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An Overview of Wearable Non-Invasive Blood Glucose Monitoring Devices

Mrs. Nilofer Farhat, Assistant Professor, Department of Computer Studies, Maulana Azad College, Dr. Rafiq Zakaria Campus, Aurangabad.

Introduction:

In 2013 it was estimated that over 382 million people throughout the world had diabetes (figure 1). [1] Diabetes, often referred to by doctors as diabetes mellitus is a chronic, lifelong condition that describes a group of metabolic diseases in which the person has high blood glucose (blood sugar), either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. High levels of blood glucose can damage the tiny blood vessels in your kidneys, heart, eyes, or nervous system. That's why diabetes -- especially if left untreated -- can eventually cause heart disease, stroke, kidney disease, blindness, and nerve damage to nerves in the feet. There are three types of diabetes mellitus. [2]

1. Type 1 Diabetes -The body does not produce insulin. Approximately 10% of all diabetes cases are type 1.
2. Type 2 Diabetes -The body does not produce enough insulin for proper function. Approximately 90% of all cases of diabetes worldwide are of this type.
3. Gestational Diabetes - This type affects females during pregnancy.

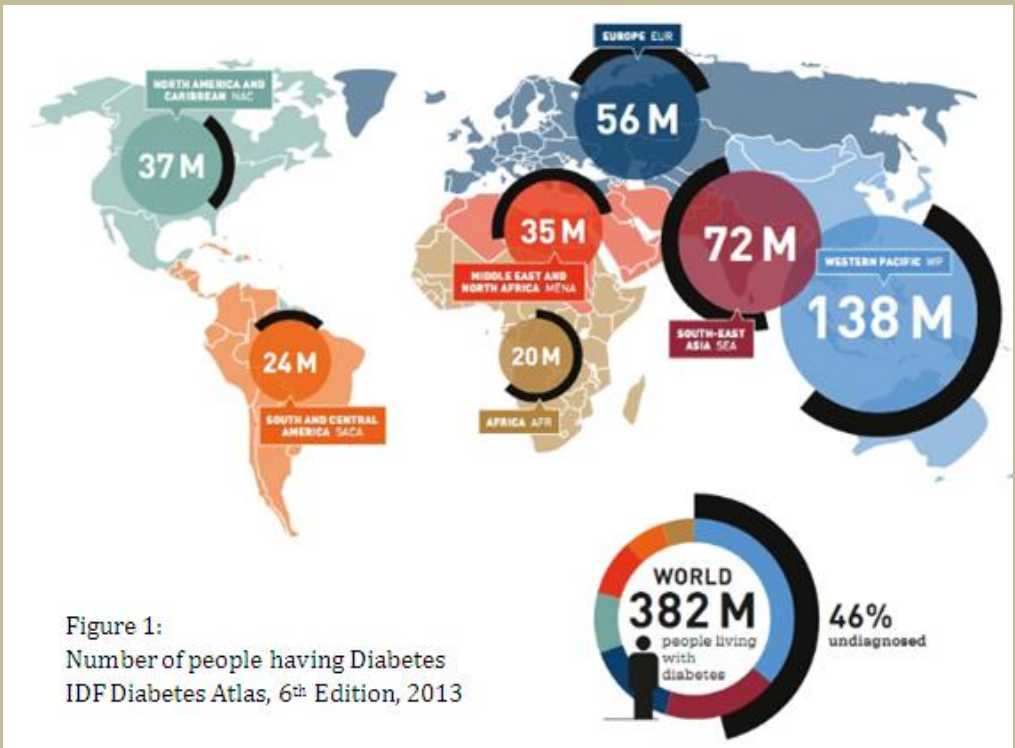

Figure 1:
Number of people having Diabetes
IDF Diabetes Atlas, 6th Edition, 2013

Need for Continuous Monitoring of Glucose:

Blood glucose monitoring reveals individual patterns of blood glucose changes, and helps in the planning of meals, activities, and at what time of day to take medications. Also, testing allows for quick response to high blood sugar (hyperglycemia) or low blood sugar (hypoglycemia). This might include diet adjustments, exercise, and insulin.

As suggested by the Diabetes Control and Complications Trial report, complications arising from diabetes can be reduced and even prevented via careful management that includes regular checking of glucose levels. It is recommended that a T1DM patient should check his/ her glucose levels at least four times per day, while a T2DM patient should check his/her glucose levels at least two times per day. For this, at present, most diabetes patients rely on glucose strips along with hand-held glucose meters that record glucose levels in blood drawn via finger pricking. However, the pain associated with finger pricking together with the inability of test strips to reflect the overall trend in the glucose level of individual patients, i.e., the direction and the pattern associated with the patients' daily habits, renders user-independent continuous glucose monitoring (CGM) a highly desirable proposition. Use of CGM devices will enable the identification of glucose trends, thereby assisting physicians in optimizing treatment plans and facilitating appropriate clinical decisions in cases of emergency. In addition, theoretical modeling has predicted that an additional 5 years of life, 8 years of sight, 6 years free from kidney disease, and 6 years free from amputations can be gained by a diabetes patient who follows tight CGM glucose control versus the standard SMBG(Self-Monitoring of Blood Glucose).[5]

Traditional Glucose Monitoring Techniques:

The available glucose monitoring techniques are classified as under. While many self-management phone applications have been flexibly tailored to individual health requirements through a routinely carried item, much research has been invested in determining blood glucose levels with wearable sensors. [3]

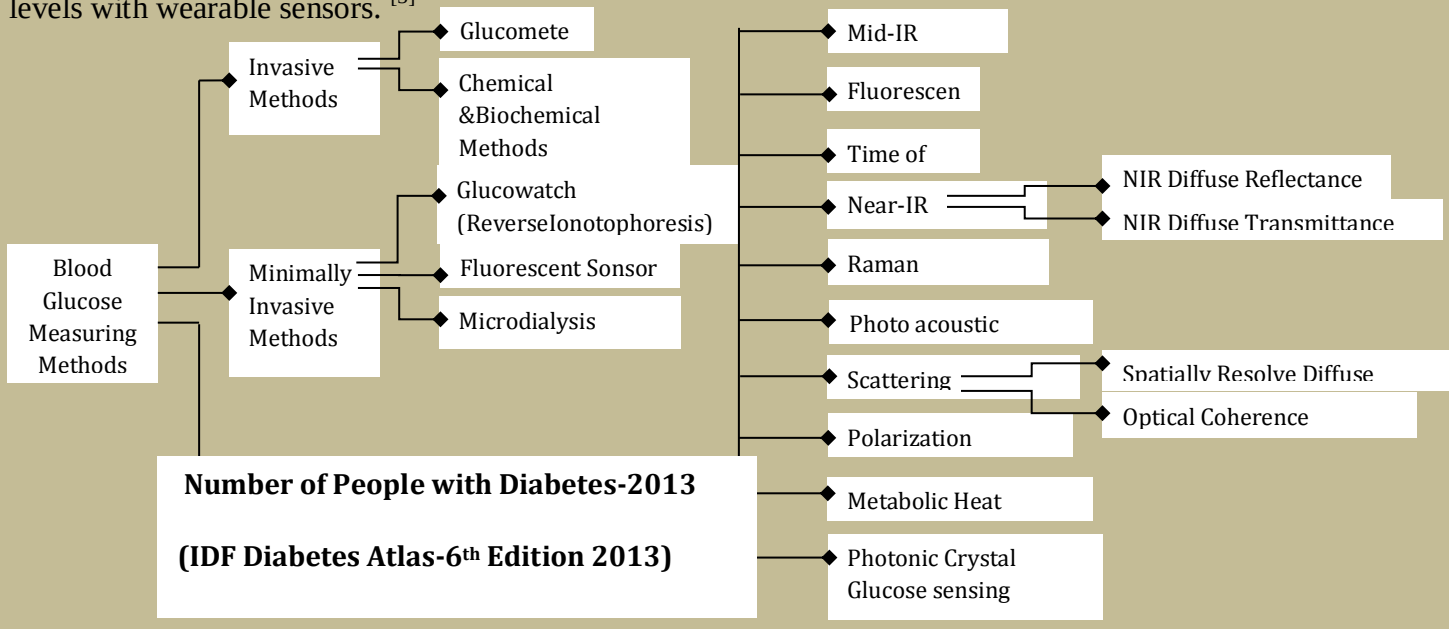

Figure2: Blood Glucose Measuring Techniques- A Classification

Principals of Non-Invasive Glucose Measuring:

A non-invasive continuous self-monitoring device could greatly increase the patient's autonomy and improve the efficacy in the management of diabetes. [4] Noninvasive glucose refers to the measurement of blood glucose levels without drawing blood, puncturing the skin, or causing pain or trauma. The search for a successful technique began about 1975 and has continued to the present without a clinically or commercially viable product. As of 1999, only one such product had been approved for sale, based on a technique for electrically pulling glucose through intact

skin, and it was withdrawn after a short time owing to poor performance and occasional damage to the skin of users. Hundreds of millions of dollars have been invested in companies who have sought the solution to this long-standing problem. However, most of the researchers in this field have been genuinely interested in helping those with diabetes find a less painful and more convenient way to measure their blood glucose. Approaches that have been tried include near infrared spectroscopy (measuring glucose through the skin using light of slightly longer wavelengths than the visible region), transdermal measurement (attempting to pull glucose through the skin using either chemicals, electricity or ultrasound), measuring the amount that polarized light is rotated by glucose in the front chamber of the eye and many others.

Non-invasive determination of blood glucose is a very challenging but difficult task, since an ideal device should meet several conditions, such as being totally non-invasive, without producing any kind of lesion in the skin or other body barrier and be able to properly detect glucose concentrations even in situations of rapid blood glucose Changes.

Glucose can be found in several compartments and body fluids, besides blood, such as interstitial fluid, tears, vitreous fluid, urine and sweat, and many methods are based on measuring the glucose in these compartments. Ideally, the technique should detect glucose concentration at any time and in any condition, showing identical and simultaneous variations in glucose concentration when referred to blood content. From the studies so far it has been demonstrated that there is a specific lag in the equilibration between blood Basically, the NI methods used to determine the blood glucose levels can be classified into two categories according they track intrinsic or extrinsic properties of glucose molecule. The glucose molecule can interact with various chemical or physical methods independently of the body compartment (the intrinsic property) or it can induce tissue specific local changes (the extrinsic property).

Non-invasive glucose monitoring techniques can be grouped as subcutaneous, dermal, epidermal and combined dermal and epidermal glucose measurements. Matrices other than blood under investigation include interstitial fluid, ocular fluids and sweat. Test sites being explored include finger tips, cuticle, finger web, forearm and ear lobe. Subcutaneous measurements include microdialysis, wick extraction, and implanted electrochemical or competitive fluorescence sensors. Microdialysis is also an investigational dermal and epidermal glucose measurement technique. Epidermal measurements can be obtained via infrared spectroscopy as well. Combined dermal and epidermal fluid glucose measurements include extraction fluid techniques (iontophoresis, skin suction and suction effusion techniques) and optical techniques. A summary of possible methods for the non-invasive measurement of blood glucose is given in Figure 2.
The range of measurement techniques usually based upon optical properties of the sample is wide that includes some of the sophisticated methods like near infrared spectroscopy, infrared spectroscopy, Raman spectroscopy, photoacoustic spectroscopy, scatter and polarization change measurements, etc. Non-invasive optical measurement of glucose is performed by focusing a beam of light onto the body. The light is modified by the tissue after transmission through the target area. An optical signature or fingerprint of the tissue content is produced by the diffuse light that escape the tissue has penetrates. The absorbance of light by the skin is due to its chemical components. The transmission of light at each wavelength is a function of thickness, color and structure of the skin, bone, blood and other material through which the light passes.
The glucose concentration can be determined by analyzing the optical signal changes in wavelength, polarization or intensity. The sample volume measured by these methods depends on the measurement site.

Most of the non-invasive methods under development are continuous glucose monitoring methods and offer the advantage of providing additional information to the subject between the conventional finger stick, blood glucose measurements and over time periods where no finger stick measurements are available. The Goal of non invasive glucose monitoring is to shift glucose testing away from medical laboratories and make it easier for diabetics to do their own testing, while capturing glucose test results in patient records.

Wearable Technology:

What is wearable technology? It is a small device that you wear in order to monitor different functions of your body. The body is complex and one symptom can mean almost anything. Different companies have created different types of devices: a device to monitor diabetes, one to monitor prescription pill taking, and one for general health. Several companies are developing wearable, watch-like devices. These are capable of tracking certain biometrics and monitoring glucose. The devices commonly use changing patterns of scattered light or the so-called "speckle pattern" effect, in which grainy interference patterns are produced on images. This happens when laser light reflects on an uneven surface or scatters on an opaque material, according to a press release issued by The Optical Society (OSA). OSA's journal, Biomedical Optics Express (BOE) published papers recently describing these types of glucose testing devices. This technique is based on tracking of temporal changes of reflected secondary speckles produced in the wrist when being illuminated by a laser beam. When the material that is scattering the light is moving, the speckle pattern changes with changes in the flow.

Certain devices for Continuous glucose monitoring systems (CGMS) are shown below. [6]

A. Dexcom SEVEN® Plus
B. Dexcom G4TM
C. Guardian REAL-time
D. FreeStyle Navigator®
E. FreeStyle Navigator II
F. HG1-c
G. GlucoTrackTM

Although these available devices promise good results, there are some limitations. Depending on the type of treatment, medical adherence to treatments for Type 2 diabetes can be as low as 38%. The reason is that the treatments are somewhat invasive, requiring the patient to keep a close watch on their glucose levels. Medical costs for these patients are on average twice as much as patients who follow the treatment regimen. The Bionic Pancreas is a small, wearable device that provides one solution to this problem. The device is in the form of a wearable patch and it checks your glucose level every five minutes to make a determination of whether you need an insulin dose or not. Google, Samsung, and Apple have also announced their own solutions to this

problem as well, with devices ranging from watches to contact lenses, which give you information regarding where your glucose level is at. [7]

Conclusion:

Wearable computing technology is changing the way people deal with their health. The future of diabetes is looking upon a way to introduce blood glucose measurements into day-to-day gadgets so as to improve the health and to reduce the efforts for the said. Wearable computing technology is focused on the development of glucose measuring devices like finger rings, wrist watches, contact lenses, ear clips, body wrapping belts and some other wearable objects.

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