Ministry of External Affairs
NEST Division

Emerging Technologies & Diabetes

1. Diabetes refers to a group of diseases that affect how the body utilizes blood glucose. Left untreated Diabetes develops into a chronic condition that causes failure of different organs like liver, kidney, eyes, neurons, and cardiovascular system. There are two main types of Diabetes -Type I and Type II, although they have similar symptoms the origins and risk factors are different for both the types. Type I is an autoimmune condition when our body's immune system attacks the Insulin producing cells in pancreas resulting in an absence of insulin. Type II Diabetes occurs when pancreas do not produce sufficient levels of Insulin or when cells poorly respond to Insulin. Insulin use is also impacted by inflammation parameters in the body.

2. India has one of the world's [largest diabetic populations](#), which is 9% of the total population in age group 20-70. Diabetes is one of the most prevalent non-communicable diseases in India and has huge economic burden on individuals/ households. Apart from costs, treatment becomes problematic depending on the progression of disease and damage incurred on other organs.

3. Type II is the most prevalent form of Diabetes and is associated with lifestyle factors. The risk factors for Type II include food habits, high blood pressure, high levels of triglycerides, sedentary lifestyle, family history and age, inflammation causing factors.

4. Diagnosis of Diabetes is by blood glucose tests such as random blood sugar test, fasting blood glucose, oral glucose tolerance test and glycated hemoglobin (Hb A1c) test. Fasting glucose test is the widely administered test to detect diabetic condition, where sugar levels in blood are determined after an overnight fast. Fasting sugar levels below 100 mg/dl is considered normal,

sugar levels of 100 mg/dl – 125 mg/dl are considered pre-diabetic and levels above 125 mg/dl are determined as diabetic patients.

5. Hemoglobin [A1C test](#) or glycated hemoglobin test is also a blood test to diagnose Diabetic condition. This test also determines how well the blood glucose levels are managed over past 2 to 3 months in diabetic patients. Higher the A1c levels mean poorer blood sugar control and greater risk of Diabetic complications. A1c test is also helpful in monitoring diabetes treatment plan.

6. For Diabetic patients regular monitoring of blood glucose levels and medication are effective ways to manage the disease and prevent further development of secondary ailments associated with Diabetes.

7. Commonly, Diabetic patients need a daily finger prick to monitor the blood glucose levels, and some patients to avoid the painful process reduce the number of tests they take.

8. This note mentions the recent emerging technology developments on pain-free minimally invasive Realtime management of blood glucose to control patient's Diabetic condition.

Saliva Biosensor Technology

9. Researchers at University of Newcastle, Australia have developed painless, world's first needle- free Diabetes test - Saliva Glucose Biosensor that can be used by both Type I and Type II Diabetes patients.

10. [Saliva Biosensor](#) is coated with the enzyme Glucose Oxidase. When the biosensor interacts with saliva, an electrochemical reaction is initiated that generates electric current, and the current is measured to detect highly accurate glucose levels. The biosensor emits the electronic signal that is picked up by a smart device (mobile phone app) that displays the individual's glucose reading. The data could be stored on the cloud where individuals or healthcare practitioners could monitor the diabetic condition over a period for better prognostic treatment.

11. Glucose in saliva exists in minute quantities. The Biosensor has proven capable of detecting glucose concentrations 100 times lower than current blood glucose monitoring devices. The saliva glucose biosensor is currently being developed to comply with universally accepted blood glucose monitoring systems.

12. Research studies related to Saliva glucose biosensors have been published in [peer reviewed journals](#) and has both [US](#) and Chinese patents.

13. Saliva glucose biosensor is advantageous over minimally invasive continuous glucose monitoring (CGM) devices because, CGM's must be replaced within a 7 -14-day period and most replacements need to be performed at a doctor's office. Saliva Glucose biosensors are non-invasive and size of a chewing gum stick.

14. This Saliva glucose sensor is currently at advanced stages of development by [GBS Inc.](#) in New York. GBS Inc. has the exclusive license to introduce and launch biosensor platform, including saliva glucose biosensor in many countries within [Asia pacific region](#) (India not included).

Other diseases

15. In collaboration with Harvard University, USA they developed a non-invasive COVID-19 [antibody detection biosensor](#), for studying the prevalence and incidence of SARS-COV2 in a population. The sensor delivers real-time results and allows detection of IgM and IgG antibodies to SARS-COV-2.

16. The inventors of Saliva Glucose Biosensor claim that their Organic Thin Film Transistor (OTFT) [biosensor technology](#) using saliva can be used for the detection of around 130 medical conditions where they can detect tumor markers, hormones, and allergens.

Continuous Glucose Monitoring (CGM) Devices

17. Continuous glucose monitoring automatically tracks blood glucose levels throughout the day. Continuous monitoring can help patients and caregivers make more informed decisions on balanced diet, physical activity, and drug regimen to better manage the treatment and control of diabetes.

18. CGM devices have a tiny sensor inserted under the skin on the upper arm. The sensor can be used to detect the glucose level every few minutes and send the data to a wireless monitor or app.

19. CGM's are used by both Type I and Type II diabetic patients. CGM devices are recommended to patients who are on intensive Insulin therapy and/ or fluctuating high and low blood glucose levels. CGM's are a prescription device recommended by doctors for use in both adults and kids.

20. Hypoglycemia is a condition where blood glucose is lower than normal (<70mg/dl). Hypoglycemia is often associated with Diabetes treatment when patients are on diabetic drugs and Insulin therapy. Symptoms of Hypoglycemia include fatigue, irregular heartbeat, sweating and more severe symptoms include seizures, blurred vision, and loss of consciousness. CGM's also alert the patients when blood glucose levels are very low or very high.

21. CGM's have an alarm system, which is activated when glucose level goes too high or too low for better management.

22. FreeStyle® Liber device by Abbot is one of the commonly used CGM devices in the US and Europe. Freestyle Libre system devices have been proven to help diabetic patients to lower their A1C levels, spend less time in high or low glucose level ranges and improve glucose control in diabetic patients. FreeStyle devices have a sensor implanted on skin that needs to be replaced every 2 weeks. The sensor delivers the result to a compatible reader, and it has an option for alarm when there is a high or low glucose level. Studies have shown that regular use of Liber devices for glucose monitoring have prevented the occurrence of Diabetic ketoacidosis (a condition where

unavailability of glucose for cells triggers the breakdown of fats and increases ketone levels in blood).

23. FDA has recently approved a new CGM device Eversense® where the sensor implanted inside the skin monitors sugar levels for 90 days continuously and delivers the readings through a mobile phone app. In clinical trial Eversense device was able to help patients keep their blood glucose level more stable and reduce the A1c by 0.5% on average. The device also provides on body vibrations alerts when there are potentially dangerous swings of blood glucose, even when there is no access to mobile device (during sleep or driving).

24. Smart Insulin Pen is a device used for delivering appropriate Insulin dosage to diabetic patients, when used along with a CGM. The smart pen system calculates dose amount, dose time and provides helpful reminders alerts and reports. These devices are more affordable and easier to use.

25. A recent development is the integration of CGM and Insulin pump – hybrid closed loop system. The Insulin pump analyses the glucose level from CGM sensor and appropriately delivers the necessary concentration of insulin into the body. This autonomous system for control of glucose levels is also referred to as 'Artificial Pancreas'.

Other Wearable devices for Diabetics

26. Most Diabetic patients usually suffer from comorbidities like hypertension (high blood pressure) and heart ailments. Smart sensor technologies like wearables are effective in monitoring, analyzing, and transmitting fluctuations in vital signs for effective management of the condition.

27. Diabetics need to maintain their blood pressure levels at 140/80mmHg. High blood pressure makes patients vulnerable to stroke, kidney malfunction and

cardiovascular disease. [Biobeat](#) a medical technology company in Israel developed a cuffless blood pressure monitor. The monitoring device includes a sensor patch and a smart watch that provides continuous monitoring of blood pressure, oxygenation, and heat beat. When the sensor is placed on heart it also provides ECG reports. It is an FDA approved product that is useful personal monitoring at home.

28. U.S. FDA has approved [LIVMOR halo system](#) that provides continuous monitoring of heart pulse rhythms and is effective in detecting in heart ailments. Clinical trials have shown that Livmor system is 100% sensitive in detection of Arterial Fibrillation (rapid heart rate that causes poor blood flow) and 93 % specific in detecting heart conditions other than AF. Smart watches (Apple Watch, Fitbit) on wrist now allow continuous monitoring of ECG and are helpful in spotting heart conditions and better management of disease.

August 2021