Indian Council of Medical Research
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FINAL REPORT – KERALA STATE

1. TITLE OF THE PROJECT : ICMR- India Diabetes [INDIAB] Study - Phase IV (Excluding North East)

2. PRINCIPAL INVESTIGATOR AND CO-INVESTIGATORS

State Principal Investigator	: Dr. P.K. Jabbar, M.D.
Co-Principal Investigator	: Dr. C. Jayakumari, M.D.
National Study Coordinator & Principal Investigator	: Dr. V. Mohan, M.D., Ph.D., D.Sc.
National Co-Principal Investigators	: Dr. R. M. Anjana, M.D., Ph.D. Dr. R. Guha Pradeepa, M.Sc., Ph.D. Dr. M. Deepa , M.Sc., Ph.D. Mrs.Sudha Vasudevan, M.Sc.

3. IMPLEMENTING INSTITUTION AND OTHER COLLABORATING INSTITUTIONS

Implementing Institutions

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Fax.:+91-44-2835 0935
Email: drmohans@diabetes.ind.in
Website: www.mdrf.in

4. **DATE OF COMMENCEMENT:** 10th December 2018

5. **DURATION:** 06 months

6. **DATE OF COMPLETION:** 31st May 2019

7. OBJECTIVES AS APPROVED

OBJECTIVES	GOALS
Primary	1. To determine the prevalence of diabetes mellitus and 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 diabetes and pre-diabetes in urban areas and rural areas across India.
Secondary	1. To determine the prevalence of hypertension and dyslipidemia 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.

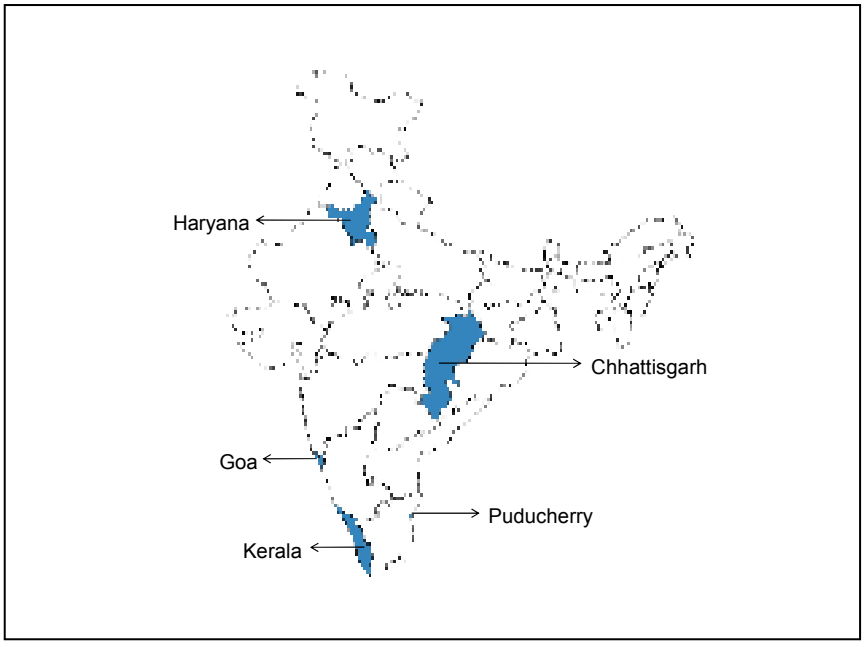
8. DEVIATION MADE FROM ORIGINAL OBJECTIVES IF ANY, WHILE IMPLEMENTING THE PROJECT AND REASONS THEREOF: NIL

9. EXPERIMENTAL WORK GIVING FULL DETAILS OF EXPERIMENTAL SET UP, METHODS ADOPTED

1. Detailed Methodology

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 in all the 28 states, National Capital Territory (NCT) of Delhi and 2 union territories (UTs) namely Chandigarh and Puducherry in the mainland of India in a phased manner. The other four union territories namely Andaman and Nicobar Islands, Dadra and Nagar Haveli, Daman and Diu and Lakshadweep are not being sampled due to logistic reasons. In each state, the National Capital Territory and the Union Territories has an urban component (towns including metros, wherever applicable]) and a rural component (villages). 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. The ICMR-INDIAB [North East] component which has been completed included the 8 north eastern states of India namely Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura. In Phase II, we have sampled Andhra Pradesh, Bihar, Gujarat, Karnataka and Punjab and in Phase III we have sampled Delhi, Madhya Pradesh, Rajasthan and Uttar Pradesh. In Phase IV, we have sampled Kerala, Pondicherry, Goa, Haryana and Chhattisgarh. In **Kerala**, we surveyed 4,000 individuals **[Figure 1]** with an urban component (towns) and a rural component (villages).

Figure 1: ICMR-INDIAB Study [Phase IV] - (Excluding North East)



A. SAMPLING:

i. Sample size calculation:

The sample size was calculated separately for urban and rural areas **[Table 1],** as previous studies have shown 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.** Thus the total sample size for the 5 states was calculated to be 20,000 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	**Rural**	Diabetes =4 %	96%	$\frac{20}{100}$ X 4 = 0.8 %	$n= \frac{(1.96)^2 (4) (96)}{(0.8)^2}$ = 2304.96 = **2305**	n = $\frac{20 \text{ X } 2305}{100}$ = 461 2305 + 461 = **2766**	**2800**
	Urban	Diabetes = 10 %	90 %	2%	$\frac{(1.96)^2 (10) (90)}{(2)^2}$ = 864.36 = **865**	n = $\frac{20 \text{ X } 865}{100}$ = 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.

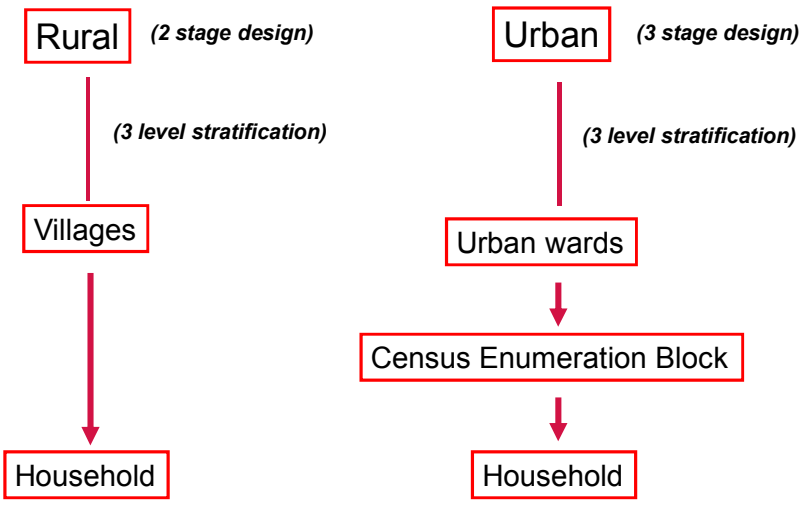
Table 2: Total Sample size required for ICMR–INDIAB Study (Phase IV): 5 States

		Sample size per state (n)	**No. of States in Phase IV**	**Total Sample Size**
ICMR-INDIAB Phase IV	**Rural**	2,800	5	14,000
	Urban	1,200		6,000
	Overall	**4,000**		20,000

ii. Sampling design:

A stratified multi-stage sampling design, [similar to the one employed in the National Family Health Survey - 3 (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 **[Figure 2]**. 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 2: 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 NFHS-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. 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' [STEP wise approach to surveillance (STEPS) World Health Organization (WHO) http://www.who.int/chp/steps/en/]. The PSUs selected for Kerala are presented in **Table 3** and the list is attached as **[Annexure 1].**

Table 3: Total PSU's selected for Kerala

State	Sample size (Households)	Rural PSU's	Urban PSU's	Total
Kerala	**4,000**	**50**	**50**	**100**

The three level stratification and sampling frame in rural and urban areas are given in **Figure 3 and 4** respectively.

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

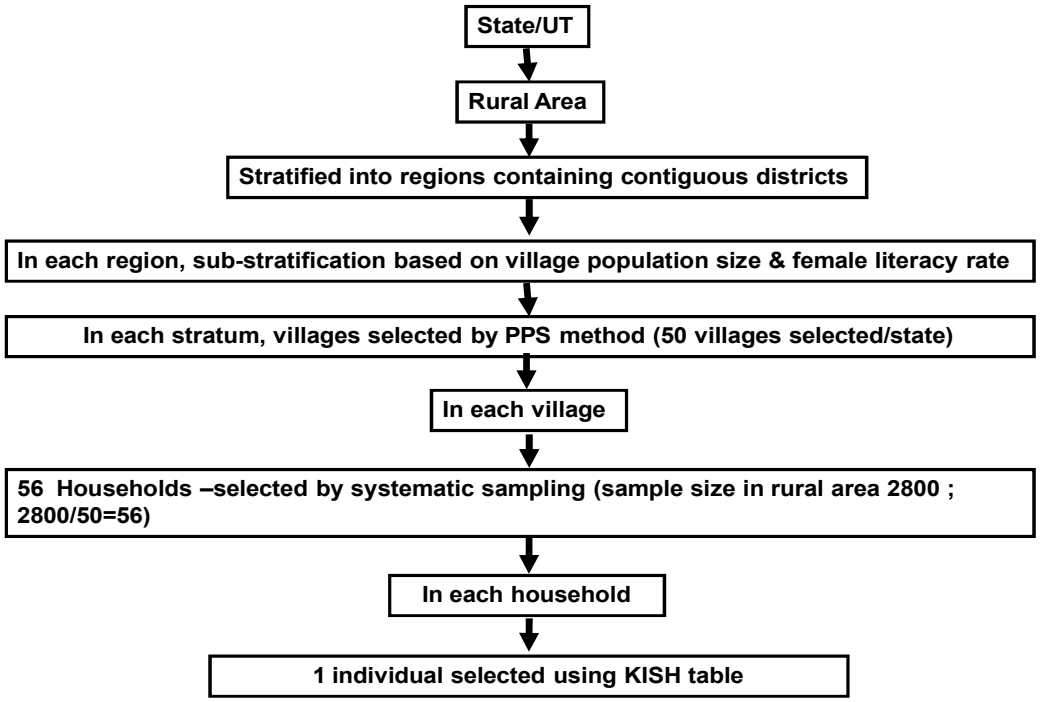
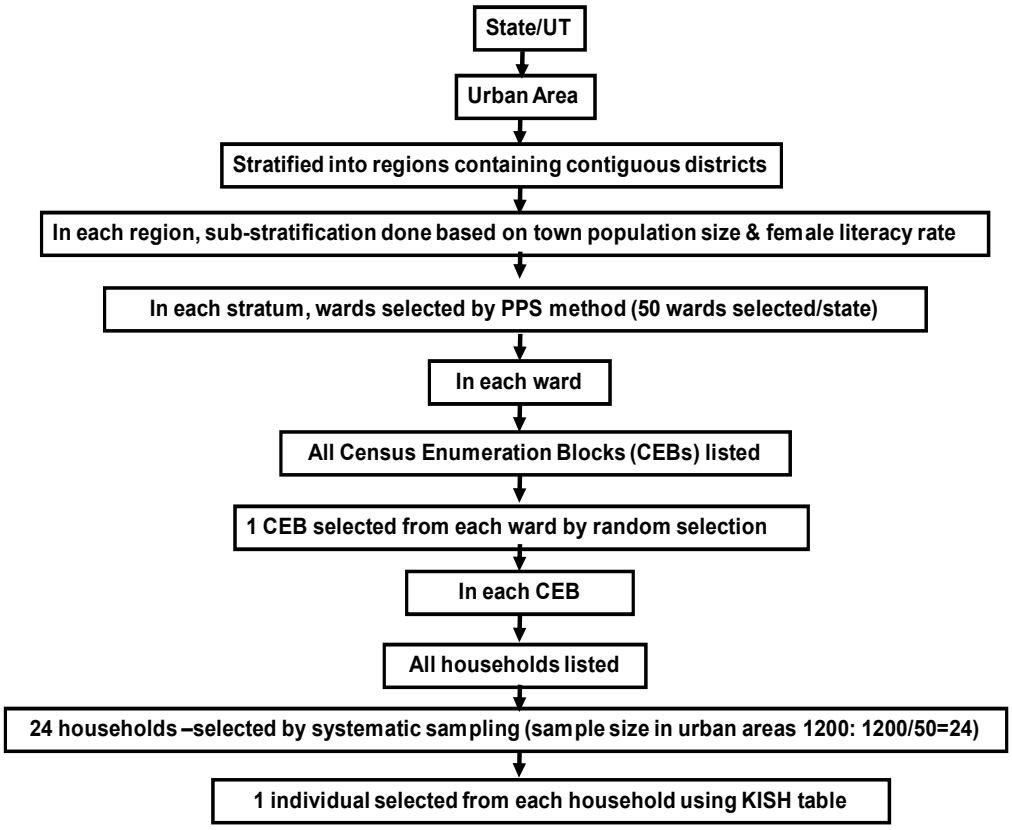


Figure 4: ICMR-INDIAB STUDY SAMPLING DESIGN IN URBAN AREAS



B. ETHICS COMMITTEE APPROVAL / CONSENT FORM:

Approval from the Madras Diabetes Research Foundation (MDRF) Institutional Ethics committee and also from the Trivandrum Medical College for the state of Kerala was obtained prior to commencement of the study **[Annexure 2 & 3].** Written informed consent in English and Malayalam **[Annexure 4a & 4b]** were obtained from respondents after ensuring that they understood and accepted their role in the study.

C. ICMR-INDIAB Study (Phase IV) – State PI's ORIENTATION WORKSHOP:

Madras Diabetes Research Foundation (MDRF) organized an '**Orientation Workshop'** at Chennai on **09th August 2018** for the State Principal Investigators (PI's) and Co-Principal Investigators (Co-PI's) of Kerala, Pondicherry, Goa, Haryana, Chhattisgarh, West Bengal, Odisha and Uttarakhand who were involved in the study **[Figures 5 & 6].** The workshop sessions covered various aspects of the study in detail. Topics covered during the workshop included, (i) pre-field activities of the study, (ii) mapping, household listing and individual selection (using Kish table), (iii) field activities, (iv) anthropometry and blood collection, (v) questionnaire discussion, (vi) post field activities, (vii) roles and responsibilities of PI and Co PI (viii) quality issues of the study and (ix) logistics in planning of the study in the state.

Figure 5: State PI's with the MDRF team during the Orientation Workshop

From (L to R): Sitting: Mrs. Sudha Vasudevan, Dr. A.K. Das, Dr. V.Mohan, Dr. R.M.Anjana and Dr. Guha Pradeepa **Standing (1st row):** Mrs. Parvathi, Dr. Deepa, Dr. Kalpana Dash, Dr. Saroj Tripathy, Dr. Jabbar, Mrs. Jayanthi and Mr. Satishraj **Standing (2nd row):** Dr. Sujoy Ghosh, Dr. Vijay Shrivas, Dr. Bharti Kalra, Dr. Anil Purty, Dr. Rajesh and Dr. Ankush Desai **Standing (3rd row):** Mr. K. Parthiban, Mr. Nirmal Elangovan, Dr. Sagar Modi and Dr. Abhilash Nair

Figure 6: State PI's and Co-PI's in a discussion during the workshop

D. RECRUITMENT OF FIELD PERSONNEL:

The recruitment of the field personnel for survey including the Quality Supervisors (QS), Field Investigators (FI's) and Field Technicians (FT's) was conducted in Medical College, Trivandrum on the **24th and 25th September 2018**. The State PI advertised through the newpapers and short listed the candidates for the interview. The panel of members for the interview **[Figure 7]** included Dr. P.K. Jabbar (State PI), Dr. C. Jayakumari (Co-PI), Dr. Abhilash Nair (Asst. Professor, Dept. of Endocrinology), Mr. Nirmal Elangovan (Project Coordinator, MDRF), Dr. Pradeep Kumar (Asst. Professor, Dept. of Medical Lab Technology) and Dr. Mini Joseph (Asst. Professor, Dept. of Medical Lab Technology). **Table 4** shows the number of field staff recruited in Kerala.

Figure 7: Field staff recruitment for the study in Medical College, Trivandrum

Members (L to R): Dr. P.K. Jabbar (State PI), Dr. Abhilash Nair (Asst. Professor, Dept. of Endocrinology), Nirmal Elangovan (Project Coordinator, MDRF), Dr. Pradeep Kumar (Asst. Professor, Dept. of Medical Lab Technology) and candidate.

Table 4: Number of field staff recruited in Kerala

State	Personnel to be recruited	Personnel recruited
Kerala	QS-06 FI - 13 FT- 13	QS-06 FI -13 FT-13
Total	**32**	**32**

FI- Field Investigator; FT- Field Technician

E. TRAINING OF FIELD PERSONNEL:

An extensive training program was conducted for **Quality Supervisors** at MDRF, Chennai from **21st to 31st October 2018 [Figures 8 & 9]**. Quality Supervisors (QS) were trained in all aspects of the study including administering the various questionnaires, mapping and listing procedures, household selection and selection of subjects for the study. Training was given on anthropometric measurements such as height, weight and waist and clinical measurements including Electrocardiogram (ECG), blood pressure and pulse rate, blood glucose measurements using the glucose meter (capillary blood glucose). The QS were also trained in rapport building, communication skills and calibration of all equipments, quality and first-aid. Special focus was given on quality check and quality logs section. Training was done using printed and digital media aids (e.g. standardized videos, handouts, show cards etc.).

Figures 8 & 9: Training session for Quality Supervisors

The intensive 15 days training programme for the Field Investigators (FI's), Field Technicians (FT's) and Quality Supervisors (QS) was carried out between the **01st to 16th November 2018**

[Figures 10–14] at MDRF, Chennai. A total of 32 individuals (FI–13, FT–13 and QS–6) were trained during this period.

Figure 10: Questionnaire administration

Figure 11: Blood Pressure training

Figures 12: Capillary Blood Collection

Figures 13: ECG Measurement

Figure 14: Project staff under ICMR-INDIAB Study (Phase IV) – KERALA

The field personnel were trained in all aspects of the study including administering the various questionnaires, mapping and listing procedures, household selection and selection of subjects for the study. Thorough training was given to the staff to take anthropometric measurements such as height, weight and waist and clinical measurements including Electrocardiogram (ECG), blood pressure and pulse rate. They were also trained in blood glucose measurements using the glucose meter (capillary blood glucose) and the lab technicians were also trained in venous blood collection. Field staffs were also trained in rapport building, communication skills, calibration of all equipment and first-aid. Training was done using printed and digital media aids (e.g. standardized videos dubbed in local languages, handouts, show cards etc.)

At the end of the training programme, all the field personnel were evaluated. The evaluation included interviewer certification rating, KISH method, anthropometry training performance rating, blood pressure performance rating, and blood drawing (venipuncture) rating, capillary one touch rating, electrocardiogram performance rating, mapping & segmentation performance rating. Only those who performed and proved good were certified to be included for the survey. The results of the training evaluation were intimated to the state PI for follow-up action.

F. PROCUREMENT OF EQUIPMENTS AND CONSUMABLES:

To achieve the objectives of the study, equipments and consumables to measure blood glucose, blood pressure, anthropometric measurements, ECG, centrifuges etc., were procured centrally at MDRF and disbursed to the Kerala field area.

G. EXECUTION OF FIELD WORK – PILOT STUDY:

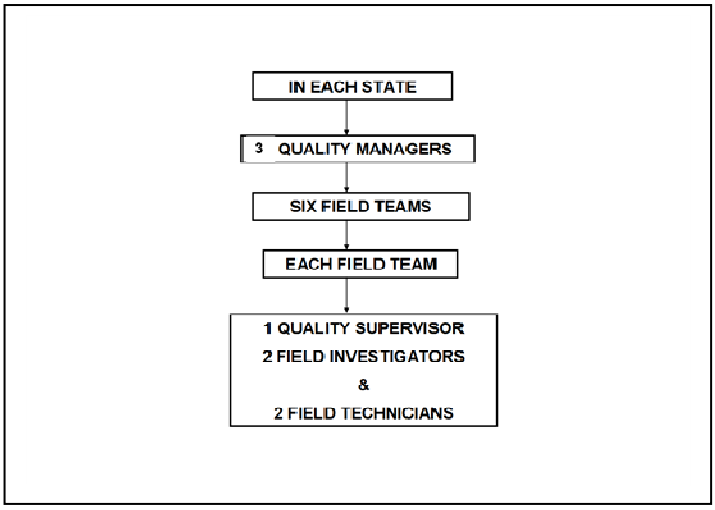
A pilot study was conducted in Trivandrum from **10th December 2018** to assess the practical difficulties of performing the study in Kerala. For the pilot study, the study procedures were tested in a few PSU's other than those included in the main study. The study procedures for the pilot study started right from mapping and household listing procedures. This was followed by selection of the household and selection of the study subject. Next, the informed consent was obtained after which the interview was conducted, anthropometric measurements were taken and finally the fasting capillary blood glucose and 2hour post load blood glucose were measured. Six field teams with five members each conducted the pilot study in Kerala. The pilot study revealed that the field teams were comfortable with the study procedures and

there was no questionnaire fatigue and there was a good response from the community in Kerala.

H. FIELD TEAM COMPOSITION & RESPONSIBILITIES:

Each field team comprised of two Field Investigators (FI's), two Field Technicians (FT's) and one Quality Supervisor (QS). Kerala had six such field teams and three Quality Managers (QM's) to monitor the field activities. **Figure 15** depicts the field team composition.

Figure 15: Field team composition in Kerala



I. EXECUTION OF FIELD WORK – MAIN STUDY:

Following the pilot study, the main study commenced on **19th December 2018** and the study was completed on **31st May 2019.**

Inclusion criteria:

The inclusion criteria listed below were applied during selection 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.

In all the 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. A quick guide to field operations was developed incorporating all necessary details required by the field staff for their ready reference in the field.

- Anthropometric measurements including height, weight, waist and hip measurements.
- Blood pressure and pulse rate are recorded using an electronic instrument (Model: HEM-7101, Omron Corporation, Tokyo, Japan) as the mean of two readings taken five minutes apart.
- Capillary blood glucose measured using a glucose meter. An oral glucose tolerance test [OGTT] was done using a 75 gm 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, 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.
- 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.

J. REFERRAL SYSTEM:

All newly diagnosed diabetic subjects were escorted by the field team members to the local public health centre/ government medical college hospital to confirm their diabetes with a venous OGTT or repeat plasma glucose values. All subjects were given a copy of their test results including details of their anthropometry, blood pressure and capillary blood glucose measurements as well as educational material on diet and life style modifications by means of a health card. Their lipids and electro cardiogram reports were posted to them at a later date. Similarly, subjects with raised blood pressure were also escorted by the field team members to the local doctor / government hospital for further follow up.

K. 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 a few PSU's in Kerala for monitoring of data collection.

Field visit by MDRF (National Coordinating Centre) team and State PI's: The MDRF Co-PI, Dr. R.M. Anjana visited the field teams on the 27th March 2019 in Ernakulam (Cochin) to supervise and check the quality of data collected **(Figures 16a-c).**

Similarly, the State PI Dr. P.K. Jabbar, Co-PI, Dr. C. Jayakumari and Dr. Abilash Nair visited the field teams in Attingal and Kottayam on the 08th and 09th February 2019 to check the quality of data collected **(Figures 16d-e)** in Kerala. During the field visits, the various field activities were observed and corrective actions (if any) were taken. These occasions were also utilized for onsite training and refresher courses. All field work and pre-field activities were documented using quality logbooks. Thirty four quality logs have been utilized in this study and have helped to ensure high standards of quality.

Figure 16: Field visit by MDRF staff and State PI and Co-PI

Figure 16(a): Questionnaire administration

Figure 16(b): Capillary blood collection

Figure 16(c): MDRF Co-PI and State PI with the field team

Figure 16(d): Questionnaire evaluation

Figure 16(e): Mapping & Listing process

ICMR Expert Team Field visit

An external quality monitoring team including members from the Indian Council of Medical Research (ICMR) Experts Group made site visit to Kerala check the quality of data collected and onsite procedures. 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.

The ICMR experts team consisting of Dr. R.S. Dhaliwal (Scientist 'G' & Head NCD Division, ICMR HQ's), Dr. A.K. Das (Member, Expert Committee), Dr. Tanvir Kaur (Scientist 'F', ICMR HQ's) along with the State PI, Dr. P.K. Jabbar, Co-PI, Dr. C. Jayakumari, Dr. Abilash Nair (Asst. Professor, Dept. of Endocrinology) and MDRF Co-PI Dr. Guha Pradeepa visited the field

area in Trivandrum on the 29th and 30th April 2019, so as to have first hand information of data collection, entry and assessment of methodological tools being used in the ICMR-INDIAB study **(Figure 17a-c).**

Figure 17: Field visit by the ICMR Experts team

Figure 17(a): Review meeting with ICMR Experts

Figure 17(b): Capillary blood collection

Figure 17(c): ICMR experts with the field team

L. 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) 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).

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

A. Recruitment status and response rate:

Table 5 shows the number of PSUs completed in Kerala. In Kerala, all 100 PSU's were completed.

Table 5: Total PSUs completed in Kerala

State	Rural PSU's Surveyed	Urban PSU's Surveyed	Total Surveyed	To be surveyed as per protocol
Kerala	50	50	100	100

In Kerala, of the total 4,000 individuals selected from 100 PSU's (50 urban PSU and 50 rural PSU) 3,803 individuals participated in the study (95.1% response rate). The detailed response rate is shown in **Table 6**. The proportion of selected subjects who refused to participate in the study was 3.5% in Kerala.

Table 6: Response rate for the state of Kerala

Status	Urban	Rural	Overall
Eligible (n)	1,200	2,800	4,000
Completed n(%)	1,141 (95.1)	2,662 (95.1)	3,803 (95.1)
Respondent not available n(%)	3 (0.3)	5 (0.2)	8 (0.2)
Refused n(%)*	40 (3.3)	100 (3.6)	140 (3.5)
House locked n(%)*	16 (1.3)	33 (1.2)	49 (1.2)

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

Of the 3,803 subjects who participated, 3,557 [93.5%] gave blood samples. Responders and non-responders for blood samples were compared and there were no significant differences in the general characteristics between the 3,557 'responders' and the 246 'non-responders' with respect to age, gender, BMI, waist circumference and systolic and diastolic blood pressure.

B. General characteristics of the study population:

Table 7 shows the educational status of the study population in Kerala. There was a slight disparity in the educational status among the rural and urban population. In Kerala, 5.1% of the population in urban areas had no formal schooling compared to 7.4% in the rural areas. Similarly, in the urban areas 24.2% of the population had completed primary school education and 52.9% continued to complete high school and higher secondary school education, while the corresponding figures in rural areas were 24.1% and 54.0% respectively. Overall, the educational status at the undergraduate and post graduate level was higher in the urban areas compared to the rural areas of Kerala.

Table 7: Educational status of the study population

Educational status	Urban (n=1,138)	Rural (n=2,658)	Overall (n=3,796)
No formal schooling	58 (5.1)	198 (7.4)**	256 (6.7)
Primary school	275 (24.2)	640 (24.1)	915 (24.1)
High school & higher secondary school	602 (52.9)	1,434 (54.0)	2,036 (53.6)
Technical education	32 (2.8)	79 (3.0)	111 (2.9)
Undergraduate degree	119 (10.5)	207 (7.8)**	326 (8.6)
PG degree or above	52 (4.6)	100 (3.8)	152 (4.0)

*p<0.05; Data presented as n (%)

Table 8 shows the occupational status of the study population in Kerala. More individuals were found to be employed as professionals or executives or managers or involved in big businesses in urban areas compared to rural areas (4.5% vs. 3.2%). Similarly, the proportion of those employed in sales was higher in urban areas compared to rural areas (2.8% vs. 1.5%). However, those involved in agriculture or those who were self-employed were significantly more in rural areas compared to the urban areas (4.2% vs. 1.7%). Nearly 29.3% of the population is unemployed in the urban areas and 21.0% of the population is unemployed in rural areas. Overall, the rate of unemployment in Kerala is 23.5%.

Table 8: Occupational status of the study population

Occupational status	Urban (n=1,125)	Rural (n=2,656)	Overall (n=3,781)
Professional/Executive/Manager/Big business	51 (4.5)	85 (3.2)**	136 (3.6)
Clerical / Medium business	34 (3.0)	66 (2.5)	100 (2.6)
Sales	31 (2.8)	40 (1.5)**	71 (1.9)
Agriculture/Self-employed	19 (1.7)	112 (4.2)**	131 (3.5)
Household & domestic work	20 (1.8)	36 (1.4)	56 (1.5)
Services	29 (2.6)	45 (1.7)	74 (2.0)
Skilled manual	141 (12.5)	275 (10.4)	416 (11.0)
Unskilled manual	46 (4.1)	164 (6.2)**	210 (5.6)
Do not work/Unemployed	330 (29.3)	558 (21.0)*	888 (23.5)
Others	424 (37.7)	1,274 (48.0)*	1,698 (44.9)

*p<0.05 and **p<0.001 compared to urban area; Data presented as n (%)

The general characteristics of the study population comparing urban and rural areas are shown in **Table 9**. In Kerala, the urban residents had a higher BMI ($p<0.05$) and waist circumference ($p<0.05$) as compared to the rural residents. Smoking was higher among the rural population compared to the urban population, whereas alcohol consumption was higher among urban population, though not statistically significant.

Table 9: General characteristics of the study population

Parameters	Urban (n=1,141)	Rural (n=2,662)	Overall (n=3,803)
Age (years)	49.9 ± 15.5	50.3 ± 15.6	50.2 ± 15.6
Male n (%)	468 (41.0)	1105 (41.6)	1573 (41.4
Height (cm)	156.6 ± 10.2	157.3 ± 9.7	157.1 ± 9.8
Weight (kg)	61.2 ± 13.2	60.5 ± 13.0	60.7 ± 13.1
BMI (kg/m^2)	24.9 ± 4.9	24.4 ± 4.7**	24.6 ± 4.8
Waist (cm) – male	87.0 ± 12.8	85.6 ± 11.7**	86.0 ± 12.0
Waist (cm) – female	88.3 ± 12.0	86.5 ± 12.8**	87.0 ± 13.3
BP Systolic (mmHg)	134 ± 21	133 ± 20	133 ± 20
BP Diastolic (mmHg)	83 ± 12	83 ± 11	83 ± 11
Current smokers	66 (5.8)	177 (6.7)	243 (6.4)
Current alcohol users	101 (8.9)	210 (7.9)	311 (8.2)

**p<0.05 compared to urban area; data are presented as n (%) / mean ± SD

Table 10: Biochemical parameters of the study population (In a subset)

Parameters	Urban (n=220)	Rural (n=531)	Overall (n=751)
Total Cholesterol (mg/dL)	199 ± 46	199 ± 50	199 ± 49
Triglycerides (mg/dL)@	144	153	150
HDL Cholesterol (mg/dL) – male	39 ± 10	40 ± 11	40 ± 10
HDL Cholesterol (mg/dL) – female	40 ± 9	41 ± 11	41 ± 10
LDL Cholesterol (mg/dL)	130 ± 41	128 ± 49	129 ± 47
Cholesterol to HDL ratio	5.2 ± 1.5	5.1 ± 1.6	5.2 ± 1.6
Creatinine (mg/dL)	0.7 ± 0.3	0.8 ± 0.3	0.8 ± 0.3
HbA1c (%)	7.1 ± 1.9	7.1 ± 2.0	7.1 ± 2.0

@ Geometric mean; * p<0.05 compared to urban area; data are presented as mean ± SD

Table 10 shows the biochemical parameters of the study population comparing urban and rural areas in Kerala (5th and Self reported diabetic subjects). Both urban and rural residents have similar cholesterol, triglycerides, HDL cholesterol, LDL Cholesterol, cholesterol to HDL ratio and glycated haemoglobin.

C. Results of Primary Objectives 1 & 2 are presented together:

Primary Objective 1: *To determine the prevalence of diabetes mellitus & prediabetes [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 diabetes and prediabetes in urban areas, and rural areas in India.*

Weighted prevalence of diabetes, prediabetes and ratio of self-reported diabetes to newly diagnosed diabetes in the study population is given in **Table 11**.

Table 11: Weighted prevalence of diabetes and prediabetes in the study Population (n=3,557)

Status	Urban (n=1,061)	Rural (n=2,496)	Overall (n=3,557)
KD % (95%CI)	18.6 (14.8,22.3)	17.0 (15.5,18.4)	17.5 (15.9,19.0)
NDD % (95%CI)	6.1 (4.3,7.9)	6.0 (5.1,7.0)	6.1 (5.2,6.9)
Ratio of KD:NDD	1 : 0.3	1 : 0.4	1 : 0.3
Total Diabetes% (95%CI)	**24.7 (20.7,28.7)**	**23.0 (21.3,24.7)**	**23.6 (21.8,25.2)**
IFG % (95%CI)	10.0 (7.3,12.8)	11.9 (10.7,13.2)	11.3 (10.1,12.6)
IGT % (95%CI)	2.8 (1.6,4.0)	3.4 (2.6,4.1)	3.2 (2.6,3.8)
IFG+IGT % (95%CI)	3.3 (1.9,4.7)	3.7 (3.0,4.5)	3.6 (2.6,4.3)
Prediabetes % (95%CI)	**16.1 (13.0,19.3)**	**19.0 (17.5,20.6)**	**18.1 (16.6,19.6)**

KD = Known Diabetes; NDD = Newly Detected Diabetes; Total diabetes = known diabetes and newly diagnosed diabetes. IFG= Impaired Fasting Glucose; IGT= Impaired Glucose Tolerance; Pre-diabetes = impaired fasting glucose or impaired glucose tolerance

The overall weighted prevalence of diabetes was 23.6%. The weighted prevalence of diabetes in urban areas was 24.7% as compared to 23.0% in rural areas. The ratio of known to newly diagnosed diabetes is a good indicator of the level of diabetes awareness in a population. It was observed that the overall ratio of newly diagnosed to known diabetes was 1:0.3, while in the urban areas it was 1:0.3 and 1:0.4 in the rural areas. The overall weighted prevalence of prediabetes in Kerala was 18.1% (IFG: 11.3%, IGT: 3.2% and IFG+IGT: 3.6%).

Figure 18 (A & B): Age and sex specific prevalence of diabetes & prediabetes in Kerala

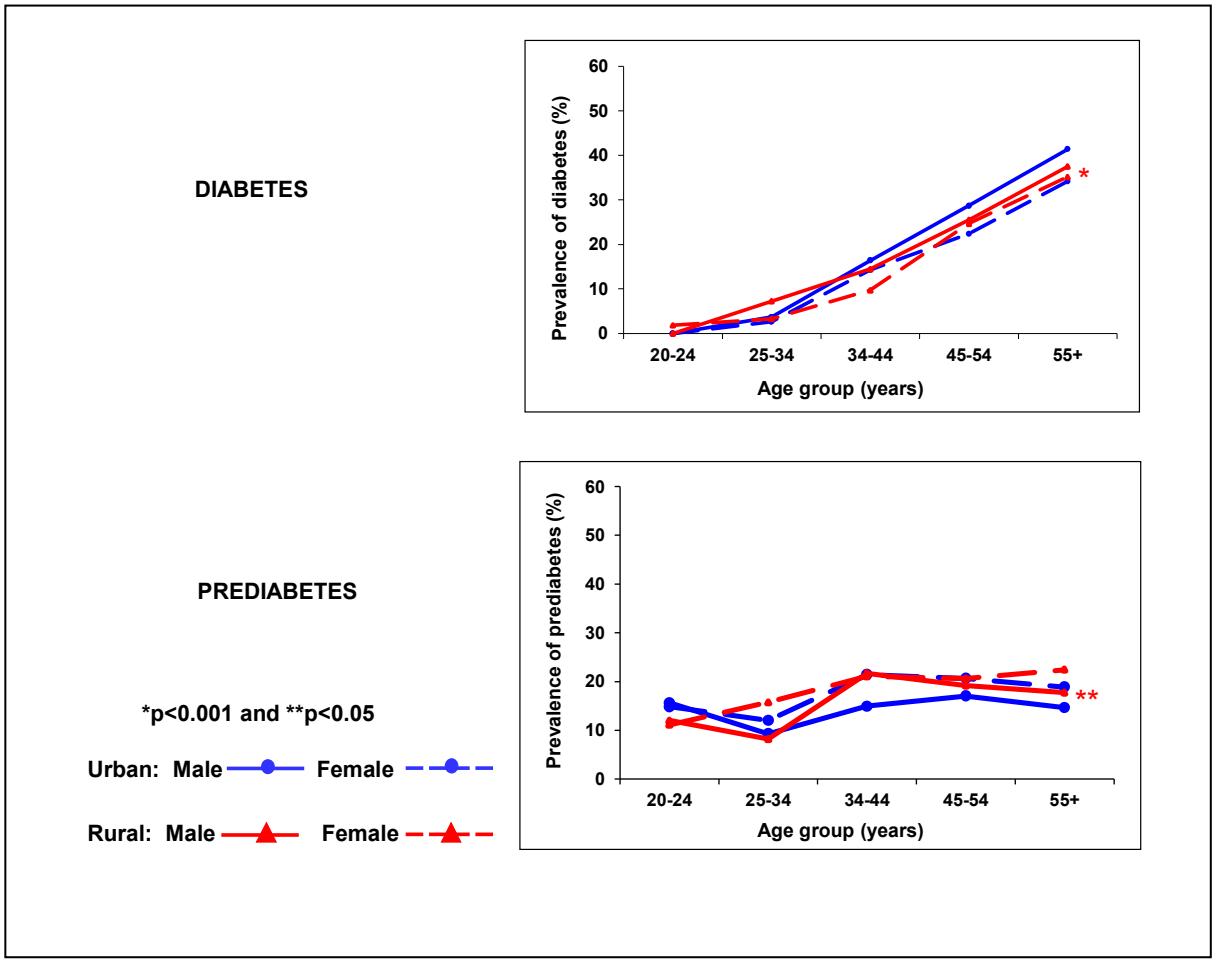


Figure 18 (A&B) presents the age and gender specific prevalence of diabetes and prediabetes in urban and rural population of Kerala. The take-off point in the prevalence of diabetes in Kerala was in the age group 34–44 years. The prevalence of diabetes was significantly higher among males in both urban and rural areas across all age groups. The prevalence of prediabetes is particularly high in the age group of 34-44 years in both the urban and rural areas of Kerala, except in urban males.

Results of Secondary Objective 1:

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

Figure 19 shows the prevalence of hypertension (self-reported, newly diagnosed and overall) in the urban and rural population of Kerala. The prevalence of hypertension in the urban and rural areas was observed to be 44.6% and 44.0% respectively. It was observed that the ratio of known to newly diagnosed hypertensive subjects in the urban and rural areas was Urban - 1:0.7 vs. Rural - 1:0.9.

Figure 19: Prevalence of hypertension (self-reported, newly diagnosed and overall) in urban and rural population

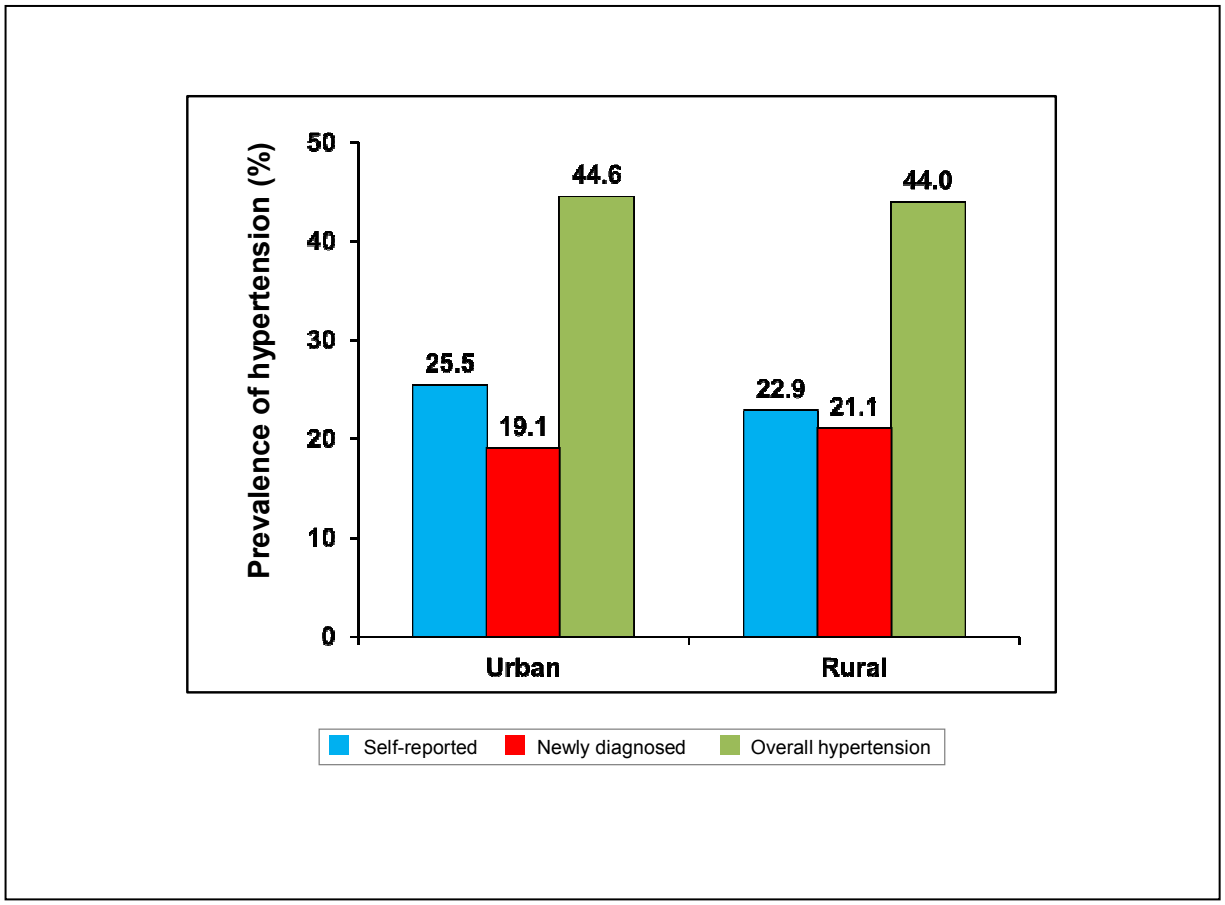


Figure 20 presents the age specific prevalence of hypertension in urban and rural areas of Kerala. The prevalence of hypertension increased with increasing age. The prevalence of hypertension in urban areas increased from 1.6% in the age group of 20–24 years to 68.9% in the age group of 55+ years. Similarly, prevalence in rural areas increased from 11.4% in the age group of 20–24 years to 66.7% in the age group of 55+ years.

Figure 20: Age wise prevalence of hypertension in urban and rural population

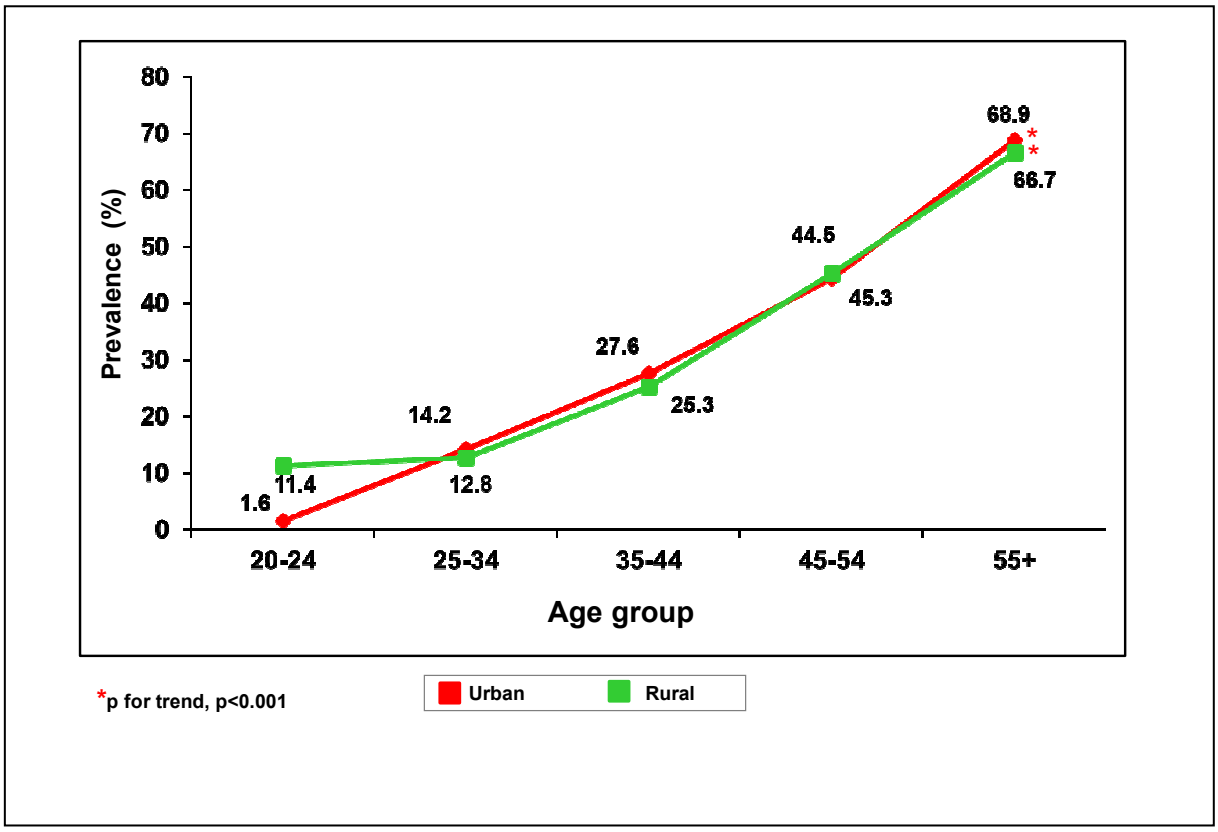


Figure 21 shows the prevalence of various lipid abnormalities namely hypercholesterolemia, hypertriglyceridemia, low HDL cholesterol and dyslipidemia in Kerala. In Kerala, the prevalence of hypercholesterolemia was slightly higher in urban areas – 51.7%, compared to rural areas – 49.1% (p=0.570). The prevalence of hypertriglyceridemia was 30.9% in urban and 30.7% in rural areas (p=0.957). The prevalence of low HDL was higher in urban areas 73.6%, compared to urban areas 69.3%. The prevalence of dyslipidemia was 89.9% in urban and 90.5% in the rural areas of Kerala.

Figure 21: **Prevalence of lipid abnormalities in urban and rural population**

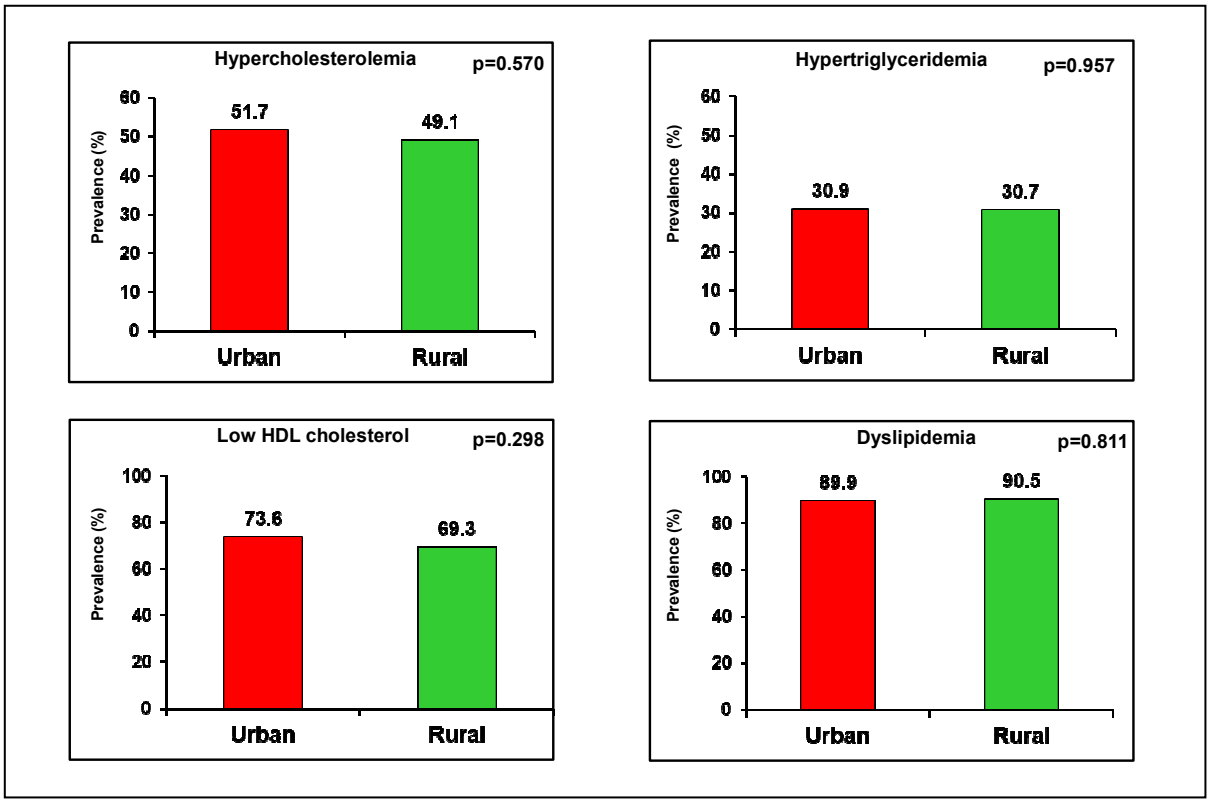


Figure 22: **Prevalence of obesity (generalized & abdominal) in urban and rural population**

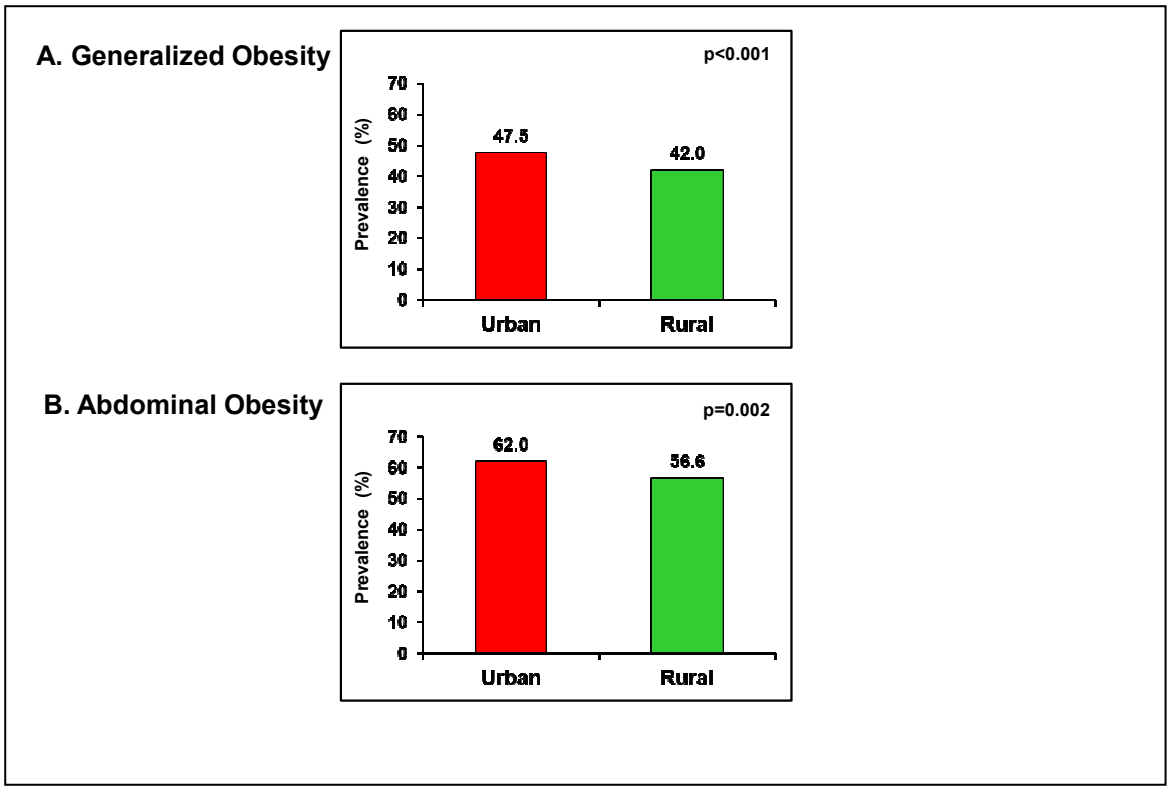
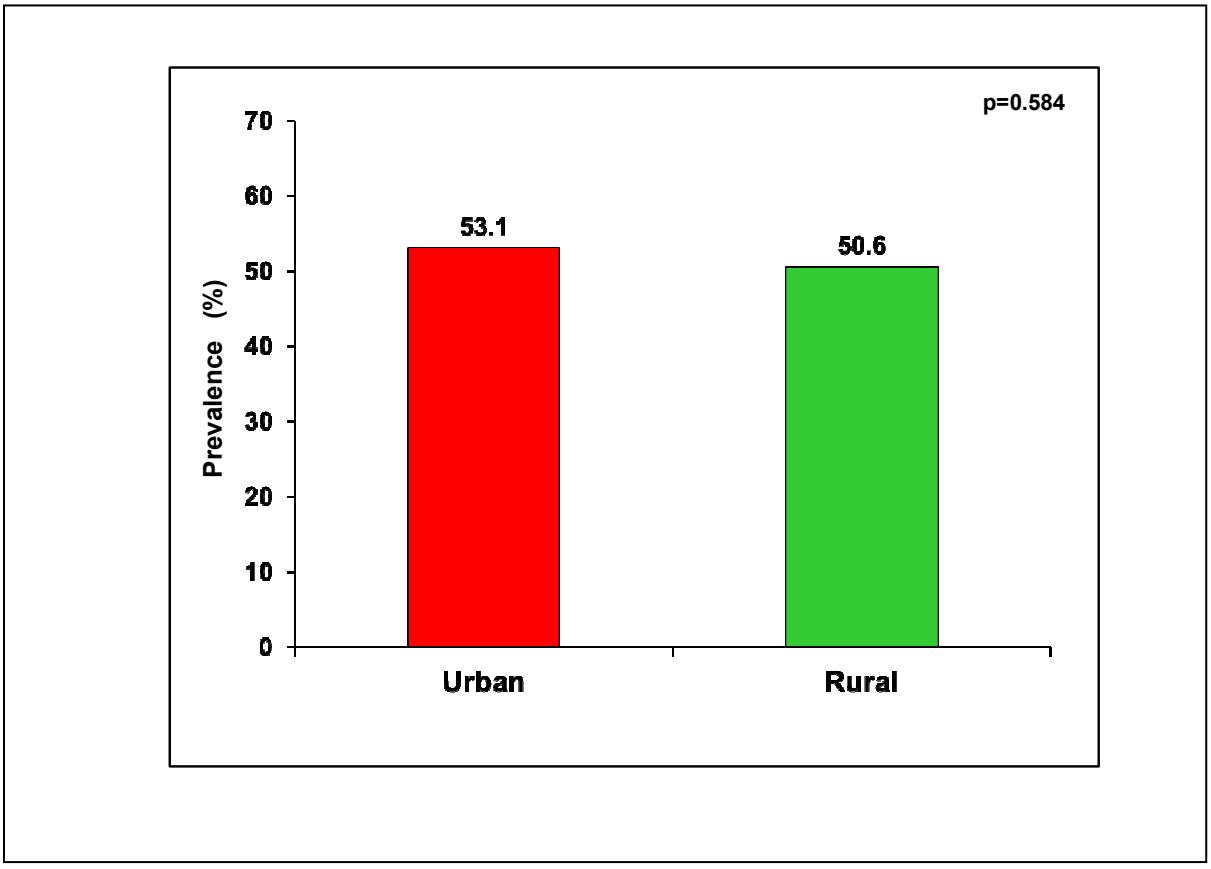


Figure 22 shows the prevalence of generalized obesity (defined as BMI ≥25 kg/m^2) and abdominal obesity (waist circumference ≥90 cm in men and ≥80 cm in women) in Kerala. The overall prevalence of generalized and abdominal obesity was 43.6% and 58.2% in Kerala. The prevalence of generalized obesity was significantly higher in the urban areas (47.5%) compared to the rural areas (42.0%). The prevalence of abdominal obesity was also higher in the urban areas (62.0%) compared to the rural areas (56.6%) in Kerala.

Figure 23 shows the prevalence of metabolic syndrome [based on south Asian modified National Cholesterol Education Programme (SAM-NCEP) criteria]. The urban areas in Kerala had slightly higher prevalence of metabolic syndrome compared to the rural areas (Urban–53.1 % vs. Rural–50.6%).

Figure 23: Prevalence of metabolic syndrome in the urban and rural population



E: Results of Secondary Objective 2: [To be included]

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 24.** The prevalence of CAD among diabetic subjects compared to subjects without diabetes in Kerala was ----------% vs. ----------% respectively.

Figure 24: Prevalence of CAD among subjects with and without diabetes

F: Results of Secondary Objective 3:

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

Table 14 presents the mean glycated haemoglobin (HbA1c) and the duration of diabetes among subjects with self-reported diabetes in Kerala. Overall, the mean HbA1c was 8.2 ± 1.9% in Kerala (Urban: 8.3±1.8% vs. Rural: 8.2±2.0%). Duration of diabetes was higher in rural areas compared to urban areas (Urban: 7.9 ± 6.9 vs. Rural: 8.5 ± 6.9) in Kerala.

Table 14: Mean HbA1c and duration of diabetes among self-reported diabetic subjects

	Urban (n=142)	Rural (n=329)	Overall (n=471)
HbA1c (%)	8.3 ± 1.8	8.2 ± 2.0	8.2 ± 1.9
Duration of diabetes (years)	7.9 ± 6.9	8.5 ± 6.9	8.3 ± 6.9

Figure 25 shows the glycemic control among subjects with self-reported diabetes. Subjects were categorized based on their HbA1c values as those with good control (HbA1c: <7%), fair control (HbA1c: 7-9%) and poor control (HbA1c: >9%). In Kerala, 24.6% in urban areas had good control, 43.0% had fair control and 32.4% had poor control while in the rural areas 30.7% had good control, 40.7% had fair control and 28.6% had poor control.

Figure 25: Glycemic control (HbA1c) among subjects with self-reported diabetes

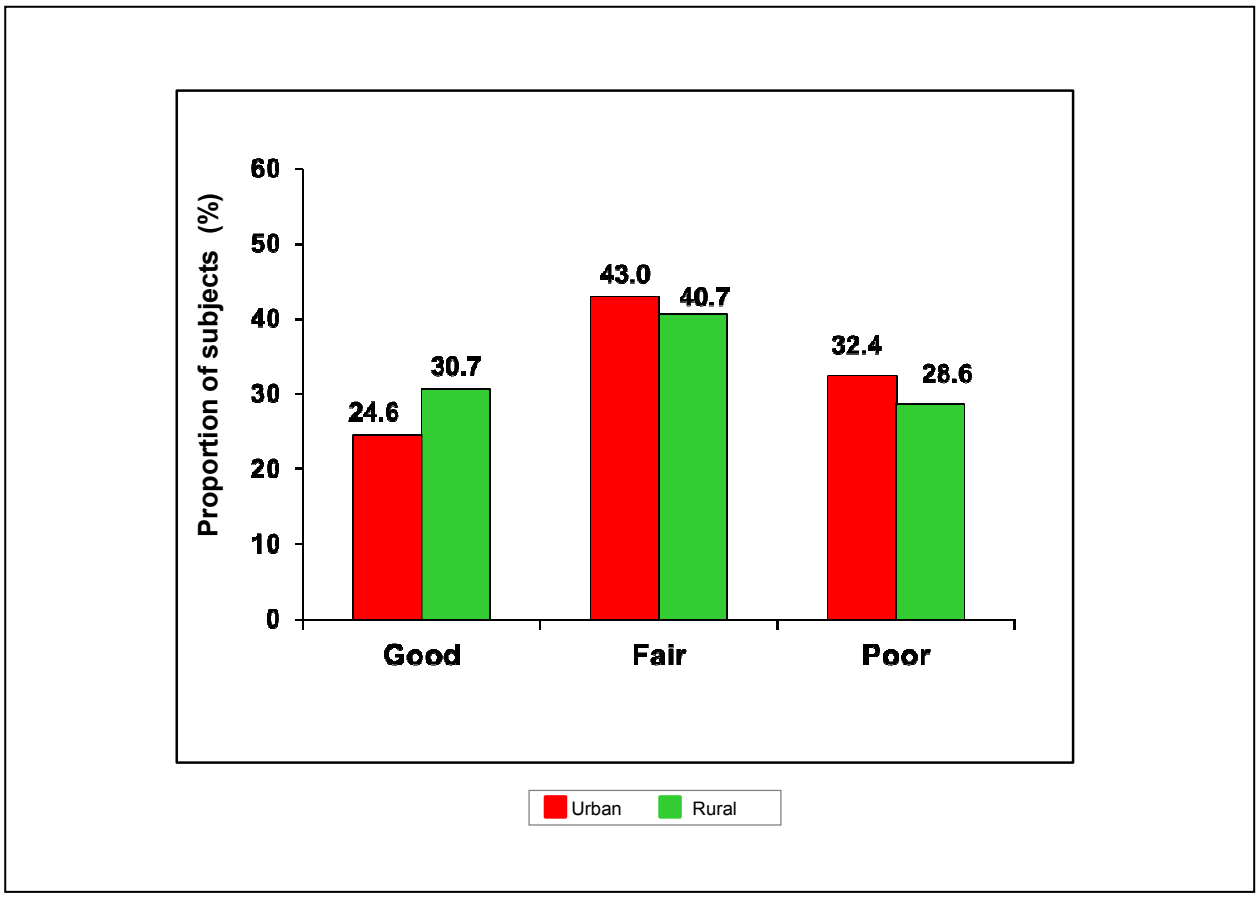


Figure 26: Management of diabetes among subjects with self-reported diabetes

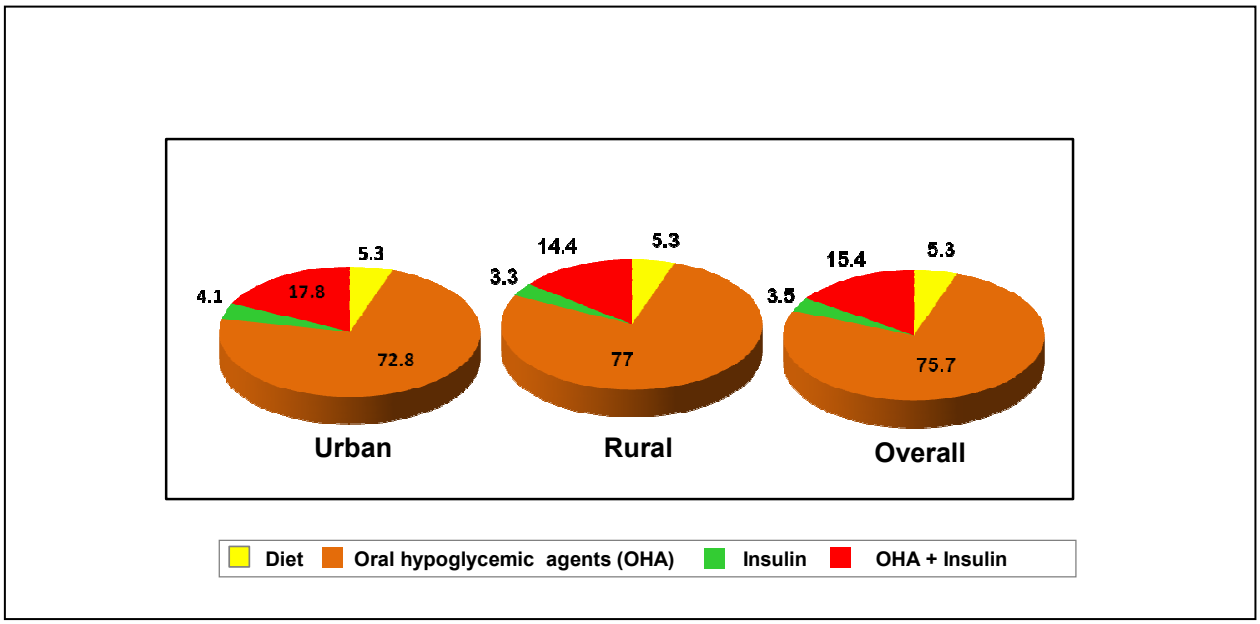


Figure 26 shows the management of diabetes among subjects with self-reported diabetes. Overall, majority (75.7%) of the subjects were on oral hypoglycemic agents (OHA), 15.4% were on both OHA and insulin, 3.5% were on insulin alone and 5.3% were on diet alone in Kerala.

F. Additional results:

Physical activity:

Pattern of physical activity in urban and rural areas is shown in **Table 15.** About 72.4% of the population in urban Kerala were involved in sedentary activity. The corresponding figure in the rural Kerala is 70.2%. A very small proportion of subjects were only involved in vigorous physical activity even in rural population (4.2%), which is much lower in urban Kerala (2.3%).

Table 15: Physical Activity Levels

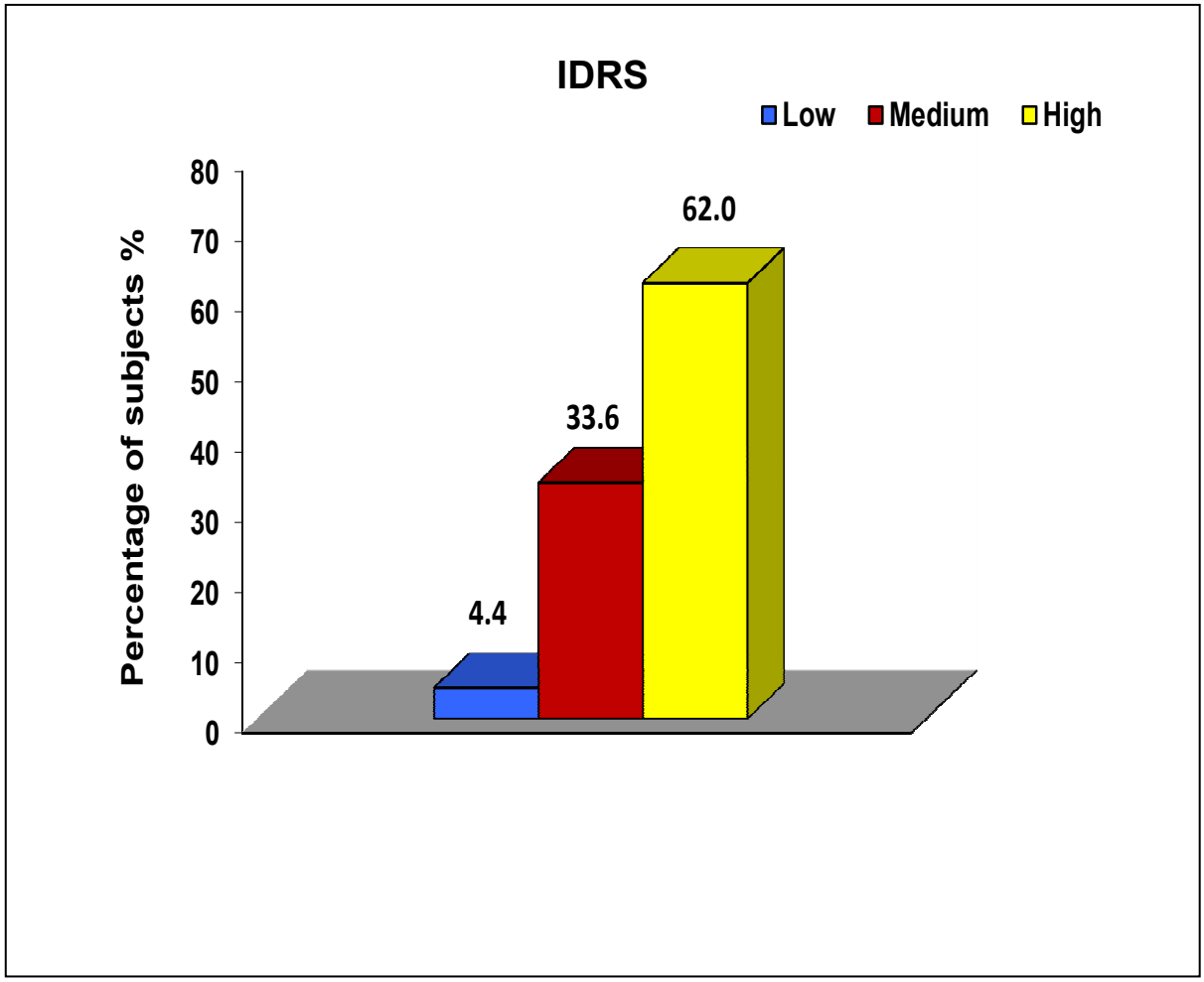
Activity	Urban (n=1,131)	Rural (n=2,654)	Overall (n=3,785)
Inactive n(%)	819 (72.4)	1,862 (70.2)	2,681 (70.8)
Active n(%)	286 (25.3)	681 (25.7)	967 (25.5)
Highly active n(%)	26 (2.3)	111 (4.2)**	137 (3.6)

**p<0.05 compared to urban area

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

Figure 27 shows the performance of IDRS in identifying subjects with diabetes in Kerala. It was observed that, of the newly diagnosed diabetic subjects screened by oral glucose tolerance test (OGTT), 62.0% of the subjects were identified by IDRS as having high risk for developing diabetes. The corresponding figures for moderate risk were 33.6%. Therefore, almost 95.6% of the newly diagnosed diabetic subjects in Kerala were either classified as having high or moderate risk for developing diabetes using IDRS.

Figure 27: Indian Diabetes Risk Score (IDRS) in identifying subjects with diabetes



Dietary profile:

The staple food consumed by the urban and rural population is shown in **Table 16**. Rice is the main staple food in both the urban as well as rural areas of Kerala. Rice was consumed by 95.7% of the population in the urban areas and 97.4% in the rural areas. It is also observed that 4.1% of the population consumes wheat in the urban areas and 2.5% in the rural areas of Kerala. Overall, 0.1% of the population consumes ragi, 0.1% consumes bajra and 0.03% consumes jowar in Kerala.

Table 16: Staple food consumed by the urban and rural population

Staple Food	Urban (n=1,132)	Rural (n=2,652)	Overall (n=3,784)
Rice	1,083 (95.7)	2,582 (97.4)	3,665 (96.9)
Wheat	46 (4.1)	66 (2.5)	112 (3.0)
Ragi	1 (0.1)	2 (0.1)	3 (0.1)
Bajra	2 (0.2)	1 (0.04)	3 (0.1)
Jowar	-	1 (0.04)	1 (0.03)

Table 17: Major cooking oil used in the urban and rural population

Cooking Oil	Urban (n=1,123)	Rural (n=2,656)	Overall (n=3,779)
Mustard oil	12 (1.1)	49 (1.8)	61 (1.6)
Coconut oil	883 (78.6)	2032 (76.5)	2915 (77.1)
Groundnut oil	3 (0.3)	8 (0.3)	11 (0.3)
Sunflower oil	151 (13.4)	389 (14.6)	540 (14.3)
Soyabean oil	2 (0.2)	1 (0)	3 (0.1)
Palm oil	59 (5.3)	136 (5.1)	195 (5.2)
Vanaspathi	0 (0)	5 (0.2)	5 (0.1)
Ghee	2 (0.2)	0 (0)	2 (0.1)
Rice bran oil	11 (1.0)	35 (1.3)	46 (1.2)
Gingelly oil	0 (0)	1 (0.04)	1 (0.03)

Table 17 shows the major cooking oil used by the urban and rural population in Kerala. The major oil used for cooking is coconut oil in the urban areas–78.6% and 76.5% in the rural areas, followed by sunflower oil (14.3%) and palm oil (5.2%). Mustard oil is consumed by 1.6%, of the population followed by rice bran oil (1.2%) and groundnut oil (0.3%).

Knowledge of diabetes and its complications:

Knowledge of diabetes and its complications is presented in **Figures 28-30. Figure 28** shows the knowledge of diabetes among the urban and rural residents of the study population in Kerala. Nearly 96.5% of the urban residents and 94.5% of the rural residents in Kerala reported that they knew about a condition called diabetes. Of those who reported that they knew about diabetes 87.6% of the urban residents and 84.7% of the rural residents felt that the prevalence of diabetes was increasing.

Figure 28: Knowledge of diabetes in the study population

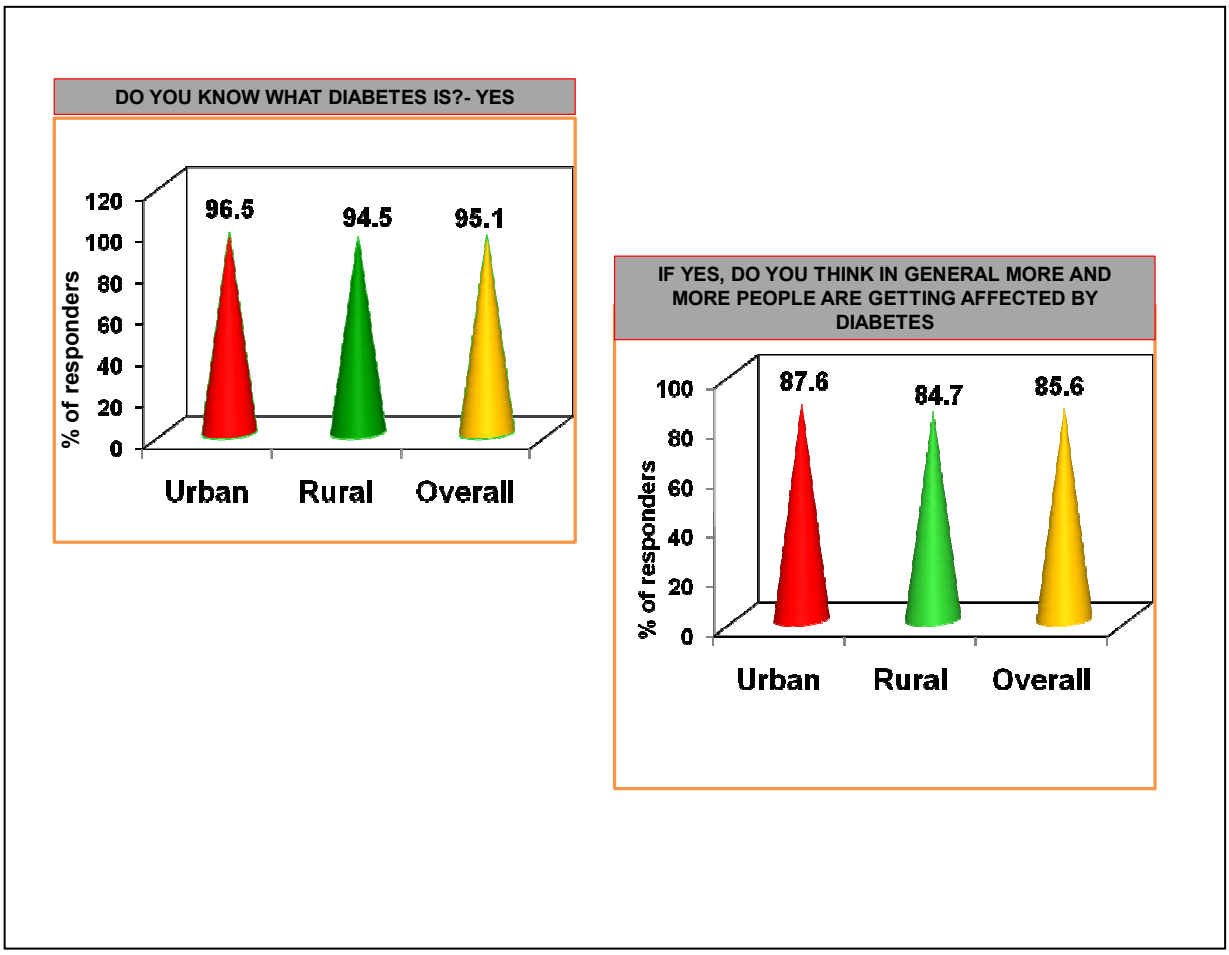


Figure 29: **Knowledge of diabetes prevention**

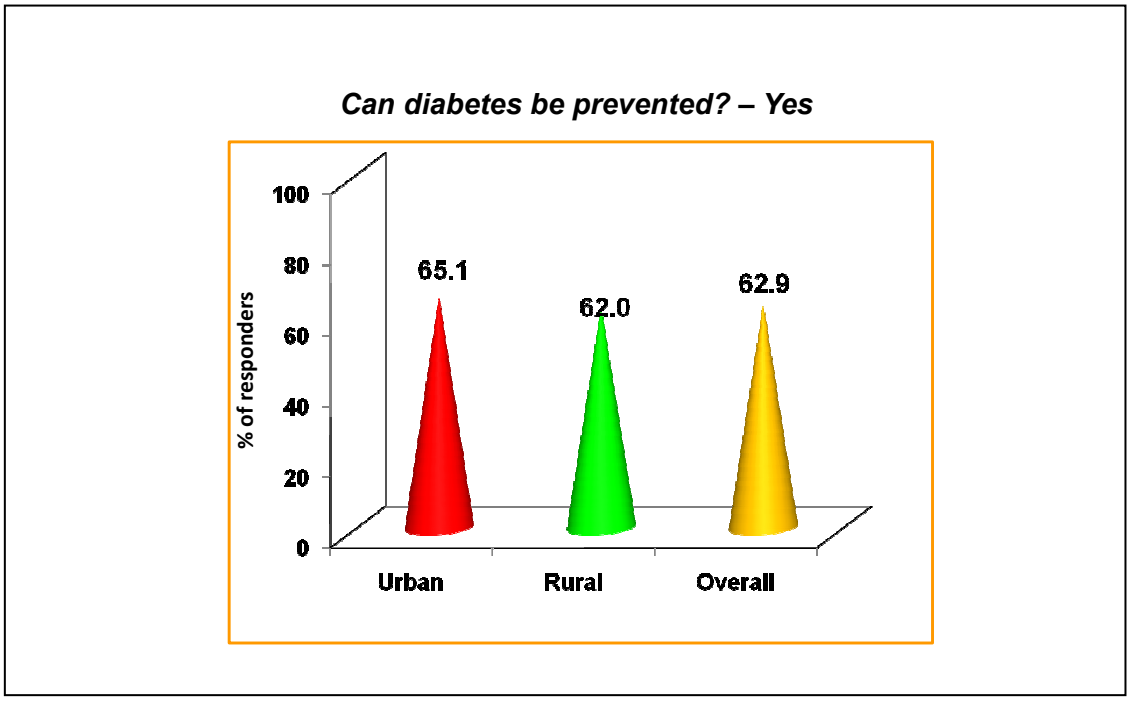


Figure 29 shows that 65.1% of the urban residents and 62.0% of the rural residents of Kerala were aware that diabetes could be prevented. Overall, 62.9% of the subjects were aware that diabetes could be prevented.

Figure 30: **Knowledge of diabetes related complications**

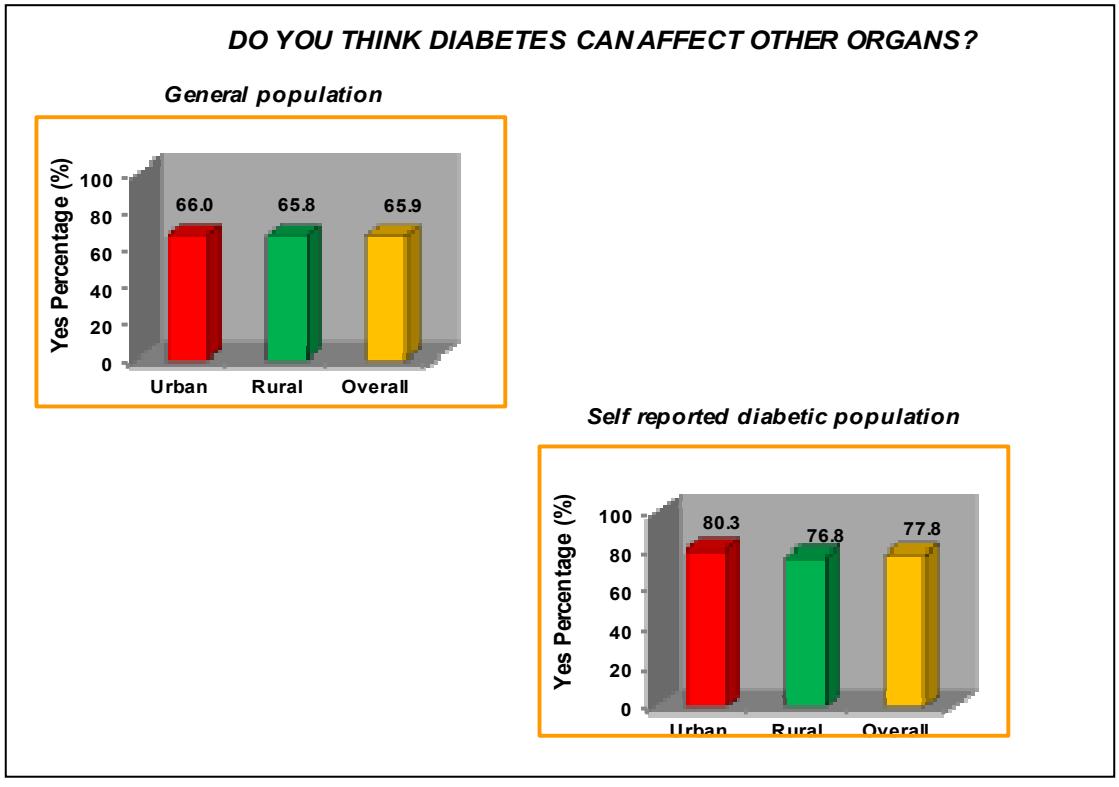


Figure 30 shows that an equal proportion of urban and rural residents in Kerala reported that diabetes could affect other organs (Urban vs. Rural 66.0% vs. 65.8%). Among self-reported diabetic subjects, the corresponding figures are (Urban: 80.3% and Rural: 76.8%). Overall, 77.8% of the self-reported diabetic subjects and 65.9% of the general population said that diabetes can affect other body organs.

Limitations:

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. Thus, the HbA1c results must be viewed in this context.

11. CONCLUSIONS SUMMARIZING THE ACHIEVEMENTS AND INDICATION OF SCOPE FOR FUTURE WORK

Conclusions:

In summary, overall weighted prevalence of diabetes was 23.6% and that of prediabetes was 18.1% in Kerala. The prevalence of diabetes was more in urban areas compared to rural areas (urban vs. rural: 24.7% vs. 23.0%), while the prevalence of prediabetes was more in rural areas (urban vs. rural: 16.1% vs. 19.0%). It was observed that the overall ratio of known diabetes to newly diagnose was 1:0.3, while in the urban areas it was 1:0.3 and 1:0.4 in the rural areas. The prevalence of hypertension was similar in urban and rural areas (urban: 44.6% vs. rural: 44.0%). The prevalence of metabolic syndrome was higher in the urban areas (53.1%) compared to the rural areas (50.6%). The prevalence of dyslipidemia was similar in urban (89.9%) and rural areas (90.5%) of Kerala. In terms of glycemic control, 28.6% of self reported diabetic subjects in rural Kerala had poor glycemic control compared to 32.4% in the urban areas. 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 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 cover 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 pre-diabetes 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. In this context, the ICMR-INDIAB study helped 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 was assessed and need for better control of diabetes was stressed. All participants in the study were also provided with general advice on prevention of NCDs. This helped to improve the awareness about NCDs in the population at large. New initiatives are needed to institute prevention programmes to curb the huge burden of NCDs in this regard. The ICMR-INDIAB study not only helped in earlier detection of diabetes through screening, but also in planning prevention programmes for the country.

12. S&T BENEFITS ACCRUED

I. List of research publications with complete details: (Annexure 5)

1. 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. J Diabetes Sci Technol. 2011 Jul 1;5(4):906-14.

2. 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; ICMR–INDIAB Collaborative Study Group. Prevalence of diabetes and prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India: phase I results of the Indian Council of Medical Research-India DIABetes (ICMR-INDIAB) study. Diabetologia. 2011 Dec;54(12):3022-7.

3. Pradeepa R, Anjana RM, Joshi SR, Bhansali A, Deepa M, Joshi PP, Dhandania VK, Madhu SV, Rao PV, Geetha L, Subashini R, Unnikrishnan R, Shukla DK, Kaur T, Mohan V, Das AK; ICMR-INDIAB Collaborative Study Group. Prevalence of generalized & abdominal obesity in urban & rural India--the ICMR-INDIAB Study (Phase-I) [ICMR-INDIAB-3]. Indian J Med Res. 2015 Aug;142(2):139-50.

4. 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. Knowledge and awareness of diabetes in urban and rural India: The Indian Council of Medical Research India Diabetes Study (Phase 1): Indian Council of Medical Research India Diabetes 4. Indian Journal of Endocrinology and Metabolism. 2014; 18: 379-385.

5. 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 BehavNutr Phys Act. 2014 Feb 26;11(1):26.

6. 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. Prevalence of and risk factors for hypertension in urban and rural India: the ICMR-INDIAB study. J Hum Hypertens. 2015 Mar;29(3):204-9.

7. 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 T, Shukla DK, Mohan V; ICMR-INDIAB Collaborative Study Group. Prevalence of dyslipidemia in urban and rural India: the ICMR-INDIAB study. PLoS One. 2014 May 9;9(5):e96808.

8. Unnikrishnan R, Anjana RM, Deepa M, Pradeepa R, Joshi SR, Bhansali A, Dhandania VK, Joshi PP, Madhu SV, Rao PV, Lakshmy R, Jayashri R, Velmurugan K, Nirmal E, Subashini R, Vijayachandrika V, Kaur T, Shukla DK, Das AK, Mohan V; ICMR–INDIAB Collaborative Study Group. Glycemic control among individuals with self-reported diabetes in India--the ICMR-INDIAB Study. Diabetes Technol Ther. 2014 Sep;16(9):596-603.

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II. Manpower trained on the project:

- **a. Research Scientists or Research Fellows:** Nil
- **b. No. of Ph.Ds produced:** Nil
- **c. Other Technical Personnel trained: 32**

III. Patents taken, if any: Nil

IV. Products developed, if any: Nil

13. ABSTRACT HIGHLIGHTING THE RESULTS ACHIEVED BY THE PROJECT FOR INCLUSION IN THE COUNCIL'S RESEARCH INFORMATION BULLETIN

The ICMR-INDIAB study reports on the results obtained from Kerala. 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 4,000 individuals selected for the study in Kerala, 3,803 [95.1%] individuals participated. Overall weighted prevalence of diabetes was 23.6% and prediabetes was 18.1% in Kerala. The prevalence of diabetes was higher in urban compared to rural areas, while the prevalence of prediabetes was higher in rural areas. The prevalence of hypertension and dyslipidemia were similar in urban and rural areas, while the prevalence of metabolic syndrome was slightly higher in urban compared to rural areas of Kerala.

In terms of glycemic control, rural areas of Kerala had poorer glycemic control compared to urban areas. Nearly 96.5% of the urban residents and 94.5% of the rural residents in Kerala reported that they knew about a condition called diabetes. ***One of the important findings identified through this study is the high prevalence of diabetes and prediabetes in both the urban and rural areas of Kerala.*** Further, it is observed that there is a significant gap in the knowledge level of diabetes and its related complications among the general population (65.9%) and self reported diabetic (77.8%) subjects in Kerala. This shows the need to devise suitable awareness and intervention programmes to ensure that that the prediabetic subjects do not become diabetics at an early stage. This study throws light on the health burden due to diabetes in Kerala and will help plan measures for both control and prevention of diabetes in the regions where the study is completed.

Name and signature with date

1. _____

(Principal Investigator)

2. _____

(Co-Investigator)