LOW COST BLOOD GLUCOSE METERS AS AN APPROPRIATE HEALTHCARE TECHNOLOGY FOR DEVELOPING COUNTRIES

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Abstract

Diabetes mellitus is one of the most common chronic diseases in the world. New diagnoses continue to rise along with the significance of the disease. Changing lifestyles lead to a reduction in physical activity and increase in obesity rates. As a result the costs for healthcare provision are rising. Along with education and healthier lifestyle choices, self monitoring of glucose levels can help keep glucose levels under control thus helping to reduce complications of the condition, thereby reducing the impact to national healthcare budgets. Technology advances, particularly in the semiconductor industry, have helped reduce the costs of electronic components. Glucose meter manufacturers have leveraged these trends to produce lower cost devices, combined with diabetes management tools purposefully designed for developing countries have enable greater penetration and reach more of the diabetic population.

1 Introduction

The non-communicable disease of diabetes is growing at an alarming rate in both developing and developed countries worldwide. Today there are 370 million cases worldwide with an estimated 450 million cases by 2019. In developing countries it is likely to increase more than two-fold in the next 30 years, from 115 million in 2000 to 284 million in 2030[1]. The prevalence of diabetes varies widely from country to country, from a low of 0.27% in Mali, to 15.54% in Mauritius. Researchers noted that age is a common factor in diabetes; the low rate observed in Mali may reflect that country’s low life expectancy due to infectious diseases. 80% of new cases are in developing countries. Furthermore in developing countries, less than half of people with diabetes are diagnosed. Without timely diagnoses and adequate treatment, complications and morbidity from diabetes will rise exponentially [2].

2 Diabetes Complications and Costs

The burden of disease associated with diabetes is substantial; at least one in 20 deaths worldwide is attributable to diabetes. In financial terms, direct health care costs range from 2.5% to 15 % of annual health care budgets, and indirect costs such as loss of production may be five times this number. In the UK diabetes accounts for 11% of all National Health Service (NHS) inpatient expenditure and cost the service around £23.7bn last year, a figure projected to increase to just under £40bn by 2035[3]. Diabetes UK state that there are 2.8 million people living with diabetes in the UK. Diabetes that is left uncontrolled can cause many serious long term problems. Excess glucose in the blood can damage blood vessels, leading to cardiovascular disease, atherosclerosis(stroke), diabetic eye disease (retinopathy and macular oedema), diabetic nephropathy (kidney disease), impotence, and diabetic neuropathy (nerve damage). In Type 2 diabetes, not enough insulin is produced by the pancreas or the insulin that is made by the body doesn’t work as it should. Type 2 diabetes tends to affect people as they get older, though is increasingly seen in younger overweight people and accounts for approximately 90% of all cases. Type 1 diabetes is a condition in which insulin usually cannot be produced at all, is responsible for the other 10% of cases.

3 Importance of Glucose Monitoring

Glucose sticks to the haemoglobin molecules in the blood to make a ‘glycosylated haemoglobin’ molecule called haemoglobin A1C or HbA1C. The HbA1C test is currently one of the best ways to check diabetes is under control. Monitoring of blood glucose levels using self monitoring blood glucose meters (SMBG) provides patients with an insight into their current glucose level and regular monitoring can help control HbA1C levels and hence reduce the risk of complications of diabetes and thus reduce the financial burden to health care budgets. The benefits of SMBG monitoring have been widely reported [4-6]. It is estimated that up to 85% of amputation cases due to diabetes could be avoided if problems are identified early enough and treated appropriately [7].
Typically SMBG monitoring involves the user lancing their finger to obtain a drop of blood. This is then applied to the end of a glucose sensor test strip that is inserted into a meter. A chemical reaction occurs between the reagent on the test strip and the glucose present in the blood. This reaction produces a small current whose magnitude is dependent on the concentration of glucose present. The glucose meter measures the resultant current, typically in the range of 0-20µA and correlates this to a glucose value which is then displayed on the screen of the meter and stored in its memory.

Blood glucose testing kits have historically been tailored for developed markets where health care providers, such as the doctors and diabetic nurses and also the payers, for example the NHS, have seen the value in meter features that help a patient manage their diabetes by providing additional functionality and information helping to put the glucose test result into context, but this can increase the meter cost. Additional meter features include on device result log book, provision of a backlight, strip port light, high resolution high contrast colour displays to help improve readability, 7, 14, 30 and 90 day averaging, pre and post prandial tagging, pattern messaging, low glucose alerts and even wireless communications to external devices such as insulin pumps. In developing markets there is a cost barrier for getting people to test, let alone having patients use extra diabetes management features.

LifeScan was one of the first glucose meter manufacturers to design a product specifically for a developing market. In 2004, in India, LifeScan launched the ‘One Touch®™ Horizon®™’ meter and test strip. The One Touch®™ Horizon®™ meter was a single button operated glucose meter that had a simple feature set that included the test result only, no time and date, no memory and no download functionality. This was achieved through the use of a custom application specific integrated circuit(ASIC), liquid crystal display and sealed coin cell battery. The aim was to reduce the meter price to a point that made it more affordable and opened up glucose testing to those where the cost of the meter was a barrier. The bill of materials cost was approximately half of a developed market meter. One Touch®™ Horizon®™ has done well being a popular meter with over 4 million meters manufactured since 2004.

The One Touch®™ Horizon®™ meter programme provided additional insights into diabetic care in developing counties. For some developing markets, the barriers to adapting and implementing a market-appropriate standard of care include, for example, adequate health care professional (HCP) infrastructure and education, patient education and access, and cost of maintaining diabetes care regimens.

In August 2011 LifeScan’s ‘One Touch®™ SelectSimple™’ was launched, recognizing and trying to address some of these barriers, including making it easier for the doctor and pharmacist to learn to use and to teach patients how to use the meter. Acknowledging the limited access to health care professionals by enabling them to explain what the number means and provide instructions on what to do with the developing country specific range indicator management tool. Another benefit is no meter setup required keeping it simple to teach. It was designed to acknowledge the need for lower a overall cost of maintaining a diabetes care regimen, lower power electronics, durable carrying case, and realizes that not every HCP office and patient home has access to a computer. Alarms/warnings provide visual and audio feedback, especially important for those with lower literacy levels to make patients aware if their blood glucose value is in the danger zone and that they need to take action immediately. So in essence, this One Touch®™ SelectSimple™ solution tries to provide some of the very basics of what a patient needs: simplicity, relevance, and reliability.

One Touch®™ SelectSimple™ has been launched in major developing market countries including India, China, Indonesia, Malaysia, and Singapore with more regions planned. One Touch®™ SelectSimple™ is competing on total value proposition, which begins with simplicity to those who are newly diagnosed with diabetes and are new to testing or even overwhelmed patients since there are no buttons and no menus. Since launch, demand has been high with nearly 1 million devices manufactured to date.

4 Technology Development

Over the last decade technological advances, price erosion due to increased competition between silicon vendors and general industry trends most notably due to consumer electronics have seen technology improvements that have led to low cost, low power electronics that have greater performance and greater levels of integration. This in turn has led to the possibility of low cost blood glucose meters such as One Touch®™ SelectSimple™ as an appropriate technology for developing countries.

Examples of these technology improvements are for example the integration of analogue and digital electronics within a single integrated circuit (IC), for instance, the Texas Instruments MSP430FG4X family of microcontrollers have integrated operational amplifiers that can be configured as in any op-amp configuration to amplify, filter and convert the signal produced by the glucose sensor to a digital signal. Higher resolution and faster analogue to digital convertors allow more precise measurement of the signal being measured and result in improved accuracy for glucose readings.

Electro-chemical glucose sensor strips tend to need a precise bias voltage applied to help stimulate the chemical reaction between the reagents on the strip and the glucose cells within the blood. Glucose meter manufacturers typically try and design their products to fit in with a users lifestyle and hence it is desirable to design a device with as wide as possible temperature test range to allow a meter to be used in as many environmental scenarios as possible. However, the temperature effect on precision voltage reference devices in the past meant the expensive precision voltage reference components were needed. Technology improvements have
seen such devices integrated in microcontrollers as standard, such as Texas Instruments MSP430F2X family with its maximum temperature variation of the voltage reference of +/- 100ppm /ºC.

Time and date can be important for a diabetic as glucose levels can vary greatly during the day. Hence, time stamping a glucose result can help put it into context. Integrated real time clocks (RTC) are becoming common in microcontrollers such as the Texas Instruments MSP430F5X or ST Microelectronics’ STM32 family allowing for lower component counts, improved time and date accuracy and ultimately lower cost glucose meters. An example of this is the list price of a typical off the shelf RTC for example Seiko Instruments S-35192 RTC module has a list price of around $0.74, whereas being integrated into the silicon of the afore mentioned microcontrollers removes this cost.

Another need that a diabetic patient has is the ability to store results in the glucose meters memory and recall them at a later date with the ability to browse records on screen thus allowing them to compare past results. This need was fulfilled with the use of non-volatile electrically erasable programmable read only memory (EEPROM). A 256Kbit EEPROM such as Microchip’s 24LC256, list price $1.56 would allow for the storage of over 500 glucose records and associated data. The HSC12X micro controllers from Freescale have integrated EEPROM memory as well as flash memory thus eliminating the need of an external EEPROM integrated circuit.

Having the ability to download stored results in a glucose meter’s memory allows results to be transferred to a personal computer where diabetes management software can help with further analysis of glucose results, provides the ability to print out a hard copy of results, the ability to graph results, email results to a doctor, etc. Historically glucose meter manufacturers tended to use proprietary solutions based on off the shelf technologies such as embedded infra red transmitter and proprietary infra red receiver cables or proprietary serial data cables. The latest glucose meters on the market now have USB functionality thus allowing commonly available cables that users may already have from their consumer electronic devices to allow the download of glucose results from a meter to a PC without the need to purchase the proprietary cable. Microcontrollers with integrated USB is therefore another desirable peripheral in the latest microcontroller technology such as ST Microelectronics STM32 family and Texas Instruments MSP430F5/6X family.

Flash memory size or code space is another desirable feature in a microcontroller as the software size of meter grows with the increase in feature sets and diabetes management tools. LifeScan’s first electro-chemical meter, OneTouch®™ Ultra®™ had a 4 bit NEC microcontroller with only16K programmable memory available; whereas LifeScan’s latest meter OneTouch®™ VerioIQ™ has the Texas Instrument MSP430F2618 with a larger 128K flash memory.

Finally power and current consumption is an important consideration in glucose meters for developing country users. The nuisance value of battery replacement is further exacerbated with affordability and availability. Hence designing glucose meters to have as low power consumption as possible helps to address this issue. Glucose meters are typically only on for ten minutes per day depending on the number of times a user tests their blood glucose. Therefore the low sleep currents offered by modern microcontrollers, for example, Texas Instruments MSP430F2618 has a power down sleep current in Low Power mode 3 of 200nA which allows a glucose meter to run for years off a single lithium coin cell CR2032 battery.

In summary, the prevalence of diabetes in developing countries continues to escalate. The treatment costs associated with diabetes will continue to rise. SMBG monitoring allows a diabetic to monitor their glucose levels to help keep them under control and help prevent complications. New technology is helping to reduce the cost of blood glucose meters making them more affordable and providing greater value to those diabetics in developing market countries.

References


