Power to the patient: diabetes management in the digital age
Self-management of diabetes

Chronic diseases such as diabetes are among the most common, costly health issues of today – and impose an increasing economic burden on health care systems worldwide.

Global health expenditure on diabetes is expected to reach at least USD 490 billion by 2030 – with diabetes accounting for an estimated 12% of total global health expenditure in 2010. Some of these costs are preventable with good diabetes self-management, which has been shown to reduce complications such as microvascular disease, neurologic dysfunction and cardiovascular disease.

Successful diabetes management implies long-term control of glycosylated haemoglobin A1c (HbA1c) levels within the recommended range and minimal drastic or short-term variations in blood glucose levels. Blood glucose levels depend on a multitude of different factors such as body constitution, carbohydrate intake, level and duration of physical exercise, sleep and stress. Thus diabetes management has a big impact on people’s lives, often requiring a change in lifestyle for those diagnosed later in life (usually type 2).

Diabetics need to think about everyday activities in a way that other people don’t. They need to regularly test their blood sugar levels, plan each meal and its nutritional content, log the intensity and length of physical activity and, for those patients on insulin therapy, calculate the appropriate injection dose. To help ease the burden, diabetics are encouraged to keep a diary of all these daily chores. However, few of them do, given how tedious and cumbersome this is to do.

“I know I should be doing it (keeping a diary) but it’s just a pain in the neck.” Diabetes patient

Today’s generation of digital migrants and digital natives do not want to write things down on paper; they expect technology to make their lives easier and perform these tasks for them. Happy to share their lives on Twitter, Facebook, Pinterest and other platforms, they are also less concerned than previous generations about data privacy.

There’s an app for that

The number of smartphone apps for diabetes has exploded over the last few years, and there are hundreds of apps available on iTunes and other web-based app stores that can deal with various aspects of diabetes self-management. Apps are also becoming more recognised by the medical community as providing tangible value in promoting adherence and helping patients achieve better glycaemic control. Mobile apps have been shown in several studies to improve HbA1c levels, which is a key measure of control over the disease. Some are even being used as a prescribed therapy – WellDoc’s BlueStar is the first FDA-approved mobile prescription-only app for diabetes. Physicians, too, are beginning to see the value in mobile apps to support self-management.

“The literature suggests that extending our reach with technology allows patient coaching to be continuous between office visits, and can be very effective.”

Dr David Katz, Yale Prevention Research Centre

An attractive commercial opportunity

The commercial potential in mobile apps for diabetes management is significant and shows attractive growth prospects – Cambridge Consultants estimates that there will be more than two million diabetic users of smartphones by the end of 2014. This user base is forecast to show compound growth of 72% per year\(^5\). When you add tablet, iPad and iPod touch users, the market will get bigger still.

Although many users are currently expecting mobile apps to be low cost or free, a recent Cambridge Consultants survey indicated that the majority of patients would be prepared to pay for an app that would truly make their life easier.

There is currently no outright winner among the various business models being used to tap into the commercial value of apps. The role and purpose of apps as enablers or revenue streams in themselves is still in flux. A variety of business models is currently being trialled – one-off payments for a one-off purchase, subscription models linked to a service offering, or offering free apps as a loss leader to drive consumption of dedicated hardware and/or services.

User dissatisfaction

Despite these favourable market conditions, many patients in today’s digital age are frustrated and dissatisfied with the quality of mobile apps currently on offer. More than half of the patients surveyed by Cambridge Consultants rated the self-management apps they were using as unsatisfactory or frustrating.

“Technology can make my life easier in so many other areas – why can it not do the same for my diabetes?”

Diabetes patient

Many of the apps on the market today still rely on manual data entry by the patient and do not integrate the various tasks that people need to do. A patient would typically use one app to work out the number of carbohydrates in his meal, and then transfer this data to another diabetes diary app, then also manually enter the value of his blood glucose levels from his blood glucose monitor (BGM), enter his exercise levels, and enter his insulin dose taken. For many patients, this becomes just too much, and fatigue eventually leads to abandonment.

“I don’t want to spend my day manually entering data” Diabetes patient

“It was just one more inconvenient thing I had to do alongside everything else.” Diabetes patient

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\(^5\) CAGR estimated from 2014 - 2017
Our survey identified the fragmented nature of the app capabilities, and the manual data entry, as the most significant complaints. The demand for a truly converged mobile app solution with automatic, wireless data transfer is resounding, as is the demand for an ‘intelligent’ app, which can identify trends in the data and give recommendations on insulin dosing. Timely feedback, support and advice from a health-care professional was also mentioned but was considered of lower importance.

“I would like to have it all in one app – one app to rule them all.“ Diabetes patient

“If there was an app that could automatically record all the different inputs and present it to me, I would be as happy as a clam.” Diabetes patient

While physicians are encouraging their patients to use self-management apps, they themselves remain reticent towards adopting mobile apps in their clinical practice. The physician community is applying good scientific rigour to these technologies and is calling for more trials and studies to be done to prove their benefits, how they would fit within their workflow, and how they could effectively be rolled out within the medical practice.

Market response is gearing up

Although slow, the market has started to respond to these unmet customer needs.

A lack of unified standards has been hindering convergence of apps and data. Many providers of hardware do not provide application programming interfaces for developers to read data from their device, thus preventing third-party mobile applications reading and using data from the hardware. Although wireless data transfer is possible, the data is encoded in such a way that the app may not be able to read it. Lack of agreement between app developers has furthermore prevented different apps communicating with each other. However, all this is about to change – the recently launched Apple HealthKit and the Google Fit platform provide frameworks which developers can use to enable sharing of data and thus enable interoperability between apps.

Manual data entry is so prevalent in self-management apps mainly because of regulatory reasons. Under FDA regulation, if an app connects to a medical device and transfers patient-specific data, it constitutes a Medical
Device Data System, and is subject to class 1 requirements. This then requires the app developer to register with the FDA and also ensure the app has been developed following proper development and design control procedures. Many app developers have so far been reluctant to take on that additional burden.

“The number one hurdle to developing a more interconnected app with wireless data transfer is regulatory.”

Kyle J Rose, MD, mysugr.com

However, this too is about to change. A number of apps can now transfer data from BGMs via cable, via a special iPhone attachment, and some even wirelessly (Glooko, DiabetesPal, SiDiary, One Touch® RevealTM).

Regulation has also been the stumbling block to the creation of ‘intelligent’ apps which can analyse data and recommend therapy. Under FDA regulation, an app becomes a regulated medical device if the app uses patient-specific data to give recommendations on dosage. Although the FDA is encouraging discourse on this point, many of the current app suppliers want to avoid the drawn-out process of pursuing FDA approval. However, the first ‘intelligent’ diabetes management apps are making their appearance on the market. Diabeo® by Voluntis (sponsored by Sanofi) is an electronic diary that takes into account the patient’s glycaemic objectives, previous days’ results and personal parameters to then suggest the appropriate treatment. It does require prescription by a medical doctor and can only be activated by a qualified health-care professional.

The app as a channel for patient-doctor interaction is also evolving. Many of the ‘first-generation’ apps offer the option of generating physician-optimised reports to show or email the data to the treating physician. The next generation of more sophisticated apps (like Diabeo® by Voluntis, WellDoc’s BlueStar, GluCoMo™ by Artificial Life, and AgaMatrix’s Health Manager) store the patient’s information in the cloud, and use different portals for physicians and family members to access and view the data. In each case, the patient is the data owner and chooses how and with whom to share the data. In the far future, we envisage that this data is likely to be integrated with the patient’s electronic health record (EHR), available in the cloud, and accessible to the patient’s treating physician when needed. Some even forecast advanced analytics programmes which would analyse patient data in the cloud and alert the treating physician if the data would indicate that the patient’s health is at risk.

“You will maybe have something like a supercomputer, which will analyse the data and flag it up as red with the doctor.”

A large pharmaceutical company

Absence of the big names in diabetes therapy

Many of the traditional providers of diabetes therapies appear to have been slow to respond to their customer needs in the digital age. Apart from Sanofi (which has a number of apps available on the app stores), the apps provided by recognised names in diabetes therapies are few and far between.

A recent market report by research2guidance6 identified that 65% of all-time downloads from the diabetes app market are generated by only 14 app publishers, the majority of which are small app developers (some are former employees from traditional diabetes companies7, and some are patients frustrated with the lack of good apps out there).

A growing number of companies (some of them from outside the realm of health care) are streaming into the market for diabetes self-management apps, and can be grouped into the following categories:

- Software and app developers
- Providers of home health-care and consumer devices
- Suppliers of BGMs (LifeScan, Roche Diagnostics, AgaMatrix)
- Providers of healthy lifestyle and weight-management technologies and services (MyNetDiary)
- Specialist media companies and publishers (LifeMed Media, Carbs & Cals, Artificial Life)
- Diabetes charities (Diabetes UK)

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6 Diabetes App Market 2014
7 Glooko was set up by ex-LifeScan employees
Specialist technology companies with the sole focus of providing software (patient-centred) technologies and services for the self-management of chronic conditions (WellDoc, LabStyle Innovations, Voluntis)

While this picture of the competitive market landscape remains fragile, it is marked by a conspicuous absence of the more traditional names in diabetes therapies such as Novo Nordisk and Eli Lilly.

No patient-centric mobile app for self-management of diabetes was identified in any of the app stores from either of these two big names in diabetes management. Merck used to have a diabetes self-management app through its subsidiary Vree Health, which did not gain enough traction in the market, and pivoted to care transition and weight management.

“A lot of the larger diabetes players have tried in the past to come up with a self-management app but failed.”
Doug Kanter, Databases and Meal Memory, Founder & CEO

One cannot help but wonder why the big names in diabetes have been tip-toeing around mobile apps, and why some of the early ventures into the app market by the larger providers of diabetes solutions have not succeeded.

Although multifaceted, the answers may be deeply rooted within corporate infrastructure.

Pharma companies have shied away from developing apps aimed directly at the patient because rules and regulations governing how they are allowed to interact with potential patients have discouraged them from directly engaging with users. A historical lack of guidance from the FDA in how to address new developments in direct-to-consumer advertising in the rapidly changing world of social media marketing has further hampered a more direct engagement with the new generation of digitally connected patients. Regulatory uncertainty over how tightly mobile apps ought to be regulated spread further anxiety among pharma companies. Scarred by previous negative experiences, many companies chose to err on the side of caution and ‘sit and wait’ until regulation would become clearer. The recent issuance of guidance documents by the FDA on using the internet and social media tools and mobile medial applications should clear these hurdles. We hope to see pharma companies pursuing more direct engagement with patients on digital platforms.

The inherent infrastructure of the larger companies in diabetes therapies is ill suited for responding to the fast-moving, digital marketplace. Built around long cycle times of decades from product discovery to launch, these companies confess themselves to be bewildered by the fast timelines in the app market.

“We’re scared of how quickly this space is moving, quite frankly.”
A large pharmaceutical company

Accustomed and geared to dealing with doctors, nurses and other health-care professionals, the traditional pharma companies may lack the necessary know-how for driving product uptake in a novel market where the key decision makers are a novel generation of patients, who choose their diabetes management app based on user reviews on iTunes and other app platforms, not in the recommendations of a healthcare professional in the diabetes clinic (as a recent Cambridge Consultants survey among diabetes patients suggests).
The market dynamics in mobile apps for diabetes self-management are more akin to those in the consumer electronics space than the health-care market, and thus require a different strategy to drive stronger user adoption. Companies must ask themselves how to create compelling value propositions – not for the medical community but for the patient.

“The large drug companies just don’t know how to appeal to patients, how to talk to patients.”

Doug Kanter, Databetes and Meal Memory, Founder & CEO

Market opportunities and challenges in mobile apps for diabetes management

The current absence of large, entrenched market leaders and high levels of unmet need in this emerging market provide a great many opportunities for a variety of companies:

- **Opportunities for companies in consumer electronics**

  Mobile apps provide the ideal opportunity for non-health-care companies to make a foray into the health-care space. Companies active in the fitness and wellness area are particularly well positioned for penetrating this market. Pedometers, activity bands (Jawbone® UP, Fitbit®, Nike+ FuelBand) and other fitness-tracking devices (for example, heart-rate monitors) can transfer data on exercise levels to a self-management app. Home health-care and general wellness devices (such as scales, blood pressure monitors, thermometers, sweat monitors and sleep monitors) can provide further data which can be streamed into an app. Companies would need to have a strategy on the acquisition of glucose data without manual entry if they want to achieve true differentiation. In the short term, this can be achieved via partnerships with a provider of blood glucose monitors or vertical integration by providing their own device (iHealth’s Glucometers). In the long term, companies are seeking ways to acquire glucose data by some type of wearable device. Various companies (Apple, Google and Samsung) in this space are seeking ways to integrate health sensors into wearable devices, including those to measure glucose levels in a non-invasive way11.

- **Opportunities for software companies and app developers**

  App developers need to focus more on quality if they want to emerge among the winners in this new market. Too many small developers have churned out apps that ended up disappointing the users. Co-operation with recognised names in diabetes circles and FDA approval will become necessary to gain traction in the market. For example, Glooko, a start-up developer of apps, partnered with the Joslin Diabetes Center to launch the Joslin HypoMap app at this year’s American Diabetes Association’s 74th Scientific Sessions. Mysugr pursued FDA approval and feels it will pay off.

  “The challenge of building an FDA-approved medical app was big. With hindsight, we feel we are now well positioned and that the time and effort we invested will pay off.” Kyle J Rose, MD, mysugr.com

Furthermore, successful collaboration with hardware providers such as suppliers of BGMs will widen market potential and increase product uptake.

- **Opportunities for diabetes diagnostic companies, such as suppliers of BGMs**

  Providers of BGMs are in the enviable position of being the data repository for the blood glucose data, so crucial to a diabetic’s daily self-management routine. Many of these companies are already carving themselves a niche in the app market – examples are AgaMatrix’ Health Manager, LifeScan’s One Touch® RevealTM (which has wireless data transfer capabilities), and Roche’s Accu-Check® 360° Diabetes Management. Suppliers of BGMs are at a competitive advantage over all the other market participants in that their hardware provides the cornerstone underpinning successful diabetes self-management – tying a dedicated app to the BGM will automatically drive uptake among patients. In the future, a ‘killer app’ is likely to become one of the key decision-making factors behind the choice of hardware, and will drive growth and increase market share for those providers who can best satisfy patient needs in the digital age. Furthermore, this may provide suppliers of BGMs with an opportunity to escape eroding margins in consumable strips – offering services tied to the app could become

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11 Google has shown off a contact lens designed to measure glucose levels, now licensed by Novartis’ eye care division, Alcon
the basis of a subscription business model and provide additional revenue streams.

Roche is already purported to be experiencing higher sales with the recent launches of products enabled with data-management software12.

Established providers of BGMs ought to be mindful of an increased threat from new market entrants in this space. Several new market entrants have gained market access with a BGM/mobile app combination. TelCare penetrated the market with its world-first FDA-cleared cellular-enabled glucose monitor and its mobile app – the Diabetes Pal – which syncs the BGM with the patient’s smartphone or tablet and sends that data to caregivers. LabStyle Innovations entered the market with its DarioTM BGM, lancing device and associated diabetes self-management app.

**Opportunities for traditional suppliers of diabetes therapies**

All these new incumbents are endangering the leadership position of the more traditional providers of diabetes therapies. Although many of them probably have mobile app projects in their pipeline, they are in danger of being left behind, and risk losing customers in coming years if they are too slow to respond to this increasingly important strategic channel to market.

Strong partnerships with experienced participants in the mobile app market can help overcome their inherent structural deficiencies and inexperience in dealing in a fast-moving market of digital technologies. However, the large providers of diabetes management solutions need to ensure that whatever app they launch is of a quality befitting the corporate brand image.

Providers of diabetes therapies need to establish a way to source the blood glucose data which is so vital to good self-management. This can be achieved by co-operating with a supplier of BGMs or by vertically integrating. The biggest challenge for providers of diabetes therapy will be how to adapt to a market where the patient is the key decision maker. These companies need to change strategy and learn to appeal to patients who are proactive in searching app stores and user reviews for the best app for them, and do not rely simply on recommendations by health-care professionals.

A potential competitive advantage for providers of diabetes therapy lies in having the drug-delivery device (such as the injection pen or pump) communicate the exact dose of therapy taken to a mobile self-management app, thus eliminating the need for manual entry. If this data transfer were to happen wirelessly, one of the biggest unmet user needs could be satisfied.

So far, Sanofi stands out as an early mover in the market for mobile self-management apps, and even used the opportunity to penetrate the realm of BGMs by launching the iBGStar® app, which links with the iBGStar® BGM, a tiny glucose meter. Sanofi also has a number of other apps such as GoMeals®, KidneyAPPetiteTM, MediKidz and MonGlucocompteur. Although these ventures hardly made any impact on corporate revenues, they did provide the company with valuable experience and understanding of a novel market, established its name among digital diabetic users, and provided it with a first-mover advantage over all its peers in the market for digital diabetes self-management apps.

**Successful mobile strategy**

As experiences in the market for mobile banking has shown, the most successful apps are the ones that have shown a strong focus on optimising user experience.

Companies need to focus on the patient experience to generate an app that truly meets their needs. Wireless connectivity, integration of different data entries into one single self-management app, and predictive analytics of the data will help generate a seamless user experience which minimises cumbersome manual data entry and help create a ‘diabetes coach in your pocket’, which can help patients manage their condition while reducing costly hospital and clinic appointments as well as minimising the risk of diabetes-related complications.

> “Diabetes is a data management challenge.” Rick Altinger, CEO, Glooko

To gain the trust of the medical professionals and payers, app suppliers need to be able to show data from clinical studies. An increasing number of app developers are now running clinical trials and pursuing FDA clearance to overcome the reservations of the medical professional who may use or recommend the app. However, these studies and trials take time. Companies who wait for too long before launching their first app are in danger of being left behind...
in this fast-moving market. Launching a patient-centric app first and then adding the physician-centric angle backed up with studies is a more prudent way of establishing a presence in this market before expanding it by adding additional features and products aimed at the more critical physician community.

“Clinical studies are important to the advancement of mobile health applications.” Suzanne Clough, CEO, WellDoc

To be successful, market participants need to adapt their sales and marketing strategy to drive uptake among a digital generation that often bypasses the health-care professional in search of the ideal digital self-management tool.

A successful mobile diabetes self-management app coupled with a comprehensive mobile strategy, which includes all the products and services the diabetic patient needs, will engage existing and attract new users. Done right, mobile strategy can help achieve corporate strategy, increase productivity and revenues, and sustain profitability.

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About Cambridge Consultants

Cambridge Consultants is a world-class supplier of innovative product development engineering and technology consulting. We work with companies globally to help them manage the business impact of the changing technology landscape.

With a team of more than 400 staff in Cambridge (UK), Boston (USA) and Singapore, we have all the in-house skills needed to help you – from creating innovative concepts right the way through to taking your product into manufacturing. Most of our projects deliver prototype hardware or software and trials production batches. Equally, our technology consultants can help you to maximise your product portfolio and technology roadmap.

We’re not content just to create me-too products that make incremental change; we specialise in helping companies achieve the seemingly impossible. We work with some of the world’s largest blue-chip companies as well as with some of the smallest, innovative start-ups who want to change the status quo fast.

Our team brings a combined experience of over 60 years in the Diabetes space having worked in everything from glucose meters and insulin delivery systems to mobile medical apps in the recent years. This domain knowledge combined with expertise of our human factors & design teams as well as the strength of our wireless technology team enables us to develop truly innovative products. Whether it is a connected drug delivery device or digital service enabled via a smart phone app, we create solutions that provide our clients competitive advantage in this increasingly crowded market.

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