Submission on the review of Blood Glucose Test Strips - Stephen Colagiuri

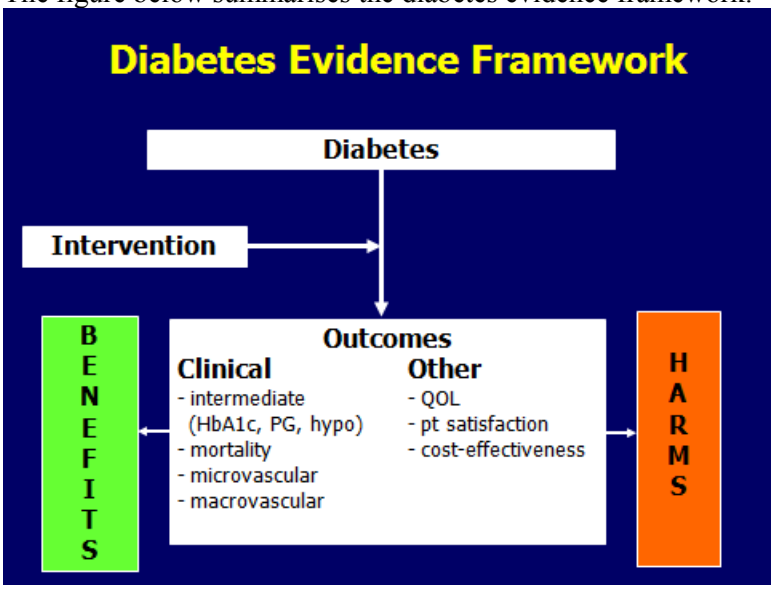
Thank you for the opportunity to make a submission on the utilization and patterns of use of self-monitoring of blood glucose (SMBG) and the clinical outcomes and benefits of SMBG for people with type 2 diabetes not treated with insulin.

My background in this area includes:

1. Lead author of the evidenced-based NHMRC endorsed guideline on Blood Glucose Control in People with Type 2 Diabetes which includes a section on SMBG (1).
2. Chair of the International Diabetes Federation (IDF) Clinical Guidelines Taskforce which developed the IDF Guideline on Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes (2).
3. Member of the Australian Diabetes Educators Association reference group which produced the document entitled "The effectiveness, appropriateness and meaningfulness of self monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review" (3).

SMBG in people with non insulin treated type 2 diabetes (T2DM) is complex and should be considered in the broad context of the management of T2DM and the role it could play in achieving desired outcomes. These include as a component of diabetes education, influencing behaviour change, assessing glycaemia and optimizing therapy.

The figure below summarises the diabetes evidence framework:



The only intervention used in the treatment of T2DM which has been shown to significantly affect intermediate outcomes such as HbA1c and in particular long term hard outcomes such as diabetes complications, is pharmacotherapy and changes in pharmacotherapy overwhelm the effect any other intervention. Therefore considering other interventions such as diabetes education or SMBG in the context of their effect on HbA1c or long term outcomes, is questionable as they are tools which may help achieve important outcomes, but they should not be expected to achieve these outcomes in isolation.

The following two examples illustrate this point. In 2009 we performed a Cochrane review on "Individual patient education for people with type 2 diabetes mellitus" (4) which showed that individual education did not significantly improve glycaemic control (HbA1c reduction 0.1%) over a 12 to 18 month period. However, there did appear to be a modest but significant benefit of individual education on glycaemic

control in people with baseline HbA1c > 8% (HbA1c reduction 0.3%). There was no significant difference in the impact on body mass index, systolic or diastolic blood pressure. There were too few studies to perform a meta-analysis on the effect of individual education on dietary self management, diabetes knowledge, psychosocial outcomes and smoking habits. No data were available on the other main outcome measures of diabetes complications or health service utilization. It would be inappropriate to conclude from this review that individual patient education should not be used as part of diabetes management. The findings of our review are quite similar to the results of the Cochrane review on SMBG in non-insulin treated T2DM (5) which are being used to question the utility of SMBG.

The LOOK AHEAD study (6) is a US National Institutes of Health–funded clinical trial investigating the long-term health impact of intensive lifestyle intervention (ILI) in overweight or obese adults with type 2 diabetes. The primary objective was to determine whether cardiovascular morbidity and mortality could be reduced by long-term weight reduction achieved by ILI which included diet, physical activity, and behaviour modification. This study was recently discontinued because it failed to show a difference in the rate of nonfatal MI, nonfatal stroke, death, or hospitalization for angina among patients randomized to ILI compared with the control arm consisting of education alone. However there were other benefits in terms of weight reduction, improvements in physical-fitness and the amount of blood glucose lowering and blood pressure lowering medications over the 11-year follow-up period. Despite this lack of cardiovascular benefit observed in Look AHEAD, it would be inappropriate to discontinue providing lifestyle modification advice to people with diabetes.

The findings of studies of SMBG use in non-insulin-treated T2DM have been mixed. There are several reasons for this. As mentioned above it is virtually impossible to separate the effects of the various components of diabetes management, including those of SMBG. A major limitation in most SMBG studies is the lack of action taken in modifying treatment in response to the SMBG results. As concluded in the IDF guideline "… SMBG in this population (non-insulin treated T2DM) has the potential to improve glycaemic control, especially when incorporated into a comprehensive and ongoing education programme that promotes management adjustments according to the blood glucose values" (2).

Data from randomized controlled trials (RCTs) suggest that SMBG is likely to be an effective self-management tool only when results are reviewed and acted on by healthcare providers and/or people with diabetes to actively modify behaviour and/or adjust treatment. To date few studies have done this but as recently reviewed by Parkin et al (7) an increasing number of studies are now using structured SMBG as an integral component of comprehensive diabetes management. The results of such studies were either excluded from the Cochrane review (8) (because it had a control group with access to SMBG), or the results were not yet officially published when the review was conducted (9).

A number of the potential benefits of SMBG are not easily tested in the clinical trial setting including:
- as an adjunct to patient education
- an instrument for objective feedback on the impact of daily lifestyle habits, special situations (illness, stress) and medication on glucose levels, thereby fostering self-management and empowering individuals to make changes
- support to the healthcare team in providing individually tailored advice about lifestyle components and blood glucose-lowering medication.

Some of these aspects of SMBG were addressed in the ADEA systematic review (3). While the review found limited effectiveness of SMBG in improving glycaemic control, the meta-analysis was confounded by clinical heterogeneity among included studies. However there was evidence that using SMBG identified more otherwise "silent" episodes of hypoglycaemia and more awareness of how lifestyle, diet

and exercise choices impact on glycaemic control. In terms of ***Appropriateness,*** there was a shared belief by care providers/educators, that SMBG should be encouraged for the purpose of facilitating effective diabetes self management and that 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 interventions that met the needs of the individual. In terms of ***Meaningfulness,*** SMBG was considered an effective means of facilitating an empowering process that raises positive and active attitudes toward self-management.

The current status of SMBG in people with non-insulin treated T2DM is summarized in the IDF document in which recommendations emphasize the following key points:

1. SMBG should be based on shared decision making between people with diabetes and their healthcare providers and linked to a clear set of instructions on actions to be taken based on SMBG results. SMBG prescription is discouraged in the absence of relevant education and/or ability to modify behaviour or therapy modalities.
2. SMBG should be used only when individuals with diabetes (and/or their care-givers) and/or their healthcare providers have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals.
3. The purpose(s) of performing SMBG and using SMBG data should be agreed between the person with diabetes and the healthcare provider. These agreed-upon purposes/goals and actual review of SMBG data should be documented.
4. SMBG protocols (intensity and frequency) should be individualized to address each individual's specific educational/behavioural/clinical requirements (to identify/ prevent/manage acute hyper- and hypoglycaemia) and provider requirements for data on glycaemic patterns and to monitor impact of therapeutic decision making.

Summary:

SMBG is an integral component of diabetes self care. The focus on assessing its benefits in terms of impact on glycaemic control is too narrow and fails to take into account its broader range of uses and relevance in diabetes care. This review provides an opportunity to focus on the more appropriate use of SMBG as outlined in the IDF guidelines. It would be a disservice to people with T2DM not being treated with insulin if the review was used to limit access to subsidized SMBG and if the review failed to acknowledge its value as an educational tool in assessing the impact of different foods and physical activity, for monitoring and safety, and to guide therapeutic choices. The key point is better use of SMBG, not abandoning its use.

Additional Observation:

As observed in the ADEA systematic review (3), it should be noted that although the use of SMBG is recommended in type 1 diabetes and in insulin-treated T2DM individuals, the evidence-base for this is very limited and there is a lack of conclusive data that it improves outcomes, including HbA1c. The main reasons for the acceptance of SMBG in insulin treated people are for safety and ability to use the data for adjusting therapy. These considerations apply equally to non-insulin treated people with T2DM.

Additional information:
The importance of personalised / individualised care of people with diabetes is increasingly recognized in overall management and in particular selection of therapeutic agents (10). The IDF will soon be publishing guidance on personalising therapeutic choices for people with T2DM which emphasizes not only the importance of HbA1c to guide therapeutic decisions, but also characterising glycaemia according to the pattern of self-measured blood glucose levels throughout the day, using a combination of readings taken fasting, pre-and postmeal. At present the only practical way to assess patterns of daily glycaemia is by SMBG.

The following paragraph is not for publication:

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