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ORIGINAL ARTICLE

The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) Study: Methodological Details

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Abstract

Background:

Currently available estimates of diabetes prevalence in India are based on published data derived from very few studies. The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study is a community-based survey conceived with the aim of obtaining the prevalence rates of diabetes in India as a whole, covering all 28 states, the National Capital Territory of Delhi, and two of the union territories in the mainland of India, with a total sample size of 124,000 individuals.

Methods:

A stratified multistage sampling design has been used. In all study subjects, a structured questionnaire was administered and anthropometric parameters and blood pressure were measured. Fasting capillary blood glucose was first determined using a glucose meter. An oral glucose load was then administered to all subjects except those with self-reported diabetes, and the 2 h post-load capillary blood glucose was estimated. In every fifth subject, a fasting venous sample was collected for measurement of lipids and creatinine, a resting 12-lead electrocardiogram was performed, and dietary assessment questionnaire was administered. In all diabetic subjects, an additional diabetes questionnaire was used and a fasting venous sample drawn for glycated hemoglobin.

continued →

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Abbreviations: (HbA1c) glycated hemoglobin, (CAD) coronary artery disease, (CEB) census enumeration block, (ECG) electrocardiogram, (FFQ) food frequency questionnaire, (ICMR–INDIAB) Indian Council of Medical Research–India Diabetes, (MDRF) Madras Diabetes Research Foundation, (NCT) National Capital Territory, (OGTT) oral glucose tolerance test, (PSU) primary sampling unit, (UT) union territory, (WHO) World Health Organization

Keywords: coronary artery disease, diabetes, hypertension, India, prevalence, state-wise, urban rural

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Abstract cont.

Results:

All biological samples collected were analyzed in a central laboratory. All data collected were stored electronically. Quality control was achieved through multiple tiers of checks.

Conclusions:

The ICMR–INDIAB study is the first of its kind attempting to provide accurate and comprehensive state- and national-level data on diabetes prevalence in India.

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Introduction

Diabetes mellitus was first described in India in the ancient texts of Charaka and Sushruta (1500 BCE).[1] Since then, the disease has gradually evolved into a major public health problem. This development has been especially rapid since the 1990s and is strongly related to lifestyle changes wrought by economic transition, industrialization, and globalization. The burgeoning epidemic of diabetes places a huge burden on individuals and families, represents a drain on health resources, and threatens to derail the productivity, growth, and development of the nation.

Although the International Diabetes Federation has updated the Diabetes Atlas and its estimates for diabetes prevalence by country,[2] the estimates for countries like India are based on published data derived from very few studies. Generally speaking, data used for these broad estimations are outdated and not representative of the whole country, in that they have been restricted to certain parts of the country[3–12] or have not considered the vast diversity of India and the heterogeneity of its population. No study on diabetes has systematically sampled all the states in the country (many of which are bigger than some European nations) or even sampled a single state completely. Therefore there is an urgent need for a well-planned, systematically designed, nationally representative study that will provide state-wise and rural–urban estimates of diabetes in India.[13] The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study directly addresses this need. In this article, we describe the methodological details of the ICMR- INDIAB study. As this will be one of the largest epidemiological studies ever conducted on diabetes, careful documentation of the study methodology is worthwhile.

Objectives of the ICMR–INDIAB Study

The primary objectives of the study are to determine the prevalence of diabetes mellitus and prediabetes in India by estimating the state-wise prevalence of the same and to compare the prevalence rates in urban and rural areas across the country.

The additional objectives of the study are to determine the prevalence of hypertension, dyslipidemia, and coronary artery disease (CAD) among subjects with and without diabetes and to assess the level of diabetes control among self-reported diabetic subjects.

Methodology

The ICMR–INDIAB study is a cross-sectional, community-based survey of adults of either sex aged ≥20 years.

The study covers all 28 states of India, the National Capital Territory (NCT) of Delhi, and two union territories (UTs), namely, Chandigarh and Puducherry. The other four UTs, namely, Andaman and Nicobar Islands, Dadra and Nagar Haveli, Daman and Diu, and Lakshadweep have been excluded because of logistic reasons. The study covers the urban and rural areas of all these states and territories (**Figure 1**).

Phases of the Study

In view of the complexity of the study and the logistics involved, the study has been planned in three phases. Phase I includes three states, namely, Tamil Nadu, Maharashtra, Jharkhand, and one UT, namely, Chandigarh, located in the south, west, east, and north of the country, respectively. Phase II comprises the eight northeastern

states, namely, Assam, Arunachal Pradesh, Manipur, Meghalaya, Tripura, Sikkim, Mizoram, and Nagaland. Phase III involves the rest of the country (**Figure 2**).

Estimation of Sample Size

Sample size calculations were performed based on the primary objective of determining the national prevalence of diabetes mellitus in India while maintaining enough power to demonstrate robust estimates when stratified by state. This was done primarily because health is a "state" subject in India. The sample size was calculated separately for urban and rural areas, as previous studies show large variations in urban and rural prevalence of type 2 diabetes mellitus (approximately 10% and 4%, respectively). Using a precision of 20% and allowing for a nonresponse rate of 20%, the sample size was calculated to be 2800 individuals in rural areas and 1200 individuals in urban areas, with a total sample size of 4000 individuals per state. Hence, the total sample size for the study, including all 28 states, NCT of Delhi, and two UTs, was 124,000 individuals (4000 × 31). The national prevalence will be calculated from the state prevalence using weight–age analysis.

Sampling Design

A stratified multistage sampling design (similar to the one employed in the National Family Health Survey-3) was adopted for this study[14] (**Figure 3**). A two-stage design was used in rural areas, while a three-stage design was adopted in urban areas. In both urban and rural areas, three-level stratification was done based on geographical distribution, population size, and socio-economic status so as to provide a sample of individuals who were truly representative of the population of India. Primary sampling units (PSUs) were villages in rural areas and census enumeration blocks (CEBs) in urban areas. Ultimate stage units were households in both areas. In rural areas, the first stage of sampling involved selection of PSUs (villages) using the probability proportional to population size with replacement method (**Figure 4**). In the second stage, households were selected by systematic sampling with a random start. In urban areas, due to the large population involved, a three-stage design was used (**Figure 5**). The first stage involved selection of wards by probability proportional to population sampling. In the next stage, one CEB was randomly selected from each ward, and in the final stage, households were selected from the CEBs by systemic sampling. In both rural and urban areas, only one individual was selected within each household using the World Health Organization (WHO) Kish method.[15]

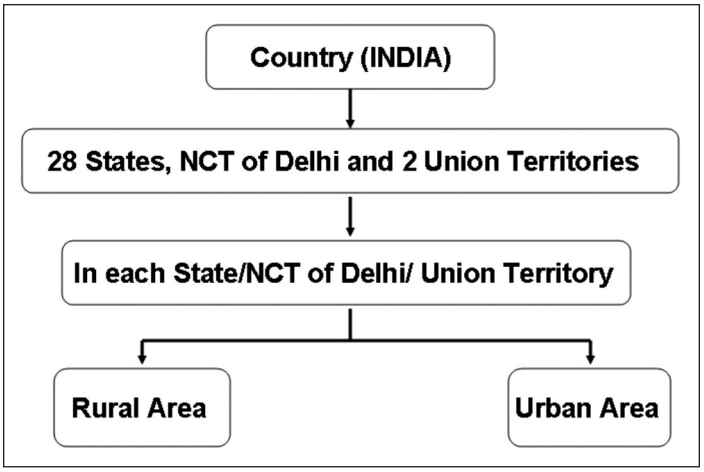

Figure 1. ICMR–INDIAB study sampling strategy.

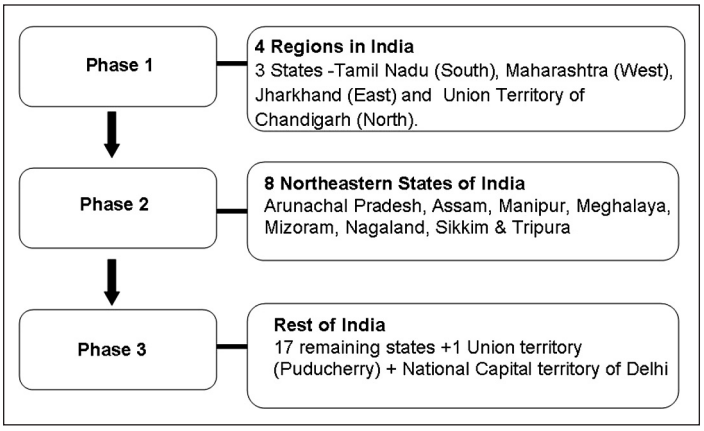

Figure 2. Phases of the ICMR–INDIAB study.

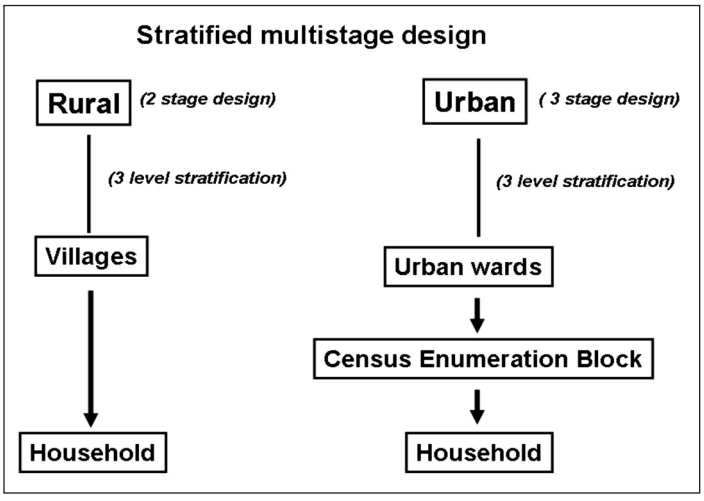

Figure 3. ICMR–INDIAB sampling design.

Study Protocol

Approval of the Madras Diabetes Research Foundation (MDRF) institutional ethics committee was obtained prior to commencement of the study. Written informed consent was obtained from respondents after ensuring

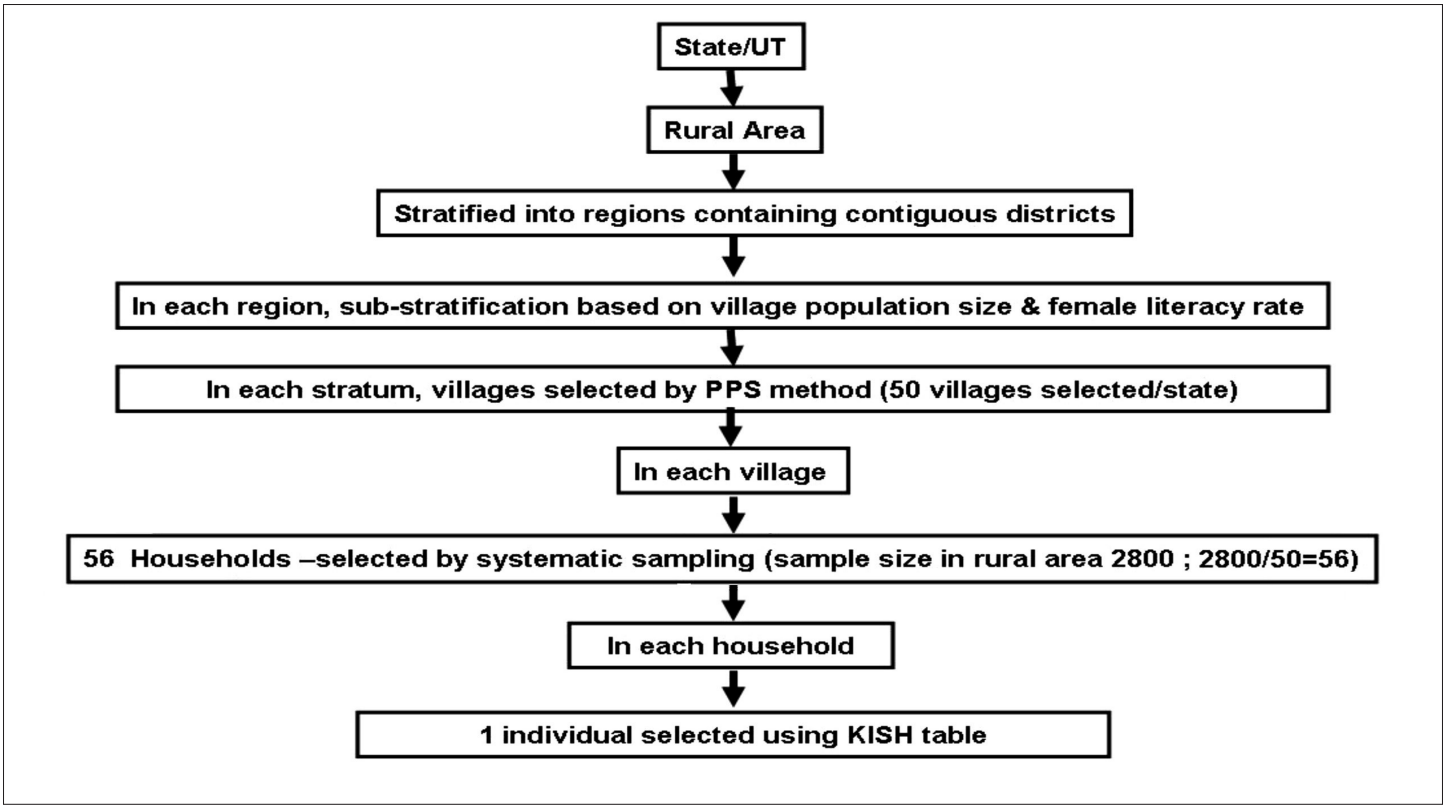

Figure 4. ICMR–INDIAB sampling framework in rural areas. PPS, probability-proportional-to-size.

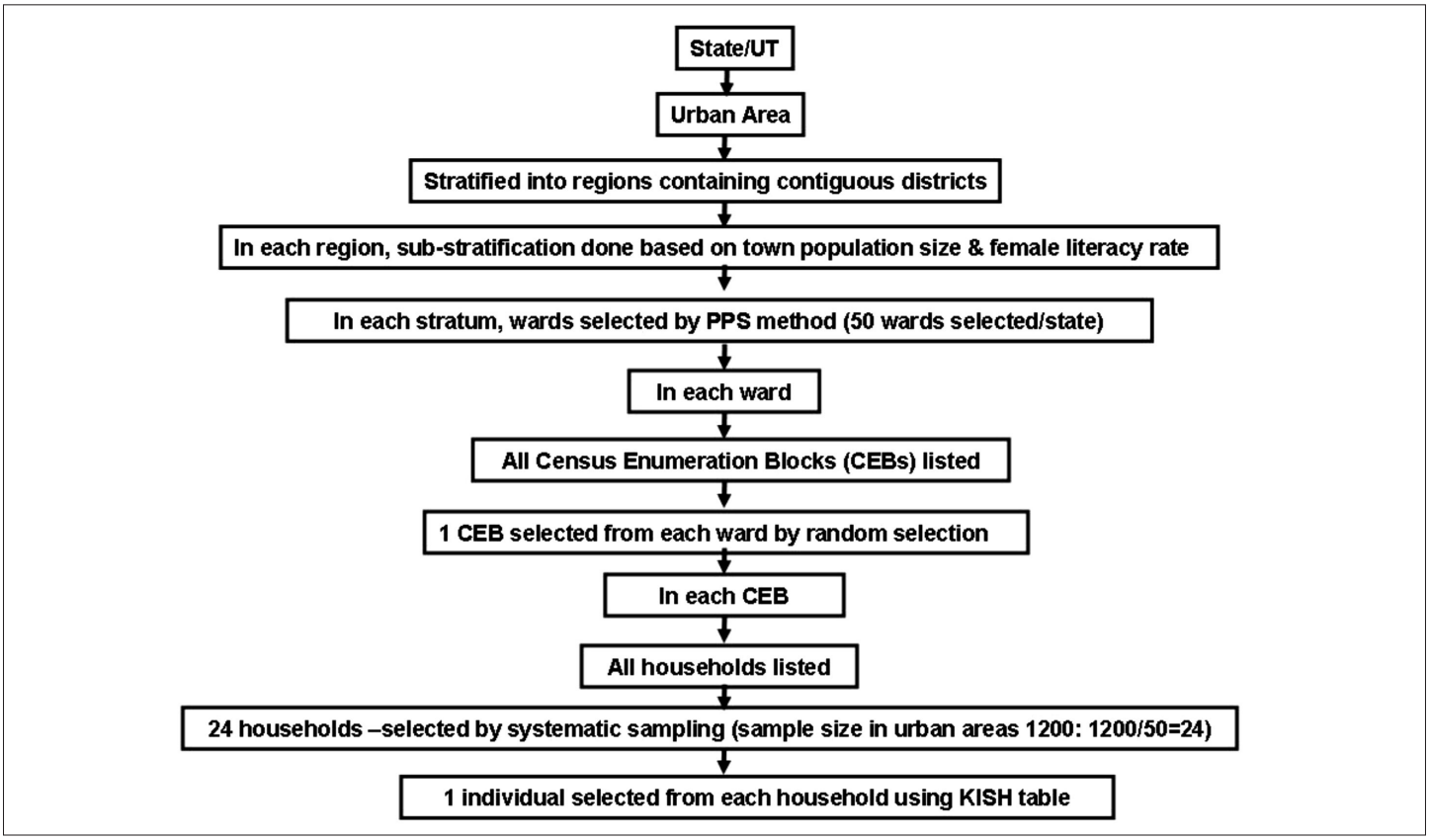

Figure 5. ICMR–INDIAB sampling framework in urban areas. PPS, probability-proportional-to-size.

that the subject understood and accepted his/her role in the study.

Training

All field workers underwent intensive training before commencing field work. The training program provided standardized training sessions on all aspects of the study. Training included printed and digital media aids (e.g., standardized videos dubbed in local languages, handouts, show cards). 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 program with a written as well a practical examination where intra- and inter-observer variability was checked. The training was an ongoing process that also took place in the field as a refresher program.

Execution of Field Work

Field work in each PSU comprised prefield, field, and postfield activities.

Prefield Activities

Prefield activities began by seeking and obtaining approval from local health authorities in each state. This was done in conjunction with individual state principal investigators. Permission was then obtained from the local counselor/ panchayat head/village elder to be able to enter the PSU to conduct the study. Prefield activities also included taking stock of inventory (consumables, stationery) and calibration of equipment.

Field Activities

Field activities began with mapping procedures, involving preparation of location, boundary, and structure maps. Following this, listing of households and selection of study subjects was carried out. Field workers ensured that all eligible respondents were invited to participate in the study. Study subjects were then requested to observe an 8 to 12 h overnight fast in order to estimate fasting capillary blood glucose levels the next morning.

In all study subjects, the following data were collected:

- A structured questionnaire was used to obtain data on demographic and socioeconomic parameters and behavioral aspects, including tobacco use, alcohol use, and physical activity. Complete medical history and family history of diabetes and heart disease were also obtained. In addition, information on diabetes awareness, costs of illness, and health service utilization were also collected. The primary questionnaire was translated into each local language and was administered by trained field interviewers. Questionnaires were validated in 100 subjects and retested after 5 weeks, and the correlation analyses revealed good reproducibility.

- Anthropometric parameters were measured as follows:

  » Height (in centimeters) was measured using a stadiometer (SECA Model 214, Seca Gmbh Co, Hamburg, Germany). The subject was asked to stand upright without shoes with his/her back against the vertical back board, heels together and eyes directed forward.

  » Weight (in kilograms) was measured with an electronic weighing scale (SECA Model 807, Seca Gmbh Co) that was kept on a firm horizontal flat surface. Subjects were asked to wear light clothing, and weight was recorded to the nearest 0.5 kg.

  » Body mass index was calculated using the formula weight in kilograms/height in meters squared.

  » Waist circumference was measured using a non-stretchable measuring tape. Subjects were asked to stand erect with both feet together. One layer of clothing was accepted. Waist circumference was measured at the smallest horizontal girth between the costal margins and the iliac crest at the end of expiration.

- Blood pressure was recorded in the sitting position in the right arm to the nearest 1 mmHg using the electronic OMRON machine (Omron Corporation, Tokyo, Japan). Two readings were taken 5 minutes apart and their mean was taken as the blood pressure.

- Fasting capillary blood glucose was first determined using a glucose meter (One Touch Ultra, Lifescan, Johnson & Johnson, Milpitas, CA). An oral glucose tolerance test (OGTT) was done using a 82.5 g oral glucose load (equivalent to 75 g of anhydrous glucose) and the 2 h postload capillary blood glucose was estimated. In subjects with self-reported diabetes, only fasting capillary blood glucose was measured.

All machines used in this study were from the same manufacturers as specified in the methods, and the same will be used throughout the study in all states.

Justification for Use of Capillary Glucose Estimation

Capillary blood glucose estimation was adopted in favor 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. The challenges associated with venous blood glucose estimation include a shortage of trained phlebotomists, poor accessibility and nonavailability of quality-controlled laboratories, varied methods of laboratory glucose estimation, difficulties associated with transporting and handling blood samples at specified temperatures within short periods of time to a central laboratory, and higher nonresponse rates associated with venous blood draws. In contrast, a simple finger-stick test, which uses only a drop of blood and gives the glucose reading in a few seconds, was more acceptable.

Validation of Capillary Glucose Testing

Prior to this study we undertook another study to validate capillary glucose estimation against the "gold standard" of venous plasma glucose estimation using an automated analyzer.[16] When capillary whole blood glucose estimation was compared with venous plasma glucose estimation, the Pearson's correlation coefficient was 0.681 ($p < .001$) in the fasting state and 0.897 ($p < .001$) 2 h after a 75 g glucose load. These data indicate good correlation between the two methods. Thus capillary whole blood glucose estimation was considered to be a reliable, accurate, and acceptable alternative to venous plasma glucose estimation for screening for diabetes.[16]

In every fifth subject, the following investigations were carried out in addition to previously mentioned parameters:

- Fasting venous sample collection for measurement of lipids and creatinine;
- Resting 12-lead electrocardiogram (ECG); and
- Dietary assessment questionnaire to obtain information regarding nutrient intake. Individual dietary intake of subjects was collected using a food frequency questionnaire (FFQ). An earlier validated FFQ[17] was modified for use in this study.

In all diabetic subjects, the following parameters were studied:

- A separate "diabetes questionnaire" was used that included questions on duration of diabetes, medication use, self-monitoring of blood glucose, and complications, if any.
- An ECG was carried out.
- Fasting venous sample was drawn for serum lipids and creatinine, as well as for glycated hemoglobin (HbA1c).

In addition, all subjects with diabetes were provided with an information booklet on diabetes.

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.

Postfield Activities

All questionnaires were checked and filed by quality supervisors and couriered to the central study coordinating center (MDRF, Chennai) once in 15 days. All collected blood samples were centrifuged within 1 hour of collection, and aliquots were stored in freezers until they were couriered to MDRF in dry ice.

Serum cholesterol (cholesterol esterase oxidase-peroxidase-amidopyrine method), serum triglycerides (glycerol phosphate oxidase-peroxidase-amidopyrine method), and high-density lipoprotein cholesterol (direct method poly-ethylene-glycol-pretreated enzymes) were measured using the Beckman Coulter AU 2700/480 Autoanalyser (Beckman AU [Olympus], Ireland). Serum creatinine was measured using Jaffe's method and HbA1c estimated using high-pressure liquid chromatography using the Variant II Turbo machine (BIORAD, Hercules, CA).

Definitions

Diabetes

Diabetes was defined by physician diagnosis of diabetes and current use of medications for diabetes (insulin or oral hypoglycemic agents) and/or fulfillment of criteria laid down by the WHO Consultation Group Report, i.e., capillary fasting blood glucose ≥126 mg/dl or 2 h capillary post-glucose value ≥220 mg/dl.[18]

Impaired fasting glucose

Impaired fasting glucose was defined based on WHO criteria, i.e., if fasting capillary blood glucose ≥110 and <126 mg/dl.[18]

Impaired glucose tolerance

Impaired glucose tolerance was defined according to WHO criteria,[18] where 2 h capillary post-glucose value

is ≥160 but <220 mg/dl with a fasting value in the nondiabetic range.

The WHO recommends that, in recognition of the widespread use of capillary sampling, conversion values for capillary plasma glucose are to be provided for postload glucose values, whereas fasting values for venous and capillary plasma glucose remain identical. Hence, in this study, we have used the conversion for postload glucose values.

Hypertension

Hypertension was defined on past medical history plus use of medication(s) to control blood pressure and/or if subject's systolic blood pressure was 140 mm Hg or greater and/or diastolic blood pressure was 90 mm Hg or greater.[19]

Dyslipidemia

National Cholesterol Education Programme guidelines were used for definitions of dyslipidemia.[20]

Hypercholesterolemia

Serum cholesterol levels ≥200 mg/dl (≥5.2 mmol/liter) or drug treatment for hypercholesterolemia.

Hypertriglyceridemia

Serum triglyceride levels ≥150 mg/dl (≥1.7 mmol/liter) or drug treatment for hypertriglyceridemia.

Low High-Density Lipoprotein Cholesterol

High-density lipoprotein cholesterol levels <40 mg/dl (<1.04 mmol/liter) for men and <50 mg/dl (<1.3 mmol/liter) for women.

High Low-Density Lipoprotein Cholesterol

Low-density lipoprotein cholesterol levels ≥130 mg/dl.

Coronary Artery Disease

Coronary artery disease was defined by a past history of documented myocardial infarction and/or medical therapy or revascularization for CAD and/or ECG changes such as Q-wave changes (Minnesota codes 1-1-1 to 1-1-7) and/or ST segment depression (Minnesota codes 4-1 to 4-2).[21]

Anthropometric measurements, blood pressure readings, and capillary glucose values were immediately conveyed to study subjects in the form of a report, and instructions to seek medical attention or adopt lifestyle measures were provided when results were found to be out of the normal range. Biochemical parameters and ECG results were mailed to the subjects later.

Data Analysis

All data collected were stored electronically. The following fields linked all records: name, date of birth, and individual study identification number. All statistical analyses were performed using SAS for Windows version 9.0 software (SAS Institute, Inc., Cary, NC) on an IBM-compatible computer. Preliminary descriptive analysis was conducted to check for the distribution of the variables of interest, and log transformation was carried out where data were not normally distributed.

Quality Control

Quality Control in Prefield Activities

Quality assurance at the prefield level involved regular calibration and checking of all instruments and equipment used in the study. Measurements from weighing machines, stadiometers, electronic blood pressure apparatus, and glucose meters were checked against accurate standards (e.g., known preweighted sand bags) to determine if there were any errors. The blood pressure machines were calibrated against manual mercury sphygmomanometer readings. This was repeated for 5–7 subjects, and the readings of both machines were compared for accuracy. Glucose meters were calibrated by comparing the control solution value against the reference value provided along with the kit. Regular examination of study tools was done to ensure that the functions of the instrument were not compromised by damage and/or failing batteries.

Quality Control during Field Activities

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 a site visit to Chandigarh to check the quality of data and onsite procedures.

All field work and prefield activities were documented using quality logbooks. To date, 26 quality logs have been utilized in this study and have helped ensure high standards of quality.

Quality Control in Postfield Activities

Data

All data collected were couriered to the central coordinating center (MDRF). At MDRF, data were cleaned and entered using a "double entry" technique.

Blood Samples

All analyses for the study were performed at the National Accreditation Board for Testing and Calibration Laboratories and the College of American Pathologists accredited central laboratory at Dr. Mohan's Diabetes Specialities Centre at Chennai. Two percent of the fasting plasma samples were analyzed for quality control. The laboratory was blinded to the results of the capillary test. Accurate coding system was followed to ensure anonymity of samples and also facilitated tracking of specific samples if the need arose.

One of the limitations of the study is that we used capillary blood glucose estimation instead of venous glucose estimation, which would have been ideal. However, in a study of this magnitude, logistical constraints of insufficient phlebotomists, limited availability of quality-controlled laboratories, varied methods of laboratory glucose estimation, and challenges in handling, transporting, and storing blood samples at the required temperature preclude venous sampling. Moreover, in an earlier study, a good correlation between capillary blood glucose and venous plasma estimations was shown.[16] Another limitation is that the cross-sectional nature of the design does not allow for cause–effect relationships to be made.

Summary

The ICMR–INDIAB study is the first effort to provide accurate and comprehensive state- and national-level data on prevalence of diabetes in India. It addresses limitations of previous nonrepresentative studies and, when completed, should provide robust and reliable estimates of diabetes prevalence in India, removing the need for modeling projections from one or two studies. 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. Thus the ICMR–INDIAB study will provide an accurate snapshot of the burden associated with diabetes in India.

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