Abstract

Smartphones and other mobile devices have become an integral component of daily life for many people worldwide, offering a broad and up-growing range of functions and utilities. Social media, the information and communication technology, and the enhanced usability and pervasiveness of mobile devices have resulted in an enormous interest in the development of a large diversity of health care applications. This dynamic time for new technologies that overlaps the current epidemic of diabetes and obesity gives smartphones the potential to play a role in increasing healthcare delivery and efficiency. Research has consistently shown that diabetes and obesity management represents the medical area where mobile devices could help in achieving therapeutic goals and enhance patients’ quality of life. This paper comprises a brief overview of the current state of development, requirements and regulations in the health mobile applications industry, and a short overlook on mobile applications diversity, safety and efficacy towards the self-management of individuals with diabetes mellitus and/or obesity and the enhancement of their quality of life.

key words: diabetes, obesity, smartphones, mobile applications; mobile health; systematic review; apps, telemedicine; glucose control; self-monitoring; diet; exercise.

Introduction

Recently, a surge in smartphone ownership has been reported by the industry. In the UK 51% of the population owns a smartphone [1] and data in the US shows that about 95 million Americans used their mobile phones either as healthcare tools or to research health information [2]. In Romania, a 2013 press release from the industry states that smartphone sales have reached 6 million units, which translates into 30% of the population owning a smartphone [3]. A new study found that there are approximately 43,000 medical applications available online only in the iTunes store, and over 8,000 in the Google Play store, and these figures are growing by 150% per year [4] which has the industry experts predicting that almost 500 million patients and healthcare providers will use a mobile health app within the next two years [5]. Statistics have demonstrated that on average, users check their smartphones every 6.5 minutes and each person has approximately 41 applications (apps) on the phone [6].

Apps can record dietary information, identify pills, perform medical calculations, keep track of physical activity, screen for diseases, manage doctor's appointments, transmit...
recorded data to a healthcare provider, and help quit smoking or substance abuse, to enumerate just a few among many functions. There is a smartphone app for nearly everything and everyone, and the industry is moving further, towards convergence between apps and devices used by either clinicians or patients. Thus, smartphones have become an “indispensable” source of healthcare information for approximately 38% of surveyed users, which are considering that their devices are “essential” for finding health or medical information and managing lifestyle interventions [5]. However, a study on nearly 43,689 English language purported health or medical apps available in Apple’s iTunes app store, found that only 54% (23,682) of them were “genuine” healthcare apps, and 69% (16,275) of those were targeting patients, while the rest of the 31% (7,407) were built for use by clinicians [7].

**Characteristics and regulatory framework of mobile health applications**

Clinicians find it is quite difficult to keep up with all the resources available to patients and also be able to determine which website or app is the best to recommend since what works for one patient may not work for another. In a review published in Telemedicine Journal and e-Health in 2010, Khaylis and colleagues had described 5 elements as being essential to a successful technology-based tool: “self-monitoring, peer or social support, counselor feedback, and individually tailored behavior change”[8]. Interactivity and self- or mass-customization are also often regarded as the most desirable, significant characteristics of medical apps [9].

The industry rapid development trends and the consumers (patients and clinicians) necessities regarding safety, efficacy and confidentiality have imposed the authoritative testing and validation of mobile apps as a requisite, with the aim of easing both physician and patient uncertainty about adopting apps more widely for daily medical use [10,11]. It has to be noted that increased reliance on handheld devices comes with the inconvenience of their frequent inadequate protection for security and confidentiality. Thus, the loss of smartphone or a breach in device’s security may pose the risk of medical information ending up in the possession of employers or private individuals [10]. In September 2013 the Food and Drug Administration (FDA) has decided to get involved in regulating medical mobile app development, therefore issuing its most recent guidance on mobile medical apps (“Mobile Applications Guidance for Industry and Food and Drug Administration Staff”) [12] although to date, there are no formal laws or regulations governing their use [12]. According to these new guidelines, an app that only records diet or exercise data would not require the control and regulation usually applied to a medical device, but an app that tells how to adjust the insulin dose based on readings from a glucometer will likely be regulated. The EU’s new edition of the Manual on Borderline and Classification also contains some borderline software (including medical apps) guidance [13].

**The beauty and the ugliness of using mobile health applications in clinical practice**

Since this new technology is readily available on the market, clinicians should use it to their advantage, encouraging patients to get benefits from it and improve health control.

A report of the IMS (Intercontinental Marketing Services) Institute for Healthcare Informatics shows that most efforts in app development have been focused on overall wellness, especially diet and exercise, although most of them have only limited functionality [7]. Overweight or obese patients may find specific apps useful to target their weight loss, keep track
of physical activity performed, and control their diets. Diabetic patients could take advantage of apps that help them count the insulin units or control the carbohydrate quantity in the food they purchase from the supermarket or put on their plates. To date, several systematic reviews have found that Web-based interventions may be moderately effective in facilitating lifestyle changes and weight loss [14]. The issues regarding the use of medical apps (as well as of medical information found by random searching on the Internet) are whether these apps (or medical information) are trustworthy, rely on scientific medical facts, and truly help the patient. Not every web page hosts accurate information nor is every app effective, so it can be very difficult for a patient to comb through this multitude of products in the search for the right one.

An overlook of the medical apps developed for either wellness maintenance, or obesity and diabetes management demonstrates a large variety, complexity and utility. The quite popular Wellness Diary is a mobile app developed by Nokia, which allows users to record health data such as body weight, daily sleep duration, daily physical activity and calorie expenditure, and receive feedback on the input [15]. Daily Carb is a diabetes targeted mobile app created by Maxwell Software, collecting data about carbohydrate and water intake, glycaemia, daily prescription drugs, blood pressure, and physical activity. Glucose Buddy by Azumio is a diabetes logbook manager with syncing, blood pressure and weight tracking, while GoMeals of Sanofi-Aventis is a popular meal tracker. PmEB app allows users to log the daily food intake from a limited database of foods and self-monitor the caloric balance in real time, which proved to be useful and feasible for weight management [1,16]. Track3 (Coheso) is a complex app, which includes various tools for managing meals and exercise activity (food database, food journal, list of restaurant menus and brands of packaged foods, and list of exercise activities) an insulin calculator and a product support team counseling by email [17]. Gluco-Phones is a glucose testing reminder capable of transmitting glucose readings to caregivers for evaluation, control and advice [10]. The iBGStar Blood Glucose Monitoring System by Sanofi-Aventis is the first FDA approved blood glucose meter designed to connect with an iPhone, iPod Touch or iPad, allowing glucose, insulin and carbs data collection, and individualized glucose patterns charts or notes development, which can be shared by email for specialized analysis [17]. As of mid-2013, WellDoc has launched BlueStar, the first prescription provided, reimbursable mobile health app in the USA, offering real-time motivational, behavioral and educational coaching for diabetes management, “smart” blood glucose testing, healthy diet and exercise choices, medication adherence aid, and quality standards of care for HbA1c measurements, foot exams, and blood pressure and lipid levels [18]. A smartphone app is also used for monitoring the function of the two pumps (one administering insulin and the other glucagon), which are part of the so-called “bionic pancreas”, a prototype developed by Boston University and Massachusetts General Hospital, holding the promise of a better type 1 diabetes control in comparison with the existent manual pumps, and a significant reduction in number and duration of hypoglycemic episodes [19].

Studies on mobile apps targeting diet, glycemic control and/or weight loss have proved that mobile phone apps are valid tools for monitoring and management of weight control and related behaviors, improving the health outcome in their users [20]. However, an evaluation of 80 Android diabetes apps with 42 unique apps eligible for
the study found that self-monitoring blood glucose (SMBG) recording was present in 36 (86%) of the apps, tracking administered insulin or oral diabetic medications were found in 19 (45%) apps, while a prandial insulin dose calculator existed in only 11 (26%) apps, suggesting a low capacity of mobile apps for comprehensive diabetes management. The Glucool Diabetes, OnTrack Diabetes, Dbees and Track3 Diabetes Planner were among the highest rated, the most reliable and suitable apps to be recommended by clinicians [21]. Eng and Lee have reported similar results in 2013 in a research conducted on mobile health apps for diabetes and endocrinology found in the iPhone store. The majority of apps (33%) focused on manual entry of health data, and on tracking glycaemia, insulin doses, or carbohydrates intake, while only two apps directly inputted glycaemia values from glucometers attached to the mobile phone. Other types of diabetes apps found were teaching/training apps (“virtual coach”) (22%), food reference databases (8%), social blogs/forums (“virtual support groups”) (5%), and physician directed apps (8%) [22].

The developers of mobile health apps frequently target physical activity behavior, a large number of diverse mobile apps being available on the market, with varying degrees of popularity and efficacy. The 10,000 Steps program which has begun in Japan, has rapidly gained in worldwide popularity, especially after the development of its mobile app iStepLog. The use of this mobile app has demonstrated that the program helps users consume approximately 500 Kcal/day less and it proved to significantly reduce the resting heart rate, systolic blood pressure and the user’s BMI [23]. Another interesting app, UbiFit, developed by Consolvo and colleagues [24], promotes changes in physical activity by transforming the background wallpaper of a mobile phone into a garden scene. As users become more active or indulge in physical activity throughout the week, the garden grows with several different flowers, each one representing a different type of activity such as walking, cardio or strength training. At the end of the week the screen is wiped blank and the flowers are regrown as activity is undertaken again. The developer has promised that eventually phones will include the majority of sensors required for a user to slip the phone into the pocket at the start of the day, with no need to remember to wear an extra device, thus improving in cases where it may be impractical to attach a pedometer or other type of devices (making it impossible to actually forget the extra device since the phone is all it would be necessary) [25].

A recent randomized clinical trial has evaluated the compliance and effectiveness of smartphone apps for loosing weight in comparison with websites or paper diary, and has concluded that the smartphone apps show an “acceptable and feasible” intervention, demonstrating a better adherence when compared to other more conventional tools, and a mean weight loss of 10.2 pounds (4.62 kg) in a 6 month trial [1]. Researchers have also investigated dietary self-monitoring-based electronic interventions using personal digital assistants (PDAs), electronic portable devices that share some of the features of mobile phones. The PDAs use proved to have the highest proportion of participants, achieving greater than 5% weight loss after a 6 month trial [26].

A systematic review published in 2013 by Marcolino et al. indicates that in diabetes patients, new technology services broadly named telemedicine, in parallel to the usual care are associated with a mean HbA1c decline of 0.44% (-4.8 mmol/l) when compared to the usual care alone, with the tendency to a higher HbA1c reduction in interventions lasting over 6 months.
The impact of telemedicine was more pronounced in patients with type 1 compared to type 2 diabetes. Also, it was observed that the interventions through telemedicine on patient’s prescriptions were associated with a greater benefit on HbA1c reduction and there was no difference regarding intervention made by physicians or nurses. There was no clinical relevant impact observed on LDL-C and no impact on blood pressure. There are some factors that are described as important elements for a positive outcome, such as patient awareness of the severity, significance, disease natural evolution and its consequences, willingness to participate actively in the treatment and in preventing complications, positive motivation, patient computer skills and finally, the adherence to technology [27].

**Keeping up with technology: the ground of the present, the promise of the future**

The reason these technologies are likely to be effective is because portable body monitors, pedometers, handheld PDAs or smartphones are mobile, easy to wear and use, promoting daily continuous self-monitoring. Also, these devices are convenient for both individuals with or without access to a high-speed Internet connection. Moreover, with the success of social media, the technology can create the social (group) support necessary for a sustained weight loss program, by offering online systems such as message and/or electronic bulletin boards, chat forums, and/or chat rooms. Social or group support can foster motivation, encouragement, and commonality, increasing the odds of success for any weight loss program [28].

With the increasing spread and affordability of the Internet, it seems that practicing medicine has to embrace the philosophy and lifestyle of the gadget era and get advantage of its benefits which had been demonstrated especially in those patients with chronic diseases or with proven difficulties in understanding how to adjust pharmacological therapy according to their biological data (i.e. adjusting doses of diuretics in chronic heart failure in correlation with the measures of blood pressure, or adjusting the insulin doses according to glycaemia). Travelers with chronic diseases may also benefit from medical smartphone applications, using them to maintain a medication schedule through different time zones. Patients living in remote rural areas may compensate the lack of nearby healthcare availability by using the new technology to help them control chronic medical conditions, communicate with healthcare providers and get real-time feedback. This new technology allows both patients and physicians to overcome the limitations of geography in health care and access information at a distance, making it possible to get a second opinion without visiting another physician [10]. It is widely agreed that the potential of medical apps to improve care and lower costs by avoiding costly hospital admissions, emergency room or general practitioner visits is enormous.

However, the use of medical apps has proved to have limitations. The IMS Institute for Healthcare Informatics research shows that the downloading and use of healthcare apps is also preponderantly limited to younger ages. Although patients over the age of 65 are among the top users of medical services, yet the medical app downloads and even the smartphone usage is the lowest in this category of patients [7]. A study on pediatric population published by Schoffman et al. in 2013 showed that apps used to combat obesity in this specific age category do not assess individual motivation to make changes, do not use motivational interviewing, do not enforce having breakfast every day and do not reduce the time spent in front of television, demonstrating the lack of expert involvement in their development [29]. Recently
published, a review on medical apps for diabetic patients has proved that the majority of successfully used apps have limited functionality while the complex, multifunctional ones have performed considerably worse, with significantly lower usability scores [30].

**Conclusions**

Medical apps, or gadgets and web-services in general, are certainly not a substitute for doctor’s advice or medical appointments, but they can supplement and complement the delivery of health care, and help the user to increase and maintain motivation to achieve the therapeutic goal. Mobile apps have a great potential for improving chronic disease care, but they face a number of challenges including the lack of integration with the health care delivery system, the need for formal evaluation, review and organized searching for health apps, and the potential threats to safety and privacy.

**REFERENCES**


