Submission from:

The Australian Centre for Behavioural Research in Diabetes, a partnership for better health between Diabetes Australia – Vic and Deakin University

For consideration by the:

Australian Government review of self-monitoring of blood glucose for people with type 2 diabetes not using insulin

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Partners for better health

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Table of Contents

Introduction

Given the increasing prevalence of diabetes and limited healthcare resources, it is entirely reasonable to consider how the costs of diabetes care can be minimised. While self-monitoring of blood glucose (SMBG) is considered an essential component of the management of type 1 diabetes and insulin-treated type 2 diabetes (T2DM), there is considerable debate about the effectiveness of SMBG in people with T2DM who do not use insulin. Several systematic reviews and meta-analyses have been published in recent years contributing to this debate, the most recent of which [1, 2] have cast significant doubt over the efficacy of SMBG in this group.

We operate within a healthcare system that strives for evidence-based policy and practice. Therefore, it is appropriate, to critically appraise the evidence and the subsidisation of blood glucose testing strips for people with T2DM who do not use insulin. We thank the Pharmaceutical Benefits Advisory Committee (PBAC) for the opportunity to contribute to this important appraisal process.

***It is our view that SMBG is beneficial for people with T2DM who do not use insulin and that access to subsidised blood glucose testing strips should be retained for this group*.**

We agree with the recent consensus report prepared by 12 physicians from academia, clinical practice and government [3] that acknowledged the following:

- SMBG is an established self-care practice for those with non-insulin-treated T2DM.
- SMBG is most effective when:
  - it is performed in a structured manner (i.e. when people with T2DM are advised explicitly when and why to check their blood glucose levels, what to look for in the patterns, and how to act upon the results), and
  - the data obtained are used to inform active treatment and self-care decisions.
- People with non-insulin-treated T2DM and their healthcare professionals need to be trained in how to interpret and respond to SMBG data obtained in a structured manner.
- Further high-quality research is needed to investigate the impact on SMBG on outcomes other than glycated haemoglobin (HbA1c).

There is no good evidence to suggest that appropriate use of SMBG is ineffective. There is however, a large collection of randomised controlled trials (RCTs) and observational studies that have evaluated inappropriate (insufficiently structured, and/or not embedded within collaborative healthcare model) or inconsistent use of SMBG [4-16]. Findings from these studies only serve to highlight the problems with how SMBG is (often) implemented, and reveal potential gaps in understand of SMBG on behalf of both healthcare professionals and their patients. However, these apparent problems are not resolved by restricting access to SMBG testing strips for people with T2DM not using insulin. On the other hand, a small number of studies have evaluated a more appropriate and structured approach to SMBG, embedded within healthcare, implemented in conjunction with relevant support and education [17-19].

The evidence from these two groups of studies (referred to hereafter as ‘unstructured SMBG’ and ‘structured SMBG’) needs to be critically evaluated, compared, and contrasted if appropriate recommendations are to be made about the use of SMBG (and, thereby, access to blood glucose testing strips) for people with non-insulin-treated T2DM.

It has been suggested by some that access to SMBG testing strips should be restricted for people with T2DM not using insulin. We vehemently disagree with this suggestion, as it is predicated on a number of faulty assumptions.

Assumption 1: SMBG does not improve HbA1c

FALSE

Glycated haemoglobin (HbA1c) is a measure of average blood glucose levels over the past 8 – 12 weeks and is a reliable indicator of future risk of developing diabetes-related micro- and macrovascular complications. The landmark United Kingdom Prospective Diabetes Study (UKPDS) demonstrated conclusively that the complications of T2DM can be prevented with sustained optimisation of HbA1c [20]. In Australia, 48% of people with T2DM have an HbA1c above the target 7%, and 34% have an HbA1c above 8% [21]. It is therefore important to consider what treatments and self-care strategies might contribute to more optimal average blood glucose levels so that the risk of complications can be reduced.

Recent reviews conclude that SMBG does not reduce HbA1c

A systematic review published in 2010 [22], which included synthesis of 11 systematic reviews, 26 randomised controlled trials (RCTs) and 36 observational studies published between 1996-2009, concluded that SMBG for people with T2DM who do not use insulin does not lead to improvements in HbA1c, and therefore has limited clinical utility. More recently, a Cochrane systematic review and meta-analysis [1] found that the mean HbA1c of those who used SMBG was 0.26% lower at six month follow-up compared to those who had not used SMBG. Similarly, a recent meta-analysis by Farmer and colleagues [2] found that, at six month follow-up, the SMBG groups had an HbA1c 0.25% lower than the non-SMBG groups. A between-group difference in HbA1c of 0.5% is required to be considered clinically significant. Thus, even though these reductions were statistically significant, they are not deemed to be of clinical significance. Therefore, both the Cochrane review and the meta-analysis by Farmer et al. concluded that SMBG does not have a clinically meaningful effect on HbA1c.

However, there are problems with this body of evidence

Systematic reviews and meta-analyses do represent the most rigorous synthesis of the available data. However, the quality and heterogeneity of the studies included in the synthesis impact on the findings. Each of the reviews cited here included a diverse range of studies which differed in how they operationalised and implemented SMBG. Some SMBG interventions gave no specific instructions as to when and how frequently to monitor blood glucose, while others instructed participants to monitor on particular days and at particular times. Even amongst those studies that did give specific instructions about when and how to conduct SMBG, the frequency and time of day vary drastically. Some studies incorporated SMBG feedback or education into the intervention, whereas others did not. SMBG is not a standardised intervention, and like all tools, can be used effectively or ineffectively. Therefore, it is imperative to examine the protocol of each SMBG study more closely to determine if there are any common aspects or features shared by the studies that did result in HbA1c reducations, as compared to those that did not.

Using the recent Cochrane review as an example [1], some RCTs evaluated ‘simple’ SMBG (that is, instructing participants to monitor their blood glucose without providing systems or education to support the process) and found minimal glycaemic benefit when compared with no SMBG [23, 24]. In contrast, other RCTs evaluated ‘enhanced’ SMBG, where some education or feedback on blood glucose patterns was included. Of these, half found a clinically significant (or near clinically significant) between-group difference in HbA1c between SMBG and non-SMBG groups for those with a diabetes duration of more than one year [25-28]. These findings highlight the potential for SMBG to have a clinically significant impact on the reduction of HbA1c – but only if people with diabetes are taught how to interpret and manipulate their blood glucose patterns and are supported by health professionals who value SMBG as a tool to inform management decisions. It seems that

the simple physical act of checking blood glucose levels and writing down the figure, without knowing how to interpret or respond to it, has no glycaemic benefits. This is, or should be, unsurprising and has been described as being akin to expecting a fever to drop purely as a result of taking a temperature [29]. The fact that SMBG is a tool and not an intervention in itself is discussed further below (see Assumption 2).

In addition to the heterogeneity of the studies, various inclusion criteria were used that may have confounded the interpretation of the review findings. First, some of the RCTs included in the reviews utilised samples that had a baseline mean HbA1c at or only slightly above target [6, 10, 15, 30-32]. In this instance, it is unlikely that SMBG, or any other intervention tool, could facilitate a clinically significant improvement in HbA1c. These so-called 'floor effects' may mask the broader potential effectiveness of SMBG when HbA1c is considered the sole outcome of interest (see Assumption 3). Second, some RCTs excluded those already undertaking SMBG [30], thereby potentially excluding those who were most motivated to use SMBG appropriately and derive benefit from it.

Furthermore, both the Cochrane [1] and Farmer et al. [2] reviews, included only RCTs, considered to be the gold standard of study designs. However, the design of RCTs does not take into account the preferences of individuals, as all participants are randomised to a study condition, typically 'intervention' or 'control / usual care'. SMBG is likely to be a self-care activity that people with diabetes have strong preferences about. For example, whether they feel they have the adequate knowledge and skills to make best use of the information, how supported they feel by their healthcare professionals, and whether they are prepared to prick their finger to take the blood sample needed. It is important that, as with many diabetes self-care activities, it is the choice of the individual to engage in SMBG. Therefore, a more appropriate study design may be a partially randomised preference trial design [33], whereby participants with strong preferences either for or against SMBG choose the condition they prefer, and those with no preferences are randomised. Such trial designs have minimised drop-out associated with disappointment effects of not being allocated to the preferred condition and maximise the likelihood that trial participants will be faithful to the protocol to which they are assigned [34].

Finally, with regards to changes in HbA1c, an important detail of the Cochrane review is often missed or ignored. While SMBG (when both simple and enhanced methods were considered together) did not appear to produce clinically significant improvements in HbA1c for those who had been living with diabetes for more than one year, HbA1c reductions of 0.5% were observed at six month *and* 12 month follow-up in people with newly diagnosed T2DM. This highlights that SMBG may be particularly important for those who in the early stages (and key motivational phase) of learning how to manage their condition.

Promising findings from a recent SMBG trial

One key study, that clearly demonstrates the glycaemic benefits of enhanced SMBG and does not suffer from floor effects, *was not included in any of the reviews cited above* – presumably because the study was not published until after the systematic searches for the reviews were undertaken. The Structured Testing Program (STeP) study [35] was a cluster-randomised trial that compared a group of people with non-insulin-treated T2DM who engaged in *structured* SMBG and received enhanced usual care with an active control group who received enhanced usual care only. Participants in both groups had a mean baseline HbA1c of 8.9% and a mean diabetes duration of 7.5 years (structured SMBG group) and 7.7 years (control group). Those in the structured SMBG group used the Accu-Chek 360^{o} View tool [36] (Roche Diagnostics) to record a 7-point SMBG profile on three consecutive days, about one week prior to visiting their doctor. The tool was also used to document meal sizes, energy levels, and comments or reflections on SMBG patterns. Both study

participants and their doctors received training on how to interpret and respond to SMBG patterns as recorded with the tool.

The intention-to-treat analysis of the STeP study analysis demonstrated that the group performing structured SMBG had significantly greater reductions in HbA1c than the control group (0.3%), however this difference is not considered clinically significant. However, a per protocol analysis is more appropriate in this instance, as we would only expect those who have closely followed a structured SMBG protocol to experience benefits. Almost all studies included in the recent Cochrane review [1] neglected to take the analyses to perform a per protocol analysis, however the STeP study did so for all relevant outcomes.

The per protocol analysis of the STeP study indicated that those who engaged in structured SMBG, as defined in the protocol, had a statistically and clinically significant reduction in HbA1c (0.5%) compared to the control group at 12 month follow-up [17]. Moreover, this was achieved with significantly fewer blood glucose checks per day at six, nine and 12 month follow-up, suggesting that *the glycaemic benefit of SMBG is likely to be associated with the quality, not the quantity, of monitoring*. While participants in both groups experienced a greater reduction in HbA1c if they received a recommendation from their doctor to modify or change their treatment, more people in the SMBG group received this recommendation [18], indicating that *structured SMBG is associated with appropriate and timely management decisions*.

These findings are promising, and highlight how critically important it is for both patients and their healthcare professionals to be trained in structured SMBG pattern interpretation, for SMBG to be embedded within care, and for SMBG to result in action plans and positive self-care strategies.

Assumption 2: SMBG is an intervention

FALSE

Most trials have evaluated the efficacy of SMBG as though it were a pharmaceutical product (an active agent), but in reality it is merely a tool to inform intervention [37]. *Like any tool, SMBG is used most appropriately by people who are motivated to use it, trained in its use and able to act on the results*. This applies to both the person with diabetes who is monitoring their own blood glucose levels, and their healthcare professional.

A review by Clar et al. [22] identified that *each of the studies that demonstrated improvements in HbA1c associated with SMBG included an education or feedback component*. Only when SMBG is conducted at the right times are the results meaningful and sufficient to inform an action – and it is the action (i.e. the dietary change, increase in physical activity, or taking of a tablet) that enables the improvement in glycaemic control to be achieved. Anything less than this is unlikely to be effective. The findings from the STeP study [17-19], as already summarised, highlight the importance of taking a structured approach to SMBG, embedding structured SMBG within diabetes healthcare, and ensuring that people with diabetes and their healthcare professionals are trained in how to interpret and manipulate SMBG patterns.

Most trials examine how frequently SMBG is used, under the premise that there is a linear relationship between the frequency of SMBG and blood glucose control – but there is not. The review by Clar et al. [22] found no effect of frequency of SMBG on HbA1c, nor was there an effect of providing free access to blood glucose testing strips. This suggests that it is not the quantity of SMBG that has an impact on HbA1c but the quality use of this tool. Clar and colleagues concluded from their review that "SMBG may lead to improved glycaemic control only in the context of appropriate education – both for patients and health-care professionals" ([22] p. iii). Similarly, Polonsky and

Fisher argue that "where education and support for SMBG are minimal or non-existent, perhaps we should not be surprised that glycemic benefits are also non-existent" [37].

We must not consider SMBG alone to be a promising intervention. *Only when SMBG is utilised as a tool for diabetes education and support for self-care is it likely to be useful*.

Assumption 3: HbA1c is the only relevant outcome when considering the impact of SMBG

FALSE

While HbA1c is a reliable indicator of future health for people with diabetes, it is not the only outcome of importance in holistic diabetes care. However, heathcare professionals, and consequently their patients, often do not recognise this. In a longitudinal (four year follow-up) interview study with 18 people with T2DM [38], it was found that participants perceived that healthcare professionals focused only on HbA1c and were not interested in SMBG results. Participants subsequently interpreted this to mean that SMBG was not important and so discontinued monitoring.

Given that 99% of diabetes care is self-care, people living with diabetes bear the daily burden of responsibility for a complex and intensive self-care regimen [19]. In addition, people with T2DM have an elevated risk of emotional problems, such as depression [39] and diabetes-related distress [40]. Thus, psychosocial outcomes are of crucial importance when evaluating diabetes management interventions to:

a) ensure that the intervention does not cause emotional harm or distress (e.g. by adding to the perceived burden of self-care), and

b) ascertain the potential benefits of the intervention (e.g. improved emotional well-being, self-efficacy, knowledge, satisfaction with treatment, quality of life).

The Cochrane review [1] considered quality of life, well-being and patient satisfaction as outcomes of interest in their data synthesis, but due to inconsistency in how these outcomes were measured, a formal synthesis of data across studies (i.e. meta-analysis) was not possible. Perhaps unsurprisingly, the findings were also inconsistent across studies. The authors of the review concluded that more research into the psychological impact of SMBG is required.

Some studies have found that SMBG causes distress or impairs quality of life. For example, the ESMON study [13] found a 6% increase in depression scores for those performing SMBG as compared to those who were not. In this trial, participants in the intervention arm were newly diagnosed, and may have found adhering to the study protocol distressing at such a time. Further, there was no negative impact of SMBG on other psychosocial outcomes, and the clinical significance of a 6% mean difference in depression scores (on a measure with no established cut-off scores) between groups is unclear. Similarly, the DiGEM study found that participants who engaged in more intensive SMBG had significantly higher scores on depression than those who engaged in less intensive SMBG [7]. However, the measure used in this study (EQ-5D) is not designed to detect clinically relevant symptoms of depression, and as with the ESMON study, the distress may have been the result of a demanding protocol, rather than SMBG itself. It is important to note that other studies, as reviewed above, have not replicated these findings and that negative psychological outcomes (e.g. increased frustration, guilt and distress) can be expected when SMBG is adhoc, unstructured and does not result in meaningful changes in self-care.

A qualitative study which reported on in-depth interviews with 40 people with T2DM found that participants perceived both benefits and costs to SMBG [38]. Benefits included encouraging self-management, enabling treatment modifications, improving knowledge of how lifestyle impacts on blood glucose readings, and feelings of reassurance and success when the reading is within target However, SMBG sometimes resulted in anxiety if blood glucose levels are consistently high, or if the results were counter-intuitive.

However, the STeP study findings are more positive. Participants who followed the structured monitoring protocol closely experienced significantly larger increases in general well-being [17] and reported greater diabetes self-confidence [19] than those in the control group. These results indicate that *structured SMBG, when effectively embedded within a collaborative care model, has the potential to have a positive impact on important psychosocial outcomes* for people with non-insulin-treated T2DM.

Other biomedical outcomes, including body mass index (BMI), blood pressure and cholesterol may also be relevant to consider when evaluating interventions that use SMBG. SMBG may reveal dietary or lifestyle behaviours that are causing high blood glucose levels, and adjusting these behaviours may have a positive impact on these other outcomes. The review by Clar et al. found no SMBG-induced changes in weight or BMI [22], while the Farmer et al. review found no changes in blood pressure or cholesterol. The Cochrane review did not include detailed discussion or analyses of these outcomes [1]. Although the STeP study protocol includes collection of clinical data such as weight, height and blood pressure [35], existing publications have not addressed these outcomes. More research is required to examine the impact of structured SMBG on biomedical outcomes other than HbA1c.

Assumption 4: SMBG is useful only to inform insulin adjustments

FALSE

Insulin is not the only diabetes treatment that can be adjusted to impact on blood glucose levels. Profiling SMBG patterns enables people to identify blood glucose levels outside the target range, to determine the cause of such excursions and to adjust self-care behaviours (including treatment) accordingly. These adjustments result in HbA1c reductions [17]. For example, a person who becomes aware of elevated blood glucose levels post-breakfast on two consecutive days might reflect on the content of the breakfast meal and decide to modify it to minimise the post-prandial excursion. Action on the third day followed by reflection on the resulting SMBG will confirm or refute the benefit of the action in terms of blood glucose excursions.

If HbA1c is >10%, then there is a clear imperative to push fasting blood glucose down to improve it. If HbA1c is around 8.5% or less, as it is for many Australians with T2DM [21], then the way to improve this is to reduce the post-prandial blood glucose levels. Thus, structured SMBG becomes particularly useful to identify which meals cause a post-prandial spike and to inform changes to diet / lifestyle that can improve post-prandial blood glucose levels [29].

Assumption 5: People with T2DM not using insulin are not at risk of hypoglycaemia

FALSE

It is important to note that people with T2DM not using insulin may be at risk of severe hypoglycaemia - as many as 7% of people taking sulphonylureas have experienced one or more severe hypoglycaemic events in the past 12 months [41].

While frequency of recognised hypoglycaemia is a rarely-reported outcome in SMBG trials, one systematic review has reported (on the basis of three trials) that SMBG may increase hypoglycaemia detection [42]. Detection of mild hypoglycaemia enables treatment before it becomes a severe hypoglycaemic episode, decreasing the likelihood that hospitalisation will be required. The Cochrane review [1] concluded that more research on the impact of SMBG on hypoglycaemia is needed.

Assumption 6: Non-insulin-treated T2DM is just 'mild' form of diabetes

FALSE

T2DM is a progressive condition, which always needs to be taken seriously. The UKPDS demonstrated conclusively that the emphasis must be on achieving optimal blood glucose (and blood pressure) from diagnosis [20]. It also demonstrated that treatment intensification – from lifestyle modification to tablets; from one to multiple tablets; from tablets to insulin – is likely to be needed every few years in order to maintain optimal blood glucose levels in the face of beta-cell destruction.

It is important that people with T2DM are advised from diagnosis not only about the potentially devastating impact of T2DM on long-term health but also that it is within their means to minimise that risk – that the long-term complications can be avoided / delayed with diligent monitoring, and timely and effective treatment. When treatment modifications and intensification are needed, people with T2DM need to be advised that it is not their fault that diabetes worsens over time.

Any policy to restrict or remove access to subsidised blood glucose testing strips would limit individual choice about performing SMBG as part of an effective management strategy. Such a policy would be likely to send an unintended and incorrect message to people with diabetes and their families: that non-insulin-treated T2DM is only a mild condition that does not require rigorous self-care. A qualitative study has found that people with T2DM perceive that those who receive a blood glucose meter from a healthcare professional to have a more advanced or serious form of the condition [43]. With the average HbA1c of Australian adults with T2DM significantly above the target of 7% [21], we need to be seeking more ways to engage people in their self-care, not limiting their options.

Assumption 7: SMBG is not cost-effective

FALSE

The best cost-effectiveness analysis to date is from the DiGEM trial (funded by the UK HTA programme, [44]), which concluded that SMBG was not cost-effective, taking into account all costs, gains and disutilities. However, this conclusion hinged on the fact that the DiGEM SMBG protocol [7] did not produce clinically significant reductions in HbA1c when analysed with both intervention groups combined [1]. Naturally, spending money on a protocol that does not produce the desired results would not be deemed cost-effective. However, investment in a SMBG protocol that is clinically effective, such as the structured 7-point SMBG profiling technique used in the STeP study [35], is more likely to be cost-effective.

A full cost-effectiveness analysis of the STeP study has not been published. However, findings from this study did demonstrate that improvements in HbA1c and general emotional well-being were achieved without increasing the frequency of monitoring over six, nine or 12 months, and without increasing strip use relative to usual care (where participants did or did not monitor, according to their usual self-care regimen;[17]). In fact, the average number of test strips used per day was around one – the same as the current usage among people with T2DM in Australia, according to current National Diabetes Services Scheme (NDSS) access data. This indicates that even if Australians with non-insulin-treated T2DM who currently monitor in an unstructured, sporadic, and

unsystematic (and therefore non-impactful) way were to adopt a structured approach to SMBG, this would not increase the number of strips used or the costs associated with subsidisation.

Cost-effectiveness analyses vary in their assumptions, and in particular, the level of HbA1c improvement they assume. A study that used Markov-state modelling and assumed a modest HbA1c improvement of 0.39%, found an increase in life expectancy and reduced cost of complications as a result of SMBG [45]. Cost per life year gained was $39,650, and therefore the SMBG intervention was deemed to be cost-effective. Using similar assumptions, the difference in HbA1c between groups in the STeP study (-0.3% in the intention-to-treat analysis; -0.5% in per protocol analysis), suggests that the structured approach to SMBG is likely to be cost-effective. However, a full cost-effectiveness analysis has not been published and further high quality utility studies are needed in relation to structured SMBG to confirm this interpretation.

Assumption 8: Regular HbA1c monitoring is sufficient in type 2 diabetes

FALSE

There are several problems with this assumption. First, all HbA1cs are not equal. As HbA1c is a measure of average blood glucose levels over the past 8-12 weeks, it does not take into account the everyday, but potentially problematic, blood glucose excursions. Two people, each with an HbA1c of 7.5%, may have very different daily blood glucose profiles, with one person recording blood glucose levels consistently between 6– 8 mmol/l, and the other person recording high (e.g. 10 mmol/l) and low (e.g. 3.5 mmol/l) blood glucose excursions. Structured SMBG profiling enables people with diabetes and their healthcare professionals to gain more insight into how their food choices, physical activity and medication impact on their blood glucose levels, and make adjustments accordingly.

Second, HbA1c explains only 25% of the variance in risk of developing complications [46, 47], and post-prandial high blood glucose levels are an independent risk factor for macrovascular disease [48]. Only structured SMBG can detect patterns of post-prandial excursions, thus providing the opportunity to adjust dietary and lifestyle behaviours or treatment regimen to reduce the risk of complications.

Third, not everyone with non-insulin-treated T2DM has their HbA1c checked regularly (due to financial and time restrictions, for example), which means that blood glucose could remain persistently elevated over a number of months without being detected. Confidential unpublished data from our NDSS-funded national Diabetes MILES – Australia 2011 survey indicate that 42% of people with non-insulin-treated T2DM did not know what their most recent HbA1c value was. In contrast, 83% of people with non-insulin-treated T2DM reported they had accessed blood glucose testing strips from the NDSS in the past 12 months, and 85% indicated they performed at least one blood glucose check per day. While we acknowledge that these findings are not conclusive, they are suggestive that relying on HbA1c monitoring alone may not be fully reliable, nor engage people in their diabetes management. We believe that SMBG provides a means engage people with T2DM in their own care, to be empowered to monitor, detect, and respond to their own blood glucose levels without being dependent on their healthcare professional.

Conclusions and key recommendations

In the last decade, there has been much academic and clinical debate about the clinical efficacy and cost-effectiveness of SMBG for people with non-insulin-treated T2DM. The issue has become more contentious as health authorities and governments have realised the growing economic burden associated with the pandemic of T2DM. The pressure to rationalise healthcare to ensure that services, treatments and interventions are both clinically and cost-effective has never been greater.

In the past decade, numerous RCTs, observational studies, systematic reviews and meta-analyses have attempted to address this issue. Yet, the evidence is more difficult to interpret than many would claim. Most trials and reviews have treated SMBG as if it were a pharmaceutical product, with an active agent capable of producing an effect. It is neither an insulin nor a glucose lowering tablet. SMBG is just a tool, capable of informing effective intervention, but with blood glucose levels unlikely to improve simply by virtue of being measured. Seminal behavioural studies have shown that the critical factor in whether or not SMBG is shown to be effective lies in the use of *structured* monitoring (at predefined times) with pattern analysis and, crucially, an appropriate self-care action.

Furthermore, the heterogeneity in research questions and SMBG protocols across studies means that the evidence base is diverse and difficult to interpret. We can consider the studies to fall into two different categories: (1) those that do not implement a structured SMBG protocol, and/or do not provide relevant, effective education and support for how to record, interpret and respond to blood glucose patterns, and (2) those that use a structured SMBG protocol and embed SMBG within a collaborative healthcare model, including relevant education and support. Studies in the first category have consistently failed to show a clinically significant reduction in HbA1c as a result of SMBG. Further, these studies have not demonstrated positive effects of SMBG on psychosocial outcomes. In contrast, studies in the second category have demonstrated that those who follow a structured SMBG regimen experience statistically and clinically significant reductions in HbA1c, and statistically significant improvements in well-being and diabetes-related self-confidence. These benefits are obtained without increasing SMBG frequency, as compared to a non-structured approach to SMBG.

These findings lead us clearly to the conclusion that SMBG, if utilised appropriately, has clinical utility for people with T2DM who do not use insulin. Indeed, insulin should <u>not</u> be the determining factor of whether or not someone with T2DM has access to SMBG. It is the quality, not the quantity, of SMBG monitoring that makes a difference to outcomes for people with non-insulin-treated T2DM. Those who are not using insulin are able to modify various aspects of the their self-care in response to daily blood glucose levels, providing they have the diabetes education, behavioural skills and motivation to undertake SMBG – all of which are influenced by the attitudes and support of healthcare professionals.

W*e advocate for the right of all people with type 2 diabetes to have universal access to blood glucose testing strips*. Restricting access by any particular subgroup is not evidence-based, and is unjustifiable and unequitable. We, therefore, make the following key recommendations:

1. People with T2DM (regardless of treatment type) should have universal access to subsidised blood glucose testing strips.

2. Structured SMBG has proven clinical benefits and should be recommended to people with T2DM, regardless of whether or not they use insulin to manage their condition.

3. Widespread education of healthcare professionals is needed to assist them to interpret the available evidence relating to SMBG. This education should focus on the benefits of structured SMBG, how to perform SMBG, as well as how to interpret and respond to blood glucose patterns and adjust or intensify treatment accordingly.

4. Evidence-based, structured education and support for people with T2DM who do not use insulin is also needed, so that they have the necessary information, skills and resources to: a) make an informed choice about whether or not to incorporate structured SMBG into their self-care regimen, and b) use structured SMBG to inform effective management of their condition leading to improved biomedical and psychological outcomes.

5. Healthcare professionals should not make assumptions as to whether or not their patients with non-insulin-treated T2DM will experience SMBG as beneficial. The decision should be made collaboratively, based upon the informed preferences of the person with T2DM.

6. Monitoring HbA1c alone is insufficient to achieve optimal outcomes and reduce the risk of complications. HbA1c is an average of blood glucose levels over the past 8-12 weeks and masks daily fluctuations. It is a reliable indicator of future health but accounts for only 25% of the variance in the development of complications. Increasing evidence shows post-prandial hyperglycaemia is an important predictor of cardiovascular complications and can only be detected and improved with pre- and post-prandial blood glucose pattern analysis using SMBG.

7. HbA1c should not be regarded as the only outcome of importance when considering whether or not to commence SMBG or evaluating the benefits of SMBG. Other possible benefits, such as gaining insight into the impact of lifestyle and medications on daily fluctuations of blood glucose, and improvements in emotional well-being, diabetes-related self-confidence and motivation are equally valuable and need to be considered in the decision-making process.

8. Notwithstanding the need for universal access to SMBG, it is particularly recommended for specific groups such as those with newly diagnosed T2DM, those who take a strong interest in learning more about and enhancing their daily self-care regimen, and those who take oral medication that may induce hypoglycaemia.

Conflicts of interest

Prof Jane Speight is a member of the Accu-Chek advisory board for Roche Diagnostics Australia. The ACBRD has received consultancy fees from Roche Diagnostics Australia for her role on this board, speaking engagements, and to support the development of the STeP IT UP study. The ACBRD has also received consultancy fees from Abbott Diabetes Care in relation to Prof Speight's speaking engagements. The ACBRD has received unrestricted educational grants from Medtronic and sanofi aventis.

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