Chapter 5
Cost-Effectiveness of Monitoring
Metabolic Control

What cannot be measured cannot be managed and improved—the golden rule of management is particularly true when it comes to managing diabetes. When we talk about measuring in diabetes, we primarily think of glucose monitoring.

In general, there have been three eras of glucose monitoring: from urine samples since the 1940s, from blood samples since the 1960s, and from interstitial fluid with sensors, i.e., continuous glucose monitoring (CGM) since the late 1990s. First compact blood glucose meter (BGM) with digital display and possibility of Self-Monitoring of Blood Glucose (SMBG) was introduced in the 1980s. Latest hybrid closed loop systems are integrating insulin delivery in a form of subcutaneous insulin infusion with the CGMs, and are adjusting the delivery of basal insulin automatically.

A 3-year study has recently reported that people with type 1 diabetes on insulin pumps and SMBG demonstrated worse glycaemic control compared to those on insulin pen therapy and CGM [1]. It suggested that metabolic control depends more on the frequency of glucose monitoring, and less on the method of delivering insulin [1]. Study results confirm that measuring glycaemia is a very critical part in the management of diabetes.

There has been a considerable increase in the CGM use by people with type 1 diabetes as reported from the real-world study T1D Exchange Registry from the US [2]. Percentage of people with type 1 diabetes on CGM from this Registry increased from 6% in 2011 to 31% in 2017 [2]. It is expected that by 2023, 87% of people with type 1 diabetes and 27% of people with type 2 diabetes on insulin treatment will be using CGMs in the US [2].

Taking into consideration the uptake of CGMs worldwide, the question is if SMBG is already dead. It is like asking a question if fossil fuel cars are already dead. According to the figures from 2018, only one in 250 cars on the roads was electric (0.4%), and the same percentage of people with diabetes were using CGM (0.4%) (Fig. 5.1) [3–5]. Despite the number of CGM users is growing considerably, mainly due to the increase in users of intermittently scanned CGM (isCGM), SMBG will not be dead in the foreseeable future. This is of particular importance for the
developing countries where the access to CGM is limited, or CGMs are not available at all, due to the much higher cost compared to SMBG.

Benefits of intensive glycaemic control on the reduction of diabetes complications in people with type 1 diabetes were initially demonstrated in the DCCT study, where SMBG was part of the multifactorial intervention [6]. Reduction in microvascular and macrovascular diabetes complications in the subjects from intensive group was also observed in the follow-up observational study EDIC (Epidemiology of Diabetes Interventions and Complications) [6].

Similar findings were reported for people with type 2 diabetes from the UKPDS and the follow-up UKPDS-PTM study, where the improvement of glycaemic control was associated with reduced risk for diabetes complications [7].

Frequent SMBG is key to achieve glycaemic targets as set by the international authorities, ADA and IDF (Table 5.1) [8, 9]. Achieving the recommended targets correlates with HbA1c below 7%, which is associated with reduced risk for diabetes complications.

Increased frequency of SMBG results in reduction of HbA1c in people with type 1 diabetes [10]. If SMBG is measured more frequently throughout the day, the glycaemic control is improved, which was demonstrated for all age groups [10].

**Fig. 5.1** Estimated proportion of electric cars on road and people with diabetes using CGM, data adapted from Ref. [3–5]. CGM Continuous Glucose Monitoring

**Table 5.1** Recommended glycaemic targets by ADA and IDF, data adapted from Ref. [8, 9]

|                         | ADA                              | IDF                             |
|-------------------------|----------------------------------|---------------------------------|
| Preprandial capillary plasma glucose | 4.4–7.2 mmol/L (80–130 mg/dL) | <6.0 mmol/L (108 mg/dL)        |
| Peak postprandial capillary plasma glucose | <10.0 mmol/L (180 mg/dL) | <10.0 mmol/L (180 mg/dL)       |
|                         | Correlate with HbA1c < 7.0% (53 mmol/mol) |                                |
Titration to target FPG by the use of SMBG also reduces HbA1c in insulin-treated people with type 2 diabetes [11–14]. Use of SMBG was critical for establishing the so-called ‘Treat-to-Target’ concept, whereby achieving the target FPG through titration of basal insulin results in HbA1c reduction associated with lower risk of diabetes complications.

Things become more complex when SMBG is used in non-insulin treated people with type 2 diabetes, as there are studies confirming that use of SMBG significantly improves glycaemic control or reduces hypoglycemia risk in these people, and studies that have not demonstrated such benefits with SMBG [15–28].

Cochrane conclusions from 2012 were that the overall effect of SMBG on glycaemic control in non-insulin treated people with type 2 diabetes is incremental up to six months after initiation, and subsides after 12 months of use [29].

Intuitively, it should be better to take a proactive approach and do SMBG in order to manage the glycaemic control. The opposite is to wait for months until the next visit at physician’s office to have HbA1c measured (reactive approach), realize it was high and glycaemic control was inadequate, and there is nothing to be done since the value of HbA1c reflects the time period that has elapsed [30].

The recommendations on SMBG in non-insulin treated people with type 2 diabetes are described in the IDF Guidelines on Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes [31]. The Guidelines introduced the concept of ‘structured SMBG’, or making sense of the SMBG in the management of diabetes.

In the Guidelines, it is recommended that SMBG should only be used if individuals with diabetes and their healthcare providers have the knowledge, skills and willingness to incorporate it into their diabetes care plan [31]. It should be considered at the time of diagnosis as part of individuals’ education, and to facilitate timely treatment initiation and titration optimization [31].

Self-monitoring of blood glucose should also be considered as part of an ongoing diabetes self-management education [31]. Protocols for SMBG in terms of frequency per day and days per week need to be individualized to address specific requirements [31].

Targets to be achieved with SMBG should be agreed between the person with diabetes and the healthcare provider [31]. Use of SMBG requires an easy procedure for regular monitoring of performance and accuracy of BGM [31].

Structured SMBG in non-insulin treated people with type 2 diabetes is a critical component of diabetes education and treatment. It is vital for glycaemic assessment, behavioral change, optimization of therapy, and diabetes education and understanding, both for the healthcare provider and the person with diabetes [31]. In addition, structured SMBG has an impact on the metabolic control, safety, quality of life (QoL), and the economic burden [31].

The role of structured SMBG in non-insulin treated people with type 2 diabetes has been confirmed by the recently published ‘The SMBG Study’ where the structured SMBG provided improvements in glycaemic control of non-insulin treated people with type 2 diabetes [32]. This study has proved the value of SMBG in people with type 2 diabetes not on insulin, if structured SMBG is implemented.
All the studies mentioned above were using SMBG as a tool to achieve lower HbA1c, and by lowering HbA1c to reduce the risk of diabetes complications. The value of HbA1c is currently acknowledged as the gold standard for measuring the glycaemic control. Nevertheless, the question is how reliable is HbA1c as a surrogate marker, and what are its advantages and limitations?

Advantages of the use of HbA1c as a measure of glycaemic control include that it is easy to measure, relatively cheap, predictive of vascular complications, and helps management decisions [33]. Limitations of HbA1c include the facts it only provides an approximate measure of glycaemia, is unable to address glycaemic variability (GV) or hypoglycemia, 50% of the HbA1c value reflects the mean BG in the previous month, and is unreliable in certain conditions [33].

Those conditions are quite numerous, including: (1) comorbidities, such as anemia, accelerated red blood cells turnover, thalassemia, reticulocytosis, haemolysis, HIV infection, ureaemia, hyperbilirubinemia, dyslipidemia, cirrhosis, hypothyroidism; (2) physiologic states, such as ageing and pregnancy; (3) medications or treatments, such as alcohol, opioids, vitamin C and E, aspirin, erythropoietin, dapsone, ribavirin, blood transfusions, hemodialysis, and (4) other circumstances, such as, different glycation rate, protein turnover, race and ethnicity, laboratory assay, glycaemic variability, smoking, mechanic heart valves, and use of exogenous testosterone [6, 33, 34].

In a real world clinical practice it is estimated that 14–25% of HbA1c results are misleading [6, 33, 34]. That is the reason we are moving beyond HbA1c as a standard of adequate metabolic control, and novel glucometrics are introduced with the wider use of CGMs. Those novel glucometrics include Time In Range (TIR, defined as time spent in range 3.9–10 mmol/L (70–180 mg/dL)), Time Below Range (TBR, defined as time spent below 3.9 mmol/L (70 mg/dL)), and Time Above Range (TAR, defined as time above 10 mmol/L (180 mg/dL)). For people with type 1 and type 2 diabetes, TIR should be more than 70%, TBR below 4% (time below 3.0 mmol/L (54 mg/dL) should be below 1%), and TAR below 25% (time above 13.3 mmol/L (250 mg/dL) should be below 5%) [34].

Other glucometrics include the time CGM was active, average glucose, Glucose Management Indicator (GMI)—formerly known as estimated HbA1c, GV, and Ambulatory Glucose Profile (AGP) [34].

It has been demonstrated by the use of DCCT data that TIR was associated with reduction of microvascular complications in people with type 1 diabetes [35]. Each 10% reduction in TIR was associated with increase in the risk of retinopathy by 64%, and microalbuminuria by 40% [35].

Similar findings were reported for the association between TIR and microvascular complications in people with type 2 diabetes—the higher the value of TIR, the lower the risk for retinopathy [36]. It was recently published that TIR was inversely associated with Carotid Intima Media Thickness in people with type 2 diabetes, suggesting it could be related not only with reduction of microvascular, but also of macrovascular complications [37].

These novel glucometrics could also be used with BGMs, which is of great importance for the developing countries where CGMs would not be widely
available soon. Glucometrics, such as average glycaemia, glucose variability, standard day, ambulatory glucose profile, change in glucose over time, glucose distribution, and integration with other relevant data including medications, insulin doses, diet, physical activity, illness, stress, or travel, could all be retrieved from SMBG data of BGMs [30].

Use of the Smart Glucometers, which are sending the SMBG data into the cloud to be further analyzed, reported, and shared with family and healthcare providers, could be of great significance for the developing countries, where the uptake of CGMs is expected to be slower due to the associated cost. There are diabetes management systems that enable BGMs to send the SMBG data into the cloud for analyses and reports in the form of novel glucometrics.

Accuracy of BGMs is crucial as critical decisions are based on the SMBG values. Current standards for SMBG accuracy include those of Food and Drug Administration (FDA) and International Organization for Standardization (ISO) 15197–2013 [8]. Recent study comparing second generation basal insulin analogues in people with type 2 diabetes reported inaccuracy of the BGMs used during the very sensitive period of insulin titration [38, 39]. It was concluded that if such inaccuracies of BGMs occur in highly controlled clinical trial settings, we can imagine what happens in everyday life of people with diabetes, and how it might affect treatment decisions and overall glycaemic control.

There are many factors affecting the accuracy of SMBG that have to be considered, especially in developing countries. Those include: (1) higher and lower oxygen tension conditions (glucose oxidase monitors are sensitive to oxygen); (2) temperature (reaction is sensitive to temperature, all monitors have an acceptable temperature range); (3) interfering substances (uric acid, galactose, xylene, acetaminophen, L-dopa, vitamin C); (4) manufacturing defects (could lead to bias in hypoglycaemic, target, and hyperglycaemic range); (5) test strip lot-to-lot variation (lot-to-lot variations as high as 11% could occur while using the same BGM); (6) alternate site testing (particularly when glucose levels are changing rapidly); (7) skin contaminants (food sources, such as fruits, juices, sodas, milk; hand lotions); (8) counterfeit test strips (pre-owned or second-hand test strips should not be used) [8, 30].

In comparison of 17 models of BGMs that were available on the market, 9 had a Mean Absolute Relative Difference (MARD) above 10%, which is unacceptable accuracy [40]. Similar results were obtained when ISO 15197 standards were applied, when out of 18 BGM on the market, only 6 met the ISO standards on accuracy [8]. Although there was a huge difference between the accuracy of CGMs and SMBG at the beginning, latest models of CGMs have a MARD comparable to SMBG in the range of 8.1% to 10.6% [41].

Affordability of BGMs and test strips for monitoring blood glucose is particularly important in a time of global crisis, such as the recent one with COVID-19 pandemic. Disruption of the global economy could lead to delays in manufacturing and supply shortages, leaving the people with diabetes without their essential tools for managing hyperglycemia. On the other hand, inadequately managed hyperglycemia makes them more prone to developing severe forms of the infectious
COVID-19 disease and increases the risk for worse outcomes after contracting the infection.

In a study conducted in developing countries, glycaemic control in individuals with type 2 diabetes remained suboptimal, indicating a need for system changes and better organization of care to improve self-management and attainment of treatment goals [42]. This also refers to improvements in monitoring of glycaemia [42].

The importance of SMBG could be elucidated from the real-world evidence reported from the Republic of North Macedonia. Although, majority of the people with diabetes in the country were on insulin analogues by 2011, it was not associated with adequate glycaemic control at a national level. People with diabetes had very limited access to free, reimbursed test strips as only 50 free test strips per year were provided for those on insulin treatment.

In addition to the rationalization of insulin treatment, since 2015 the number of free test strips was increased seven-fold to 350 free test strips per year for people with type 2 diabetes on insulin treatment, whereas the people with type 1 diabetes were provided with 125 free test strips per month.

Test strips were procured through centralized procedure that resulted in a significant reduction of the price per test strip, as higher volumes were associated with lower prices. Bidders were obliged to provide BGMs, lancets and lancet devices free of charge. Procurement of the test strips was part of the general procurement procedure, including insulins, glucagon, insulin pumps, ancillaries, and novel classes of diabetes medications (SGLT2i, GLP-1RA, DPP-4i). The cost savings achieved for test strips were significant and comparable to the cost savings achieved with the diabetes medications.

The considerable increase in the number of free test strips was associated with reduction of acute diabetes emergencies, such as DKA and HHS. In only a year, the number of acute diabetic complications was reduced by 9%, despite the increase in the number of people with diabetes and those who were on insulin treatment (Fig. 5.2) [43].

**Fig. 5.2** Reduction of acute diabetes emergencies, DKA and HHS, after seven-fold increase in free test strips for people with type 2 diabetes on insulin treatment [43]. DKA Diabetes ketoacidosis, HHS Hyperglycaemic Hyperosmolar State.
It confirms that it is possible even in a setting with limited resources to increase the frequency of SMBG by considerably increasing the number of free test strips. Those actions could result in reduction of acute complications, and could potentially lower the risk for long-term diabetes complications through improved glycaemic control.

Above findings confirm the results from the COMISSAIR study that frequent measuring of glycaemia is critical for adequate glycaemic control, and more important than the method of insulin delivery [1]. If resources in diabetes care are limited, they should be adequately allocated for glucose monitoring. Each person has to be provided with a certain number of free or affordable test strips per month. It is equally important as the provision of free insulin.

Instead of fragmented procurement that is associated with lower volumes and higher prices, centralized procurement results in higher volumes and lower prices. Bidders who comply with the procurement specification could be included in the negative bidding process where they are competing by lowering the price, preferably using an electronic bidding system.

Reduced diabetes comorbidities by the frequent use of SMBG was reported from India, demonstrated to have economic and QoL implications [44]. In a simulation analysis, the cohort with at least one SMBG per day was associated with a 10-year estimated saving of INR 120,173 compared to the cohort with no SMBG [44].

Proactive diabetes management with SMBG was demonstrated to improve treatment outcomes and reduce morbidity and mortality in this simulation from India [44]. Near-normal BG levels could bring in cost savings from reduced long-term complications and avoidance of repeated hospitalizations along with an improved QoL [44].

Low adherence to the use of SMBG was reported even in people with type 1 diabetes from developed countries, such as Sweden [45]. In a survey study done before the wider use of CGMs in Sweden, it was reported that less than 50% of people with type 1 diabetes perform SMBG at least 4 times per day, according to the ADA guidelines, and 30% of people were unaware of the guidelines at all. The top two most reported reasons for not performing more frequent SMBG were ‘not remembering’ and ‘lack of time’ [45].

There is an underutilization of SMBG in people with type 2 diabetes from developed countries. Recent real-world study on the use of SMBG in people with type 2 diabetes from Italy concluded that there is an urgent need for improvement [46]. Non-insulin treated people with type 2 diabetes were using 15–23 test strips per month, people treated with basal insulin were using 32 test strips per month, and people with type 2 diabetes on basal-bolus insulin treatment were using 53–58 test-strips per month [46]. Similar findings were reported from other developed countries, such as Canada, the UK and France [47–49].

Unfortunately, there is a low rate of SMBG adherence according to the national guidelines, in both developed and developing countries. According to the available survey based studies, the rate of adherence was reported to be 28% in China, 39% in South and Central America, 50% in the UK, 52% in the US, and 59% in Jordan [50–52].
The rate of adherence was reported to be 58% in the recent study of real-world use of SMBG in people with type 2 diabetes in China [53]. It was not a survey based study and the SMBG was automatically recorded in a real-time manner by using a blood glucose monitoring platform [53]. For the first time intelligent BGMs were used to record the SMBG in people with type 2 in a real-time manner; unlike the survey based studies before that were relying on individuals’ memory of the SMBG frequency [53].

Inadequate utilization of SMBG in people with type 2 diabetes mellitus in Sub-Saharan Africa has also been reported [54]. Based on 15 real-world, observational studies, it was found that percentage of people with type 2 diabetes able to do SMBG at home, ranges from 0% in Uganda, 3% to 10% in Ethiopia, 4% in Zimbabwe, 5% in Ghana, 20% in Kenya, 25% in Sudan, 26% in Tanzania, and 32% to 43% in Nigeria [54].

On average, only 15% of all people with type 2 diabetes in Sub-Saharan Africa were doing SMBG at home. Most of those people possessing BGMs at home performed SMBG only once a month, or at no regular interval, not adhering to the guidelines. In addition, only 1% to 2% of those people measured their blood glucose on a daily basis [54].

Only half of the people who performed SMBG at home, also kept records of their results, so they could analyze and discuss them with the healthcare providers as part of the structured SMBG process. There has been no study on the use of structured SMBG, i.e. of individuals’ ability to analyze SMBG results and whether they know what to do if their blood glucose is above or below agreed target values [54].

In many developing countries test strips for SMBG are only available in private clinics where people with diabetes are financially capable to afford SMBG, and not in public clinics where test strips are not covered by public healthcare insurance. Understandably, glycaemic control is much better in private clinics compared to clinics with limited or no access to SMBG. In many developing countries, CGMs are not available at all [55].

In a small number of developing countries CGMs are available, but only to those on the most expensive healthcare insurance who can afford the consumables. As a result, almost everyone is on SMBG—and even then, getting enough test strips in public healthcare is very difficult [55].

Additionally to monitoring glycaemic control via HbA1c and novel glucometrics, it is vital to monitor other parameters important for adequate metabolic control, such as the lipid profile, SBP and DBP, BMI, smoking status, creatinine and UACR, and the other related laboratory parameters. Such information needs to be recorded in the individual EHRs of a centralized, integrated e-Health system.

Integration of BGM or CGM data into the individual EHRs could further facilitate the monitoring of glucose control in people with diabetes. Despite the novel technologies for measuring glycaemia, the vast majority of people with diabetes are using SMBG: The frequent use of SMBG and the novel glucometrics in the countries with limited resources could significantly contribute to the improved glycaemic control and reduced risk for diabetes complications.
What should be done to provide cost-effectiveness of monitoring of metabolic control in developing countries?
Each developing country should...

- ...ensure adequate number of free or affordable test strips for people with diabetes, primarily those who are on insulin treatment;
- ...consider central procurement of test strips to achieve reduction of prices;
- ...introduce the concept of structured SMBG for improved glycaemic control;
- ...ensure that healthcare providers and people with diabetes are familiar with the measures of SMBG accuracy;
- ...ensure that healthcare providers and people with diabetes are familiar with the novel glucometrics,
- ...ensure the metabolic control parameters are recorded in the individual EHRs, and continuously monitored.

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