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Review of Tools for Early Detection and Screening of Diabetes

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Research-in-progress

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Abstract

This paper reviews features of numerous tools, techniques and technologies that help to identify and detect early risk of diabetes. The paper uses systematic literature review (SLR) guidelines and searched most of the popular journals limiting the results tied to studies that discussed the screening and detection of the risk of diabetes. We reviewed the architecture, features and limitations of the various tools and technologies using the following classification: Continuous Glucose Monitoring Systems (CGMS), Flash Glucose Monitoring Systems (FGMS) and the Unobtrusive Systems. Under the unobtrusive system, we studied the Child Health Improvement through Computer Automation (CHICA) system and while there are pieces of evidence that proves its benefits and usefulness, we found some required enhancements in areas of decision support system, data entry automation and flexible integration with other systems. Future work will examine the usage of intelligent automation to detect early risk of diabetes during a patient-physician visit.

Keywords automation, blood glucose monitoring, decision support system, diabetes mellitus, Electronic Management Records (EMR).

1 Introduction

The statistics from the World Health Organization (2016) are staggering sowing a reported rise of diabetes globally. The number of people living with diabetes soar to 422 million in 2014 from 108 million in 1980 representing an 8.5% increase. In 2012, 3.7 million people reportedly died before they reached the age of 70 years while 1.6 million people died in 2016 as a result of diabetes (WHO, 2016).

In a subsequent report published by the International Diabetes Federation (IDF) (2019), based on the WHO (2016) data it is estimated that 463million people are currently diabetic with about 4.2 million deaths in 2019. A further projection showed 578.4 million and 700.2 million people will be suffering from diabetes in 2030 and 2045 respectively. These figures illustrate the stark reality that diabetes has become a major global health issue that needs to be managed and is also fast becoming a threat to human life.

The objective of this study is to review the tools, techniques and technology that can help screen, identify, and detect the risk of diabetes at an early stage. We hope that this work will benefit the research communities in the area of automated screening, diagnosis and detection of diabetes while avoiding the expensive management of Diabetes. According to El-Gayar, Timsina, Nawar, and Eid (2013), diabetes is a chronic illness that requires constant continuous care, management, and support to prevent further complications. Dovc and Battelino (2020) describe diabetes as a condition caused by autoimmune destruction of the cells responsible for secreting insulin into the body causing an unbalanced glucose level with reliance and dependence on the infusion of insulin. This disease occurs if adequate insulin is not produced by the pancreas for regulating blood sugar or glucose (WHO, 2016).

After diabetes is screened detected and diagnosed, the affected individual will then undergo a tough regime or series of tasks that include constant glucose monitoring, care, supports, management, and exercise. These are required to avoid hypoglycaemia (low blood sugar), hyperglycaemia (high blood sugar level) in the blood and lead a normal life. Unfortunately, these tasks must be self-managed by the individual and supervised by a healthcare professional. El-Gayar et al. (2013) defined Self-management as a set of tasks that must be done by an individual to live well and deal with the associated chronic conditions or complications of an illness noting also that these tasks can have an associated mental and emotional and physical effect on an individual.

Diabetes self-management process often comes with the following challenges. First, high cost of devices, proper treatment plans, changes in lifestyle, absence of resources for education and lack of adherence to treatment plans (Brown & Bussell, 2011; Buysman, Anderson, Bacchus, & Ingham, 2017) set a high barrier to constant monitoring and control of sugar level. Second, according to Bailey, Walsh, and Stone (2018), there are various factors to consider and more than one way to measure and achieve good glycaemic control. Finally, the self-management process requires a great deal of data acquisition, storage and analysis according to El-Gayar et al. (2013), which can be expensive and demand a high learning curve despite the advances in care and support monitoring tools and technology that helps with these processes.

Early screening aid preventive care according to the guidelines set by WHO. As acknowledged by the US Preventive Task Force (1996), preventive care in line with set standard guidelines is an important factor to prevent diseases and avoiding future complications among children. Preventive care also aligns with the American Diabetes Association (ADA) recommendation for detecting Type 1, 2 Diabetes (T2D) through screening. Attaining preventive care through screening by medical institutions have a lot of barriers such as physician time constraints, lack of knowledge about screening, basic management for diabetes capacity, lack of education and poor communication with patients and families (Lee et al., 2014). Hannon et al. (2017) acknowledge that an unobtrusive automated system could help eliminate the barriers of screening for prediabetes and Type 2 Diabetes.

This paper is a *research-in-progress* and the outcome will eventually assist in constructing an unobtrusive automated system for detecting diabetes.

The review is organized in the following way: Section 2 talks about the methodology used in carrying out the literature review. Section 3 presents a detailed review of the tools and technologies of diabetes as a result of the literature analysis and synthesise. while section 4 concludes the paper and introduces future works.

2 Methodology

The following steps were adopted in our strategy to search and analyse the relevant literature for reviewing the various tools and technologies.

We used the SLR methods provided by Chomutare et al. (2011) who observed that the research-based literature provides adequate history, justification and applications of the tools, Additionally, the literature-based applications compare the functionality alongside the recommendations in clinical guidelines.

2.1 Search Strategy

The search was mainly conducted using Google Scholar, an online search platform and the School University Library portal. Using these portals, we were able to access works from popular journals such as Medline, ScienceDirect, ACM (Association for Computing Machinery) Digital Library, IEEE (Institute of Electrical and Electronics Engineers), Scopus, PubMed and School University library. The following combinations of words and phrases such as "automation", diabetes" "self-management" and "glucose sensors" were used to search while limiting the results to articles that were published from 2016 to date. The search was initially based on the metadata of the paper such as title, abstract, and keywords. Further reviews were conducted on the full-body text to extract journals that were relevant to the early screening and detection of diabetes using automation or computer applications.

2.2 Selection Criteria

Using the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow diagram (depicted in Figure 1) as proposed by McInnes et al. (2018), we were able to depict and show the selection flow through the different phases of the systematic review.

Due to the rapid changes in technology in this domain, our scope of the search was restricted to articles published during the last 4 years (2016–2020). This allowed us to reduce our search results to 2380. The large number of publications were because the search returned widespread results and included articles that covered a wide range of topics from management, administration to psychology of diabetes treatment.

The second phase was the manual review of the titles and abstract. This review aimed to restrict the results to articles that directly talks about the technologies for early screening and detection of diabetes. This inclusion criterion allowed us to narrow the results to 475 papers that had a clear focus on diabetes method for early screening and detection.

Papers which were focused on the discussion of Machine Learning and artificial intelligence procedures were further excluded because the objective of our research was aimed at automation, decision support system, tools and technologies that help the detection of diabetes. To finally select relevant literature, we narrowed our results to diabetes detection and screening tools filtering out research papers that are not written in the English language bringing the search results to 70. We were able to include an additional 10 articles from the review of references from some of the selected published work.

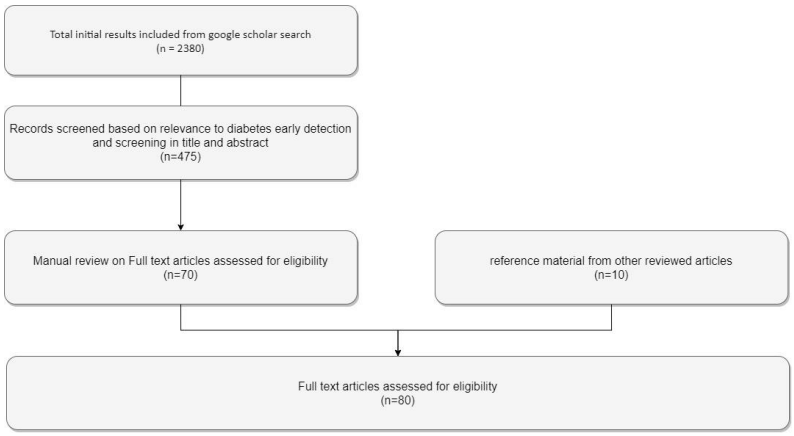

Figure 1: Literature Review Selection Process

3 Literature Review

In line with our objective early detection of the risk of diabetes, we begin by summarizing the list of requirements that must be satisfied by the tools and technologies under review. The requirements include self-monitoring (by capturing weight, insulin levels, blood pressure), alerts and reminders, integration with a Personal Health Record system (PHR), communication and a decision support system for screening for diabetes. As suggested by Huang, Soljak, Boehm, and Car (2018) there are numerous diabetes applications, tools technology available both commercially and understudy which meets these requirements.

Next, we proceed to classify and discuss the various tools and technologies. Ghosh, Bhattacharjee, and Nasipuri (2020) classified blood glucose estimation and measurement as direct and indirect based on the level of involvement and participation of the patient. They defined the direct method as technologies that enable the determination of diabetes by taking blood samples with the awareness of the patient and indirect as a non-invasive method of screening for diabetes when the patient is unaware. This non-invasive nature was also implicitly referred to as unobtrusive in Anand, Biondich, Liu, Rosenman, and Downs (2004)'s study. However, for ease of review, we have classified the technologies that can help detect, and screen for the risk of diabetes as follows: Continuous Glucose Monitoring Systems (CGMS), Flash Glucose Monitoring System (FGM) and Unobtrusive Systems. The CGMS and FGMS are classified as direct method while Unobtrusive is indirect.

3.1 Direct Method Systems

3.1.1 Continuous Glucose Monitoring Systems (CGMS)

A popular method for screening and early detection of diabetes is glucose monitoring. Glucose monitoring helps individuals to assess their glycaemic status and know their insulin requirements. Historically, glucose concentration was decided and assessed by using placing a piece of copper in the urine (Dovc & Battelino, 2020). These evolved into the Self-Monitoring of Blood Glucose (SMBG). SMBG works by detecting the glucose level from the blood through finger pricking. SMBG is considered inconvenient and unacceptable by diabetic patients (Lucisano, Routh, Lin, & Gough, 2016) evolving to a more portable handheld meter called the Continuous glucose monitoring (CGM) device which can be used to measure glucose level directly from the blood. CGM systems have been available for 15 years (International Standard Organisation, 2003).

The CGM systems consist of disposable sensors that are used for measuring the level of glucose in interstitial fluid (Dovc & Battelino, 2020; Fokkert et al., 2017) at intervals and can send the semi-continuous glucose (Fokkert et al., 2017) data to a dedicated receiver or smartphone or cloud systems for further processing, analysis and decision. The shared data provides information on glucose levels fluctuations and variability. The CGM can exist in an implantable where the form sensor is implanted in the skin by health care professionals and data can be sent to a body device (Dovc & Battelino, 2020).

Various studies highlight the usefulness of CGMS and improved glycaemic control because of its use (Langendam et al., 2012; Poolsup, Suksomboon, & Kyaw, 2013). Research has also shown the efficacy of CGM in reducing HBA1c and avoiding hypoglycaemia (Juvenile Research Group, 2008). Dovc and Battelino (2020) note that the CGMS have been successfully used in pregnancy complicated by Type 1 Diabetes(T1D) leading to savings worth millions of US dollars. CGM, as endorsed by the American Diabetes Association (2019) have also been used as a standard of care for people with T1D.

Besides the high prediction accuracy (Bailey et al., 2018) of the CGM devices, there are other important features of the CGM such as the ease of use, miniaturization, data management and a secure connection with different applications and data. The capability to connect to other devices is an important feature that allows the device to provide add-on features such as decision support, notification and reminders to the individuals and healthcare professionals. Dovc and Battelino (2020) compared a few of CGM products such as G6, Guardian Sensor 3, Eversense and Freestyle libre/libre 2 manufactured by Dexcom, Medtronics, Senseonics and Abbott respectively. Out of the 4 devices, only Eversense is implanted while the others are inserted.

In addition, the G6, Guardian Sensor 6 and Eversense have claims, trends or alerts with some data sharing capabilities (Bailey et al., 2018; Dovc & Battelino, 2020). The data-sharing features allow vendors to develop apps that can extend the features of the CGM devices. Bailey et al. (2018) list mobile phone apps and software that integrates with CGM to provide and display glucose data. Dexcom has G5mobile phone, Medtronic has a Guardian connect app, Abbot has libre link and libre

linkup software. Bailey et al. (2018) further note that these mobile apps allow for the data sharing, connectivity and provide other experience that allows the increase in the safety of Seniors who are either incapable of self-management or support.

However, the device comes with its limitations. CGMS require frequent calibration of the system, about twice daily to allow for a reliable "correlation" (Fokkert et al., 2017) between interstitial and capillary glucose results. Secher, Ringholm, Andersen, Damm, and Mathiesen (2013) and Murphy et al. (2008) argued that there are limited benefits and mixed outcomes for the application on pregnant women with diabetes and they provided a list of barriers that includes skin limitations, frequent alarm notifications, cost and inconsistencies between sensor values. Feig et al. (2017), in his study documents about 80% expressing frustrations with 48% experiencing skin irritations. Most of these devices have been less intuitive and not particularly user friendly and will require the help of professionals to set up and use. Deriving the maximum benefits of the CGM and CGM Extensions is largely dependent on appropriate usage. The integration with an Electronic Medical Record (EMR) or Personal Health System (PHR) system or the sharing of data with a qualified healthcare professional is vital. Some of the CGM devices reviewed by Bailey et al. did not show any visible integration with these systems. The chance of preventing diabetes is significantly reduced if the data is not thoroughly analysed by a healthcare professional.

3.1.2 Flash Glucose Monitoring (FGM)

The frequent calibration of the CGM among other limitations were the reasons for the introduction of the Flash Glucose Monitoring (FGM) System. Abbott introduced the Freestyle Libre, a Flash Glucose Monitoring system into the market in 2014 (Heinemann & Freckmann, 2015) and as the time of this study, they were the only manufacturer of the system. According to Fokkert et al. (2017), FGM systems are compact and lightweight and do not require frequent calibration by CGMs only a factory calibration. Heinemann and Freckmann (2015) further confirm that frequency of calibration is a major difference between the FGM and CGM is calibration. FGM systems also measure interstitial glucose using disposable electronics and subcutaneous sensor attached to the skin using a button look-alike to hold it firmly in position. This can measure glucose every minute for 14 days. The sensor is then scanned, and data displayed on a screen to show trends.

The FGM systems are a vital substitute for individuals who do not want the painful finger pricking associated with Self-Monitoring Glucose System (SMBG) or who do not want to be bothered with the frequent alarm notification and calibrations from CGMs. Scott, Bilous, and Kautzky-Willer (2018) report the high accuracy of the device and that it was not affected by parameters such as type of diabetes, pregnancy sage, age or BMI and the system is easy to use and can provide up to 14 days glucose data. According to, Heinemann and Freckmann (2015), the FGM devices surpasses the Conventional blood group self-monitoring in the following ways.

- "Intermittent capillary sampling only provides a snapshot of glucose concentrations" (Heinemann & Freckmann, 2015).
- Accuracy, according to international standards (Fokkert et al., 2017) is +/- 15% for glucose level greater than or equal to 100mg/dl and +/- 15 mg/dl for glucose level less than 100mg/dl.
- Scott et al. (2018) described the accuracy of the Freestyle Libre System as a combination to the robustness of patient characteristics such as age, BMI, insulin usage, pregnancy stage and type of diabetes.
- BG self-monitoring might take a few minutes while the FGM can scan and read results within seconds. This information according to their study is enough to recommend its usage in pregnant women to support and optimize their glycaemic control.
- Conventional BG monitoring is more expensive than FGM at an average rate of 5-8 tests per day.

Despite its benefits and applications for detecting the glucose status of individuals, the FGMS has some limitations. In a study carried out by Scott et al. (2018), although there was a favourable rating in user experience, they found out that 7% of the participants reported associated symptoms such as bleeding, bruising, erythema, itching, and pain while Fokkert et al. (2017) reports limitations such as physiological lag time, sensitivity to local fluctuations. Comprehensive Education is also essential and plays a huge role in the adoption (Al Hayek, Robert, & Al Dawish, 2017; Bruttomesso et al., 2019). Adolfsson, Parkin, Thomas, and Krinelke (2018) sees the less frequent factory calibration as a limitation as patients are unable to recalibrate when glucose values do not match confirmed blood

glucose test results. They also argued that the 8-hour monitoring trend might make the system easy to use but offers a potentially dangerous limitation to patients at risk of hypoglycaemia.

3.2 Unobtrusive Systems

There are few justifications for the need for unobtrusive systems. Firstly, limitations such as frequent calibration, alarm notifications, costs, sensor value inconsistencies, skin irritation, intensive education associated with invasive systems and direct systems like Glucose monitoring systems have made them very popular. Secondly, the increasing need for further analysis by a healthcare professional and integration with an EMR system. Lastly, the rising importance and popularity of preventive health care where healthcare providers place a priority on understanding the risk profile of patients to eliminate future interventions. An ideal glucose monitoring system would be unobtrusive, "not attached to the skin, retain stable long-term calibration, and require minimal maintenance, if any, by the user" (Lucisano et al., 2016, p. 1).

According to the US Preventive Services Task Force, unnecessary interventions can be prevented by early analysis and screening for diabetes based on established guidelines and using technological tools that can be used by patients and comply with set guidelines (Carroll et al., 2011). The guidelines talk about the Just-in-time information delivery and defined it as screening and receiving notifications during the patient-physician visits while the physician is taking notes (Carroll et al., 2011). Although Preventive systems are increasingly becoming popular and ubiquitous, we shall limit the scope of discussions to the Child Health Improvement through Computer Automation (CHICA) system which is considered a CHICA system.

3.2.1 Overview of CHICA System

Anand et al. (2004) described the CHICA system as a client-server architecture system while Hannon et al. (2017) explains that the system is tightly integrated with an electronic medical record and uses a pre-screener form for eliciting information from patients. The pre-screener form can be accessed on basic mobile devices (Hannon et al., 2017) and captures information on family history, race, ethnicity, and an assessment form for physicians. The forms are subsequently scanned using Optical Character (OCR).

It contains a module that applies pre-defined logic using Ardern MLM Rule-based parsing processor to analyse captured data and decision support while ensuring compliance with the general standard practice in a paediatric clinic (Carroll et al., 2013; Carroll et al., 2011). A tightly coupled integration with an Electronic Medical Record (EMR) provides the setups and configuration of diagnostic codes, orders, prescriptions and laboratory data from an integrated and centralized portal (Biondich & Grannis, 2004). Integration with other systems provides the CHICA system with a feature extension that allows the sending of information to the laboratory for testing, send out a notification for follow up appointments and generates reminder phone calls for an appointment. It also makes the referral and follow-up calls based on glucose levels.

The CHICA system has many applications and benefits. Hannon et al. (2017) study showed that the application of CHICA automation increased the rates of screening of diabetes 4 times among youths with a BMI above 85th percentile and 2 or more risk factors according to the recommended ADA guidelines. The increase in follow-up attendance can also be attributed to the system.

However, the tight integration of the system with the Indiana University Health primary health care portal and application serves as a major limitation for the CHICA system. Although as quickly noted by Hannon et al. (2017), there is ongoing work to redevelop CHICA as a web service to provide more availability and widespread usage.

4 Conclusion

In this paper, we classified the different ways of detecting and screening for glucose into a continuous glucose monitoring system, flash glucose monitoring system and the unobtrusive system. For each of the category, we discussed the architectural differences, strengths, and limitations. Both FGM and CGM have been shown to share limitations such as skin irritations, frequent alarm notifications, cost and inconsistencies between sensor values and difficulty in learning to use the devices. These limitations with FGMs and CGMs devices have made the Unobtrusive systems very popular. Our study is limited to the CHICA system for the unobtrusive system. The main benefits of the Unobtrusive system are the capability to assist in detecting and early prevention of diabetes thereby potentially avoiding the hassles of self-management\care of diabetes and making required lifestyle changes.

The CHICA system also comes with limitations such as tight integration with the institutions EMR and the manual method of completion of forms by patients and physicians. Our studies show that there could be improvements in areas such as data entry automation, decision support system and flexibility to integrate and work with the various hospital systems. We believe that recent technological advances such as the highly fast-paced and scalable robotics process automation, artificial intelligence, and machine learning in the combined areas of automation and decision support can greatly improve the outcomes of the unobtrusive system. Future work will examine how to improve these areas for the screening of the risk of diabetes during patient-physician visits.

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