ICMR - INdia DIABetes [INDIAB] Study

PHASE I

FINAL REPORT

(2008-2011)

Indian Council of Medical Research
Ansari Nagar, New Delhi – 110 029

Madras Diabetes Research Foundation
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FOREWORD

It gives me great pleasure to write this Foreword for the final report of the ICMR-INDIAB study (Phase I), which was conducted in the states of Tamil Nadu, Maharashtra, Jharkhand and the Union Territory of Chandigarh between 2008 and 2010. Non Communicable Diseases (NCDs) have now become a major cause of death and account for over 55% of all deaths in India. Diabetes represents one of the important NCDs.

Reliable population based data on the burden of NCDs such as diabetes is necessary to plan preventive and curative health services in the country. In this context, the ICMR-INDIAB study gains significance as it is collecting representative data from the various States and Union Territories in India. I am very happy to note that the Phase I of the ICMR-INDIAB study representing the states of Tamil Nadu, Maharashtra, Jharkhand and the Union Territory of Chandigarh has now been completed and the data has been compiled in a report. I am also happy to hear that the results of these four regions have been shared with the respective state governments. Data such as these are invaluable, as they provide a snap shot of the existing burden of disease in the country.

I congratulate the Principal Investigators of various states who have been involved in collecting these data, and the Madras Diabetes Research Foundation (MDRF) which is the national coordinating centre for this study, as well as my colleagues at ICMR. I also wish to thank the INDIAB Expert Committee Members for providing valuable guidance throughout the study. I hope to see the other phases of the ICMR-INDIAB study also completed in a timely fashion and the results presented and published in due course. I am sure this report will stimulate further research on NCDs in our country.

Dr. Soumya Swaminathan
Secretary, Department of Health
Research and Director General, ICMR

PREFACE

It gives me great pleasure to write this Preface for the ICMR-INDIAB study (Phase I) comprising of 4 regions of India and conducted between 2008 and 2010. The ICMR- INDIAB study is one of the first national studies to look at the prevalence of diabetes, hypertension, obesity and dyslipidemia in whole states of the country.

The study is being done in Phases and as the Chairman of the ICMR-INDIAB study Expert Group or Committee Group, I am pleased to note that the first Phase of the study done in the three states of Tamil Nadu, Maharashtra, Jharkhand and the Union Territory of Chandigarh, has been completed and the final report is brought out. I am also happy to note that 8 publications have come out of this phase of the ICMR INDIAB study till date. I hope that before long, the other phases of the ICMR INDIAB study including the North Eastern states of India and the Rest of India will also be completed so that we will have accurate and valuable data on the burden of non communicable diseases such as diabetes, hypertension and obesity from urban and rural areas of all parts of our country. Such data is extremely valuable to policy makers and other stake holders.

I wish to congratulate the Principal Investigators of the various states for conducting and completing the study in a timely manner and the Madras Diabetes Research Foundation (MDRF), the National Coordinating Centre, for supervising the study. I am particularly happy that the study has ensured capacity building in Non Communicable Diseases Prevention and Control in the various states where the study is being done and particularly help individual states in planning and policy formulation for Diabetes in the context of the disease status in their urban and rural areas.

I commend Dr.Bela Shah, Head, NCD and her team at the Division of NCD, ICMR for facilitating the planning and implementation of this nationally relevant study.
I am sure that this report will be useful to all researchers in this country and abroad.

Dr. Lalit M. Nath
Chairperson
Expert Group,
ICMR-INDIAB Task Force Project

PREFACE

In recent years, there is reportedly a sharp increase in the number of individuals sufferings with diabetes which has reportedly increased from 19 million in 1995 to 66.8 million in 2015 according to the International Diabetes Federation. These figures are predicted to increase to 123.5 million by 2040. Most of the currently available estimates of diabetes prevalence in India are regional and limited by small sample size. No study on diabetes has systematically sampled all the states in the country or even a whole state.

The Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) study is aimed as a representative national survey. The Phase I data from the ICMR-INDIAB study, conducted in three states of Tamil Nadu, Maharashtra, Jharkhand and the Union Territory of Chandigarh serves as an important benchmark and highlights areas for public health and policy action. This Phase of the study has enhanced capacity building in combating Non Communicable Diseases in these States. I am also happy to note that several publications have come from this study which will help the scientific community and public health professionals in planning for prevention and control of diabetes and other metabolic NCDs.

I gratefully acknowledge the role played by the National Principal Investigator and the State Principal Investigators of Phase I in successfully conducting and completing the study in a timely manner. I am grateful to Prof LM Nath, chairperson of ICMR-INDIAB Expert Group and the members who have devoted their time and provided generous suggestions throughout the planning and implementation of the study.

The ICMR–INDIAB study will help provide nation wide data and establish a national framework for monitoring diabetes and cardiovascular risk factors in India.

Dr. Bela Shah
Head, Division of NCD, ICMR

MESSAGE

It gives me great pleasure to write a message for the final report for the ICMR- India Diabetes INDIAB study-Phase I which was conducted in 3 states and 1 Union Territory of India viz., Tamil Nadu, Maharashtra, Jharkhand and Chandigarh. India is a country with huge diversity. The heterogeneous nature of the country means that studies done in one part of the country cannot be extrapolated to another part, as there is so much cultural, socio economic and other differences from one part of the country to the other.

Hence, the Indian Council of Medical Research (ICMR) thought it fit to undertake a national study. ICMR decided to undertake a study to obtain reliable data on the prevalence of diabetes, hypertension, obesity, dyslipidemia and other non-communicable diseases in the various States of India. The total sample size planned for the study is 1, 24,000 which will make it one of the largest epidemiological studies on diabetes ever done. We are privileged that the Madras Diabetes Research Foundation (MDRF) was chosen as the National Coordinating Centre to execute the study. We were ably supported by the ICMR-INDIAB Expert Group. The Principal Investigators of every state provided their full co-operation and support to the study. The ICMR Headquarters and specially Dr. Bela Shah at Division of NCD and her team also extended their full support and thanks to the great team work of all the stake holders, the study has already been completed in 14 states and 1 Union Territory of the country. This report deals with the results of the study in the first regions. The INDIAB study has already resulted in several excellent publications and many more are to follow. On behalf of my colleagues at MDRF, we extend our grateful thanks to ICMR and to the Department of Health Research (DHR) for their support to the INDIAB study and we look forward to completing the study as early as possible.

Dr. V. Mohan
National Principal Investigator,
ICMR-INDIAB Task Force Project, MDRF

ACKNOWLEDGEMENT

The various ongoing research programmes in non-communicable diseases undertaken at the ICMR aim to identify risk factors, their prevention, health services requirements and control strategies. This ICMR INDIAB study is a joint effort of a large number of individuals and institutions to determine the prevalence of type 2 diabetes mellitus and pre-diabetes in urban and rural areas across India, by estimating the state-wise prevalence of the same. It is my pleasure to acknowledge the dedication and determination of each member who worked towards completing this phase of the study in these four regions.

I would also take this opportunity to thank Dr. L.M. Nath, Chairman of the ICMR-INDIAB study Expert Group for his constant guidance and support in conducting this study. The Chairman of the Expert Group is specially acknowledged for his critical inputs, suggestions and his initiative to ensure the quality of field data during the ICMR Expert Group audits.

I would like to express gratitude to Dr. VM Katoch, the former Secretary, Department of Health Research (DHR) and Director General, Indian Council of Medical Research, for his interest and understanding of the need to have this study implemented in the entire country so that reliable and valuable national data will be available on the burden of NCDs such as diabetes, hypertension and obesity. I also wish to thank Dr. Soumya Swaminathan, Secretary, DHR and DG, ICMR for her support and encouragement.

I would like to acknowledge here the initiatives undertaken under the able guidance of Dr. Bela Shah for this study. I would also like to thank Dr. D.K. Shukla, for his support. I would like to thank Dr. V. Mohan for his support and coordination in finalizing this report. I would also like to acknowledge the assistance provided by the ICMR administrative staff in this study.

The ICMR appreciatively acknowledges the valuable contribution of the Expert Group members, the National Principal Investigator and all the Principal Investigators of the States for extending their support in conducting this study.

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4. Lilavati Hospital, Mumbai
5. King Edward Memorial Hospital & Research Centre, Pune

DATE OF COMMENCEMENT: 1st June 2008

DURATION: 3 years

DATE OF COMPLETION: 31st May 2011

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OBJECTIVES OF THE STUDY

OBJECTIVES	GOALS
Primary	1. To determine the national prevalence of type 2 diabetes mellitus & pre-diabetes [Impaired fasting glucose (IFG) / Impaired glucose tolerance (IGT)] in India, by estimating the state-wise prevalence of the same. 2. To compare the prevalence of type 2 diabetes and pre-diabetes in urban and rural areas across India.
Secondary	1. To determine the prevalence of hypertension and hyperlipidemia in urban and rural India. 2. To determine the prevalence of coronary artery disease among subjects with and without diabetes. 3. To assess the level of diabetes control among self reported diabetic subjects in urban and rural India.

DETAILED METHODOLOGY

EXPERIMENTAL WORK GIVING FULL DETAILS OF EXPERIMENTAL SET UP, METHODS ADOPTED, DATA COLLECTED SUPPORTED BY NECESSARY TABLES, CHARTS, DIAGRAMS AND PHOTOGRAPHS

The **ICMR-INDIAB Study** is a cross-sectional, community- based survey of adults of either sex, aged 20 years and above, aimed at estimating the prevalence of diabetes and pre-diabetes from all the 28 states, National Capital Territory (NCT) of Delhi and 2 union territories (UTs) namely Chandigarh and Puducherry in the mainland of India (the other 4 union territories namely Andaman and Nicobar Islands, Dadra and Nagar Haveli, Daman and Diu and Lakshadweep are not being sampled due to logistic reasons). Each state, the National Capital Territory and the Union Territories will have an urban component [towns including metros, (wherever applicable)] and a rural component (villages). The study was initiated to estimate the prevalence of diabetes in India in a phased manner. In Phase I, we have studied three states namely Tamil Nadu, Maharashtra, Jharkhand and one Union Territory namely Chandigarh located in the south, west, east and north of the country, respectively. Phase III, which is now ongoing includes the 8 north eastern states of India namely Sikkim, Assam, Meghalaya, Tripura, Mizoram, Manipur, Nagaland and Arunachal Pradesh. In Phase II, the rest of India is currently ongoing.

A. SAMPLING:

i. Sample size calculation:

The sample size was calculated separately for urban and rural areas **[Table 1],** as previous studies show large variations in urban and rural prevalence of type 2 diabetes mellitus. Assuming an expected prevalence of 10% in urban areas and 4% in rural areas, allowing a relative error of 20% on these, a non response rate of 20% and an α error of 5%, the sample size was estimated to be 1200 in urban areas and 2800 in rural areas in each of the regions studied **[Table 2],** with a total of **4,000 individuals / state** and thus the total sample size for Phase I is 16,000 individuals.

Table 1: Sample size calculation for the ICMR- INDIAB study

Study-wise Sample size calculation		Prevalence (p)	q = (1-p)	Relative error (d) = 20% of "p"	Sample Size per state (n)		
					$n = \frac{Z^2 (p) (q)}{d^2}$	Accounting for Non-responders [20%]	Approx
ICMR-INDIAB Phase I	**Rural**	Diabetes =4 %	96%	$\frac{20}{100} \times 4 = 0.8$ %	$n = \frac{(1.96)^2 (4) (96)}{(0.8)^2} = 2304.96 =$ **2305**	$n = \frac{20 \times 2305}{100} = 461$; 2305 + 461 = **2766**	**2800**
	Urban	Diabetes = 10 %	90 %	2%	$\frac{(1.96)^2 (10) (90)}{(2)^2} = 864.36 =$ **865**	$n = \frac{20 \times 865}{100} = 173$; 865 + 173 = **1038**	**1200**

Formula:

Sample size (n) = $\frac{Z^2 (p) (q)}{d^2}$

Z= Z statistic for a level of confidence. For the level of confidence of 95%, the conventional Z value is 1.96 {2 SD}

p= prevalence or proportion of the aspect being studied in the population.

q= (1-p)

d= relative error of the estimated prevalence.

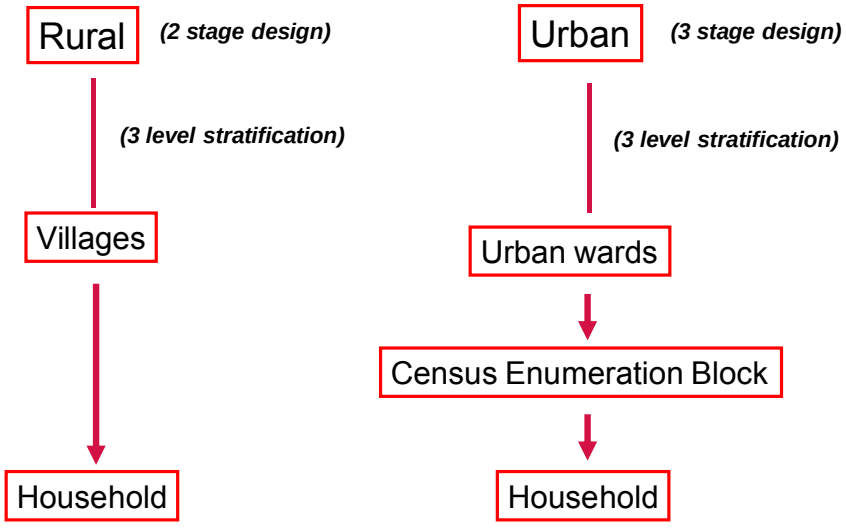
Table 2: Total Sample size required for the ICMR- INDIAB - Phase I

		Sample Size per state (n)	No. of States in Phase I	Total Sample Size
ICMR- INDIAB *Phase I*	**Rural**	2800	4	11200
	Urban	1200		4800
	Overall	**4000**		16000

ii. Sampling design:

A stratified multi-stage sampling design, [similar to the one employed in the National Family Health Survey (NFHS - 3)] was adopted for this study. A two-stage design [Village-Household] was used in rural areas, while a three-stage design [Wards – Census Enumeration Blocks (CEBs)-Household] was adopted in urban areas **[Figure1]**. In both urban and rural areas, three-level stratification was done based on geographical distribution, population size and female literacy rate (as a surrogate of socio-economic status) so as to provide a sample of individuals that was truly representative of the population of the region under study.

Figure 1: ICMR-INDIAB sampling frame work



The **first level of stratification** was based on geographic distribution with each State/UT being divided into contiguous districts. This was based on the NFH3-3 sampling methodology. The **second level of stratification** was based on population size to ensure that there was no bias in the study and that all villages/wards, big and small, were represented in the sample studied proportionate to their contribution to the total rural/urban population of a state. The Probability Proportional to Population size (PPS) method was used to achieve this and arbitrary cut offs were chosen. The **third level of stratification** was based on the rural/urban female

literacy rate, which was used as a surrogate of socio-economic status, to ensure that the sample of villages / wards selected is truly representative of the region studied.

The primary sampling units (PSUs) were villages in rural areas and Census Enumeration Blocks (CEBs) in urban areas. In every village / CEB selected, a mapping and household listing operation was carried out. The census location map was used to identify all the boundaries of the selected sampling unit [village or CEB] correctly. If the boundaries of the sampling unit had undergone change since the census location map was prepared, the team obtained assistance from local authorities to identify the new boundaries and a boundary map was prepared using standard mapping symbols in the form provided.

The household listing operation involved preparing up-to-date notional and layout sketch maps, assigning numbers to structures, recording addresses or the location of the structures and identifying residential structures in the selected villages. In rural areas with ≥ 500 households (large sample villages) segmentation was done, and listing was carried out in two segments selected at random. In urban areas from the list of selected wards provided, one CEB was selected at random.

The ultimate stage units were households in both areas. Households were selected by systematic sampling with a random start. In both rural and urban areas, only one individual was selected within each household using the World Health Organization (WHO) 'Kish method' [STEPwise approach to surveillance (STEPS) World Health Organization (WHO) http://www.who.int/chp/steps/en/]. The complete PSU list for each region is enclosed **(Annexures 1-4)**.

The three level stratification and sampling frame in rural and urban areas are given in **Figure 2 and 3** respectively.

Figure 2: ICMR-INDIAB STUDY SAMPLING DESIGN IN RURAL AREAS

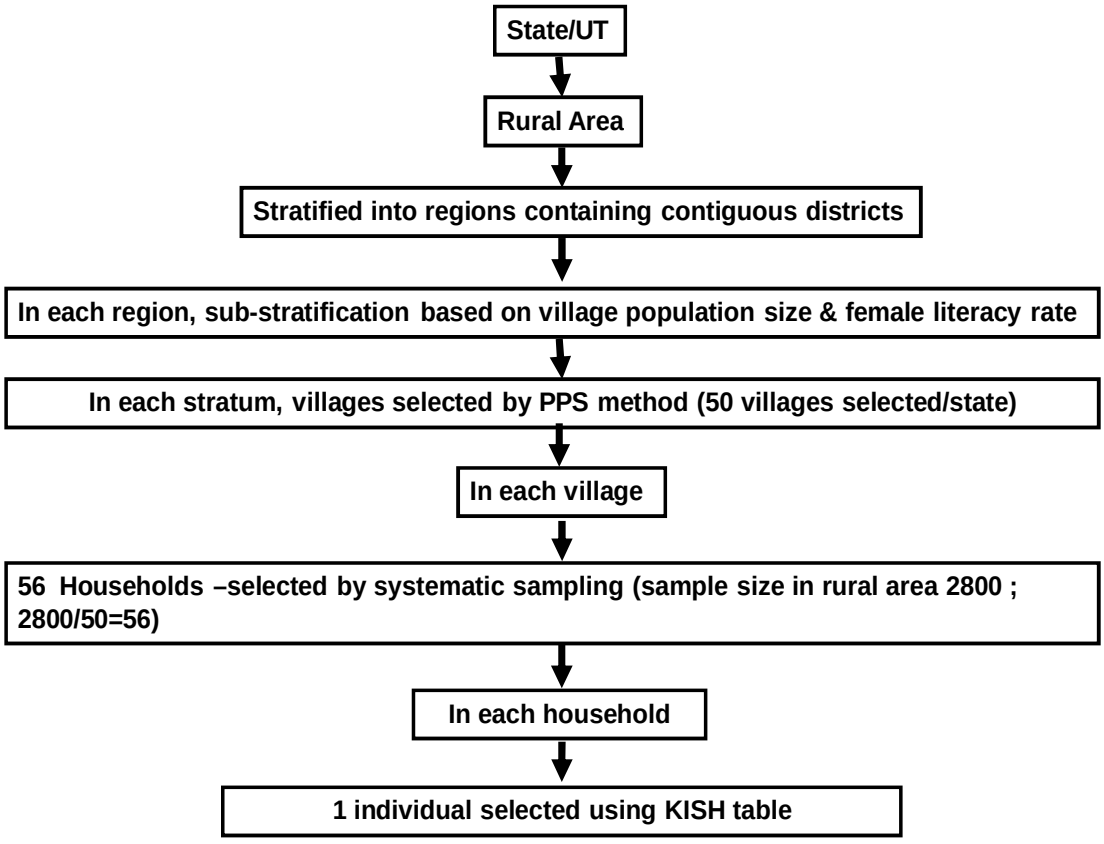
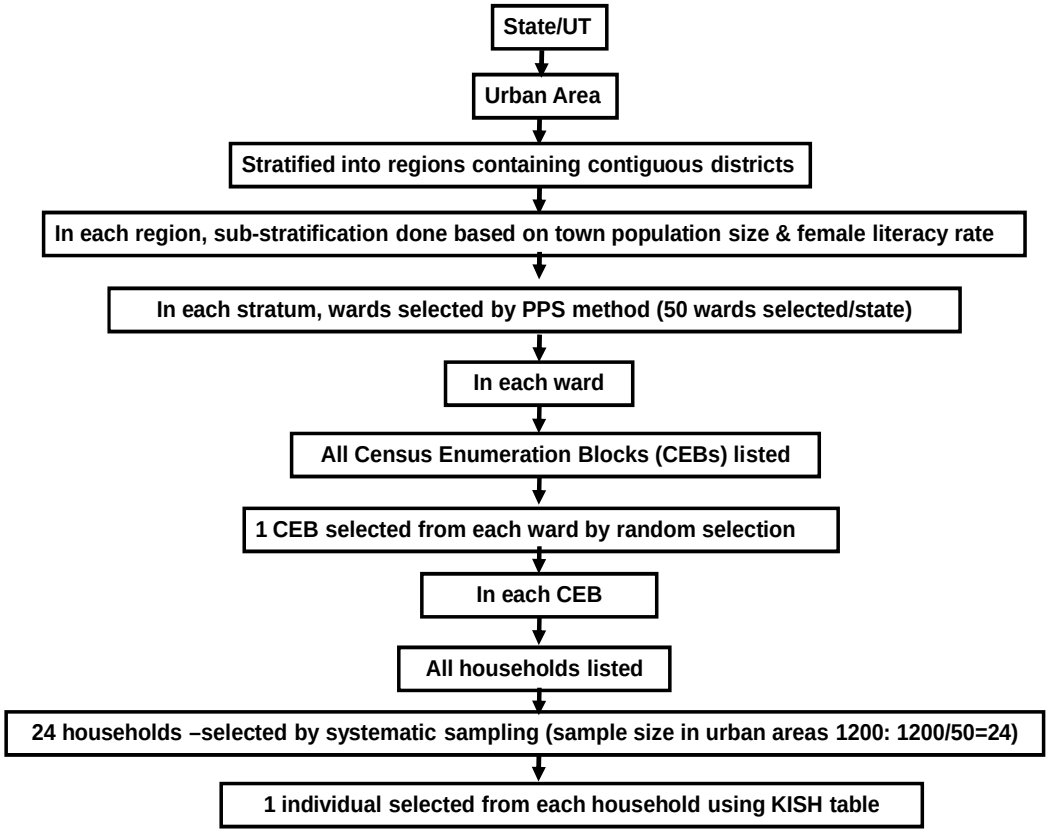


Figure 3: ICMR-INDIAB STUDY SAMPLING DESIGN IN URBAN AREAS



B. ETHICS COMMITTEE APPROVAL / CONSENT FORM:

Approval of the Madras Diabetes Research Foundation [MDRF] Institutional Ethics committee was obtained prior to commencement of the study. Written informed consent **(Annexures 5)** was obtained from respondents after ensuring that they understood and accepted their role in the study.

C. TRAINING OF FIELD STAFF:

All field workers underwent intensive centralized training **[Figures 4 & 5]** at the Madras Diabetes Research Foundation [MDRF] before commencing field work. The training programme provided standardized training sessions on all aspects of the study. The field staffs were trained to administer the questionnaires used in the study. In addition, they were trained in mapping and listing procedures to systematically select the household and individual, to take anthropometric measurements such as height, weight and waist and clinical measurements such as ECG (electrocardiogram), blood pressure and pulse rate. They were also trained in blood glucose measurement using the glucose meter (capillary blood glucose) and the lab technicians were trained in venous blood collection. Training on quality assurance and quality control measures was given to ensure quality in each and every step involved in the study. Details of various procedures adopted in the study are provided in the annexures: Mapping **(Annexure 6)**, Segmentation & Household Listing **(Annexure 7)** and Selection of subject using KISH method **(Annexure 8).** Training also included calibration of all equipment used in the study **(Annexure 9)**.

Training was done using printed and digital media aids (e.g. standardized videos dubbed in local languages, handouts, show cards etc.) Field workers were also trained in rapport building, communication skills and first-aid. All trainees were evaluated and certified at the end of the training programme with a written as well a practical examination where intra- and inter-observer variability was checked.

Figure 4: Questionnaire training to the field team

Questionnaire training session

Group discussion during training

Figure 5: Training on anthropometry & clinical measurement

ANTHROPOMETRY , BLOOD PRESSURE & ECG TRAINING

Weight measurement

Height measurement

Waist measurement

Blood pressure recording

ECG recording

D. QUALITY CONTROL:

Quality control refers to the efforts undertaken during the study, to monitor the quality of data at identified points of data collection and processing. Quality control in the field was achieved through multiple tiers of checks. In the first tier of quality control, the quality supervisors performed daily checks on all questionnaires, anthropometric measurements, and biological samples collected and/or recorded by the field personnel. The second tier of quality control was carried out by quality managers who randomly chose 10 PSUs in each state for monitoring of data collection. These occasions were also utilized for onsite training, refreshers, and/or collecting repeat samples for validation. The state principal investigators provided a third tier of quality control via regular field visits to supervise field activities. Finally, an external quality monitoring team including members from the Indian Council of Medical Research Expert Group made site visits to check the quality of data and onsite procedures **[Figure 6]**.

During the monitoring visits, the various field activities were observed by the experts and valuable inputs were provided to the field personnel. These visits by the experts greatly motivated the field team and helped to assure quality of data collected. For the Chandigarh visit, Dr. L.M.Nath, Dr. Anil Bhansali, Dr. Ashok Kumar Das, Dr. Tanvir Kaur, Dr. Shukla, Dr. V.Mohan and Dr. Guha Pradeepa visited the field area. Field visits were made by the State Principal Investigators, Dr. V.K.Dhandania for Jharkhand, Dr. Prashant Joshi for Maharashtra, Dr. Anil Bhansali for Chandigarh and Dr. V.Mohan for Tamil Nadu **[Figure 7]**. The MDRF team accompanied the State Principal Investigators for all the site visits.

Figure 6: Monitoring visits by experts from ICMR

Dr.Anil Bhansali, Dr.Ashok Kumar Das, Dr.V.Mohan, Dr.Tanvir Kaur (hidden), Dr.L.M.Nath and Dr.Shukla during the monitoring visit

Figure 7: Site visits by the State Principal Investigators during Phase I Of the ICMR-INDIAB survey

TAMILNADU

Dr.V.Mohan, Tamilnadu State PI

JHARKHAND

Dr.V.K. Dhandania, Jharkhand State PI

CHANDIGARH

Dr.Anil Bhansali, Chandigarh State PI

MAHARASHTRA

Dr.Prashant Joshi, Maharashtra State PI

All field work and pre-field activities were documented using quality logbooks. Twenty two quality logs have been utilized in this study and have helped ensure high standards of quality. **Table 3** shows the various documentations (quality logs) used in the study. These logs are enclosed as **Annexure 10.**

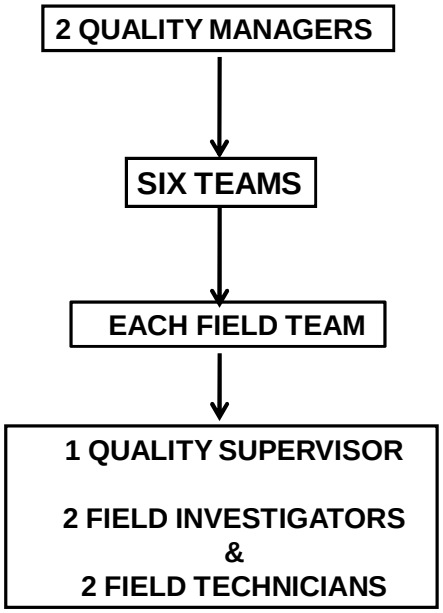
Table 3: Documentation (Quality logs) for the ICMR-INDIAB Study

S. No	Format Name	Format No.
1	Equipment Calibration Log - Stadiometer	INDIAB 2008 -001
2	Equipment Calibration Log – Weighing Machine	INDIAB 2008 -002
3	Equipment Calibration Log – Measuring Tape	INDIAB 2008 -003
4	Equipment Calibration Log – BP Apparatus	INDIAB 2008 -004
5	Equipment Calibration Log – Glucose meter	INDIAB 2008 -005
6	Field Investigator Daily Log	INDIAB 2008 -006
7	Wastage Log	INDIAB 2008 -007
8	Interviewer Certification Rating Form	INDIAB 2008 -008
9	Anthropometry Trainee Performance Checklist	INDIAB 2008 -009
10	Blood Pressure Performance Checklist	INDIAB 2008 -010
11	Blood Drawing Checklist (Venipuncture)	INDIAB 2008 -011
12	Capillary One touch & Filter paper Checklist	INDIAB 2008 -012
13	Electrocardiogram Performance Checklist	INDIAB 2008 -013
14	Mapping &Segmentation Checklist	INDIAB 2008 -014
15	QS- Courier log-Paper documents	INDIAB 2008 -015
16	QS- Courier log-Biological Samples	INDIAB 2008 -016
17	Courier Receipt Register-Pharmacy	INDIAB 2008 -017
18	Courier Receipt register-Paper Documents	INDIAB 2008 -018
19	Courier Receipt register- Biological Samples	INDIAB 2008 -019
20	Item Transaction Register-Lab/Received Item Quality register-Lab	INDIAB 2008 -020
21	Item Transaction Register-Epidemiology/Received Item Quality register-Epidemiology	INDIAB 2008 -021
22	Item Transaction Register- Nutrition/Received Item Quality register- Nutrition	INDIAB 2008 -022

E. FIELD TEAM COMPOSITION & RESPONSIBILITIES:

Each field team comprised of two Field Investigators (FIs), two Field Technicians (FTs) and one Quality Supervisor (QS). Each region studied in Phase I had five such teams and two Quality Managers (QMs) to monitor the field activities. An additional team was later included to speed up the study. **Figure 8** depicts the field team composition in each region. The job responsibilities of FI, FT, QS and QM are provided in **Annexure 11**.

FIGURE 8: FIELD TEAM COMPOSITION IN EACH REGION



F. STUDY PARAMETERS:

Inclusion criteria:

The inclusion criteria listed below were applied during recruitment of subjects for the study:

- All adults (both men & women) aged 20 years and above.
- Usual resident of the selected locality.
- Willing to provide written consent to participate in the study.
- Mentally stable to provide the details required for the study.

An interviewer-administered questionnaire was used to obtain demographic, behavioural and medical information. Weight, height, and waist circumference were measured and body mass index (BMI) was calculated. Blood pressure was recorded using an electronic instrument (Model: HEM-7101, Omron Corporation, Tokyo, Japan) as the mean of two readings taken five minutes apart.

In addition, in every 5th subject (n=2046), a fasting venous sample was collected and assayed for total cholesterol, triglycerides and HDL cholesterol. LDL cholesterol was calculated. A resting 12-lead electrocardiogram (ECG) was carried out in these subjects. The questionnaire **[Annexure 12]** and show cards **[Annexure 13]** used for the study are enclosed. A quick guide to field operations was developed incorporating all necessary details required by the field staff for their ready reference in the field **[Annexure 14]**.

In all 16,000 subjects the following was administered:

- A structured questionnaire was used to obtain data on demography, personal details (smoking, alcohol etc.), family income, physical activity level, medical history and family history of diabetes and heart disease **[Annexure 12].**
- Anthropometric measurements including height, weight, waist and hip measurements.
- Measurement of blood pressure [OMRAN electronic equipment] and pulse rate.
- Capillary blood glucose measured using glucose meter. An oral glucose tolerance test [OGTT] was done using a 75 gms oral glucose load and the 2 hour post load capillary blood sugar was estimated. In self-reported diabetic subjects, only fasting capillary blood glucose was measured.

In every 5th subject (n= 3,200) the following was administered in addition to the above mentioned parameters:

- A fasting venous sample for measurement of lipids and creatinine. Aliquots from this sample have been stored for future use (3,962 aliquots out of 1,981 subject's serum samples are currently available at MDRF – Details of the stored samples are enclosed in **Annexure 15**).
- A nutrition questionnaire was also administered to obtain information on fruit and vegetable intake, oil and salt intake etc**.,**
- An ECG was also done.

In **all diabetic subjects** the following parameters were also studied:

- An ECG was done.
- In addition, a fasting venous sample was drawn for lipids as well as HbA1c.

G. JUSTIFICATION FOR USING CAPILLARY BLOOD GLUCOSE:

Fasting capillary blood glucose [CBG] was determined using One Touch Ultra glucose meter (Johnson & Johnson, Milpitas, California) after eight hours of overnight fasting. Oral glucose 82.5 grams [equivalent to 75 grams of anhydrous glucose] was given and a 2-hour post load CBG was collected. In individuals with self-reported diabetes, only fasting CBG was measured. CBG estimation was adopted in favour of venous plasma glucose estimations as it was neither practical nor feasible to collect, handle, and store such a large volume of samples in an epidemiological study of this magnitude. Moreover, when CBG estimation was compared to venous plasma glucose [VPG] estimation, based on the WHO criteria, 43.2% of subjects had diabetes by the CBG method, whereas 38.6% of subjects had diabetes by the VPG method ($k = 0.816$, $P < 0.001$)", which indicate good correlation between the two methods.

The Pearson's correlation between the capillary whole blood method and the venous plasma glucose method in the fasting state was $r = 0.681$, while for the 2 hour post glucose state it was $r = 0.897$. **Figure 9** shows the regression between capillary blood glucose and venous plasma samples in the fasting state and in the 2 hour post-glucose load indicating good correlation between the two methods. The Bland and Altman Plot **[Figure 10]** drawn to study the limits of agreement between the capillary whole blood and venous plasma methods indicates good agreement between the two methods both in the fasting as well as the 2 hour post glucose states.

Figure 9: Regression analysis comparing venous plasma glucose [lab] and capillary OneTouch® Ultra® glucose concentrations

Figure 1a: Fasting

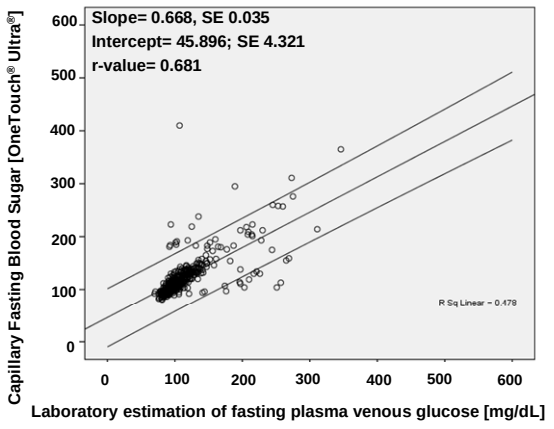


Figure 1b: Two hour post glucose Load

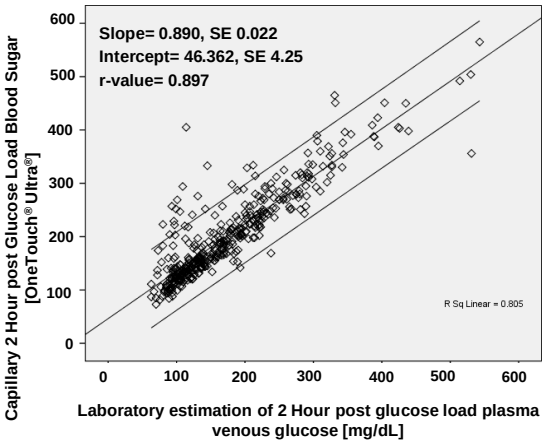


Figure 10: Bland and Altman Plot of venous plasma glucose [lab] and capillary OneTouch® Ultra® glucose concentrations

Figure 2a: Fasting

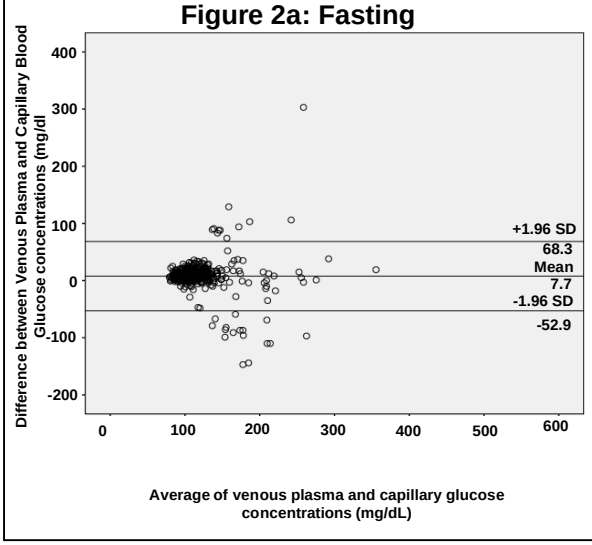
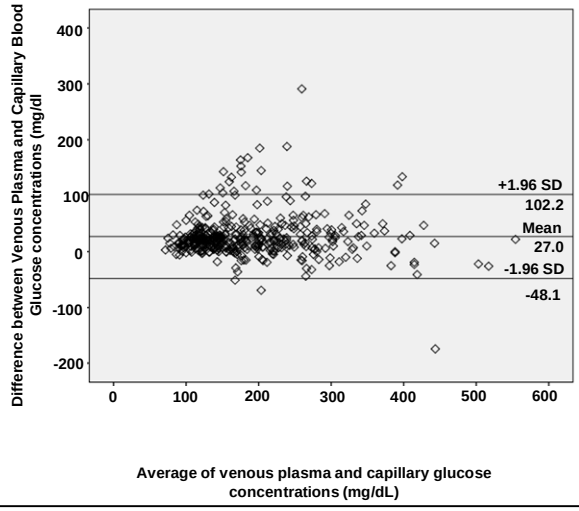


Figure 2b: Two hour post glucose load



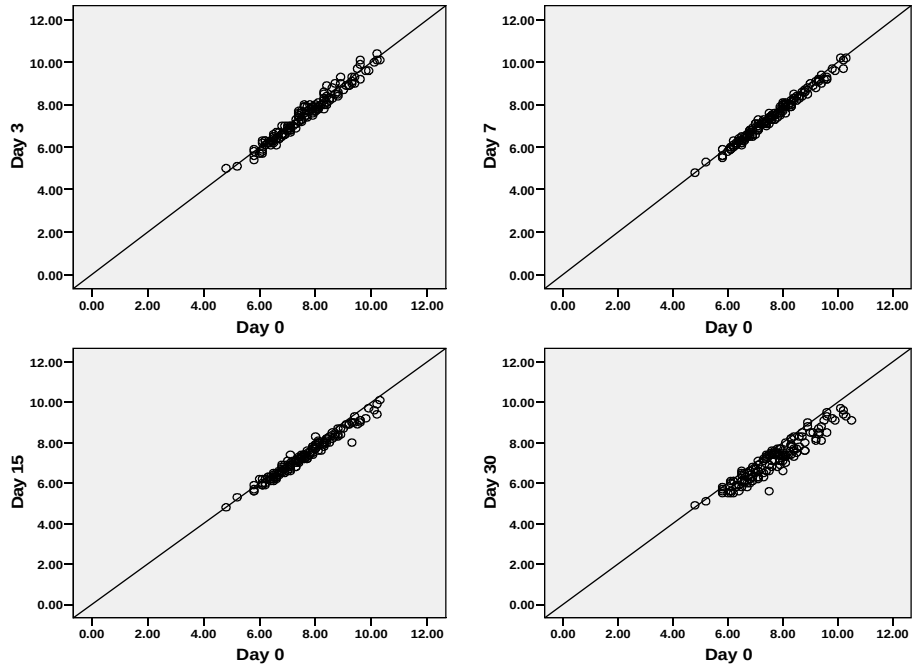
H. REFERRAL SYSTEM:

All newly diagnosed diabetic subjects were asked to confirm their diabetes with a venous OGTT or repeat plasma glucose values at the local public health center, at a government medical college hospital, or with a private practitioner who specializes in diabetes care, whose details were provided by field investigators on request **[Annexure 16a]**. A result slip was provided to all subjects in the field with details of their anthropometry, blood pressure and capillary blood glucose measurements. Their lipids and electro cardiogram reports were posted to them at a later date **[Annexure 16b]**. All subjects were given a copy of their test results. Educational material on diet and life style modifications was also provided.

I. STABILITY OF HBA1C IN STORED BLOOD SAMPLES:

The stability of HbA1c in blood samples stored at -20°C up to a month was tested at Madras Diabetes Research Foundation. This study was conducted in a sample of 142 self-reported diabetic subjects. HbA1c assay was done on the fasting blood sample on Day 0 (day of blood sample collection) and several aliquots were stored in the deep freezer at -20°C. The assay was repeated with the aliquots of the blood samples on 3rd, 7th, 15th and 30th day. HbA1c levels were measured using the Biorad Variant machine. Statistical analysis was done considering HbA1c levels of Day 0 as gold standard. Scatter plot comparison between HbA1c levels of Day 0 and 3rd, 7th, 15th and 30th days were shown in **Figure 11.**

Figure 11: Scatter plot comparison between HbA1c levels of Day 0 and 3rd, 7th, 15th and 30 Days



No significant underestimation or overestimation in HbA1c levels measured on 3rd, 7th, 15th, and 30 days, which assures the stability of HbA1c in blood samples stored at -20°C up to a month.

J. DEFINITIONS USED:

Diabetes: Individuals diagnosed by a physician and on anti-diabetic medications (self-reported) and/or those who had fasting capillary blood glucose (CBG) ≥126 mg/dl and/or 2-hr post-glucose CBG value ≥220 mg/dl [World Health Organization (WHO) criteria].

Impaired fasting glucose [IFG]: Fasting CBG ≥110 mg/dl and <126 mg/dl and 2-hr post-glucose value <160 mg/dl [WHO criteria].

Impaired glucose tolerance [IGT]: Two-hour post-glucose CBG ≥160 mg/dl but <220 mg/dl and fasting value <126 mg/dl [WHO criteria].

Prediabetes: Individuals with IFG or IGT or both.

Hypertension: Individuals with systolic blood pressure (SBP) ≥140 mmHg, and/or diastolic blood pressure (DBP) ≥90 mmHg and/or on treatment with anti-hypertensive drugs [Joint National Committee (JNC) 7 Criteria].

Dyslipidemia: Individuals with total cholesterol ≥200mg/dl or triglycerides ≥150mg/dl or HDL cholesterol <40 (males) and <50 mg/dl (females) or on drug treatment for dyslipidemia [National Cholesterol Education Programme (NCEP) guidelines].

Obesity: Generalized obesity (BMI ≥25 kg/m2) and abdominal obesity (WC ≥90cm in males and ≥80cm in females) were defined using WHO Asia Pacific guidelines.

Metabolic syndrome: Metabolic syndrome was defined as the presence of any three risk factors – hyperglycemia Fasting (CBG ≥110 mg/dl), high blood pressure, abdominal obesity, hypertriglyceridemia and low HDL cholesterol [South Asian Modified (SAM)–NCEP criteria].

Coronary artery disease (CAD): CAD was diagnosed on the basis of documented history of myocardial infarction (MI) or drug treatment for CAD and/or Minnesota codes 1-1-1 to 1-1-7 (Q-wave changes), 4-1 to 4-2 (ST segment depression) or 5-1 to 5-3 (T-wave abnormalities).

K. STATISTICAL ANALYSIS:

The study population was weighted for calculating prevalence rates **[Annexure 17 a-d].** Sample weights were calculated using the National Family Health Survey (NFHS 3) model, which is designed for self weighting at the domain level. The domains were urban and rural areas of each state/UT. The design weight is the inverse of the overall sampling fraction in each domain. The overall sampling fraction is the product of the selection probabilities at each sampling stage (two stages in rural areas and three stages in urban areas).The design weight was adjusted for household non-response in the calculation of the household sampling weight. The household sampling weight was further adjusted for individual non-response to obtain the individual sampling weight. Both adjustments for non-response were done at the domain level in order to preserve the self-weighting nature of the sample within domains. The sampling weights were further normalized at the state level to obtain standard state weights. The state standard weights were calculated to ensure that the total number of weighted cases equals the total number of unweighted cases for each state.

RESULTS

DETAILED ANALYSIS OF RESULTS INDICATING CONTRIBUTIONS MADE TOWARDS INCREASING THE STATE OF KNOWLEDGE IN THE SUBJECT.

Phase I of the ICMR-INDIAB study has been successfully completed in 4 regions namely, Tamil Nadu, Jharkhand, Chandigarh and Maharashtra.

A. Phase I recruitment status and response rate:

In Tamil Nadu, of the total 4,216 individuals selected to be interviewed in 105 PSUs (52 urban PSU and 53 rural PSU), 3,664 individuals participated in the study (86.9% response rate). In Jharkhand, of the total 4,000 individuals to be interviewed in all 100 PSUs (50 urban PSU and 50 rural PSU) 3,337 individuals participated in the study (83.4% response rate). In Chandigarh, of the total 3,991 individuals to be interviewed in all 44 PSUs (21 urban PSU and 23 rural PSU), 3,356 individuals participated in the study (84.1% response rate) and in Maharashtra, of the total 4,400 individuals to be interviewed in all 114 PSUs (62 urban PSU and 52 rural PSU) 3,920 individuals participated in the study (89.1% response rate). **Figures 12 and 13** depicts the primary sampling units (PSUs) selected in urban and rural areas of the selected states.

Figure 12: PSUs selected in urban and rural Tamilnadu and Jharkhand

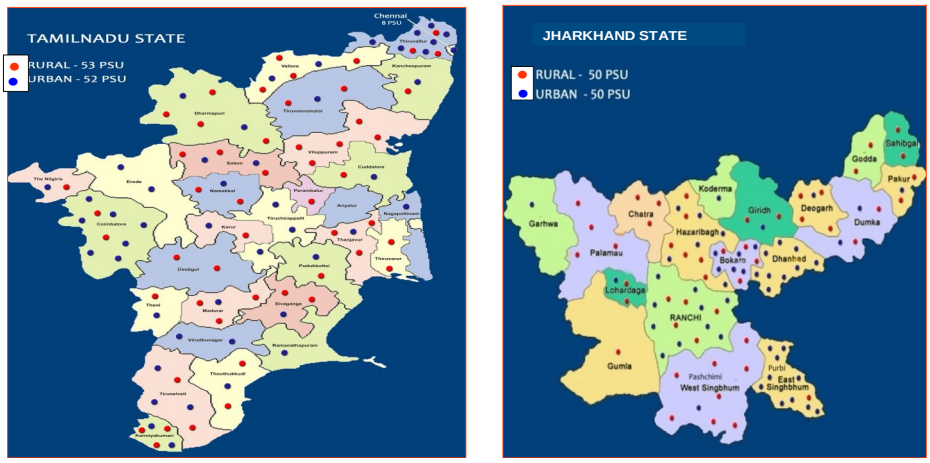
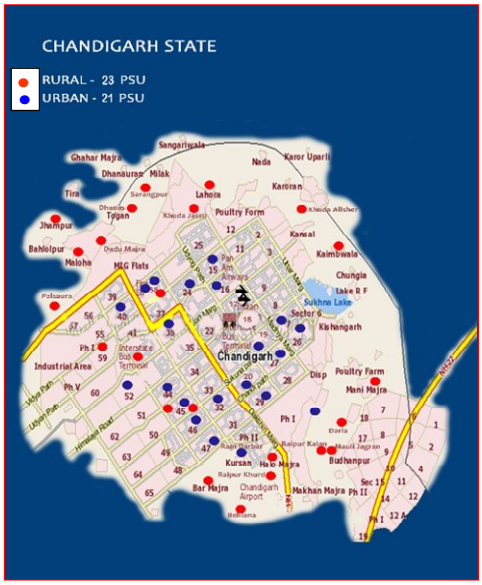
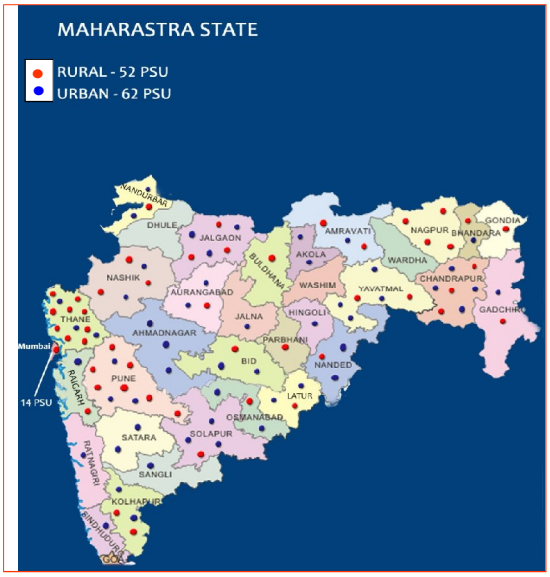


Figure 13: PSUs selected in urban and rural Chandigarh and Maharashtra





The state wise detailed response rate is shown in **Table 4**. The proportion of selected subjects not available during the study period is high in urban areas compared to rural areas in all 4 regions and it ranged from 2.5% in rural Tamil Nadu to 8.5% in urban Chandigarh. Houses remained locked and subjects could not be contacted in 0.5 to 4.3% of households and 4.3 to 13.6% of subjects refused to participate even after repeated visits and requests.

Table 4: State wise response rate for Phase I of the study

Status	Tamil Nadu			Jharkhand			Chandigarh			Maharashtra		
	Urban	Rural	Over all	Urban	Rural	Over all	Urban	Rural	Over all	Urban	Rural	Over all
Completed n(%)	1076 (86.2)	2588 (87.2)	3664 (86.9)	945 (78.8)	2392 (85.4)	3337 (83.4)	911 (77.5)	2445 (87.0)	3356 (84.1)	1254 (84.3)	2666 (91.6)	3920 (89.1)
Respondent not available n(%)	93 (7.3)	73 (2.5)	166 (3.9)	50 (4.2)	114 (4.1)	163 (4.1)	100 (8.5)	117 (4.2)	217 (5.4)	60 (4.0)	90 (3.1)	150 (3.4)
Refused* n(%)	71 (5.7)	287 (9.7)	358 (8.5)	163 (13.6)	173 (6.1)	333 (8.3)	136 (11.6)	191 (6.8)	327 (8.2)	147 (9.9)	125 (4.3)	272 (6.2)
House locked* n(%)	6 (0.5)	19 (0.6)	25 (0.6)	39 (3.3)	119 (4.3)	162 (4.1)	29 (2.5)	49 (1.7)	78 (2.0)	25 (1.7)	24 (0.8)	49 (1.1)
Others** n(%)	2 (0.2)	1 (0.03)	3 (0.1)	3 (0.3)	2 (0.7)	5 (0.1)	- -	13 (0.5)	13 (0.3)	2 (0.1)	7 (0.2)	9 (0.2)

*** Responses are after repeated visits (at least 3)**
**** Partially completed**

Overall, of the 16,607 subjects selected for the study, 14,277 [86%] subjects participated, of whom 13,055 gave blood samples. Responders and non-responders were compared and there were no significant differences in the general characteristics between the 13,055 'responders' and the 1,222 'non-responders' with respect to age, weight, height, BMI, and waist circumference in all 4 regions studied.

B. General characteristics of the study population:

Figure 14 shows the gender distribution of the study subjects in ICMR-INDIAB survey compared to the Census of India, 2001. The gender distribution of all four regions almost exactly matches with the census population showing that the survey is representative of each region studied.

Figure 14: Gender Distribution of study subjects in ICMR-INDIAB compared to the census 2001

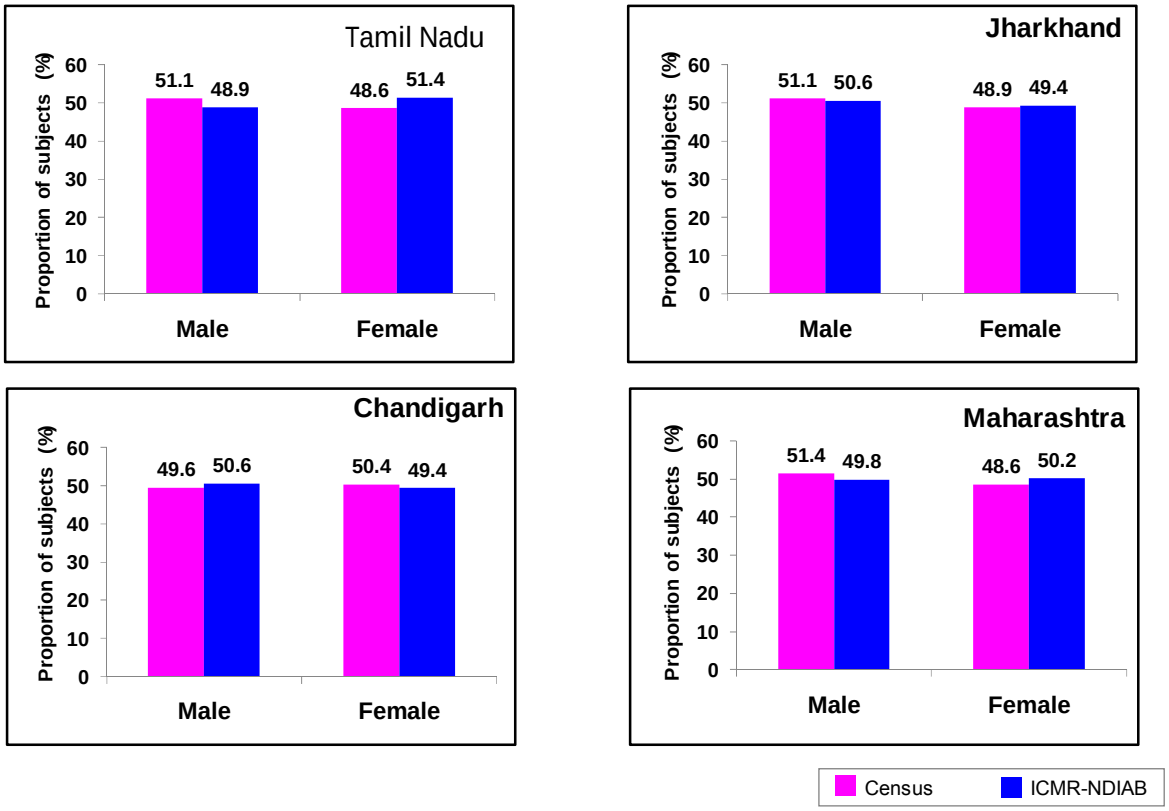


Table 5 shows the educational status of the study population. Jharkhand had the highest number of subjects with no formal schooling (urban: 20.8% and rural: 58.1%) compared to other Phase I regions. In urban areas, Chandigarh had the highest proportion of subjects with higher educational status i.e., undergraduate degree or above (17.7%) followed by Jharkhand (13.8%), Maharashtra (10.3%) and Tamil Nadu (10.2%). In rural areas also, Chandigarh had the highest proportion of subjects with higher educational status (5.5%) followed by Maharashtra (3.8%), Tamil Nadu (3%) and Jharkhand (1.3%).

Table 5: Educational status of the study population

Educational status	Tamil Nadu (%)		Chandigarh (%)		Jharkhand (%)		Maharashtra (%)	
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural
No formal schooling	17.7	35.4	14.3	22.5	20.8	58.1	16.9	35.9
Primary school	48.8	47.8	24.2	29.4	21.9	22.1	34.7	34.6
High school & higher secondary school	20.0	12.0	41.2	40.3	39.2	18.1	35.9	24.6
Technical education	3.3	1.8	2.7	2.3	4.3	0.5	2.3	1.0
Undergraduate degree	7.6	2.2	15.4	5.0	11.7	1.2	8.6	3.2
PG degree or above	2.6	0.8	2.3	0.5	2.1	0.1	1.7	0.6

Table 6: Occupational status of the study population

Occupational status	Tamil Nadu (%)		Chandigarh (%)		Jharkhand (%)		Maharashtra (%)	
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural
n	1071	2582	909	2439	934	2389	1250	2657
Professional /Executive /Manager/Big business	6.2	1.7	10.3	3.5	9.0	1.5	6.0	2.2
Clerical /Medium business	1.7	0.6	6.4	4.1	5.4	0.7	4.7	1.1
Sale	4.8	2.1	8.2	6.4	7.6	3.4	5.6	8.3
Agriculture/Self-employed	11.2	43.5	2.7	4.3	6.9	24.3	6.5	39.3
Household & domestic work	2.7	0.5	2.4	1.0	5.3	2.6	6.7	3.0
Services	3.2	1.9	7.9	5.2	2.3	1.7	5.7	3.8
Skilled manual	16.3	8.5	8.1	16.9	8.3	5.7	13.9	9.2
Unskilled manual	14.4	10.3	5.2	9.8	6.7	13.2	8.5	6.0
Do not work/Unemployed	38.4	30.3	48.2	48.5	46.9	46.7	41.8	26.7
Others	0.9	0.6	0.3	0.1	0.5	0.1	0.5	0.1

Table 6 shows the occupational status of the study population. Professionals or executives or managers or those involved in big business were found in higher proportion in urban areas with 10.3% in Chandigarh followed by 9% in Jharkhand, 6.2% in Tamil Nadu and 6% in Maharashtra. Subjects involved in agriculture or those self-employed were more in rural areas with 43.5% in Tamil Nadu followed by 39.3% in Maharashtra, 24.3% in Jharkhand and 4.3% in Chandigarh. In urban areas, the unemployed proportion ranged from 38.4% in Tamil Nadu to 48.2% in Chandigarh and in rural areas, it ranged from 26.7% in Maharashtra to 48.5% in Chandigarh.

The general characteristics of the study population, comparing urban and rural areas in all the four regions is shown in **Tables 7-10**. In Tamil Nadu and Chandigarh, the urban residents were significantly older, heavier, had higher BMI, waist circumference and blood pressure compared to the rural residents. In Jharkhand, the urban residents were significantly taller, heavier and had higher BMI, waist circumference and blood pressure compared to the rural residents. In Maharashtra, the urban residents were significantly younger, taller, heavier and had higher BMI, waist circumference and diastolic blood pressure compared to the rural residents.

Table 7: General characteristics of the study population [Tamil Nadu state]

Parameters	Urban	Rural	P-value
N	1076	2586	
Age (yrs)	41 ± 14	43 ± 15	**< 0.001**
Height (cms)	157.4 ± 9.4	157.0 ± 8.9	0.289
Weight (Kgs)	58.6 ± 12.7	53.6 ± 11.0	**< 0.001**
BMI	23.6 ± 4.6	21.7 ± 3.9	**< 0.001**
Waist (cms)	80.9 ± 12.2	76.1 ± 11.5	**< 0.001**
BP Systolic (mmHg)	130 ± 19	128 ± 19	**0.005**
BP Diastolic (mmHg)	81 ± 11	78 ± 11	**0.002**

Table 8: General characteristics of the study population [Jharkhand state]

Parameters	Urban	Rural	P-value
N	945	2388	
Age (yrs)	40 ± 14	40 ± 14	0.774
Height (cms)	157.2 ± 9.4	155.4 ± 8.8	**< 0.001**
Weight (Kgs)	56.3 ± 13.2	46.7 ± 9.3	**< 0.001**
BMI	22.7 ± 4.7	19.2 ± 3.0	**< 0.001**
Waist (cms)	80.8 ± 13.6	71.4 ± 10.4	**< 0.001**
BP Systolic (mmHg)	130 ± 19	126 ± 19	**< 0.001**
BP Diastolic (mmHg)	79 ± 11	76 ± 11	**< 0.001**

Table 9: General characteristics of the study population [Chandigarh state]

Parameters	Urban	Rural	P-value
N	910	2445	
Age (yrs)	40 ± 13	34 ± 12	**<0.001**
Height (cms)	159.3 ± 9.5	158.8 ± 9.1	0.329
Weight (Kgs)	61.9 ± 13.1	57.7 ± 12.8	**<0.001**
BMI	24.4 ± 4.7	22.8 ± 4.5	**<0.001**
Waist (cms)	83.8 ± 12.5	79.7 ± 12.7	**<0.001**
BP Systolic (mmHg)	130 ± 18	124 ± 16	**<0.001**
BP Diastolic (mmHg)	79 ± 11	76 ± 11	**<0.001**

Table 10: General characteristics of the study population [Maharashtra state]

Parameters	Urban	Rural	P-value
N	1254	2666	
Age (yrs)	40 ± 14	42 ± 15	**<0.001**
Height (cms)	157.7 ± 9.6	156.9 ± 9.3	0.013
Weight (Kgs)	55.4 ± 12.3	50.7 ± 11.2	**<0.001**
BMI	22.2 ± 4.4	20.5 ± 3.8	**<0.001**
Waist (cms)	77.3 ± 12.4	72.7 ± 11.7	**<0.001**
BP Systolic (mmHg)	128 ± 19	127 ± 18	0.111
BP Diastolic (mmHg)	80 ± 12	77 ± 11	**<0.001**

The biochemical parameters of the study population comparing urban and rural areas in all four regions are shown in **Tables 11-14**. In Tamil Nadu, the urban residents had significantly higher cholesterol, triglycerides, LDL cholesterol and glycated haemoglobin and lower HDL cholesterol compared to rural residents. In Jharkhand, the urban residents had significantly higher cholesterol, triglycerides, LDL cholesterol and glycated haemoglobin compared to rural residents. In Chandigarh, the urban residents had significantly higher cholesterol, LDL cholesterol and glycated haemoglobin compared to rural residents. In Maharashtra, the urban residents had significantly higher cholesterol, triglycerides and glycated haemoglobin compared to rural residents.

Table 11: Biochemical parameters of the study population (In a subset) [Tamil Nadu state]

Parameters	Urban (n=195)	Rural (n=465)	P-value
Total Cholesterol (mg/dL)	172 ± 48	165 ± 37	**0.031**
Triglycerides (mg/dL)*	122	114	**0.032**
HDL (mg/dL)	38 ± 10	40 ± 12	**0.044**
LDL (mg/dL)	104 ± 36	98 ± 31	**0.047**
Creatinine (mg/dL)	0.86 ± 0.24	0.87 ± 0.24	0.528
HBA1C (%)	6.0 ± 1.2	5.8 ± 1.0	**0.009**

* Geometric mean

Table 12: Biochemical parameters of the study population (In a subset) [Chandigarh state]

Parameters	Urban (n=154)	Rural (n=364)	P-value
Total Cholesterol (mg/dL)	170 ± 41	155 ± 38	**<0.001**
Triglycerides (mg/dL)*	140	127	0.151
HDL (mg/dL)	40 ± 12	39 ± 11	0.441
LDL (mg/dL)	98 ± 33	86 ± 31	**<0.001**
Creatinine (mg/dL)	0.69 ± 0.19	0.73 ± 0.17	**<0.001**
HBA1C (%)	5.8 ± 1.3	5.5 ± 1.1	**0.009**

* Geometric mean

Table 13: Biochemical parameters of the study population (In a subset) [Jharkhand state]

Parameters	Urban (n=133)	Rural (n=278)	P-value
Total Cholesterol (mg/dL)	158 ± 40	128 ± 29	**<0.001**
Triglycerides (mg/dL)*	132	96	**<0.001**
HDL (mg/dL)	38 ± 11	37 ± 10	0.248
LDL (mg/dL)	88 ± 31	70 ± 23	**<0.001**
Creatinine (mg/dL)	0.73 ± 0.22	0.72 ± 0.27	0.891
HBA1C (%)	5.4 ± 1.1	5.0 ± 0.6	**<0.001**

* Geometric mean

Table 14: Biochemical parameters of the study population (In a subset) [Maharashtra state]

Parameters	Urban (n=116)	Rural (n=362)	P-value
Total Cholesterol (mg/dL)	164 ± 35	159 ± 36	0.165
Triglycerides (mg/dL)*	118	105	0.065
HDL (mg/dL)	42 ± 16	40 ± 13	0.397
LDL (mg/dL)	94 ± 29	94 ± 33	0.979
Creatinine (mg/dL)	0.8 ± 0.2	0.8 ± 0.3	0.816
HBA1C (%)	5.7 ± 1.3	5.5 ± 1.3	0.155

* Geometric mean

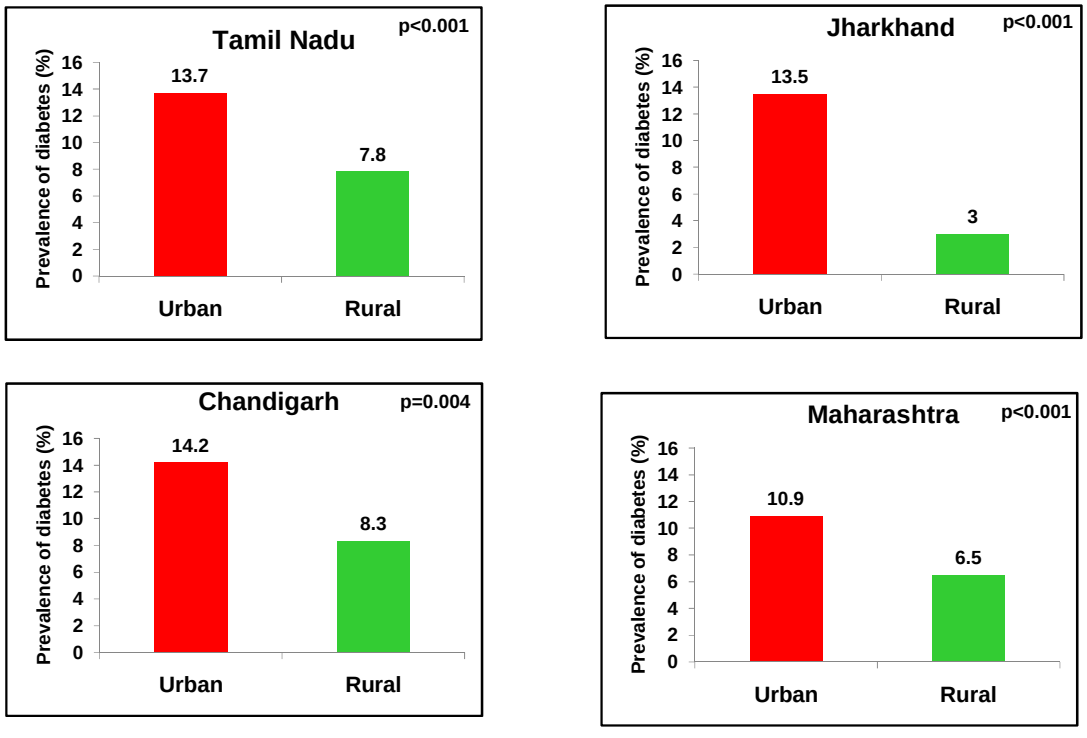
C. Results of Phase I – results of Primary Objectives 1 & 2 are presented together:

Primary Objective 1: *To determine the national prevalence of type 2 diabetes mellitus & pre-diabetes [Impaired fasting glucose (IFG) / Impaired glucose tolerance (IGT)] in India, by estimating the state-wise prevalence of the same.*

Primary Objective 2: *To compare the prevalence of type 2 diabetes and pre-diabetes in urban and rural areas across India.*

The weighted prevalence of diabetes (both self-reported and newly diagnosed diabetes) in the urban and rural population of the four regions is shown in **Figure 15**. In Tamil Nadu, the prevalence of diabetes in urban areas (13.7%) is almost double the rate found in rural areas (7.8%). In Jharkhand, the prevalence of diabetes in urban area is four fold higher than rural areas (urban: 13.5% vs. rural: 3%, p<0.001). In Chandigarh, the prevalence of diabetes in urban is higher than the rates in rural areas (urban: 14.2% vs. rural: 8.3%, p<0.001). In Maharashtra also, the prevalence of diabetes in urban is higher than the rates in rural areas (urban: 10.9% vs. rural: 6.5%, p<0.001). In Chandigarh, the prevalence of diabetes, both in urban and rural areas was higher than in other three regions, viz., Tamil Nadu, Jharkhand and Maharashtra.

Figure 15: Prevalence* of diabetes in the urban and rural population in all the 4 regions studied



*Weighted prevalence

Overall, in all four regions studied, the prevalence of diabetes was higher in urban, compared with rural areas. This difference was most marked in Jharkhand, where rural–urban disparities in socioeconomic status are among the highest in India. This could be because urban Jharkhand is built around industries and hence the population is a mix of people of several cultures and states. Rural Jharkhand is really quite poor and has very low obesity rates. Chandigarh was found to have the highest prevalence of diabetes, in both urban (14.2%) and

rural (8.3%) areas. This is not unexpected, as Chandigarh serves as the joint capital of Punjab and Haryana, two prosperous states in India. Moreover, in Chandigarh the rural areas are not really “rural”, but a suburb of an urban area.

Figure 16 shows the weighted prevalence of diabetes (self-reported, newly diagnosed and overall diabetes) in the urban and rural population of the four regions. Only in Tamil Nadu (both urban and rural) and in urban Jharkhand, the proportion of subjects with self-reported diabetes is higher than newly diagnosed diabetes and in all other regions, the proportion of newly diagnosed diabetes is higher than self-reported diabetes.

Figure 16: Prevalence* of diabetes (self-reported, newly diagnosed and overall) in the urban and rural population in all the 4 regions studied

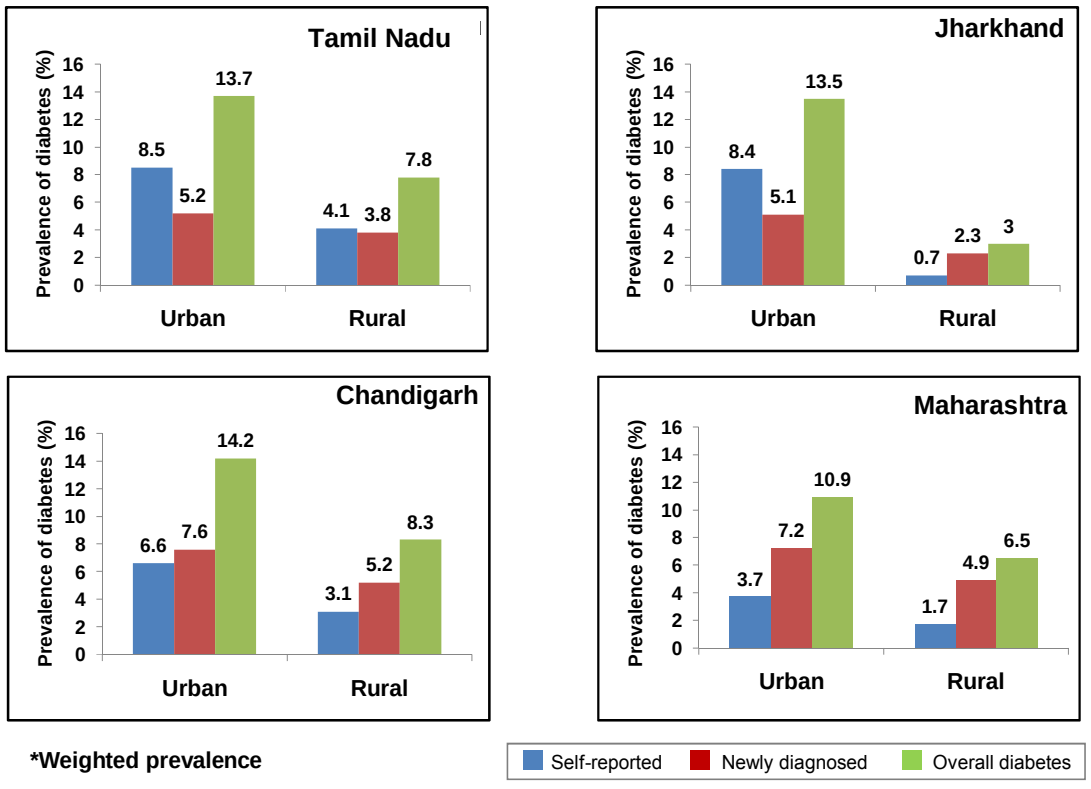
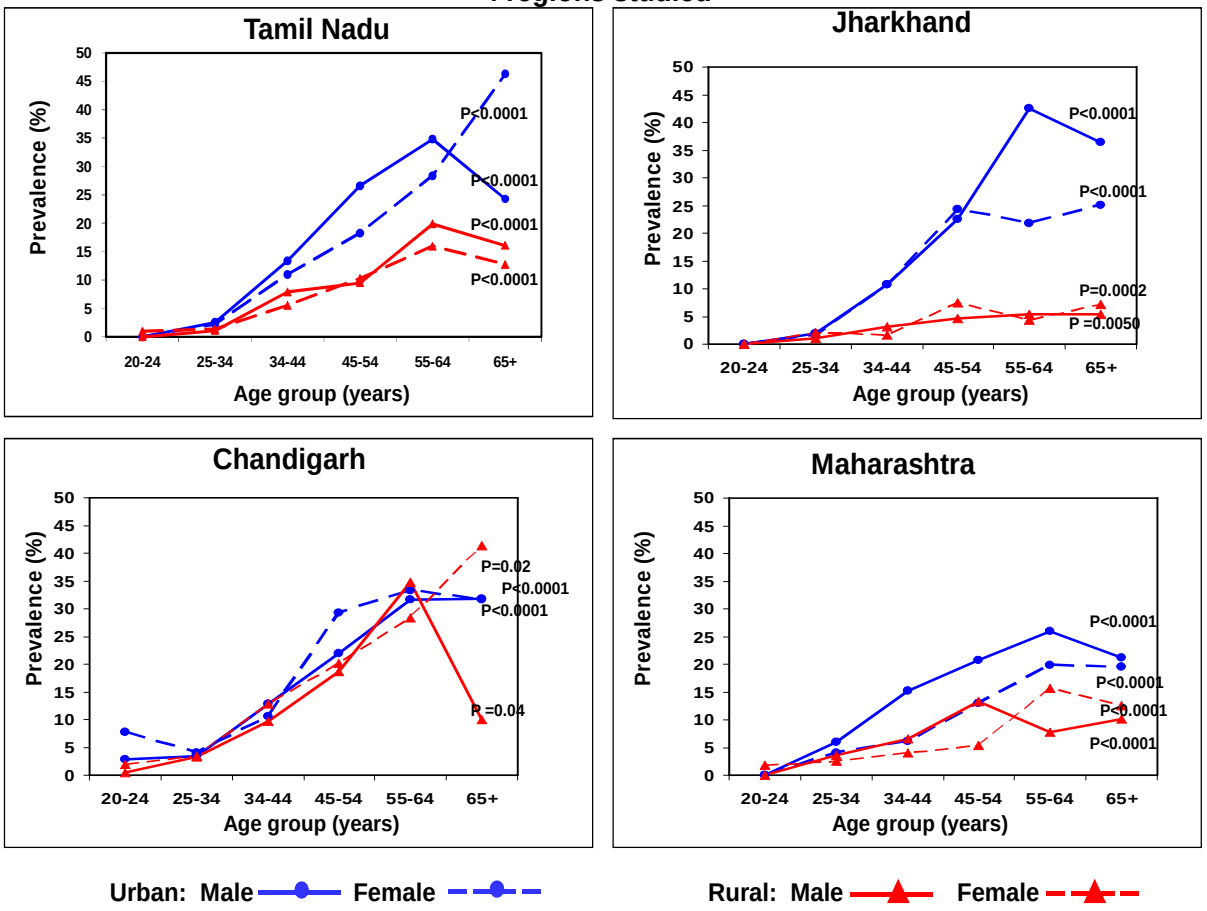


Figure 17 presents the age and gender specific prevalence of diabetes in urban and rural population. In all 4 regions, the take-off point in prevalence was in the age group 25-34 years. At every age interval, the prevalence of diabetes in urban areas was higher compared to rural areas.

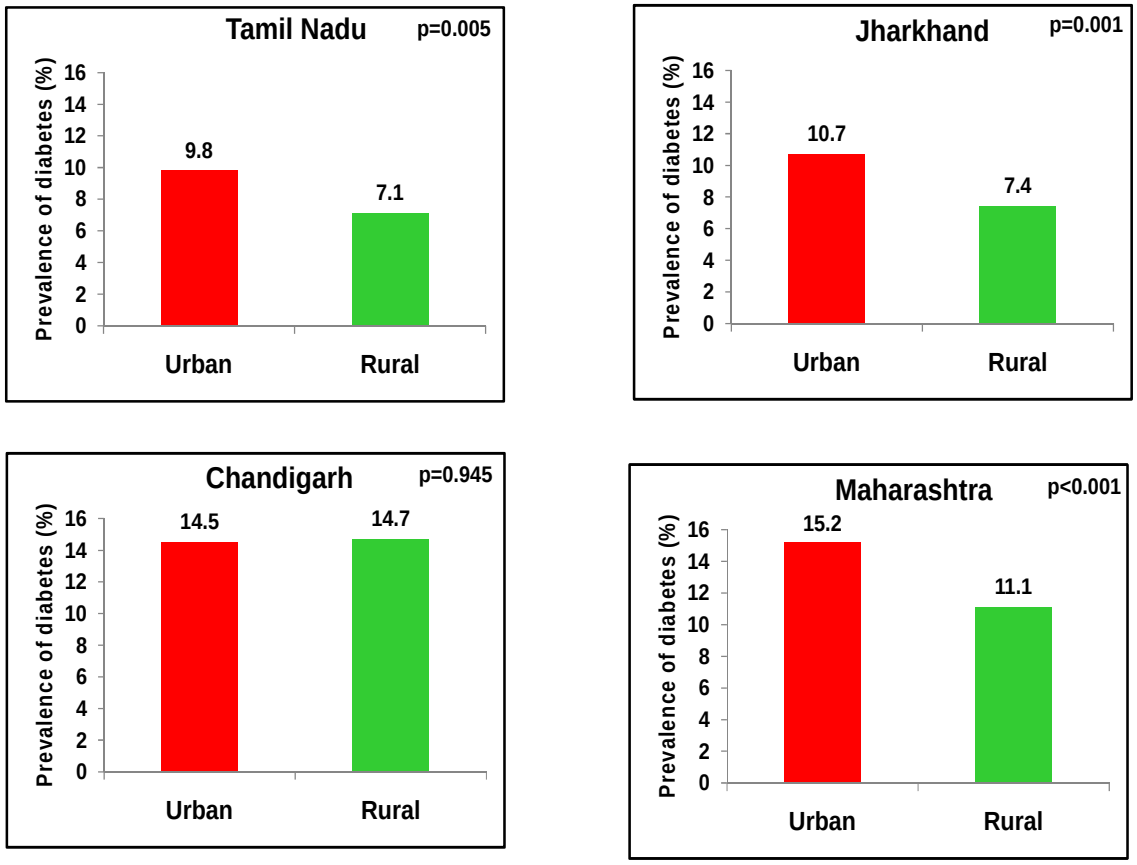
Figure 17: Age and gender specific weighted prevalence of diabetes in all the 4 regions studied



The prevalence reaches a peak around 35 years and thereafter tends to plateau off or decline. This is probably due to survivor bias whereby the older people reflect survivors who tend to be healthier and relatively disease free.

Figure 18 shows the weighted prevalence of prediabetes in the urban and rural population of all the four regions studied. In Tamil Nadu, Jharkhand and Maharashtra, the prevalence of prediabetes is higher in urban areas compared to rural areas, whereas in Chandigarh, the prevalence is higher in rural areas compared to urban areas [Urban vs. Rural: Tamil Nadu – 9.8% vs. 7.1%, $p<0.05$; Jharkhand - 10.7% vs. 7.4%, $p<0.05$, Chandigarh – 14.5% vs. 14.7%, $p=0.302$ and Maharashtra – 15.2% vs. 11.1%, $p<0.05$].

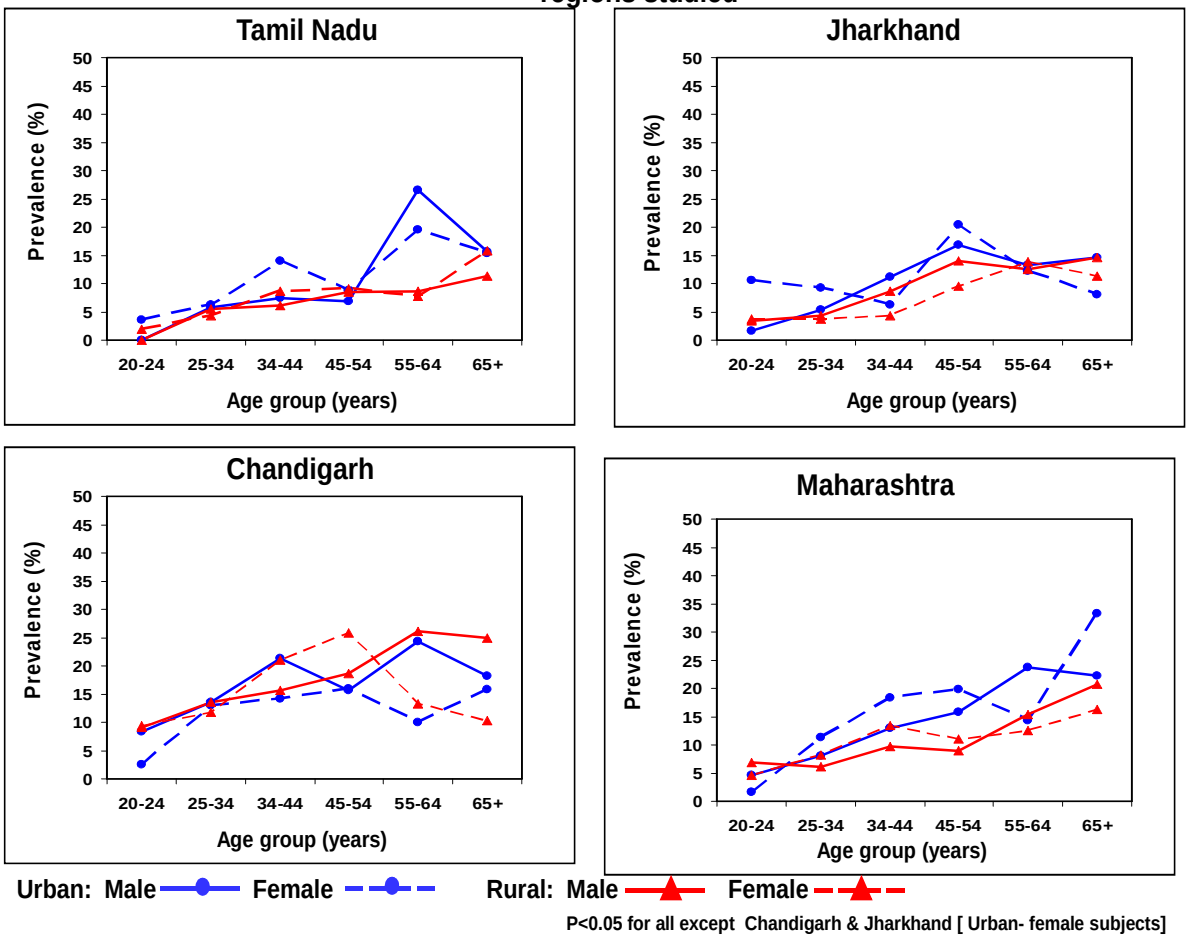
Figure 18: Prevalence* of prediabetes in the urban and rural population in all the 4 regions studied



*Weighted prevalence

Figure 19 presents the age and gender specific prevalence of prediabetes in the urban and rural population. Except in Chandigarh, the prevalence of prediabetes is higher in urban areas in all age groups.

Figure 19: Age and gender specific weighted prevalence of prediabetes in all the 4 regions studied



P<0.05 for all except Chandigarh & Jharkhand [Urban- female subjects]

Weighted prevalence of diabetes, prediabetes and ratio of self-reported diabetes to newly diagnosed diabetes in the study population is given in **Table 15.** The ratio of known to newly diagnosed diabetes is a good indicator of the level of diabetes awareness in a population. In all the four regions studied, the newly detected diabetes cases outnumbered individuals with known diabetes, except in Tamil Nadu where periodic screening is done.

Table 15: Weighted prevalence of diabetes and prediabetes in the study population (n=13,055)

Status	Tamil Nadu			Maharashtra			Jharkhand			Chandigarh[#]		
	Urban	**Rural**	**Overall**	**Urban**	**Rural**	**Overall**	**Urban**	**Rural**	**Overall**	**Urban**	**Rural**	**Overall**
N	1029	2480	3509	1093	2476	3569	840	2051	2891	839	2247	3086
KD%	8.5*	4.1	6.0	3.7*	1.7	2.5	8.4*	0.7	2.4	6.6*	3.1	6.2
(95% CI)	(7.1-9.9)	(3.2-5.0)	(5.2-6.8)	(2.7-4.7)	(1.2-2.3)	(2.0-3.0)	(6.3-10.5)	(0.3-1.0)	(1.8-3.0)	(5.7-7.5)	(1.2-5.0)	(5.4-7.1)
NDD%	5.2*	3.8	4.4	7.2*	4.9	5.9	5.1*	2.3	2.9	7.6	5.2	7.4
(95% CI)	(4.1-6.3)	(3.0-4.7)	(3.7-5.1)	(6.0-8.5)	(3.9-5.8)	(5.1-6.7)	(3.4-6.8)	(1.7-2.9)	(2.3-3.5)	(6.6-8.6)	(2.8-7.7)	(6.5-8.3)
Ratio of KD: NDD	1:0.6	1:0.9	1:0.7	1:1.9	1:2.9	1:2.4	1:0.6	1:3.3	1:1.2	1:1.2	1:1.7	1:1.2
Total Diabetes%	**13.7***	**7.8**	**10.4**	**10.9***	**6.5**	**8.4**	**13.5***	**3.0**	**5.3**	**14.2***	**8.3**	**13.6**
(95% CI)	(12.3-15.7)	(6.6-9.0)	(9.0-11.0)	(9.4-12.6)	(5.4-7.6)	(7.5-9.3)	(11.3-16.7)	(2.3-3.7)	(4.5-6.1)	(12.7-15.3)	(5.3-14.4)	(12.8-15.2)
IFG%	4.8	4.4	4.6	8.7	7.6	8.0	5.3	4.7	4.8	9.3	10.9	9.5
(95% CI)	(3.7-5.9)	(3.5-5.3)	(3.9-5.3)	(7.3-0.1)	(6.5-8.8)	(7.1-8.9)	(3.6-7.0)	(3.8-5.6)	(4.0-5.6)	(8.2-10.4)	(7.6-14.4)	(8.5-10.5)
IGT%	3.9*	2.2	2.9	3.9*	2.6	3.1	4.3*	2.2	2.7	3.9	2.5	3.8
(95% CI)	(2.9-4.9)	(1.6-2.9)	(2.3-3.5)	(2.9-4.9)	(1.9-3.3)	(2.5-3.7)	(2.7-5.9)	(1.6-2.8)	(2.1-3.3)	(3.2-4.6)	(0.8-4.2)	(3.1-4.5)
IFG+IGT%	1.1	0.6	0.8	2.6*	0.9	1.6	1.1	0.5	0.6	1.3	1.3	1.3
(95% CI)	(0.6-1.6)	(0.3-1.0)	(0.5-1.1)	(1.8-3.4)	(0.5-1.3)	(1.2-2.0)	(0.3-1.9)	(0.2-0.8)	(0.3-0.9)	(0.9-1.7)	(0.1-2.1)	(0.9-1.7)
Prediabetes%	**9.8***	**7.1**	**8.3**	**15.2***	**11.1**	**12.8**	**10.7***	**7.4**	**8.1**	**14.5**	**14.7**	**14.6**
(95% CI)	(8.3-11.3)	(6.0-8.2)	(7.4-9.2)	(13.2-7.0)	(9.7-12.4)	(12.0-14.1)	(8.6-13.4)	(6.3-8.5)	(7.1-9.1)	(12.7-15.3)	(11.1-19.0)	(13.7-16.3)

[#] Union Territory; * p <0.05 compared to rural population; KD = Known Diabetes; NDD = Newly Detected Diabetes; Total diabetes = known diabetes and newly diagnosed diabetes. IFG= Impaired Fasting Glucose; IGT= Impaired Glucose Tolerance; Prediabetes = impaired fasting glucose or impaired glucose tolerance.

Summary of Phase I - Primary Objectives 1 & 2:

State wise prevalence: The overall weighted prevalence of diabetes was 10.4% (95% CI: 9.0-11.0%) in Tamil Nadu, 5.3% (95% CI: 4.5-6.1%) in Jharkhand, 13.6% (95% CI:12.8-15.2%) in Chandigarh and 8.4% (95% CI:7.5-9.3%) in Maharashtra. The overall weighted prevalence of prediabetes in Tamil Nadu, Jharkhand, Chandigarh and Maharashtra was 8.3%, 8.1%, 14.6% and 12.8% respectively. This translates to 4.8 million individuals with diabetes and 3.9 million with prediabetes in Tamil Nadu. In Jharkhand, an estimated 0.96 million have diabetes and 1.5 million, prediabetes. Chandigarh would have 0.12 million people with diabetes and 0.13 million with prediabetes and in Maharashtra, 6.0 million have diabetes and 9.2 million, prediabetes.

D. Results of Phase I – Secondary Objective 1:

Secondary Objective 1: *To determine the prevalence of hypertension and hyperlipidemia in urban and rural India.*

Figure 20 shows the prevalence of hypertension (self-reported, newly diagnosed and overall) in urban and rural population of all the 4 regions studied. In urban areas, the highest prevalence of hypertension (overall) was observed in Chandigarh (32.6%) and Tamil Nadu (32.3%) followed by 30.5% in both Jharkhand and Maharashtra. In rural areas, Tamil Nadu had the highest prevalence of hypertension (28%) followed by Maharashtra (24.5%), Jharkhand (22.2%) and Chandigarh (20.4%).

Figure 20: Prevalence of hypertension (self-reported, newly diagnosed and overall) in the urban and rural population in all the 4 regions studied

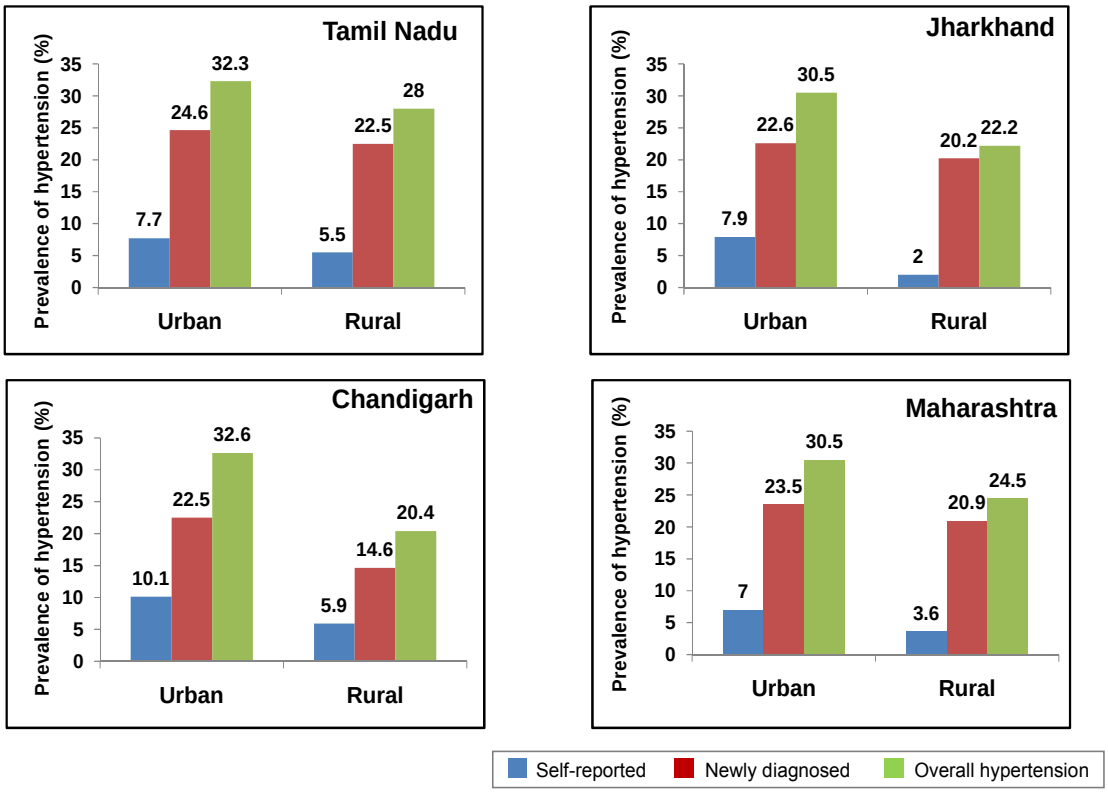
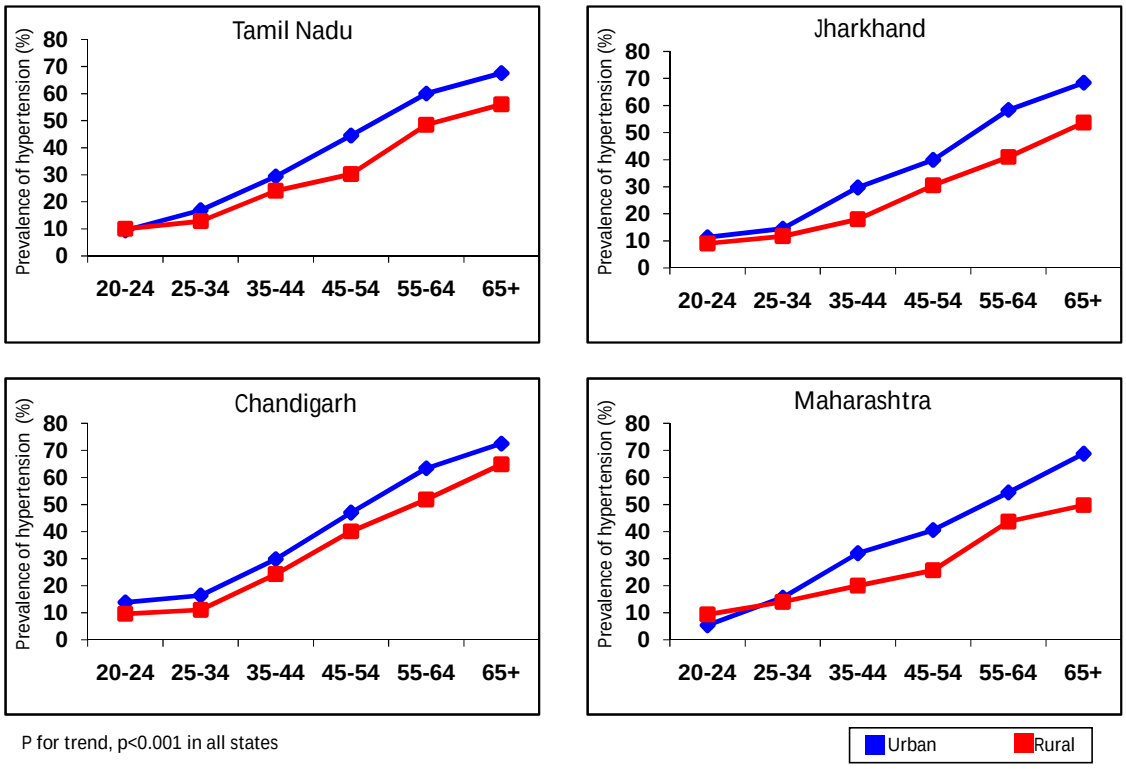


Figure 21 presents the age specific prevalence of hypertension in urban and rural areas. In all regions, the prevalence of hypertension increases with increasing age. Even in the age group of 20-24 years, the prevalence of hypertension ranged from 5.4%–13.9% in urban and

9%–10% in rural areas. At every age interval, the prevalence of hypertension in urban areas was higher compared to rural areas in all the 4 regions studied.

Figure 21: Agewise prevalence of hypertension in the urban and rural population in all the 4 regions studied



Figures 22–24 shows the prevalence of different components of dyslipidemia [hypercholesterolemia (cholesterol ≥200 mg/dl), hypertriglyceridemia (triglycerides ≥150 mg/dl) and low HDL cholesterol (HDL-C <40 mg/dl in men and <50 mg/dl in women). **Figure 25** shows the prevalence of dyslipidemia (presence of hypercholesterolemia or hypertriglyceridemia or low HDL cholesterol).

In urban areas, Chandigarh (25%) and in rural areas, Tamil Nadu (16.0%) had the highest prevalence of hypercholesterolemia compared to the other regions. In the case of hypertriglyceridemia, both urban and rural Chandigarh had the highest prevalence (urban: 45.9%, rural: 35.6%) compared to their counterparts in the other regions. About 67–78% of the population had low HDL cholesterol irrespective of the region under study. The prevalence of dyslipidemia ranged from 75.7% in urban Maharashtra to 87.2% in urban Chandigarh.

Figure 22: Prevalence of hypercholesterolemia in the urban and rural population in all the 4 regions studied

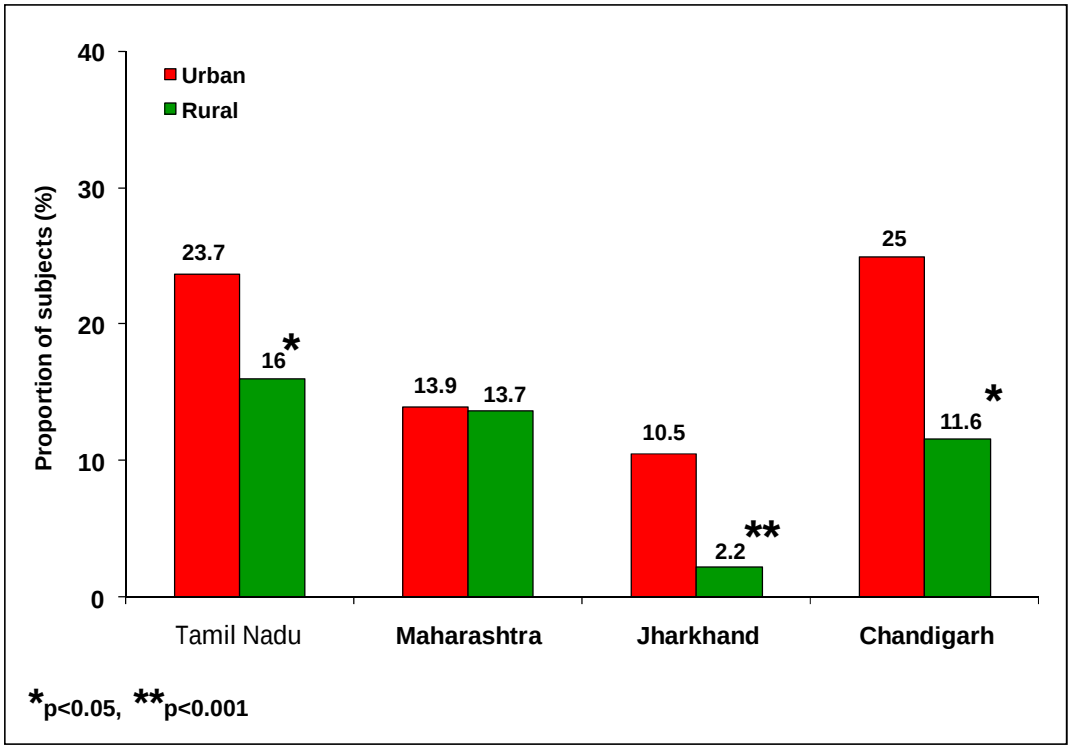


Figure 23: Prevalence of hypertriglyceridemia in the urban and rural population in all the 4 regions studied

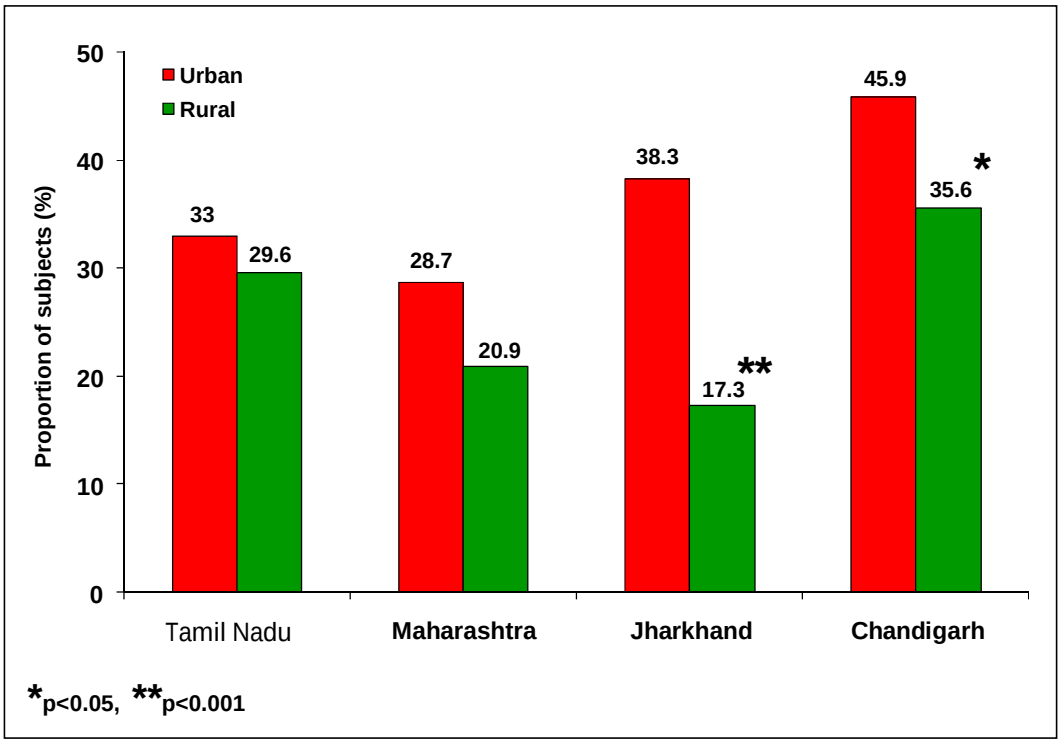


Figure 24: Prevalence of low HDL cholesterol in the urban and rural population in all the 4 regions studied

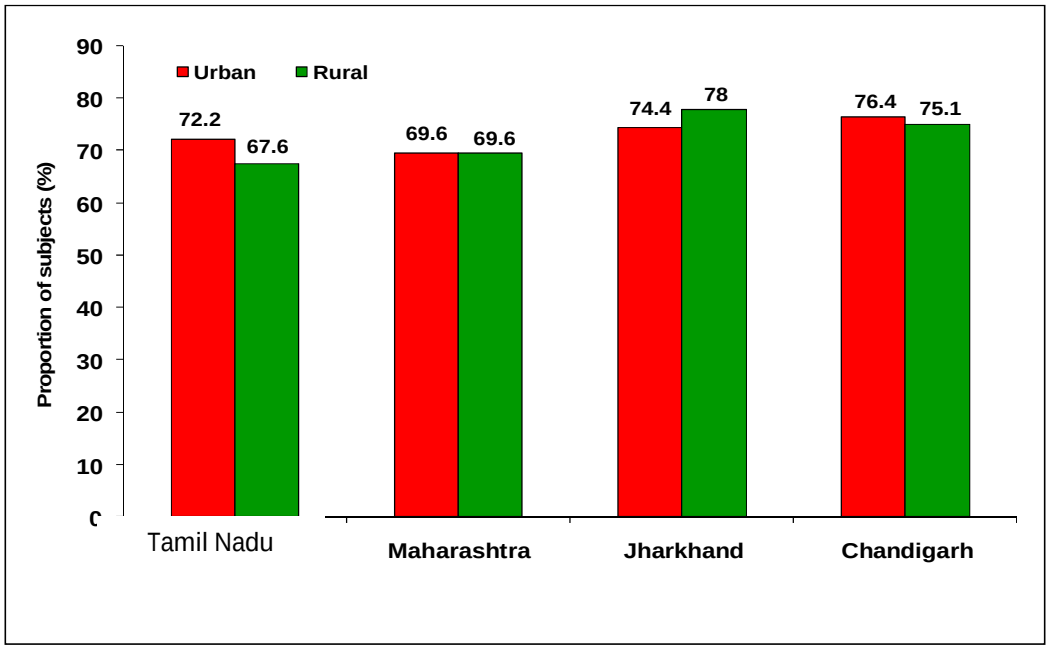


Figure 25: Prevalence of dyslipidemia in the urban and rural population in all the 4 regions studied

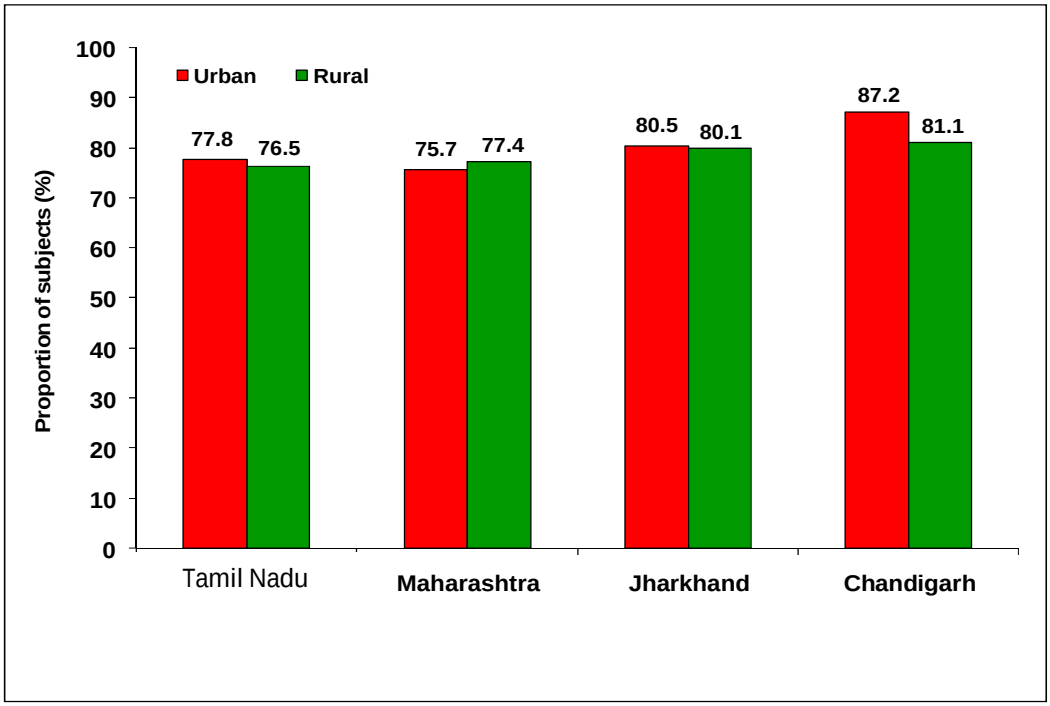
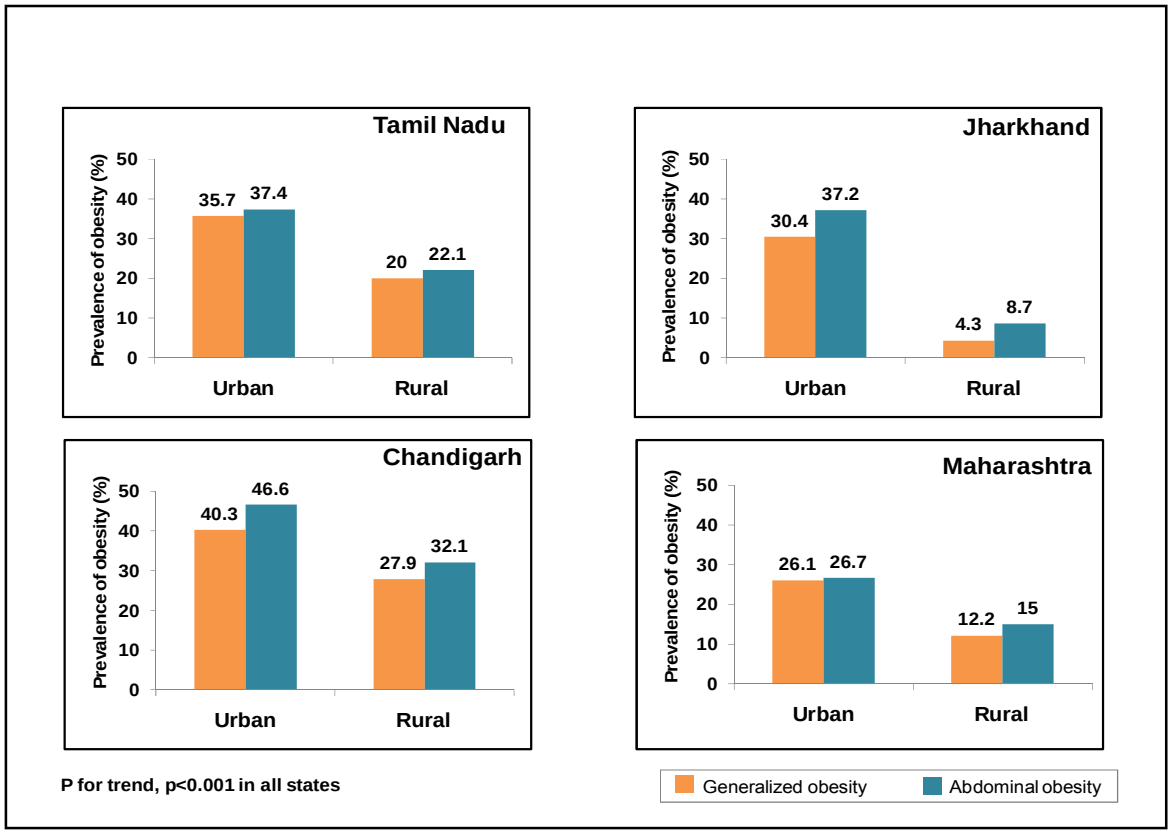


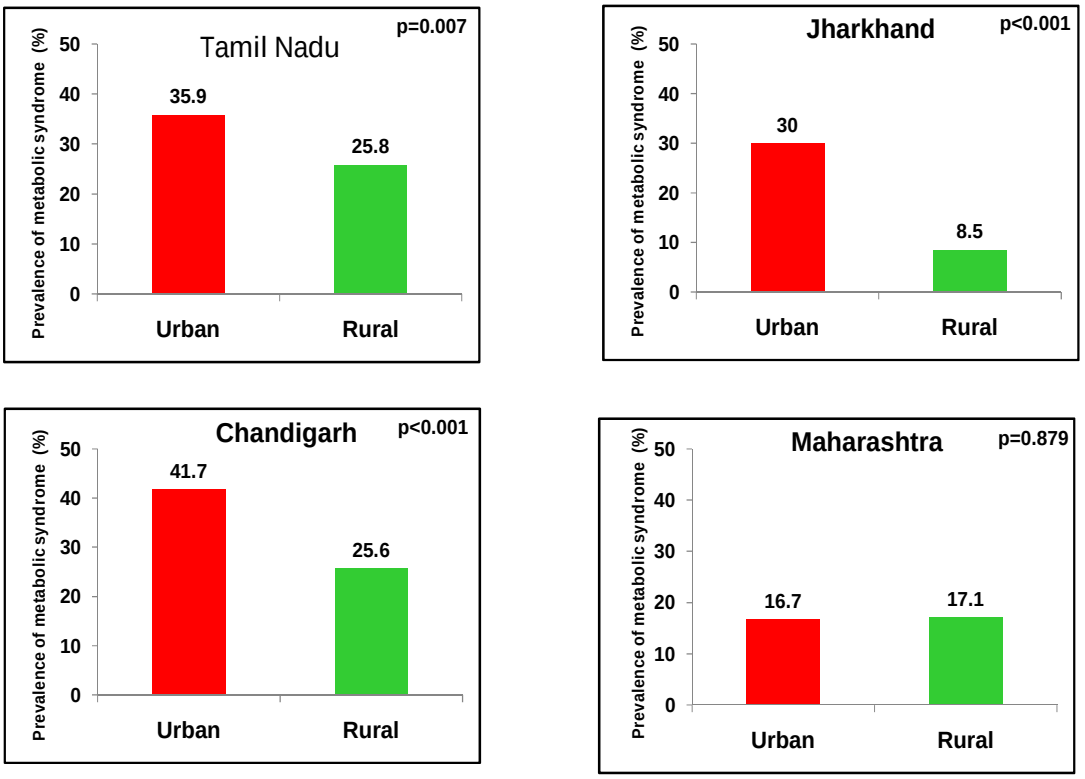
Figure 26: Prevalence of obesity (generalized and abdominal) in the urban and rural population in all the 4 regions studied



The prevalence of generalized obesity (as defined by BMI ≥25 kg/m^2) and abdominal obesity (as defined by waist circumference ≥90 cm in men and ≥80 cm in women) in all four regions is shown in **Figure 26**. The highest prevalence of both generalized and abdominal obesity was seen in urban and rural Chandigarh and the lowest prevalence in urban areas was seen in Maharashtra, whereas for rural areas the lowest prevalence was seen in Jharkhand. In all the regions, prevalence of both generalized and abdominal obesity was higher in urban areas compared to rural areas.

The prevalence of metabolic syndrome [based on south Asian modified National Cholesterol Education Programme (SAM-NCEP) criteria] is shown in **Figure 27**. In all regions studied, urban areas had higher prevalence of metabolic syndrome compared to rural areas except in Maharashtra. The prevalence ranged from 16.7% to 41.7% in urban and 8.5% to 25.8% in rural areas. Urban Chandigarh had the highest prevalence of metabolic syndrome (41.7%) compared to other regions.

Figure 27: Prevalence of metabolic syndrome in the urban and rural population in all the 4 regions studied

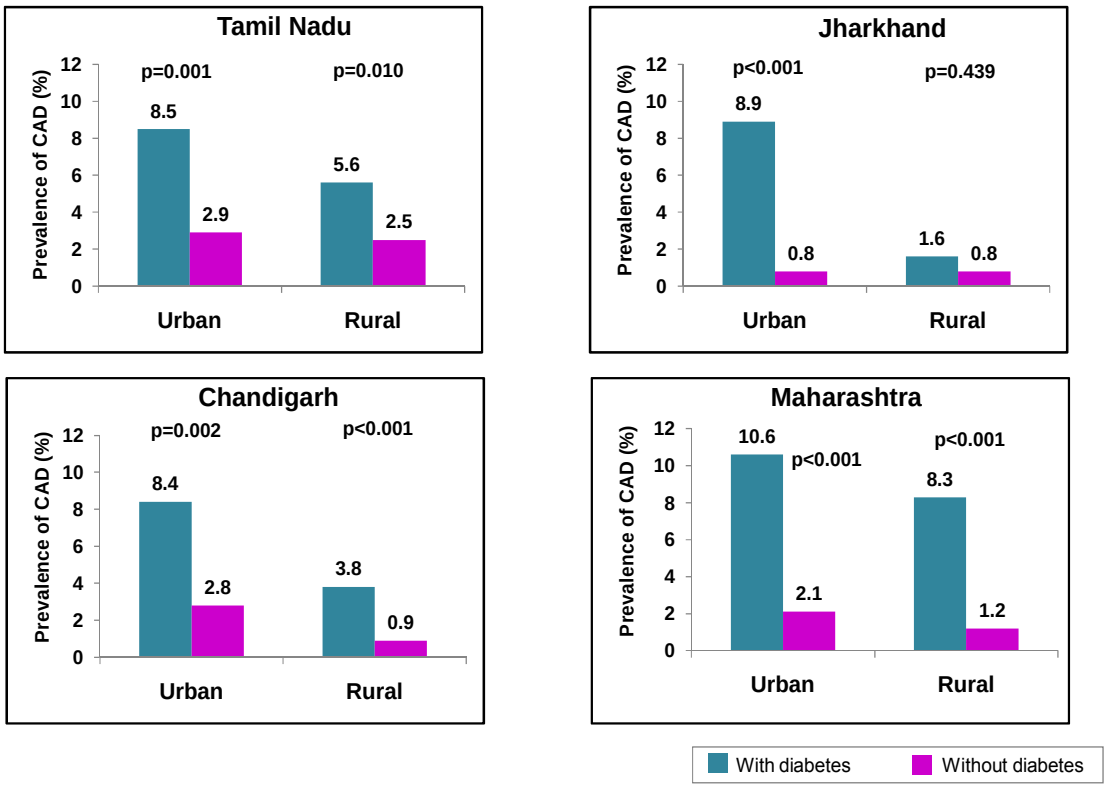


E. Results of Phase I – Secondary Objective 2:

Secondary Objective 2: *To determine the prevalence of coronary artery disease among subjects with and without diabetes.*

The prevalence of coronary artery disease (CAD) among subjects with and without diabetes is shown in **Figure 28.** In both urban and rural areas, the prevalence of CAD was higher among diabetic subjects compared to subjects without diabetes. Maharashtra (both urban and rural) had the highest prevalence of CAD among diabetic subjects compared to other regions.

Figure 28: Prevalence of coronary artery disease (CAD) among subjects with and without diabetes in the study population

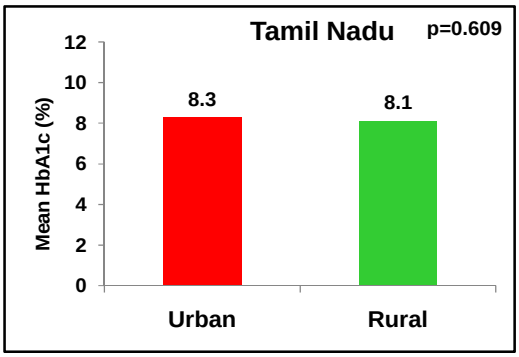


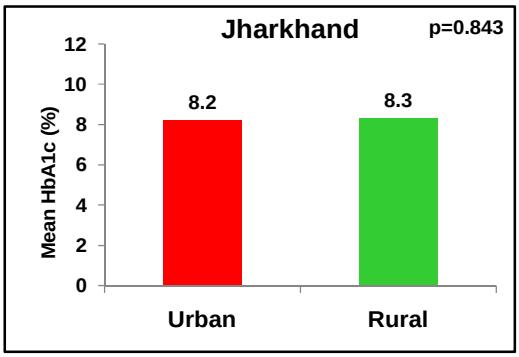
F. Results of Phase I – Secondary Objective 3:

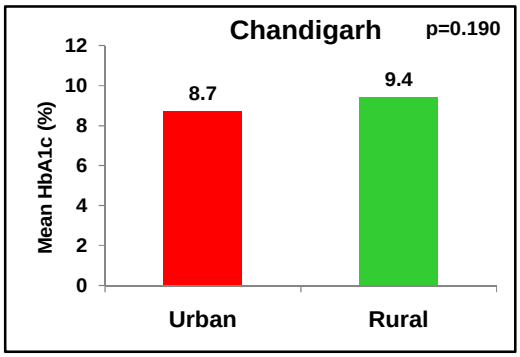
Secondary Objective 3: *To assess the level of diabetes control among self reported diabetic subjects in urban and rural India.*

Figure 29 shows the mean glycated haemoglobin (HbA1c) among subjects with self-reported diabetes. In urban areas, the mean HbA1c was highest in Chandigarh (mean ± SD: 8.7 ± 2.2%) followed by Tamil Nadu (8.3 ± 1.9%), Jharkhand (8.2 ± 2.4%) and Maharashtra (8.0 ± 1.9%). In rural areas, the mean HbA1c was highest in Chandigarh (9.3 ± 2.4%) followed by Jharkhand (8.3 ± 2.1%), Tamil Nadu (8.1 ± 2.1%) and Maharashtra (7.9 ± 2.3%).

Figure 29: Mean glycated haemoglobin (HbA1c) among subjects with self-reported diabetes







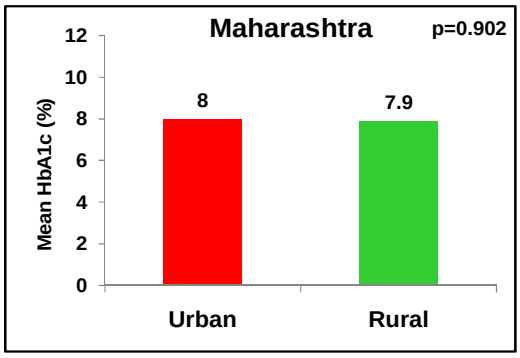


Figure 30 shows the glycemic control among subjects with self-reported diabetes. Subjects were categorized based on their HbA1c values as those under good control (HbA1c: <7%), fair control (HbA1c: 7-9%) and poor control (HbA1c: >9%). Proportion of diabetic subjects with good glycemic control ranged from 30% to 34.7% in urban areas and 17% to 40% in rural areas. Urban Jharkhand and rural Maharashtra had the highest proportion of subjects with good glycemic control. About one-third of the diabetic subjects were under poor glycemic control in all

regions except in Chandigarh, where 40.9% of urban and 52.8% of rural subjects were under poor control.

Figure 30: Glycemic control (HbA1c) among subjects with self-reported diabetes

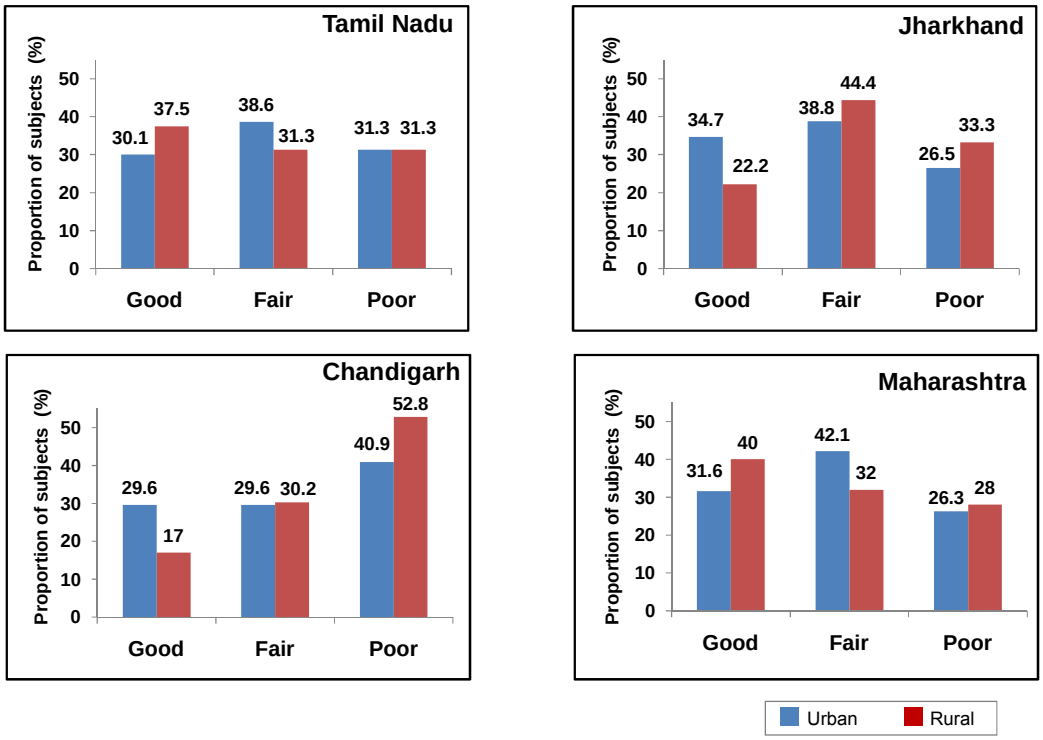
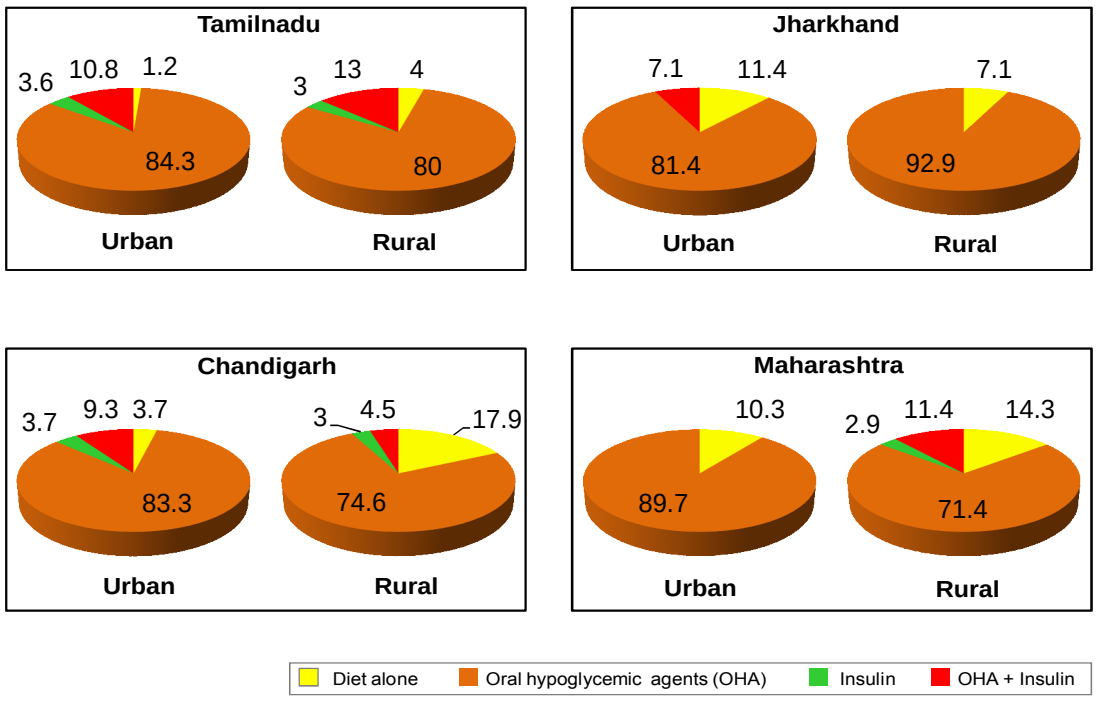


Figure 31: Management of diabetes among subjects with self-reported diabetes



Management of diabetes among subjects with self-reported diabetes is depicted in **Figure 31**. In all 4 regions, 71.4% to 89.7% were on oral hypoglycaemic agents (OHA), 2.9% to 3.7% were on insulin, 4.5% to 13% were on both OHA and insulin and 1.2% to 17.9% were on diet alone. Surprisingly in the Maharashtra urban sample, none of the subjects reported taking insulin. The reason for this is not clear. This could be one of the limitations of the study.

G. Additional results:

Physical activity:

Pattern of physical activity in urban and rural areas is shown in **Table 16.** Overall, in all the four regions studied inactivity was significantly more in urban areas compared to rural areas (65.0% vs. 50.0%; p<0.001). Similarly there was a significant difference between physically inactive males and females. Highly active subjects were significantly more prevalent in rural areas compared to urban areas. In Chandigarh, there was a significant difference between inactive males and females and between urban and rural residents (73.2% vs. 63.4%, p<0.001), Highly active subjects were significantly higher in rural compared to urban areas (10.8% vs. 6.5%;p<0.001). In Jharkhand, inactivity was significantly higher in urban compared to rural areas (47.8% vs. 28.9%, p<0.001), while active and highly active subjects were significantly higher in the rural areas compared to urban areas. Female subjects were more inactive compared to males in the rural areas (44.2% vs. 13.3%; p<0.001). In both urban and rural areas, males were significantly highly active than females. In Maharashtra also, inactivity was significantly higher in urban areas compared to rural areas (65.4% vs. 50.4%, p<0.001), while subjects were highly active in rural areas (17.8% vs. 10.3%, p<0.001). A significantly greater proportion of male subjects were highly active in both urban and rural areas. In Tamil Nadu as well, significantly more urban residents were inactive compared to rural residents (71.0% vs. 55.4%, p<0.001), while subjects were highly active in rural compared to urban areas (13.3% vs. 8.3%,p<0.001). In rural and urban areas, females were physically inactive than males (Rural: 62.3% vs. 48.2%, p<0.001; urban: 77.4 vs. 64.1%, p<0.001). In both the rural and urban areas, males were highly active than females.

TABLE 16: PHYSICAL ACTIVITY LEVELS IN THE STUDY POPULATION

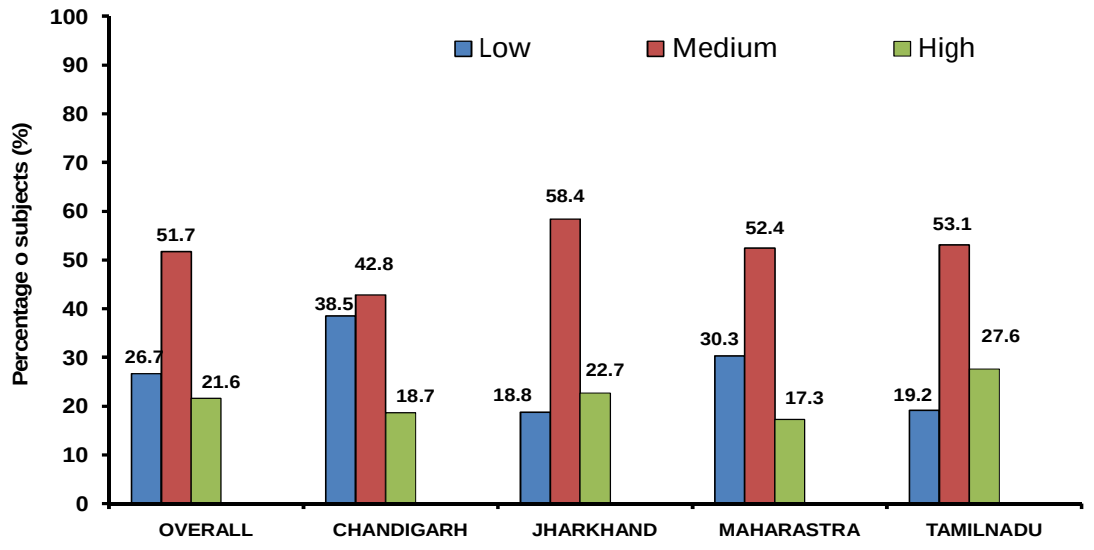
PHYSICAL ACTIVITY	RURAL			URBAN		
OVERALL						
	Male (n=5002)	**Female (n=5052)**	**Total (n=10054)**	**Male (n=2069)**	**Female (n=2104)**	**Total (n=4173)**
Inactive n (%)	2014(40.3)	3011 (59.6)*	5025 (50.0)	1214 (58.7)#	1498 (71.2)*@	2712 (65.0)$
Active n (%)	2040(40.8)	1407 (27.8)*	3447 (34.3)	605 (29.2)#	485 (23.0)*@	1090 (26.1)$
Highly active n (%)	948(18.9)	634 (12.6)*	1582 (15.7)	250 (12.1)#	121 (5.8)*@	371 (8.9)$
CHANDIGARH						
	Male (n=1240)	**Female (n=1192)**	**Total (n=2432)**	**Male (n=444)**	**Female (n=464)**	**Total (n=908)**
Inactive n (%)	670 (54.0)	895 (75.1)*	1578 (63.4)	279 (62.8)#	386 (83.2)*@	665 (73.2)$
Active n (%)	379 (30.6)	224 (18.8)*	603 (24.8)	122 (27.5)#	62 (13.4)*@	184 (20.3)$
Highly active n (%)	191(15.4)	73 (6.1)*	264 (10.8)	43 (9.7)#	16 (3.5)*@	59 (6.5)$
JHARKHAND						
	Male (n=1197	**Female (n=1187)**	**Total (n=2384)**	**Male (n= 482)**	**Female (n=463)**	**Total (n=945)**
Inactive n (%)	165 (13.8)	525 (44.2)*	690 (28.9)	214 (44.4)##	256 (55.3)**@	470 (47.8)$
Active n (%)	732 (61.2)	460 (38.8)*	1192 (50.0)	205 (42.5)#	176 (38.01)@	381 (42.2)$
Highly active n (%)	300 (25.1)	202 (17.0)*	502 (21.1)	63 (13.1)#	31 (6.7)*@	94 (10.0)$
MAHARASHTRA						
	Male (n=1313)	**Female (n=1343)**	**Total (n=2656)**	**Male (n=625)**	**Female (n=623)**	**Total (n=1248)**
Inactive n (%)	576 (43.9)	763 (56.8)*	1339 (50.4)	389 (62.2)#	428 (68.5)@	816 (65.4)$
Active n (%)	474 (36.1)	370 (27.6)*	844 (31.8)	159 (25.5)#	144 (23.1)@	303 (24.3)$
Highly active n (%)	263 (20.0)	210 (15.6)**	473 (17.8)	77 (12.3)#	52 (8.4)**	129 (10.3)$
TAMIL NADU						
	Male (n=1252)	**Female (n=1330)**	**Total (n=2582)**	**Male (n=518)**	**Female (n=554)**	**Total (n=1072)**
Inactive n (%)	603 (48.2)	828 (62.3)*	1431 (55.4)	332 (64.1)#	429 (77.4)*@	761 (71.0)$
Active n (%)	455 (36.3)	353 (26.5)*	808 (31.3)	119 (23.0)#	103 (18.6)@	222 (20.7)$
Highly active n (%)	194 (15.5)	149 (11.2)**	343 (13.3)	67 (12.9)#	22 (4.0)*@	89 (8.3)$

* p <0.001 compared to male subjects; ** p <0.05 compared to male subjects; $ p < 0.001 compared to rural residents; # p <0.001 compared to rural male subjects; ## p <0.05 compared to rural male subjects; @ p <0.001compared to rural female

Indian Diabetes Risk Score (IDRS):

The Indian Diabetes Risk Score (IDRS) in the population in all the four regions studied is shown in **Figure 32**. 18.7% of subjects in Chandigarh, 22.7% in Jharkhand, 17.3% in Maharashtra, and 27.6% in Tamil Nadu had high risk of developing diabetes based on IDRS. In all 4 regions, the proportion of subjects with moderate risk of developing diabetes ranged from 42.8% in Chandigarh to 58.4% in Jharkhand.

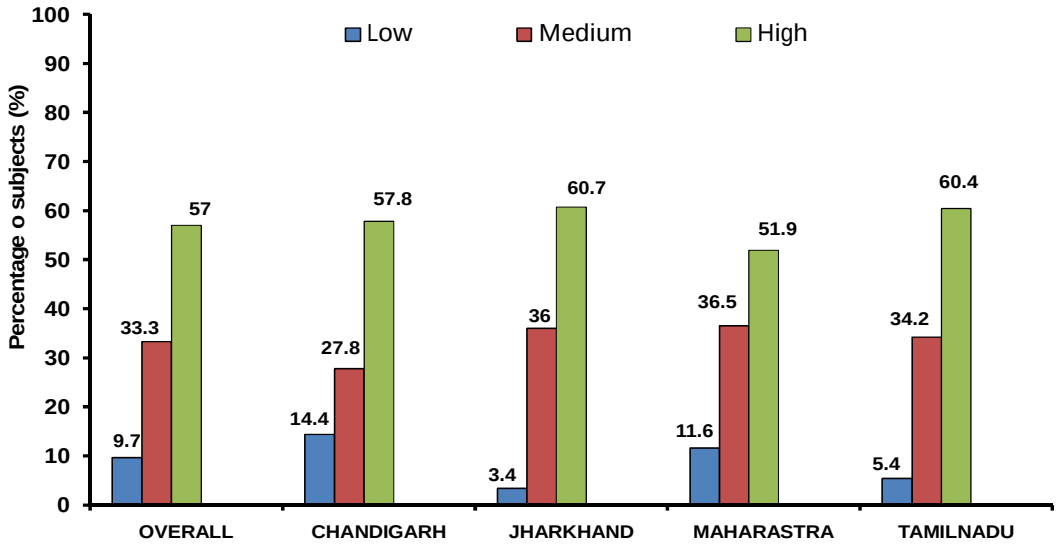
Figure 32: Indian Diabetes Risk Score (IDRS) in all the 4 Regions



Indian Diabetes Risk Score (IDRS) in identifying subjects with diabetes:

Figure 33 shows IDRS in identifying subjects with diabetes in all the four regions studied. It was observed that, of the newly diagnosed diabetic subjects screened by oral glucose tolerance test (OGTT), 60.7% of the subjects in Jharkhand, 60.4% in Tamil Nadu, 57.8% in Chandigarh and 51.9% in Maharashtra were identified by IDRS as having high risk for developing diabetes. The corresponding figures for moderate risk ranged from 27.8% in Chandigarh to 36.5% in Maharashtra. Almost 90% of the newly diagnosed diabetic subjects were either classified as having high or moderate risk for developing diabetes using IDRS in all the four regions studied (Tamil Nadu: 94.6%, Jharkhand: 96.7%, Chandigarh: 85.6% and Maharashtra: 88.8%).

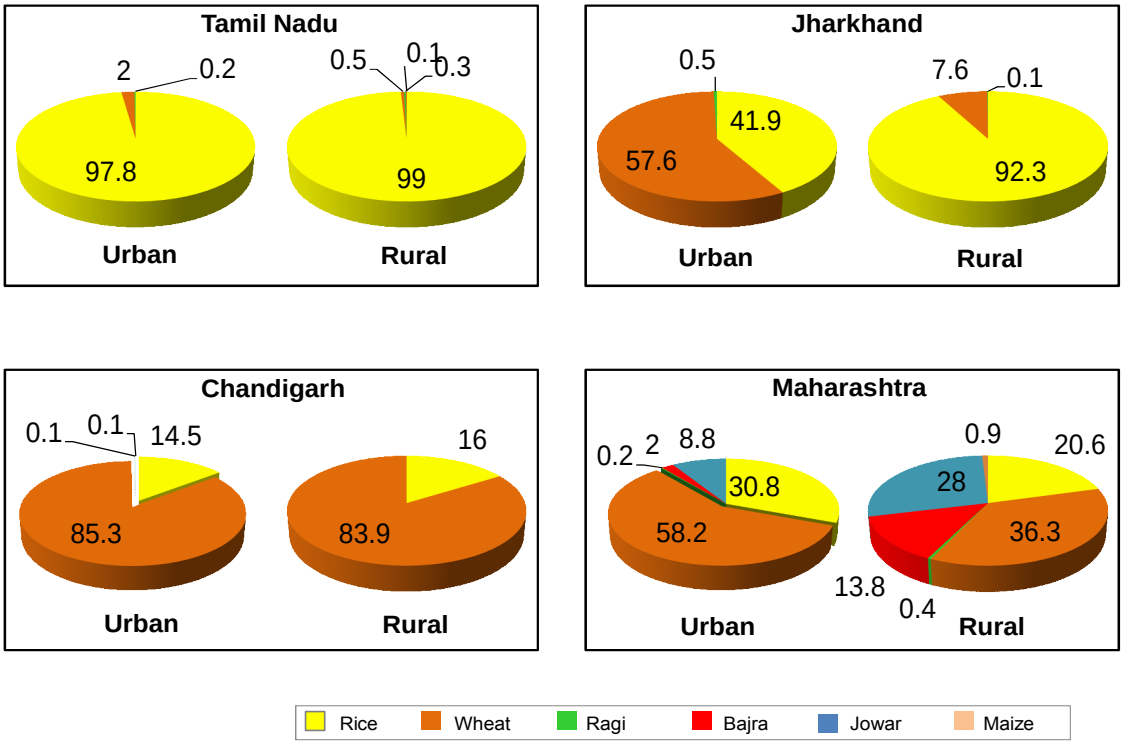
Figure 33: Indian Diabetes Risk Score (IDRS) in identifying subjects with diabetes in all the 4 Regions



Dietary profile:

The staple food consumed by the urban and rural population in all the four regions studied is shown in **Figure 34**.

Figure 34: Staple food of the urban and rural population in all the 4 regions studied



Rice is main staple food in Tamil Nadu and rural Jharkhand. Wheat is main staple for both urban and rural Chandigarh. About half of the population in urban Jharkhand and urban Maharashtra consumes wheat as the main staple food. The staple food in rural Maharashtra is varied and comprises of 36.3% wheat, 28% Jowar, 20.6% rice, 13.8% Bajra, 0.9% maize and 0.4% ragi consumers.

Table 17 shows the major cooking oil of the urban and rural population in all the 4 regions studied. In Tamil Nadu, the major oil used for cooking is sunflower oil, followed by palm oil, groundnut oil and gingelly oil. The major cooking oil in Jharkhand is mustard oil. In Chandigarh, in addition to mustard oil, the next major oil used is soyabean oil. In Maharashtra, the major oil used is soyabean oil, followed by groundnut and sunflower oil.

Table 17: Major cooking oil used of the urban and rural population in all the 4 regions studied

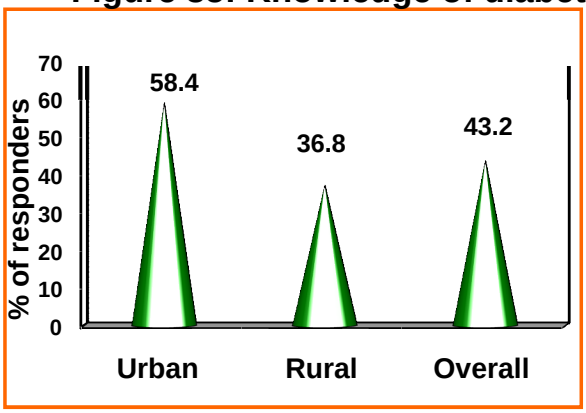
Cooking oil	Tamil Nadu		Jharkhand		Chandigarh		Maharashtra	
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural
Mustard oil	0.3	0.1	90.4	98.7	65.4	81.6	4.1	0.9
Coconut oil	2.3	3.2	0.2	0	0	0.2	0.6	0.2
Groundnut oil	21.4	39.7	1.1	0.1	1.2	0.3	29.6	20.2
Sunflower oil	40.0	15.9	2.3	0.1	4.2	0.5	14.9	5.3
Soyabean oil	0.2	0	4.7	0.2	23.2	14.2	45.1	65.0
Palm oil	29.6	29.7	0.2	0.1	0.4	0.1	3.3	5.6
Gingelly oil	5.4	11.2	0.3	0	0.1	0	0	0.1
Others*	0.9	0	0.8	0.7	5.4	2.9	2.5	2.7

**Others include rice bran oil, vanaspathi, ghee & butter*

Knowledge of diabetes and its complications:

Knowledge of diabetes and its complications is presented in **Figures 35-37. Figure 35** shows the knowledge of diabetes among the urban and rural residents of the study population. Only 58.4% of the urban residents and 36.8% of the rural residents reported that they knew about a condition called diabetes. Of those who reported that they knew about diabetes, 86.3% of the urban residents and 78.4% of the rural residents felt that the prevalence of diabetes was increasing. 64.6% of urban and 46.2% of rural residents reported that diabetes could affect other organs. Among self-reported diabetic subjects, the corresponding figures are 82.8% and 78.1%. Only 65.7% of the urban residents and 51% of the rural residents were aware that diabetes could be prevented.

Figure 35: Knowledge of diabetes in the study population



DO YOU KNOW WHAT DIABETES IS? - YES

IF YES, DO YOU THINK IN GENERAL MORE AND MORE PEOPLE ARE GETTING AFFECTED WITH DIABETES NOWADAYS?

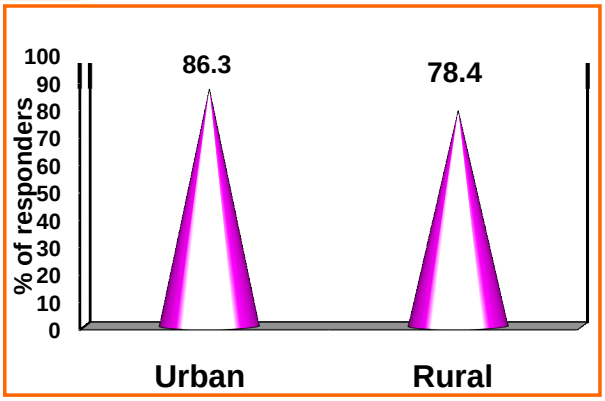
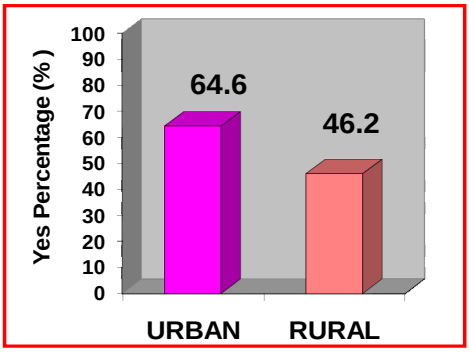


Figure 36: Knowledge about diabetes related complications



DO YOU THINK DIABETES CAN AFFECT OTHER ORGANS? – General population

DO YOU THINK DIABETES CAN AFFECT OTHER ORGANS? – Self reported diabetic population

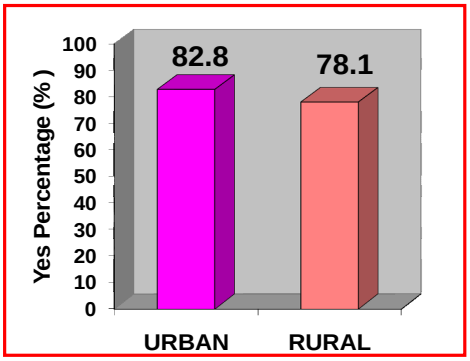
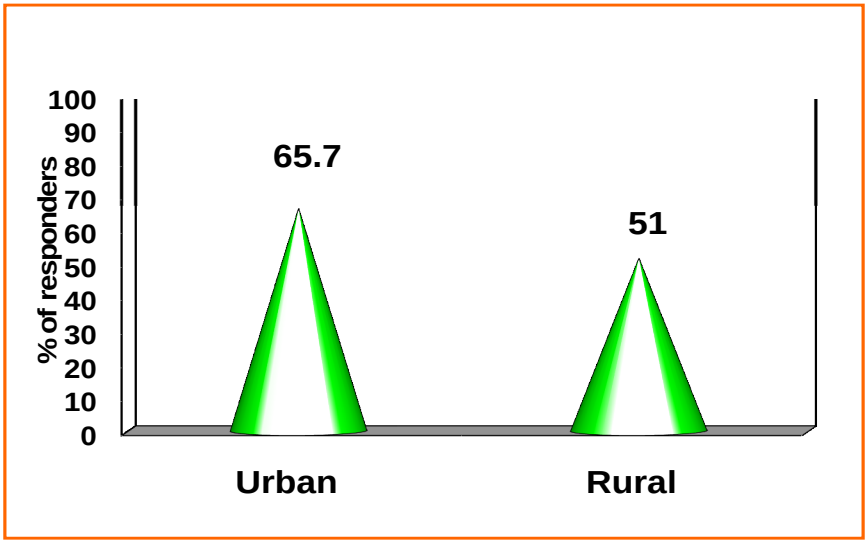


Figure 37: Knowledge of diabetes prevention

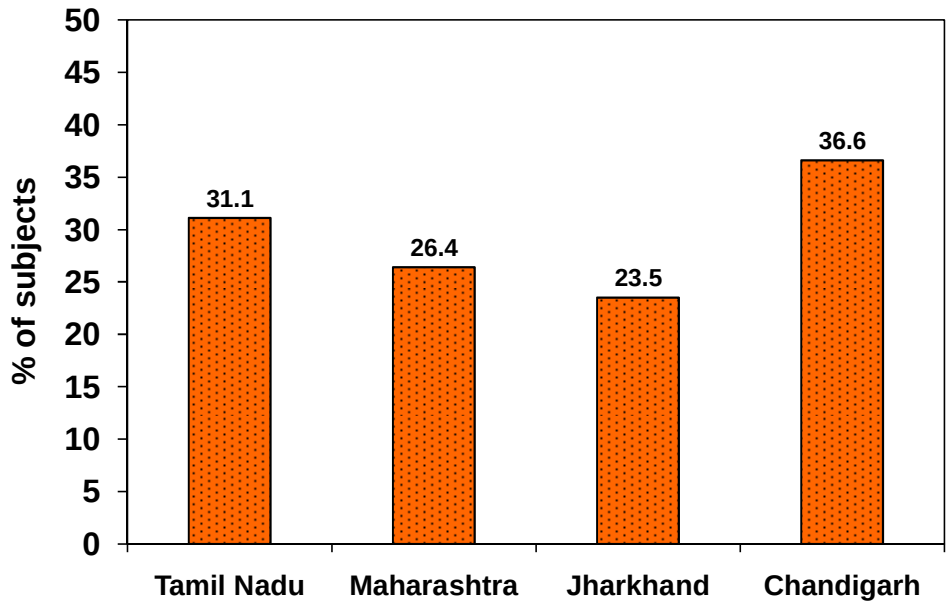
Can diabetes be prevented? – Yes



Migration & its effect on diabetes rates:

Figure 38 shows the proportion of subjects based on migration from rural to urban areas in the 4 regions. Individuals migrating from rural–urban ranged from 23.5% in Jharkhand, 26.4% in Maharashtra, 31.1% in Tamil Nadu to 36.6% in Chandigarh.

Figure 38: Rural-Urban migration rates in all 4 regions studied



LIMITATIONS OF THE STUDY

One of the limitations of this study is the use of capillary blood glucose to screening for diabetes, which has wider coefficient of variation than venous plasma. However, the logistical constraints of poor compliance, limited availability of quality-controlled laboratories, challenges in transporting and storing blood samples at the required temperature and insufficient phlebotomists preclude the use of venous sampling. Secondly, the cross-sectional nature of the design does not allow for cause–effect relationships to be made. Only prospective longitudinal follow-up studies can throw light on the true risk factors associated with diabetes. Third, the results and conclusions for glycemic control have been derived from a single cross-sectional estimation of HbA1c, which may be normal/abnormal at a given point of time, and do not represent a prospective evaluation of glycemic control over a period of time.

CONCLUSIONS

In summary, of the four regions studied, the prevalence of diabetes was highest in Chandigarh followed by Tamil Nadu, Maharashtra and Jharkhand. Again, the prevalence of prediabetes was highest in Chandigarh followed by Maharashtra, Tamil Nadu and Jharkhand. The prevalence of hypertension, dyslipidemia and metabolic syndrome are highest in Chandigarh compared to other regions. In terms of glycemic control, Chandigarh had the highest proportion of diabetic subjects under poor control. Urban Jharkhand and rural Maharashtra had the highest proportion of subjects with good glycemic control. These preliminary analyses meet the primary and secondary objectives of this study.

SIGNIFICANCE OF THE STUDY

The ICMR–INDIAB study provides accurate and comprehensive data on prevalence of diabetes and prediabetes in regions representing the north, south, east and west of India. The study also provides valuable information on the distribution of risk factors in the regions studied. This study is also unique in that it is designed to be representative of both rural and urban areas and provide estimates for prediabetes, dyslipidemia, hypertension, obesity, and the level of glycemic control among the confirmed cases of diabetes. Early detection of diabetes and prediabetes will help in early implementation of interventions to reduce morbidity and mortality associated with it. The study helps to throw light on the health burden due to diabetes in India and also to plan measures for both control and prevention of diabetes in the regions where the study is completed.

PUBLIC HEALTH IMPLICATIONS

Diabetes and other non communicable disease risk factors like dyslipidemia, hypertension, obesity and metabolic syndrome are imposing a large and growing burden on public health. These conditions are preventable, but are often silent in their manifestation. Therefore the ICMR-INDIAB study will help to throw light on the large burden of undiagnosed risk factors and provides an opportunity for prevention of disease in this group of people. In addition for those with an established diagnosis of diabetes the level of control is assessed and opportunity for better control of diabetes. All participants in the study are also provided with general advice on prevention of NCDs. This will help to improve the awareness about NCDs in the population at large. Thus new initiatives like these are needed to institute prevention programmes to curb the huge strain of NCDs on the national healthcare systems. The ICMR-INDIAB study helps not only in earlier detection of diabetes through screening, but also in planning prevention programmes for the country.

LIST OF RESEARCH PUBLICATIONS FROM THE PROJECT (TILL 2015)

1. **ICMR-INDIAB study methodology (Annexure 18)**

   Anjana RM, Pradeepa R, Deepa M, Datta M, Sudha V, Unnikrishnan R, Nath LM, Das AK, Madhu SV, Rao PV, Shukla DK, Kaur T, Ali MK, Mohan V. The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) Study: Methodological Details. [ICMR-INDIAB-1] J Diabetes Sci Technol 2011; 5: 906-914.

2. **Prevalence of diabetes and prediabetes (Annexure 19)**

   Anjana RM, Pradeepa R, Deepa M, Datta M, Sudha V, Unnikrishnan R, Bhansali A, Joshi SR, Joshi PP, Yajnik CS, Dhandhania VK, Nath LM, Das AK, Rao PV, Madhu SV, Shukla DK, Kaur T, Priya M, Nirmal E, Parvathi SJ, Subhashini S, Subashini R, Ali MK, Mohan V for the ICMR– INDIAB Collaborative Study Group. Prevalence of diabetes and prediabetes in urban and rural India: results of the ICMR-INDIAB study (Phase-1) [ICMR-INDIAB-2]. Diabetologia 2011; 54: 3022-7.

3. **Prevalence of generalized and abdominal obesity (Annexure 20)**

   Pradeepa R, Anjana RM, Joshi SR, Bhansali A, Deepa M, Joshi PP, Dhandhania VK, Madhu SV, Rao PV, Geetha L, Subashini R, Unnikrishnan R, Shukla DK, Kaur T, Mohan V, Das AK, for the ICMR– INDIAB Collaborative Study Group. Prevalence of generalized and abdominal obesity in urban and rural India- the ICMR-INDIAB study (phase-I) [ICMR-INDIAB-3]. Indian J Med Res, 2015:142: pp 139-150

4. **Knowledge and awareness of diabetes (Annexure 21)**

   Deepa M, Bhansali A, Anjana RM, Pradeepa R, Joshi SR, Joshi PP, Dhandhania VK, Rao PV, Subashini R, Unnikrishnan R, Shukla DK, Madhu SV, Das AK , Mohan V, Kaur T for the ICMR–INDIAB Collaborative Study Group. Knowledge and awareness of diabetes in urban and rural India: The ICMR–INDIAB study (Phase I) [ICMR-INDIAB 4]. Indian J Endocrinol Metab. 2014;18:379-85.

5. **Physical activity and inactivity patterns (Annexure 22)**

Anjana RM, Pradeepa R, Das AK, Deepa M, Bhansali A, Joshi SR, Joshi PP, Dhandhania VK, Rao PV, Sudha V, Subashini R, Unnikrishnan R, Madhu SV, Kaur T, Mohan V, Shukla DK; ICMR– INDIAB Collaborative Study Group. Physical activity and inactivity patterns in India - results from the ICMR-INDIAB study (Phase-1) [ICMR-INDIAB-5].Int J Behav Nutr Phys Act. 2014;11:26.

6. **Prevalence and risk factors of hypertension (Annexure 23)**

Bhansali A, Dhandania VK, Deepa M, Anjana RM, Joshi SR, Joshi PP, Madhu SV, Rao PV, Subashini R, Sudha V, Unnikrishnan R, Das AK, Shukla DK, Kaur T, Mohan V, Pradeepa R for the ICMR– INDIAB Collaborative Study Group. Prevalence and risk factors for hypertension in urban and rural India: the ICMR-INDIAB Study (Phase-1) [ICMR-INDIAB- 6]. J. Hum Hypertens. 2015; 29:204-9.

7. **Prevalence of dyslipidemia (Annexure 24)**

Joshi SR, Anjana RM, Deepa M, Pradeepa R, Bhansali A, Dhandania VK, Joshi PP, Unnikrishnan R, Nirmal E, Subashini R, Madhu SV, Rao PV, Das AK, Kaur K, Shukla DK, Mohan V, for the ICMR– INDIAB Collaborative Study Group. Prevalence of dyslipidemia in urban and rural India: The ICMR-INDIAB study [ICMR-INDIAB- 7]. PLOS One 2014;9: e96808.

8. **Glycemic control in self reported diabetes (Annexure 25)**

Unnikrishnan R, Anjana RM, Deepa M, Pradeepa R, Joshi SR, Bhansali A, Dhandania VK, Joshi PP, Madhu SV, Rao PV, Lakshmy R, Jaishri R, Velmurugan K, Nirmal E, Subashini R, Vijaychandrika V, Kaur T, Shukla DK, Das AK, Mohan V, for the ICMR–INDIAB Collaborative Study Group. Glycemic control among individuals with self-reported diabetes in India-the ICMR-INDIAB Study (PHASE-1) [ICMR-INDIAB-8]. Diabetes Techno Ther. 2014;16:596-603.

ABSTRACT

The ICMR-INDIAB study (Phase I) reports on the results obtained from three states [Tamil Nadu, Jharkhand and Maharashtra] and one Union Territory [Chandigarh] of India. A stratified multi-stage sampling design was used to survey individuals aged ≥20 years with the primary objective to determine the prevalence of diabetes and prediabetes in India. Of the 16,607 individuals selected for the study, 14,277 [86%] individuals participated. The weighted prevalence of diabetes (both known and newly diagnosed) in Tamil Nadu was 10.4%, Jharkhand, 5.3%, Chandigarh, 13.6% and Maharashtra, 8.4%. The prevalence of prediabetes was 8.3%, 8.1%, 14.6% and 12.8% respectively. The prevalence of hypertension, dyslipidemia and metabolic syndrome are highest in Chandigarh compared to other regions. In terms of glycemic control, urban Jharkhand and rural Maharashtra had the highest proportion of diabetic subjects with good glycemic control. Maharashtra had the highest prevalence of coronary artery disease among diabetic subjects compared to other regions. This study throws light on the health burden due to diabetes in India and will help plan measures for both control and prevention of diabetes in the regions where the study is completed.

SYNOPSIS

The ICMR-INDIAB Study is a cross-sectional, community- based survey of adults of either sex, aged 20 years and above, aimed at determining the national prevalence of type 2 diabetes mellitus & pre-diabetes [Impaired fasting glucose (IFG) / Impaired glucose tolerance (IGT)] from all the 28 states, National Capital Territory (NCT) of Delhi and 2 union territories (UTs) namely Chandigarh and Puducherry in the mainland of India. Each state, the National Capital Territory and the Union Territories will have an urban component [towns including metros, (wherever applicable)] and a rural component (villages). The secondary objectives are 1) to determine the prevalence of hypertension and hyperlipidemia in urban and rural India; 2) to determine the prevalence of coronary artery disease among subjects with and without diabetes and 3) to assess the level of diabetes control among self reported diabetic subjects in urban and rural India. The study was initiated to estimate the prevalence of diabetes in India in a phased manner. In Phase I, three states namely Tamil Nadu, Maharashtra, Jharkhand and one Union Territory namely Chandigarh located in the south, west, east and north of the country, respectively were studied. ICMR-INDIAB north east component, which is now ongoing includes the 8 north eastern states of India namely Sikkim, Assam, Meghalaya, Tripura, Mizoram, Manipur, Nagaland and Arunachal Pradesh. The ICMR-INDIAB-Rest of India (ROI) component (Phase II) involving all the other states in India are currently in progress.

The ICMR-INDIAB study (Phase I) reports on the results obtained from three states [Tamil Nadu, Jharkhand and Maharashtra] and one Union Territory [Chandigarh] of India. A stratified multi-stage sampling design was used. Of the 16,607 individuals selected for the study, 14,277 [86%] individuals participated. The weighted prevalence of diabetes (both known and newly diagnosed) in Tamil Nadu was 10.4%, Jharkhand, 5.3%, Chandigarh, 13.6% and Maharashtra, 8.4%. The prevalence of prediabetes was 8.3%, 8.1%, 14.6% and 12.8% respectively.

In urban areas, the highest prevalence of hypertension (overall) was observed in Chandigarh (32.6%) and Tamil Nadu (32.3%) followed by 30.5% in both Jharkhand and Maharashtra. In rural areas, Tamil Nadu had the highest prevalence of hypertension (28%) followed by Maharashtra (24.5%), Jharkhand (22.2%) and Chandigarh (20.4%). The prevalence of dyslipidemia ranged from 75.9% in urban Maharashtra to 84.4% in urban Chandigarh. About 70–78% of the population had low HDL cholesterol irrespective of the region under study. The highest prevalence of both generalized and abdominal obesity was seen in urban and rural

Chandigarh and in all the regions, prevalence of both generalized and abdominal obesity was higher in urban areas compared to rural areas. The prevalence of metabolic syndrome ranged from 16.7% to 41.7% in urban areas and 8.5% to 25.8% in rural areas. Urban Chandigarh had the highest prevalence of metabolic syndrome (41.7%) compared to other regions.

In terms of glycemic control, urban Jharkhand and rural Maharashtra had the highest proportion of diabetic subjects with good glycemic control. Proportion of diabetic subjects with good glycemic control ranged from 30% to 34.7% in urban areas and 17% to 40% in rural areas. Regarding awareness of diabetes in the study population, only 58.4% of the urban residents and 36.8% of the rural residents reported that they knew about a condition called diabetes. Only 65.7% of the urban residents and 51% of the rural residents were aware that diabetes could be prevented. Maharashtra had the highest prevalence of coronary artery disease among diabetic subjects compared to other regions. This phase of the study throws light on the health burden due to diabetes in 3 selected states and on union territory and will help plan measures for both control and prevention of diabetes and other non communicable diseases in the regions where the study is completed.

ANNEXURES