

## Barriers and solutions to diabetes management: An Indian perspective

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### ABSTRACT

India, with one of the largest and most diverse populations of people living with diabetes, experiences significant barriers in successful diabetes care. Limitations in appropriate and timely use of insulin impede the achievement of good glycemic control. The current article aims to identify solutions to barriers in the effective use of insulin therapy viz. its efficacy and safety, impact on convenience and life-style and lack of awareness and education. Therapeutic modalities, which avoid placing an undue burden on patients' life-style, must be built. These should incorporate patient-centric paradigms of diabetes care, team-based approach for life-style modification and monitoring of patients' adherence to therapy. To address the issues in efficacy and safety, long-acting, flat profile basal insulin, which mimics physiological insulin and show fewer hypoglycemic events is needed. In addition, therapy must be linked to monitoring of blood glucose to enable effective use of insulin therapy. In conjunction, wide-ranging efforts must be made to remove negative perception of insulin therapy in the community. Patient- and physician – targeted programs to enhance awareness in various aspects of diabetes care must be initiated across all levels of health-care ensuring uniformity of information. To successfully address the challenges in facing diabetes care, partnerships between various stakeholders in the care process must be explored.

**Key words:** Delivery of health-care, diabetes mellitus, health-care disparities, insulin, life-style, medication adherence, patient compliance, patient-centered care, physician-patient relations, safety

### INTRODUCTION

Epidemiological studies from India and international bodies have raised alarm on diabetes prevalence. Current

global prevalence of 366 million is expected to rise to 552 million (51% increase) by 2030.<sup>[1]</sup> More than 60% of world's population with diabetes comes from Asia<sup>[2]</sup> of which two nations; India and China contribute the largest. The large scale DiabCare Asia study designed to describe and investigate the diabetes control, management and complication status in patients with diabetes from Asian countries, reports approximately half the patients with diabetes in India have poor glycemic control and that type 2 diabetes begins at an early age among Indians.<sup>[3]</sup> The estimated prevalence of 61.3 million in India is expected to rise to 101.2 million (65% increase) by 2030 resulting in every fifth person with diabetes in the world to be an Indian.<sup>[1]</sup>

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Currently, an estimated 77.2 million people in India<sup>[4]</sup> and 280 million world-wide suffer from pre-diabetes increasing the future burden of diabetes.<sup>[1]</sup> Asian Indian phenotype and life-style changes associated with urbanization and sedentary life-styles are reported to contribute to the rise in diabetes in India.<sup>[5]</sup>

### Micro/macro-vascular complications of diabetes

The burden of diabetes increases due to the associated micro- and macro-vascular complications. India and China have the highest number of people with diabetes and cardiovascular diseases, one of the leading causes of threat to public health.<sup>[6]</sup> The burden of diabetes complications affects the productive younger age group in developing countries, which has serious economic implications. Prevalence of diabetic retinopathy, microalbuminuria and peripheral neuropathy from the Chennai Urban Rural Epidemiological Study were 17.6%,<sup>[7]</sup> 26.9%<sup>[8]</sup> and 26.1%<sup>[9]</sup> respectively. Similarly, prevalence of 11.3%<sup>[10]</sup> to 21.4%<sup>[11]</sup> of coronary artery disease and 6.3%<sup>[12]</sup> to 11.5%<sup>[13]</sup> of peripheral vascular disease has been reported in Indian diabetes patients. In people with diabetes, early intensive glucose control therapy not only lowers blood glucose levels, but also reduces blood pressure, cholesterol and its atherogenic sub-fractions; is known to reduce the risk of both microvascular and macrovascular complications of diabetes albeit at different times of follow-up.

### Access to medical care

Diabetes is a chronic condition that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. Yet, health systems have not kept pace in evolving mechanisms to tackle diabetes effectively and the result is reflected in the sheer number (50-60%) of people with diabetes who do not achieve the glycemic target of glycated hemoglobin (HbA1c) below 7% as reported in the limited studies available on diabetes care in India.<sup>[14]</sup>

The lower levels of self-reported diabetes observed in people with diabetes living at low socio economic groups is due to unawareness of the true condition owing to lack of access to medical care, diagnosis and testing.<sup>[15]</sup> This might be due to lack of financial affordability or logistic issues for patients living in rural settings, or poor public health-care infrastructure in India. Despite reports that a well-designed community health insurance scheme can improve access to medical care even for people with diabetes living in poor socio-economic conditions,<sup>[16]</sup> the most common cause of death in type 1 diabetes is lack of access to insulin.<sup>[17]</sup>

### Adherence and patient issues

Adherence to medication, especially insulin is a key contributor to diabetes treatment outcome. Poor adherence

results in worse glucose control and increased hospital admissions of patients due to diabetes complications.<sup>[18]</sup> Factors like medication costs, regimen complexity, patient's emotional well-being, and patient's perceptions of medication side effects and medication-related intrusions on activities of daily living are associated with adherence to any diabetes medication.<sup>[19]</sup> In specific relation to insulin adherence, both patients and physicians indicated being too busy, travelling, skipped meals, stress/emotional problems and public embarrassment as reasons for insulin-omission/non-adherence.<sup>[20]</sup> In addition, adherence to medical advice is an expensive affair for most patients with diabetes in India. At an individual level, each patient is estimated to be burdened with an expenditure of Rs. 41,998 in direct (Rs. 15,096) and indirect (Rs. 26,902) costs. Accurate understanding of patient perceptions of diabetes impact and its seriousness is important in effective patient-physician communication and diabetes management. From the physician point of view, significant barriers exist to the practice of evidence-based diabetes management. In a survey of clinical diabetologists conducted through a semi-structured questionnaire in India, poor awareness among physicians (22.7%), western guidelines being not applicable to Indian patients (22.7%) and cost to patients (18.2%) were some of the barriers identified.<sup>[21]</sup>

The timely initiation and proper use of existing therapies can facilitate significant glycemic control. However, clinical inertia defined as 'recognition of the problem, but failure to act' is the principal cause of poor glycemic control.<sup>[22-24]</sup> In India, it is known that insulin is not initiated in patients till their HbA1c reaches > 9%<sup>[25]</sup> and this confirms global trends of lack of timely interventions being correlated to worsening glycemic control.<sup>[23]</sup> In light of these facts, initiatives like the global action meeting and the subsequent action Asia meeting are prominent examples of an emerging consensus across the globe to manage diabetes in an integrated manner. The local interpretation of guidelines to manage type 2 diabetes and making it suitable to the local socio-economic and cultural sensitivities is important. The current article is the result of an on-going effort to evolve a national consensus on these issues by partnering with a multi-professional expert panel within specialist and community diabetes care.

## BARRIERS AND CHALLENGES IN DIABETES MANAGEMENT

It is known that early insulin initiation is needed for tight glycemic control and delay in the onset of complications.<sup>[26]</sup> Even though a large number of Indians with diabetes fail to achieve glycemic targets,<sup>[27]</sup> Diabetes Attitudes, Wishes and Needs (DAWN) survey reported that Indian physicians

delay insulin initiation longer than physicians from among 13 countries studied.<sup>[28]</sup> Physicians' view of insulin efficacy is correlated with delay in insulin initiation<sup>[28]</sup> which in turn is correlated with patient acceptance of insulin. Physicians' and patients' perception of efficacy and safety of insulin depends on their awareness of insulin therapy and its benefits. The ease of administration and flexibility of use is an important factor affecting the acceptance of treatment recommendations. Patients feel using insulin therapy is inconvenient due to its interference with eating, exercise and daily routines and dissatisfaction associated with hypoglycemia, injection pain, time required to administer, and embarrassment.<sup>[29]</sup> The broad picture that emerges, presents an interconnected causal chain of factors, which strengthen each other, thereby impeding the use of insulin therapy [Figure 1].

### Efficacy and safety

There is considerable evidence, which suggests that early initiation of insulin is associated with effective glycemic control and delay the onset of complications.<sup>[30]</sup> However, significant concerns about its efficacy and safety remain in both patients and physicians. Recent data from DAWN

study found that patients on insulin therapy, both globally (around 50%) and in India expressed concern over hypoglycemia (25-55%) and weight gain (40%).<sup>[31]</sup> Fear of hypoglycemic episodes (day-long, nocturnal and severe) and weight gain among patients and physicians has delayed the initiation and intensification of insulin.<sup>[32]</sup> Globally, physicians reported that they would treat patients with diabetes more aggressively if not for concern about hypoglycemia.<sup>[20]</sup> The cardiovascular complications associated with high glucose levels might also contribute to delay in insulin initiation for tight glycemic control by physicians.<sup>[33]</sup> Insulin and insulin analogues were also reported to be associated with higher cancer incidence<sup>[34]</sup> and raised concerns over their mitogenic potential. Physicians also believed that variability in the current insulin therapies can cause complications in patients.<sup>[17]</sup>

Regular monitoring of blood glucose through self-monitoring devices is insufficiently practiced by diabetes patients. Pain, inconvenience and financial constraints<sup>[35]</sup> along with low knowledge of diabetes and low rate of physician recommendation<sup>[36]</sup> influence the use of self-monitoring devices by patients. Taken together,

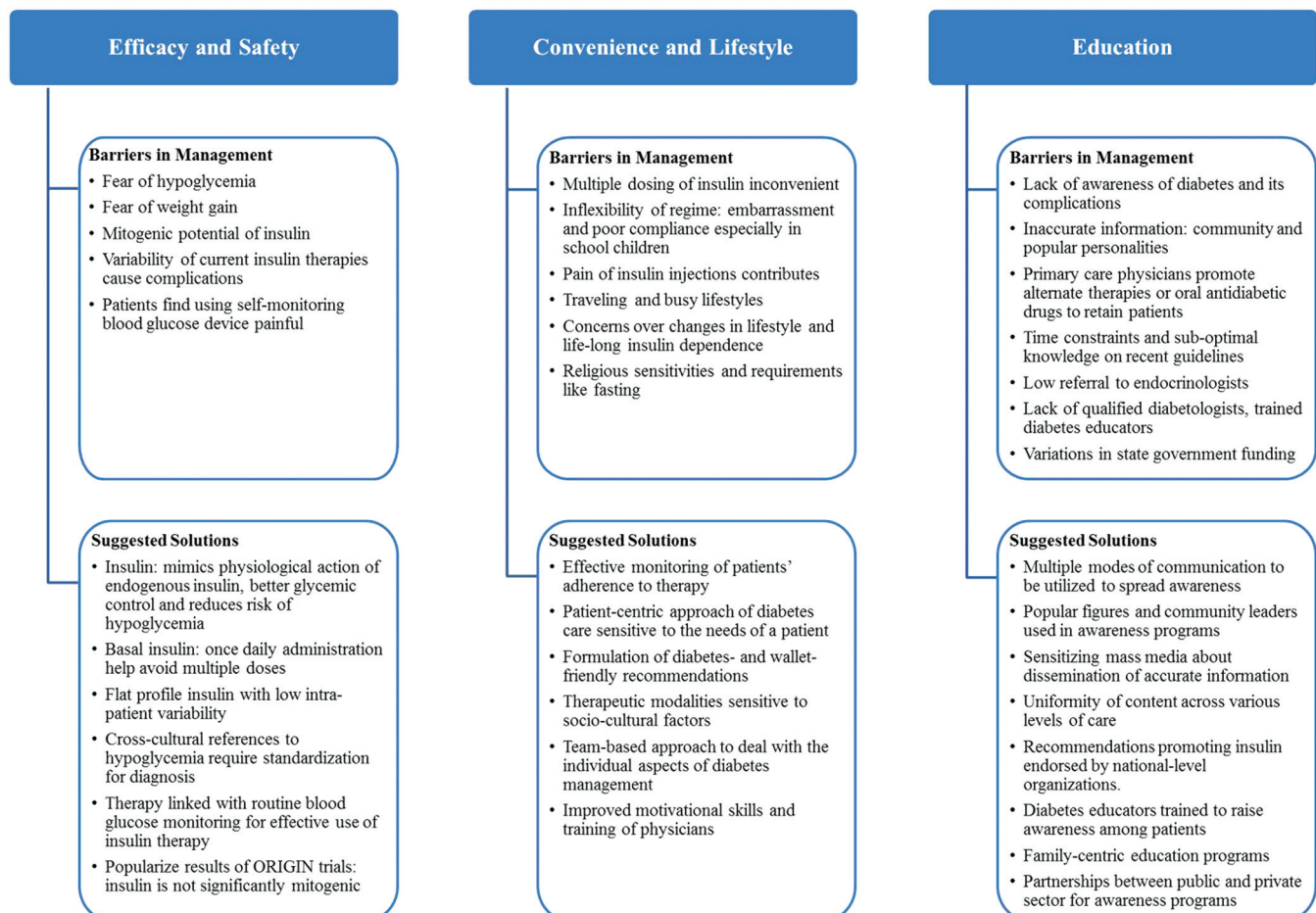


Figure 1: Barriers and solutions for diabetes management in India

these concerns contribute to delay in insulin initiation and intensification, which lead to poor glycemic control and occurrence of secondary complications. Figure 1 summarizes the barriers with respect to efficacy.

### Convenience and life-style

Inflexibility of insulin regimen in terms of administration and multiple doses potentially contribute to a feeling that insulin therapy causes inconvenience in patients' life-style. Injecting at a specific time in a day especially in public places might lead to inconvenience and embarrassment which along with busy life-styles lead to poor compliance.<sup>[37]</sup> Pain caused due to insulin injection also contributes for non-adherence to treatment among people with diabetes.<sup>[38]</sup> Similarly, some patients also reported self-monitoring their blood glucose levels as cumbersome and painful and do not effectively comply with the monitoring.<sup>[35]</sup> Physicians delay insulin initiation due to concerns over changes in life-styles, life-long insulin dependence and patients' perception of insulin therapy being associated with aggravated disease.<sup>[25]</sup>

Children with type 1 diabetes are stigmatized for taking afternoon injections at school and often miss doses. Teacher's awareness about the disease and importance of timely dosing of insulin contribute to the stigma of children with diabetes.<sup>[17]</sup> DAWN study reports that ~ 85-90% Indian patients showed non-compliance to therapy confirming the findings of other studies, which also found low levels of compliance to therapy.<sup>[39,40]</sup> Religious requirements, which mandate practices like fasting etc., plays a role in limiting patients' ability to comply with medical advice on proper diabetes care<sup>[41]</sup> leading to hyperglycemia, diabetic ketoacidosis, dehydration and thrombosis.<sup>[42]</sup> Figure 1 summarizes, the barriers with respect to convenience and life-style.

### Education

Awareness of diabetes and diabetes care is needed for successful disease management. The low level of awareness of diabetes and its complications among patients and physicians results in poor glycemic control in Indians with diabetes.<sup>[25]</sup> In Indian patients, the awareness that diabetes could be a consequence of current life-styles is low.<sup>[31]</sup> On the other hand, negative perceptions to insulin therapy can be based on inaccurate information disseminated through community networks<sup>[43]</sup> and by popular personalities in media.<sup>[17]</sup> Lack of awareness amongst physicians also impacts use of insulin therapy. Practitioners prescribe alternate/traditional therapies or oral antidiabetic drugs (OADs) for diabetes care to retain patients or due to lack of proper information.<sup>[17]</sup> This results in the use of insulin therapy as a last resort of disease management; with insulin being delayed until HbA1c levels deteriorate to around 9%.<sup>[25]</sup> Majority of the patients too

think that good control of diabetes can be achieved by simply complying with medication, diet and exercise plan, despite a lack of knowledge of their blood glucose levels.<sup>[25]</sup>

General physicians and family doctors, the primary contact of diabetes care for patients are responsible for the delay in the initiation and intensification of insulin therapy due to their sub-optimal knowledge of guidelines, time constraints, and attitudinal issues.<sup>[44]</sup> Poor referrals to endocrinologists, and other specialists, lack of patient counseling and lack of practice of evidence based medicine impede the effectiveness and efficiency of patient care in India.<sup>[44]</sup>

Studies report that in India a substantial percentage of patients are unaware of diabetes condition (~25%), risk factors (obesity and physical inactivity) and secondary complications of diabetes (~60%).<sup>[45]</sup> Further almost half of the patients are unaware that good glycemic control would help to avoid complications related to diabetes.<sup>[46]</sup> In a study, only 7.6% patients were aware of HbA1c testing for the diagnosis of diabetes in year 2000<sup>[46]</sup> and 21.7% in the year 2006.<sup>[40]</sup> While only 10.3% of patients reported receiving diabetes self-management education,<sup>[40]</sup> 20-30% respondents reported not being up-dated about new information and developments on diabetes.<sup>[31]</sup>

The lack of trained diabetes educators in India leaves the burden of educating patients to physicians. Differences in the standard of diabetes medical education across the universities result in inconsistent patient education.<sup>[17]</sup> Primary care physicians (PCPs) getting certified as diabetologists at low-level universities and colleges and the lack of requirement of national qualification for practice are impeding the regulation of quality diabetes care and education programs.<sup>[17]</sup> The disparity in funding for diabetes seen among different state governments in India might be due to variable levels of awareness of diabetes and the economic impact of diabetes care on the people and government.<sup>[17]</sup> Figure 1 summarizes the barriers with respect to education.

## ADDRESSING BARRIERS IN DIABETES MANAGEMENT

### Efficacy and safety

Novel options in insulin therapy with better features has been a crucial necessity to improve the efficacy and safety of prescribed therapeutic options. Patients either skip doses or take less than the recommended dose due to their concerns about insulin therapy.<sup>[28]</sup> Several key concerns, which are associated with non-adherence to insulin therapy have been identified, off which several relate to the deficiencies in efficacy or safety profile of

existing insulin. Several independent risk factors like multiple injections, interference of injections with daily activities, and injection pain and embarrassment play a significant role in insulin omission.<sup>[29]</sup> To avoid multiple dosing, a truly basal insulin must be designed which requires once daily administration. Further, to have better efficacy and safety, a flat profile basal insulin, which mimics the pharmacokinetic/pharmacodynamic action of physiological insulin and ensures minimal intra-patient variability and longer duration of action is necessitated.

Better safety profile will lead to better acceptance of insulin therapy and the results from the recently concluded Outcome Reduction with an Initial Glargine Intervention (ORIGIN) trial which demonstrated that insulin is not significantly mitogenic, must be popularized in patients and physicians.<sup>[47]</sup> Another major concern associated with insulin therapy is the incidence of hypoglycemic events, perceived to be a result of insulin administration.<sup>[48]</sup> Designing insulin's which mimics the basal component of the physiological action of endogenous insulin secretion will allow for better glycemic control while avoiding or decreasing the risk of hypoglycemia. In an international survey of diabetes, patients and physicians showed that insulin with a lower incidence of hypoglycemic event was high on the wish list of both.<sup>[37]</sup> Cross-cultural references to hypoglycemia are currently varied and fail to provide a common basis for diagnosis of hypoglycemia and thus require standardization.

While improvements in currently available insulin modalities are important, the capacity of physicians to deal with contingencies arising out of insulin administration must also be enhanced. Embarrassment in taking insulin is one of the biggest stumbling blocks in regular insulin administration and easy-to-use insulin options must be designed for ease of administration in a variety of situations.<sup>[28]</sup> Long-acting insulin's, with lower frequency of dosing must be designed for better patient convenience, if and when possible. The need of insulin pumps, which are one such innovation, is growing in India with the recognition of multiple benefits associated with it. Indian insulin pump guidelines assist physicians for proper selection of the candidate to assure long term compliance and success.<sup>[49,50]</sup> For better outcomes, therapy must also be linked with timely and routine blood glucose monitoring. To enable this, partnership between the government and industry should be explored to facilitate free/highly subsidized distribution of self-monitoring blood glucose (SMBG) tools. Figure 1 summarizes the proposed solutions with respect to efficacy.

### Convenience and life-style

Diabetes management requires significant modifications in patient life-styles; new patterns of behavior and thought must be integrated into their everyday life and adherence

to these patterns must be consistent. Often these changes place consequential demands on time and resources of patients.<sup>[51]</sup> Patients are known to negatively view therapeutic recommendations for diabetes as demonstrated by the impact of therapy on patient quality of life (QoL). The negative impact of diabetes therapy on QoL extends to both pharmacological and life-style management recommendations.<sup>[52]</sup> This has led to low rates of adherence to therapy in many patients as seen from well-cited reports in the medical literature.<sup>[39,40,53]</sup> Effective monitoring of adherence to therapeutic measures by patients is needed to keep doctors informed of the on-ground behavior patterns of the patient. Evolving tools to monitor adherence of patients (daily journals etc.) to specific recommendations is necessary to provide information which will help make physicians' recommendations responsive to patient behavior.

A patient-centric approach of diabetes care must be built, which is sensitive to the needs of a patient and avoids placing an undue burden of therapy on the patient. An accelerated process of negotiation and motivation should be initiated, support enlisted from family, friends and paramedical staff, and a "finite" trial of appropriate therapy begun.<sup>[54]</sup> It is known that improved well-being, self-care, and diabetes control are seen in patients who report more involvement in making treatment decisions.<sup>[55]</sup> There is a need for the formulation of diabetes- and wallet-friendly recommendations.<sup>[56]</sup> The use of folk dance therapy is an example of recommendations which promote better outcomes without placing an undue burden on the patient.<sup>[57]</sup> In traditional societies like India, socio-cultural factors play an important role on determining patient attitude to diabetes and its management.<sup>[58]</sup> The therapeutic modalities must also bear in mind the socio-cultural sensitivities of patients which impact their ability to adhere to treatment recommendations (fasting, religious requirements etc.).<sup>[59]</sup> A large number of physicians find themselves unable to base their treatment decisions on culturally-dissonant western guidelines which do not accommodate uniquely Indian concerns (social and cultural).<sup>[21]</sup> Socio-culturally responsive Indian national guidelines must be evolved to address this need.

While, the physician is the central figure with oversight of the disease management process, the complex nature of diabetes management modalities require a comprehensive team-based approach to effectively deal with the individual aspects of care. Team-based care has been shown to be more effective in diabetes management, resulting in better care outcomes than conventional therapy without team care.<sup>[60]</sup> Hence, a pool of well-informed and adequately trained paramedical personnel must be created to counsel patients for facilitating better and easier adherence to therapy. The training of these personnel must be uniform

in content and quality and viable career opportunities must be ensured to encourage greater interest in such training. A greater degree of customization of therapy to individual needs can thus be achieved. The physician too must be empowered by improving motivational skills to make meaningful interventions and blending clinical knowledge with psychosocial support. Figure 1 summarizes the proposed solutions with respect to convenience and life-style.

### Education

Diabetes education and awareness of the disease is an important modulator of the success of a therapeutic strategy. The two components of an effective diabetes awareness program need to encompass: (a) Strategies to reach out to the general populace to spread awareness of the disease and its complications and (b) educate and reach out to diabetes patients and physicians to improve outcomes. Spreading awareness about diabetes in India will require a large outlay of resources and efforts to succeed. Given the vastly varied demography of India, multiple modes of communication need to be utilized to spread awareness of diabetes and its complications. There is a need to increase the awareness of public and physicians on modern medicinal care like insulin analogues and the harmful effects of dependence on alternate and complementary medicine for patients with diabetes. A strategy utilizing both conventional (dramas, skits, newspaper, TV etc.) and non-conventional (internet, short message service, mobile phone apps etc.) modes of communication must be adopted to maximize the reach of diabetes education programs. Diabetes awareness programs conducted through community involvement have reported improved awareness about diabetes and its complications in a South Indian city.<sup>[61]</sup> Cost effectiveness of telemedicine based multi-disciplinary care in achieving glycemic targets and providing continuous education may be considered. Titration of insulin and oral drugs in this program precludes the need for physical visits to the hospital and avoids hypoglycemia even in patients on insulin therapy.<sup>[62]</sup> Popular figures and community leaders can prove to be an invaluable part of such awareness programs for popularizing insulin therapy. The inauguration of a program on “Changing Diabetes in Children” by former President APJ Abdul Kalam is an example of increasing awareness through public personalities. The program observed huge media coverage and increased awareness among public from all the states of India about the needs of children with type 1 diabetes. Similarly, Changing Diabetes Barometer, a public-private-partnership program launched in five states of India to improve lives of people with diabetes observed an increased awareness and glycemic control in patients from all these states after diabetes awareness programs. As media lays a pivotal role in the dissemination of information, sensitizing mass media personnel about the importance and the factual details of insulin will help in

the dissemination of accurate information on insulin use.

Educational programs must be simultaneously planned to educate and sensitize various stakeholders in diabetes management about the disease and insulin therapy.<sup>[63]</sup> Uniformity of content in diverse diabetes education programs especially with regard to insulin therapy must be ensured, to assure consistency of information across various levels of care. To ensure multi-stakeholder participation and to reflect a broad consensus of opinions, recommendations for promoting insulin therapy should be endorsed by national-level organizations.<sup>[64]</sup> The information resources and communication processes thus created can often be challenging for the patient to comprehend and translate into simple applicable everyday strategies for diabetes care. It must become a matter of routine for endocrinologists to teach their patients with diabetes the difficult nuances of self-monitoring, self-adjustment of insulin dosage, and sick day management.<sup>[65]</sup> As noted earlier there is a need to create space for specialized diabetes educators who will effectuate the larger goals of educating and raising awareness of diabetes and insulin therapy.<sup>[66]</sup>

Designing and implementing programs and strategies of such wide-ranging consequences requires collaboration and partnership between different constituents with an interest in diabetes care. Exploring multiple partnerships between the government and the private sector in diabetes education is one way of finding synergies between these constituents. In addition, integrating diabetes education across all levels of healthcare professionals (HCPs), patients and the community will ensure effective channels for flow of information. One final stakeholder in the care process that is often forgotten is the family of diabetes patients, who bear a significant burden of the disease indirectly. Designing family-centric education programs using a team of HCPs, to address the immediate care environment, i.e., the family will help in encouraging insulin use by patients. Figure 1 summarizes the proposed solutions with respect to education.

### SUMMARY

The current consensus paper summarizes the key barriers in the initiation and intensification of insulin therapy in diabetes care and proposes solutions to overcome these barriers. The triumvirate of barriers includes: (a) Concerns about the efficacy and safety, which are fed by (b) the perceived impact on patients' life-style and (c) the lack of information or dissemination of inaccurate information about insulin therapy. Addressing concerns about the efficacy and safety of insulin therapy will require using innovation to create new insulin products. Ultra-long, flat action insulin that is truly basal in nature with improved

physiologic profile, minimum risk of hypoglycemia and weight gain is high on the wish-list of both physicians and patients, world-wide. Patients must be enabled to effectively use insulin for improved outcomes by linking monitoring of blood glucose (with cost-effective self-monitoring devices) to insulin therapy. Patient-centric treatment modalities must be created to help in the easy integration of the treatment process in patients' life-style. A team-based view of the care process, which caters to different aspects of patients' well-being is known to improve care outcomes and can help in creating resources for better monitoring patients' adherence to recommendations.

Simultaneously, patients must be educated about the inevitable need for and benefits of insulin therapy. Ensuring consistency of information about therapy across all levels of health-care is essential for effective diabetes education. Complementarily, recommendations which promote insulin use should be endorsed by national-level organizations to promote dissemination of accurate bias-free information from varied sources. To empower patients to easily access and adapt this information in their everyday life, certified paramedical staff for diabetes education are needed. The central role of families in creating the immediate context of patient care in India must be recognized in diabetes education, too.

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