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Special Report

ICMR-MDRF Diabetes Biosamples: Cohort profile

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***Background & objectives*: Biobanks are crucial for biomedical research, enabling new treatments and medical advancements. The biobank at the Madras Diabetes Research Foundation (MDRF) aims to gather, process, store, and distribute biospecimens to assist scientific studies.**

***Methods*: This article details the profile of two cohorts: the Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study and the Registry of people with diabetes in India with young age at onset (ICMR–YDR). The ICMR–INDIAB study is the largest epidemiological study on diabetes**

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in India, encompassing a nationally representative sample of individuals aged 20 yr and older from urban and rural areas in every State across the country. The ICMR–YDR is the first national-level, multicentric clinic-based registry focusing on youth-onset diabetes in India, aiming to understand the disease patterns and variations in youth-onset diabetes across different country regions.

***Results*: Key operations at the MDRF biobank include collecting and processing samples, where serum and whole blood samples are aliquoted and transferred through a cold chain to the central laboratory, and then stored in Siruseri (29 km from the capital city of Chennai, Tamil Nadu). Samples are barcoded, linked to subject information, and stored in freezers or liquid nitrogen (LN2) vessels, with inventory tracked *via* software for easy retrieval. A register records access to the biobank, ensuring sample integrity and compliance with regulatory requirements. The biobank adheres to the ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants.**

***Interpretation & conclusions*: The biobank enables the analysis of biomarkers in stored samples, aiding in scientifically sound decisions, treating patients, and potentially curing diabetes.**

Keywords Asian Indians – biobank – biorepository – biospecimen – diabetes – registry

The rising burden of non-communicable diseases (NCDs) is a significant global health concern. Earlier estimates of NCDs for India relied on regional studies, which were not fully representative and lacked proper diagnostics[1-4]. A nationally representative study was crucial for understanding prevalence, risk factors, healthcare planning, and policy decisions. The 'Indian Council of Medical Research–India Diabetes Study (ICMR–INDIAB)' was designed to report on diabetes and metabolic NCDs in India, with stored blood samples for future research[5-7]. Further, there is a notable gap in understanding youth-onset diabetes in India, with no nationwide registries and most studies are from individual clinics[8,9]. This leaves the broader distribution and long-term outcomes unexplored. To address this, the Indian Council of Medical Research (ICMR) has initiated the Registry of People with Diabetes with Young Age at Onset (YDR).

Materials & Methods

Biobank at Madras Diabetes Research Foundation (MDRF): Biobanks are critical in biomedical research, collecting, processing, storing, and distributing biospecimens to support scientific research. There is no universally agreed common terminology for biobank and several terminologies exist, such as biorepository, bio-library, biospecimen resource, *etc*. However, all of them broadly refer to a 'large-scale collection of human biological materials'. The ICMR guidelines define biobanks as organized collections of human biological materials with associated data for research and potential commercial purposes. MDRF, a non-profit organization recognized by various Indian research organizations [ICMR Center for Advanced Research on Diabetes, ICMR - Collaboratiing Centre of Excellence (ICMR-CCoE) the Department of Scientific

and Industrial Research (DSIR) of the Ministry of Science and Technology, Government of India as a Scientific and Industrial Research Organization (SIRO) (since Nov. 1996)], houses a biobank at its Siruseri facility (29 km from the heart of Chennai city, Tamil Nadu). The 3,700-square-foot facility includes liquid nitrogen containers (–196°C) and freezers (–20°C or –80°C), with over 800,000 samples stored. The key operations of the MDRF biobank include (*i*) collection and processing of samples, (*ii*) barcoding the sample and linking to the participant information, (*iii*) sample storage and inventory system in the appropriate vials and boxes, and (*iv*) retrieval of the samples as and when required.

Samples available at the MDRF Biobank: This article focuses on two ICMR-funded projects:

(*i*) *ICMR–India Diabetes (ICMR–INDIAB) study*: It is one of the large epidemiological studies on diabetes with a sample size of 1,20,000 nationally representative individuals, covering every State of India. This cross-sectional, community-based study was done in adults of either sex, aged 20 yr in phases from 2008 to 2020 and sampled 33,537 urban and 79,506 rural residents (total, n=113,043) in 31 States/ Union Territories (UT) of the country[7]. In Phase I, four States *viz* Tamil Nadu (south), Chandigarh (north), Jharkhand (east), and Maharashtra (west) were studied from 2008 to 2010. The remaining States were surveyed as follows: Phase II: Andhra Pradesh, Telangana, Bihar, Gujarat, Karnataka and Punjab (2012–2013), Phase III: Delhi, Madhya Pradesh, Rajasthan and Uttar Pradesh (2017–2018), Phase IV: Kerala, Goa, Puducherry, Haryana and Chhattisgarh (2018–2019), North East Phase: Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura (2011–2017) and Phase V: Himachal Pradesh, Uttarakhand, Odisha and West Bengal (2019–2020). The surveys of Andaman and Nicobar, Dadra and Nagar Haveli and Daman and Diu, Lakshadweep and Kashmir, Jammu and Ladakh were completed recently in 2024[7].

Each State, National Capital Territory, or Union Territory was divided into urban (towns, including metropolitan areas, where applicable) and rural (villages) components. A stratified multistage sampling approach was employed. Villages served as the primary sampling units for rural areas, while census enumeration blocks were used for urban areas. Households were then selected systematically, 24 from urban and 56 from rural areas. A door-to-door assessment was conducted, and from each selected household, one individual was chosen at random using the World Health Organization (WHO) Kish method, ensuring unbiased selection across sex and age categories[6]. In every fifth individual and those with diabetes (both self-reported and newly diagnosed diabetes), fasting samples were drawn, and the aliquots from these samples have been stored for future use.

(*ii*) *Registry of people with diabetes in India at a young age at the onset*: Registries are crucial for understanding disease conditions, including demographic, socioeconomic, clinical, and biochemical profiles, complications, and treatment modalities. In 2006, ICMR launched the country's first national multi-centre clinic-based registry on youth-onset diabetes. The initiative aimed to investigate disease patterns and variations across different regions of India[10]. The ICMR–YDR comprises 11 Regional Collaborating Centers (RCCs) selected for their expertise in clinical trials and diabetes research. RCCs recruit patients and oversee data collection from Reporting Centers (RCs), ranging from individual physician clinics to comprehensive hospitals[10,11].

The ethics committee approvals were obtained from all Regional Collaborating Centres. An ethical approval letter was obtained from the Institutional Ethics Committee of Madras Diabetes Research Foundation for the YDR at the onset, for all the three phases of the study. Phase I of the registry used baseline and follow-up proformas to collect data on demographics, clinical history, family history, biochemical details, treatment, and complications. In Phase II, blood samples were collected for serum and genetic analysis where the facilities allowed. Phase III (2020–2025) includes registry, cohort, and surveillance components, managed by the Technical Coordinating Unit at the All India Institute of Medical Sciences (AIIMS), New Delhi. Detailed methods have been published elsewhere[10], including annual follow-up data managed electronically. Phase I baseline data, and Chennai's RCC03 results have been published[11,12]. Phase II's biobank at Dr. Mohan's Diabetes Specialities Centre (DMDSC) stores 709 serum samples from type 1 diabetes (T1D) and type 2 diabetes (T2D). Phase III's ongoing cohort biobank aims to recruit multiple aliquots of biospecimens from 750 individuals with T1D and T2D from four centres in Chennai, South India.

Key operations of the biobank at MDRF:

Collection and processing of samples: After collection of samples at the field, upon centrifugation, serum samples are separated and aliquoted in pre-labeled vials. Whole blood samples are transferred to the pre-labeled vials. Both whole blood and serum samples are then transferred to the MDRF through a cold chain. At the central laboratory at MDRF, after the required vials are sent for assaying, the remaining vials are transferred to Siruseri for storage in the biobank.

Barcoding the sample and linking to the participant information: At the biobank, the samples are arranged in the vial box for storing in the deep freezer or liquid nitrogen (LN2) vessel. Barcoding labels are printed for all samples to be stored in the freezer or LN2 vessel. The barcoded labels are stuck to the appropriate vials arranged in the vial box.

Sample storage and inventory system in the appropriate vials and boxes: The vial boxes are then properly stacked and placed in the freezer or LN2 vessels. Details of the vial position (*e.g.*, Freezer: Box#4 of Rack#5 of Freezer #1; LN2 vessel: Box#4 of Rack#5 of Chamber A of the LN2#1) are updated in the software to enable sample tracking. These vials are linked to the corresponding clinical information in a database.

Retrieval of the samples as and when required: With the help of the Freezerworks Sample Management Software (*https://freezerworks.com/index.php/freezerworks*) that has a full-featured sample tracking and biobank management programme, retrieval of samples can be made as and when required.

Maintaining a register for accessing the biobank: A Register records individuals who access the freezer or liquid nitrogen container in the biobank, which is essential for ensuring accountability, tracking sample handling, and adhering to regulatory requirements. While there may not be specific universal guidelines dictating the exact frequency of freezer or liquid nitrogen container openings, the frequency of opening is carefully regulated and kept at a minimum to ensure sample integrity and minimize the risk of contamination or degradation.

Frequency of participant follow up:

ICMR–INDIAB study: This cross-sectional study contacted participants only once for data collection.

Registry of people with diabetes in India at young age at onset: In Phase II, serum and genetic samples were collected once and stored. In Phase III, samples are being collected at baseline and during two follow-up visits within five years (2020 to 2025).

Assessment of baseline clinical and biochemical measures:

ICMR-INDIAB study: A standardized questionnaire collected demographic and socioeconomic data. Details of the available measures in the study are presented in Table I. Measurements included weight, height, waist circumference, blood pressure, and body mass index (BMI). Capillary blood glucose was measured after an overnight fast. An oral glucose tolerance test (OGTT) was done for those without a previous diabetes diagnosis. For individuals with diabetes, fasting blood glucose was measured. Venous samples were drawn for glycated hemoglobin (HbA1c), lipids, and creatinine. Samples were centrifuged and stored for future analysis. Baseline characteristics of the study participants on whom the stored samples are available are tabulated in Table II, and the details of samples stored at MDRF Biobank are provided in Table III.

Registry of people with diabetes in India with young age at onset: Phase II: Clinical and biochemical details were collected, and routine tests were done. Available study variables under the young diabetes registry are given in Table IV. Table V provides the clinical and biochemical characteristics of individuals with T1D and T2D.

Phase III: Blood and urine samples were collected at baseline and follow-up visits and stored at -80°C. Tests include fasting plasma glucose, HbA1c, lipid profile, serum creatinine, microalbuminuria, C-peptide (fasting), C-reactive protein, Glutamic acid decarboxylase (GAD), anti-thyroid peroxidase (anti-TPO) antibodies, retinal examination, bio-thesiometry, and foot examination. The biospecimens being collected for the cohort are given in Supplementary Table I. Supplementary Table II provides the total number of serum, plasma, and genetic samples collected during Phase II from DMDSC and Phase III samples proposed for future storage (Baseline, 1st Follow-up, and 2nd Follow-up).

Quality assurance and quality control strategies:
ICMR-INDIAB study:
Pre-field quality control: All the equipment and instruments used were periodically calibrated as per

Table I. ICMR-INDIAB study - available study measures at baseline

Domain	Variables collected	Data available
Participant identification details	State code; district code; PSU details; contact information; participant identification details (not to be shared)	In all individuals
Demographic information	Age; sex; religion; marital status; educational status; occupation	In all individuals
Socio-economic information	Household income; expenditure for health care	In all individuals
Standard of living index	Type of house; toilet facility; source of lighting; main fuel for cooking; drinking water source; availability of separate room for cooking; house ownership; agriculture & irrigated land availability; livestock ownership; ownership of durable goods	In all individuals
Migration details	Duration of residence in urban/rural areas	In all individuals
Behavioural measures	Smoking tobacco use – type, frequency; smokeless tobacco use – type, frequency; alcohol consumption – type, frequency	In all individuals
Diet	Main staple; fruit & vegetable consumption frequency; milk, oil & salt intake	In all individuals
Physical activity	Domain-wise physical activity (occupation, general, transport & leisure time/ recreational activities) –MPAQ for all phases, except in Phase 1, where GPAQ was used	In all individuals
Knowledge of diabetes	Awareness and knowledge of diabetes – risk factors and prevention	In all individuals
Medical history	Rose angina questionnaire; self-reported history of heart attack; heart disease; stroke; kidney transplant; cancer; bone fracture; amputation; high blood pressure; diabetes; family history of diabetes	In all individuals
Medication status	Medication details of diabetes, hypertension, hyperlipidemia, stroke, heart/kidney disease	In all individuals
Pregnancy-related questions	Gestational age-current pregnancy; previous pregnancy details; gestational diabetes history; pregnancy outcomes; menopause details	In all individuals
Anthropometric & clinical measurements	Height; weight; waist circumference; blood pressure	In all individuals
Capillary blood glucose measurement	Fasting blood glucose; 2h post-glucose blood glucose	In all individuals
Venous blood glucose	Lipids; glycated haemoglobin (HbA1c); creatinine	In a subset of the population (every 5th individual & those with diabetes)
Electrocardiogram	Resting 12-lead electrocardiogram	In a subset of the population (every 5th individual & those with diabetes)
Dietary information	MDRF– FFQ	In a subset of the population (every 5th individual & those with diabetes)
Detailed information on diabetes	Duration of diabetes; medication use; whether or not blood glucose was self-monitored; choice of health facility (government or private); system of treatment (allopathic medicine, ayurveda, unani, siddha, or homeopathy)	In those with self-reported diabetes

PSU, primary sampling units; MPAQ, madras diabetes research foundation; physical activity questionnaire; GPAQ, global physical activity questionnaire; MDRF-FFQ, Madras Diabetes Research Foundation-food frequency questionnaire

standard protocols to ensure quality assurance at the pre-field level. The study equipment and instruments were regularly examined to ensure that the functionalities of the equipment/instrument were not compromised by physical damage and/or failing batteries.

Field activities quality control: A three-tier system ensured data quality. Quality supervisors, quality managers, and principal investigators conducted daily checks, random monitoring, and field visits, respectively. An external quality monitoring team from

Table II. Baseline characteristics of the ICMR-INDIAB study participants with available stored blood samples

Characteristics	Urban	Rural	Male	Female	Total
Number of participants	8,420	17,462	13,217	12,665	25,882
Age (yr.)	45.6 (0.24)	45.4 (0.15)	46.3 (0.17)	44.7 (0.16)†	45.5 (0.12)
Education$					
No formal schooling	16.3 (15.–17.5)	29.2 (28.2–30.2)*	15 (14.2–15.9)	34.6 (33.5–35.8)	24.7 (23.9–25.5)
Primary, high, or higher secondary school	64.6 (63.2–66)	62.7 (61.7–63.7)	68.8 (67.8–69.9)	57.8 (56.6–59.)†	63.4 (62.6–64.2)
Technical, undergraduate, or postgraduate education	19.1 (17.8–20.5)	8.1 (7.5–8.6)*	16.1 (15.2–17)	7.6 (6.9– 8.2)†	11.9 (11.3–12.5)
Anthropometry					
Body mass index (kg/m^2)	24.8 (0.08)	22.8 (0.05)*	23(0.05)	24 (0.07)†	23.5 (0.05)
Waist circumference,(cm)	87.1 (0.23)	81.8 (0.15)*	84.5 (0.15)	82.7 (0.19)†	83.6 (0.13)
Blood pressure					
Systolic blood pressure (mmHg)	133 (0.36)	131 (0.22)*	133 (0.23)	130 (0.25)†	132 (0.19)
Diastolic blood pressure (mmHg)	83 (0.21)	82 (0.12)**	83 (0.13)	81 (0.14)†	82.1 (0.11)
Glycemic parameters					
Fasting blood glucose (mg/dl)	126 (0.9)	116 (0.5)*	118 (0.56)	121 (0.67)†	119 (0.46)
2h post glucose blood glucose (mg/dl)	136 (1.13)	127 (0.57)*	128 (0.7)	131 (0.70)†	129 (0.53)
HbA1c (%)	6.33 (0.03)	5.92 (0.02)*	6.08 (0.02)	6.05 (0.02)	6.06 (0.02)
Lipid parameters					
Total serum cholesterol (mg/dl)	177 (0.67)	171 (0.5)*	171 (0.5)	175 (0.53)†	173 (0.4)
Serum triglycerides (mg/dl)	160 (1.7)	147 (1.11)*	163 (1.32)	140 (1.21)†	152 (0.95)
Serum HDL cholesterol (mg/dl)	40 (0.18)	41 (0.13)*	39 (0.14)	42 (0.14)†	41 (0.11)
Serum LDL cholesterol (mg/dl)	105 (0.59)	101 (0.41)*	99.6 (0.41)	105 (0.47)†	102 (0.34)
Total cholesterol to HDL cholesterol ratio	4.7 (0.03)	4.41 (0.02)*	4.63 (0.02)	4.39 (0.02)†	4.51 (0.01)

Values are mean (SE); $ Percentage (95% confidence interval); P†<0.001, **<0.05, compared to †male *vs* female; *urban *vs.* rural residence

Table III. ICMR-INDIAB samples stored in the MDRF Biobank

	Urban			Rural			Overall			Total no. of vials
	No. of individuals	Serum	Whole blood	No. of individuals	Serum	Whole blood	No. of individuals	Serum	Whole blood	
ICMR-INDIAB – 31 States	8,420	16,840	12,822	17,462	34,924	26,665	25,882	51,764	39,487	91,251
ICMR-INDIAB – Union Territories	698	1,396	1,396	1,256	2,512	2,512	1,954	3,908	3,908	7,816
Total	9,118	18,236	14,218	18,718	37,436	29,177	27,836	55,672	43,395	99,067

Stored samples per participant: For Phase 1 – Serum (2 vials*0.5 ml) and whole blood (1 vial*5 ml); Northeast (Assam, Mizoram, Manipur, Arunachal Pradesh, Tripura & Meghalaya) & rest of India (Andhra Pradesh, Karnataka, Gujarat, Bihar & Punjab) – Serum (2 vials*1 ml) and whole blood (1 vial*1 ml); All other phases, follow-up studies and Union Territories – Serum (2 vials*1 ml) and whole blood (2 vials*1 ml)

ICMR also evaluated the data. All fieldwork, pre-field, and post-field activities were documented using quality logbooks. To date, 41 quality logs have been utilized in this study and have helped ensure high standards of quality.

Post-field activities quality control: Data were cleaned and entered using a 'double entry' technique. Blood samples were couriered using dry ice from the respective States/Union Territories to the National Accreditation Board for Testing and Calibration

Table IV. Study variables in the ICMR YDR – Registry component

Domain	Variables	Baseline proforma	Data available from 2012 to 2023
Registration details	Patient identification number, date of first visit at the centre, hospital registration number	From medical records	√
Identification and demographic details	Name or initial of patient, father, mother, guardian, spouse, date of birth, age on the day of registration, sex, religion, place of residence & phone number, e-mail ID, Universal Identification (Aadhaar number), mother tongue, education, socio-economic status	From medical records	√
Family history of diabetes	Diabetes status of mother, father, maternal grandfather, maternal grandmother, paternal grandfather, paternal grandmother, no. of siblings and their diabetes status and classification.	From medical records	√
Clinical information	Date of first diagnosis, duration of diabetes, mode of presentation at the time of onset (osmotic, weight loss, ketosis, incidental, others), laboratory values at the onset, OHA, previous hospitalization, history of hypoglycemia / DKA / sepsis / any other	From medical records	√
Anthropometric measurement	Height (cm), weight (kg), BMI (kg/m2), waist circumference, blood pressure (systolic & diastolic) (mmHg)	From medical records	√
Laboratory investigations at the time of registration	Fasting plasma glucose (mg/dl), post prandial plasma glucose (mg/dl), glycosylated hemoglobin (%), lipid profile (Total cholesterol, LDL cholesterol, HDL cholesterol, serum triglycerides), C-peptide (Fasting & Stimulated), immunological markers, availability of blood for genetic markers	From medical records	√
Clinical classification refer methodology paper	Type 1 Diabetes / Type 2 Diabetes / MODY / GDM / Chronic pancreatitis / secondary diabetes – FCPD and other genetic syndrome cases	From medical records	√
Complications	Vascular complications like retinopathy, nephropathy, neuropathy, coronary artery disease, peripheral vascular disease. Infective complications like tuberculosis and sepsis. Other complications if any	From medical records	√
Current treatment	The type of insulin that the patient was taking at the time of registration. Regular, intermediate-acting, pre-mixed, long-acting analogue, short-acting analogue, and pre-mixed analogue with regimens like thrice a day, once a day, twice a day, multidose or pump. OHA: biguanides, sulphonylureas, glitazones, alpha glucosidase inhibitor, meglitinide, DPPV IV Inhibitor	From medical records	√
Treatment for other co-morbidities	Co-morbidities like hypertension, autoimmune thyroid disease, celiac disease dyslipidaemia, and others if any	From medical records	√

OHA, oral hypoglycemic agents; DKA, diabetic ketoacidosis; BMI, body mass index; MODY, maturity onset diabetes of the young; GDM, gestational diabetes mellitus; FCPD, fibro calculous pancreatic diabetes; DPPV IV, dipeptidyl peptidase – 4 inhibitor

Laboratories (NABL) and the College of American Pathologists (CAP) accredited central laboratory at DMDSC, Chennai. Throughout the cold chain process, the field personnel ensured that the samples' quality and integrity were maintained following standard protocols. An accurate coding system ensured sample anonymity and tracking.

Registry of people with diabetes in India with young age at onset:

Quality control measures: A uniform protocol, training manuals, and proformae were developed and adopted across all centers during YDR-Phase-I and II, and will continue in YDR-Phase-III. The technical coordinating

Table V. Gender-wise distribution of clinical and biochemical characteristics of type 1 and type 2 diabetes - Registry component

Variables	Type 1 diabetes (n=400)		Type 2 diabetes (n= 309)	
	Male (n=224)	Female (n=183)	Male (n=147)	Female (n=155)
Current age (yr)	15.5 ± 8.6	15 ± 8.6	25.7 ± 9.5	25.6 ± 9.7
Age at onset of diabetes (yr)	12.8 ± 6.3	11.7 ± 5.9	19.9 ± 3.5	20 ± 3.8
Duration of diabetes (yr)	2.5 ± 4.9	3.2 ± 6.1	5.5 ± 8.5	5.4 ± 8.3
Height (cm)	150 ± 25	144 ± 17**	170 ± 9	157 ± 7*
Weight (kg)	42.8 ± 17.6	39.2 ± 15.5**	76.7 ± 18.4	67.4 ± 14.1*
Body mass index (kg/m^2)	17.9 ± 3.5	17.9 ± 4.3	26.3 ± 5.8	27.2 ± 5.1
Waist circumference (cm)	68.1 ± 12.9	66.3 ± 13.4	93 ± 14	89.4 ± 14.8**
Systolic blood pressure (mmHg)	106 ± 15	103 ± 12	120 ± 14	115 ± 13**
Diastolic blood pressure (mmHg)	69 ± 9	69 ± 8	78 ± 9	75 ± 9**
Fasting plasma glucose (mg/dl)	208 ± 103	218 ± 95	199 ± 75	193 ± 78
HbA1c (%) (Target HbA1c <7.0%)	10.8 ± 2.8	10.4 ± 2.4	9.9 ± 2.6	9.5 ± 2.3
Total cholesterol (mg/dl)	166 ± 44	180 ± 40**	184 ± 44	185 ± 34
LDL cholesterol (mg/dl)	98 ± 30	107 ± 30**	113 ± 35	115 ± 30
HDL cholesterol (mg/dl)	47 ± 13	50 ± 13	40 ± 10	41 ± 9
Serum triglycerides (mg/dl)	108 ± 109	113 ± 97	166 ± 97	144 ± 76
C-peptide fasting (pmol/ml)	0.2 ± 0.1	0.2 ± 0.1	0.8 ± 0.4	0.9 ± 0.4
C-peptide stimulated (pmol/ml)	0.3 ± 0.3	0.3 ± 0.3	1.9 ± 1.2	2.0 ± 1.0

Values are mean ±SD; *P<0.001, **<0.05, comparing males *vs*. females. HbA1c, glycated hemoglobin

unit at AIIMS, New Delhi, oversees data collection and entry. Data are periodically checked for missing values and errors, with incomplete proforma notified to the respective centers.

Statistical analysis: All statistical analyses were conducted using SPSS software version 24.0 (SPSS Inc., Chicago). An independent t-test was used for continuous variables and the chi-square test for categorical variables to compare baseline clinical and biochemical characteristics. In Table II, the continuous variables were expressed as mean ± standard error (SE), and categorical variables as percentages with 95 per cent confidence interval (CI). In Table V, continuous variables were expressed as mean ± standard deviation (SD). A *P*-value of <0.05 was considered statistically significant.

Results

ICMR-INDIAB study: This large, nationally representative study reported that the prevalence of diabetes and metabolic NCDs in India was greater than the earlier estimates, with 101 million individuals diagnosed with diabetes and 136 million with prediabetes[7]. Hypertension, generalized, and abdominal obesity affected 315 million, 254 million, and 351 million people, respectively. Additionally, 213 million had hypercholesterolemia, and 185 million had high LDL cholesterol. The study also indicated that the diabetes epidemic was stabilizing in more socio economically advanced States but rising in less developed States[13].

The prevalence of undiagnosed hypertension was high, with salt intake ≥6.5 g per day increasing hypertension risk. Factors associated with hypertension included age, male sex, urban residence, obesity, diabetes, physical inactivity, and alcohol consumption[14]. High rates of obesity were found, with independent risk factors including female sex, hypertension, diabetes, higher socioeconomic status, physical inactivity, and urban residence[15]. Dyslipidemia was also highly prevalent, with over 80 per cent of individuals aged 35–64 yr exhibiting lipid abnormalities, and high rates even among those aged 20–24 yr[16].

The study found that less than 10 per cent of Indians engaged in recreational physical activity, highlighting the need to promote physical activity[17]. Only 43.2

per cent of the population had heard of diabetes, emphasizing the need for large-scale diabetes awareness and education programme[18]. Rural-to-urban migration was associated with an increased risk of diabetes and cardiometabolic abnormalities[19]. The MDRF-Indian Diabetes Risk Score (IDRS) was effective for diabetes screening in Asian Indians[20]. Age-specific HbA1c cut-offs were suggested to prevent overdiagnosis and unwarranted treatment in the elderly[21].

This study also recorded the achievement of diabetes treatment targets in India. It found that about a third of the population with diabetes had good glycaemic control, and fewer than half had good blood pressure control and good LDL cholesterol control[22]. In the past year, the majority of individuals with diabetes had not assessed their HbA1c level[23]. These findings can help governments improve diabetes care delivery and surveillance. The study also derived macronutrient recommendations for diabetes remission and prevention in Asian Indians, suggesting reduced carbohydrates and increased protein intake[24].

Registry of people with diabetes in India with young age at onset:

Phase I: 5546 participants with youth onset diabetes were enrolled (49.5% male; 50.5% female) from 205 centres linked to eight RCCs across India. T1D (63.9%; n=3,545; [95%CI: 62.6, 65.2]) and T2D [25.3%; n=1,401; (95%CI: 24.1, 26.4)] were the most common form of diabetes. The mean age (±SD) at diagnosis was 12.9 ± 6.5 yr for T1D and 21.7 ± 3.7 yr for T2D. Half of T1D cases were registered within six months of onset, while 47.3 per cent of T2D cases were registered after 3 yr; 56.1 per cent had already had at least one hospitalization by the time of registration[11]. RCC03 (Chennai) data showed 48.1 per cent T1D and 43.4 per cent T2D, indicating an equal contribution of both types in Chennai[12].

A subset of 2104 newly diagnosed T1D youth, aged 0–19 yr, and 227 youth with newly diagnosed T2D from 2006 to 2012 were analyzed. The results showed that the incidence of T1D was 4.9 cases/100,000 [95% CI: 4.3, 5.6], whereas it was 0.5/cases/100,000 [95% CI: 0.3, 0.7] in T2D[25,26]. The prevalence of diabetic ketoacidosis (DKA) among T1D and T2D was 28.7 per cent and 6.6 per cent respectively[27]. The mean HbA1c was high in both T1D: 11.0±2.9 per cent and T2D: 9.9±2.8 per cent. Among T1D youth, 52.8 per cent were on a once/twice daily insulin regimen and insulin pumps were used by only 1.5 per cent. Among T2D, a majority were on metformin only (30.0%), followed by insulin plus any oral hypoglycemic agents (13.7%) and insulin only (18.9%), respectively[28].

Discussion

Biobanks are essential infrastructure in research, facilitating discoveries that improve human health and advance medical knowledge. The biobank at MDRF storing the samples from two cohorts funded by ICMR, namely the ICMR–INDIAB study and the registry of YDR are the focus of this article. This diabetes biobank could help in the identification of novel biomarkers for early diagnosis and the development of personalized treatment strategies. Additionally, it would support longitudinal studies to track the progression of diabetes and its complications over time, leading to better management and prevention strategies. By fostering collaborative research efforts, a diabetes biobank in India could significantly advance our understanding of the disease and contribute to the global fight against the diabetes epidemic. Involving private agencies in developing biobanks and research is essential for translating research into practice. Adopting new technologies for specimen storage, preservation, data management, and sharing is crucial for creating a cost-effective, long-lasting disease-specific biobank in India[29].

Major biobanks available globally: Of the various biobanks available globally, the most well-known is the UK Biobank, supported by the National Health Service (NHS), which is a vast biomedical database with genetic, lifestyle, and health information from 500,000 UK participants. The collected information comprises phenotypic, genomic, and imaging data derived from direct assessments, verbal interviews, online questionnaires, and electronic health records. This dataset continues to expand as new biomedical data are added through ongoing assessments and longitudinal follow up. The UK biobank's key features include easy accessibility, a large-scale prospective approach, extensive and varied risk factor data, and thorough linkage to health outcomes. These features allow researchers from academia and industry worldwide to make scientific discoveries[30]. The findings from the UK biobank are invaluable, but its significance extends beyond immediate clinical relevance, as it provides valuable insights for researchers setting up population-cohort and genomic-medicine projects in other regions. The UK biobank has about 3,229

publications so far, which keeps growing[31-33]. Some other prominent biobanks in the world and the number of publications from each of these are as follows: JDRF Network for Pancreatic Organ Donors with Diabetes (nPOD)[34], United States (n=354), Mayo Clinic Biobank[35], United States (resource for 280 studies), Australasian Biospecimen Network, Australia (n=11), BancoADN, Spain (n=100), National Institute of Diabetes and Digestive Kidney diseases, United States (n=2,358), China Kadoorie Biobank[36,37], China (n=1,658), FINNGEN Biobank[38], Finland(n=1,629), the Danish Centre for Strategic Research in Type 2 Diabetes[39], Denmark, Australian Prostate Cancer Bio-Resource, Australia, Canadian Tumor Repository Network[40], Canada, Shanghai Outdo Biobank, China and BioMe Biobank, United States.

Available biobanks in India: Many biobanks exist in India, each focusing on a particular area of biomedical and health research. These biobanks make major contributions to a range of research domains, such as cancer, genetics and liver diseases. Some examples include, the National Cancer Tissue Biobank (NCTB)[41], Chennai, TamilNadu, National Liver Disease Biobank (NLDB)[42], New Delhi, Rajiv Gandhi Cancer Institute and Research Centre (RGCIRC)[43], New Delhi, National Institute of Mental Health and Neurosciences (NIMHANS)[44], Bangalore, Karnataka, the Tata Medical Centre Biorepository (TiMBR)[45] Kolkata, West Bengal, Sapien BioSciences[46], Hyderabad, Telangana, National Centre for Cell Sciences (NCCS)[47], Pune, Maharashtra and Accelerator Programme for Discovery in Brain Disorders using stem cells (ADBS)[48], Bangalore, Karnataka. However, diabetes-specific biobanks are limited[29]. Given India's high prevalence of diabetes, there is a pressing need for a diabetes biobank. Such a biobank would be an invaluable resource for researchers and healthcare professionals, providing a comprehensive repository of biological samples and related health data. This would facilitate in-depth studies on the genetic, environmental, and lifestyle factors contributing to diabetes in the Indian population. Over 150,000 samples are stored in the MDRF biobank. Combining the data sources with the biobank can enhance the knowledge base and sample utility. Only with the establishment of long-standing, well-characterized biobanks combined with a continuous stream of innovative ideas and strategies, will the health care costs be reduced[29].

Biobanks are vital for advancing biomedical research, offering invaluable biological materials that support personalized medicine through omics technologies. They maintain high standards in sample collection, processing, and storage, ensuring sample quality and research reproducibility. Centralized sample collection is efficient, reducing duplication of effort, and enabling longitudinal studies over extended periods. However, biobanks face challenges including high costs for infrastructure, equipment, and ongoing operations, limiting accessibility and financial sustainability. Ethical complexities around informed consent and privacy must be carefully managed, along with operational hurdles in personnel, equipment, and sample transportation. Addressing these challenges with improved technology, funding, and ethical oversight can enhance biobanks' impact on health research.

The MDRF biobank serves as a repository for biological samples from various research projects, equipped with high-quality practices including monitored freezers, IT infrastructure for sample tracking and management, and ample space for future expansion. It adheres to the ICMR guidelines[49] and supports diabetes research, providing insights into disease mechanisms and facilitating long-term studies. Investment in biobanks is crucial for health research infrastructure, enabling scientifically sound decisions and potential treatments. Future plans include automating biobank operations with technologies like AI and robotics to optimize sample handling and analysis.

Recommendations & conclusions

Biorepositories, acting as central hubs, should implement best practices for data collection and storage as per ICMR National ethical guidelines for biomedical and health research involving human participants. With sample management software, biobanks can monitor the complete lifecycle of a sample, guaranteeing the maintenance of the sample chain of custody. This helps ensure compliance with regulatory guidelines and biobanking best practices. Robotic sample management in biorepositories enhances biobank workflows both quantitatively and qualitatively. It further improves traceability of samples, ensures secure storage, preserves sample integrity, enables faster retrieval of samples and protects staff from occupational hazards.

Data access statement: Data from the ICMR-INDIAB and the YDR will be available on reasonable request to the corresponding author, Dr.Viswanathan

Mohan (email: drmohans@diabetes.ind.in), and lead investigator, Dr. Ranjit Mohan Anjana (email: dranjana@drmohans.com).

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