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# POST MARKET REVIEW OF PRODUCTS USED IN THE MANAGEMENT OF DIABETES

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Stage 1 - Review of 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.

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Australian Diabetes Council

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## Acronyms and Abbreviations

ADEA	Australian Diabetes Educators Associations
ADS	Australian Diabetes Society
AIHW	Australian Institute of Health and Welfare
CALD	Culturally And Linguistically Diverse
DoHA	Department of Health and Ageing
DA	Diabetes Australia
DSM	Diabetes self-management
DSME	Diabetes self-management education
GP	General Practitioner
HbA <sub>1c</sub>	Glycosolated haemoglobin on glycated haemoglobin
IDF	International Diabetes federation
NDSS	National Diabetes Services Scheme
NHMRC	National Medical Research Council
NSW	New South Wales
PIP	Practice Incentive Payment
SCRGSP	Steering Committee for the Review of Government Service Provision's
SIP	Service Incentive Payment
SMBG	Self-monitoring blood glucose
SR	Systematic Review
Type 2	Type 2 diabetes

## Executive Summary

Australian Diabetes Council is the first, oldest and largest diabetes consumer organisation and welcomes the opportunity to participate in the review of access to self-monitoring blood glucose test strips for people with non-insulin treated type 2 diabetes. We support the Government's efforts to ensure that clinical evidence underpins all aspects of diabetes management and care.

Australian Diabetes Council promotes evidence based, effective and sustainable health care delivery. As the peak Australian consumer body for people living with and at risk of diabetes, Australian Diabetes Council advocates on behalf of our members as well as the wider community living with and at risk of diabetes, and their families to ensure their voices are heard and their views well represented.

When examining the potential for reducing the total health expenditure by introducing eligibility criteria for access to blood glucose test strips for National Diabetes Services Scheme registrants diagnosed with non-insulin treated type 2 diabetes, Australian Diabetes Council recommends the Expert Advisory Group advising the Government considers:

- Strategies and initiatives that can improve the access to quality diabetes self-management education to ensure all people with diabetes have access to support for the development of an individual and targeted blood glucose testing regimen and information about how to interpret and apply the results to their daily diabetes self-management.
- Recognition of factors that limit the accuracy of HbA1c as a measurement of glycaemic control, barriers to timely access to HbA1c measurement and the need and wishes of some National Diabetes Services Scheme registrants to undertake targeted self-monitoring of blood glucose to gain information about real-time blood glucose levels in order to maintain personal safety and inform daily self-management.
- Further research into the benefits, or otherwise, of targeted self-monitoring blood glucose in non-insulin treated type 2 diabetes on long-term glycaemic control and diabetes end-point outcomes, and on quality of life measures, self-determination, active engagement in self-care and ongoing monitoring of the condition.
- National Diabetes Services Registrants with type 2 diabetes continue to be eligible to access government subsidised test strips for targeted self-monitoring blood glucose.
- The decision about self-monitoring of blood glucose continues to be based on the clinical judgement of the individual's diabetes care team in consultation with the person with non-insulin treated type 2 and their family or carer.

## Introduction

### Australian Diabetes Council

Formed in 1938, Australian Diabetes Council is Australia's, first, oldest and largest diabetes organisation. We focus on providing support and services locally, nationally and internationally to people living with and at risk of diabetes, and to their families and carers, friends and health care providers. We **Challenge**, **Listen**, **Educate**, **Advocate** and **Research**. Our strategy is **CLEAR** and is developed in recognition of the fact that **Diabetes can no longer be solved by medical intervention alone**.

Australian Diabetes Council makes a positive difference to the everyday lives of those living with and at risk of diabetes, their family and carers. We do this by ensuring decisions in areas of policy, research, services delivery and programs are made in the best interest of those affected by the condition.

As the peak consumer body for people with and at risk of diabetes, and the third oldest diabetes association in the world, we welcome all opportunities to support and engage in planning and review of policies and services affecting the diabetes community. Australian Diabetes Council has a long and successful history working with over 170,000 members. Their views, together with recent research and best-practice recommendations, inform our engagements.

### The Type 2 Diabetes Journey

The prevalence of diabetes in Australia has more than doubled from 1.5% in 1989 to 4.1% in 2008<sup>1</sup>. The prevalence of diabetes has now increased to 5.3%. According to the National Diabetes Services Scheme (NDSS) as of 31 October 2012, 909,438 (86%) of the 1,057,731 Australians diagnosed with the condition have type 2 diabetes (type 2)<sup>2</sup>.

An estimated 3 million Australians over the age of 25 years may have diabetes by the year 2025 if diabetes continues to rise at the current rates. Increasing rates of type 2 will be the major reason with rise of obesity, the ageing population, dietary changes and sedentary lifestyles the major contributors<sup>3</sup>.

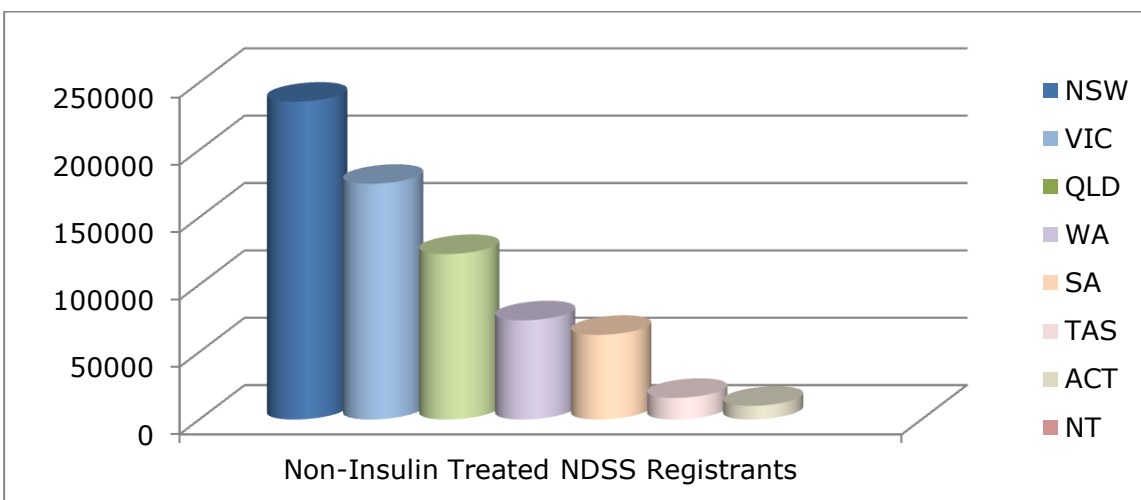
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<sup>1</sup> Australian Institute of Health and Welfare (AIHW) 2011, *Diabetes prevalence in Australia: detailed estimates for 2007-08*, Diabetes series no. 17, Cat. No. CVD 56, Canberra: AIHW; Viewed 7 November 2012, <<http://www.aihw.gov.au/publication-detail/?id=10737419311>>.

<sup>2</sup> National Diabetes Services Scheme (NDSS) 2012, *NDSS Database*. NDSS: October 31 2012; Canberra.

<sup>3</sup> Shaw J, Tanamas S 2012, *Diabetes: The silent pandemic and its impact on Australia*. Baker IDI Heart and Diabetes Institute, Diabetes Australia and Juvenile Diabetes Research Foundation. 2012: Canberra.

New South Wales (NSW) has 235,869 (33.5%) of the 704,716 of non-insulin treated type 2 NDSS registrants<sup>4</sup>.



**Figure 1 Australian Distribution of Non-Insulin Treated Type 2 Diabetes**

As people with type 2 progress along their diabetes journey, pharmacological initiation, multi – pharmacological combinations and intensification of therapy will most likely be required to achieve glycaemic targets as beta-cell capacity for insulin secretion decline with age and duration of diabetes<sup>5</sup>. Research findings suggest that between 30-50% of all people with type 2 progresses to secondary failure and requiring insulin to manage their condition within 10 years of diagnosis<sup>6</sup>.

In the period 2000 to 2009, 172,246 Australians with type 2 started to use insulin to manage their condition. Moreover, 77% of all people using insulin were diagnosed with type 2<sup>7</sup>. In NSW, 69,625 (23%) NDSS registrants with type 2 diabetes use insulin to treat their condition<sup>8</sup>.

<sup>4</sup> National Diabetes Services Scheme (NDSS) 2012, *NDSS Database*. NDSS: October 31 2012; Canberra.

<sup>5</sup> Ramlo-Halsted BA, Edelman SV 2000, The Natural History of Type 2 Diabetes: Practical Points to Consider in Developing Prevention and Treatment Strategies. *Clinical Diabetes*. Spring 2000: Vol. 18 (2).

<sup>6</sup> UKPDS Study Group 1998, Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998: Vol. 352; pp. 837-853.

<sup>7</sup> AIHW 2012, *Insulin treated diabetes in Australia 2000 -2009*. March 2012: Viewed 7 November 2012, <<http://www.aihw.gov.au/diabetes/incidence/>>.

<sup>8</sup> NDSS 2012, *NDSS Database*. NDSS: October 31 2012; Canberra.

Australian Diabetes Council promotes timely access to evidence based best-practice diabetes management and care for all Australians with diabetes. In light of the current and predicted future rise of type 2 and insulin-treated type 2, we recognise the need to ensure the most cost-efficient, effective and safe care practices and use products such as test strips for self-monitoring blood glucose (SMBG). After 25 years of research, there is still no consensus among diabetes health professionals about the value from SMBG in terms of end-point health outcomes or in the daily self-management and lives of people living with non-insulin treated type 2. Therefore, any decisions regarding introduction of eligibility criteria for NDSS registrants with non-insulin treated type 2 for access to SMBG strips must take a balanced view. Evidence regarding the contributions of SMBG to long-term health outcomes should be considered in conjunction with the contribution to quality of life, self - efficacy, self - determination and a sense of personal control as well as the potential to increase the individual's ability to actively engage in daily diabetes self-management (DSM) and ongoing monitoring of the condition.

Australian Diabetes Council urges careful consideration of the need to balance short-term cost efficiencies with the possibilities of achieving long-term cost efficiencies from a reduction of morbidity and mortality from diabetes and an increased quality of life and work force participation by people living with the condition and their carers. Our Diabetes and Sustainable Populations Forum held this year included a panel debate exploring the value, or not, of SMBG in non-insulin treated type 2.

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*The Forum debate concluded with both the debaters in the positive and the negative recommending targeted testing in non-insulin treated type 2 diabetes. An electronic vote was held and the Forum participants supported this recommendation.*

*(Australian Diabetes Council Sustainable Populations Forum July 2012)*

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As the views and long-term health interests of people living with non-insulin treated type 2 and their lived experience through their own diabetes journey must be at the centre of the decision making process. Australian Diabetes Council canvassed the opinion of its members to ensure their views and practices informed our submission.

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*In preparation for this submission, Australian Diabetes Council developed an electronic survey in October 2012 to gain an understanding of the perspective on and practices of the self-monitoring blood glucose of our 36,620 members with non-insulin treated type 2 diabetes who have access to email. When the survey closed after six (6) days, 6500 members had already responded. This represents a total response rate of 18%. Examination of the response rate revealed that 48% of those who opened the email completed the survey.*

*(Australian Diabetes Council Non-Insulin treated Type 2 Diabetes Member Survey 2012)*

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## Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes

### Use of self-monitoring blood glucose in non-insulin treated type 2

The National Health and Medical Research Council (NHMRC) endorsed Australian *Guidelines for Blood Glucose Monitoring in Type 2 Diabetes* recommend that SMBG should be considered for and discussed with all people with type 2<sup>9</sup>.

A 2009 mixed - method systematic review (SR) undertaken by Australian Diabetes Educators Association (ADEA) and Australian Diabetes Society (ADS) examines the appropriateness and meaningfulness in addition to the effectiveness of SMBG in people with non-insulin treated type 2. The recommendations from this SR are based on quality quantitative and qualitative evidence. The review states that SMBG is a learning process to facilitate daily DSM and ongoing monitoring that should be undertaken in conjunction with

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<sup>9</sup>Colagiuri S, Dickinson S, Girgis S, Colagiuri R 2009. *National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes*. Diabetes Australia (DA) and the National Health and Medical Research Council (NHMRC). 2009: Canberra.

adequate assessment and supervision. This SR also stresses that incorporating individualised educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG. For the individual with a recent type 2 diagnosis, the ADEA/ADS SR recommends that the introduction should be supported with strategies to evaluate and enhance the individual's psychosocial status to minimize any potential risk of undue stress and hardship from SMBG<sup>10</sup>.

The International Diabetes Federation (IDF) recommends that SMBG be considered as part of ongoing and structured diabetes self-management education (DSME) in its 2008 guideline *Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes*<sup>10</sup>. This guideline recommends that SMBG should be considered at the time of diagnosis of type 2 to assist the person's understanding of the condition and to support timely initiation and ongoing optimal treatment. This guideline also recommends that both the person with diabetes and their health care provider should have the knowledge, skills and willingness to use it as part of the diabetes care plan and that the SMBG results are used to monitor that management adjustment has achieved the agreed targets.<sup>11</sup>

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*Ninety-four percent (94%) of Australian Diabetes Council survey respondents self-monitor their blood glucose levels.*

*(Australian Diabetes Council Non-Insulin treated Type 2 Diabetes Member Survey 2012)*

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### Patterns of use of self-monitoring blood glucose

Whilst there is mostly expert opinion and only very limited scientific evidence on which to base recommendations about the pattern and frequency recommended for SMBG, there is some evidence supporting specific timing.

The IDF *Guideline for the Management of Post Meal Glucose* from 2007 finds that in light of the strong evidence that post meal hyperglycaemia is harmful and significantly increases the risks of developing chronic diabetes complications such as cardiovascular

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<sup>10</sup> Australian Diabetes Educators Association (ADEA) 2009, *The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose in type 2 diabetes: a mixed methods systematic review*. ADEA: Joanna Briggs Institute; Adelaide.

<sup>11</sup> International Diabetes Federation 2008 (IDF), *Guideline: Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes*. Geneva 2008: Viewed 8 November 2012; <  
[http://www.idf.org/webdata/docs/SMBG\\_EN2.pdf](http://www.idf.org/webdata/docs/SMBG_EN2.pdf)>.

disease, post meal SMBG should be considered as it is currently the only practical method of measurement<sup>12</sup>.

The Australian *National Evidenced Based Guideline for Blood Glucose Control in Type 2 Diabetes* lists sulfonylurea which lowers blood glucose levels by increasing a person's endogenous insulin production and release as the second line oral hypoglycaemic agent when metformin alone does not achieve blood glucose levels in target ranges for people with type 2<sup>13</sup>. Although the risk varies within this class of oral hypoglycaemic agents, it is well established that hypoglycaemia is an adverse effect from therapy that increases the person's risk of serious injuries and illness, and that this can be prevented, or at least minimized, by SMBG. This is supported by the finding in the ADEA/ADS SR that reports that SMBG increases the detection of episodes of hypoglycaemia<sup>14</sup>. Underreporting of hypoglycaemia and hypoglycaemic unawareness are not only prevalent among people treated with insulin, but are also a frequent occurrence among people with type 2 treated with sulfonylurea. Therefore, any restriction of access to subsidised blood glucose testing strips may severely disadvantage people with type 2 treated with sulfonylurea. For example, people with type 2 and their carers have been found to be socioeconomically disadvantaged from the condition<sup>15</sup> and loss of license and livelihood because of loss of ability to adhere to the *Assessing Fitness to Drive* regulations of 2012 that advises people with diabetes against driving unless their blood glucose levels is above 5mmol/L<sup>16</sup> will add to the financial burden of diabetes.

Importantly, SMBG is a tool that can assist gaining insight into the daily effect of lifestyle adjustment such as food choices and physical activity, illness and pharmacological therapy adjustment and other aspects of DSM. The ADEA/ADS SR recommends that, due to lack of conclusive evidence, the frequency of SMBG should be decided depending on individual circumstances and clinical judgment. The *National Evidenced Based Guideline for Blood Glucose Control in Type 2 Diabetes* states that the frequency and timing of SMBG in non-insulin treated type 2 should be matched to the person's diabetes and its treatment, circumstance and needs<sup>17</sup>. This is supported by the IDF recommends that intensity and

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<sup>12</sup> IDF 2007, *Guidelines for Management of Postmeal Glucose*. 2007: Brussels.

<sup>13</sup> Colagiuri S, Dickinson S, Girgis S, Colagiuri R 2009, *National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes*. DA and the NHMRC, Canberra 2009.

<sup>14</sup> ADEA 2009, *The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose in type 2 diabetes: a mixed methods systematic review*. ADEA: Joanna Briggs Institute; Adelaide.

<sup>15</sup> Colagiuri S, Colagiuri R, Conway B, Grainger D, Davy P 2003, *DiabCo\$ Australia: Assessing the burden of type 2 diabetes in Australia*. DA: Canberra; Australia.

<sup>16</sup> Austroads 2012, *Assessing Fitness to Drive: Medical Standards for Licensing and Clinical Management Guidelines*. Fourth Edition: March 2012; Sydney.

<sup>17</sup> Colagiuri S, Dickinson S, Girgis S, Colagiuri R 2009. *National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes*. DA and the NHMRC, Canberra 2009.

frequency of SMBG should be aligned to the person's needs including identification, prevention and management of hypoglycaemia<sup>18</sup>.

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*Of the 94% of our survey respondents who self-monitor their blood glucose levels, 52% do so every day and 32% more than once per week. More importantly, 79% use the results to adjust their diabetes self-management.*

*(Australian Diabetes Council Non-Insulin treated Type 2 Diabetes Member Survey 2012)*

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## Recommendations

With respect to the utilisation and patterns of use of SMBG for people with non-insulin treated type 2 diabetes, Australian Diabetes Council recommends considerations of the following:

- Strategies and initiatives that can improve the access to quality diabetes self-management education to ensure all people with diabetes have access to support for the development of an individual and targeted blood glucose testing regimen and information about how to interpret and apply the results to their daily diabetes self-management.
- Further research into the benefits, or otherwise, of the effects of targeted self-monitoring blood glucose in non-insulin treated type 2 diabetes on long-term glycaemic control and diabetes end-point outcomes, and on quality of life measures, self-determination and active engagement in self-care and ongoing monitoring of the condition.

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<sup>18</sup> IDF 2008, *Guideline: Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes*. Geneva 2008: Viewed 8 November 2012; < [http://www.idf.org/webdata/docs/SMBG\\_EN2.pdf](http://www.idf.org/webdata/docs/SMBG_EN2.pdf)>.

## Self-Monitoring of Blood Glucose Relative to HbA1C Monitoring

### Clinical outcomes of self-monitoring glucose relative to HbA<sub>1c</sub> monitoring

There has to date been limited scientific evidence demonstrating any efficacy and effectiveness from SMBG in non-insulin treated type 2 in reducing the incidence and prevalence of chronic diabetes complications and thus improving end-point outcomes in diabetes. This was confirmed by a recent systematic review conducted under the auspice of the Cochrane Collaboration<sup>19</sup>.

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*The majority (57%) of our member survey respondents has an HbA<sub>1c</sub> measured once or twice a year and 40% every three to four months to monitor glycaemic control.*

*(Australian Diabetes Council Non-Insulin treated Type 2 Diabetes Member Survey 2012)*

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However, emerging evidence suggests that SMBG monitoring may contribute to improved outcomes. Whilst being aware that poor glycaemic control as measured by SMBG may not lead to changes in DSM, adding targeted, or structured, SMBG have been shown to significantly improve HbA<sub>1c</sub><sup>20</sup>.

Whilst measuring HbA<sub>1c</sub> is the internationally recognised 'gold standard' for measuring glycaemic control and risk of chronic diabetes complications, not all Australians have their HbA<sub>1c</sub> measured at the recommended time intervals, or at all. The NHMRC recommends HbA<sub>1c</sub> measurement twice per year<sup>21</sup>.

The Department of Health and Ageing (DoHA) recommends that people with diabetes have their HbA<sub>1c</sub> measured at a minimum once every year. General Practitioners (GPs) are encouraged through Medicare's Practice Incentive Payment (PIP) scheme's and its Service

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<sup>19</sup> Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM 2012,. Self - monitoring blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database of Systematic Reviews*. 2012: Issue 1.

<sup>20</sup> Polonski W, Fisher L, Schikman C, Hinnen D, Parkin C, Jelsovsky Z, Petersen B, Schweitzer M, Wagner R 2011, Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled, noninsulin-treated type 2 diabetes. *Diabetes Care* 2011; Vol. 34:262-7.

<sup>21</sup> Colagiuri S, Dickinson S, Girgis S, Colagiuri R. *National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes*. DA and the NHMRC, Canberra 2009.

Incentive Payment (SIP) to monitor the glycaemic control of people with diabetes in their care by measuring HbA<sub>1c</sub> yearly<sup>22</sup>. However, it has been suggested that many people with diabetes do not have their HbA<sub>1c</sub> measured at the minimum standard of care level as defined by the DoHA. This is supported by the 2011 Steering Committee for the Review of Government Service Provision's (SCRGSP's) report which found that only 18% of people with diabetes had Medicare claims for a completed annual cycle of care in 2009 – 2010<sup>23</sup>.

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*An alarming 3% reported never having had their HbA<sub>1c</sub> measured.*

*(Australian Diabetes Council Non-Insulin treated Type 2 Diabetes Member Survey 2012)*

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### Benefits self-monitoring glucose relative to HbA<sub>1c</sub> monitoring

There are many factors that impact on glycaemic control and measuring HbA<sub>1c</sub> yearly, or even twice per year, may not be frequent enough to recognise worsening glycaemic control in non-insulin treated type 2.

The IDF suggests that Randomized Control Trials (RCTs), which traditionally are used to grade the scientific evidence that inform the development of best-practice guidelines, have certain limitations when assessing the value of SMBG as diagnostic measure for modifying behaviour and guiding therapeutic decisions<sup>24</sup>. However, qualitative research has produced some evidence for the value of SMBG as a measure of glycaemic control.

Meta-syntheses of critical literature and interpretative studies suggests that both people with non-insulin treated type 2 diabetes and their care providers find that SMBG can give

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<sup>22</sup> Medicare Australia 2011, *Practice incentive Program: Diabetes Incentive Guidelines*. Department of Health and Ageing (DoHA): Viewed 9 November 2012; < <http://sehpa.com.au/wp-content/uploads/2012/05/DiabetesPIP.pdf>>.

<sup>23</sup> Steering Committee for Government Service Provision (SCRGSP) 2011, *Report on Government Services 2011*. Canberra: Productivity Commission.

<sup>24</sup> IDF 2008, *Guideline: Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes*. Geneva 2008: Viewed 8 November 2012; < [http://www.idf.org/webdata/docs/SMBG\\_EN2.pdf](http://www.idf.org/webdata/docs/SMBG_EN2.pdf)>.

meaningful insight into the cause and effect of diabetes related self-care behaviour and lifestyle choices such as adjustment to food and exercise<sup>25</sup>.

As people with non-insulin treated type 2 have to make many daily decisions about how to manage their condition, SMBG has also been found to provide reassurance regarding successful DSM, a sense of achievement, peace of mind and can be used to support empowerment and self-determinations required to develop positive and active attitudes to DSM<sup>23</sup>. Providing peace of mind that glycaemic control is maintained through SMBG is particularly valuable for people with non-insulin treated type 2 living in rural or remote communities who may experience difficulties accessing regular consultations with their GP or allied diabetes health care providers.

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*"It's good to know that testing my sugar can help me know that my diabetes is on track between visits to my doctor. Thank you.*

*(Person with non-insulin treated diabetes living in a rural area calling the Australian Diabetes Council Customer Care Line November 2012)*

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Whilst measuring HbA<sub>1c</sub> is the recommended standard for assessing glycaemic control, it may in some clinical situations provide unreliable information. Any conditions that affect the lifespan of red blood cells and hemoglobinopathies affect the accuracy of the HbA<sub>1c</sub> measure<sup>26</sup>.

Sickle cell disease is the most common form of hemoglobinopathies and more commonly found in African American populations, but is also frequently seen in some of Australia's largest Culturally and Linguistically Diverse (CALD) populations<sup>27</sup>, Greek, Italian and Hispanic CALD communities<sup>28</sup>. There are more than 700 forms of hemoglobinopathies, many of which are clinically silent, or not diagnosed, and may occur at a much greater

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<sup>25</sup> ADEA 2009, *The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review*. ADEA: Joanna Briggs Institute; Adelaide.

<sup>26</sup> Smaldone A 2008, Glycemic Control and Hemoglobinopathy: When A1C May Not Be Reliable. *Diabetes Spectrum*. January 2008: Vol. 21 (1); 46-49.

<sup>27</sup> Colagiuri R, Thomas M and Buckley A 2007, *Preventing Type 2 Diabetes in Culturally and Linguistically Diverse Communities in NSW*. Sydney: NSW Department of Health, 2007.

<sup>28</sup> Smaldone A 2008, Glycemic Control and Hemoglobinopathy: When A1C May Not Be Reliable. *Diabetes Spectrum*. January 2008: Vol. 21 (1); 46-49.

rate than previously realised<sup>29</sup>. Self-monitoring blood glucose may provide an indication of people with diabetes who have undiagnosed hemoglobinopathies thus preventing inaccurate assessment of glycaemic control as the SMBG results will be inconsistent with HbA<sub>1c</sub> results.

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*People from Italy are the third and people from Greece the eight largest group of Australian born overseas. Both population groups have a significantly higher prevalence of type 2 diabetes than the general population.*

*(Colagiuri, Thomas & Buckley 2007)*

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Conditions and illness which affects the lifespan of red blood cells will also affect accuracy of HbA<sub>1c</sub> results. Some examples are severe blood loss and transfusions, chronic liver and kidney disease and anemia due iron and vitamin B12 deficiencies. Whilst HbA<sub>1c</sub> can be used to assess glycaemic control prior to pregnancy, pregnancy changes in blood profile and volume together with the lack of real time results makes it an inappropriate measurement during pregnancy. Self-monitoring blood glucose is essential for ensuring blood glucose levels remain in the range for pre and post meal targets in pregnancy to minimize the risk of fetal loss and for ensuring healthy pregnancy outcomes for mother and baby<sup>30, 25</sup>.

There is little or no evidence that SMBG during periods of pharmacological initiation or intensification improves long-term glycaemic control. None the less, SMBG results and patterns provide valuable information for clinicians when considering therapeutic options and assessing the effect of the choice of oral hypoglycaemic agents for hyperglycaemia caused by progression of type 2, acute illness and infections, stress and medications such as steroids for concurrent illness.

Self-monitoring blood glucose provides timely and objective access to information about glycaemic control in a convenient and practical manner<sup>31</sup>. It can at times be essential and

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<sup>29</sup> Gunton JE, McElduff A 10.2337/diacare.23.8.1197 Hemoglobinopathy and HbA<sub>1c</sub> Measurement. *Diabetes Care*. August 2000; Vol. 23 (8); 1197-1198.

<sup>30</sup> McElduff A, Cheung NW, McIntyre DH, Lagström JA, Walters BNJ, Oats JN, Wein P, Ross GP, Simmons D Australian Diabetes in Pregnancy Society. Position Statement: Australian Diabetes in Pregnancy Society Consensus Guidelines for the Management of Patients with Type 1 and Type 2 in Pregnancy. *Medical Journal of Australia*. 2005; 183 (7); 373-377.

<sup>31</sup> ADEA 2009, *The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review*. ADEA: Joanna Briggs Institute; Adelaide.

provide life-saving information throughout the person with non-insulin treated type 2 continuum of life. For some, SMBG can maintain safety at work, at home and during leisure activities when at risk of hypoglycaemia from oral hypoglycaemic agents, e.g. a farmer having to operate heavy machinery, a parent driving children to school and person going for an early morning surf as part of their exercise regimen for DSM. Family members caring for non-insulin treated type 2 living with a disability also frequently rely on the results of assisted SMBG to provide timely intervention for both hyperglycaemia and hypoglycaemia.

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*Mrs. T. is a member of the Australian Diabetes Council and cares for her husband at home who is unable to speak following stroke. He has started to become aggressive early mornings and she wants to know if this is related to his non-insulin treated type 2. Early morning self-monitoring blood glucose is recommended and Mrs. T. calls back later to say that the result showed hypoglycaemia and Mr. T's doctor has changed his oral hypoglycaemic agents.*

*(Australian Diabetes Council Customer Care Line, November 2012)*

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## Recommendations

With respect to the clinical outcome and benefits of SMBG to HbA<sub>1c</sub> monitoring, Australian Diabetes Council recommends considerations of the following:

- Recognition of factors that limit accuracy of HbA<sub>1c</sub> as a measurement of glycaemic control, barriers to timely access to HbA<sub>1c</sub> measurement and the need and wishes of some National Diabetes Services Scheme registrants to undertake targeted self-monitoring of blood glucose to gain information about real-time blood glucose levels in order to maintain personal safety and inform daily self-management.

## Clinical Criteria for Subsidised Access to Blood Glucose Test Strips

### Potential clinical criteria for subsidised access

Development of clinical criteria for subsidised access to test strips for SMBG through the NDSS will require consideration of a vast number of factors. In addition to considerations of the need to achieve cost efficiencies and the current scientific evidence, criteria should be developed in collaboration with people with non-insulin treated type 2 and their diabetes health practitioners.

International and Australian best-practice guidelines recommend considering SMBG as an adjunct tool for learning the effects of the condition and use in the adjustment of DSM and monitoring of glycaemic control from the time of diagnosis<sup>32,33</sup>. Quantitative research findings suggest that there are limited benefits of SMBG in regards to the long-term glycaemic outcomes for people with non-insulin treated type 2, but acknowledge the limit of using the current study designs of RCTs to explore wider benefits of SMBG<sup>30</sup>. Emerging qualitative research suggests that there is some value in using SMBG in addition to HbA<sub>1c</sub> for the assessment of glycaemic control, particularly with respect to encouraging people with non-insulin treated type 2 to actively engage with the condition and its management challenges<sup>34</sup>. Moreover, in the presence of certain medical conditions, SMBG may provide a more accurate picture of glycaemic control than HbA<sub>1c</sub> monitoring<sup>35</sup>, and is always recommended as the glycaemic control assessment tool in pregnancy<sup>36</sup>. Furthermore, SMBG results may be used in the clinical assessment to inform choice of therapy and assessments of its effectiveness. Self-monitoring blood glucose can also assist people with non-insulin treated type 2 who experience difficulties accessing equitable access to regular HbA<sub>1c</sub> measurements.

Importantly, a large number of criteria for subsidised access to test strips for SMBG in non-insulin treated type 2 could potentially contribute to confusion and different interpretation amongst health care practitioners resulting in inequitable access to SMBG

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<sup>32</sup> IDF 2008. *Guideline: Self-Monitoring Blood Glucose in Non-Insulin Treated Type 2 Diabetes*. Geneva 2008: Viewed 8 November 2012; < [http://www.idf.org/webdata/docs/SMBG\\_EN2.pdf](http://www.idf.org/webdata/docs/SMBG_EN2.pdf)>.

<sup>33</sup> Colagiuri S, Dickinson S, Girgis S, Colagiuri R. National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes. DA and the NHMRC, Canberra 2009.

<sup>34</sup> ADEA 2009, *The effectiveness, appropriateness and meaningfulness of self-monitoring blood glucose (SMBG) in type 2 diabetes: a mixed methods systematic review*. ADEA: Joanna Briggs Institute; Adelaide.

<sup>35</sup> Smaldone A 2008, Glycemic Control and Hemoglobinopathy: When A1C May Not Be Reliable. *Diabetes Spectrum*. January 2008: Vol. 21 (1); 46-49.

<sup>36</sup> Gunton JE, McElduff A 10.2337/diacare.23.8.1197 Hemoglobinopathy and HbA<sub>1c</sub> Measurement. *Diabetes Care*. August 2000: Vol. 23 (8); 1197-1198.

test strips. Lastly, people with diabetes do use SBGM to adjust their DSM<sup>37</sup> and their life circumstances may require daily SMBG to maintain safety at home, work or during leisure activities<sup>38</sup>.

In conclusion, introduction of numerous clinical criteria for subsidised access to test strips for SMBG through the NDSS may impact on equitable, appropriate and timely access to best-practice care for all Australian's with non-insulin treated type 2.

The health expenditure related to diabetes will continue to rise as:

- rates of diabetes increases,
- people develop diabetes earlier, and
- People live longer with diabetes.

This, together with an aging population and age as an independent risk factor of developing diabetes are the main drivers for the need to seek cost efficiencies in diabetes management and care so that extra funding may become available to redirect into diabetes programs. However, cost efficiencies should not impact on access to quality care. Structured programs for DSME that includes discussions of targeted SMBG and information about how to interpret and apply the results to daily DSM at the time of diagnosis in and access to timely support when experiencing periods of poor glycaemic control may offer a solution to achieving cost efficiencies without compromising care delivery.

### Recommendations

In light of the evidence, the views of people with type 2 and their carers and concerns about maintaining equitable access to timely and appropriate care, Australian Diabetes Council recommends that:

- National Diabetes Services Registrants with type 2 diabetes continue to be eligible to access government subsidised test strips for targeted self-monitoring blood glucose.
- The decision about self-monitoring of blood glucose continues to be based on the clinical judgement of the individual's diabetes care team in consultation with the person with non-insulin treated type 2 and their family or carer.

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<sup>37</sup> Australian Diabetes Council 2012, *Self-Monitoring Blood Glucose in Non-Insulin treated Type 2 Diabetes; A Member Survey*. October 2012: Australian Diabetes Council; Sydney.

<sup>38</sup> Australian Diabetes Council 2012, *Member Views*. Personal Communications.