

2012

Post Market Review of Products Used in the Management of Diabetes

Submission to the Pharmaceutical Benefits
Scheme, Department of Health and Ageing



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Executive Summary

This year the Pharmaceutical Benefits Advisory Committee (PBAC) “agreed to a complete review of diabetes medicines due to considerable recent changes in diabetes management”.

This encompasses other aspects of diabetes management, including, for the purpose of this paper, “the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) and the clinical outcomes and benefits of SMBG for people with type 2 diabetes not treated with insulin”.

The worth of self-monitoring of blood glucose in people with type 2 diabetes not treated with insulin has long been debated both in Australia and worldwide. The overall consensus from the literature is not supportive of self monitoring of blood glucose as an effective tool in a management regimen. Why this is so when the evidence supports the effectiveness of this tool in self management of glucose levels in people with type 1 diabetes and people with type 2 diabetes using insulin therapy and the benefits, such as providing feedback on the impact of lifestyle choices related to food intake and activity, seem clear, has led to further investigation. Questions such as:

Are there select sub-groups within this population where the tool is more effective? With the ensuing, can the use of this tool be better targeted?

Is the way the information is provided the key?

Is more support required for people with type 2 diabetes not treated with insulin and if so, at what time should this support be provided?

Our submission will argue that:

- the exploration of the effect of food intake and activity on an individual’s blood glucose levels in a structured approach that includes pattern analysis and takes into consideration the person’s response to illness and self-care behaviour be supported;
- self monitoring of blood glucose be used to measure and treat postprandial hyperglycaemia;
- self monitoring of blood glucose in people whose diabetes is managed using sulfonylureas be supported due to the benefit of identifying and treating hypoglycaemia in this group;
- self monitoring of blood glucose be used in clinical situations where HbA_{1c} results are affected and to improve control in people with of sub-optimal HbA_{1c} results.

The ADEA considers Credentialed Diabetes Educators to be pivotal in the use of structured self monitoring blood glucose as a tool to achieve glycaemic management targets.



About the ADEA

The Australian Diabetes Educators association (ADEA) is the leading organisation for all health care professionals providing diabetes education and care and actively promotes evidence-based best practice diabetes education for all people, affected by, and at risk, of diabetes. The ADEA sets the guidelines, standards and expected competencies for diabetes self management education and has registered the trade mark – Credentialed Diabetes Educator[®].

Background

Credentialed Diabetes Educators (CDE) are mainstream healthcare professionals with registration to practice in a primary discipline of dietetics, exercise physiology, medicine, nursing, pharmacy or podiatry followed by post-graduate qualifications in diabetes management and education who have then achieved credentialing status through the ADEA.

Credentialing encompasses:

- Completion of 1800 hours of practice in diabetes education, including a referee's report addressing core competencies and practice in accordance with the ADEA's Code of Conduct and Standards of Practice.
- Completion of a mentoring partnership.
- Evidence of undertaking continuing professional development.

To maintain currency of the credential CDEs apply for re-credentialing every three years. This credential is the hallmark of a commitment to the ongoing study of diabetes and its management, and the implementation of best practice in a clinical area of considerable and continuing change. CDEs are best placed to provide holistic education to support and empower people to manage their diabetes and to prevent or delay the development of diabetes complications across type 1, type 2, gestational diabetes and pre-diabetes.

CDEs are the recognised providers of choice for diabetes self-management education for Medicare and the Department of Veterans Affairs. In addition, CDEs are recognised by the National Diabetes Services Scheme for authorisation of NDSS registrations and authorisation to access insulin pump consumables.



The ADEA Position

The ADEA has long recognised the lack of support for self monitoring blood glucose levels in people with type 2 diabetes not treated with insulin and has sought answers to provide diabetes educators with a framework for best practice that supports better health outcomes.

In 2009 the ADEA and the Australian Diabetes Society commissioned a mixed methods systematic review of the effectiveness, appropriateness and meaningfulness of self monitoring blood glucose (SMBG) in type 2 diabetes.¹

This review produced a number of recommendations that included:

- The use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment. (Grade A)
- SMBG increases the detection of episodes of hypoglycaemia. Health professionals should make people aware of the benefits of increased detection. (Grade B)
- It is recommended that clinicians be aware that qualitative research findings revealed the individual's overall preference for SMBG. (Grade B)
- The autonomous decision making of individuals should be supported and facilitated in the use of SMBG. (Grade B)
- Individualized educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. (Grade B)
- It should be understood that SMBG itself is not a goal, but the learning process to actualize self-management of diabetes including the use of SMBG. (Grade B)
- Multifactorial assessment and interventions are necessary in order to meet each person's various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. (Grade B)
- In the absence of conclusive evidence, the frequency of SMBG should be decided depending on individual circumstance and clinical judgment. (Grade B)
- Education should include the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimize glycaemic control. (Grade B)
- For the individual with a recent diagnosis, the introduction of SMBG should be supported with strategies to evaluate and enhance the individual's psychosocial status. (Grade B)

A further review of the literature was completed by the ADEA in 2011² leading to the development of a Position Statement³ on the *Effectiveness, Appropriateness and Meaningfulness of Self-monitoring Blood Glucose In Non-insulin Treated Type 2 Diabetes* for use by health professionals involved in diabetes education and care. Three key recommendations were made:



1. Diabetes educators should facilitate development and use of a clear plan of action for the person with diabetes to deal with inappropriately high or low glucose levels.
2. Diabetes educators should recommend SMBG for all patients on medications that can cause hypoglycemia especially before driving, regularly during long drives or operating potentially dangerous equipment or participating in potentially dangerous activities.
3. Appropriate SMBG should be taught by the diabetes educators in recognition of barriers to learning including poor health literacy and numeracy skills, dexterity, hearing or sight loss common diabetes and the elderly. There are also issues related to cultural sensitivity and ethnicity that must be considered in order for SMBG to be an appropriate tool to use in the management of diabetes.

To guide the development of educator skills in structured SMBG and pattern analysis the ADEA has conducted workshops at the Educators Day which is held the day preceding the ADS-ADEA Annual Scientific Meeting. The workshop also covered activities to assist communication through the recognition of a range of learning styles and behaviours that come with patient heterogeneity. In 2012, a workshop at this event focussed on Driving and Sustaining Best Practice, which explored the barriers and enablers of implementing this Position Statement in the workplace.

The International Diabetes Federation Position

In 2009, the International Diabetes Federation (IDF) released their guideline *Self-monitoring of Blood Glucose in Non-insulin Treated Type 2 Diabetes*.⁴ The IDF recognises that SMBG in consultation with their healthcare provider can assist people with non-insulin treated type 2 diabetes to better understand their condition, and to actively and effectively participate in its control and management. The recommendations included:

- SMBG should be considered at the time of diagnosis of type 2 diabetes to enhance the understanding of diabetes and facilitate timely treatment initiation and titration optimization.
- SMBG should be considered as part of ongoing diabetes self-management education.
- Intensity and frequency of SMBG should be individualised and aligned to the person's education, behavioural and clinical requirements such as hyper- and hypoglycaemia identification, prevention and management.
- The purpose of performing SBGM and use of generated data should be agreed between the person with diabetes and the health care provider, which are then documented and reviewed.

Although there is no evidence base regarding optimal SMBG regimens, consensus is that often daily SMBG is not required, rather that SMBG should be used strategically as a tool to obtain meaningful clinical data on blood glucose levels that can be interpreted within the context of the day's activities.^{5,6} This is best achieved by performing a 5-point or 7-point SMBG regimen (testing blood glucose levels before and after meals and before bedtime for a period of one to three days). The IDF



has identified several situations in which short-term focused SMBG may be beneficial to the patients with non-insulin treated type 2 diabetes. ⁴This includes when the individual:

- has symptoms of hypoglycaemia
- has infection, are travelling or are under stress
- is undergoing adjustments in medication, nutrition and/or physical activity
- is entering a new life experience, such as starting a new job or changing work hours
- is experiencing a worsening HbA_{1c} value
- is unclear or requires additional information about the nature of their disease and/or impact of their treatment (non-pharmacological and pharmacological) on their blood glucose control
- is pregnant or planning to become pregnant (please note that more pregnant women with pre-existing diabetes have a diagnosis of type 2 and not type 1 diabetes).

It has been demonstrated that when SMBG is incorporated into a more comprehensive treatment regimen, it becomes a valuable tool for patients to understand the impact of their dietary intake, physical activity and medications on their blood glucose levels that in turn results in improved glycaemic control.⁷

Further, it has been shown that in people with poorly controlled non-insulin treated type 2 diabetes, knowing their sub-optimal HbA_{1c} was not enough to generate change in self-management strategies. However, when structured SMBG was introduced to a randomized intervention, HbA_{1c} significantly improved ($P < 0.0001$)⁶ and ($P = 0.0097$).⁸

The 2005 International Diabetes Federation *Global Guideline for Type 2 Diabetes* was updated and published this year. A series of recommendations were made with respect to SMBG which included that SMBG be used in association with HbA_{1c} testing to:

- Provide information on, and help avoid, hypoglycaemia.
- Assess changes in blood glucose control due to medications and lifestyle changes.
- Monitor the effects of foods on postprandial glycaemia.
- Monitor changes in blood glucose levels during undercurrent illness.

The guideline highlighted that provision should be made for the supply of glucose strips on a continuing basis to people with diabetes.



Other factors to be considered

Postprandial Hyperglycaemia

In 2007, the International Diabetes Federation released a *Guideline for Management of Postmeal Glucose*.⁹ The document acknowledges that strong emphasis on HbA_{1c} and fasting plasma glucose, however, presented ‘a growing body of evidence suggesting that reducing postmeal (post prandial) plasma glucose excursions is as important, or perhaps more important for achieving HbA_{1c} goals’. Several key questions were investigated, each producing evidence states and recommendations; two of which are relevant to this submission.

The authors found that postmeal and post challenge hyperglycaemia are independent risk factors for macrovascular disease. [Level 1+] In addition, post meal hyperglycaemia:

- is associated with increased risk of retinopathy. [Level 2+]
- is associated with increased carotid intima-medial thickness. [Level 2+]
- causes oxidative stress, inflammation and endothelial dysfunction. [Level 2+]
- is associated with decreased myocardial blood volume and myocardial blood flow. [Level 2+]
- is associated with increased risk of cancer. [Level 2+]
- is associated with impaired cognitive function in elderly people with type 2 diabetes. [Level 2+]

When investigating the targets for postmeal glycaemic control and how they should be assessed the authors determined the following evidence statements:

- Self-monitoring of blood glucose (SMBG) is currently the optimal method for assessing plasma glucose levels. [Level 1++]
- It is generally recommended that people with insulin perform SMBG at least three times per day; SMBG frequency for people who are not treated with insulin should be individualised to each person’s treatment regimen and level of control. [Level 4]

The conclusions drawn were that postmeal hyperglycaemia is harmful and should be addressed; SMBG should be considered as it is currently the most practical method for measuring postmeal glycaemia; and efficacy of treatment regimens should be monitored as frequently as needed to guide therapy toward achieving postmeal plasma glucose target.

Hypoglycaemia

Hypoglycaemia is usually associated with the use of insulin secretagogues such as sulfonylurea agents in people with non-insulin treated type 2 diabetes. The risk of hypoglycaemia varies within this class of agents. Sulfonylureas are recommended as the second line agent to commence after the established failure of metformin alone.¹⁰



Table One: Risk of hypoglycaemia by class of sulphonylurea

Sulphonylurea	Frequency of administration	Risk of hypoglycaemia
Glibenclamide	Once or twice daily	High
Gliclazide	Once or twice daily	Intermediate
Glimepiride	Once daily	High/intermediate
Glipizide	Once or twice daily	Low/intermediate

Source: Australian Medical Handbook, 2012

Hypoglycaemia unawareness is also prevalent in people with type 2 diabetes treated with sulphonylurea agents.¹⁰ Hypoglycaemia under-reporting, especially in older people is considered to be not uncommon when clinical symptoms of dizziness, weakness, delirium, confusion are missed or misconstrued as other neurological conditions.¹¹ Anecdotal data would suggest that the occurrence of frequency of hypoglycaemia is not always established for people with type 2 diabetes treated with sulphonylureas when reviewed by their general practitioner.

Hypoglycaemia is not normally an adverse effect of metformin, thiazolidinediones, α -glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists; however when food intake is limited for patients taking metformin, hypoglycaemia has been reported.¹² In the ADOPT study 10% of participants treated with either metformin or rosiglitazone self-reported hypoglycaemia.¹³

Factors associated with an increased risk of severe hypoglycaemia occurring include:

- Increasing age
- Past history of vascular disease
- Renal failure
- Hepatic impairment
- Reduced ingestion of food
- Alcohol consumption
- Impaired counter regulatory capacity such as Addison's disease, growth hormone deficiency, hypopituitarism¹⁴
- Interactions with other drugs (including gemfibrozil and warfarin).^{11,12,15}



Hypoglycaemia can result in serious adverse events and injuries and can be fatal, particularly in the elderly resulting in:

- Stroke
- Myocardial infarctions
- Acute cardiac failure
- Ventricular arrhythmias
- Convulsions
- Bone fractures resulting from falling

The ACCORD study¹⁶ identified a threefold increase in the occurrence of severe hypoglycaemia in the intervention group treated with a variety of glucose lowering agents, compared with the conventional arm and an excessive number of deaths.

Hypoglycaemia and driving

Hypoglycaemia is identified as a key factor determining an individual's ability to drive safely. In the United Kingdom, a study commissioned by the Department for Transport published self-reported rates of mild hypoglycaemia of 39% and severe hypoglycaemia of 7% from participants with type 2 diabetes treated with sulfonylureas.¹⁷ During the study, those prescribed sulfonylureas were also connected to continuous glucose monitoring with 14% experiencing a blood glucose level <2.2mmol/L for at least 20 minutes.

Austrroads and the National Transport Commission (NTC) released their updated manual in March this year with specific advice for people with diabetes at risk of hypoglycaemia to ensure blood glucose level is above 5mmol/L when preparing to drive.¹⁸ Conditional licences for commercial vehicle drivers are issued by the driver licensing authority based on advice from an appropriate medical specialist (Endocrinologist) when treated with glucose lowering agents other than metformin alone. Austrroads and the NTC define satisfactory control of diabetes as an HbA_{1c} less than 9.0% measured within the preceding three months and a record of SMBG.

The National Diabetes Services Scheme (NDSS) released the publication *Above 5 To Drive* in 2011 and this resource recommends that all people who take glucose lowering medications test their blood glucose level prior to driving to ensure it is above 5mmol/L.¹⁹ SMBG is the only available method to ensure adhering to the recommendations for driving and diabetes.

Hypoglycaemia in the workplace

Hypoglycaemia should also be considered within other contexts of daily life; primarily the workplace. People with type 2 diabetes treated with sulfonylurea agents are employed in environments where it is imperative to reduce the risk of hypoglycaemia occurring, for example, the mining industry, construction and industrial sites, child and healthcare. SMBG is vital to identify trends of blood



glucose levels, particularly when such levels fall below glycaemic targets and the onset of adrenergic and neuroglycopenic effects begin to occur.

Legacy Effect

The 'legacy effect' has been defined as the phenomenon by which the body's tissues continue to respond to poor or good glycaemic control for years after glucose control has either improved or deteriorated. This effect exists for both people diagnosed with type 1 and type 2 diabetes. Tissues shown to be susceptible to glucose-induced memory include the retina, kidneys, arteries and nerves. While the mechanism for this remains unclear, a 30 year study conducted by the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that participants with newly diagnosed type 2 diabetes achieving glycaemic control within target early into the study, continued to enjoy better health outcomes years after the cessation of randomized intervention.²⁰

Maintaining blood glucose levels in the recommended target range from the time of diagnosis significantly decreases the risk of myocardial infarction and death from any cause, (in addition to well-established reduction in risk of developing microvascular disease), enhancing the consequences of the legacy effect.

Glycated Haemoglobin (HbA_{1c}) Testing

The NHMRC recommends that glycated haemoglobin (HbA_{1c}) measurement should be undertaken at least twice in a year for people with type 2 diabetes and stable blood glucose control.¹⁰ More frequent testing is required in people with sub-optimal glycaemic control or following changes to management and therapy. The NHMRC also recognises that a number of clinical situations can affect the HbA_{1c} result including:

- Red cell survival
- Iron deficiency anaemia
- Blood transfusion
- Haemoglobin variants
- Uraemia
- Vitamins C and E
- Hypertriglyceridaemia
- Alcohol
- Aspirin

One of the benefits of SMBG in people with non-insulin treated diabetes is a statistically significant reduction in HbA_{1c} ($P < 0.00001$). The effect was greater for those whose baseline HbA_{1c} was $\geq 8.0\%$.²¹

However, it has been shown that patients with poorly controlled non-insulin treated type 2 diabetes, knowing their sub-optimal HbA_{1c}, was not enough to generate change in self-management strategies. The introduction of structured SMBG to a randomized intervention, significantly improved HbA_{1c} ($P < 0.0001$)⁶ and ($P = 0.0097$).⁸



In Australia, an annual cycle of care is used as a measure of the clinical management of diabetes. An annual cycle of care is a detailed set of diabetes management steps that is implemented by general practitioners (GPs) for people with diabetes. It currently has the benchmark of measuring a HbA_{1c} level once every year. In 2009-2010, only 18% of Australians with diabetes completed an annual cycle care. Further, people with type 2 diabetes often report that GPs do not initiate requests to review their SMBG which can reduce their enthusiasm and motivation to maintain SMBG. Such clinical inertia has been shown to contribute to poor glycaemic control in people with type 2 diabetes who are managed in primary care settings.²²

Perceptions of the Seriousness of Type 2 Diabetes

Type 2 diabetes is one the key attributing factors for the development of end-stage renal failure, blindness in people aged less than 75 years, myocardial infarction, heart failure, stroke, dementia and cancer. The UKPDS indicated that good glycaemic control had a direct benefit in reducing the risk for any diabetes-related endpoint, diabetes-related death and all cause mortality. Yet health professionals tend to view type 2 diabetes as mild. This was particularly so for diet-treated diabetes.²³ It has also been demonstrated that beliefs about health and illness affect self-care behaviour even for those with complications of diabetes. For some help seeking only occurs when a new problem arises rather than as active management of the issue.²⁴ Once the person seeks advice the degree to which the advice is followed is determined by their health beliefs of diabetes.²⁵

Motivation to actively manage diabetes may be affected by the person's perceived: likelihood that adverse events will occur; severity of the condition; impact on their everyday life; personal control and perceptions of effectiveness of preventative strategies. Illness representations related to treatment effectiveness and seriousness of diabetes have been demonstrated to be most important in diabetes self-management. Interventions that consider these perceptions and motivations maximise the achievement of improved glycaemic outcome.

Summary

Management of type 2 diabetes continues along the diabetes continuum from pre-diabetes to diabetes with a wide range of co-morbidities and complications. It affects people, young and old, who have varying perceptions of their condition, management goals and treatment strategies.

While self monitoring of blood glucose has not been shown to be effective at achieving glycaemic management, glycaemic management within target is associated with the delay and prevention of diabetes complications. The sooner glycaemic control is achieved and maintained the better the lifelong outcomes. Further, structured self monitoring of blood glucose has been demonstrated to be effective if provided within a structured program which takes into consideration the heterogeneity of the condition, varying life needs and the illness representations of the person with diabetes.

Structured self monitoring of blood glucose is effective as a tool to interpret glucose levels in the context of the day's activities, to measure postmeal hyperglycaemia and to assess the efficacy of



treatment regimens. Introducing self monitoring of blood glucose in people with suboptimal HbA_{1c} improves the HbA_{1c} result.

Self monitoring of blood glucose is essential for people who are on some classes of sulphonylureas to prevent hypoglycaemia unawareness.

The following three case studies outline different benefits of SMBG for people with type 2 diabetes who do not require insulin therapy at this stage in their journey.

Case Study One

John is a 43 year old man with type 2 diabetes. He is highly motivated to self-manage his diabetes, hypertension and raised cholesterol levels. When a DPP4 inhibitor was added to his metformin to assist in maintaining glycaemic control, he experienced side effects. This agent was changed to a sulphonylurea agent and has been well tolerated by John.

John is employed as a forklift driver with varying working hours that include day, evening and night shifts. John measures his blood glucose levels vigilantly while at work to ensure that feelings such as tiredness and difficulty concentrating are not as a result of hypoglycaemia. By utilising a free app on his mobile phone, John is able to produce detailed reports of his blood glucose levels which he then makes available to the onsite occupational health nurse and takes with him to discuss with his Credentialed Diabetes Educator during his regular review.

Case Study Two

Maria is a 67 year old women recently discharged from hospital following an exacerbation of her chronic obstructive pulmonary disease (COPD). She has a number of medical conditions including type 2 diabetes. As part of her ongoing treatment of COPD, Maria is prescribed corticosteroids that are gradually weaned over several weeks to a lower maintenance dose. This ongoing treatment directly affects her blood glucose levels and Maria required insulin when she was very unwell as an inpatient. Now home, Maria continues to need to alter her other glucose lowering medicines in response to changes in corticosteroids dosages and resulting blood glucose level patterns. This requires her to check her self-monitor her blood glucose more frequently, specifically when the steroids are working at their highest level. The Credentialed Diabetes Educator assists Maria to analyse the glucose pattern and provide a framework for these changes.

Case Study Three

Rebecca is a 28 year old Indigenous woman who was diagnosed type 2 diabetes during a recent health review. She is hoping to start a family in the next 12 months and is currently prescribed metformin. As part of her individualised diabetes management plan, her glycaemic goal is to achieve as normal blood glucose levels as possible as an integral component to her pre-pregnancy strategies. Rebecca's General Practitioner refers her to health care professionals, including a credentialed Diabetes Educator, for appropriate follow-up.



These case studies exemplify the diversity of diabetes as a disease and how the pattern of self monitoring of blood glucose varies according to each particular case. In each of these cases, diabetes education that is targeted to the needs of the individual is pivotal to a successful outcome.

Recommendations

The Post Market Review of Products Used in the Management of Diabetes Expert Advisory Group:

- 1. acknowledge structured self-monitoring of blood glucose as an important component of education and treatment programs for people with non-insulin treated type 2 diabetes as it supports understanding of the condition and of the factors affecting glycaemic control, for example the effect of behavioural changes and lifestyle choice, with the potential to optimise glycaemic control.**
- 2. consider that the timing and frequency of self-monitoring blood glucose be structured and strategic to obtain meaningful clinical information for people with diabetes and their healthcare providers.**
- 3. consider aligning self-monitoring of blood glucose with the current best-practice recommendations from the International Diabetes Federation.**
- 4. consider linking the purchase of blood glucose test strips for people newly diagnosed with non-insulin treated type 2 diabetes with an assessment consultation with a Credentialed Diabetes Educator.**
- 5. consider outcomes measures in addition to HbA_{1c} and initiatives which may help to determine the value of self-monitoring blood glucose. For example safety issues related to hypoglycaemia when treated with sulfonylurea agents, patient empowerment, improved identification of glucose excursions.**
- 6. continue to make access available to blood glucose test strips in order for people with non-insulin treated type 2 diabetes to self determine when to undertake self-monitoring of blood glucose.**
- 7. acknowledge the current gaps between best-practice and minimum standards of care in relation to the frequency of HbA_{1c} monitoring and the interpretation of its results and considers initiatives that may improve standard of care.**



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