Review Article

IMPACT India: A Novel Approach for Optimum Diabetes Care

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Abstract

India has the second largest population with diabetes mellitus in the world. Long-term, uncontrolled diabetes is associated with increased microvascular and macrovascular (commonly cardiovascular) complications and death. The large burden of uncontrolled diabetes in India could be because of lack of treatment adherence, limited access to laboratory testing, lack of physical activity, and poor dietary habits. This creates a compelling need for a greater involvement of healthcare professionals (HCPs) in improving societal awareness and regular monitoring of glycemic control, which is limited in patient outreach programs. IMPACT India, launched in November 2018, is a diabetes control program with a three-pronged approach aimed at creating an impact at the level of HCPs, society, and individuals living with diabetes. The India Diabetes Care Index (iDCI®), a quarterly aggregate index of glycated hemoglobin, fasting plasma glucose (FPG), and postprandial plasma glucose (PPG), forms the backbone of IMPACT India. The program uses iDCI® to evaluate glycemic control at periodic intervals, sensitize HCPs about the glycemic control status, and optimize diabetes care by escalating pharmacotherapy including insulin whenever required. Societal awareness will be created by social media to achieve actionable awareness based on the iDCI® reports. At baseline (January 2018 to June 2018), the database (2.39 million) revealed an average glycated hemoglobin of 8.56%, FPG of 172 mg/dL, and PPG of 253 mg/dL. Also, 74% of the patients had HbA1c >7% and FPG >130 mg/dL and >83% of the patients had PPG >160 mg/dL. The IMPACT India program aims to positively impact diabetes care in India by achieving at least 1% glycated hemoglobin reduction in 1000 days.

Keywords: 1000-day challenge, diabetes mellitus, glycated hemoglobin, IMPACT India, India Diabetes Care Index

Introduction

In India, non-communicable diseases (NCDs) are prevalent, causing 61% of all deaths.[1] Diabetes, cardiovascular diseases, respiratory diseases, and cancer are the major contributors to the NCD epidemic.[2] The United Nations has identified diabetes as one of the four priority NCDs because of the growing disease burden.[3] In India, among other NCDs, diabetes has had the greatest increase (39.6%) in the age-standardized disability-adjusted life years between 1990 and 2016.[2] The prevalence of diabetes in India is continuously rising.[4] In 2019, India had the second largest population in the world with diabetes (77.0 million persons living with diabetes), which is expected to rise to 134.2 million persons by 2045.[4] Also, diabetes-related mortality rate in India in 2016 was 3.1% of all deaths, up from 0.98% deaths in 1990.[5] Additionally, a large number (42.2 million, 57.9%) of persons living with diabetes in India remains undiagnosed.[4] Diabetes is associated with a significant economic burden. In 2017, India had the fourth highest healthcare expenditure on diabetes in the world.[4] The high prevalence of diabetes in India may be explained by the fact that Asian Indians have a phenotype of poor insulin secretion, about one-half to

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one-third of insulin secretion compared with Pima Indians.[6] Strikingly, in those with a normal weight, the prevalence of diabetes was 10.1% in Asians and American Indians/Alaskan Natives.[7] Additionally, a higher waist-to-hip ratio makes them highly susceptible to diabetes, even though they have a relatively lower body mass index (BMI).[8]

Long-term, uncontrolled diabetes causes metabolic changes and subsequently leads to development of macrovascular and microvascular complications.[9] Evidence suggests that every 1% increase in the glycated hemoglobin (HbA1c) level in persons living with diabetes is associated with approximately 40% increase in cardiovascular disease mortality and a 30% increase in all-cause mortality.[10] In contrast, every 1% reduction in HbA1c is associated with reduction in risk of 21% for any endpoint related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction, 12% for stroke, 16% for heart failure, 43% for amputation or death from peripheral vascular disease, 37% for microvascular complications, 31% for retinopathy, and 33% for nephropathy.[11-13] The DiabCare 2011 study conducted at 330 centers across India in 6168 patients reported a mean HbA1c of 8.9%.[14] This prevalence was consistent with the burden of diabetes observed a decade ago.[15] Inadequate HbA1c control may be because of poor treatment adherence and lack of access to medical care and diagnostic facilities.[16-18]

Another hurdle in the management of diabetes in India is the inadequate adoption of the HbA1c test for the diagnosis of diabetes. Although HbA1c is a useful tool to detect chronic hyperglycemia and to assess the risk of long-term complications, clinicians still depend on fasting plasma glucose (FPG) testing.[19,20] Limited use of HbA1c testing may be because of the cost constraints, issues with standardization, and lack of availability of the test in some regions of India.[21]

To overcome the challenge of poor glycemic control, a multilevel outreach program to educate healthcare professionals (HCPs), encourage patients, and assess the glycemic control is the need of the hour.

Diabetes Outreach Programs—The Current Status in India

India has the second largest population with diabetes in the world, yet a large number of individuals living with diabetes remain undiagnosed and untreated, suggesting lack of awareness among general population.[5,22] This gap in providing diabetes care could be reduced by patient outreach programs.[23] The currently available patient outreach programs are presented in Tables 1 and 2 and Figure 1.[24-32]

Table 1: Structure of current diabetes outreach programs in India

Program	Year of inception	Program structure
HOPE[24]	2007	• A global initiative for prevention and management of NCDs • Role in India: ◦ 2007—Started 4-year, India Diabetes Educator Project (>3600 HCPs), ◦ 2013—Started India Diabetes Educator E-Learning Program—self-paced, online course, ◦ 2014—Collaboration with Government of Maharashtra to train health workers on NCDs, ◦ 2015—Supported Project UDAAN, ◦ 2015—Started Innovations India: Positive Deviance for Diabetes
SPARSH[25]	2009	• Telephonic counseling for healthy diet, exercise, and lifestyle
mDiabetes[28,29]	2012	• A Government of India-led program • Ministry of Health and Family Welfare in collaboration with WHO launched a text message-based patient awareness and education program • The program intended to improve awareness about diabetes, healthy diet, active lifestyle, patients' healthcare seeking, early diagnosis, treatment adherence, and self-care
UDAY[30,31]	2013	• A 5-year initiative to decrease risk and improve management of diabetes and hypertension • Patient data collected prior to program: Physical and clinical information, patients' knowledge of diabetes and hypertension, demographic and socioeconomic status, behavioral risk factors, and medical history • Program implementation: Patient education, identifying high-risk patients, diabetes registry, geographic mapping of communities, guideline training for HCPs, preparing diabetes registry, and healthcare access advocacy
iTAP[32]	2014	• A 4-year, patient education program to improve insulin adherence • T2DM patients enrolled in a six-visit study: initiative of insulin usage (visit 0 or baseline), recap of visit 0 (visit 1), diabetes overview (visit 2), importance of exercise (visit 3), healthy diet and lifestyle (visit 4), education on foot care (visit 5), and reinforcement of earlier training (visit 6)
UDAAN[24]	2016	• Implementation of Government of India's NPCDCS guidelines in the Kanke block of Ranchi district, Jharkhand, India • Three-pronged strategy: 1. Health promotion and demand generation, 2. health system strengthening on NCDs, 3. NCD capacity building

HCP: healthcare professional, IDEEL: India Diabetes Educator E-Learning Program, iTAP: Insulin Therapy Assistance Program, NA: not available, NCD: non-communicable disease, NPCDCS: National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke, T2DM: type 2 diabetes mellitus, WHO: World Health Organization

Despite the intense efforts put through different programs launched in India, the prevalence of diabetes in India is still on the rise.[4,33,34] Currently available programs focus on specific areas of diabetes care and may be falling short in ensuring a collective effort from the different stakeholders [Table 1]. Hence, there is a need for a robust and versatile program to work communally.

IMPACT India Program

Need for IMPACT India

The Research Society for the Study of Diabetes in India (RSSDI; 2019) recommends an HbA1c goal of <7% for non-pregnant adults, which is aligned with the 2019 American Diabetes Association (ADA) clinical practice guidelines.[35,36] However, according to the DiabCare India 2011 study, the average HbA1c of Indian living with diabetes (8.9 ± 2.1; n = 5272) is well above the ADA and RSSDI recommended levels.[14] An HbA1c >7% is associated with an increase in micro- and macrovascular complications. Hence, there is a need to reduce HbA1c to physiological levels to reduce diabetes-related mortality.[11] Therefore, there is a need for a program that not only promotes diabetes care at the HCP level and societal awareness of diabetes burden level, but also focusses on a patient-specific treatment; thus representing an impactful three-pronged approach aimed at the level of HCPs, society, and persons living with diabetes to create actionable awareness.

What is IMPACT India?

IMPACT India is a project of the Novo Nordisk Education Foundation in collaboration with like-minded partners with an aim to improve the current status of diabetes care in India. It was initiated on 13 November 2018 (eve of World Diabetes day) with the ambition of achieving a 1% reduction in the average HbA1c of the country by 31 July 2021, marking 100 years of insulin discovery. This interval period has a duration of 1000 days and hence has been named as the 1000-day challenge.[37] This challenge plans to increase awareness and education among 150,000 practitioners and 10,000 paramedics with the help of medical meetings and continuous medical education programs using electronic media such as radio and television.[37]

iDCI: A tool to understand the burden of diabetes in India

Patient education and motivation are now considered as an integral part of diabetes care.[37] Indian Diabetes Care Index (iDCI®) is a tool to create awareness of diabetes mellitus at the national, state, and city levels. It intends to sensitize HCPs, society, and persons with diabetes about the current status of glycemic control and motivate them toward the importance of optimizing diabetes care. Information, from across India as well as from 35 selected cities, is being aggregated on a quarterly basis from the "Big Data" aggregator database (2.39 million in January–June

Table 2: Benefits and limitations of current diabetes outreach programs in India

Program	Inception year	Benefits	Limitations
HOPE[24]	2007	• Trained HCPs. Supported UDAY, UDAAN, and Innovations India	Did not include glycemic monitoring or societal awareness program
SPARSH[25]	2009	• Improved patients' (n = 1283) health habits • Reduced smoking and consumption of carbohydrate, fat, alcohol, and junk food • Increased consumption of protein, cereals, fruits, vegetables, dietary fiber, and self-care	Did not include glycemic monitoring, HCP education, or societal awareness program
mDiabetes[28,29]	2012	• 31,725 patients registered • Post-study telephonic interview revealed that participants found the program feasible and acceptable • The study proved the ability of mDiabetes to improve the awareness of diabetes and early diagnosis and management	Did not include an interactive voice response system, glycemic monitoring, or societal awareness program
UDAY[30,31]	2013	• 59,540 patients registered, of which 31% identified as high-risk patients • 88% of high-risk patients counseled for testing and treatment • The program demonstrated a cost-effective, scalable, and comprehensive mode for the prevention and management of diabetes and high blood pressure	Did not include glycemic monitoring or societal awareness program
iTAP[32]	2014	• n = 10,426 • Patients completing educational program had significantly higher insulin adherence (P < 0.001)	Did not include glycemic monitoring or societal awareness program
UDAAN[24]	2016	NA	Did not include glycemic monitoring or societal awareness program

HCP: healthcare professional, iTAP: Insulin Therapy Assistance Program, NA: not available, NCD: non-communicable disease, NPCDCS: National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke

2018 quarter). The data of patients who undergo HbA1c, FPG, and postprandial plasma glucose (PPG) and fulfill the ADA diagnostic criteria for T2DM are filtered and included for the calculation of iDCI®. Additional information available includes demographics (age, gender, weight), common co-morbidities (dyslipidemia, liver, and renal dysfunction) in diabetes, and diabetes complications (retinopathy, nephropathy, neuropathy, coronary artery disease, cerebrovascular disease, and peripheral vascular disease) and has been captured wherever available. Also, data of patients with uncontrolled diabetes are identified. Due vigilance is taken to ensure that the information is de-identified, which means that no patient-level data are provided by the data vendor. An average of each glucose control parameter obtained from the different cities for a particular quarter forms the iDCI® for that quarter. This diabetes care barometer will have analysis sets, which will help assess the total population disease burden and total population with established or potential diabetes and establish the correlation among glycemic measures, co-morbidities, and vascular complications.

iDCI® was used to transmit a live feedback of the IMPACT India program to all stakeholders to ensure that the 1000-day challenge is successfully executed. At baseline (January 2018 to June 2018), iDCI® demonstrated that the average HbA1c in some key cities is much greater than 7% (Delhi 8.5%, Mumbai 8.1%, Chennai 8.4%, Kolkata 8.2%).[38] The database (2.39 million) revealed an average HbA1c of 8.56%, an FPG of 172 mg/dL, and a PPG of 253 mg/dL. In addition, 74% of the patients had an HbA1c >7% and FPG >130 mg/dL, whereas 83% of the patients had PPG >160 mg/dL, indicating suboptimal glycemic control. These data indicate that there is a continuous need to increase awareness about diabetes to ensure timely treatment and to improve diabetes management. The IMPACT India program incorporates more than

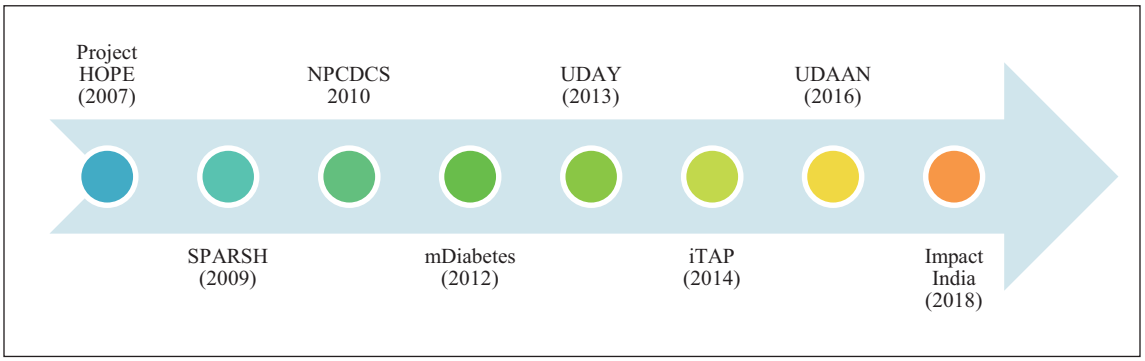

Figure 1: Inception of current diabetes outreach programs in India

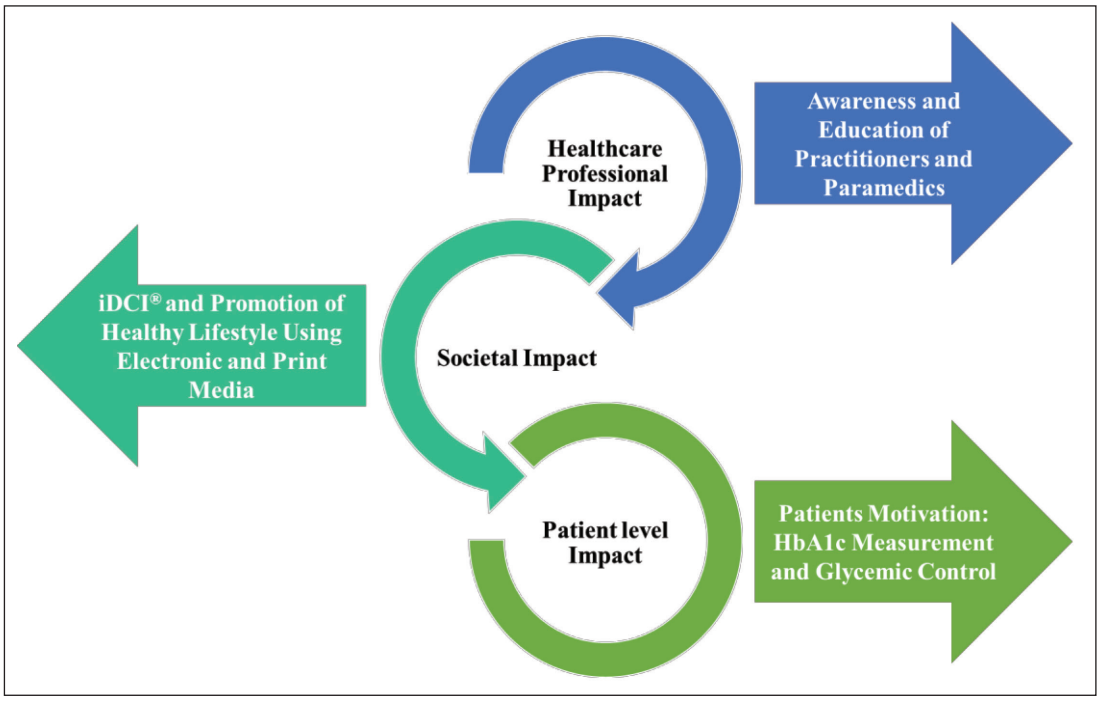

Figure 2: IMPACT India: three-pronged program. HbA1c: glycated hemoglobin, iDCI®: India Diabetes Care Index

90 diagnostic laboratories and 1000 centers through 35 cities, including a database of 25 million patients of over 10 years (based on glycemic measures, comorbidities, and complications). This could prove be a great initiative to enable all stakeholders to work in a targeted fashion to improve diabetes care. It would motivate HCPs, patients, and society as a whole to ensure optimum diabetes care by creating awareness at the national, state, and city levels.[39]

The three-pronged approach of IMPACT India

1. *Healthcare profession*: It has been proposed that clinical inertia, i.e. the failure to reach clinical targets and therapies to achieve treatment goals, mostly, insulin initiation, could be due to lack of knowledge and resources, therefore delaying treatment intensification.[27] Clinical inertia includes three factors: physician factors, patient factors, and system factors. IMPACT India is addressing the provider or physician factor by conducting medical education workshops, designed to discuss the key components of hyperglycemia leading to uncontrolled HbA1c, and the tools available to treat T2DM. The Indian reality of managing T2DM with addition of insulin therapy as a last resort, when multiple oral antidiabetic drugs prove to be ineffective, makes achievement of the desired HbA1c target difficult. These focussed workshops include case-based training on various aspects of diabetes management with a special focus on managing patients uncontrolled on multiple OADs. These case-based discussions are being designed to specifically address the challenge of clinical inertia in treatment intensification; specifically the expert faculty along with the IMPACT facilitators (HCPs who act as the change agents in the 1000-day challenge) discusses the various options to bring HbA1c under control. A mobile-based application support is also extended to the IMPACT facilitators to capture the demographic parameters and monitor the glycemic control of their patients. An important component of this application is that each facilitator could view the average national, respective state, and city HbA1c generated by the iDCI® and compare it with his/her clinic HbA1c. This acts as an efficient tool to compare and motivate for better care. The IMPACT facilitators offer to participate in a nation-wide survey to understand the Indian reality of T2DM management and factors influencing the choice of treatment options in their routine clinical practice [Figure 2].
2. *Society level*: A key component of improving the status of diabetes control and care in India is to focus efforts on educating the general public about the growing burden of diabetes and the perils of uncontrolled diabetes. A 3-monthly diabetes awareness activity is an integral part of IMPACT India and will run until July 31, 2021. Data generated from the iDCI® are being used by way of media (television, radio, and newspaper) to build awareness about the status of control in India and benefits of good glycemic control. Healthcare experts in the field of diabetes and endocrinology are being actively involved to reflect upon the iDCI® inputs and provide simple, actionable messages to the public to improve the healthcare status of the society at large. Encouraging healthy lifestyle through daily exercise, yoga, and reducing "social snacking" and intake of high calorie and processed food are also a vital part of the societal awareness activities [Figure 2].
3. *Person level*: A key component of good diabetes control is monitoring HbA1c regularly. Under the initiative of IMPACT India, patients are being supported with HbA1c testing through their treating physicians to improve awareness about their level of control and motivate them toward attaining better glycemic control. IMPACT patient starter kits are being provided which include a diet guide, importance of timely HbA1c monitoring, self-monitoring blood glucose diary, living well with diabetes, healthy living with diabetes, diabetes wallet card, and travel pouch with coolant gel for insulin [Figure 2].

The impact of IMPACT India

In India, suboptimal awareness, focus on acute management rather than on preventive care, competing care demands, and constraints of time and facility are some of the physician-related issues in delivering optimum diabetes care.[40] This HCP-related barrier in diabetes care could be overcome by targeted training provided through the IMPACT India program.

In a survey on "IMPACT India: Insights for Insulin Therapy in Routine Clinical Practice," insights were obtained from 314 physicians on factors that influence the choice of insulin therapy. Results of the study demonstrated that Indian physicians prescribe insulin logically, based on patients' characteristics such as gluco-phenotype, dietary patterns, psychosocial needs, clinical needs, and comorbid conditions, suggesting a positive HCP impact of the IMPACT India program.[41]

In the UDAY program that covers the districts in Vizag, Andhra and Sonipat, Haryana, it was observed that high-risk patients avoided visiting the healthcare facility to confirm their increased risk because of lack of awareness.[31] Similar results were also observed in Chennai-based patients, who indicated lack of knowledge of diabetes-related complications.[42] The IMPACT India program could help patients improve their awareness about diabetes and encourage them to adopt a healthy lifestyle. Under this program, a social media and radio campaign including messages from experts in 12 cities is being conducted to spread the awareness about the relationship between uncontrolled diabetes and heart disease.[38] The benefits of using electronic media in motivating patients

for diagnosis and care of diabetes are evident from past studies such as the mDiabetes project and the UDAY initiative.[29,31]

Although evidence-based guidelines help to prevent disease complications and reduce morbidity and mortality, real-time epidemiological data remain a critical component of patient-centric management of chronic illnesses.[33,34,43,44] These real-time epidemiological data invloving a large number of patients from various centers across India act as a reminder to the healthcare services to comply with the clinical practice guidelines. These data also provide a feedback to the physicians on disease prognosis and help in the planning of individual patient- and population-based care.[44] One of the key components of the IMPACT India program is the iDCI®. The iDCI® helps to create awareness in the society and among diabetes practitioners on a regular basis as opposed to the awareness activities which earlier used to happen only on the World Diabetes Day (14 November) and the Insulin Day (31 July). Similarly, the DiabCare India 2011 study conducted at 330 sites, in 5272 persons with diabetes, demonstrated a suboptimal glycemic control in persons with type 2 diabetes (mean HbA1c was 8.9 ± 2.1%) and indicated a need for systematic treatment at an early stage of the disease and increased awareness with regard to benefits of glycemic control. However, because of its cross-sectional nature, the study lacked causality assessment, continuous HbA1c monitoring, and feedback to physicians.[14] Other large population studies, such as A1chieve (n = 20,554), PRESENT (n = 3559), and IMPROVE (n = 17491), despite describing the high burden of diabetes and its complications, lacked the live and continuous tracking of patient's HbA1c that could raise the glycemic control awareness in HCPs and persons with diabetes.[45-47] On the contrary, IMPACT India could have a greater societal impact through better awareness of glycemic control among HCPs and persons with diabetes.

In addition to raising awareness, to ensure quality diabetes care, a patient-centric approach is required.[26] Through IMPACT India, HCPs can help individualize their diet plans and rationalize their antihyperglycemic drug intake for optimal glycemic control. Such a customization of treatment regimen was evident from "IMPACT India: Insights for Insulin Therapy in Routine Clinical Practice" survey. The survey highlighted the use of basal bolus therapy in pregnant women (>47%) and in acute illness (62%). Premix insulin was favored in patients with high carbohydrate intake (73%), whereas in patients with variable meal timings (39%) or pronounced postprandial glucose excursions (45%) basal bolus was preferred.[38]

Conclusions

The prevalence of diabetes is continuously rising in India and its management remains a challenge. Clinical inertia among HCPs, lack of awareness among diabetes patients and the society, and poor monitoring of diabetes contribute to sub-optimal glycemic control in India. To address these unmet needs of diabetes care in India, a collective effort from various stakeholders is required. IMPACT India is an initiative to bring together all the like-minded partners in diabetes care to reduce the diabetes burden in India by a three-pronged approach: education of HCPs, increasing awareness among society, and encouraging patients to timely monitor and control their diabetes. The 1000-day challenge within this program aims to reduce the average HbA1c of the country by 1% and thereby contribute to the reduction in the micro- and macro-vascular complications. IMPACT India aims to deliver a strong multipronged impact. HCPs will be able to offer more efficient and patient-centric management for their diabetic patients. Patients will be more aware, informed, and motivated, resulting in fewer complications and a better quality of life. Societal impact will have the potential to reduce the incidence of diabetes by encouraging a healthier lifestyle. At the country level, it will mean a significant reduction in healthcare expenditure. Thus, through IMPACT India, various stakeholders could work together to have a positive impact on the lives of people with diabetes in India.

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Conflicts of interest

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