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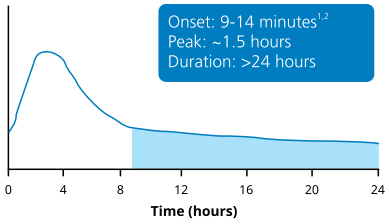

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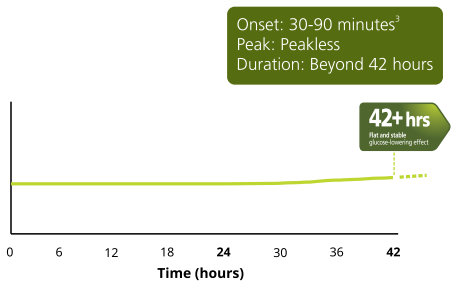

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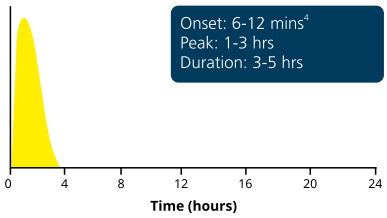

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JOURNAL OF DIABETES EDUCATION

To Dispel Darkness of Diabetes

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CONTENTS

PSYCHOSOCIAL AND ECONOMIC PROBLEMS IN TYPE 1 DM

Rishi Shukla* , Vibha Yadav**

Background

Type 1 diabetes mellitus (T1DM) is a prevalent chronic disease that affects children and adolescents. Based on current data, approximately 651,700 children worldwide are affected by this severe condition. The peak onset of T1DM typically occurs between the ages of 10-14 years, a critical period for mental and social development. This disease is accompanied by various complications which tend to increase in frequency and severity with increasing duration of the disease.

Every child possesses unique qualities and experiences that shape their behavior and personality, which also evolve as they grow older. Each individual holds their own perspective regarding their disease. The primary concerns revolve around the psychological and socioeconomic struggles faced by individuals with T1DM. These challenges may arise due to the chronic nature of the disease, its complicated and expensive treatment as well as the lack of awareness among the general public. Both genders are equally affected by T1DM but females often experience additional challenges related to marriage and relationships. However, there are also shortcomings on the part of physicians. Frequently, they fail to dedicate sufficient time or address the mental health of these individuals. They neglect to inquire about person's real-life challenges and often employ complex medical terminology while explaining the management of the disease. Furthermore, they tend to treat every child on a standardized platform, disregarding their unique circumstances.

Parents

Parents play a crucial role in the management of T1DM, shouldering the responsibilities of medication, nutrition and overall care. However, this responsibility often comes with its own set of challenges. Not only parents have to deal with the demands of their own jobs but also have to navigate the complexities of caring for a child with diabetes. The diagnosis of T1DM can be overwhelming, causing shock and anxiety for parents. It is common for them to experience behavioral issues such as excessive rigidity, overprotection and depression. On the other hand, some parents may display denial and non-compliance in the face of their child's diagnosis.

Due to the anxiety surrounding their child's condition, parents often find themselves checking their child's blood glucose levels multiple times a day particularly after episodes of hyperglycemia or hypoglycemia. A study involving 102 diagnosed cases of T1DM revealed that within four weeks of diagnosis, most parents exhibited signs of depression, stress, anxiety and difficulties in managing and caring for their child's diabetes. The study also found that women tended to experience higher levels of anxiety.

Lack of education and knowledge regarding the management of acute complications like hypoglycemia can lead to serious consequences. In their pursuit of lower HbA1c levels, some

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parents resort to measures like restricting food intake, administering excessive insulin doses or even skipping both food and insulin administration. Meanwhile, other parents struggle to provide a balanced and healthy diet for their child with T1DM due to factors such as time constraint, financial limitation or a lack of awareness about available food options. This situation can create anxiety and frustration for parents. Additionally, some parents refuse to administer insulin to their children, fearing multiple injections and the potential for hypoglycemia. Instead, they turn to alternative home or indigenous therapies. Parents often lack faith in their adolescent children's ability to independently manage their diabetes, doubting their proficiency in administering insulin and handling acute complications.

The incidence of parental psychological distress ranges from 10% to 74% with an average of 33.5% of parents experiencing anxiety at the time of diagnosis and 19% experiencing it one to four years after the diagnosis. Parental psychological stress has a detrimental impact on the mental well-being of children with T1DM. Parents often live in constant fear of their child being accepted by society. In a study, 41 parents of children with T1DM were educated through at least three programs conducted by SPAD (Society for Prevention and Awareness of Diabetes). Subsequently, they were surveyed on their awareness of the disease, financial planning and social issues including marriage and social stigma. The results showed that 89% of parents understood the chronic nature of the disease, 25% were hesitant to disclose the condition in society and 75% grasped the concept of leading a normal life including marital relationships.

School

The diagnosis of T1DM can be shocking and anxiety-inducing for young children with limited understanding. It typically takes around 6-9 months for them to adapt to the disease. Children often feel different from their peers, hesitant to share their condition and experience a sense of shame leading to social isolation and depression. Some may even hold their parents responsible for the numerous daily injections they have to endure. Frustration arises from the restrictions on their food choices and they may feel suffocated and irritated by their parents' overprotective nature.

Many children manipulate their blood glucose log books just before their clinic visits either by not measuring their levels or by reporting fictitious high or low readings. Some children secretly consume sweets and chocolates, while others avoid eating altogether due to fear of multiple injections or out of anger. Older children may intentionally administer higher doses of insulin or skip doses to seek attention or express their anger.

Children face different challenges at school, often lacking proper medical facilities and feeling ashamed to take insulin in front of others. In order to fit in, they may eat snacks from the school canteen and engage in physical activity like their peers. Teachers often have limited awareness of T1DM and management of acute complications. Children are asked to test their blood sugar levels in unhygienic urinals and administer insulin. They may also be excluded from participating in school activities. A study conducted in schools revealed that 6.5% of children experienced bullying, 9.7% of schools lacked school nurses, 12.6% of schools wanted to keep the child's T1DM a secret, and 40.4% of schools provided full support to children with T1DM. Approximately 55.6% of children were able to administer insulin at school, but for children under the age of 6.5% of parents had to visit the school for insulin administration. A study reported that early diagnosis of T1DM (before age 5) was associated with a decline in cognitive function, particularly in boys.

Adolescence

During puberty, significant changes occur in both physical and emotional aspects of an individual due to fluctuation in hormone levels. Managing diabetes becomes challenging during this phase due to various factors such as uncontrolled exercise, irregular meals, risky behavior, poor

adherence to treatment and increased insulin resistance resulting from hormonal changes.

Adolescents often experience a revolution and denial phase when it comes to caring for their diabetes which is commonly referred to as "Diabetes burnout." This burnout is characterized by a combination of behavioral and emotional factors, including feelings of physical, mental and emotional exhaustion, detachment from self-care behaviors and the disease itself and a sense of powerlessness in dealing with diabetes.

Furthermore, adolescents face additional pressure as they strive to cope with the demands of stringent diabetes treatment while trying to keep up academically and participate in extracurricular activities. They often start their day early, skip breakfast, attend private tuition after school and may even miss insulin doses. The lack of time for physical activity due to their hectic schedule leads to fluctuations in their blood sugar levels and they may struggle to find adequate time to monitor their glucose levels.

Adolescents with T1DM also desire to fit in with their peers and adopt new social trends, often trying to minimize the stigma associated with their condition. Some teenage girls may reduce insulin doses to avoid weight gain, while boys may develop a tendency towards substance use and exhibit aggressive behaviour. Poor glycemic control during this phase can persist for around 5-7 years and the risk of complications increases for the following 6-10 years.

A study conducted among adolescents with T1DM showed that anxiety (15.5%) and mood disorders (3.9%) were the most common psychiatric disorders observed. Over one-third of the participants (31.9%) had experienced at least one psychiatric disorder in their lifetime. The study also found an association between the presence of psychiatric disorders and elevated HbA1c levels.

Overall, managing diabetes during adolescence can be particularly challenging due to the myriad of physical, emotional and social factors that adolescents face. It is important to provide support and guidance to help adolescents navigate through this phase and maintain optimal glycemic control.

Socio-economic issues

Social issues play a significant role in glycemic variation and control and they are also responsible for the development of depression, anxiety and diabetes distress in individuals with diabetes. In India, a developing nation, the management of T1DM presents challenges due to poverty, social acceptance of the disease, educational barriers, marriage concerns, nutritional deficiencies, limited job opportunities and relationship issues.

The financial constraints imposed by poverty often lead to treatment failure, poor adherence and complications in T1DM management. The absence of government reimbursement policies for T1DM treatment exacerbates these challenges. Additionally, lack of knowledge, awareness and low literacy rates contribute to suboptimal T1DM management. Caregivers and patients often struggle to understand the disease, its complications and the instructions provided to them. Consequently, some individuals turn to alternative remedies, diverting their attention from appropriate medical interventions.

Individuals with T1DM frequently experience anxiety regarding their careers. They question which jobs they should pursue and whether they should disclose their diabetes during interviews or among colleagues. Legally, individuals with T1DM are restricted from certain professions such as pilots, train drivers and defense services. However, they remain suitable for high-profile jobs like doctors, engineers, advocates and even sports. Nevertheless, concerns regarding career prospects persist.

With the diagnosis of T1DM in a child, parents often worry about their child's future marriage prospects, particularly in the case of girls. They fear societal acceptance and the ability of their child to assume responsibility for others. From childhood to adulthood, individuals with T1DM face numerous physical and emotional challenges

resulting in feelings of loneliness, misery, anxiety and agitation.

Marriage becomes a significant source of distress for T1DM individuals. They encounter numerous rejections solely due to their diabetes, despite possessing excellent education and high socioeconomic status. These rejections contribute to depression and a negative outlook on life. Individuals with T1DM often prefer to conceal their disease from potential partners, desiring genuine love and care rather than sympathy for their illness. Females in particular, face more difficulties in relationships compared to males.

Individuals with diabetes often face rigid attitudes from parents and relatives who may oppose their marriage to a T1DM individual. In a study, it was observed that 70% of females preferred arranged marriages despite the option of love marriages.

Post-marriage, specific issues require attention, such as safe sex counseling, genital hygiene, contraception, preconception counseling and management of high-risk pregnancies. Regular follow-up visits with clinicians, dieticians, psychologists and counselors, preferably on an annual or six-monthly basis should be arranged.

A survey following T1DM patients of both genders over a span of 20 years revealed their fear of marriages and relationships. While T1DM females were often willing to marry T1DM males, T1DM males generally expressed unwillingness to marry T1DM females. In such instances, clinicians should strive to address misconceptions, provide counseling and discuss relevant issues with young adults and their families in a nonjudgmental, empathetic manner.

Emotional burden in T1DM was found to be associated with younger age, female gender, shorter diabetes duration, lower education levels, comorbid chronic illnesses, lower quality of life and lower diabetes support. Women tend to experience a higher emotional burden than men with T1DM.

From childhood onward, individuals with T1DM encounter numerous challenges that affect their daily lives. These challenges include adapting to multiple insulin injections, adhering to a strict diet, facing bullying from peers and experiencing rejections in relationships, marriage and job opportunities. It is imperative for us to take on the responsibility of supporting them and making their lives easier, happier and more meaningful. In our study concerning the effects of mindful meditation on individuals with T1DM, we observed a significant decrease in psychological stress levels, leading to improved glycemic control and overall enhancement in quality of life.

Smaller steps have better outcomes

1) It is essential to create greater awareness among the public about T1DM. We should develop robust educational awareness programs targeting individuals with T1DM as well as their friends and families.
2) The media can play a significant role in dispelling myths and misconceptions surrounding T1DM.
3) Promoting women's financial independence through education and expanded career opportunities is crucial.
4) We should encourage an open-minded acceptance of love marriages, disregarding orthodox traditions of caste and religion that may hinder the union of individuals with T1DM.
5) Including sessions with psychologists during regular visits can help reduce diabetes distress and address other psychological disorders.
6) It is important to provide comprehensive preconception and high-risk pregnancy management facilities at affordable costs in a single hospital setting.
7) To foster equality and combat the perception of T1DM individuals as "sick," a well-structured awareness campaign is needed to educate society about T1DM and its impact on relationships.
8) Effective communication should be conducted in a positive manner, as positivity

can greatly contribute to the happiness and resilience of individuals with T1DM. Additionally, practices such as meditation can have transformative effects.

9) A multidisciplinary approach to T1DM management involving diabetologists, dieticians, counselors and psychologists should be followed.

10) Maintaining a regular follow-up checklist can help monitor compliance, insulin administration and dose titration.

11) The government should take initiatives to alleviate the financial burden of families dealing with T1DM by implementing measures aimed at reducing their financial strain.

Conclusion

Type 1 diabetes mellitus presents numerous challenges for children, parents and adolescents impacting their physical, emotional and social well-being. The management of T1DM requires a comprehensive approach that addresses the unique needs of each individual. Awareness campaigns, media involvement and education are crucial in dispelling misconceptions and promoting understanding in society. Providing support to parents, adolescents and individuals with T1DM through counselling and psychological interventions is useful. Social initiatives in form of informal gathering, thought and meal sharing is an effective tool to help. A multidisciplinary approach involving healthcare professionals, educators and policymakers is necessary to ensure optimal T1DM management and improve the quality of life for those affected. Government support in terms of financial assistance and policy reforms is vital to alleviate the economic burden on families. By implementing these smaller steps, we can create a more supportive and inclusive environment for individuals with T1DM helping them lead happier, healthier lives.

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PSYCHOSOCIAL AND ECONOMIC PROBLEMS IN TYPE 2 DM

Shobha A. Udipi*

Ensuring good health and wellbeing as well as preventing and minimizing micro- and macro-vascular complications is the goal of diabetes management. This can be achieved through life long adherence to dietary and exercise plans, regular physical activity, adherence to the medical prescriptions and frequent glucose monitoring. The keys to these are self-awareness, self-management and self-control that are essential for self-care behaviour. Self-care behaviour is associated with personality characteristics such as openness, conscientiousness, extraversion, agreeableness, neuroticism.

Openness: Such persons tend to have open and honest communication with the physician and health care team and are prepared to work with the team to develop a self-care plan. Conscientious persons are more consistent at self-care that includes glucose monitoring, physical activity and regular visits to physician. They are less impulsive, have control over impulsive eating and are more organized and so tend to have better glycemic control. Extraversive people are more social and talk more, are less introverted and value broad experiences. Good self-care is also associated with agreeableness i.e. willingness of the person to take a favorable view of the care plan and advice given. A person who is neurotic is likely to be emotionally unstable, is anxious, fearful, tends to worry persistently, thinks too much and may be in a negative mood. These personality traits need to be considered because they can interfere with self-management, adherence to the care plan and could contribute to increased likelihood of the person with diabetes developing psychiatric comorbidity.

Whatever the disease or disorder, every person with diabetes is likely to face one or more challenges. These challenges are life long and often multiply, requiring the person as well as his/her family to develop strategies to tackle the challenges as and when they encounter them. This brings the importance of the fact that health and disease are not just biological phenomena but the socio-cultural and economic environment in which we live, our culture, faith, taboos and beliefs all influence our health. Just having the health problem itself can be a source of anxiety and stress. Persons with chronic disease often struggle with several challenges simultaneously: expenditure on the illness, perhaps social isolation, loneliness, one or more disability, discomfort or even pain, fatigue, feelings of distress, anger, hopelessness, frustration, anxiety and even depression in some cases. Depression itself can result in lethargy and lack of motivation, indecisiveness, low energy levels and mood swings. Depression can compromise the management of diabetes because the person may not want to undertake exercise and physical activity, may indulge in unhealthy behaviours such as smoking, drinking and consumption of unhealthy foods. More often than not, there is a bidirectional relationship between such behaviours and the physical and psychological effects. Thus, living with a chronic disease could adversely influence not only the person's physical state but also the mental and social functions and have implications for the quality of life.

Diabetes-Related Distress (DRD) is experienced by persons with diabetes. It is defined as an individual's concern about disease management, support, emotional burden and access to care. Diabetes-related distress could be more in those whose BMI is higher and/or who have had diabetes for a longer duration and whose HbA1c

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levels are elevated. People with diabetes that are younger and have less social support and lower self-efficacy also may be at risk of DRD. Type D personality has also been associated with DRD. A Type D person tends to be negative and in social interactions, their emotional expression tends to be restricted. It has been found that persons with diabetes who are Type D personality are likely to have problems complying with the treatment especially the prescription and routine check-ups with the physician. They also do not have a positive attitude about following recommendations for physical activity and controlling BMI or consumption of high energy foods or even controlling cholesterol levels. They are also likely to have depression and anxiety. Overall, for such persons the prognosis may not be favorable since the clinical consequences would be adverse.

Diabetes-related distress is concerned about emotional experiences of people with diabetes mellitus, their concerns about its management, support or its lack thereof, emotional burden and access to health care. It has been estimated that about half of persons with diabetes have DRD and it has been found in about half the persons within three months of being diagnosed. In the Western world, anywhere from 18% to 63% persons with diabetes have been found to have DRD. In mainland China, the prevalence of DRD was found to be 64% in two public hospitals. Several factors contribute to DRD but they are content and context-specific to living with diabetes. Besides personality characteristics, the strain of coping with changes in the life routine, family conflict, non-conducive living and/or work environments, the fear of or the presence of comorbidities in addition to economic insecurity are all contributory factors. Some individuals could feel powerless and there could be despair and a fatalistic attitude.

DRD should be addressed because it has been found to be associated with higher diastolic blood pressure, increased LDL cholesterol levels as well as elevated glycated HbA1c levels. Also, there is an increased risk of cardiovascular disease. During a two-year follow up study, at 6 and 18 months respectively, DRD was found to be predictive for adherence to medication and glycated hemoglobin. If left unmanaged, DRD which is essentially a maladaptive process, can adversely affect glycemic control and increase the risk of cardiovascular complications besides compromising the quality of life. Left unattended DRD could lead to depression.

DRD poses considerable challenges for the medical/care team including the educators. These challenges include:

- Psychological insulin resistance - the person has a strong negative response when the health care provider recommends that adding insulin to the treatment regimen would help in diabetes management. The person could be anxious or lack confidence about self-administering insulin injections.
- There could be fear of hypoglycemia particularly nocturnal hypoglycemia. Many persons may consume carbohydrate or sugar containing foods in amounts that are not required, resulting in compensatory hyperglycemia and may do so without objectively confirming the suspected hypoglycemia by measuring the capillary blood glucose concentrations.
- There could be physician distress as well.

Symptoms of DRD can be emotional, vegetative, behavioural and/or cognitive as shown in the Table 1:

Table 1

Symptoms and features of Diabetes-Related Distress

Symptoms	Features
Emotional	sleep, appetite, fear, worry, anger, guilt, sadness, frustration, low energy levels and burn out
Vegetative	low mood, reduced enjoyment of usual activities
Behavioural	agitation or slowing of movements
Cognitive	poor memory or reduced concentration or feelings of guilt; thoughts of self-harm

Source: D.J. Robinson et al. Can J Diabetes, 2018

Comorbid depression worsens clinical outcomes, possibly because there is lethargy and lower levels of motivation for self-care. Ultimately, there could be a downward spiral leading to lower physical and psychological fitness and then higher use of health-care services concomitantly with the possibility of reduced participation in medication regimens.

Thus, is important to pay attention to DRD as an integral part of the care process throughout the lifespan of the person. The American Diabetes Association has recommended that evaluation of psychosocial factors should be included in all diabetes clinic visits in order to improve diabetes-related outcomes for the persons concerned and their quality of life. Treating DRD and depressive symptoms has been found to improve mood although it may not necessarily improve glycemic control.

Interventions for DRD:

The interventions could be emotion-focussed or cognition-focused. Both types of interventions are targeting different aspects as outlined in Table 2. If diabetes educators and care providers are to successfully intervene, it is important for them to focus on emotion-focussed as well as cognition-focussed interventions, for which they would require training. It would be useful to also incorporate stress-combating techniques like mindfulness-based stress reduction.

Table 2

Focus of Interventions for DRD and their outcomes

Emotion focussed	Cognition focussed	Outcomes
• Positive affects, e.g. hope, happiness, excitement, contentment. • Positive well-being. • Resilience. • Managing negative affects eg. anxiety, depression, distress, anger, hatred, fear, guilt, sadness or nervousness. • Integrating psychosocial adjustment to daily life. • Healthy coping: coping skills taught, mainly from the perspective of emotion management. • Motivation.	• Knowledge, comprehension/ awareness about diabetes, complications & treatment options. • Adherence to medications. • Healthy eating. • Being active. • Goal setting to promote health. • Risk reduction. • Self-efficacy and confidence in one's own ability to manage diabetes.	• Cognition-focused interventions alone are probably not beneficial for reducing DRD in people with T2DM. • Psychological interventions can improve self-efficacy and HbA1c compared to usual care. • Improvement good with brief & simple emotion cognition. • Focused interventions. • Subjects age <60 yr may benefit more. • Delivery by nurses as effective as those by physicians or psychologists.

Source: Chew BH, et al. Cochrane Database of Systematic Reviews, 2017

Economic burden and financial insecurity contribute to psychological stress and DRD. In a study reported from Delhi, in all the persons with diabetes who were studied, economic insecurity or financial instability was identified as an important stressor due to which they were permanently under stress. Therefore, it is important to consider the economic burden that diabetes and its treatment imposes. In a study conducted in 17 high-income and low-middle-income countries, it was observed that about one-tenth of the persons with diabetes surveyed, were permanently under stress. The economic impact is influenced by the level of development of the health care system. Also, technical advances in medicine and devices used for management, influence the future economic impact. It must be clearly recognized that costs of diabetes care is not only lifelong, but does not remain the same through the lifespan of the person. The costs depend on the age at which diabetes was diagnosed and the presence of comorbidities as well as their severity.

In a country like India, the economic burden is fairly substantial because majority of the persons with diabetes are required to meet all costs of treatment including consultations with the physician. Dearth of affordable insurance schemes and policies contribute to the cost of diabetes care. Even the policies that are available require charge large premiums. Oberoi and Kansra (2020) reported that anywhere from 5 to 25% of the household earning is spent on diabetes care. Nagarathna and colleagues (2020) also reported that approximately one-fourth of household income was spent on diabetes-related care. Generally, the economic burden is naturally more for those from lower income groups and rural areas in contrast to urban areas.

Worldwide the costs of diabetes care have been found to increase between 2014 and 2019. Among the prices of all major components that contribute to cost of diabetes care, namely non-insulin medications, insulin supplies and meters and strips have increased. However, comparison of the components indicates that the increase in the non-insulin medications and insulin has increased in almost linear fashion over the five-year period, whereas that for meters and test strips have not increased to the same extant. Added to this, many complex and expensive treatment regimes are still not available in rural areas and these people would need to travel to urban centres for the treatment.

Cost of diabetes care has been categorized as direct, indirect and intangible. Each of these has several cost components (Table 3). Also, in rural areas or in semi- urban areas, persons are likely to be diagnosed late because they are unable to afford a consult with a doctor. Not surprisingly, they develop complications, all of which adds to the treatment cost.

Table 3

Components of Direct, Indirect and Intangible Health Care Costs

Costs	Components of Cost
Direct Health Care	Diagnosis, Laboratory (tests), monitoring, consultation, treatment, health care and prevention, hospitalisation and food, surgery (less common) Non-health care costs: transport, housekeeping, social service and legal cost
Indirect	Costs of absenteeism, loss of productivity and disability
Intangible	Costs of social isolation and dependence, low socio-economic status, mental health Behavioral disorder and loss of quality of life

Source: Nagarathna R, et al. Annals of Neurosciences, 2020

Oberoi and Kansra (2020) reviewed economic costs in four geographic zones in India (Table 4).

Table 4

Economic costs incurred for Diabetes Management in four zones in India

Region/ Zone (no of studies)	States	Cost	Main items included in study
North (8)	Direct: Median cost (Range) Indirect:Median cost (Range)	₹18,890/- per annum (₹999/- to ₹1,09,344/-) ₹18,146/- per annum (₹4642/ - to ₹98,808/-)	Medicines, diagnostic expenses, transportation cost, hospitalization, consultation fee, wage loss and leisure time foregone
South (11)	Direct: Median cost (Range) Indirect:Median cost (Range)	₹10,585/– per annum (₹377/- to ₹21,258/-) ₹1198/- per annum, (₹462/- to ₹3572)	Medicines, consultation costs, hospitalizations, Monitoring, absenteeism and impairment.
North East (1)	Direct: Median cost Indirect:Median cost	₹45,792/- per annum ₹18,707/- per annum	Surgical procedures, expenditure on drugs/medicines, clinical fees, loss of wage, spending on health class, travelling and diet control.
West (1)	Direct: Median cost Indirect:Median cost	₹8822/- per annum ₹3949/- per annum	Loss of wages, health related expenditure, health class, travel and expenses for dietary management
INDIA	Direct: Median cost (Range) Indirect:Median cost (Range)	₹9996/- per annum (₹4724/- to ₹25,391/-) ₹5237/- per annum (₹2435/- to ₹12,756/-)	

Source: *Oberoi S & Kansra P. International Journal of Diabetes in Developing Countries, 2020*

Nagarathna and coworkers and also reported annual direct and indirect costs for India. The median annual direct and indirect costs for diabetes care were ₹25,391/- and ₹4970/- respectively. They also reported that there is a high burden of missed clinic appointments in tertiary care centres in government health settings. The time spent on each visit was on an average 2.6 hours including travel time, waiting to meet the doctor and the consultation process.

At population level, there is a need to consider Disability adjusted Life Years (DALYs) and diabetes. One year DALY represents the loss of the equivalent of one year of full health. Globally, in 2019, the number of DALYs due to Type 2 DM was reported to be 66.3 million, the age-standardized rate being 801.5 DALYs per 100,000 population. Over three decades, between 1990 and 2019, there has been an increase of 27.6% in the number of DALYs. Global DALYs for Type 2 DM contributed to 93.5% of the total diabetes burden.

In India, the age-standardised DALY rate for diabetes increased by 39.6% between 1990 and 2016, this being the highest increase among major non-communicable diseases. There has been an increase in every Indian state. In 2016, about one-third (36.0%) of the DALYs could be attributed to overweight. In India, for every 100 overweight adults who were ≥ 20 years of age,

38 adults had diabetes, this is about twice the global average which is 19 adults.

In summary, as recommended by Kalra et al in the national recommendation, it is important that a holistic approach that goes beyond pharmacological interventions is needed as persons with diabetes require psychological, social and emotional support that should be aimed at problem solving. It needs to evolve in the lifetime of the patient. This is especially relevant in the Indian context, as persons with diabetes in India have been reported by the World Health Organization to have a low level of psychological well-being. The approach used by educators should be patient and relationship-centred. A psychiatric assessment done by a qualified psychologist may be necessary and the cognitive, behavioural and motivational therapies should be done by trained personnel.

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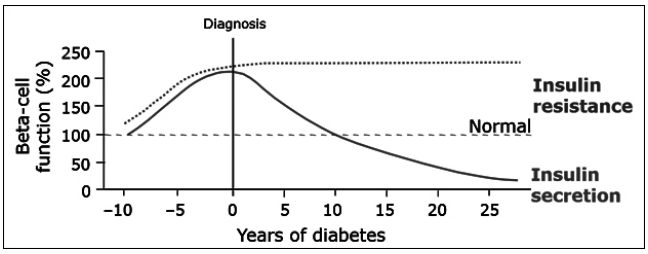
CHOOSING APPROPRIATE INSULIN

Ameya Joshi*, Anuradha Joshi**

Type 2 diabetes mellitus (T2DM) is a condition involving impaired glucose metabolism, leading to escalating levels of high blood sugar and reduced effectiveness of treatment as time goes on. In the development of T2DM, insulin resistance plays an early role, often associated with unhealthy lifestyle habits and weight gain. It's worth noting though, that weight loss alone cannot resolve all issues related to T2DM. As per Figure 1, furthermore, the decline in insulin secretion starts occurring gradually in individuals with T2DM, even before the condition is diagnosed.

Figure 1

To maintain proper blood sugar levels, exogenous insulin is necessary to offset the reduction in natural insulin production



Source: Bergenstal RM et al. Endocrinology, 2001

The discovery of insulin in 1921 by Frederick Banting, Charles Best and their colleagues is considered a groundbreaking milestone in the field of medicine. This discovery revolutionized the treatment of diabetes. In the early years following the discovery, insulin was derived from animal sources primarily from pigs and cows. However, these animal-based insulins posed challenges due to their impurities and variations in potency.

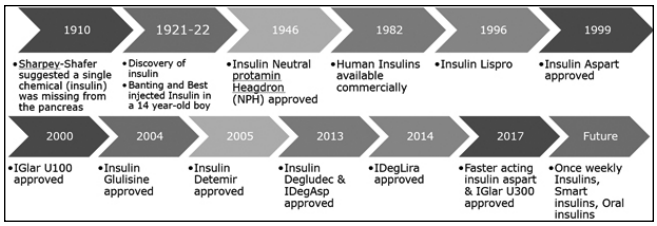
In the 1980s, recombinant DNA technology and genetic engineering techniques were employed to produce human insulin synthetically. This development allowed producing purer and more consistent insulin.

As research progressed, modifications were made to insulin molecules, leading to the creation of insulin analogues. These analogues have different properties, such as rapid-acting, short-acting, intermediate-acting, and long-acting insulins. These advancements provided more options for individualizing diabetes treatment regimens. Figure 2 shows the milestones in the evolution of insulin therapy. Looking ahead, there is ongoing research and anticipation for the development of oral insulins and smart insulins in the future.

Figure 2

Milestones in the evolution of insulin therapy

GLOBAL



Source: Vecchio I et al. 2018

The availability of different insulins addresses the diverse needs of individuals with diabetes, providing options for basal and prandial coverage, rapid or long-acting action, flexibility in dosing, and personalized glycemic control. These choices enable healthcare professionals to optimize diabetes management and improve patient outcomes. Figure 3 shows time-action profile of different insulin.

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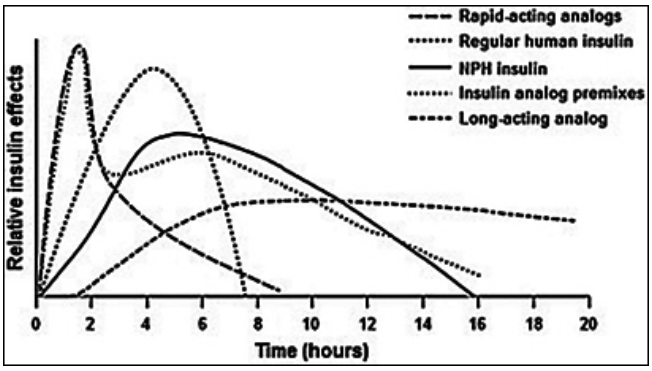
Figure 3
Time-action profile of different Insulins



Source: Eliaschewitz FG et al. Diabetology & Metabolic Syndrome, 2016

In humans, basal insulin characterized by rapid oscillatory pulses, occurring every 8-15 minutes and ultradian pulses, happening every 80-150 minutes, contribute to the regulation of fasting plasma glucose (FPG) and inter-prandial glucose. Additionally, these pulses help suppress glycogenolysis, lipolysis and proteolysis. Prandial insulin, comprising of a first phase lasting 5-15 minutes and a second phase lasting 30-90 minutes, plays a vital role in regulating post-prandial glucose levels.

Insulin viewed as an ultimate tool in diabetes. Relentless advances in insulin therapy against a relentless disease has put this molecule in the place of pride. Before exploring the recent advancements in insulin therapy, let us take a moment to revisit the currently available insulins as shown in Table 1. While the following information may appear overwhelming, it highlights the growing range of options that are becoming available in this field.

Table 1

Pharmacology of Insulins

	Insulin	Onset of action	Peak	Duration	Frequency of administration
BASAL INSULINS	NPH	1-1.5 hr	4-12 hr	Upto 24 hr	OD/BD
	Glargine U100	2-4 hr	No peak	Upto 24 hr	OD
	Detemir	~2 hr	No peak	Upto 24 hr	OD/BD
	Glargine U300	2.6 hr	No peak	Upto 36 hr	OD
	Degludec	~1 hr	No peak	>42 hr	OD
PRANDIAL INSULINS	Regular human Insulin	30 min	1.5-3.5	7-8 hr	OD/BD/TID
	Aspart, Lispro, glulisine	<15 min	~1	3-5 hr	OD/BD/TID
	Fast acting insulin aspart	4.9 min qucker	7 min quicker*	Shorter than aspart (~3-5 hr)	OD/BD/TID
MIXED INSULINS	Human premix 30/70 and 50/50	0.5 to 1 hr	Dual[a]	18-24 hr	OD/BD
	Lispro 75/25 and 50/50	<0.25 hr	Dual[a]	Upto 24 hr	OD/BD/TID
	Aspart 70/30 and 50/50	<0.25 hr	Dual[a]	Upto 24 hr	OD/BD/TID
	IDegASP	IDeg: ~1 hr Asp:<0.25 hr	IDeg: No peak Asp:1.2 hr	IDeg: >42 hr Asp:3-5 hr	OD/BD

Source: Atkin S et al. Ther Adv Chronic Dis. 2015

Let us look into the evolution of basal insulins and examine the profiles of various options available. The top panel of Figure 5 illustrates the pharmacokinetic/pharmacodynamic (PK/PD) profiles of different basal insulins. Notably, advancements have been made to develop peakless basal insulins with reduced glycemic variability.

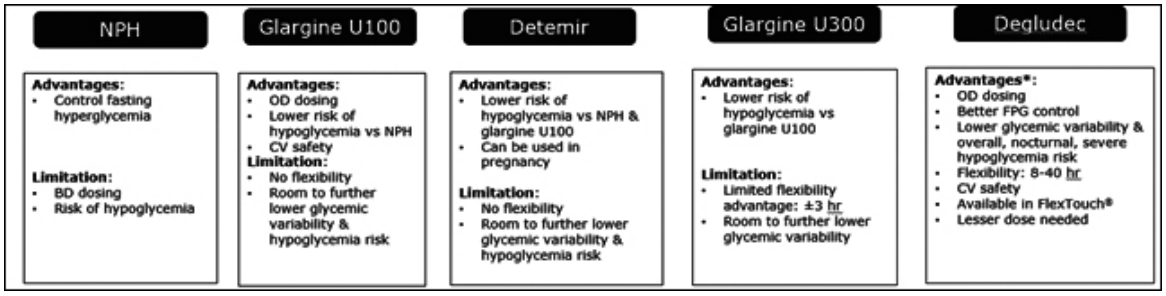
The first human basal insulin developed to address fasting glucose control was NPH. However, its drawbacks included the need for twice-daily dosing and a higher risk of hypoglycemia. Recognizing these limitations, the first basal insulin analogue, insulin glargine U100 was introduced. It offered the advantage of once-daily dosing, a lower risk of hypoglycemia compared to NPH. Cardiovascular safety has also been documented with Glargine insulin. However, there were still challenges in terms of limited flexibility in day-to-day dosing and the potential for further reducing glycemic variability and hypoglycemia risk.

To address these concerns, insulin Detemir was developed, which demonstrated a lower risk of hypoglycemia compared to glargine U100 and NPH. However, the need for increased flexibility and reduction in glycemic variability persisted. Figure 5 shows this advantage and limitations of basal, bolus premix and Coformulations.

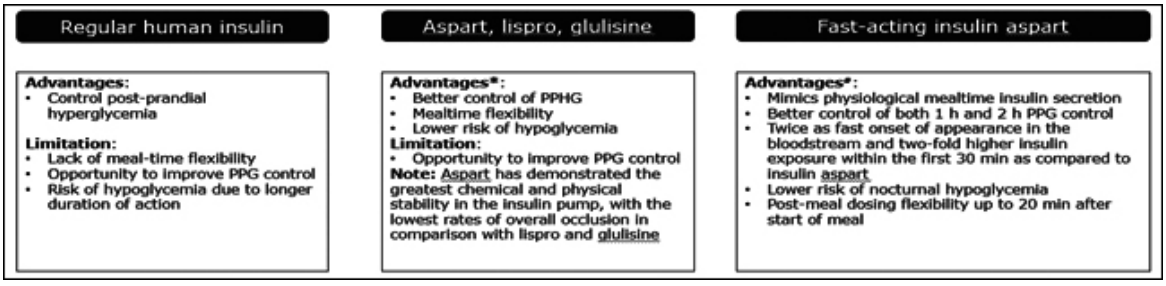
Figure 5

Advantage and Limitations: Basal, Bolus, Premix and Coformulations

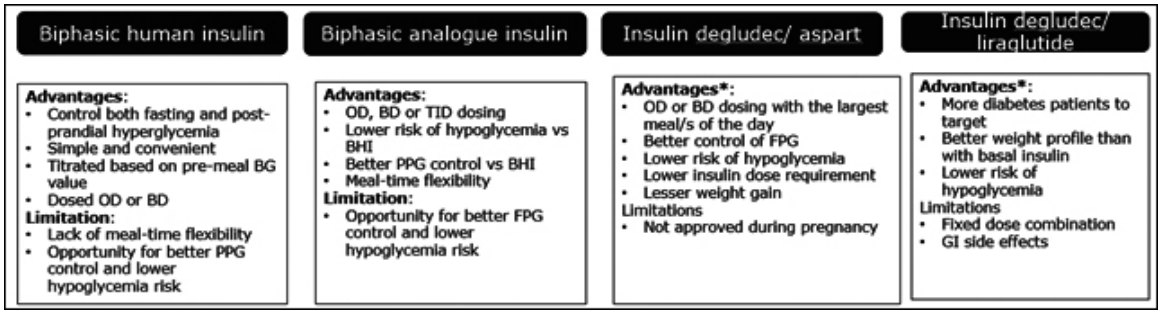
Basal Insulins



Bolus or Prandial Insulins



Insulin Mixtures



Source: Becker et al. Diabetes Care, 2015; Heise et al. Diabetes, 2004

The introduction of insulin glargine U300, a concentrated form of glargine U100, showed promise of reducing glycemic variability and lowering the risk of hypoglycemia compared to glargine U100. Additionally, there was a slight improvement in flexibility with a range of ±3 hours for time of administration.

A notable advancement came with the development of insulin degludec, an ultralong-acting basal insulin with a half-life of approximately 25 hours. It offers several advantages, including once-daily dosing, better fasting plasma glucose (FPG) control compared to glargine U100, reduced glycemic variability compared to glargine U100 and glargine U300, lower overall, nocturnal and severe hypoglycemia risk compared to glargine U100, enhanced flexibility in time of administration (±3 hours), cardiovascular safety and availability in the FlexTouch® device, which provides lower dose force and improved dose accuracy compared to other pens like SoloStar. Real-world studies, such as EU-TREAT, REFLECT and others have also demonstrated improved FPG control and better reduction in HbA1c after switching from other basal insulins to degludec.

The evolving landscape of basal insulins offers a range of options with varying benefits, addressing concerns such as hypoglycemia risk, glycemic variability, dosing flexibility and cardiovascular safety. These advancements in basal insulin therapies have the potential to enhance glucose control and improve overall management in individuals with diabetes.

Biphasic human insulin (BHI) offers the benefit of reducing the number of needle pricks required for injecting separate insulin to control fasting and post-prandial glucose levels. It is a simple and convenient method that can be adjusted based on the blood glucose levels before meals and it can be taken once daily or twice daily. However, it lacks flexibility during mealtimes and there is still room for improvement in post-prandial glucose control and hypoglycemia risk reduction. This led to the development of biphasic analogue insulins, which can be taken once daily, twice daily, or three times daily and have a lower risk of hypoglycemia compared to BHI. They also provide better post-prandial glucose control and offer more flexibility during mealtimes.

Further advancements in insulin formulation resulted in the creation of IDegAsp, a coformulation of insulin. It has several advantages, including the option to take it once daily or twice daily with the largest meals of the day. It provides better control of fasting plasma glucose levels, lowers the risk of hypoglycemia, requires a lower dose of insulin and causes less weight gain compared to BIAsp 30, a different type of insulin formulation.

As per Figure 6, the recommendations for glycemic control by the Research Society for the Study of Diabetes in India (RSSDI) and the American Diabetes Association (ADA) share several key points. They both suggest aiming for an HbA1c target of less than 7% for most non-pregnant adults with diabetes, although personalized targets may be established based on factors like age, duration of diabetes, comorbidities, and hypoglycemia risk. Fasting plasma glucose levels of 80-130 mg/dL (4.4-7.2 mmol/L) are recommended by both organizations. However, their postprandial plasma glucose targets differ slightly, with RSSDI recommending levels below 140 mg/dL (7.8 mmol/L) at 2 hours after meals, while ADA suggests a stricter target of less than 180 mg/dL (10 mmol/L) at 1-2 hours after meals. Both RSSDI and ADA emphasize the significance of regular self-monitoring of blood glucose levels, although the frequency and timing of monitoring may vary based on the individual's treatment plan, medication regimen and glycemic control goals. Individualized treatment plans are advocated by both encompassing lifestyle modifications, oral antidiabetic medications, injectable therapies such as insulin or glucagon-like peptide-1 receptor agonists, or a combination of these approaches. Lastly, the prevention of hypoglycemic events is prioritized by RSSDI and ADA, with careful medication selection and dosage adjustments considering the risk of hypoglycemia, particularly in vulnerable populations like the elderly or those with multiple comorbidities.

Figure 6

Glycemic control recommendations

Age group	Target HbA_{1c} values
Young (<18 years)	<7.0%
Adult	<7.0%
Older adults Healthy* Complex/intermediate Very complex/poor health	 <7.5% <8.0% <8.5%

Association	FPG target	PPG target (1-2 h post-meal)
ADA[1]	80-130 mg/dL	<180 mg/dL
RSSDI/ ESI[2]	<100 mg/dL	<140 mg/dL

Source: ADA – American Diabetes Association, RSSDI – Research Society for the Study of Diabetes in India, 2022

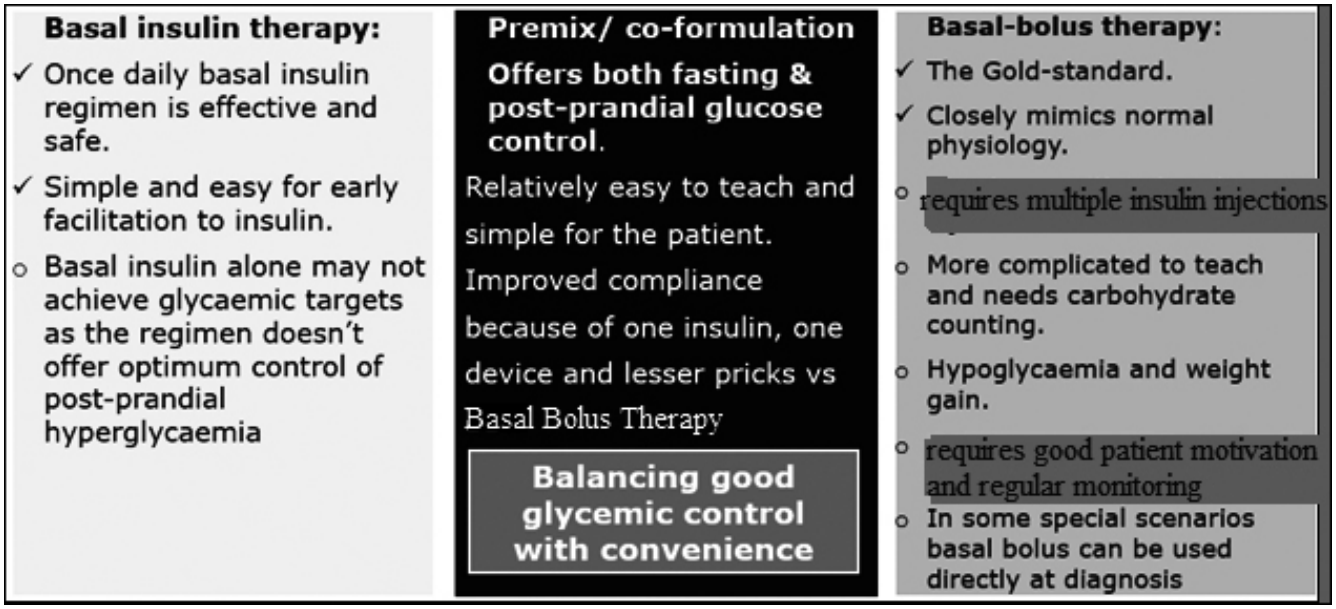
According to the guideline recommendations from the Research Society for the Study of Diabetes in India (RSSDI) and the Endocrine Society of India (ESI) Consensus in 2022, it is crucial to break treatment inertia and initiate insulin therapy in a timely manner for achieving better glycemic control. For persons with diabetes who have not reached their glycemic targets despite treatment with three oral agents, a three-step protocol involving initiation, titration and intensification of insulin therapy is recommended. The choice of initial insulin regimen, whether once-daily basal insulin, once-daily premixed or co-formulation insulin or twice-daily premixed insulin should be based on factors such as the individual's age, clinical features, glucose profile, risk of hypoglycemia and patient preference. In cases of severe hyperglycemia or life-threatening situations that pose a risk to organs or limbs, a basal bolus insulin regimen may be necessary. These guidelines emphasize the importance of individualized treatment plans to optimize glycemic control and improve patient outcomes.

Insulin therapy at the time of diagnosis may be necessary in various situations. If individuals present with severe symptoms of hyperglycemia, organ dysfunction, metabolic decompensation or ongoing catabolism (weight loss), immediate insulin therapy is recommended to address the significant glucose dysregulation and achieve rapid glycemic control. Similarly, when individuals exhibit symptoms of hyperglycemia such as excessive thirst, frequent urination, blurred vision or fatigue, initiating insulin therapy promptly is important to alleviate symptoms and prevent further complications. In cases where HbA1c levels exceed 10% or blood glucose levels consistently exceed 300 mg/dL, insulin therapy is typically initiated due to poor glycemic control, aiming to lower blood glucose levels and mitigate the risk of complications. Furthermore, during pregnancy or when planning for pregnancy, insulin therapy is often preferred for women with diabetes as it provides safer glycemic control for both the mother and the developing fetus, ensuring stable blood glucose levels and reducing the risk of pregnancy-related complications.

As per Figure 7, achieving optimal balance in insulin therapy while initiating with basal insulin is a straightforward approach. Relying solely on basal insulin may not achieve optimal glycemic targets due to its limited control over post-prandial hyperglycemia. The gold standard in insulin regimens is considered to be basal bolus therapy, as it closely mimics the body's natural insulin secretion patterns. However, this regimen requires multiple insulin injections and necessitates carbohydrate counting. Concerns such as hypoglycemia and weight gain are associated with basal-bolus therapy and it requires strong patient motivation and regular monitoring.

Figure 7

Options for Insulin initiation

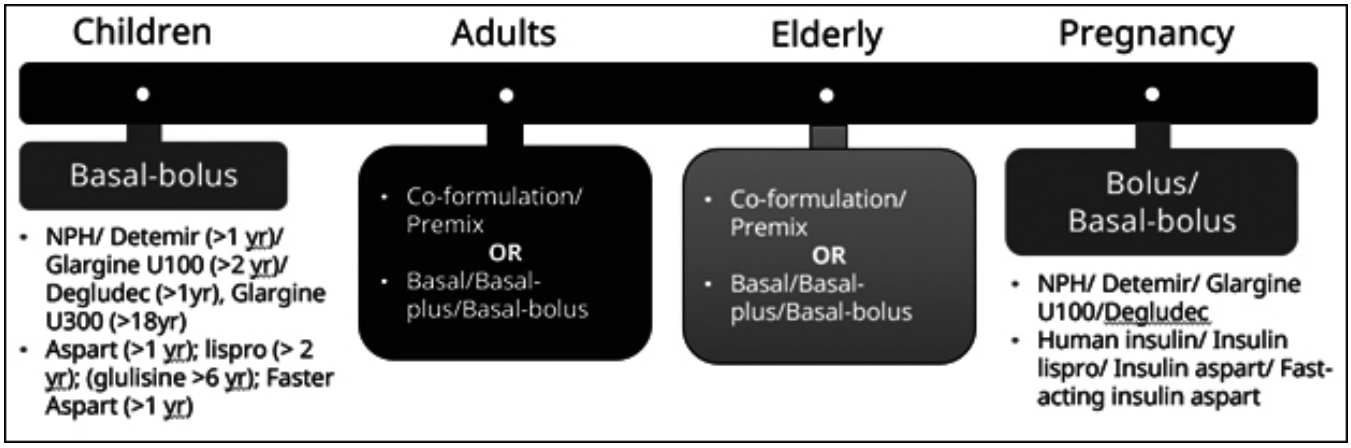


Source: Kumar, A., et al. Journal of Diabetology, 2020

As per Figure 8, on the other hand, premix insulin or co-formulation provides both fasting and post-prandial glucose control, is relatively easier to practice and simplifies the treatment for individuals. It improves compliance as it involves only one insulin, one device and fewer injections compared to basal bolus therapy. Therefore, premix insulin or co-formulation offers a potential balance between achieving good glycemic control and providing convenience to patients.

Figure 8

Preferred regimens for initiation - based on Phase of life



Source: Atkin Set al. Ther Adv Chronic Dis, 2015

As per Figure 9, when making the initial selection for insulin therapy, it is advisable to choose premix insulin based on specific glycemic factors.

1. *Glycemic factors*: If individuals experience a significant rise in post-meal glucose levels that exceeds 54mg/dl (post-lunch PPG), premix insulin is a suitable option. Additionally, if the ratio of fasting plasma glucose (FPG) to HbA1c is less than 20, premix insulin can be considered as an appropriate choice. Moreover, if the post dinner blood glucose value, which indicates beta-cell activity, exceeds 55mg/dl, it suggests a potential requirement for the prandial insulin component. In such cases, premix insulin is beneficial as it contains both basal and prandial insulin components, helping to address the specific glycemic needs of the individual.
2. *Psychosocial factors*: In situations where the patient has limited literacy and requires a regimen for initiating insulin that is straightforward and easy to comprehend, it is important to choose a regimen that is simple and easily understandable. Similarly, if there is a need for convenient and uncomplicated options for future intensification of insulin therapy, it is advisable to prioritize regimens that offer simplicity and convenience. By considering the person's limited literacy and providing them with easy-to-understand and convenient insulin regimens, healthcare professionals can ensure effective insulin initiation and facilitate future adjustments or enhancements to the treatment plan.
3. *Indian realities:* In situations where resources are limited, and there is a need for a simple and easily explainable insulin therapy for both initiation and intensification, it becomes crucial to prioritize simplicity in treatment options. This is particularly important for individuals who follow a high carbohydrate diet. By providing a regimen that is straightforward and easy to understand, healthcare professionals can ensure that patients can effectively initiate and intensify their insulin therapy within the constraints of limited resources. Simplifying the regimen will help persons navigate their treatment more confidently, resulting in improved adherence and better glycemic control.

Figure 9

Right regimen for initiation: Choosing a patient centric insulin regimen

Choose basal insulin for initiation:	
Glycaemic factors	• If the post-prandial increment is <18 mg/dl • If FPG/HbA1c ratio is >20 • Post dinner blood glucose >55 mg/dl requirement of prandial insulin
Psychosocial factors	• If patient has limited literacy and simple and easy to understand regimen is needed for insulin initiation • If open to switch to different insulin regimen with progressing diabetes
Phase of life	• If patient is a child (use as basal-bolus therapy) • If patient is an adult one with an early stage of disease • If patient is pregnant (use as basal-bolus therapy) • If control of only FPG is needed in elderly patients
Indian realities	• If resources allow detailed discussion during future intensification with switch to premix or basal-bolus therapy • If patient consumes lesser carbohydrates in diet • If insulin is initiated early in the disease stage with minimum diabetes comorbidities and complications • If patient is willing for timely intensification of insulin therapy to a different regimen when basal insulin alone is insufficient

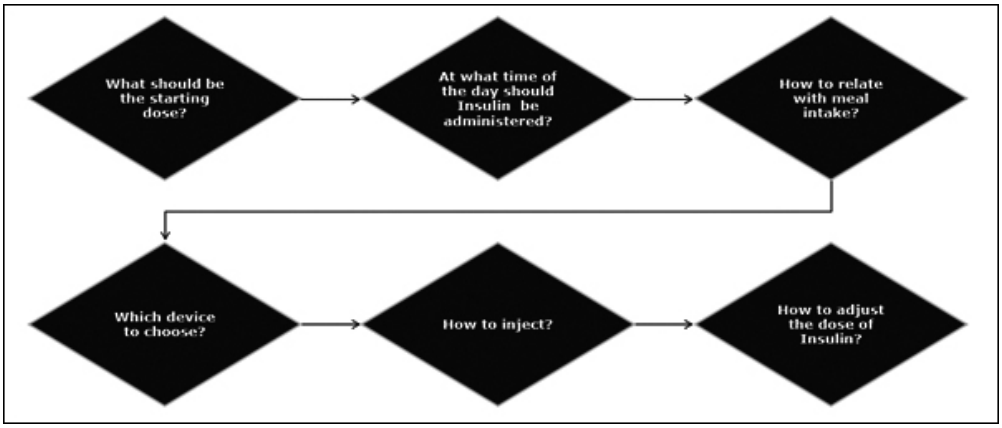
Source: International Journal of Diabetes in Developing Countries. 2022

What do we want from Insulin therapy?

Our goal with insulin therapy is to achieve comprehensive glycemic control, surpassing what oral antidiabetic drugs (OADs) can provide. By attaining this level of control, we can effectively prevent or reduce the risk of future complications associated with diabetes. Additionally, we aim for insulin therapies that come with fewer side effects, specifically minimizing the occurrence of hypoglycemia and weight gain. It is also important to consider the convenience and injection burden for patients, which is why newer insulin formulations offer a reduced risk of hypoglycemia. Moreover, advancements in insulin delivery devices have led to the development of next-generation devices that offer virtually painless injections, simplifying the process of administering the dose and adjusting it as necessary. Figure 10 shows the key clinical consideration before starting insulin and Figure 11 shows different insulins.

Figure 10

Key clinical considerations to INITIATE Insulin



Source: American Diabetes Association, 2023

Figure 11

Choices of Insulins

Insulin regimen	Insulin	Recommended starting dose	Time of administration & Related to meal		Approval in India	
					Paediatrics	GDM
Bolus	Regular Insulin	4U	30 min before meal		Yes	Yes, B
	Insulin glulisine	4U	immediately before or soon after a meal		>6 y	No, C
	Insulin lispro	4U	immediately before or soon after a meal		>2 y	Yes, B
	Insulin aspart	4U	immediately before or soon after a meal		>1 y	Yes, B
	Faster aspart	4U	Can be administered from -2 min before meal to +20 min after the start of meal		>1 y	Yes, B
Premix	BHI 30/70 or BHI 50/50	6U	pre-breakfast or pre-dinner	An injection should be taken 30 minutes before meal	>18 y	Yes, B
	BiLis 75/25 or BiLis 50/50	10U	pre-breakfast or pre-dinner	Immediately before a meal (within 15 minutes)	>18 y	No, B
	BIAsp 30/70 or BIAsp 50/50	10U	Split the dose into equal breakfast and dinner doses.	Immediately before a meal	>10 y	No, B
Co-formulation	IDegAsp	10U	With the main meal		>18 y	No, C
	IDegLira	10 dose steps	At any time (same time of the day)		>18 y	No, C
Basal - Intermediate	NPH insulin	10U	Once daily or twice daily as required		Yes	Yes, B
Basal – Long	Insulin glargine	10U	At any time (same time of the day)		>2 y	Yes*, C
	Insulin detemir	10U	At any time (same time of the day)		>1 y	Yes, C
Basal – Ultra long acting	Insulin degludec	10U	flexibility in daily dosing ±3 h, window when needed		>1 y	Yes, B
	Insulin glargine U300	10U	At any time (Same time ±3 hr of the day)		No	No, C

Source: Chawla, R., et al, Int J Diabetes Dev Ctries, 2019

When prescribing an insulin delivery device, several factors should be considered to ensure the best fit for the individual's needs as per Figure 12. Here are some important factors to consider:

Figure 12

Factors to Be Considered While Prescribing an Insulin Delivery Device

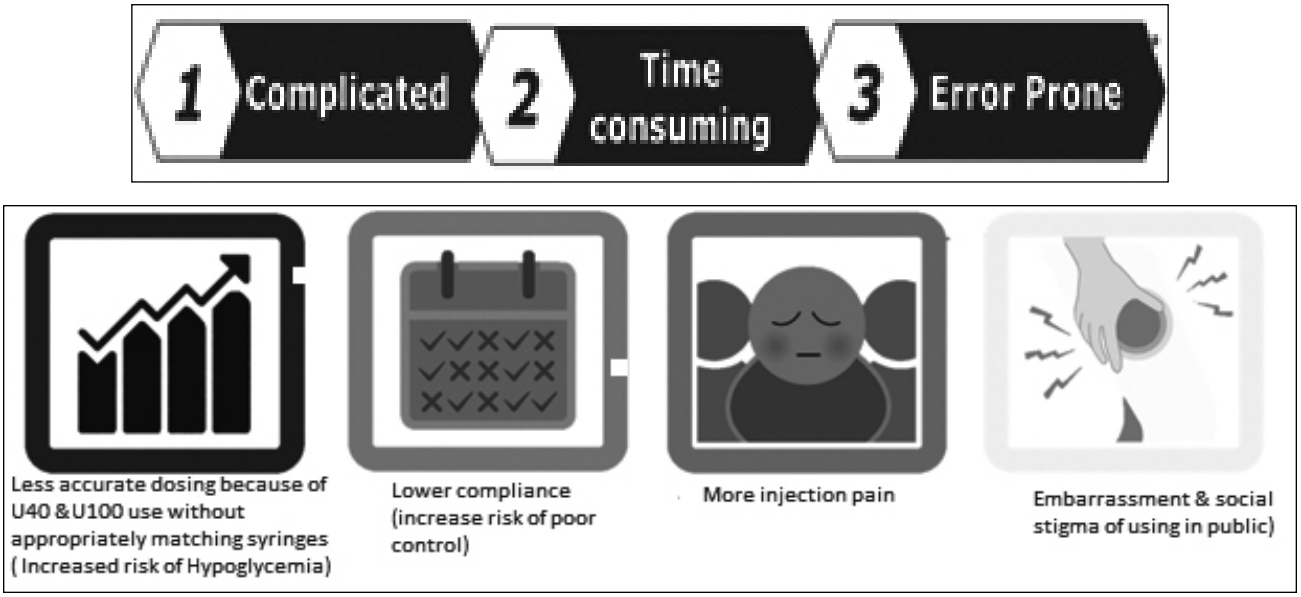
Biomedical factors	Psychological factors	Environmental factors	Pragmatic factors	Medication counselling factors
Accuracy, needle diameter, length of the needle, degree of insulin increment, suitability for children/visual or dexterity-challenged	Discreteness/size Comfort/ease of use Ease for transportation/ storage	Temperature stability Biodegradability Availability of compatible insulin Availability of ancillary parts	Cost of device, Cost of insulin refills, Needles, Expected duration of insulin therapy (with prescribed regimen) Monthly dose requirement	Time taken to reach Time taken to learn Risk of error in delivery Availability of post prescription follow-up

Source: Chawla, R., et al, Int J Diabetes Dev Ctries, 2019

Vials and syringes are commonly used in insulin management for individuals who prefer a more traditional method of insulin administration. However, there are some considerations when using vials and syringes in insulin management. The use of vials and syringes for insulin administration is associated with less accurate dosing, which can increase the risk of hypoglycemia as shown in Figure 13. Additionally, the lower precision in dosing may lead to lower compliance and an increased risk of poor glycemic control. Moreover, vials and syringes are often associated with more injection pain and may cause embarrassment or social stigma when used in public. On the other hand, the use of pen devices offers numerous advantages, including improved adherence by patients.

Figure 13

Vials & Syringes



Source: Chawla, R., et al, Int J Diabetes Dev Ctries, 2019

Insulin pen devices are a popular and convenient option for administering insulin. These devices offer several advantages over traditional vials and syringes. Insulin pens are designed to be portable and discreet, making them ideal for individuals who need to inject insulin outside of their homes or in public settings. They come in different types such as disposable pens, cartridge-based pens, prefilled pens and smart pens, providing flexibility in insulin selection and dose adjustment as shown in Figure 14.

Figure 14

Types of Insulin Pens devices - Available pen devices

Pen	Insulin Types	Disposable or Reusable	Dosing increments	Maximum dose
Novo Nordisk				
Novopen	Tresiba®, Ryzodeg®, Fiasp®, Xultrophy®, Novomix® 30 , Novorapid®, Levemir®, Actrapid®, Mixtard ®, Mixtard® 50	Reusable	1.0	60
FlexPen	Novomix®, Novorapid®, Levemir®, Actrapid®,Mixtard®, Mixtard®	Disposable	1.0	60
FlexTouch	Tresiba®, Ryzodeg®, Fiasp®, Xultrophy®	Disposable	1.0 for Ryzodeg	80 for Tresiba, Ryzodeg™,FIAsp 50 dose steps for Xultrophy
Sanofi Toustar	Toujeo	Reusable	1.0	80
Allstar	Lantus	Reusable	1.0	80
Biocon Biologics Insupen pro	Insugen R, Insugen N, Basalog	Reusable	1.0	60
Lilly HumaPen Ergo II	Humalog, Eglucent, Humisnulin, Basaglar	Reusable	1.0	60

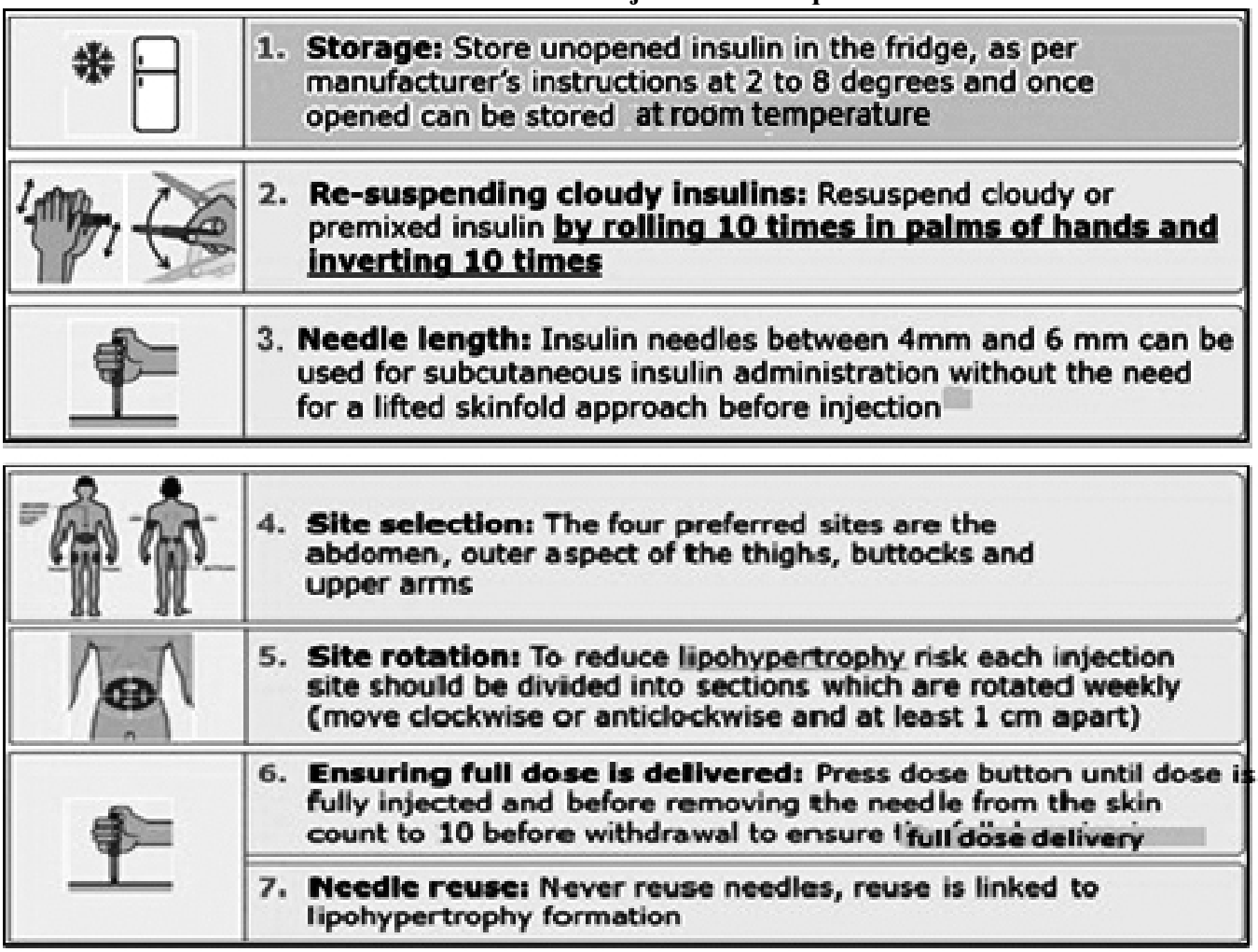
Source: Chawla, R., et al, Int J Diabetes Dev Ctries, 2019

Insulin pens are easy to use, featuring clear dose markings and simple injection mechanisms. They also offer more accurate dosing compared to vials and syringes, reducing the risk of dosing errors. The use of insulin pen devices can enhance adherence to insulin therapy, as they offer convenience, ease of use and better portability.

When administering insulin injections, it is important to follow the recommended injection technique as shown in Figure 15. This includes selecting appropriate injection sites and rotating them to prevent tissue damage. Proper preparation, such as washing hands and checking insulin for abnormalities, is crucial. Needle insertion should be done at the correct angle, and the insulin should be slowly injected into the subcutaneous tissue. After injecting, the needle should be safely disposed off.

Figure 15

Recommended Injection technique



Source: Diabetes Care, 2023

In some cases, the concomitant use of oral antidiabetic drugs (OADs) alongside insulin may be necessary for optimal glycemic control. The choice of OADs depends on individual factors, including diabetes type, blood glucose levels, renal function and cardiovascular risk profile. An individualized approach should be taken to determine the most appropriate combination of insulin and OADs for each patient. Regular monitoring and adjustment of the treatment regimen may be required to achieve and maintain target glycemic control.

Insulin storage is also essential to maintain its effectiveness. Unopened insulin vials or pens should be refrigerated within a specific temperature range. Once opened, insulin can be stored at room temperature for a limited duration. Protection from light and extreme temperatures is important. When traveling, insulin should be carried in an insulated bag or container as shown in Figure. 16. Insulin should be stored at +2°C to +8°C. The insulin in use can be kept at room temperature (<30°C) for 28 days.

Figure 16

Recommendations on Insulin Storage

Temperature and storage	Temperatures during Transportation
• Insulin should be stored at +2ºC to +8ºC • Storage below 0ºC may lead to the product being frozen, causing cracking of vials and cartridges and/or displacement of the plunger in the cartridges. • All of which will cause the product to become inhomogenous and non-sterile • Keep insulin cartridges and pens that are currently in use at room temperature (<30ºC).	• The risk of freezing insulin products must be minimised during transportation, therefore storage at +2ºC to +8ºC during transportation is required. • Avoid extremes of temperatures such as o Direct sunlight, kitchen, freezer o Closed cars, the top of a radiator o Check in luggage as it is frozen in the hold during flight o The top of a television o Luggage in the boot of the car

Source: Kumar, A., et al. Journal of Diabetology, 2020

In insulin therapy, the concomitant use of certain oral antidiabetic drugs (OADs) may be recommended, depending on the specific insulin regimen and patient's condition.

In clinical practice, it is common to combine insulin therapy with oral antidiabetic drugs (OADs). The addition of metformin to insulin therapy has been shown to improve insulin sensitivity and reduce the required daily insulin doses. The strategy of combining bedtime insulin with daytime sulfonylurea (BIDS) has demonstrated significant reduction in HbA1c levels, although the reduction is relatively lower compared to insulin monotherapy. Combining insulin with other anti-hyperglycemic agents has also shown substantial reduction in HbA1c levels.

Guidelines such as those from the American Diabetes Association (ADA) and the Research Society for the Study of Diabetes in India (RSSDI) recommend continuing the use of metformin when combining insulin therapy with OADs and glucagon-like peptide-1 analogs (GLP-1 analogs). If basal insulin has been adjusted to achieve an acceptable fasting plasma glucose (FPG) level or if the insulin dose exceeds 0.5 unit/kg per day and the HbA1c remains above the target, it is suggested to switch to a combination injectable therapy by adding a GLP-1 receptor agonist (GLP-1RA). Discontinuing sulfonylureas is also recommended when using combination injectable therapy. The decision to continue or discontinue other OADs, apart from metformin, should be based on individual circumstances.

Despite being prescribed dual- or triple-oral antidiabetic drugs (OADs), a majority of patients fail to achieve their desired target for HbA1c levels. The delay in initiating insulin therapy is often due to various factors such as limited time, lack of training, inadequate healthcare teams and insufficient tools. It is crucial to prioritize timely initiation of insulin therapy, taking into account the local circumstances and challenges in order to minimize the risk of complications related to diabetes. When selecting the appropriate insulin regimen, a patient-centered approach should be followed, considering factors such as the clinical practice environment, available consultation time, dietary habits, glycemic control indicators, stage of life, psychosocial factors, presence of complications, and comorbidities. The goal is to integrate insulin therapy seamlessly into the lives of patients. Given the progressive nature of T2DM, insulin intensification should be implemented in a timely manner, while ensuring simplicity and convenience. Patient

friendly insulin regimens should be preferred. Considering cost factors, human insulins are generally favored over analog insulins. Concomitant use of other antihyperglycemic agents should be carefully evaluated, with appropriate dosage adjustments to enhance the safety and effectiveness of insulin therapy.

Summary

Choosing the right insulin therapy is a crucial step in the management of Type 2 DM. By adopting a patient-centered approach, prioritizing timely initiation, considering lifestyle factors, cost considerations and optimizing insulin intensification, treatment outcomes and the quality of life can be improved. Individualized insulin regimens that are well-integrated into patients' lives are key to achieving optimal glycemic control and minimizing the risk of diabetes-related complications.

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QUESTION AND ANSWERS

Q. What is a good diet to follow for a person with diabetes who has a very active lifestyle?

A. Close monitoring of blood glucose becomes important with an active lifestyle, especially for people with diabetes who are on insulin or certain OHA's in order to prevent hypoglycemia. It is important not to skip meals and plan to eat on time. A balanced combination of protein, carbohydrate and fat at each meal can help keep blood glucose stable.

Active individuals with diabetes may need an extra snack based on how strenuous the activity is. According to the ADA, blood glucose levels can be impacted after exercise for up to 24 hours or more, as insulin sensitivity is increased. Hence meals and insulin dosing following physical activity has to be tailored. Testing blood glucose after extended period of physical activity can help to understand how the body responds to particular activities. Consulting the healthcare professional for an individualized meal plan guideline based on the caloric and nutrient needs is advisable.

Q. What is a good pre-bedtime snack to prevent lows?

A. Most people with diabetes do not require a bedtime snack prior to bedtime and eating extra can add unwanted calories that make weight management difficult.

If the blood glucose goes below 70 mg/dl at bedtime or between 2-4 am, a very general guideline is to consume 15 grams of carbohydrate and a protein serving at bedtime. This could be in the form of 100 gm of fruit and nuts (7-8 pieces) or 150 ml milk. This snack recommendation varies based on age, medications/insulin and risk of nocturnal hypoglycemia. The physician or dietician would be able to advise on bedtime snack options.

Q. If I am unwell, do I need to stop taking Insulin?

A. This is a big myth! During intercurrent illness, blood glucose levels tend to rise. Insulin dose in such cases may in fact need to be increased.

A sick day routine for people on insulin can be as follows:-

1. Always take a small fractional dose of insulin. Never omit completely even if unable to eat.
2. Test blood glucose every 2-4 hours. A minimum of 4 times a day testing (before each meal and at bed time) is essential.
3. If blood glucose is more than 200 mg/dl, test urine for ketones. If ketones are present along with high glucose levels, an extra dose of insulin is required. Short acting insulin should be used. Do not use extra insulin if only ketones are present or urine glucose is less than 1% or blood glucose <150 mg/dl.
4. Consume liquids every hour. If unable to consume because of nausea or vomiting, the individual should contact the local physician to prescribe for nausea or vomiting. In case of nausea or vomiting, more palatable drinks, which are often high in carbohydrates should be given. This may raise the blood glucose but combats ketone body formation effectively.
5. Rest and do not exercise if blood glucose is >250mg/dl and if urine ketones are positive.

6. If too ill to follow usual diet plan, eat or drink whatever you can tolerate or retain.
7. Extra insulin: If test indicates need for extra insulin above the regular dose, every 3-4 hr take 20% (1/5) of the usual dose (e.g. if the usual daily dose is 40 units, person may take 8 units of regular insulin) every 3 to 4 hours depending on the outcome of blood and urine tests.
8. If unimproved by these measures, please contact the diabetologist or report to the emergency room in a hospital.
9. If vomiting is severe, it is advisable to suspend oral feed for a while and give glucose or glucose-saline or plain saline intravenously. If intravenous (IV) fluids are being given, one may add regular insulin to IV fluids and give each pint over 3-6 hours, as required for correction of dehydration and maintenance of fluid balance.
10. Although it may be possible to treat a patient with diarrhea at home, repeated vomiting requires IV fluids and hospitalization. Person with Type 2 diabetes on oral anti diabetic agents (OADA), most minor illnesses like cough, cold may not necessitate any change. On the other hand, severe intercurrent illness would require omission of oral agents and institution of insulin therapy, usually in a hospital setting.

JJ

RECIPES

TOFU & VEGETABLE PATTIES

INGREDIENTS

50 gm grated Carrot

50 gm sliced Spring onions

1 crushed Garlic clove

1¼ inch one piece grated Ginger

100g firm Tofu, drained and crumbled

1 tsp Sesame oil

1 tsp sweet chilli sauce, to serve

METHOD

Combine all the ingredients except the oil in a large bowl with some seasoning and mix well.

Divide the mixture into 8 equal portions and shape each portion into a small pattie.

Now heat oil in a non-stick tava, place the pattie on it and shallow fry them on a medium flame till they are golden brown in colour from both the sides.

Serve hot with green chutney

Provides 2 servings

Nutritional information per serving

Energy (Kcal)	Carbohydrate (gm)	Protein (gm)	Fats (gm)	Fibre (gm)	Glycemic Index
165	5	18	8	2.5	Low

Special features

- A healthy snack
- A recipe rich in protein

VEGETABLE & BEAN CHILLI

INGREDIENTS

30 gm Red lentils, soaked and boiled

30 gm Kidney beans soaked and boiled

1 clove Garlic, finely chopped

One piece Ginger, finely chopped

50 gm Onion, chopped

50 gm diced Cucumber

20 gm Red pepper, deseeded and chopped

1 yellow pepper, deseeded and chopped

Chilli powder to taste

50 gm chopped tomatoes

50gm Sweet corn, drained

1tsp Olive oil

METHOD

Heat the oil in a large pan. Cook the garlic, ginger, onion, cucumber and peppers for about 5 minutes until starting to soften. Add the chilli powder and cook for 1 minute more.

Stir in the lentils, tomatoes and add little water. Bring to the boil and cook for 15-20 minutes.

Add the sweet corn, beans and cook for a further 10 minutes. Serve hot.

Provides 2 servings

Nutritional information per serving

Energy (Kcal)	Carbohydrate (gm)	Protein (gm)	Fats (gm)	Fibre (gm)	Glycemic Index
235	40	11	5	9	Low

Special features

- A healthy snack
- A recipe rich in fibre

JJ

HOW KNOWLEDGEABLE ARE YOU?

1. Type 1 diabetes is triggered in auto immunity-prone subjects by?
   A. Lifestyle
   B. Environmental factors
   C. Viral infections
   D. None of the above

2. Which scientists discovered role of pancreas in diabetes?
   A. Frederick Banting and Charles Best
   B. Joseph Von Mering and Oskar Minkowski
   C. Aeratus and Avicenna
   D. Charak and Sushrat

3. Insulin secretion by Beta cells requires glucose transport into the cells; this is in part mediated by the glucose transporter –
   A. Glucagon
   B. Leptin
   C. GLUT – 2
   D. GLUT – 4

4. Which of the following is not a secondary cause of obesity?
   A. Cushing syndrome
   B. Diabetes mellitus
   C. Insulinoma
   D. Hypothyroidism

5. What is the likely explanation for the increasing incidence of childhood-onset type 1 diabetes over the past 2–3 decades in many populations?
   A. Changes in the genetic pool of the population
   B. Increased frequency of viral infections
   C. More sugar in the diet
   D. Unknown non-genetic factors

6. Adipose tissue inflammation in obese subjects is characterized by all of the following except:
   A. Accumulation of macrophages
   B. Accumulation of lymphocytes
   C. Elevated free fatty acids in serum
   D. Elevated leptin concentrations
   E. Elevated adiponectin concentrations

7. Excessive thirst and markedly increased volume of very dilute urine may be symptoms of:
   A. Urinary tract infection
   B. Diabetes insipidus
   C. Viral gastroenteritis
   D. Hypoglycemia

8. One of the fat-soluble vitamins involved in coagulation is:
   A. Vitamin K
   B. Vitamin A
   C. Vitamin D
   D. Vitamin E

9. Products that contain live microorganisms in sufficient numbers to alter intestinal microflora and promote intestinal microbial balance are known as:
   A. Antibiotics
   B. Probiotics
   C. GLP 1
   D. Digestive enzymes

10. Risk factors for type 2 diabetes include all of the following except:
    A. Advanced age
    B. Obesity
    C. Smoking
    D. Physical inactivity

ANSWERS:

1.	C	2.	B	3.	C
4.	B	5.	D	6.	E
7.	B	8.	A	9.	B
10.	C				

MYTHS AND FACTS

1. **Myth: Insulin means taking Multiple Daily Injections**

   Fact: This is not true because every person with diabetes has a different requirement. At first long-acting once-a-day insulin (usually given at night), which mimics the low level of insulin normally found in the body all daylong is prescribed. This may be enough to control blood sugar on its own or it can be combined with oral medications.

   As per the American Diabetic Association (ADA) guidelines, if blood sugar is still too high after meals, than one may need to take insulin before meals 2 to 3 times a day.

   The Diabetologist or the Physician is the right person to decide which type is to be prescribed and frequency of insulin to control blood glucose.

2. **Myth: I can use the same needle of the insulin pen for taking insulin till the cartridge is over?**

   Fact: It is not true. Insulin needle should be used only 1-3 times. Most people with diabetes change the needle only when it pains. At this point the tip of the injection needle is bent, as can be seen by a magnifying glass. There is increasing evidence that reusing a needle can cause micro-trauma, bleeding, leakage and lead to lipohypertrophy (bumps and lumps under the skin) at injection sites.

   Changing your needle offers benefits such as:

   - Less painful injections
   - Less damage to the skin at the injection site
   - Reduced contamination of the needle

3. **Myth: Insulin causes excessive weight gain**

   Fact: Insulin therapy or intensification of insulin therapy commonly results in weight gain in both Type 1 and Type 2 diabetes. This weight gain can be excessive, adversely affecting cardiovascular risk profile. Insulin is a hormone that regulates blood sugar, promotes fat storage and inhibits break down fats and proteins. This is because their body begins utilising glucose again and converting into excess fat. A 3 to 9 kg insulin-associated weight gain is reported to occur in the first year of initialling insulin therapy. The potential cause for this weight gain include increase in energy intake linked to a fear of hypoglycemia, catch up weight and appetite regulation. However, it is important to know that the weight gain is partly to restore the weight loss prior to institution of insulin therapy.

   Strategies include limiting the insulin dose and increasing insulin sensitivity through diet and exercise or by using adjunctive anorectic or insulin-sparing pharmacotherapies such as metformin. Also measuring portion size can help people with diabetes to understand what portion size works best for them and prevent from eating extra calories as per their body requirement. One should aim for at least 150 min of moderate intensity exercise each week.

JJ

CERTIFIED DIABETES EDUCATOR COURSE

Dr Chandalia's DENMARC in association with Help Defeat Diabetes Trust (HDDT) presents to you a course to be a Certified Diabetes Educator (CDE)!

Help Defeat Diabetes Trust (HDDT) is a registered, non-profit public trust, having amongst its many objectives, the main objective of promoting education and awareness about diabetes among people from different fields.

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6 months, including 3 months (300 Hours) of hands-on training and experience with a recognized mentor in your own town (see this on our website).

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What are the course fees?

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Where can I get more information about this course?

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(For eligibility criteria: Check Website www.diabeteseducatorsindia.com)

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Telephone: Res: …… Office: …… Cell: ……

E-mail id: ……

Educational Qualifications:……

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Work Experience: ……

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Currently employed at: ……

……

Certificates attached*: ……

……

Please pay the membership fees through NEFT / RTGS to the following bank account.

Account name: Association of Diabetes Educators
Account type: Savings Account
Name of the bank: Bank of India
Account number: 006610110001734
IFSC Code: BKID0000066

……
Signature

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Challenges in Diabetes Education 2023 places special emphasis on supporting educational initiatives that have the potential to improve and significantly revolutionize diabetes care, enhance self-management and/or support patients with Type 1 or Type 2 Diabetes Mellitus. The educator should describe an individual or group case history and identify the problem in diabetes education. Furthermore, s/he should describe the plan of education to resolve the issue, partly or totally. The issue described may be related to patient perceptions, knowledge, behaviors and implementation of advice given. S/He should describe her struggle in resolving the issue including her triumphs and failures, the methodologies used and ethical, socio-economic and behavioral aspects of the case.

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- The case discussion should be on the subject of Diabetes Education.

The best case chosen by a group of referees will be awarded "Challenges in Diabetes Education Award- 2023" which will carry a cash prize of Rs 10,000. The awardee will get the opportunity to present the case in the annual meeting of Association of Diabetes Educators and publish it in the journal of Diabetes Education.

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