (neck) cuff and the blue lead to the distal (thigh) cuff.
- 9. Ensure that the subject has been resting in the supine position for TEN MINUTES before the PWV reading
- 10. Take the subject's blood pressure 3 times and record the values on the questionnaire.

- 11. Measure path lengths in cm with tape measure and enter into questionnaire.
  - a. Carotid to suprasternal notch
  - b. Suprasternal notch to thigh (upper part of cuff)
- 12. Click PWV icon on the quick launch tab on the right hand side of the screen. This will bring up the study folder.
- 13. Enter subject details in study folder
  - a. Study Name (real), Patient ID, First name, Last name, Sex, DoB (to change DoB you need to highlight each section of the date and use the up and down arrow keys)
- 14. For the proximal site, select **carotid** from the drop down menu. For the distal site, select **right femoral** from the drop down menu.
- 15. Enter the following into the study folder:
  - a. Distance from notch to thigh
  - b. Systolic blood pressure (use the third reading)
  - c. Diastolic blood pressure (use the third reading)
- 16. Explain to the subject that you are about to inflate the cuffs and that they will feel some pressure on their neck and thigh. Ask them to tell you if they feel any discomfort.
- 17. Press SPACEBAR to inflate the cuffs
- 18. Once inflated, acquire steady pulse (there should be 2 screens of even waveforms for both carotid and thigh). Capture data by pressing SPACEBAR.
- 19. Wait for a couple of seconds for the PWV and TT values to stabilize. Record PWV and TT values on questionnaire.
- 20. To save data
  - a. Press ENTER.
  - b. Browse to find the *PWV actual results* spreadsheet in the Real study PWV folder. Select this and Click OK. A message will appear asking if you want to overwrite this file, click Yes.

21. Press SPACEBAR for second reading. Repeat steps 17-20.

NOTE: For the second and third readings for a subject, the readings will automatically be saved to the same spreadsheet when you press ENTER.

- 22. Repeat for third reading
- 23. Press ESCAPE to close the PWV screen when you have completed the 3 readings.

Quality Control

To check the quality of the waveforms, for one subject per day, the images of the PWV waveforms should be recorded. To do this:

- 1. After saving a recording, press F4 to export the data. Browse to the *qc PWV* folder in the *real study PWV* folder.
- 2. Save the image as a jpeg and name it with the patient ID, name and number of the recording eg 1,2,3

Problem spotting

• If the carotid waves are not uniform, make sure that the vicorder wires are not twisted, that the neck cuff is not too loose and that the subject's head and shoulders are raised at an angle of 30°.

Pulse Wave Analysis

- 1. See steps 1-4 in the PWV protocol for setting up the vicorder equipment.
- 2. Ask the subject to lie down in the supine position.
- 3. Take the subject's blood pressure in their right arm three times.
- 4. Explain to the subject about the two vicorder cuffs (brachial and thigh). Check that the subject is comfortable with the cuffs.
- 5. Place a 10cm blue cuff as high as possible on the thigh, making sure it is not too tight or too loose. The tube on the thigh cuff should be pointing towards the head and should be in line with the femoral artery. Attach the tube of this cuff to the blue vicorder lead.
- 6. Place a 10cm blue cuff around the upper arm with the tube pointing downwards. Attach the tube of this cuff to the red vicorder lead.
- 7. Measure the distance from the top of the brachial cuff to the top of the femoral cuff with a tape measure.
- 8. In the quick launch tab on the right hand side of the vicorder programme, select PWA. This will bring up the study folder.
- 9. Enter the subject details in the study folder: Study Name (real), Patient ID, First name, Last name, Sex, DoB (to change DoB you need to highlight each section of the date and use the up and down arrow keys)
- 10. For the proximal site, select **right brachial** from the drop down menu. For the distal site, select **right femoral** from the drop down menu.
- 11. Enter the following into the study folder:
  - a. Aortic path length (distance between cuffs)
  - b. Systolic blood pressure (use the third reading)
  - c. Diastolic blood pressure (use the third reading)
- 12. Click on OK. This will bring up the data capture screen.
- 13. Press F3. The screen should now split in half, with the top half for the brachial readings and the bottom for the thigh readings.
- 14. Inform the subject that you are about to inflate the cuffs and that they will feel some pressure on the thigh and upper arm.
- 15. Press the SPACEBAR to inflate the cuffs.
- 16. Wait until there have been several successive screens of uniform waves in both windows and the values in the grey boxes have stabilised.
- 17. Press the SPACEBAR to capture the data.
- 18. To save the data:
  - a) Press ENTER.
  - b) Browse to find the *Brachial PWA* spreadsheet in the Real study PWV folder. Select this and Click OK. A message will appear asking if you want to overwrite this file, click Yes.
- 19. Repeat steps 14-17 twice more so that you capture 3 readings for each subject.

NOTE: For the second and third readings for a subject, the readings will automatically be saved to the same spreadsheet when you press ENTER.

#### Quality Control

To check the quality of the waveforms, for one subject per day, the images of the PWV waveforms should be recorded. To do this:

- 1. After saving a recording, press F4 to export the data. Browse to the *qc Brachial PWA* folder in the *real study PWV* folder.
- 2. Save the image as a jpeg and name it with the patient ID, name and number of the recording eg 1,2,3

## VICORDER INSTRUCTIONS

Plug in VICORDER to laptop with main USB / 8-way cable.

Load up software onto the laptop once prompted to do so.

On the main screen, click on the START menu in the bottom left hand corner.

Then go to SETTINGS.

Then go to CONTROL PANEL.

In Control Panel, switch to CATEGORY VIEW if you are in Classic View. Once in Category view, select PERFORMANCE & MAINTENANCE.

In Performance and Maintenance, select SYSTEM at the bottom of the window and then select HARDWARE, then select DEVICE MANAGER.

In Device Manager, scroll down the list until you find the USB driver name with an exclamation mark next to it. If you cannot see this, then double click on the USB name (Universal Serial Bus Controllers).

Previously when this software has been loaded problems arose with the USB <-> Serial

Right click on the USB name which has the exclamation mark next to it and select UPDATE DRIVER.

This opens the HARDWARE UPDATE WIZARD. Within the Wizard window, select the option to INSTALL FROM A LIST OR SPECIFIC LOCATION, then click NEXT.

Then select the option to SEARCH FOR BEST DRIVER IN THESE LOCATIONS.

Tick the box to INCLUDE THIS LOCATION IN THE SEARCH (make sure the other option is unticked).

Select BROWSE and select C drive, Programme Files, Skidmore Medical, Vicorder, Driver. If Driver is not one of the options listed in Vicorder, double click on DATA and DRIVER should be available from this list.

Then click NEXT

Then click FINISH

The light on the VICORDER should now come on and remain on.

Now attach the leads to the front of the vicorder box and the audio lead at the back and open the vicorder programme via the icon on the desktop.

Once the vicorder programme is open, select FILE, FIX DATABASE. A message should appear saying there is no error to fix. Select OK and then the programme will automatically check the license. This will then allow the

## Data back-up of coronary data

Every Friday, all of the data from the previous week needs to be backed up onto a CD which must be clearly labelled with the study name and end date for that week. E.g.

- DXA Hyderabad Study 23<sup>rd</sup> January 2009
- DXA Hyderabad Study 30<sup>th</sup> January 2009

Files for the three separate medical measurements need to be copied onto the CD.

## 1) SphygmoCor Arterial stiffness- Protocol for saving data

Arterial stiffness data is saved in an Access database on the Toshiba laptop in the following location: C:\Program Files\Spygmocor\Data\Realstudy

Copy the whole SCOR database (in the RealStudy file) on to the CD.

## 2) Vicorder – Protocol for Saving Data

Data will be stored each day for each individual subjects in two main excel spreadsheets on the Wipro laptop: C:\Documents and settings\DOCTOR\My Documents\real study PWV

Spreadsheet names:PWV actual resultsBrachial-PWAPulse Wave Velocity recordingsBrachial Pulse Wave Analysis recordings

At the end of each week the data stored within the two spreadsheets must be tidied up to remove excess information that is not required.

- 1. Open the file *PWV actual results* file in excel.
- 2. Scroll through the data and delete each row that has titles but no values e.g. Study Name, ID N<sup>o</sup>, Last Name etc. This will be every fourth line or so and any empty rows in between.
- 3. The database should only contain the output for each individual subject and not the title headings for their data. So, rows starting with 'real', 'ID=' etc all need to be kept.
- 4. Repeat steps 2, 3 and 4 for the *Brachial-PWA* file.

Once the databases have been tidied up each week, they both need to be saved to the CD. In addition there are 2 folders in the "real study PWV" folder with the quality control images stored as jpegs. These should also be saved to the same CD.

#### 3) Carotid IMT- Protocol for saving data

Images for Carotid IMT will be saved as jpegs each day in date labelled folders on the Wipro laptop in: C:\Documents and settings\DOCTOR\My Documents\real study IMT

- 1. In the real study IMT folder, create a new folder for the week that has just been completed and name it with the date eg 19 23 Jan 2009.
- 2. Drag all of the day folders for this week into the new folder.
- 3. Save the week folder on to the CD.
- 4. Compress the weekly folder into a zip file. To do this, right click on the folder, go to SEND TO, then COMPRESSED (ZIPPED) FOLDER.
- 5. Email the zip file to Dr Ravi Kumar in Chennai: hemarrk@yahoo.co.uk

## Station 7: Departure from clinic – completed by Team Leader

#### **Reimbursement of participants**

Distribution of reimbursement to participants is the responsibility of the team leader, and is undertaken at the end of the day when all examinations have been completed.

The level of reimbursement was arrived at using the following principles. Understanding of these principles may be useful at times for clarification, or in unusual circumstances where an appropriate level needs to be calculated. However, these do not need to be routinely explained to the participant, and reimbursement should be offered, as far as possible, on a lump sum basis using the suggested scales. In case there is doubt about the correct scale, please err on the higher side remembering that participants are volunteers, under no obligation to participate.

Principles:

- Participants are classed as follows
  - a) Index person (factory employee or spouse)
  - b) Intra-city relative (relatives resident in Hyderabad)
  - c) Day-travel relative (relative living outside Hyderabad but up to 2.5 hours travel time)
  - d) Overnight stay relative (living between 2.5 6 hours travel time from Hyderabad; thus needing to be away from home for up to 2 days)
  - e) Long-distance relative (relative living beyond 6 hours travel from Hyderabad; thus needing to be away from home for up to 4 days)
  - f) Hyderabad Nutrition Trial participants
- The lump sums are calculated as follows
  - a) Index person (Rs 400/-)
  - b) Intra-city relative (Rs 400/-)
  - c) Day-travel relative (Rs 500/-)
  - d) Overnight-stay relative (Rs 1000/-)
  - e) Long-distance relative (Rs 2000/-)
  - f) Nutrition trial participant (Rs 400/-)
- All payments should be based on DISTANCE FROM N.I.N. AND NOT THE FACTORY

#### Proof of identity

It is important that some proof of identity is available for the relative that confirms the relationship and place of residence of the relative. This requirement will be explained in the invitation letter. Examples of proof of identity include the ration card, voting card, work identity card, driving or other license, or letter from the village head. The relatives will be requested to bring a photocopy along with the original. The photocopy should be checked against the original and retained for record. If the relative brings the original but forgets the photocopy, the study team should get a photocopy made locally (the money for this can be claimed back). Where the relative forgets to bring a proof along, they should still be recruited, but only after asking suitable questions to the index person and the relative to confirm the identity. This will have to be done in a very careful manner to avoid upsetting the participants. In such cases the participants should be asked to post a photocopy of the proof after their return home, and they should be chased up for this if necessary. Where no proof becomes available, this fact should be recorded in the database.

	Summary sheet (to be compl	Instructions		
	Component completed			This section should be completed at the end just before the subject departs, generally at the time of reimbursement
	Reimbursement			
1.1	Reimbursement given	[1=Yes; 2	2=No]	Subject's signatures should be taken on receipt
1.2	Identity proof taken	[1=Yes; 2	2=No]	Proof should be copied & filed away
	Subject recall			
1.3	Subject needs to be recalled	[1=Yes; 2	2=No]	Recall may be needed for repeatability, validation or incomplete study
1.4	Recall for repeatability study	[1=Yes; 2	2=No]	Repeatability studies will be done on random 5% sample
1.5	Recall for validation study [1=Yes; 2=No]			Validation studies will be done on random 5% sample
1.6	Recall for incomplete study	[1=Yes; 2	2=No]	Subject may need to be recalled if some of the information was not completed
1.7	If yes, is the subject willing to	return?	[1=Yes; 2=No; 3=Undecided]	
1.8	If undecided, date status will b	be reviewed:	// [DD/MM/YY]	Negotiate the date with participant
1.9	If recalled, clinic visit details			
	(a) Date of clinic visit [DD/MM/YY]	(b) Travel [1=Self; 2=Tear	n] (c) Outcome [1=Yes; 2=No]	Start and end dates of period relate to time over which the relative is expected to arrive at the clinic e.g. if the person is expected anytime in the month of august, enter start and end dates for the month
				Travel relates to whether the subject has agreed to make his/her own travel/stay arrangements or if the team has to make part/all of the arrangements
1.10	Summary sheet notes			

# BIOCHEMISTRY

#### PROTOCOL FOR SAMPLE COLLECTION

- 1. Preparation of Subjects:
  - Inform your subject at least two days before about sample collection.
  - To come after 10-12 hours of fasting.
  - Inform the 'Place' and 'Venue' of sample collection
- 2. Prepare kits with the following contents for sampling: INDIAN MIGRANT STUDY
  - Vacutainers: 1 Red capped 2 Grey capped and 2 Purple capped (All vacutainers should be prelabeled)
  - Accessories: Tourniquet, Needle, Holder, Swab.
  - Pasteur pipette
  - Storage vials (11 in nos.) (Prelabeled)

HYDERABAD NUTRITION TRIAL

- Vacutainers: 1 Red capped 1 Grey capped and 2 Purple capped (All vacutainers should be prelabeled)
- Accessories: Tourniquet, Needle, Holder, Swab.
- Pasteur pipette
- Storage vials (9 in nos.) (Prelabeled)
- 3. Items not provided in the kit but required for sampling
  - Centrifuge machine
  - Test-tube stand
  - Gloves
  - Needle destroyer & bio-waste disposal packets
- 4. Preparation for transportation and Storage
  - Ice-bucket
  - Ice-packs (Keep overnight in deep freezer or in the ice compartment of the normal refrigerator)
- 5. Enter the id no., Name, Age, Sex and Date in a logbook.

### **Protocol for blood collection at zero time (fasting)**

- Take blood from the subject at recumbent position. Make the subject sit for 10 min. before starting sample collection.
- Keep ready one holder, one needle, one red-capped vacutainer, one grey-capped vacutainer and two purple-capped vacutainer.
- Attach needle to the holder.
- After applying the tourniquet insert the needle into the vein. (Avoid application of tourniquet for more than one minute)
- Insert red-capped vacutainer. Collect blood up to the capacity.
- Take out the red-capped vacutainer and insert grey-capped vacutainer. Ensure that the tube is filled to the mark.
- Take out the grey-capped vacutainer and insert purple-capped vacutainer. Ensure that the tube is filled to the mark.
- Mix grey capped vacutainer (containing fluoride) and purple capped vacutainer (Containing EDTA) by inversion for 7-8 times (**Do not shake vigorously**) and keep them in ice- bucket (at 4 degree temperature).
- Allow the blood in red-capped vacutainer (Plain tube) to stand for 30 min at room temperature and allow blood to clot. Centrifuge the tube at **3500 rpm for 15 min**.
- Hemoglobin estimations to be performed simultaneously with fresh blood from EDTA vacutainer.

#### **Protocol for giving glucose load**

- Participants of the Indian Migrant Study only.
- People with diabetes or women who are pregnant are excluded.
- Provide the person with 75 gm glucose solution. Ask the participant to drink this over a period of five minutes. He/She should consume all the glucose within 10 minutes.
- Record time of giving glucose load on front of questionnaire.

### Protocol for blood collection after 120 minutes of glucose intake

- Keep ready one holder, one needle and one grey-capped vacutainer.
- Attach needle to the holder.
- After applying the tourniquet insert the needle into the vein. (Avoid application of tourniquet for more than one minute)
- Insert grey-capped vacutainer. Collect blood up to the capacity.
- Mix vacutainer by inversion for 7-8 times (**Do not shake vigorously**) and keep them in ice- bucket (at 4 degree temperature).
- Centrifuge the tube at **3500 rpm for 15 min**.
- Transfer plasma into two storage vials labeled 'PP'.
- Use one vial to estimate glucose. Store another vial to be dispatched to the coordinating lab.

# It is important that serum is separated as soon as possible and at no cost later than 45 minutes after blood collection.

- Aspirate the serum using the given plastic pipette into three labeled storage vials provided (Vials labeled as 'S' for serum)
- Similarly centrifuge the grey-capped vacutainers for **15 minutes at 3500 rpm**. Aspirate the plasma and transfer into three labeled vials provided in the kit (Vials labeled as 'P' for Plasma)
- Ensure that the storage vials are closed tightly.
- Do not centrifuge the purple-capped vacutainer.
- Mix well by inversion and Estimate Hemoglobin
- Centrifuge the tubes at **3500 rpm for 15 min**
- Transfer EDTA plasma into three storage vials labeled 'EP'.
- The storage vials (all 'S', 'P'& 'EP') are then transported in ice bucket to the medical college.
- Transfer three labeled 'S', two labeled 'P' and three labeled 'EP' vials to  $-20^{\circ}$  C deep freezer immediately. (To be dispatched to the coordinating lab)

One vials each of 'P'& 'PP' should be used for glucose estimation without much delay.

• Needle should be destroyed by needle destroyer and vacutainers collected as bio-waste material should be sent to incinerator.

#### Sending samples to AIIMS

- Every alternate Monday, the three labeled 'S', two labeled 'P', three labeled 'EP' and one labeled 'PP' vials should be dispatched to the coordinating lab in dry-ice by Courier.
- Fill the **'Format of storage'** for each box and sent the soft copy to the coordinating lab when sending the samples.
- Ensure that the samples do not reach the coordinating lab on Saturdays / Sundays / Holidays. Preferably dispatch samples on Monday/ Tuesday.
- Inform coordinating lab before dispatching the samples. Send the details of dispatch to the coordinating Lab through e-mail.
- The address to which the samples should be dispatched is

#### Dr. R. Lakshmy

Assoc. Professor Room no. 61 Cardiac Biochemistry Lab CN Center, AIIMS, New Delhi-110029

E-mail: lakshmy\_ram@yahoo.com

Phone (O) 011-26594426 (M) 9811458621 Fax 011-26850588 Attention: Dr. R. Lakshmy

#### **Delivery and reporting of results**

- Monday

   Team Leader will send the blood samples and excel sheet (APPENDIX X) By courier from NIN to AIIMS, alternate Mondays.
   Tuesday

   Samples and excel sheet are received at AIIMS. Check excel sheet
- 2) Tuesday Samples and excel sheet are received at AIIMS. Check excel sheet.
- 3) Wednesday AIIMS technician checks samples. AIIMS technician sends e-mail to Team Leader about quantity and quality of samples received and any problems
- 4) Thursday AIIMS technician analyses samples
- 5) Friday AIIMS technician analyses samples
- 6) Thursday AIIMS technician sends report of results to Team Leader and UK PI

If it is not possible to send on Monday, send samples Tuesday or Wednesday, but no later.

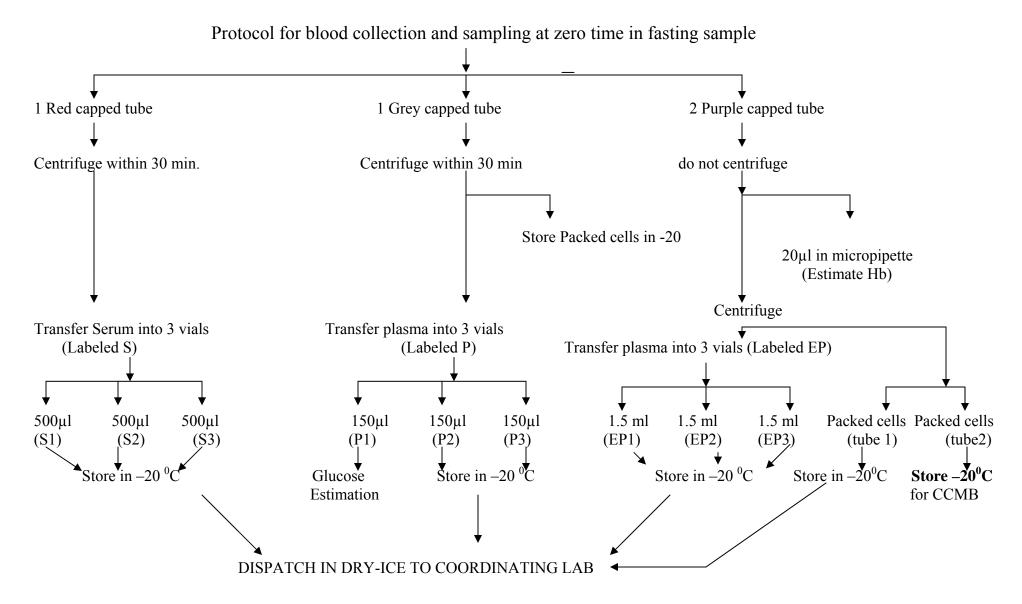
Excel sheet shows:

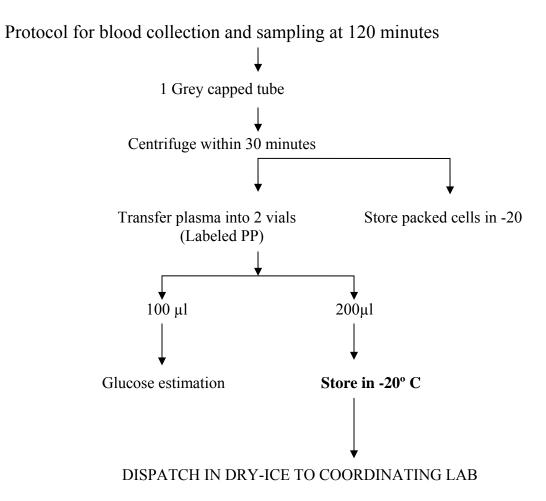
- Per subject
  - Study id
  - Names
  - Tubes collected
- Details of box
  - Volume
  - Sample ID
- Summary
  - Number of subjects
  - Number of samples

# Details of Samples (To be filled for each sample)

Study ID no:						
Name:		А	ge:		Sex:	
Date of Sampling:						
Samples collected at	t zero time	:				
1) Serum (S)	Aliquot 1		Aliquot 2		Aliquot 3	
2) Plasma (P)	Aliquot 1		Aliquot 2		Aliquot 3	
3) EDTA plasma (EP)	Aliquot 1		Aliquot 2		Aliquot 3	
4) Packed cells (Fluoric	le) Tube	e 1 🛛	Tube 2	2		
5) Packed cells (EDTA) Tube 1 Tube 2						
Sample collected aft	er 120 mir	nutes:				
Plasma (PP)		quot 1	] Ali	quot 2		
		1		1		
Any other detail:						
Details of Sample A	nalysis					
(1) Fasting Plasma	Glucose .		mg/	dl		
(2) Plasma Glucose after 120 min mg/dl						

#### **FLOW CHART**





# Format for storage of samples in storage box

#### Box no

1	2	3	4	5	6	7	8	9
	_	-	•	-	-		-	-
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
10	11	12	13	14	15	16	17	18
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
19	20	21	22	23	24	25	26	27
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
28	29	30	31	32	33	34	35	36
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
37	38	39	40	41	42	43	44	45
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
46	47	48	49	50	51	52	53	54
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
<b>S</b> 1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
55	56	57	58	59	60	61	62	63
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
64	65	66	67	68	69	70	71	72
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
S1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume
73	74	75	76	77	78	79	80	81
Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id	Lab id
<b>S</b> 1	S2	S3	P1	P2	EP1	EP2	EP3	PP
volume	volume	Volume	volume	volume	volume	volume	volume	volume

#### Annexure I

Items required for sample collection (per person)

a. Fluoride vacutainer (2ml) - 3	[from Becton-Dickinson]
b. Plain vacutainer (4 ml) – 1	[ do ]
c. EDTA vacutainer (3 ml) – 2	[ do ]
d. Needles (22G) - 3	[ do ]
e. Pasteur pipettes – 5	[ from TARSON]
f. Storage vials $(2 \text{ ml}) - 15$	[ from TARSON]

g. Swab -1

Items required for the Lab.

- i. Field Cetrifuge machine
- ii. Needle destroyer
- iii. Gloves
- iv. Discard bags
- Table Sheets v.
- Pipette 10 µl vi.
- vii. Pipette 1000 µl
- viii. Test tube stand
- Cold-bucket ix.
- Ice-packs Х.
- Glucose Reagent with standard xi.
- xii. Controls
- xiii. Spectrophotometer
- xiv. Test-tubes
- Analyzer XV.
- Deep freezer xvi.

### **Annexure III**

#### AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME

Enclosed herewith one vial containing lyophilized serum labeled MSEQC. Reconstitute in 1 ml distilled water, mix by swirling and keep for 30 min to ensure complete mixing. Assay for Total cholesterol, Triglycerides, HDL- cholesterol and Glucose on the same day. Reports should be dispatched to the coordinating lab by e-mail or fax.

**Center Name:** 

Total Cholesterol	MSEQC no.	mg/dl
Triglycerides	MSEQC no.	mg/dl
HDL-Cholesterol	MSEQC no.	mg/dl
Glucose	MSEQC no.	mg/dl

Date of receipt at the center:

Date of Reconstitution & Analysis:

Return results by:

E-mail <u>lakshmy\_ram@yahoo.com</u> or g\_ruby2123@yahoo.co.in

Fax: 011-26167397 Attn Dr R.Lakshmy / Dr Ruby Ph: 26594426

# Annexure IV HYDERABAD DXA STUDY-BLOOD REPORT

Name:	
Age:	Sex:
Address:	
Blood haemoglobin:	[gm/dl]
Fasting plasma glucose:	[mg/dl]
PP plasma glucose	[mg/dl]
Total cholesterol:	[mg/dl]
Triglycerides:	[mg/dl]
LDL – cholesterol:	[mg/dl]
VLDL – cholesterol:	[mg/dl]
HDL – cholesterol:	[mg/dl]
Gamma GT - liver	[mg/dl]
LGOT – liver	[mg/dl]
GPT – liver	[mg/dl]
Advice:	
Date:	
Signature:	

#### MEDICAL REFERRAL

Who should be referred?

- Medical help can be obtained from the senior medical staff at the Medical College
  - Complaining of possibly serious medical conditions
    - Chest pains on exertion, breathlessness, severe pain
  - Wanting a second opinion for known medical conditions
    - Discuss with SRF and negotiate with College

#### Abnormal results and Referral:

All reports will be communicated to the subjects. For any abnormal results based on the clinical examination and laboratory results like anaemia, high blood pressure or sugar etc. the subject will be seen by medical officer and if required referred to the IMO (?) or the associated local medical college hospital.

#### Postal reports

Reports to the subjects coming from a distance will be sent through post The SRF will communicate the reports based on subject's clinical and biochemical parameters. In the report the following will be communicated: Normal/abnormal results

#### Written advice

Need for check up/follow up with the local practitioner as and if required.

#### First aid:

The doctor will provide first aid as needed or refer the subject to the local medical college hospital as needed. In our scenario, we are most likely to encounter cases as:

#### Heat exhaustion:

If you suspect heat exhaustion, get the person out of the sun into a shady location. Lay the person down and elevate the feet slightly. Loosen or remove person's clothing. Cool the person by spraying him or her with cool water and fanning and have the person drink cool water. Monitor the person carefully. If person shows symptoms and signs of a heatstroke like temperature greater than 104 F, fainting, confusion or seizures, the person should be immediately referred.

#### Fainting

If a subject looks or feels faint during the procedure, it should be discontinued. The subject should be asked to place their head between their knees. They should subsequently be asked to lie down. If they are happy for the test to be continued after a suitable length of time, it should be done so with the subject supine and the circumstances should be recorded. They may wish to discontinue the procedure at this point, but willing to give the blood sample at a later time.

#### Needle stick injuries

The wound should be encouraged to bleed. The wound should be washed with soap and warm water, if available. Other hand cleaner may be used if water is not available.

#### Bruises

For any bruises following the blood sampling, elevate the injured area and apply ice or cold pack for 30 to 60 minutes at a time for a day or two after the injury.

#### INVENTORY AND CARE OF EQUIPMENT

All the equipments will have to be handled with care. It is the responsibility of the Team Leader to ensure at the end of the day when clinics are over; research assistants who are carrying out the anthropometric measurements will pack the equipments properly and keep in a safe place. In case of any damage to the instruments or loss of instruments, this will have to be communicated to LSHTM or NIN immediately so that a replacement can be made.

An inventory of the general items as well as biochemistry items will have to be maintained by the centre and sent to LSHTM and NIN at the end of the month. Any item which needs to be procured will have to be informed well in advance.

ITEM	USED BY	TYPE AND NUMBER NEEDED IN STOCK
Batteries		
	Scales (6xAA)	40xAA
	BP machine (4xAA)	
	Spirometer (1x9V)	4x9V
	Grip Strength (2x1.5V)	8x1.5V
Anthropometry		
Spirit	Anthropometry	2 bottles
Cotton wool	Anthropometry and doctor	4 packs
Calculator	Anthropometry	2 spare
Spirometry tubes	Anthropometry	200 per month used
Nose clips	Anthropometry	10 spare
Doctor		
Ultrasound gel	Doctor	2 bottles spare
Stationery		
Pens	All	50 pens
CDs	Doctor	30 spare
Biochemistry		
Glucon D		
Needles disposal bin		
Glasses		
Soap		
Toilet tissue		
Questionnaires		
Labels		

#### **Communications-**

- Every day the Team Leader will check the mail once in the morning and once at the end of the day. Mails which require immediate attention should be given high priority. All such mails must be replied by the evening of the day and even if the mentioned task cannot be done immediately, this should be communicated with the likely date of completion.
- Wherever deadlines have been specified, it is important that these are met. If for some unavoidable reasons it is not possible to complete a task in time, then this should be communicated well ahead of time so that a backup plan can be thought of.
- The Team Leader must have a date diary-a large size one with a page to date. This is to make note on that day of the diary of the things to be done. Once any action is completed, it can be cancelled off from the list. With the diary you can also plan ahead for actions.
- Matters related to biochemistry, database and finances should be addressed to the concerned person and copied to the Team Leader.
- All urgent/important mails need to be acknowledged.
- Anything sent through post (photocopy of questionnaires, bills, attendance etc.) should be preceded by a mail to keep the other centre informed. Again receipt of anything should also be acknowledged by mail.

#### <u>Proforma-3</u> NATIONAL INSTITUTE OF NUTRITION (ICMR) Jamai Osmania PO, Hyderabad – 500 007

# Travel/Incidental payment to the participant

#### **Details of the Participant**

Name:	_ Study ID No.:
Address:	
Classification of the Relative: (Tick the appropria Intra-city/Nutritional Trial Day-traveller Address verification Document attached (essentia • Ration Card Election I-Card Telepho • Any other (Pl. specify) Proof of Travel attached: Yes No T Approx. distance travelled: KMs	Over-night Stay  Long Distance al) one Bill Driving License

Detail	s of payment	Voucher No:	D	ate
1.	Travel Cost (Attach a copy of	the Train/Bus Ticket)	:	Rs
2.	Incidental Expenses		:	Rs
3.	Total Amount paid		:	Rs
(Rup	ees		only)	
Prepa	ared by Ve	rified by		Approved by

#### **Receipt for payment**

Received a sum of Rupees	only (Rs	) towards my expenses
for participation in the Hyderabad DXA Study research	project.	

Recipient Relative/ Thumb impression

(Phone number:

#### **CALIBRATION SYSTEM**

#### **Daily Calibration**

- All instruments which are being used for measurements in the clinics have to be calibrated on all the days when clinics are held.
- As far as possible, readings for the calibration to be taken on the same 2 fieldworkers everyday.
- Calibration has to be done early morning on arrival at the clinics before the subjects come.
- This has to be entered into a calibration sheet provided and then saved into the PC at the end of the day.
- Calibration needs to be done on active instruments only i.e., the one being currently used. In cases where both instrument is being used at the same time, then calibrations to be done for both.
- These readings need to be reviewed at the weekly meetings and if there is a very wide variation in the readings, then this needs to be communicated to the coordinating centre.
- For calibration of the calipers, measurements of a thin and thick book will suffice.

#### Monthly Calibration

Besides daily calibration, monthly calibration of the instruments needs to be done. The procedure for this is as below:

Weighing Machine:

- This can be done by comparing against standard weights starting from 5kg and above.

Stadiometer:

- The metallic tape can be use for this and readings to be taken at 75 and 150 cms on the stadiometer.

Calipers:

- Same as the daily calibrations, i.e, using 2 books with different thickness.

BP apparatus:

- Comparing it against a sphygmomanometer. It is important however to remember that the same sphygmomanometer to be use throughout the study.

### DAILY CALIBRATION SHEET

Date	wt of FW			measurement		Comments
	no.	no.		of thick	FW no.	
	(weighing	(stadiometer	book(caliper	book(caliper	(Omron	
	machine	no)	no)	no)	No)	
	no)					

## MONTHLY CALIBRATION

Date	Standard weights(5,10, 15kgs) against digital weighing scale (no)	Ht of (stadiomet er no) at 75 and 150 cms	measuremen t of thin book(caliper no)	measuremen t of thick book(caliper no)	BP of FW no. using Omron No)	BP of FWno. Using sphymomano meter	Comments

### FAQs

What if a woman (or in some cases men e.g. if elderly) refuses to travel alone?

• In such cases additional payment (50% extra) may be made for an accompanying person. However, the accompanying person is not to be included in the study. If the accompanying person wishes to have him or herself checked, a short examination (or blood pressure measurement) may be considered to ensure cooperation of the family; however, the data will not be recorded.

Can the index person be clinically examined before the relative?

• Preferably not. As the data on index person cannot be used without data on the relative, it is better to avoid collecting data on index persons beforehand as it will be useless if the relative doesn't turn up (despite indicating that they would). As far as possible, clinics should be conducted on the index person either at the same time as the relative or soon afterwards.

Can the index/urban residents be examined at times when there is low attendance of rural relatives, say for example in the harvest season?

• Seasons can have an important effect on the health of the individual and its assessment. Therefore it is important to avoid examining one type of participant during one or the other season. While some seasonal variation in recruitment of participants may be unavoidable (and also time effective), it is important to try and spread out the recruitment of any category of participant throughout the year.

What if the subject arrives to the clinic but is not completely fasting?

• As long as the subject has not eaten or drank anything other than water in the last 4 hours, the sample should be collected and the subject recruited.

What if a woman is pregnant or may be pregnant?

- If there is any possibility that a woman may be pregnant, ask her to take a pregnancy test. Women who are pregnant undergo all the questionnaires and tests in the same way but do **not** undergo screening through DXA.
- Women who are pregnant are not asked to fast before the examination clinic.

#### <u>Reporting System</u>

This will be a regular reporting system from NIN to LSHTM.

#### NIN to LSHTM-

The study coordinator is required to send the weekly reports to LSHTM by Wednesday afternoons. Reports for a week will contain data through the last Wednesday to the current Tuesday. The weekly reports to be send to LSHTM are:

- Weekly summary report
- Fieldworker performance sheet
- Database copies

At the end of each month (on the last Wednesday of the month along with the weekly reports), Team Leader is required to send the following:

- inventory of the general items
- inventory of biochemistry items

\* Each research assistants will also maintain the daily progress report which can be reviewed by the team leader every week at the weekly meeting on Friday.

\*\* Every Friday there is a phone call between the Team Leader and PI at LSHTM so as to keep them abreast with the activities carried through the month and also discussing any issues/problems requiring solution.

IMPORTANT: All reports to be prepared by the Data Entry Operator and reviewed by the /Team Leader before sending it to LSHTM.

#### DATA QUALITY CONTROL PROTOCOL Data quality of the questionnaires

Every week when the team meets, the Team Leader picks 2 questionnaires filled in the current week by one interviewers. The Team Leader needs to go through the questionnaire, question by question with the entire team, to identify incomplete/missing entries and any errors. The purpose of this is to rectify and clear any doubts which the interviewers may still have.

#### Data quality of the database

For the data quality of the database, the Team Leader needs to compare the questionnaires with the same entered into the database. For this, 2 current questionnaires per interviewer per week, already entered into the database, could be checked. A blank questionnaire is kept at hand when doing this exercise and errors/missing data identified in the database can then be noted as tally lines against the particular question in the blank questionnaire. For e.g, if there is an error in Qs. 3.1 of the questionnaire, then a tally line needs to be marked against the question. This exercise has to be repeated every week so that by the end of the month, 8 questionnaires (2 per interviewer) would have been covered. Then the tally lines in the blank questionnaire can be added up for all the 8 questionnaires and this adds up to the total number of errors and gives us the numerator for the error rate.

 $Error rate = \frac{Total number of tally lines}{Total number of filled fields in the questionnaire x 8}$ 

#### Filing System

- 1) All the questionnaires filled should be filed appropriately.
- 2) For completed questionnaires pending for data entry, one separate box can be maintained. All questionnaires in this box should be filed according to ID. For easy management, boxes with ranges of IDs starting in a series.
- 3) Once the completed questionnaires have been checked by the Team Leader these will be filed by ID in the filing cabinet draw "For Data Entry".
- 4) After data entry the questionnaires are filed by ID in the filing cabinet draw "Entered Questionnaires"
- 5) The photocopies of the ID will also be filed by ID in the filing cabinet draw "IDs".

#### Clinics

For the clinics, 12 file folders will be maintained. On arrival of a subject to the clinic, a file folder containing the following will be handed over to him/her by the fieldworker who is receiving them. The file folder for the participant will contain the following:

- Participant Info sheet
- Consent Form
- Questionnaire
- Labels
- Reimbursement form
- Feedback form

This file folder will then be handed to the Team Leader at the end of the clinic procedures who will then check for missing/incomplete data. If everything is complete, this is to be piled in the box pending for data entry. The empty file folders will then be use for the next batch of subjects. The photocopies of the ID will also be filed.

#### Appendices

#### Information sheets

For participants of the Indian Migrant Study:

#### PARTICIPANT INFORMATION SHEET

# Study title: "Nutritional challenges, abdominal adiposity and type 2 diabetes in Indians"

#### Purpose of the study

Researchers here in Hyderabad and the London School of Hygiene & Tropical Medicine are interested in understanding the effects of migration on health problems like diabetes and obesity. They will study urban factory employees, their spouses and their rural-dwelling brothers and sisters. Differences in life-style, risk factors for common diseases and the presence of diabetes and other cardiovascular diseases will be compared between rural and urban dwelling people. These comparisons will help to predict future needs for health services in India which will benefit planning. The research will also help in understanding the health effects – both positive and negative – of migration which may lead to ideas for preventing bad outcomes. Finally, the study provides an opportunity for employees and their relatives to gain important information about their health status.

#### **Questions and concerns**

You are being invited to participate in this medical research study. Kindly read this information sheet attentively. If you are not clear about anything or there is any uncertainty, then you are free to ask any questions when you receive a visit from the study staff. Sign the consent letter only when you are able to understand the nature of this study fully along with your rights as a participant. You are free to discuss it with anybody, whose consultation is important to you.

#### **Voluntary participation**

It is entirely your decision to participate in the study. If you want to discontinue at any point of time, you are free to leave this study without stating any reason. Your medical care or employment will not be affected by your decision.

#### What does it mean to participate?

Participation in this study involves answering some questions about your general medical habits, having body measurements taken, your blood drawn and a short medical examination, which includes some measures of your heart and a breathing test. You will have a special type of X-ray taken to measure your body fat. Your answers are confidential and will be used only for the study.

#### You will be required to give a blood sample

You will be asked to fast overnight before the visit in which you give your blood samples. During the visit we will ask you to donate a small sample of your blood. Trained personnel will draw the blood. The supplies used for drawing blood will be safe and sterile and used only once and the supplies will be destroyed after use. The blood you give will be used for research purposes only.

#### Follow up in the future

The present research does not require the research team to see you again. However, important information can only be gained by linking your current health and life style to what happens to you in the future. Therefore, we would like to invite you to continue to participate in the future if you wish.

#### Benefits from the study

You will get a medical examination by an experienced team, including doctors. You will undergo the following tests: blood pressure, blood glucose for diabetes, haemoglobin, DXA scanning to measure fat levels, three tests on your heart and blood vessel function (arterial stiffness, pulse wave velocity and carotid intima media thickness) and respiratory

function. Counseling will be given to you based on the results of the medical examination and blood levels. You will be given your blood results.

By participating in this study you will help researchers gain a clearer understanding of how migration has an effect on diseases like obesity and diabetes. Your participation will also help them understand how lifestyle, physical activity and dietary habits affect your health.

#### **Risks of participating in the study**

We do not expect that you will incur any risks by participating in this study. Blood drawing may cause a small amount of 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.

#### **Financial costs**

You will not incur any costs as a result of your participation in this study. Your travel fare and loss of daily wages will be reimbursed. Refreshments will also be provided.

#### Confidentiality

If you decide to take part in the study, all details provided by you will be kept confidential and it will only be made available to investigators related to this study. Information will be stored in password protected computer in Hyderabad and in London. The results will be published in research magazines and reports. However, the names and details of the study subjects will not be disclosed and you will not be recognized from them.

#### Funding & Coordinating agency

The funds for this study are being provided by the Wellcome Trust, a major UK based research charity.

#### **Ethical Review**

The study proposal has been approved by the London School of Hygiene & Tropical Medicine and the National Institute of Nutrtion.

#### **Contact for further information**

If you require any further information or need to clarify some issue, you can contact any of our study team members at National Institute of Nutrition, Hyderabad

#### What your signature means

Your signature on the next page means that you understand the information given to you about the study. If you sign the form it means that you agree to join the study. You will be provided a copy of this patient information sheet to keep with your records.

For participants of the Hyderabad Nutrition Trial:

#### PARTICIPANT INFORMATION SHEET

# Study title: "Nutritional challenges, abdominal adiposity and type 2 diabetes in Indians"

#### Purpose of the study

Researchers at the National Institute of Nutrition in Hyderabad and at the London School of Hygiene & Tropical Medicine are interested in understanding the effects of poor nutrition during childhood, particularly from the time of being in the mother's womb, on getting diabetes and heart disease in later life. You have been chosen for this study as your mother participated in an earlier study conducted by National Institute of Nutrition when she was pregnant with you. At

that time, some but not all the participants were provided with extra food with the help of the Anganwadi. We are trying to know from this research whether the chances of getting heart diseases have been reduced in the children born to the women who got extra food. These comparisons will help to predict future needs for health services in India which will benefit planning. The research will also help in understanding the health effects – both positive and negative – of nutritional supplementation which may lead to ideas for preventing bad outcomes. Finally, the study provides an opportunity for you to gain important information about your health status.

#### **Questions and concerns**

You are being invited to participate in this medical research study. Kindly read this information sheet attentively. If you are not clear about anything or there is any uncertainty, then you are free to ask any questions when you receive a visit from the study staff. Sign the consent letter only when you are able to understand the nature of this study fully along with your rights as a participant. You are free to discuss it with anybody, whose consultation is important to you.

#### **Voluntary participation**

It is entirely your decision to participate in the study. If you want to discontinue at any point of time, you are free to leave this study without stating any reason. Your medical care or employment will not be affected by your decision.

#### What does it mean to participate?

Participation in this study involves answering some questions about your general medical habits, having body measurements taken, your blood drawn and a short medical examination, which includes some measures of your heart and a breathing test. You will have a special type of X-ray taken to measure your body fat. Your answers are confidential and will be used only for the study.

#### You will be required to give a blood sample

You will be asked to fast overnight before the visit in which you give your blood samples. During the visit we will ask you to donate a small sample of your blood. Trained personnel will draw the blood. The supplies used for drawing blood will be safe and sterile and used only once and the supplies will be destroyed after use. The blood you give will be used for research purposes only. Any blood that is left over after the test will may be used for further test related to medical research including tests to find out whether any diseases run in the family.

#### Follow up in the future

The present research does not require the research team to see you again. However, important information can only be gained by linking your current health and life style to what happens to you in the future. Therefore, we would like to invite you to continue to participate in the future if you wish.

#### Benefits from the study

You will get a medical examination by an experienced team, including doctors. You will undergo the following tests: blood pressure, blood glucose for diabetes, haemoglobin, DXA scanning to measure fat levels, three tests on your heart and blood vessel function (arterial stiffness, pulse wave velocity and carotid intima media thickness) and respiratory function. Counseling will be given to you based on the results of the medical examination and blood levels. You will be given your blood results.

By participating in this study you will help researchers gain a clearer understanding of how nutritional supplementation has an effect on diseases like obesity and diabetes. Your participation will also help them understand how lifestyle, physical activity and dietary habits affect your health.

#### Risks of participating in the study

We do not expect that you will incur any risks by participating in this study. Blood drawing may cause a small amount of 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.

#### **Financial costs**

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# Fieldworker Booklet

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2.	List of Million plus cities	2
3.	Village flow diagram	3
4.	Occupation codes	4

#### STATE/UNION TERRITORY NAMES

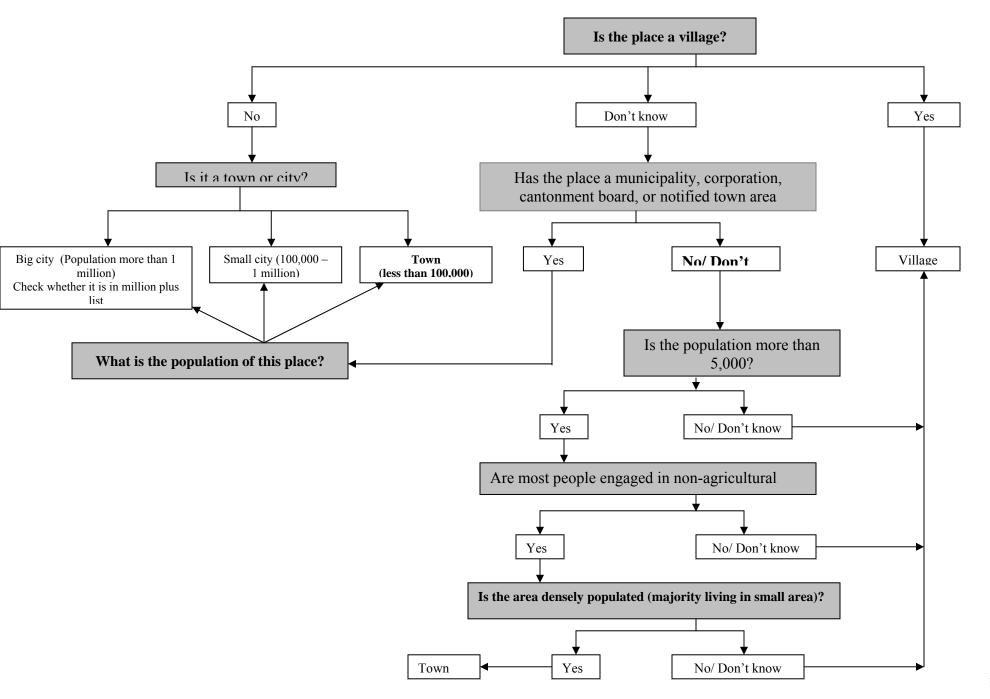
State code	State name	Sub-district name
1	Jammu & Kashmir	Tahsil
2	Himachal Pradesh	Tahsil/Sub-Tahsil
3	Punjab	Tahsil
4	Chandigarh *	Tahsil
5	Uttaranchal	Tahsil
6	Haryana	Tahsil
7	Delhi *	Tahsil
8	Rajasthan	Tahsil
9	Uttar Pradesh	Tahsil
10	Bihar	C.D.Block
11	Sikkim	Sub-Division
12	Arunachal Pradesh	Circle
13	Nagaland	Circle
14	Manipur	Sub-Division
15	Mizoram	R.D.Block
16	Tripura	C.D.Block
17	Meghalaya	C.D.Block
18	Assam	Circle
19	West Bengal	C.D.Block
20	Jharkhand	C.D.Block
21	Orissa	Police Station
22	Chhatisgarh	Tahsil
23	Madhya Pradesh	Tahsil
24	Gujarat	Taluk
25	Daman & Diu *	Taluk
26	Dadra & Nagar Haveli *	Taluk
27	Maharashtra	Tahsil
28	Andhra Pradesh	Mandal
29	Karnataka	Taluk
30	Goa	Taluk
31	Lakshadweep *	Sub-Division
32	Kerala	Taluk
33	Tamil Nadu	Taluk
34	Pondicherry *	Commune Panchayat
35	Andaman & Nicobar Islands *	Tahsil

#### LIST OF MILLION PLUS CITIES

# Urban Agglomerations/Cities having population of more than one million in 2001

2         Kolk           3         Dell           4         Che           5         Ban           6         Hyd           7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Luch           13         Nag           14         Patr           15         Indox           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	ater Mumbai	
3         Dell           4         Che           5         Ban           6         Hyd           7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Luch           13         Nag           14         Patr           15         Indox           16         Vad           17         Bho           18         Coir           19         Ludh           20         Koc		UA
4         Che           5         Ban           6         Hyd           7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	ata	UA
5         Ban           6         Hyd           7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	ni	UA
6         Hyd           7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Luch           13         Nag           14         Patr           15         Indox           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	nnai	UA
7         Ahm           8         Pun           9         Sura           10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Ludl           20         Koc	galore	UA
8         Pun           9         Sura           10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	erabad	UA
9         Sura           10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	adabad	UA
10         Kan           11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	e	UA
11         Jaip           12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	at	UA
12         Lucl           13         Nag           14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	pur	UA
13         Nag           14         Patr           15         Inde           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	ur	M.Corp.
14         Patr           15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	know	UA
15         Indo           16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	pur	UA
16         Vad           17         Bho           18         Coir           19         Lud           20         Koc	a	UA
17         Bho           18         Coir           19         Lud           20         Koc	re	UA
18         Coir           19         Lud           20         Koc	odara	UA
19 Lud 20 Koc	pal	UA
20 Koc	nbatore	UA
	niana	M.Corp.
21 \/ioc	ni	UA
21 1156	khapatnam	UA
22 Agra	1	UA
23 Vara	anasi	UA
24 Mac	urai	UA
25 Mee	rut	UA
26 Nas	hik	UA
27 Jaba	alpur	UA
	shedpur	UA
29 Asa	nsol	UA
30 Dha	nbad	UA
31 Fari	dabad	M.Corp.
32 Alla	nabad	UA
33 Amr	itsar	UA
34 Vija	/awada	UA
35 Rajl	ot	UA
TOT	AL	

#### VILLAGE FLOW CHART



Code number	Name	Activity	Training	Education	Examples
1	At home doing housework	NA	NA	NA	Any member of household
2	Unemployed, not seeking work	NA	NA	NA	Student, training, retired, disabled
3	Unemployed, seeking work	NA	NA	NA	Unemployed
4	Unskilled manual	Unskilled	None	None	<ul> <li>Landless labourers</li> <li>unskilled manual labourer,</li> <li>Servant,</li> <li>Watchman/chowkidar/gate-keepers</li> <li>Coolly,</li> <li>Sweeper/Dhobi(washing and iron)</li> <li>Hawkers/vendors</li> <li>Packers, labellors</li> <li>delivery boys(paper,milk etc)</li> <li>Garbage collectors</li> <li>Car cleaner</li> </ul>
5	Semi-skilled manual	Semi-skilled, manual	Some training	None	<ul> <li>Marginal landowner</li> <li>Petty shopkeeper</li> <li>Peon</li> <li>Rickshaw driver</li> <li>Barber</li> <li>Cobbler</li> <li>Welder/fitter</li> <li>Fisherman</li> <li>Sweet maker(halwai)</li> <li>Butcher</li> <li>Farmer/gardener</li> <li>Semi-skilled manual labour</li> </ul>
6	Skilled manual	Highly skilled, manual activity	Long training	None or little	<ul> <li>Machine and plant operators</li> <li>Painters/Plumber</li> <li>Carpenters/Furnishers</li> <li>Mason,</li> </ul>

# Table of occupational classification in IMS

					<ul> <li>Mechanic,</li> <li>driver, .</li> <li>Sculptors/potters</li> <li>Spinners/weavers/carpet makers</li> <li>Tailors</li> <li>Blacksmith/goldsmith/engravers</li> <li>Street artist and performers/circus people</li> <li>Hunters/trappers</li> <li>Poultry farmers/animal rearers</li> <li>Fire-fighters</li> <li>Army jawan</li> </ul>
7	Skilled non-manual	Highly skilled, non-manual activity	Long training	Some education (read, write, arithmetic) will often be required	<ul> <li>Small business owner(&lt;15 employees)</li> <li>Farm owner/landlord</li> <li>big Store keeper/ shopkeeper</li> <li>Clerk/typist/stenographer/librarian</li> <li>Receptionist(small organization)</li> <li>Ticket collectors/ sellers &amp; examiners/bus conductors</li> <li>Playhome teachers</li> <li>Electrical repair works/ Electrician/watch makers</li> <li>Telephone/telegraph operators</li> <li>Post masters/telegraph masters</li> <li>Station Masters &amp; Station Superintendent</li> <li>Alternative healers</li> <li>Musicians/dancers/artists (village level)</li> <li>Midwives / Health Visitors/field workers/vaccinators</li> <li>X-ray Technician/Lab technicians/OT assistants.</li> <li>Postman</li> </ul>

8	Semi-professional	Lower grade professional	Lower grade professional training	High school or university education	<ul> <li>Medium business owner (15-49 employees),</li> <li>Teachers/College lecturers</li> <li>Personnel managers/Junior Administrators</li> <li>Inspectors(police,school,insuranceetc.)/Ag ents(customs,insurances etc.)</li> <li>Maintenance (in-charge),</li> <li>Nurses/Pharmacist/Dietician</li> <li>Accountant</li> <li>Secretary/ Receptionist(big organisation)</li> <li>Diploma Engineers</li> <li>Musicians/dancers/artists (the teachers)</li> </ul>
9	Professional	Higher grade professional	Higher grade professional training	Generally but not necessarily university education	<ul> <li>Doctors (Allopathy,Ayurveda,Homeopathy)/Veteri narians</li> <li>Lawyers/Judges/Magistrate</li> <li>Engineers/Architects/designers</li> <li>University lectures/Readers/Professors/Principals</li> <li>Class I IAS/IFS/IPS officers</li> <li>Senior administrative officers/Managing Directors</li> <li>Bank Managers/Auditors</li> <li>Newspaper Editors</li> <li>Musicians/dancers/artists (national/international level)</li> <li>Big business(&gt;50 employees)</li> <li>Pilots/Navigators</li> </ul>