**Journal of Diabetes Science and Technology**
Volume 5, Issue 4, July 2011


ORIGINAL ARTICLE

# Analysis of the Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) Study

K. M. Venkat Narayan, M.D., and Justin B. Echouffo-Tcheugui, M.D., Ph.D.

## Abstract

The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study is the first nationally representative survey of diabetes in India. It aims to provide national and regional counts of diabetes and prediabetes and also of cardiovascular risk factors. This ambitious and complex survey uses robust sampling techniques, standardized methods, appropriate quality assurance, and a three-phase data collection. However, the survey should be completed within a reasonable time span to avoid a differential effect of secular trends on regional estimates. A high response rate and low missing values must also be ensured.

Reliance on capillary whole blood glucose (CBG) for the diagnosis of hyperglycemic states is a limitation of the survey. However, this is a reasonable compromise given the practical challenges of such a large study. Despite a good correlation between CBG and venous plasma glucose (VPG), the use of CBG may misclassify glycemic status. A better characterization of the CBG–VPG relationship, and the performance of CBG for detecting hyperglycemia, using a much larger sample, seems therefore advisable. This should be possible given that venous blood has been collected on a sizeable subset of participants.

The Indian Council of Medical Research and the Madras Diabetes Research Foundation deserve praise for this massive undertaking, which will highlight areas for policy action and establish a national framework for noncommunicable disease (NCD) surveillance. The ICMR–INDIAB survey lays the foundation for effective NCD prevention and control and for applied public health research.

*J Diabetes Sci Technol 2011;5(4):915-917*

India, a massive and highly diverse country, has a long history with diabetes mellitus, with some of the earliest references to the disease in the ancient Ayurvedic textbooks.[1] Over 25 words in the ancient Sanskrit language relate to diabetes, and India is often credited for having invented sugar around 500–400 BCE.[1] With the rapid economic and urban transformation of India, the country is currently witnessing a rapid and widespread rise in the prevalence of diabetes (predominantly driven by type 2 diabetes). It is estimated that India is home to the largest number of people with diabetes worldwide.[2] Yet estimates of numbers of people with diabetes in India are based on extrapolations from a few regional population-based studies to a complex, heterogeneous

**Author Affiliation:** Rollins School of Public Health, Emory University, Atlanta, Georgia

**Abbreviations:** (CBG) capillary whole blood glucose, (ICMR–INDIAB) Indian Council of Medical Research–India Diabetes, (NCD) noncommunicable disease, (VPG) venous plasma glucose

**Keywords:** capillary glucose, diabetes, India, prevalence, survey

**Corresponding Author:** K. M. Venkat Narayan, M.D., Hubert Department of Global Health, Rollins School of Public Health, Emory University, 1518 Clifton Road NE, Room 757G, Atlanta, GA 30322; email address knaraya@emory.edu

nation of 1.2 billion people. The proposed Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study, the methods for which are published in this issue of *Journal of Diabetes Science and Technology*,[3] when completed, will be the first nationally representative survey of diabetes in India.

The ICMR–INDIAB study is an ambitious, community-based survey of adults aged 20 to 80 years, across the 28 states of India, the National Capital Territory of Delhi, and two union territories of Chandigarh and Puducherry, involving a sample of 124,000 individuals. Despite massive logistical complexities and resource constraints, the study has been designed with statistical rigor, using standardized methods suggested by the World Health Organization.[4] The complex, stratified, multistage sampling design, with appropriate weights applied, will permit a robust estimation of diabetes prevalence for each state, separately for urban and rural India, and for the nation as a whole. The study protocol incorporates detailed training and quality assurance techniques, and data collection will be conducted in three phases, starting with three states and one union territory in phase 1 and other areas covered in subsequent phases. This three-stage scheme is akin to the task of census enumeration or national elections in India, which are done in phases, and speaks to the daunting challenges of organizing national data collection in a country as large and complex as India. It is, however, important that all three phases of the ICMR–INDIAB study be completed without too much delay so that estimates across the various regions of India are not differentially affected by any potential secular trends and thus comparable. Another potential bias that investigators need to avoid carefully is participant selection by ensuring high response rates and low missing values.

As the investigators acknowledge, one limitation of the ICMR–INDIAB study is its reliance on capillary whole blood glucose (CBG) fasting and 2 h postload measurements, as part of the oral glucose tolerance test, to estimate prediabetes and diabetes prevalence. However, this is an understandable compromise given the very real practical, logistical, and resource challenges associated with venous blood collection, handling, transportation, and storage in a very large epidemiological study spanning the breadth and length of a country as big and complicated as India. The authors of the study have undertaken a small validation study, comparing capillary glucose estimation against venous plasma glucose (VPG) estimation.[5] While CBG and VPG had a good correlation of 0.90 for 2 h postload samples, the correlation in fasting samples was much lower at 0.68.[5] However, correlation ignores any systematic bias between the measurements of the two methods.[6,7] The validation study indicates that the use of CBG may misclassify glucose tolerance status and thus may affect the accuracy of the estimation of the true prevalence of hyperglycemic states, irrespective of the diagnostic criteria used.[5] In previous studies, postloaded CBG levels have tended to be significantly higher than those in venous blood.[8,9] The relationship between fasting CBG levels and their venous equivalent is controversial.[9–11] Furthermore, even with a cutoff point of 112 mg/dl for the diagnostic of prediabetes, for example, using fasting CBG, the sensitivity CBG may be as low as 44% (specificity 94%).[10] It will therefore be helpful to better understand and characterize the potential bias from using capillary samples through an assessment using more than one set of reference criteria, as there is no international consensus between professional organizations over these criteria.[6] It is also difficult to have a clear and definitive idea about the sensitivity and specificity of fasting and 2 h CBG for detecting hyperglycemia solely on the basis of the results of the validation study,[5] which is relatively small in size, as is a previous study claiming comparable levels of sensitivity and specificity for diagnosing diabetes—84% and 98%, respectively.[12] Furthermore, a few other existing studies on the performance of the fasting CBG test on the matter deliver a mixed message.[10,11] The 2 h CBG performance has seldom been explored in nonpregnant adults for the diagnosis of hyperglycemic states in general and in prediabetes in particular. As venous bloods have been collected on every fifth participant, it may be useful to use those samples to estimate VPG and to perform a validation within the ICMR–INDIAB study on a much larger number of people, evaluating potential heterogeneity in performance across age, gender, and urban/rural regions. It may also be worthwhile to consider correction factors to calibrate prevalence, obtained from CBG, to arrive at estimates compatible with VPG assessments.[13] This may help overcome any bias introduced by the CBG measurement and also make prevalence estimates comparable with standard VPG measures in other studies across the world.

The Indian Council for Medical Research and the Madras Diabetes Research Foundation need to be applauded for undertaking the mammoth task of a national diabetes prevalence survey for India, especially in a context characterized by resources constraints and the gargantuan complexity characterizing the country. The ICMR–INDIAB survey will provide a detailed count of diabetes and prediabetes states and profiles of

the quality of care among people with diabetes and of cardiovascular risk factors in the population. These data will serve as an important benchmark and highlight areas for public health and policy action. Indeed, the intention of the ICMR–INDIAB study is to obtain robust estimates by state, as the authority for health in the Indian Republic resides at the state level.

The ICMR–INDIAB study fills a huge gap in data and establishes a national framework for monitoring diabetes and cardiovascular risk factors in India. But it should be viewed as a starting point for an evolving system of diabetes and noncommunicable disease (NCD) surveillance, which means that the Indian Council of Medical Research and the investigators should put mechanisms in place for rapid dissemination of information from the study, aimed at influencing debates and policy action to prevent and control diabetes and NCDs. It is also important to begin thinking about developing a national surveillance system for India similar to the National Health and Nutrition Examination Surveys in the United States,[14,15] wherein periodic cross-sectional surveys using standard methods together with limited cohort follow-up for mortality and morbidity are employed to monitor risk factors, diseases, and health trends. Such an undertaking will provide ongoing national and local data and stimulate policy and public health action while also laying an infrastructure for applied public health research.

Good surveillance is the bedrock of effective public health. The ICMR–INDIAB survey is thus a bold and highly commendable vision that opens exciting avenues for more effective prevention and control of NCDs in India.

**References:**


1. Weaver LJ, Narayan KM. Reconsidering the history of type 2 diabetes in India: emerging or re-emerging disease? Natl Med J India. 2008;21(6):288–91.
2. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(1):4–14.
3. Anjana RM, Pradeepa R, Deepa M, Datta M, Sudha V, Unnikrishnan R, Nath LM, Das AK, Madhu SV, Rao PV, Shukla DK, Kaur T, Shah B, Ali MK, Mohan V. The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study: methodological details. J Diabetes Sci Technol. 2011;5(4):906–14.
4. World Health Organization. STEPwise approach to surveillance (STEPS). http://www.who.int/chp/steps/en/. Accessed June 2, 2011.
5. Priya M, Mohan Anjana R, Pradeepa R, Jayashri R, Deepa M, Bhansali A, Mohan V. Comparison of capillary whole blood versus venous plasma glucose estimations in screening for diabetes mellitus in epidemiological studies in developing countries. Diabetes Technol Ther. 2011;13(5):586–91.
6. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol. 2009;3(4):903–13.
7. Wentholt IM, Hart AA, Hoekstra JB, Devries JH. How to assess and compare the accuracy of continuous glucose monitors? Diabetes Technol Ther. 2008;10(2):57–68.
8. Kuwa K, Nakayama T, Hoshino T, Tominaga M. Relationships of glucose concentrations in capillary whole blood, venous whole blood and venous plasma. Clin Chim Acta. 2001;307(1-2):187–92.
9. Colagiuri S, Sandbaek A, Carstensen B, Christensen J, Glumer C, Lauritzen T, Borch-Johnsen K. Comparability of venous and capillary glucose measurements in blood. Diabet Med. 2003;20(11):953–6.
10. Rush E, Crook N, Simmons D. Point-of-care testing as a tool for screening for diabetes and pre-diabetes. Diabet Med. 2008;25(9):1070–5.
11. Marley JV, Davis S, Coleman K, Hayhow BD, Brennan G, Mein JK, Nelson C, Atkinson D, Maguire GP. Point-of-care testing of capillary glucose in the exclusion and diagnosis of diabetes in remote Australia. Med J Aust. 2007;186(10):500–3.
12. Kruijshoop M, Feskens EJ, Blaak EE, de Bruin TW. Validation of capillary glucose measurements to detect glucose intolerance or type 2 diabetes mellitus in the general population. Clin Chim Acta. 2004;341(1-2):33–40.
13. Tonyushkina K, Nichols JH. Glucose meters: a review of technical challenges to obtaining accurate results. J Diabetes Sci Technol. 2009;3(4):971–80.
14. Imperatore G, Cadwell BL, Geiss L, Saadinne JB, Williams DE, Ford ES, Thompson TJ, Narayan KM, Gregg EW. Thirty-year trends in cardiovascular risk factor levels among US adults with diabetes: National Health and Nutrition Examination Surveys, 1971-2000. Am J Epidemiol. 2004;160(6):531–9.
15. Flegal KM, Graubard BI, Williamson DF, Gail MH. Cause-specific excess deaths associated with underweight, overweight, and obesity. JAMA. 2007;298(17):2028–37.