# ADEA POSITION STATEMENT

**9 June 2011**

# The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in non-insulin treated type 2 diabetes

## At a glance

**The Evidence**

Although previous research found no clinical benefit to self-monitoring of blood glucose (SMBG) in non-insulin treated people with type2 diabetes, the latest meta-analyses have concluded there is a small benefit on HbA1c of 0.2-0.3%. A recent trial with a clearly defined structured response to blood glucose levels has found a greater benefit on HbA1c of 0.5%.

The most important component of SMBG is a clear plan of action both for the patient and the doctor to deal with inappropriately high or low glucose levels.

The optimal frequency and timing of SMBG is not defined.

**Key Recommendations**

EO1    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.

EO2    Diabetes educators should recommend SMBG for all patients on medication that can cause hypoglycaemia especially before driving, regularly during long drives or operating potentially dangerous equipment or participating in potentially dangerous activities.

EO3    Appropriate SMBG should be taught by the diabetes educator in recognition of barriers to learning including poor health literacy and numeracy skills, dexterity, hearing or sight loss common in 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.

**Background**

The first aim in the management of type 2 diabetes is the control of blood glucose levels.  One of the primary "gold standard" measures for blood glucose is HbA1c which measures the amount of circulating glucose over a 120 day period but this does not provide daily information of blood glucose levels for the patients themselves. As glucose fluctuations have been shown to have a strong impact on the development of diabetes-related complications, short term surveillance of blood glucose is also important through Self- Monitoring of Blood Glucose (SMBG). [1]

SMBG has been demonstrated to be clearly effective for people with insulin treated type 2 diabetes but some recent studies in non-insulin treated patients with type 2 diabetes have reported differing results. [2] Therefore, the ADEA has commissioned an updated review of the relevant literature in order to produce this position statement, based upon best evidence to date.

## The ADEA Position

This position statement has been based upon an updated review of the literature which supplements the systematic review previously commissioned by the ADEA in July 2009 entitled "The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review". This combined information formed the evidence base which was augmented with expert clinical opinion from a review panel which included an endocrinologist, a team of diabetes educators in an Australian tertiary centre specialising in cardiovascular disease and diabetes, as well as members of the ADEA Clinical Practice Committee.

**Clinical effectiveness of self -monitoring in people with non-insulin treated type 2 diabetes**

Previous evidence related to clinical effectiveness of SMBG in non-insulin treated people with type 2 diabetes is mixed.  Some studies report significant glycaemic benefits resulting from SMBG use while others have shown no significant benefits. [3-5]  However, these inconsistent findings may be due to a number of factors including  subject selection criteria, level of glycaemic control prior to study entry or intervention adherence or analysis including or not including dropouts, as well as the type of advice given to patients and whether there was a structured response protocol for the treating doctor. [6]  As the costs of type 2 diabetes care are rising, it has become increasingly important to determine whether resources devoted to SMBG in this population are effectively applied in a manner that is both appropriate and meaningful to all people with type 2 diabetes.

In one of the largest single studies, 518 subjects, all placed on a long acting sulphonylurea at baseline, in addition to other drugs were assessed after 6 months. [5]  A significant 0.25% difference in change in HbA1c was seen (P<0.01). Subjects assessed their blood glucose on 2

days per week (one working day and one non-working day) at the following times: before each meal (breakfast, lunch and dinner), 2 hours after the main meal and before bedtime. Once per month, on a day timed to fall between study visits, subjects were required to increase the frequency of their postprandial measurements to after each of the three main meals. Patients in the SMBG group were instructed to up-titrate their gliclazide MR dose if their fasting plasma glucose (FPG) levels were >7 mmol/L (7.8 mmol/L in patients aged over 65 years), and also to adjust their medication downwards, according to instructions in the glucose diary if hypoglycaemia occurred.  No specific information was provided on dietary or exercise adjustments required in response to the glucose levels.  In the SMBG group, 27 (8.7%) patients had a total of 51 hypoglycaemic events of which 27 were symptomatic, 11 asymptomatic, 11 SMBG-confirmed hypoglycaemia and 2 non-graded. In the non-SMBG group, 21 (7.0%) patients had a total of 66 hypoglycaemic events of which 64 were symptomatic and 2 were non-graded. The greater number of symptomatic hypoglycaemic events in the control group suggests that detection of asymptomatic "hypos" may have enabled dosage adjustment and avoidance of symptomatic "hypos".

An updated search of the literature identified a recent meta-analysis which pooled the data from 12 studies to confirm a small benefit of SMBG in HbA1c of 0.3%. [2].  This review is problematic in that some of the studies included education with the SMBG group and not the control group. In addition using only intention to treat studies and concealed allocation and assessment studies showed the difference was likely to be smaller at about 0.2%.  There was no effect of having or not having a treatment algorithm, so the cause for the difference in HbA1c is not clear.  Also trials of more frequent versus less frequent monitoring showed no differences. A later larger (25 articles) meta analysis from Macintosh [7] showed a similar small effect (0.25%) as did an updated meta analysis from Poolsup. [8]

Clar [9] for the Aberdeen Health Technology assessment group concluded the clinical effectiveness of SMBG was relatively low and the technology was not cost effective. Subsequent studies not in the Allemann [2] or Poolsup [8] reviews, such as the large study from Farmer [10] showed no benefit.  Polonsky [6] showed  that a more structured use of SMBG may lower HbA1c by 0.3% on intention to treat (0.5% for per protocol patients), but this difference may be entirely due to greater treatment modification at month 1 (76% vs 28% of patients), prompted by the treatment algorithms taught only to the structured group physicians.  The patient response did not appear to be related to the change in HbA1c.  The patients performed a 7-point SMBG profile (fasting, pre-prandial/ 2-hour post-prandial at each meal, bedtime), on 3 consecutive days prior to each scheduled study visit (months 1, 3, 6, 9, and 12), to document meal sizes and energy levels, and to comment on their SMBG experiences.  Patients were given instructions on modifying meal size and composition and exercise patterns while only the intervention physicians received a treatment algorithm.  The control group continue their usual pattern of glucose monitoring as dictated by their own physician. The conclusion was, rather than more blood glucose monitoring, what was required was a more intelligent use of the data both by the physician and the patient.

Franciosi [11] found a difference between a self-monitoring group and a control group with no monitoring of –0.5% (95% CI –0.9 to –0.0%; $P$ = 0.04) after 6 months in 57 patients.  At study end, 61.9% of patients in the intervention group and 20.0% in the control group reached the target level of HbA1c <7.0%.  Patients were instructed to measure their blood glucose levels according to the following weekly schedule: 1st day: before and 2 hours after breakfast; 3rd day: before and 2 hours after lunch; 5th day: before and 2 hours after dinner.  This pattern was repeated 2 weeks every month.  Feedback to the patient was provided by a diabetes nurse with a 1 day training session and face to face every 3 months and telephone contact every month.  Physicians responded with drug changes based on algorithm if fasting glucose was >6.9mmol/L and post-prandial glucose was >8.9 mmol/L.  Ninety-four percent of the patients in the intervention group were prescribed metformin only and diabetes duration was 3 years.  Weight loss occurred in the self-monitoring group.

There is also evidence that suggests that people using SMBG will identify more otherwise "silent" episodes of hypoglycaemia, although the impact of this on treatment is not clear (i.e. whether the patient reduces drug doses  with or without instructions from their doctor), and may be more aware of how lifestyle, diet and exercise choices can impact on their glycaemic control. [12]  Certainly silent hypoglycaemia is common in type 2 diabetes and in 108 patients assessed using continuous glucose monitoring, 24% of those with an HbA1c<7% and 11% of those with an HbA1c>7%, had a silent hypoglycaemic episode (glucose<3 mmol/L) over 48 hours,  lasting 27 minutes and this occurred regardless of the use of insulin. [12]  The implications of this for driving are significant especially given the driving decisions made by patients with type 2 diabetes and experimental hypoglycaemia.  [13]

Glycaemic control is associated with frequency of SMBG, people who use higher numbers of monitoring strips/electrodes having better glycaemic control than other people on SMBG using less monitoring strips/electrodes. [14]

A recent retrospective cohort study followed over 3000 subjects from diagnosis of type 2 diabetes for a mean period of 6.5 years. [15]  A high proportion of subjects in the study used SMBG while being treated with diet or oral antidiabetic agents (808 of 2515, 32%). The use of SMBG was associated with significant reductions in diabetes-related morbidity and all-cause mortality, which remained in the subgroup of patients who were not receiving insulin, and when statistical adjustments were made for the type of hypoglycaemia treatment received by patients in the two cohorts.

EO1    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.

EO2    Diabetes educators should recommend self-monitoring of blood glucose for all patients on medication that can cause hypoglycaemia.

**Appropriateness**

For the purposes of this position statement, "appropriateness" has been defined as the extent to which an intervention or activity is apt in a situation. SMBG in non-insulin treated patients with type 2 diabetes is appropriate, if it can lead to a change i.e. the patient is empowered to and capable of making changes.

Much of the literature which examines the concepts surrounding appropriate self-monitoring of blood glucose, investigates the broader concepts of educating people with type 2 diabetes to maintain appropriate self-care activities. The major themes that were explored examined the development of education for self-care activities that took into account poor health literacy and numeracy skills, the particular challenges faced by socioeconomically deprived groups, cultural issues related to ethnic background and education that took into account the common issues of sight impairment and hearing loss in people with type 2 diabetes.

Countries such as Australia , with people of various ethnicities with a higher prevalence of type 2 diabetes than the majority population; delivering culturally appropriate education on self-care, including the SMBG is a necessity. Often, issues such as migrant status, relative deprivation and low socioeconomic standing combined with added language, cultural and communication barriers inhibit learning. A study examining barriers to appropriate self-care in people with type 2 diabetes in an economically disadvantaged group in the US, discovered that the emotional toll from the diagnosis of and lifestyle changes to treat diabetes was a recurrent theme, and included stress, frustration, social isolation, interpersonal conflicts, depression, and fear. [16] Denial was often mentioned as the key factor that inhibited adherence to a healthy mode of living. The educational barriers were failure to recognise the risks and consequences of an asymptomatic condition.

Patients with low health literacy and numeracy may have difficulty translating information from traditional diabetes educational programs and materials into effective self-care. Wolff et al., decided to address this potential barrier by developing the Diabetes Literacy and Numeracy Education Toolkit (DLNET), which was composed of 24 interactive modules covering standard diabetes care topics such as SMBG, customised to individual patient needs and used by all members of the multidisciplinary diabetes care team. This material made full use of illustrations for key concepts, colour-coding and other accommodations to guide patients through instructions for self-care. [17]

A diabetes self-management support package, combining literacy-appropriate patient education materials with brief counselling, suitable for use in primary care has been shown to result in some patients improving short-term health-related psychological and behavioural changes across literacy levels.[18] This suggests that coupling literacy-appropriate education materials with brief counselling in health care settings may be an effective and efficient strategy for imparting the skills necessary for diabetes self-management such as SMBG. In a study by Matthews in 2009, women with type 2 diabetes were able to clearly identify

consequences of poor glycaemic control as major factor in management of their disease. [19] This study concluded that patient–provider communication was the most important factor affecting diabetes adherence.  They also noted that individual autonomy asserted in day-to-day management can often be perceived as "non-compliance'' by the healthcare provider and commented that in some cases, the provider's descriptions of potential severe complications are viewed as 'scare tactics" by the patients, which points to the need for improved communication to empower the individual with skills needed to negotiate treatment regimens.  Empowering the person with diabetes will encourage positive health decisions and improve adherence and outcomes.

A study by Williams also points out the importance of delivering diabetes education programs, including training in SMBG, that are developed with a view to full accessibility for people with visual impairment and diabetes. [20]

Recent research suggests that hearing loss, a frequent problem for ageing adults, is more prevalent in people with diabetes. [21] Hearing impairment affects a patient's learning and simple diagnostic tests are available to screen for hearing loss to improve communication.  Diabetes educators have a responsibility to learn how to communicate better with their patients who have a hearing impairment.  Diabetes educators are also uniquely positioned to improve the health status of their patients by identifying persons who need referral for further evaluation of their hearing.

The major finding of the previously published review [14] was that there was a shared belief that the use of SMBG should be encouraged for the purpose of facilitating effective diabetes self-management.  SMBG is considered to be a superior method of self-monitoring of glycaemic control to that of urinalysis. The autonomous decision-making and active involvement of people were considered to be important in the use of SMBG, as were the provision of tailored educational/supportive intervention to meet the needs of the individual.

EO2    Diabetes educators should recommend self-monitoring of blood glucose for all patients on medication that can cause hypoglycaemia, especially before driving, regularly during long drives or operating potentially dangerous equipment or participating in potentially dangerous activities.

**Meaningfulness**

Meaningfulness can be defined by how an intervention such as SMBG or activity is experienced by the people with diabetes or health professionals.  Meaningfulness can relate to the personal experience, opinions, values, thoughts, beliefs and interpretations of people with diabetes.
As was found to be the case when examining the literature surrounding the "appropriateness" of SMBG for patients with type 2 diabetes who are not insulin-treated, the literature that examined whether SMBG was "meaningful" for the patient or the educator, also focused upon

the broader concepts of the meaning that patients and educators attached to all self-care activities related to the daily management of type 2 diabetes.

Self-management in type 2 diabetes is a complex activity and includes 'the ability to monitor one's condition and to affect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life'.

The current literature suggests there is a lack of appropriate education in how to meaningfully interpret and use SMBG data and that the failure to act appropriately, based upon the blood glucose readings, was common.  Some multi-component self-management interventions have been shown to be effective in changing dietary behaviour – independent of type and method – and diabetes-specific quality of life.  Group interventions with a practise component have also been shown to have the potential to improve metabolic control; and interventions using a collaborative learning approach can improve understanding of diabetes and some self-management behaviours.  Current evidence is poor but there is some preliminary data which suggests that, although levels of patient satisfaction do not increase due to SMBG, there are some quality of life improvements.

It should also be recognised that SMBG has been shown to cause depression, anxiety and self-chastisement in certain patients which appears to be both due to the blood glucose readings themselves which often appear beyond their control, as well as the need to take frequent measurement.  In addition, the combined requirement for exercise, weight management, SMBG and foot care can seem overly burdensome to some patients and can result in social and emotional consequences. [22]

In confronting SMBG, people are required to prioritise their life needs (such as financial cost in the use of SMBG), or individual-physical circumstances (such as poor eyesight).  Individualised assessment of such factors is recommended.  One of the findings of the previous systematic review was that SMBG was often understood as a therapeutic tool for people who required insulin treatment; therefore, non-insulin treated type 2 diabetes individuals were not "bad enough" to start SMBG. This review also concluded that inconsistency between the HbA1c values and everyday readings could raise questions about the accuracy of the blood glucose meter and the need for use of SMBG itself.  [14]

Social support plays a vital factor in contributing to the facilitation of self-care behaviour.  A study by Bai demonstrated the importance of social support, education and duration of diabetes in determining self-care behaviour for older patients with diabetes.[23]  This study also noted that heath care educators should be cognisant that patients with social support have good support systems available during their disease treatment which enhance all self-care abilities and improves quality of life.

SMBG may help people to foster positive attitudes and consciousness towards the importance and value of diabetes self-management.  This notion runs parallel with the educators' belief

that peoples' autonomous decision making in the process of learning diabetes self-management should be encouraged and respected.

EO3    Appropriate SMBG should be taught by the diabetes educator in recognition of barriers to learning including poor health literacy and numeracy skills, dexterity, hearing or sight loss common in 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.

**The diabetes educator's role in terms of education and continued support**

A study by Clarke found that post-attendance at diabetes education, people with type 2 diabetes adopt behaviours at variable rates and may not sustain the change. [24]  These study findings indicate that healthcare professionals should monitor continually the need for behavioural change.  In particular, they noted physical exercise behaviours in women and dietary and medication adherence in men.  They should also continuously assess the maintenance of diabetes self-management behaviours which would include SMBG of all people with diabetes, while promoting confidence in achieving desired outcomes.

The American Diabetes Educators Association has published guidance derived from a multidisciplinary expert panel that included diabetes educators and behavioural science and mental health professionals to identify 'healthy coping' in people with type 2 diabetes. They determined that a team approach to addressing the patient's coping was critical and noted that healthy coping is a complex, qualitative behaviour that cannot be easily quantified. [25]

**SMBG results – who should interpret them and how are they best used?**

There is limited evidence on interpretation of SMBG results. The assumption is the patient makes some dietary or exercise response (usually not medication), except in the Polonsky paper in which it was physician focused. [6]  The interpretation and subsequent decisions are often left to the doctor.  However doctors and educators should be promoting patient empowerment and self-management.  Therefore, patients should be given guidelines about how to self-adjust medication based on blood glucose levels.

**Special Considerations for self-monitoring**

**Pregnancy**
- More frequent testing is recommended and the usual target levels will be lowered during pregnancy and increased during intercurrent illness.

**Intercurrent Illness**
- Please refer to the ADEA Guidelines for Sick Day Management for People with Diabetes (revised 2011), for patient with type 2 diabetes re: testing during intercurrent illness.

**Commencement of a new medication**
- This may affect glucose control that includes glucose lowering and other medicines, for example, corticosteroids or atypical antipsychotics, and therefore, may require commencement of testing or an increase in the number of tests performed.

**Expected competencies - when can self-monitoring be considered effective?**

The essentials for teaching SMBG are found in the ADEA Position Statement Use of Blood Glucose Meters (March 2010). [26]  A person with type 2 diabetes can be considered to be successfully monitoring their blood glucose if they demonstrate the following competencies:

- Correct skin preparation of the testing site.

- If relevant, callibrating the blood glucose meter as required.

- Qualtiy control procedures according to the manufacturer;s instructions.

- Able to insert test strip into the blood glucose meter.

- Able to set up lancet device.

- Able to obtain capillary blood sample and place onto test strip.

- Able to change lancets in lancet device as required.

- Be aware of additional meter features such as averages and download capabilities,

- Know reportable levels.

- Know who and when to contact if levels outside of reportable range.

- Understands safe sharps disposal of used lancets.

- Problem solving of meter action and function.

- Aware that consumables can be purchased through the National Diabetes Services Scheme at a subsidised cost and know who to purchase such equipment.

- Blood glucose levels should be recorded in some way. If the treating health care professional can download the meter, then a record book may not be required. However, if the treating health care professional is unable to download the meter, a record should be maintained. Computer compatability problems are increasing.

-  For patients with visual or dexterity problems a variety of meters should be tested to ensure the patient can operate it. Strips/electrodes that are not individually packaged (ie multistrip meter options) may be helpful for the latter group.

**Recommendations for how often to test:**

The optimal frequency and timing of SMBG is not well-defined in the literature. Successful SMBG trials have used testing with 3 tests/week every second week with people with reasonable/good glucose control being managed on metformin.  A successful SMBG trial used testing only two days/week with testing before and after all meals one day/month for people managed on sulphonylureas.  This low frequency still picked up frequent silent hypoglycemia. A second trial did 7 tests/day on only 3 days immediately before the next clinic meeting. [6]

| Treatment | Glucose Control | Frequency |
| --- | --- | --- |
| Management with metformin | Good | 1, 2 or 3 times a week<br><br>Alternating testing times (before and after  meals) is advised |
| Management with metformin | Poor | 3 tests/week<br><br>Alternating testing times (before and after  meals) is advised |
| Management with sulphonylureas | Good | Once a day<br><br>Alternating between fasting and pre-dinner particularly to detect silent hypoglycemia<br><br>Before driving and regularly during long drives or operating potentially dangerous equipment or participating in potentially dangerous activities |
| Management with sulphonylureas | Poor HbA1c > 8% | More than once a day<br><br>Testing before and after all meals one day/month |

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