Barriers to Deploying Diabetes Self-management mHealth Services in the Chinese Market

Ying Li
Key Laboratory of Biorcheological Science and Technology
Bioengineering College, Chongqing University
Chongqing, China
e-mail: liyingberry@hotmail.com

Daidi Zhong
Key Laboratory of Biorcheological Science and Technology
Bioengineering College, Chongqing University
Chongqing, China
e-mail: daidi.zhong@cqu.edu.cn

Xiaolian Duan
Chongqing Academy of Science and Technology
Chongqing, China
e-mail: dxl@cast.gov.cn

Jianning Qu
the Second Affiliated Hospital of Chongqing Medical University
Chongqing, China
e-mail: 360113522@qq.com

***Abstract*—Recently, a large number of mobile applications have been developed to address the needs of patients for diabetes self-management mobile health (mHealth) services. Given the explosion of mHealth technology enablers, increasing investment, and more favorable government policies, diabetes self-management mHealth services are generally seen as a promising domain by Chinese investors. However, the meta-analysis described here showed that even large numbers of cases and environmental factors did not result in a massive adoption or deep market penetration. The root causes of this were analyzed and there were five barriers, i.e., human resources, trust from clinical service providers, policies, functionality, and business models, preventing the adoption of this technology. This finding may serve as a reference for future decision-making with regard to the research, development, use, and policy-making related to mobile health services.**

Keywords-mHealth; diabetes; self-management; mobile applications.

I. INTRODUCTION

Diabetes mellitus is one of the most common chronic disorders in the world, and insufficient self-management can involve both considerable personal suffering and enormous costs. In 2013, diabetes caused 114 million deaths in the adult population of China. The estimated cost of managing people diagnosed with diabetes in 2014 was $612 billion [1]. Improving self-management is an important part of improving cost-effective patient-centered care and dealing with the growing health care challenge posed by diabetes [2][3].

Self-monitoring of blood glucose (SMBG) has been shown to be a useful tool in improving glycemic control in type 2 diabetes, helping patients make informed decisions in managing blood glucose [4]. Mobile health (mHealth) technology renders SMBG more flexible and efficient for the treatment of patients. Figure 1 presents a general architecture of such mHealth-based SMBG system.

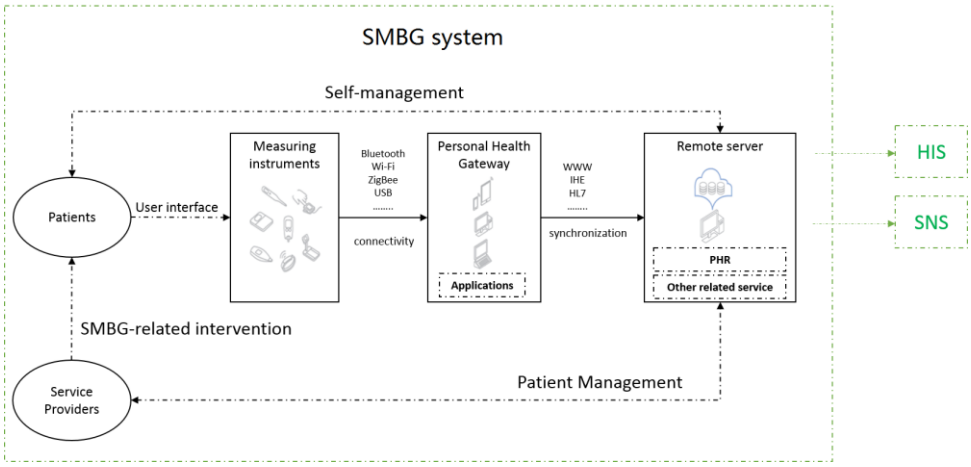

Figure 1. SMBG system

When practicing SMBG, patients normally monitor and manage their glucose level by themselves at home. Such activity may benefit from a SMBG system, which allows patients transmitting their data to service provider via an end-to-end data channel. Such a system is often constituted with one or more measuring instruments (e.g., a glucose meter), a gateway device (e.g., a mobile device) and a remote server. Patients can collect their glucose measurements and other context health data with glucose meter and other instruments. The common devices employed here are blood glucose monitor (BGM) and continuous glucose monitor (CGM). The remote server contains Personal Health Record (PHR) and other related services.

The established connectivity between measuring instruments and personal health gateway, and the connectivity between gateways to remote server, together populate an end-to-end data channel. Via this channel, the collected data can be transmitted from patients to service providers via uplink, and the instructions from service providers can be sent to patients via downlink. This allows patients and service providers to access the health data at any time. Service providers can further give appropriate interventions to patients based on certain data-driven strategy. Moreover, the external partners contain the Hospital Information System (HIS), the Social Network Site (SNS), etc.

The study [5] about the SMBG applications in EU (European Union) or foreign countries shows that (1) perceived barriers to use or continuous use, (2) perceived benefits of desired features of diabetes self-management, (3) facilitators to motivate use, and (4) information sharing with family, friends, and health professionals. The result shows that there is a problem about the usage of the SMBG applications in EU or foreign countries.

In recent years, the government of China has issued several policies that affect mHealth [6]–[8]. Top policymakers are targeting the development of portable health data collection devices, integration with the Internet and mobile Internet, and improvement of the level of automatic and intelligent health information services.

Under the support of government policy and the catalysis of the market demand, more and more companies and investment organizations have swarmed into the diabetes self- management application market. Such stakeholders are the key actors of the operation of online diabetes self-management.

In order to assess the status of adoption of diabetes self-management mHealth services in China, we conducted a meta-analysis [9], the meta-analysis was about the diabetes self-management related applications in China, and some aspects are compared, including the innovative functionalities, defects, prospects, conformance of standards, etc. And the following facts were observed: (1) the number of SMBG applications in China is low; there are only 78; (2) there is only 1 application whose download count exceeds 5000, and only 3 iOS applications have been scored by users; (3) the most common features of applications that have been studied include recording of blood health data, notification, and decision support. Obviously, the rate of adoption of diabetes self-management tools in the market is low, which seems to be contradicting to the continuously increasing investment interest in this domain.

In order to fully understand the root causes of this paradox, as well as the gains and gaps of the current Chinese mHealth-based SMBG industry, a thorough analysis was provided in Section 2, with regards to the barriers of its development and deployment.

II. BARRIERS TO THE DEVELOPMENT AND DEPLOYMENT OF DIABETES SELF-MANAGEMENT APPLICATIONS

A. Lack of human resources to support diabetes self-management

A sufficient number of service providers is needed to provide remote diabetes management services. This is a prerequisite to any good deployment of diabetes self-management applications. However, China lacks proper human resources for such purposes. This country is especially short of primary care service providers (e.g. GP, family doctors, family nurses). It has been reported that the amount of community-level service providers in 2010 was only 4.04% of the total amount of healthcare service professionals [10][11]. The same statistic in America, Britain, and Canada is 30–50%. There are 2.466 million registered primary care providers in China, which translates to 1.82 providers per thousand civilians. This ratio places China 80th among 193 countries, according the WHO. Until 2011, there were no dedicated personnel training system or official promotion channels for this group of providers. To solve this issue, the State Council issued guidance to improve the training of general practitioners (GP) [12]. It sets the goal of establishing a rigorous training system by 2020 to satisfy people's basic health service needs. It will be a long time before any substantial change will become observable.

Another reason for the shortage of service providers is that the current management policy for clinical practice does not fully allow clinicians to practice at multiple sites. In 1995, the Chinese government enforced the law establishing the national clinician registration system [13][14]. According to that law, clinicians can only practice at the point-of-care to which they were originally registered, and practicing at any other location is considered illegal. This situation is now changing because the State Council has recently issued a policy promoting multiple-site practicing [15][16]. However, the mobile Internet, where diabetes self-management applications are used, has not yet been acknowledged by this guideline as a permissible place to practice medicine. For this reason, further extensions to this policy are expected.

B. Lack of trust from service providers

The level of support from professional service providers is critical to accelerating the massive adoption of diabetes self-management mHealth services. When providing SMBG-related services, the service providers have to base their interventions on existing clinical guidelines [17][18]. These are generally considered the best practices in the field. However, the fact is that the currently available clinical

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guidelines were established mainly based on the medical studies conducted over controlled data within controlled environment, which is quite different from patients' self-generated data from ambient environments (including home and traveling). Those guidelines describe a SMBG process that is driven and managed solely by service providers (although the patient is the main actor); this is somewhat different from purely patient-dominant activities.

Theories underlying evidence-based medicine must be established based on clinical evidence. However, due to the lack of interoperability, regulation, and business impetus, no large-scale patient-oriented SMBG system has been established or used in the field. For this reason, the clinical researchers have no way to acquire useful research data, generated from patients' personal health devices in their personal environments in sufficient quality and quantity. Correspondingly, there has been no foundation upon which to create any clinical guidelines for SMBG activities. Without such guidelines, the service providers have generally hesitated to enter this market or to provide meaningful support for these SMBG-practicing patients. This can be seen as a classic chicken-egg puzzle: No deployment means no data, which means no research, no trust, no service, and no deployment. Solving this puzzle has become a core topic in today's SMBG industry.

Also, many users have the interest to use the apps, they said that "the app has made the SMBG more efficiently, it pontificated me to have medicine and record the glucose data".

There has recently been a rapidly increase in interest and investment in the Chinese mHealth market. Some personal connected health platforms are being established and deployed in many Chinese cities [19][20]. Many of them are designed for general health management services, but some of them do have the capability to support SMBG services. Domestic investors fully understand that mHealth is an emerging market, so they are patient enough to tolerate long revenue turn-around. Given the large population of China, this may provide the industry with an opportunity to collect enough data and to conduct proper medical studies before the true clinical efficiency of these applications can be proven and the dedicated best practices can be established. Hopefully, the puzzle will be solved in a few years.

C. Domestic regulatory policy regarding to the use of diabetes self-management applications

The diabetes self-management applications fall into a multidisciplinary domain between medical device and IT industry. The Food and Drug Administration of China (CFDA) and the Ministry of Industry and Information Technology (MIIT) are the corresponding regulatory bodies. However, none of them has published regulation policy dedicatedly for this multidisciplinary domain. The regulations issued by CFDA only cover situations inside hospitals, and they do not include the diabetes self-management applications outside hospitals. The regulations issued by MIIT only address Internet-based information services and promotes the development of the IT industry. None of them address the specific needs of the remote clinics and Personal Health Record (PHR) data utilization, which can be seen as another gap of this industry.

Currently, there is no clear legal definition of diabetes self-management applications. When using them, patients are unable to protect their rights in cases in which anything goes wrong (e.g., receiving the wrong prescription). Furthermore, due to the legal requirement that clinicians register at a certain physical point-of-care for all clinical work, the legal status of medical care provided online (such as via diabetes self- management applications) has remained murky. There is a true need to develop a proper regulatory policy for this type of technology and service, and there are currently no such policies in China.

The U.S. diabetes management platform developed by WellDoc [21] received FDA clearance. It is the first application approved by the FDA for the optimization of doctors' prescriptions. Unlike the U.S. FDA, the CFDA has not issued any dedicated regulation guidelines for mHealth. However, this does not necessarily mean there is no chance that it will get approval. A glucose meter device, Dnurse and its associated Internet-based service, both of which were developed by Beijing Dnurse Technology Ltd. [22], did get clearance from the CFDA. It operates in manner similar to WellDoc.

D. Functionality of diabetes self-management applications in China

In applications related to the diabetes self-management, most functionalities have conformed to those listed in the international standards and clinical guidelines. However, for some other types of functionalities, the situation is different. The missing key functionalities may lead to the low rate adoption.

Most applications provide no connectivity to measuring instruments. One possible reason for this is the obsolete mindset of domestic application developers and instrument manufacturers. When building their own products, their design logic is purely application-centric or device-centric rather than a holistic vision established over an interconnected infrastructure. In contrast, the leading tech company Google recently released Google Fit and Apple released Health Kit. Both of these applications leverage modern connectivity technologies to simplify or automate the heath data collection process. A similar trend is likely to appear in China in the future. It is only a question of when and how.

Despite of the benefits of PHR synchronization reported in some studies [23][24], the rate of adoption of such applications has small, partially because of end-to-end usability issues. Our interpretation of the possible reason is: gateway device vendors are quite dominant in current Chinese mHealth market (including the ecosystem of diabetes self- management mHealth services), the vendors have focused mainly on data synchronization with gateway devices, rather than on the cloud platform. Improving the aforementioned usability issue will require joint effort from all the stakeholders (operators, integrators, medical device manufacturers, application developers, healthcare providers, etc.) to establish a data synchronization channel.

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E. Business models of diabetes self-management applications in China

According to the results of our meta-analysis, the business models of diabetes self-management applications in China were found to be less diverse. We have observed three categories of business models in China: (1) Consumers as payers; (2) device vendor providers as the payers; (3) service providers as payers.

In contrast, the variety of business models in developed countries is much better. For example, the Zocdoc [25] is free to patients but not to doctors. The Welldoc [21] charges insurance companies and cooperates with pharmaceutical companies in the sale of applications to hospitals. Vocera [26] charges hospitals.

The current business models in China have not incorporated hospitals, pharmaceutical companies, commercial insurance companies, and doctors. The current business models have not fully engaged all the stakeholders of the ecosystem of the diabetes self-management mHealth services. No operational infrastructure for diabetes self-management mHealth services has yet been established. All of the observed business models are purely technology-driven or product-driven, rather than built from the perspective of the stakeholders. Correspondingly, such business models cannot properly satisfy the needs of all potential stakeholders, thus cannot adapt to the quickly evolving business environment. There is an immediate need in the Chinese market for business models with enough comprehensiveness and sustainability for diabetes self-management applications. It is not practical to directly copy business models from developed countries. A local process must be developed to suit the actual situation in the domestic market. One of the future trends is to acquire large quantities of user data and to trigger innovative business projects based on this big data.

III. CONCLUSION

We observed that the low adoption rate of the diabetes self-management mHealth services was not consistent with the high level of interest in the domain. In this paper, a root cause analysis is performed to investigate barriers to technology adoption. As a result, five barriers to the development and deploying of applications in China have been identified and elaborated. There is a shortage of primary care service providers and those who are available are not allowed to practice at multiple sites. This leaves diabetes self- management applications without the support of doctors. The lack of validation from clinical data and large-scale data support leaves doctors reluctant to recommend diabetes self- management applications to patients. Without the protection of relevant regulations, patients cannot protect their rights in cases of harmful error (e.g., receiving the wrong prescription). Undeveloped functionalities leave doctors and patients unable to use the applications or realize actual diabetes self- management. The current business models are not diverse enough and do not incorporate hospitals, pharmaceutical companies, commercial insurance companies, and the doctors, leaving patients and doctors unable to reap the benefits of the system.

These findings may serve as a reference for future decision-making regarding the research, development, deployment, and policy-making related to these applications. Stakeholders may take action to reduce barriers to the development and deployment of diabetes self-management applications for public consumption.

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