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Data-Driven Carbohydrate Counting Accuracy Monitoring: A Personalized Approach

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Abstract

Accurate carbohydrate counting is crucial for type 1 diabetes mellitus patients on intensive insulin therapy to get on-target blood glucose values. So, it is fundamental to assess their ability to estimate meals' carbohydrate content and, if needed, recommend carbohydrate counting training. In this context, we propose a personalized data-driven approach to monitor the patients' ability to estimate the carbohydrate content of meals.

The proposed approach uses personalized data to compute a safe range for the carbohydrate counting error according to the characteristics of each patient and adjust this interval to the patient's daily routines and food habits. Initially, the proposed method uses the insulin-to-carbohydrate ratio, the insulin sensitivity factor, the blood glucose limits, and the blood glucose target to compute a safe interval for the carbohydrate counting error, so the patient could train to reach this goal. Then, the app uses collected daily life data (i.e., blood glucose, meals carbohydrates content, and insulin bolus) to adjust the initial safe interval for the carbohydrate counting error according to the patient's needs.

Preliminary assessment using the FDA-approved University of Virginia (UVA)/Padova Type 1 Diabetes Simulator shows the potential of the proposed approach to help type 1 diabetes patients being aware of their needs for carbohydrate counting education and how accurate they should be to achieve suitable blood glucose levels. Therefore, this tool has the potential to be a great asset to healthcare professionals and patients, improving the carbohydrate counting learning outcomes and leading to better glycemic control.

Keywords: Healthcare; Personalized Medicine; Carbohydrate Counting Education; Accurate Carbohydrate Counting

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1. Introduction

Diabetes Mellitus (DM) is a chronic metabolic disease characterized by hyperglycemia. Therefore, the main objective in diabetes treatment is keeping blood glucose levels near normal. The Carbohydrate Counting (CC) method plays a crucial role in this respect. Planning meals and adjusting carbohydrate intake to insulin dose is essential for proper diabetes management. Several studies show a relation between the use of CC and the reduction of glycated hemoglobin (HbA1c). Although, this nutritional strategy implies good knowledge and commitment of the patient. Most patients consider performing CC a complicated task and commit errors when estimating the carbohydrate content of meals. To overcome these difficulties, the medical team should educate and empower patients [1, 2]. Since diabetes is a chronic disease in which the daily choices and behavior of the patient are crucial for the control of the disease and, consequently, for their quality of life, education for self-management must be a continuous process, starting from the diagnosis and must last for life [3].

Recent technological advances in sensor technologies and communication networks allow the collection of a large quantity of daily life data. This data collection and further analysis using machine learning and Artificial Intelligence (AI) algorithms will provide the ability to "learn" from the data and generate new and more accurate knowledge for the prevention, diagnosis, and treatment of diabetes [4]. This paradigm shift allows for the emergence of more personalized medicine, which in the case of diabetes can lead to better control of the disease, avoiding acute and long-term complications. Regarding this, we propose a new intelligent data-driven personalized approach to define safe limits to the CC error and posterior adjustments based on collected data (e.g., Blood Glucose (BG), carbohydrates intake (CHO), and Insulin Bolus (B)), allowing to design personalized educational programs and defining learning outcomes according to the specific needs of each patient.

2. Background

Diabetes is a chronic disease caused by an inherited or acquired deficiency in insulin production. In other words, DM is related to the bodys inability to regulate BG levels. Thus, the diabetes treatment goal is to maintain homeostasis and BG within safe limits to avoid hyper or hypoglycemic events [5]. To achieve this, patients must measure the BG levels several times a day and combine insulin medications with a strict diet and physical activity.

Managing diabetes is a time-consuming task, particularly for Type 1 Diabetes Mellitus (T1DM) patients. Fortunately, there are several technologies available to help patients with it. Indeed, personal digital technologies are changing the healthcare sector and improving the way diagnosis, monitoring, and treatment are performed nowadays [6]. In addition to the benefits of personal digital technologies in medical care, it also allows patients empowerment, giving them more security in the process of daily self-management of the disease and, consequently, leading to an enhancement in their quality of life [7].

2.1. Monitoring and management technologies

Personal medical devices, including mobile applications and wearables, are flourishing in the market, being those dedicated to diabetes the ones that evolved the most. In particular, blood glucose meters and monitors, blood glucose sensors, insulin pumps, and personal advisors and diaries play a vital role in the patient's daily life [8].

2.1.1. Blood glucose meters and monitoring devices

Managing and treating diabetes relies on keeping BG within a safe interval. Therefore, BG monitoring is one of the most important processes in the patients' daily life. Traditionally, BG monitoring involves multiple daily finger-prick testing of capillary blood using a Self-Monitoring Blood Glucose (SMBG) device. SMBG is a tool for patients to adjust medications, nutrition, and physical activity, to avoid hypo and hyperglycemic events [9].

Recent technological advances bring to light Continuous Glucose Monitoring (CGM) devices. Current CGM devices measure blood glucose subcutaneously in the interstitial fluid through a wearable sensor placed under the skin. This technology makes it possible to measure BG in real-time and continuously and send the readings to an external receiver, e.g., a smartphone or an insulin pump. CGMs have become very popular, especially for T1DM patients, as these patients need to perform more rigorous glycemic control [10, 11].

CGM devices brought several benefits, such as avoiding several finger-pricks a day, but mainly they provide valuable knowledge about the glycemic profile of an individual. Whereas with SMBG, the glycemic data collected is limited to a few BG samples a day, CGM allows the collection of a large amount of BG measurements per day, allowing the detection of small BG excursions and sending alerts to an external device. All the information collected is crucial for the patients daily routine, giving insights into how carbohydrates intake and physical activities impact their glycemic metabolism [12].

2.1.2. Insulin pumps

In T1DM and some cases of T2DM, patients are insulin-dependent, so they need to receive insulin several times a day. There are two main methods for delivering insulin therapy, the traditional Multiple Daily Injections (MDI) with syringes or insulin pens and the Continuous Subcutaneous Insulin Infusion (CSII) system using insulin pumps. Evidence shows that both methods are associated with improved glycemic control, expressed in terms of lower HbA1c. However, CSII therapeutic also correlates with a reduction of hypoglycemic events [13, 14].

Insulin pumps are wearable electronic devices that enable the continuous delivery of small doses of basal insulin, bolus insulin according to the carbohydrate intake of meals, and a personalized correction bolus to compensate glycemic peaks. Technological advances in sensors and software allow recent smart insulin pumps to integrate excellent accuracy calculators to suggest proper insulin doses. Combine sensors to detect blockages, volume, flow, and air bubbles, having the capacity to generate alerts to improve patients' safety. Such systems provide greater flexibility to patients, lower the burden of managing the disease and, consequently, improve their quality of life [15].

2.1.3. Mobiles applications

The ubiquity of smartphones led to the development of countless mobile applications, aiming to improve health outcomes and enhance patients' quality of life [16]. The importance of such technologies originates a new application field known as mHealth. mHealth applications (mHealth apps) dedicated to diabetes encompass disease prevention and diagnosis, disease monitoring and management, and treatment. Furthermore, mHealth facilitates the communication between healthcare professionals and patients, strengthening the relationship between them [17].

Several studies showed that different mHealth apps successfully help patients to manage diabetes [18, 19]. Besides the applications integrated with medical devices such as CGM systems and insulin pumps, there are standalone mHealth apps for managing diabetes focused on keeping blood glucose history, calculating the insulin bolus, and sending reminders and alerts. More complete apps also consider physical exercise and diet, enabling telemedicine and a secure data connection with healthcare providers. Fewer apps are focused on education or motivation, in particular, on nutritional information and carbohydrate counting education or achieving goals in exercise and diet [20, 21, 22].

Regarding automatic carbohydrates counting, several food recognition platforms and mHealth apps are available. Asbroeck *et al.* [23] assessed seven popular food and drinks recognition application programming interfaces and found that the most accurately recognized 63% of foods and beverages. They also found that none of them correctly estimated the quantity of food. In addition, there are several mHealth apps available for different mobile platforms. As an example, we stand out: GoCarbs and iSpy. The first does a near real-time estimate of the carbohydrate content using computer vision. The app recognizes food, estimates volume, and finally estimates the carbohydrate content on a plate. Further, GoCarbs does the optimization of the bolus insulin dose calculation. According to Vasiloglou *et al.*, GoCarbs has difficulty in estimating some foods, such as rice, pasta, potatoes, and mashed potatoes. Nevertheless, GoCarbs can estimate the carbohydrate content of 54 central European plated meals with a mean error of 15 g, which is comparable to the dietician's accuracy [24]. Similarly, iSpy applies computer vision and artificial intelligence to estimate the carbohydrate content of food but also enables voice or text descriptions. This app, intended for T1DM youth, showed to reduce the frequency of patient estimates with errors greater than 10 g [25].

In this context, patients' ability to accurately estimate the carbohydrate content of meals is still a priority. To the best of our knowledge, there is no mHealth app to compute a safe range for the carbohydrate estimation error nor to assess the patients' characteristics and daily routine and detect the need for reeducation on CC. So, our proposal has the potential to fulfill a gap and help patients manage the disease, and improve their quality of life.

2.2. Privacy and security concerns

Technological advances such as wearable sensors, wireless connections, and cloud computing allow medical data to be collected and processed in near real-time. It makes healthcare more dynamic and responsive, which reduces costs. Data collected through medical sensors also facilitate large-scale statistical studies and knowledge extraction applying artificial intelligence. Therefore, it is crucial to guarantee the confidentiality, integrity, and availability of such data [26]. Moreover, the sensitive nature of healthcare data leads to legal and ethical concerns and raises privacy and security issues [27]. Thus, governments and regulatory bodies established rules and standards to regulate the security policies of mHealth apps and other personal medical devices connected through the internet [28].

The Food and Drug Administration (FDA) recognized this need and published a guidance report defining software clusters for medical purposes. FDA report aimed to clarify which subsets of software functions will be under its authority. Centered in mHealth apps for diabetes, The European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) did a consensus report highlighting the concerns related to stand-alone diabetes apps that are largely unregulated. The lack of evidence on apps accuracy and clinical validity, standardization, and security issues are some of the topics addressed [19]. Hence, the procedure to ensure security and privacy on mHealth apps is clearly defined, e.g., to guarantee the users' privacy, it is necessary to observe the European General Data Protection Regulation (GDPR). In addition, it is relevant to give the user control over which data he wants to share for research and which he does not [27]. Regarding security, users authentication is a critical topic. The user must be aware of the importance of using a strong password and must be careful not to share it. Furthermore, authentication ensures that the information is linked to the correct user and that only authorized users can gain access to these data and the system. Cybersecurity protocols recommend using two-factor authentication if sensitive or potentially harmful information is involved. Inherence factors such as facial recognition or fingerprint authentications can also be a valid option in mHealth apps. Moreover, data encryption before the transfer process is critical because it preserves anonymity and prevents malicious attacks [29].

2.3. Personalized medicine

In the last decade, studies using big data in the healthcare field have entailed a new way of thinking on medical care. The evolution of artificial intelligence and the emergence of machine learning allowed a deep knowledge of how to treat each patient according to its specific characteristics and needs. Thus, the concept of Personalized Medicine (PM) or Precision Medicine emerged. PM central goal is to achieve individualized solutions to prevent, diagnose or treat a disease based on advanced knowledge about an individual's genetics, environment, and lifestyle [30, 31]. Personalized medical care has been applied to diabetes for a long time, but empirically. The complexity associated with this task requires employing AI techniques to assist healthcare professionals in improving clinical decision [30, 32]. In the case of DM, this personalized approach allows thinking about preventing, controlling, and treating the disease using data-driven knowledge about each patient.

mHealth technologies for diabetes self-management are now common practice, at least for patients with some technological literacy. There are mHealth apps capable of connecting with CGM, smartwatches, and other wearable sensors, collecting data automatically, which helps to understand the patient's glycemic profile. Subsequently, these apps can make suggestions based on prior knowledge, allowing more informed choices. In this way, it is offered a personalized solution, having the potential to improve patients' health outcomes. Additionally, the information gathered with these apps can help clinicians understand the patient's daily habits in a real-life context, and unobserved factors can be highlighted. Therefore, doctors can make more reliable recommendations [4, 8, 33, 34].

Individualized nutritional therapy for DM patients is related to positive effects to enhance health outcomes leading to a lower cardiovascular risk [35]. Therefore, CC education must be tailored to the individual needs of each patient. Each patient has a specific insulin sensitivity factor (ISF) and an insulin-to-carbohydrate ratio (ICR), which leads to different metabolic responses to the same insulin dose. Customizing CC education and training the patient according to its needs has the potential to improve patient adherence and confidence in CC.

3. Proposed tool

Several mHealth apps address CC aiming to help DM patients on this vital task. However, to the best of our knowledge, it does not exist a mHealth app designed to help healthcare professionals establish learning outcomes on CC education, according to the particular characteristics and daily practices of each patient.

The proposed approach encompasses an initial stage followed by an adjustment stage. Initially, a physician evaluates the patient and determines its ICR, ISF, the BG limits, and the BG target. The proposed app stores these data as the patient clinical data. During the adjustment stage, the app collects data from several other sources, namely, the BG, the CHO content of each meal, and the corresponding insulin bolus.

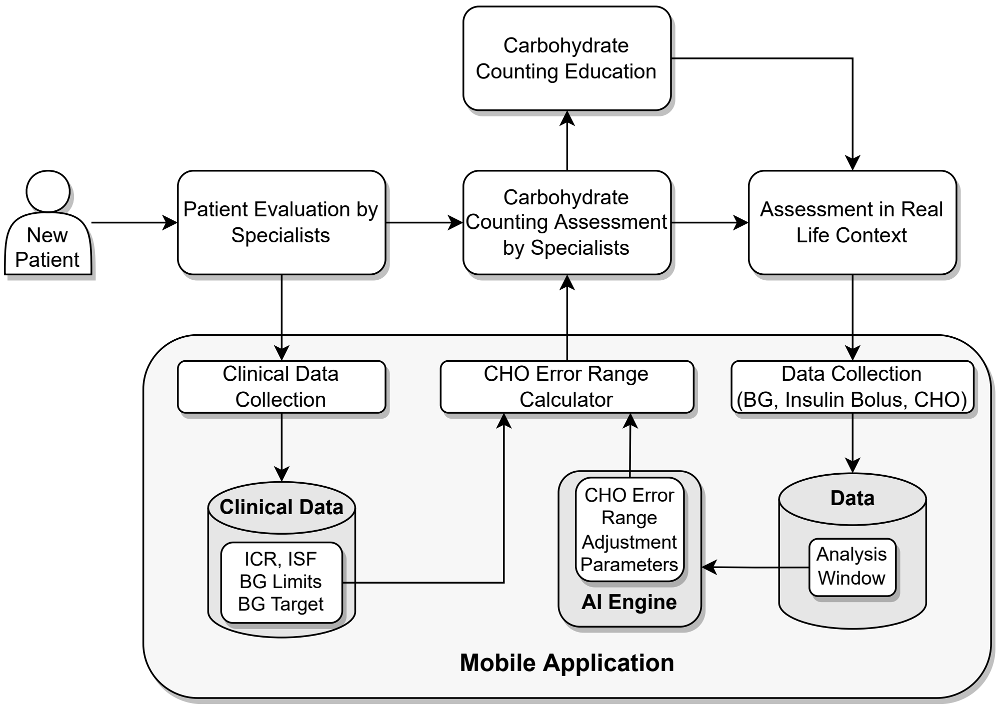

Fig. 1. Proposed mHealth app architecture and its interaction with the carbohydrate counting education and assessment process.

Figure 1 shows the main blocks within the proposed app and illustrates how it interacts with the CC educational program. In the first stage, the proposed app uses the patient clinical data and the method proposed by Abreu *et al.* in [36] to compute the initial safe range for the CC error allowed for each patient. Then, if necessary, the patient gets education and training on CC until its CC error is within the safe range calculated previously. When the patient fulfills the criteria to be autonomous in CC (i.e., when the CC error performed by the patient be within the safe range calculated for that patient), the app starts monitoring the patient's daily activities related to DM management.

Since the patient's performance on CC could be different in real life than in the training context, the proposed mHealth app collects data entered by the patient or/and data automatically gathered from personal medical devices, such as continuous glucose monitors to compute adjustments to the initial safe range of CC error. Moreover, the proposed method allows not only to adjust the CC error allowed for each patient according to its ability to accurately perform CC but also, according to its needs and daily routines.

This mHealth app uses an analysis window, pre-defined by the healthcare specialists, to analyze the data and compute the new safe range of CC error allowed for that patient using AI. If the new CC error range does not include the previous one, the patient is informed that he/she should make an appointment with its medical team.

Figure 1 also illustrates the relevant phases to empower patients in CC and how the app intervenes in this process. This cyclic process allows not only a personalized treatment but also adaptation to the patients' daily life changes.

If the patient changes their physical activity habits or even undergoes an emotional or job change that modifies their eating and glycemic patterns, using this mHealth system will overcome this.

The proposed mHealth app has been developed under the project TECH – Technology, Environment, Creativity and Health, in collaboration with the School of Health of the Polytechnic Institute of Viana do Castelo, and will be assessed in strict cooperation with the Santa Luzia Hospital, located in Viana do Castelo, northern region of Portugal.

4. Conclusions

Accurate carbohydrate counting is vital for type 1 diabetes mellitus patients on intensive insulin therapy to get controlled blood glucose values. So, it is essential to assess their ability to evaluate meals' carbohydrate content and, if needed, recommend carbohydrate counting education. In this context, we propose a mHealth application that uses patient-specific data and artificial intelligence to establish a safe limit for the carbohydrate counting error allowed for each patient. The proposed mHealth application could be a great asset to healthcare professionals and patients, improving the carbohydrate counting learning outcomes and leading to better glycemic control. Assessing the need for re-education in CC, this solution personalizes nutritional care for diabetes. Thus, patients can have a more flexible diet and feel more confident in the daily management of the disease.

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