

Disruption in the diabetic device care market

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Abstract: As diabetes mellitus (DM) has approached pandemic proportions, the pressure for effective glycemic management is mounting. The starting point for managing and living well with DM involves early diagnosis and monitoring blood glucose levels. Therefore, self-monitoring of blood glucose (SMBG) can help patients maintain their blood glucose levels within the appropriate range. The general principle behind the current SMBG method involves a finger prick test to obtain a blood drop, which is applied onto a reagent strip and read by an automated device. Novel techniques are currently under evaluation to create the next generation of painless and accurate glucose monitoring for DM. We began by outlining how the emerging technology of the noninvasive glucose monitoring devices (NIGMDs) provides both economic and clinical benefits for health systems and patients. We further explored the engineering and techniques behind these upcoming devices. Finally, we evaluated how the NIGMDs disrupt the diabetic device care market and drive health care consumerism. We postulated that the NIGMDs play a pivotal role in the implementation of next generation of diabetes prevention strategies.

Keywords: medical devices, medical technology, diabetes management, innovation

Introduction

Diabetes mellitus (DM) is a metabolic disorder characterized by a chronic state of hyperglycemia. The global prevalence of DM has increased dramatically over the years. According to the 2014 World Health Organization (WHO) report, ~422 million adults have DM,¹ which will almost double by 2040.² As DM has approached pandemic proportions, the pressure for effective glycemic management is mounting. Both hypo- and hyperglycemia pose risks for patients with DM. Hypoglycemia is often associated with overuse of antidiabetic medications, which can result in convulsions, coma and even death. Hyperglycemia can also cause severe impairment to the heart, kidneys and brain. The starting point for managing and living well with DM involves early diagnosis and monitoring blood glucose levels. Therefore, self-monitoring of blood glucose (SMBG) can help patients maintain their blood glucose levels within the appropriate range. Blood glucose testing costs ~£175 million/year for the UK's National Health Service (NHS).³ Guidance regarding the frequency of SMBG varies. It is generally recommended that patients taking insulin should frequently monitor their blood glucose levels. The American Diabetes Association advises patients using insulin to test their blood glucose levels three to four times per day.⁴ In the UK, >25 blood glucose meters are marketed to patients and health care professionals. The general principle behind the current SMBG method involves a finger prick test to obtain a blood drop, which is applied onto a reagent strip and read by an automated

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device. Novel techniques are currently under evaluation to create the next generation of painless and accurate glucose monitoring for DM.

Limitations of the current SMBG technique

Studies and guidelines highlight the importance of regular monitoring to maintain patients' glycemic status as close to the normal range as safely as possible.⁴ However, each test strip and lancet can only be used once and thus bears a significant economic burden for both health systems and patients. Between 2013 and 2014, 581 million blood glucose tests were undertaken in the UK at a weighted average cost of £0.28.⁵ The current spending on blood glucose testing items per person in the Quality and Outcomes Framework (QoF) diabetes register is £60.88.⁶ Clinical commissioning groups are struggling to regulate these escalating SMBG costs, and SMBG is now a major contributor to NHS prescribing spending. For patients, the cost of test strips and needles has been associated with poor adherence to SMBG,⁷ increasing the risk of severe hypoglycemic episodes. Therefore, a noninvasive glucose monitoring device (NIGMD) has the potential to achieve significant efficiency savings for the NHS, without compromising care. A higher initial cost for the technology would be outweighed by greater cost savings using a reusable and more accurate device over a longer term.

Furthermore, current SMBG tests involve pricking the skin, typically on the finger, with the lancet. This process presents both a physical and mental barrier for diabetic patients. Pricking the fingertip four to ten times each day over several decades can cause scarring and loss of sensibility and perception. Burge⁸ reported that lancing pain and finger soreness, alongside cost, are leading reasons for self-reported patient noncompliance with physician's recommendations for SMBG. An NIGMD removes this physical and psychological barrier, improving patient compliance with respect to adequate glycemic control.

Finally, a major drawback of conventional SMBGs is the requirement to draw blood, thus increasing the risk of transmitting blood-borne infections. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries.¹ In these regions, conditions such as hepatitis and HIV predominate. Particularly, Africa has the highest WHO-estimated regional hepatitis C virus (HCV) prevalence of 5.3%.⁹ Although many of these cases occur due to transmission by nondiagnostic causes (e.g., mother to fetus), an NIGMD would reduce all risks associated with fingerstick glucometers. Infection

transmission is not just restricted to developing countries; bacterial contamination of glucose test strips by highly pathogenic organisms including methicillin-resistant *Staphylococcus epidermidis* and *Staphylococcus haemolyticus* have been reported in Spain.¹⁰ Since 1990, at least 147 people have acquired HBV infection over 18 outbreaks in USA, each attributed to glucose monitoring practices.¹¹ Both studies highlight that outbreaks from current SMBG practices are currently underestimated due to underreporting and under-recognition of acute infections. An NIGMD eliminates risks of blood-borne infection transmission, allowing safer blood glucose measurement to improve patient safety.

Emerging NIGMDs

Most current noninvasive technologies are still in the early stages of development. Blood is the most obvious candidate for measuring glucose; however, other more accessible biological fluids, including interstitial fluid (ISF), ocular fluid, sweat and urine, are also under investigation as sample media. These techniques are outlined in Table 1 and are classed by the same regulatory approval as conventional blood glucose measuring devices.

In USA, a Class III in vitro device (IVD), which includes glucose monitors, requires premarket application, including a 180-day review with clinical data to assess safety (risk of misdiagnosis due to false positive or false negative) and to demonstrate effectiveness. However, the 21st Century Cures Act legislation seeks to boost the efficiency, predictability and transparency of MedTech approval processes and creates an expedited pathway for breakthrough medical technologies, such as an NIGMD.¹² In Europe, there has been much debate that device regulation in the UK is insufficiently robust, with negligent approval processes putting patients at risk.¹³ Manufacturers can place a CE mark on their product to show that the medical device has met the requirements of their national competent authority, i.e., the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. However, these independent notified bodies do not necessarily require clinical trial data of calibration, testing and inspection and has led to weak independent surveillance of technology. Thus, new EU regulations for IVDs entered into force in May 2017 with a 3- and 5-year transition period for the new risk classification criteria and greater safety and performance requirements.

Any NIGMD should be accurate and ideally be suitable for all age groups and patients. This is challenging as most technologies indirectly estimate glucose and suffer from interfering factors, due to the complexity of human body

Table I Current noninvasive glucose monitoring techniques

Technique			Advantages	Disadvantages
Optical	Infrared spectroscopy	Beam of light with wavelength 600–10,000 nm is focused on the body to measure glucose in tissues	Low scattering, low-cost materials and good penetration	Hardware sensitivity and stability and scanning pressure required
	Raman spectroscopy	Assesses the scattering of a single wavelength of light, which depends on vibrational or rotational energy states within a molecule	Sharper spectra and less sensitive to temperature changes	Instability of laser wavelength and low signal:noise ratio
	Fluorescence	Absorption of light at a high wavelength and emission of light at a lower wavelength, which vary with glucose concentration	Very sensitive. Little/no damage to the body	Scattering phenomena can affect accuracy
	Surface plasmon resonance interferometry	Sensor (metal surface covered in glucose-sensitive ligand) is exposed to light, causing variation in the generated plasmon (electron wave) correlating with glucose concentration	Rapid, real-time monitoring of glucose levels ¹⁷	Limited to high molecular weight biomolecules – glucose requires complex setup
	Optical coherence tomography	Measures the intensity of scattered/reflected light, which changes with subcutaneous glucose concentration	High signal:noise ratio, high resolution and good penetration	Sensitive to individual's movement. Slightly affected by temperature
	Photoacoustic spectroscopy	Light at a specific wavelength illuminates and heats the tissue, causing volumetric expansion and a detectable ultrasound pulse. Velocity of the generated pulse changes with glucose concentration	Higher detection sensitivity and signal:noise ratio ¹⁸	Sensitive to changes in temperature and pressure ¹⁹
Transdermal	Impedance spectroscopy	Glucose is measured by its concentration-dependent interaction with red blood cells through an alternating current applied across the skin (impedance)	Differentiates between extracellular and intracellular fluids	Requires 60 min of equilibration process
	Reverse iontophoresis	Glucose molecules collect at the electrode after a small current is applied across the skin	Electrodes are easily applied to the skin	Skin irritation, inaccurate and electrodes in place for 60 min
Electrochemical	Enzymatic detection of glucose	Electrodes coated with glucose oxidase react with glucose to form proportional amounts of hydrogen peroxide	Specific frequencies can differentiate between glucose and glucose-containing compounds	Temperature influences optimal investigation frequency
	Amperometry	Sensor detects ions in body fluids through an electric current (or change in current)	Well commercialized. Multiple sensors increase accuracy ²⁰	Sensor error from drift, calibration error and delays ²¹
Others	Refractive changes in the eye	Measures the angle of rotation of polarized light, which is proportional to glucose concentration	Low sensitivity to scattering, so high signal:noise ratio	Practicality – requires device to be fitted into eye
	Ultrasonic, electromagnetic and heat capacity	Three independent, integrated techniques, as in GlucoTrack, combined by a weighted average of each	Higher sensitivity than normal spectroscopy and a wide range of laser light wavelength used	Sensitive to interference from other compounds and temperature and pressure changes

composition and the natural variation of physiological processes. For example, transdermal approaches are affected by variations in skin characteristics (age, type and color) and patch replacements can also increase costs. Device calibration, especially for electrochemical techniques, can also be long and complex, varying from 30 minutes to 3 hours.

Thus, there has been a shift to the integration of multiple methods, and studies have shown that combining multiple technologies and sensors increase the signal-to-noise ratio of glucose to other contributors, giving an improved accuracy of blood glucose level.^{14,15} Furthermore, developments in

continuous glucose monitoring, using analytic approaches and closed-loop control algorithms,¹⁶ have improved the accuracy of these devices to almost finger-stick levels. Similar applications of NIGMDs to incorporate analytic approaches may also close the accuracy gap and expedite regulatory approval. The accuracy of any NIGMD should fall within clinically accepted zones compared to a finger-stick glucometer, e.g., using Pearson coefficient, Clarke error grid or mean absolute relative difference. Unless a device meets this minimum threshold for all types of diabetes, it should not be approved for commercial use. One example of this is the

“GlucoWatch”, which was the first NIGMD. Measurement was based on reverse iontophoresis of ISF through the skin. Although initially approved by the US Food and Drug Administration (FDA), it was later withdrawn from the market due to low accuracy, skin irritation and procedural problems.

As device accuracy remains elusive, currently, there is only one NIGMD that is available to the public; Abbott’s FreeStyle Libre was granted FDA approval in September 2016. It uses sensors to measure glucose in the ISF using an electrochemical technique, which is one of three general categories of current NIGMD technologies (Table 1). The sensor costs £57.95 and lasts up to 14 days of continuous use, leading to costs of just over £1,500 per patient per year. However, two key devices are planned to enter the market in 2017/2018, and we estimate that the resulting competition will drive down prices.

SugarBEAT uses a transdermal and electromagnetic technique to draw glucose from the ISF onto an adhesive skin patch. It is marketed as being suitable for people with Type I diabetes, Type II diabetes and prediabetes, has recently received a CE approval and is anticipated to be launched in early 2018 in the UK. GlucoTrack measures glucose levels using three different technologies: ultrasonic, electromagnetic and thermal sensors. Each measurement is then combined via a proprietary algorithm to calculate the weighted average of the patient’s glucose level. The device has received a CE approval and is intended for people with prediabetes and Type II diabetes but is not yet marketed in the EU/UK.

Other products are currently in clinical trials and are expected to come to market in the next 3–5 years. GlucoWise uses high-frequency (65 GHz) radio waves and nano-composite films on the sensor to penetrate through tissues. NovioSense is a spring-like coil inserted under the lower eyelid that uses enzymatic action to detect glucose levels in tears. Finally, iQuickit and Glucose Pop Test devices use enzymatic action to detect glucose in saliva; however, there are concerns about how well the glucose levels in saliva and tears correlate with capillary blood glucose. We also have reservations about how keen potential users will be on a subconjunctival implant, especially with regard to children.

Recently, large tech companies, including Google and Apple, have entered this market with a view to revolutionize NIGMDs. The Google X lab and Novartis have collaborated on smart contact lenses, and Microsoft has designed sensory electrodes that could detect glucose when incorporated into flexible hydrogels. Thus, there is a significant market potential for NIGMDs and the technology is beginning to catch up.

Disruptive innovation

In 2016, the global diabetic care device market was valued at \$19.05 billion.²² This valuation is estimated to reach \$27.42 billion by 2022.²³ The increasing prevalence of DM is the key driver for this trend, fueling the growth of the global SMBG device market at a compound annual growth rate (CAGR) of 12% (Figure 1).²² Bower and Christensen described “disruptive technologies” as entities that revolutionize an existing saturated business, much like the current SMBG market.²⁴ The NIGMDs create a new market and value network that could not only disrupt but also replace current test strips. Furthermore, in some emerging markets including China and India, governmental support for health care and insurance is increasing and becoming more widespread.²⁵ In these countries, the diabetic population is among the highest in the world;²⁶ consequently, spending on diabetes treatment constitutes a large proportion of total medical expenditure.²⁴ These long-term macro fundamentals will therefore continue to fuel demand in the health care market, providing favorable economic conditions for developing technological innovations, such as the NIGMDs.

Larger companies generally work with sustaining technologies, which rely on incremental improvements to previously established products. Disruptive innovations require large capital investment and divert scarce resources for improving the accuracy and reliability of current products against current competition. This is especially true in the SMBG business environment of tight profit margins and declining test strip prices.²⁷ As a result, larger firms rarely capitalize on the potential efficiencies, synergies or new marketing provided by disruptive technologies. Consequently, smaller biotech firms are given an opportunity to compete with larger companies and enter a competitive market through product differentiation.

Currently, just four companies – Roche Diagnostics, LifeScan, Bayer Healthcare Division and Abbott Laboratories – control 90% of the global diabetic care device market. Although these market leaders are dissuaded from pursuing disruptive innovations for the aforementioned reason, they may seek to acquire emerging technologies through mergers and acquisitions (M&A) to drive efficacy in health care. Indeed, the current economic conditions favor health care M&A activity, which has grown at a 50% CAGR from 2012 to 2015,²⁸ over twice as fast as overall M&A activity. This pattern is largely attributed to historically low interest rates,²⁹ which is being used strategically for debt financing. This increase in corporate leverage is driving financial engineering (i.e., buy-

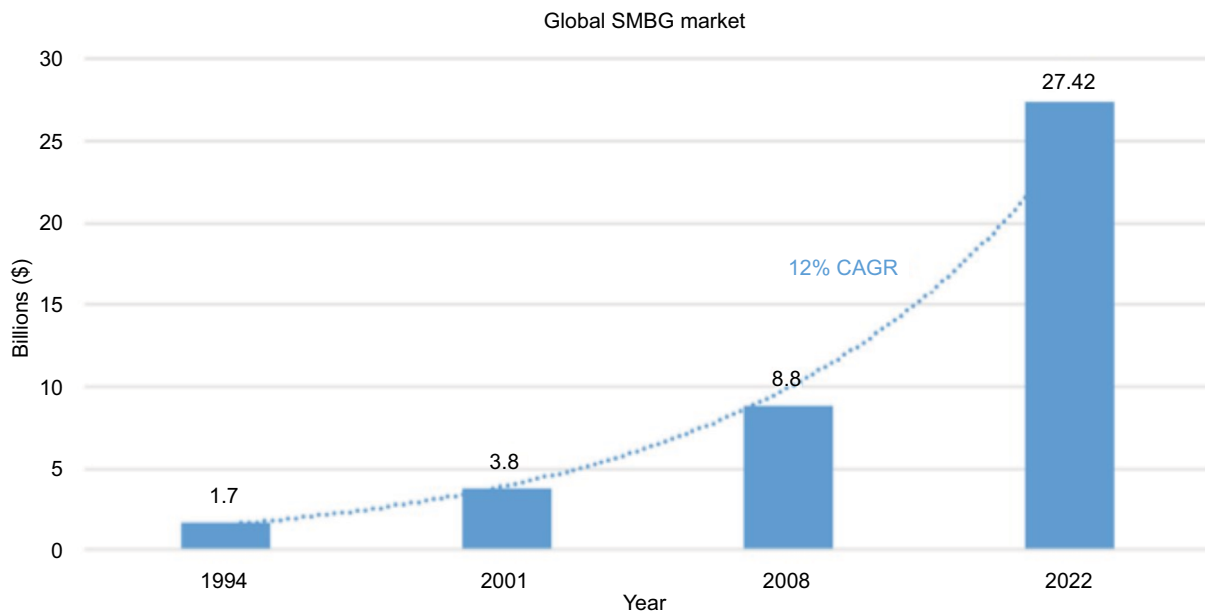


Figure 1 Global sales of SMBG products.

Notes: Sales in SMBG devices were ~\$1.7 billion in 1994. By 2000, the market climbed to \$3.8 billion, and by 2008, global sales reached \$8.8 billion. It is estimated by 2022, sales will reach \$27.42 billion at a CAGR of 12% since 1994. Data from Visiongain.²³

Abbreviations: SMBG, self-monitoring of blood glucose; CAGR, compound annual growth rate.

ing rival companies). Conventional use of cash by companies, such as paying debt and dividends can be regarded as “doing nothing” by company shareholders. Therefore, in order to maintain shareholders’ interest, company boards may be more inclined to exploit low interest to fund inorganic expansion. Hence, global MedTech M&A activity will continue at pace and intensify competition between large health care corporations to acquire disruptive technologies.

Perspectives and concluding remarks

In order to reduce the financial burden on health systems, policy makers are now focusing their attention on implementing effective prevention programs. The use of mobile phone messaging has shown great promise in delivering personalized advice and tackling diabetes prevention. In a randomized control trial by Ramachandran et al,³⁰ men with impaired glucose tolerance were assigned into either a control arm, receiving standard diabetic care advice, or an interventional arm, receiving personalized advice via mobile phone messaging. The group reported that the cumulative incidence of Type II DM was lower in those receiving mobile phone messages. Although the study is limited to Indian males, the authors provide compelling insight into how technology can shape more successful avenues for preventing diabetes. New technologies are being developed that couple blood glucose monitoring devices to mobile phone applications and send blood glucose levels to patients’ mobile phones, allowing

them to keep track of their progress. Each patient therefore receives recommendations about managing their diabetes, which is tailored to their needs. Bibbings et al³¹ tested the accuracy of an NIGMD based on a smartphone application that uses artificial neural network to detect blood glucose levels. The authors showed that this technique is capable of accurately measuring both low and high blood glucose levels. Recently, a new blood glucose monitoring meter, the Contour[®]Next One, has been engineered, which can be linked via Bluetooth connectivity to smartphones. Christiansen et al³² reported that this new device shows analytical and clinical accuracy and is easy to use in clinical settings among patients who have never used blood glucose monitoring devices previously.

The availability of a device for rapid assessment of blood glucose levels without skin puncture will not only revolutionize glucose monitoring at home and hospitals but also significantly disrupt the SMBG market space. In the UK, an NIGMD would achieve the greatest benefit per pound spent by NHS and reduce escalating SMBG costs. Clinically, patient compliance would increase alongside eliminating the risk of blood-borne infection transmission. It is conceivable that an NIGMD will play a pivotal role in the implementation of next generation of prevention strategies.

Author contributions

UO and RM were involved in the conception, design, drafting, revising and final approval of the article.

Disclosure

The authors report no conflicts of interest in this work.

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