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Review

Consensus recommendations on exploring effective solutions for the rising cost of diabetes



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ABSTRACT

Diabetes remains asymptomatic for a long period of time and its real burden gets noticed only once the complications set in. The number of individuals affected with the disease is also on the rise and more so in the low income countries. This scenario calls for urgent precautionary measures that need to be undertaken to equip ourselves to fight against this chronic disease. Individuals with financial constraints cannot afford to access even the basic treatment facilities and thus stands the most burdened. The International Diabetes Federation calls for 'Eyes on Diabetes' for the society to focus on early screening and early intervention. The rising cost of diabetes results from delayed and denied treatment. The panel discussion organized as a part of 4th Annual global diabetes convention of Jothydev's Professional Education Forum (JPEF, 2016) facilitated a platform to address diabetes as a serious health concern that needs to be given immediate priority by the policymakers as well as public and also to discuss about the feasible measures that will help achieve cost effective and affordable diabetes treatment. This was followed by in-depth literature search and finally a set of recommendations have been arrived at by the key opinion leaders to realize the dream of affordable diabetes care to all deserving individuals.

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1. Background

Diabetes is a progressive disease and remains asymptomatic until complications set in. Uncontrolled diabetes, overtime, leads to complications such as cardiovascular diseases (CVD) [1,2], eye diseases [3], kidney diseases [4] and neurovascular limb diseases [5]. As per International Diabetes Federation (IDF) 2015 statistics, approximately 415 million people are affected with diabetes globally which is predicted to rise to 642 million by 2040 and the greatest increase is predicted to occur in low income countries than middle or high income countries. Around 318 million adults are also reported to be affected with impaired glucose tolerance [6,7].

The financial burden borne by diabetes affected individuals, their families as well as national health systems is enormous (see Table 1). Furthermore, with the onset of micro and macrovascular complications, the cost of therapy gets escalated more than 3 to 5 folds. A panel discussion was organized as a part of 4th Annual global diabetes convention of Jothydev's Professional Education Forum (JPEF 2016, held on August 20th–21st at Trivandrum, Kerala) to address diabetes as a serious health concern that needs to be paid significant attention by the policymakers as well as public and also to discuss about the feasible measures to make diabetes treatments cost effective and affordable. The Panel, chaired by Dr. Shaukat Sadikot (President, IDF) consisted of key opinion-leaders from India as well as from other parts of the world and represented a cross-section of the scientific society and policy-makers consisting of eminent physicians and healthcare professionals with wide range of experience in public sector, private sector and research. The current article is an amalgamation of inputs provided

by the key-opinion leaders, supplemented by extensive literature search and proposes feasible strategies that could be undertaken to attain affordable diabetes care to all deserving individuals.

2. Diabetes burden

In the case of middle and low income countries, diabetes is seen to affect more of younger populations (59% under the age of 50) in contrast to that of high-income countries (26% under the age of 50) [8,9]. This fact combined with the increased life expectancy makes diabetes a burden that needs to be borne for a longer period of time. Higher rates of urbanization, changes in dietary and lifestyle practices, gestational diabetes mellitus, intra-uterine malnutrition and foetal programming, and the 'thrifty genotype', reductions in infectious disease burden etc. serve as contributing factors towards this higher prevalence in diabetes [8,10]. The disease exerts a dramatic negative impact both on the patient's household budgets and overall healthcare budget of the government. Healthcare expenses seems to be two to three folds higher for patients with diabetes [6] and owing to the long standing nature of illness and its associated complications, management and treatment of diabetes is a costly concern especially for those belonging to middle or low income categories. Related complications that arise in the long run further escalate the burden and cost of diabetes [11].

3. The economics of diabetes management

Around 12% of global health expenditure is estimated to be disbursed towards diabetes care whereas a developing country like India with second-highest number of people living with diabetes

Table 1
Major reasons behind rising cost of diabetes.

- Dearth of regular screening programs that aids in early detection and management of the disease
- Absence of proper awareness about the disease and its management among patients and their supporting members
- Patients non-complaint during initial years when diabetes is asymptomatic
- Newer therapies and ancillary supplies being expensive
- Lack of proper financial support or insurance schemes for the deserving patients to meet the treatment expenses often resulting in increased drop-out rates
- Use of complementary and alternative medicinal (CAM) practices with unproven benefits leading to future complications
- Practitioners not being aware of CAM use by patients and resulting in undesirable drug interactions and associated complications
- Widespread advertisements in print and electronic media giving fake publicity to unproven therapies and unhealthy fast-food culture
- Wrong injection techniques and wrong timing of oral anti-diabetic drugs resulting in treatment failure and development of future complications
- Lack of proper training among the practitioners regarding chronic disease management and sub-optimal knowledge of clinical practice protocols
- 'Clinical inertia' among the physicians to start on insulin therapy and sub-optimal intensification of therapy due to the fear of hypoglycaemia
- Time constraints faced by the physician to spend more time with the patient to teach them and impart them education

(69.2 million), spends only less than 3% of the global total expenditure on diabetes [6]. A population based, cost of illness study from India estimated the direct cost (medical and non-medical) towards treatment of diabetes and its complications, indirect cost associated with loss in productivity due to diabetes related morbidity and intangible cost associated with pain and sufferings. Patients and their families mostly relies on household incomes to meet almost 85–95% of all healthcare costs and thus the lowest income group stands the most burdened. A low income family was found to spend as much as 20% of its family income for an adult with diabetes and up to 35% of income for a child with diabetes. In average, over a period of five years, a diabetes affected person will have set aside around Rs. 150,000 towards diabetes treatment [12,13].

4. Recommendations for reducing the costs of diabetes treatment

The following recommendations have been proposed by the panel members that can aid in dispensing affordable diabetes care to all the diabetes affected individuals irrespective of their socio-economic status. Key strategies are cited in Fig. 1.

4.1. Early detection

Diabetes, if screened at a very early stage and managed professionally by a multi-disciplinary team, will not turn out to be

an expensive disease. However due to its asymptomatic nature, diabetes can remain undiagnosed for several years and by the time diagnosis is made; patients would have already developed further complications [14].

Screening for diabetes and pre-diabetes is highly recommended by American Diabetes Association (ADA) for all individuals 45 years and older and also for adults with BMI ≥ 25 kg/m² who have additional risk factors like physical inactivity, a first-degree relative with diabetes, belonging to a high-risk ethnic population, and having a history of gestational diabetes, polycystic ovary syndrome, or one of several clinical risk factors such as hypertension, abnormal levels of HDL, triglycerides, A1C, IGT, IFG, or cardiovascular disease. Separate testing and disease management criteria have been proposed for pregnant women and children [15–17]. In Asian Indians who belongs to high-risk ethnic population, just meeting the diagnostic criterion of BMI ≥ 25 kg/m² itself puts them at high risk of developing diabetes and available evidences strongly endorses lower limits for ideal BMI among populations with Asian origin [18–20]. High population density compounded with limited resources a characteristic of most of the developing countries, often makes it cumbersome to conduct regular screening programmes for its whole population. Several feasible approaches such as entire population, opportunistic and targeted screenings have been proposed by WHO [21]. A simpler screening method, Finnish Diabetes Risk Score (FINDRISC) has been validated and allows screening a large number of individuals [22,23].

Early detection

- *Regular monitoring and screening programmes*
- *Empower locally available staff to conduct screening programmes*

Spreading awareness among the public

- *Lifestyle interventions (diet and physical activity modifications)*
- *Legal actions against unscientific remedies and magical therapies*
- *Legal actions against unethical advertisements*

Affordable and accessible healthcare

- *Rational prescribing of drugs*
- *Subsidized healthcare*
- *Community insurance schemes*
- *Discount pharmacies*
- *Government supported community health programmes*
- *Government initiatives to monitor and control the prices*
- *Delivery of essential medicines at the doorsteps*
- *Multidisciplinary team based telehealth modalities*
- *Integrating healthcare systems into a clinical network*
- *Promote local research for the development of economic and cheaper therapies*
- *Explore for evidence based indigenous therapies*

Educating the practitioners

- *Standardized Clinical practice guidelines*
- *Training in chronic disease management*
- *Awareness on appropriate initiation and intensification of therapy*
- *Importance of multidisciplinary team approach*

Role of media

- *Spreading awareness among public and practitioners*

Fig. 1. Key recommendations for reducing the cost of diabetes care.

The dependency on specialist centres for regular monitoring and screening for diabetes and its complications should be reformed such that general physicians, primary health workers, diabetes educators, nurses or any locally available medical professionals are equipped to provide the necessary screening and identify patients at risk and guide them for early specialist intervention. Specific training should be provided for these medical professionals so that these resources could be efficient and relied upon.

4.2. Spreading awareness among the public

Diabetes in India (CODI) and Bangalore Urban District (BUD) diabetes studies pointed out that delayed diagnosis of diabetes and occurrence of disabling complications were highly related with the awareness about the disease, employment and educational status (college educated individuals were diagnosed on average 7 years earlier than the illiterate counterparts) [24]. Individuals with better educational status showed lesser complications (55%) than the poorly educated category (80%) [25]. Notion of seriousness about diabetes arises in the common man only when the complications set in. Before that they are not thoughtful with the management of the disease. Numerous instances are observed where even after diagnosis of pre-diabetes, patients fail to get motivated towards adopting precautionary measures and finally end up with diabetes within few years. Patient compliance thus forms the corner stone in diabetes prevention, diagnosis as well as management. Building awareness and educating the public on these aspects can do wonders in combating this deadly disease.

4.2.1. Life style interventions

Before embarking on any therapeutic modalities for diabetes treatment, prior emphasis must be given on lifestyle modifications since such interventions are more effective, cheaper and safer than medications and have also been found to provide sustained benefits [10,22,26,27]. Several studies have been reported that assessed the applicability of lifestyle and other non-pharmacological interventions in preventing T2DM and its complications in developing countries [28]. Progression rates from pre-diabetes to diabetes have been found to be reduced through lifestyle interventions by almost 40% in the Da Qing study, by 58% in the Finnish Diabetes Prevention Study (DPS) and by 58% in the Diabetes Prevention Program [29]. Furthermore, Diabetes Prevention Program Outcomes Study (DPPOS) revealed that participants who returned to normoglycemia at least once during the Diabetes Prevention Program (DPP) were associated with a significantly reduced risk of developing diabetes in future [30]. Similar findings were also reported by DPS where, the maintenance of beneficial lifestyle changes even after the discontinuation of the intervention led to a 36% relative risk reduction [31]. Several aspects such as good family support, availability of spare time, higher health consciousness, more frequent visits to dietician, advice that includes elements to promote overall health, diet counselling that is easy to understand and adopt are known to have a positive impact on patient compliance. Barriers to compliance either patient related or healthcare provider related could be overcome by changing the approach from transactional to that of a motivated team based one [32]. Government of India, in collaboration with its state governments have also launched several diabetes awareness and screening programs focussing on diabetes and related complications [33]. National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS) is one such initiative with an aim to increase awareness among individuals regarding the risk factors of NCDs and significance of lifestyle changes [34].

Awareness programmes can turn out more productive and cost-effective if, (i) they are included in the school curriculum which will help nurture healthy lifestyle habits in younger generations and (ii) by imparting preliminary training to non-medical persons in order to get actively involved in community outreach programmes. In addition to creating awareness, appropriate amenities (customised food, areas for physical activities etc.) must be made available along with special efforts to make the environment more cordial for accomplishing such lifestyle interventions.

4.2.2. Legal actions against unscientific remedies and magical therapies

A major issue that poses as a limiting factor to accomplishing effective diabetes care is with regard to the use of unproven complementary and alternative medicines (CAM) [35]. There could be CAM therapies which are effective in glucose reduction but there is little evidence on their consistency and little knowledge is available regarding their long term efficacy and drug interactions. Even so, such “magical remedies” attract many which include even the educated lot, due to the misconceptions regarding their safety and efficacy, cost effectiveness etc. This situation is of much relevance to India where, due to its tradition and a rich history of healing practices, almost 67% of its diabetes affected population follows some form of CAM [36]. Unfortunately in most of the cases, the conventional health practitioners are not aware about CAM use by their patients. Patients may combine or stop the conventional drugs (that have undergone clinical trials) when they start such unscientific remedies. Finally after a couple of years, when they find these unconventional approaches failing to manage their disease, they get back to modern medicine. Too late since, they might then require costlier interventions due to their declining health status.

Given the possible harmful effects of CAM use such as drug interactions, adulterations etc. [37], clinicians must be more vigilant and understand the potential impact of these unproven therapies on diabetes management. They must put in efforts to alert their patients regarding cautious use of these practices [38]. Government should frame stricter guidelines for such therapeutic practices and appropriate legal actions should be imposed on those which deviate from these mandatory norms.

4.2.3. Legal actions against unethical advertisements

Now-a-days, media is found loaded with enormous amount of fake publicity and advices. Many a times, the alternative systems of medicine and some unscientific therapies as mentioned above are massively advertised in the media with claims of curing diabetes. This gives a wrong idea to the general public and incidences have been reported where they stop all the therapies including insulin resulting in serious mishaps [39,40]. Issues concerning promotion of unproven drugs for treating diabetes and dyslipidemia were raised by Luthra et al. They attributed the rapid growth of therapeutics market to, the anticipated approval and introduction of new drugs coupled with increasing prevalence of diabetes. Media as well as other professional forums often gives huge publicity to these unproven drugs or remedies merely with a marketing point of view, seldom based on any scientific facts [41]. Another serious concern which requires prompt attention is the way fast foods are getting so popularised via media which has gradually started to change the conventional diet patterns, especially among the younger generation.

The spread of such misleading information and fake advices should be restricted legally so as to prevent any unhealthy consequences. Furthermore, medical professionals should get actively involved through conventional as well as social media and contribute to educating the public.

4.3. Affordable and accessible healthcare

Physicians and individuals with diabetes are always excited about the latest new drug or technological development in diabetes, and justifiably so, as many of these make a real difference to patients' lives. Nevertheless they are expensive and many health care systems and individuals cannot afford them. Even the wealthy people are concerned about the cost of therapy and hence the treatment options are more based on cost and not based on guidelines which again increase the future escalation of cost by several fold. Access to uninterrupted supply of insulin (as a minimum, regular quick-acting human insulin and longer-acting NPH-insulin) has been recommended by International Diabetes Federation (IDF) to all T1DM individuals worldwide. Likewise, well-established and most effective oral anti-diabetic agents like metformin, and gliclazide a sulfonylurea are recommended by the World Health Organization (WHO) and IDF for T2DM individuals [6]. However, the expenses incurred in terms of medications and medical supplies are often not covered under any government schemes or by insurance providers thus leading to suboptimal diabetes care particularly in developing countries [10].

Only 10–12% of the patients with diabetes receive modern pharmacological treatment as demonstrated by the estimates from sales of anti-diabetic pharmaceuticals [42]. The common man always desires for a reasonable cost to get his disease treated and hence when it comes to selecting a treatment modality, most practitioners are forced to decide based on the financial condition of their patients. Very often patients take advice, spend money and are forced to cut off somewhere else causing their family to suffer. Insurance schemes are less resorted to and mostly unaffordable to the common man. Patients from low and middle income groups were not enrolled in any such schemes while only 2% of high income group were dependent on them. Low literacy rate and limited awareness levels are other reasons for less insurance coverage in the low and middle income groups. This scenario often leads the patients to depend on loan or mortgage their assets to meet these unbearable expenses [43].

4.3.1. Rational prescribing of drugs

Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) emphasises that the diabetes therapy should be individualized in terms of both treatment targets and treatment strategies. The options should be given to the patients and the choice of therapy should result from a shared decision making, not taken by the physician alone [44]. It is imperative that a physician need to weigh out the circumstances of the patients in terms of affordability, before deciding on the treatment modality. He should be able to come up with a solution wherein the patient gets the best available treatment at the cost that he/she can bear. Prices of medications of difference strengths are often similarly priced. Physicians can opt to prescribe scored tablets that contain a higher dosage than required by the patient so that it could be divided to obtain the required dose. This practice will aid the patients to access essential medicines cost effectively [45,46]. A large part of the medical expenditure is known to be wasted in terms of irrational prescribing, dispensing and patient use of medicine. This trend can be halted to a large extent if clinicians can avoid prescribing un-necessary medicines like multivitamins, minerals and enzymes unless it is highly essential for the patient. The Essential Drug List (EDL) by WHO turns out to be a very handy tool which frequently updates the practitioners on essential drugs available and thus aids them to prescribe the medicines in a rational way. Special interests must be taken to prescribe less expensive generic drugs rather than costlier brand-name drugs. Prescribing medications which demand less frequent monitoring is also worthwhile. Such

approaches will help enhance the patient compliance by decreasing the drop-out rates arising from higher treatment expenditures [47–50].

4.3.2. Subsidies, community insurance schemes, discount pharmacies

Pharmaceutical companies must undertake possible measures to maintain pricing schemes that are affordable for the least developed countries and this pricing should also be available through NGO and voluntary organizations. Patient assistance programs (PAPs) sponsored by certain pharmaceutical companies have been helpful to provide access to brand-name medications at negligible costs to patients facing financial constraints [51]. Organizations like WHO should assist countries in developing policies to reduce the price of medicines and increase the availability of quality assured generic medicines. Medicines may be purchased in bulk by professional bodies of physicians and supplied to the needy patients based on the recommendations by their members. Patients groups or organizations should raise their voice against abnormal price hike and counsel their members for proper control of diabetes and prevention of complications.

Earlier, diabetes was excluded from eligible list of insurance claims and currently, the scenario has started to change with many new schemes being introduced, though with several riders. However, presence of these riders often poses a hindrance to patients from claiming reimbursement for the vast majority of their expenses [52]. Government must take initiatives to monitor and control the prices, availability and affordability of diabetes medicines with transparent publications. Patients from low income categories should be supported by means of subsidies and social insurance schemes. A well-designed community health insurance scheme managed by a trustworthy organization, can improve access and provide quality healthcare to vulnerable sections of the society [53,54]. A government controlled community health programme to focus on diabetes and related complications need to be implemented at least in the government facilities, starting from primary healthcare centres to the district hospitals. Such a scheme should enable access to an economical treatment with continuous follow-up, to all sections of the community. It should also include provisions for continuous availability of accessories for diabetes monitoring and management such as glucometers, test-strips, syringes and essential drugs at affordable rates. Discount pharmacies like Affordable Medicines and Reliable Implants for Treatment (AMRIT) which distributes drugs for cancer and heart diseases at subsidised rates is an example of one such noteworthy initiative by Government of India [55]. Appropriate measures could also be undertaken to promote local research for the development of economic and cheaper therapies and also explore for evidence based indigenous therapies. Apart from the cost of the drugs, the cost required to procure these medicines in terms of travel expenses also restricts individuals from approaching healthcare services especially during initial stages of the disease and hence it would be commendable if initiatives are also taken to implement programmes that will facilitate preliminary screening as well as delivering essential medicines literally at the doorsteps.

4.3.3. Multidisciplinary team based telehealth modalities

Usefulness of telemedicine facility such as DTMS[®] for diabetes management where patients report their blood glucose levels and health status via phone, email or secure website to get therapeutic or lifestyle advices from a the multi-disciplinary team is well established as a cost effective option. Initially, there will be an extra cost for availing the telemedicine facilities whereas future escalations in costs in terms of treating complications may be successfully avoided. This approach also reduces the number of physical visits to the clinic and also aids patients in attaining their

glycaemic targets [56]. The Chunampet Rural Diabetes Prevention Project (CRDPP) is another telemedicine model which used a tele-diabetology mobile van loaded with appropriate diagnostic facilities, trained multidisciplinary team and satellite technology. It was proven successful in screening and delivering diabetes care to rural areas of India where such facilities hardly exists [57].

4.3.4. Integrating healthcare systems into a clinical network

Screening and prevention programmes can be conducted cost effectively by integrating different healthcare systems under one roof. Data from routine clinical information systems could be used to identify individuals at risk for diabetes or the patient samples taken during a particular screening programme say, cardiovascular might be used for screening diabetes. As in the case of diabetes, HIV and tuberculosis which often exist as co-morbid conditions, the prevention and care of these diseases may be integrated into a clinical network [21,58].

4.4. Educating the practitioners

Most of the times, it is seen that the patients initially approach general practitioners for treating diabetes. Sub-optimal knowledge of protocols for clinical practice among these physicians, huge number of patients, constraints of time and facilities etc. often lead to treatment failures and poor patient outcomes. Ideally the doctor needs to spend 15–20 min with the patient for administering all the measures that have been described in this manuscript such as discussing the therapies, a shared decision making based on patients choices, discussing the benefits and side effects of drugs, timing of medications etc. Taking the example of India, known to have a low doctor to patient ratio [59], discussing the choices with the patient and then choosing the option based on a shared decision making is never feasible. Besides, doctors are usually trained in acute management of the disease and not much focus is given on the applicability of a long term treatment protocol to prevent complications of diabetes. Situation seen in hospitals is not different, where the treatment modality that one hospital follows will be totally different from that by another one. Screening protocols are seldom followed which leads to ineffective management and prevention of the disease. HbA1c tests or even practice of regular monitoring of blood glucose are never given proper emphasis, neither at the government centres nor at speciality clinics [33]. Among primary care physicians who often form the primary point of contact due to unavailability of specialists care, knowledge about modern treatment options such as insulin regimen is relatively poor. In Indian scenario, approximately 8–10 years are spent on an HbA1c above 9% before the patients are initiated on insulin. This late initiation of insulin as well as suboptimal intensification of therapy is mainly due to the underlying fear of hypoglycaemia. The same trend is also observed among patients where, they exhibit a tendency to either reduce the dose of insulin or totally eliminate insulin therapy so as to avoid hypoglycaemic events. This issue was raised as one of the major challenges in management of T1D in South East Asian countries. Improper injection techniques and wrong timings of drug administration seen among patients are also noted as the reasons for treatment failures [60–62].

Western guidelines not being entirely applicable to all individuals, framing of ethnic-specific guidelines should be given emphasis in order to address prevention, diagnosis, and management of diabetes [63–65]. In order to keep health practitioners updated on clinical practice protocols, conduct of continued medical education and regular interaction programmes among PCPs, endocrinologists and diabetologists should be considered a priority [60]. A multidisciplinary team based comprehensive approach involving diabetes educators, nurses, dieticians and

pharmacists in the diabetes prevention and management programmes is highly recommended. A well trained team also reduce the burden on clinicians and will be able to instil awareness among the patients by spending more time with them and ensure that they are adhering to the prescribed interventions [66,67].

4.5. Role of media

Media can play a central role in spreading awareness, educating as well as motivating the public and the practitioners on various aspects like importance of early diagnosis, management of diabetes and prevention of related complications, role of lifestyle modifications, information on various patient support schemes, advancements in treatment modalities, harmful effects of unproven therapies etc. To maximise the outreach, both conventional (dramas, skits, newspaper, TV etc.) and non-conventional (internet, short message service, mobile phone apps etc.) modes of communication can be used to spread the message. Social acceptance of these awareness programs can be enhanced if public figures are made to participate in these campaigns [68].

5. Conclusions

It is high time that we come up with simple framework and ethnic-specific clinical practice recommendations for screening, preventing as well as managing diabetes that are relevant to the socio-economic norms of a particular nation. In developing countries majority of the population being below the poverty line and living in rural areas, these guidelines should at first hand be applicable to these individuals. The simple strategies which are suggested here are expected to turn helpful in achieving effective and affordable healthcare to all deserving individuals with robust support of various stakeholders including government and non-governmental agencies, health practitioners, pharmaceutical industries and media.

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