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Submission
Department of Health and Ageing's *Review of self-monitored blood glucose test strips for people with type 2 diabetes mellitus*

Australian College of Nursing (ACN) is pleased to provide the following input to the Department of Health and Ageing's Review of products and medicines used in the treatment of diabetes: phase 1 *Review of self-monitored blood glucose test strips for people with type 2 diabetes mellitus.*

With a focus on the Terms of Reference for phase 1, this submission emphasises the importance of self-monitoring for people with T2DM and outlines that people who use SMBG derive improved clinical outcomes as compared to people who do not. It is ACN's position that the demonstrated effectiveness of SMBG warrants its continued subsidisation. The assumptions and evidence supporting ACN's position on SMBG for individuals with T2DM are explicated below.

1. Underlying assumptions

- All people with diabetes have the right to self-monitor their blood glucose (SMBG) regardless of their treatment mode. Depriving some people with diabetes of that right could be discriminatory.

- People with diabetes undertake a considerable amount of self-care for a lifetime and make day-to-day decisions about their care. In most cases health professional consultations occur on a three, six or twelve monthly basis.

- People with diabetes are expected to be active participants in their care. SMBG and medicine self-management are two key inter-related self-care behaviours that influence HbA1, but they are not the only factors.

- Type 2 diabetes (T2DM) is a progressive disease characterised by declining beta cell function, which means lifestyle management (diet and exercise) eventually needs to be supplemented with glucose lowering medicines such as oral agents and/or insulin.

- Type 2 diabetes is a serious, insidious disease. Often, few symptoms are present and complications can be silent. SMBG should be offered to all people with T2DM; not doing so could send an incorrect message about the seriousness of the disease and engender complacency that affects self-management and outcomes.

- SMBG provides information about the prevailing blood glucose pattern and is used to make day-to-day decisions about food intake, activity and medicine doses. It also provides important information during illnesses and hypoglycaemic events that enable timely treatment adjustments to be made.

- SMBG is important to detecting hypoglycaemia and hyperglycaemia. Hypoglycaemia has significant mental and physical effects and can lead to unnecessary presentations to hospital, falls, driving accidents and other accidents that place the individual and others at risk. Hyperglycaemia leads to elevated blood glucose levels and ketosis in serious illness. Hyperglycaemia predisposes people with T2DM to dehydration, lowered mood, lethargy, difficulties in concentration as well as hypermosmolar states requiring hospitalisation.

- There are times when non-diabetic individuals will need to perform SMBG. For example, women who develop gestational diabetes and people with diabetes risk factors who have commenced diabetogenic medicines such as corticosteroids and atypical antipsychotic medicines.

- Most glycaemic improvement occurs in non-insulin treated people with T2DM in the first three to nine months after it is commenced and declines thereafter unless strategies are in place to sustain SMBG. The same principle applies to most self-care behaviours, which is why regular reminders and re-education programs are essential and could be a part of the Annual Cycle of Care.

- HbA1c reflects the average blood glucose level over about 120 days. The average does not account for normal blood glucose fluctuations over the day. HbA1c is useful for making longer term decisions and is used with the SMBG pattern e.g. when to add a GLM to diet and exercise and/or add insulin to oral GLMs. That is HbA1c is *part* of the overall clinical information needed to recommend management options.

- HbA1c may not be a direct measure of the outcomes of SMBG. Many factors influence HbA1c including medicines self-management and appropriate prescribing, dose adjustment and monitoring, and factors that affect the red cell survival as well as the assay method used.

- Costs need to be considered. An individualised structured approach to SMBG could help manage costs.

2. Key issues and recommendations

There is evidence that structured SMBG testing to obtain a seven-point SMBG profile performed on three consecutive days in the week preceding an appointment with the managing health professional is associated with improved HbA1c. The testing schedule equates to 21 BG strips over the three days (Polonsky et al. 2011). People allocated to structured SMBG testing regimen used fewer strips than the usual care group and achieved better outcomes.

Undertaking a structured SMBG regimen quarterly would represent approximately 84 BG strips. A recent systematic review, (Clar et al. 2010), indicate s people who perform SMBG at least once per day have better outcomes than those who do not. Thus, there is reasonable evidence for placing a cap on access to approximately 400 strips per year providing the system is flexible enough to enable people to test more frequently when circumstances change e.g. during illness, frequent hypoglycaemia, and when prescribed

diabetogenic medicines. Women who develop gestational diabetes (GDM) and non-diabetics with diabetes risk factors commenced on diabetogenic medicines also need to monitor blood glucose patterns.

ACN makes the following additional recommendations concerning SMBG for people with T2DM not treated with insulin:

- Structured SMBG is the most appropriate way to ensure people with T2DM and health professionals have meaningful and actionable information that supports effective diabetes self-management including medicine self-management.

- SMBG is valuable to people with T2DM in the context of self-management. The value relates to the quality of and how SMBG is used rather than the frequency of testing.

- SMBG is a right of all people with diabetes. It should continue to be available to Australians with non-insulin treated T2DM because it is an important component of self-management and person-centred, individualised care. Structured use of SMBG within the context of individualised care is in the best interest of people with T2DM.

- Sufficient resources should be available to ensure people with T2DM and health professionals have the relevant knowledge, competencies and training to educate people how to undertake SMBG and interpret and apply the results.

- The proposed restrictive options such as placing an annual limit on the number of subsidised testing strips available to people with non-insulin treated type 2 diabetes should be undertaken in close cooperation with people with diabetes, the range of health professional disciplines who manage people with diabetes, Diabetes Australia and the National Diabetes Services Scheme.

3. Background

Diabetes is a significant health problem throughout the world. Currently 1.5 million Australians have diabetes (Australian Institute of Health and Welfare (AIHW) 2010) and T2DM is the most common type of diabetes. However, because of the insidious nature of T2DM it is difficult to determine when the disease process begins, thus T2DM is under-diagnosed. Most T2DM is diagnosed after age 45 but the prevalence in children and adolescents is increasing and these children are likely to develop complications earlier in their lives. Significantly, diabetes will be the leading cause of disease burden in Australia by 2023 (AIHW 2010).

Rights and responsibilities

Self-management principals have underpinned diabetes education and service delivery for many years. In Victoria, the Department of Health's Chronic Disease Management Guidelines, Integrated Chronic Disease Management Guiding Principles and Health Independence Guidelines underpin the delivery of services to people with diabetes and other chronic conditions. Respecting the individual's right to choose management options and to receive optimal care in their social and health context mandates that SMBG is available to all, but not mandatory for all. SMBG could be recommended for people with T2DM and others at high risk of adverse events and diabetes complications who choose to include SMBG in their diabetes self-management regimen.

Thus, it is difficult to formulate standard SMBG recommendations for everybody with T2DM because of the current focus on person-centred care and individualising care to the individual's social and physical context.

Type 2 diabetes

Type 2 diabetes (T2DM) is a progressive disease of declining beta cell function. Thus, endogenous insulin production gradually decreases and glucose lowering medicines and/or insulin (GLM) are needed to supplement lifestyle activities (diet and exercise) and maintain blood glucose within an acceptable range to prevent the costly long term diabetes-related complications.

The United Kingdom Prospective Study (UKPDS) (1998) showed > 50 of people with T2DM will eventually require insulin. Significantly, only 25% of people with T2DM in the UKPDs treated with diet and exercise achieved the target HbA1c. Likewise, Guisasola et al. (2008) found only approximately 25% of European outpatients achieved adequate glycaemic control after a mean of 2.5 years following initiation of a combination of oral GLMs in an observational study. Glycaemic control declined over time even though more people were treated with insulin, which highlights the progressive nature of T2DM.

Many people with T2DM already have diabetes-related complications such as cardiovascular disease at diagnosis and worryingly, as indicated, the prevalence of T2DM is increasing in children and adolescents and they are likely to suffer hyperglycaemia-induced changes at an earlier age.

Many people think T2DM is not as serious as type 1 diabetes and they 'do not have to worry,' especially if they are managed with lifestyle interventions (Dunning & Martin 1997 and 1998). Yet, as indicated, a majority of people with T2DM have established complications at diagnosis, which puts them at high risk of adverse outcomes. Removing access to SMBG test strips for people not treated with insulin could send a message that T2DM is only serious when it is treated with insulin and important education and primary and secondary prevention opportunities could be missed.

T2DM and its short and long term complications are often 'silent' and produce few symptoms, thus, early management is often delayed and could be further delayed if health professionals have to rely on three monthly HbA1c results. HbA1c is an important indicator of the effectiveness of management strategies and reflects the average blood glucose over three months. However, it does not reflect BG fluctuations throughout the day and in relation to meals and exercise that can, and should be, used on a day-to-day basis to appropriately tailor treatment.

Most people with T2DM experience periods of stable blood glucose and periods of explained and unexplained blood glucose fluctuations during times of illness and stress; therefore adequate provisions for extra testing during unstable periods is essential.

HbA1c

The American Diabetes Association (ADA) (2010) and the World Health Organization (WHO) (2011) recommend aiming for HbA1c < 6.5%. The National Institute of Clinical Excellence (NICE) Guidelines (2009) for type 2 diabetes recommend aiming for HbA1c < 6.5 % for people taking one blood glucose lowering medicine (GLM) and < 7.5% for those taking two or more GLMs. However, NICE acknowledged these levels might not be

appropriate for all people with type 2 diabetes. The Australian Diabetes Society (2009) suggested a general HbA1c target < 7%, but indicated some people should aim for < 6% and > 8%, depending on individual circumstances e.g. frail older people and children.

Significantly, HbA1c < 7% is associated with more frequent hypoglycaemic episodes in people using some GLM especially long acting sulphonylureas and insulin, especially those with renal and liver disease that increase the risk of adverse events such as cognitive impairment, impaired decision-making, falls and myocardial infarction in older people (ACCORD Study Group 2011). Thus, there is growing recognition that HbA1c < 7% may not be appropriate for everybody with diabetes and that management goals need to be individualised (NICE 2009; Australian Diabetes Society 2009; SIGN 116 2010; Gale 2010). In addition, HbA1c might not be reliable in every person with diabetes.

Some factors that affect HbA1c besides the prevailing blood glucose

Herman (2009) suggested only approximately one third of the variance in HbA1c is due to glycaemia. Other factors that affect HbA1c include frequent hypoglycaemia, genetics, female gender, sex hormones, visceral fat distribution (Cohen et al. 2006) and the HbA1c assay method: immunoassay methods yield are lower results than High Pressure Liquid Chromatography (HPLC) (Schweitzer et al. 2012). HPLC is referred to as 'the gold standard method' and most frequently used HbA1c assay method in Australia.

HbA1c is less reliable in people with cystic fibrosis-related diabetes (Dyce and Wallymahmed 2012), people on long term corticosteroid medicines, those with long standing iron deficiency anaemia (Stranks and Doogue 2012) and people with renal disease on haemodialysis. In addition, although point of care HbA1c test methods are useful to monitor glycaemic control, they may not be accurate enough to diagnose diabetes (International Expert Committee 2009).

SMBG

Many management guidelines recommend people with T1DM perform SMBG at least three times per day. There is less agreement about the value and frequency of SMBG for people with non-insulin treated T2DM within the literature. Generally there is little evidence that SMBG improves HbA1c or body weight (Faas et al. 1997; Davis et al. 2007; Farmer et al. 2012). The latter is not surprising given insulin and several other GLMs induce weight gain. Many studies are old and use different technology from modern SMBG testing methods.

The assumption that HbA1c is a viable alternative to SMBG requires careful consideration. The evidence for and against a beneficial effect needs careful consideration that takes account of the methodological flaws in existing studies and failure to account/control for the various factors that affect HbA1c and selecting HbA1c as the best outcome measure in the first place.

HbA1c is only one clinical endpoint that should be monitored; other endpoints include personal empowerment and self-efficacy and other diabetes self-management parameters. These outcomes are more likely to be achieved if a combination of structured SMBG and education are implemented to help the person use their SMBG

information to adjust their management regimen (Polonsky et al. 2011; Clar et al. 2012).

SMBG gives people 'real time' feedback about the effects of diet, exercise, stress and medicines on BG levels. It is much harder to relate day-to-day SMBG changes to HbA1c because it is a three month BG average and cannot account for all the factors operating at the time a SMBG test is performed. Thus, essential adjustments to the management regimen are more difficult if health professionals predominantly rely on one parameter.

Few SMBG studies have been conducted in Australia to inform the SMBG evidence base (with exceptions such as Davis et al. (2007)). Additionally a new study, the STeP structured SMBG approach led by Professor Jane Speight and an independent advisory board is underway, but the results will not be available in time to inform the current review. The NDSS data are limited in that SMBG test strip purchase data are available, but these data are not linked to clinical outcomes. Thus, it is difficult to determine what effect limiting access to BG strips for people with T2DM not on insulin would actually have. It is reasonable to assume that people with T2DM would not access SMBG test strips if they did not feel they benefitted from SMBG.

A recent meta-analysis (Farmer et al. 2012) has suggested SMBG in non-insulin treated T2DM does not lead to a convincing 'clinically meaningful effect' and found a significant difference between HbA1c in the test versus the non-test group. The authors qualified the finding by stating the effect on HbA1c was influenced by personal and clinical factors. In other words there were confounding variables not accounted for in the study.

Additionally, Polonsky et al. (2011) and Parkin et al. (2012) demonstrated that structured SMBG improves glycaemic control in people with T2DM not on insulin and can facilitate more timely treatment changes. In addition, SMBG enhanced collaboration between people with diabetes and their health professionals, which is essential to optimal outcomes. Significantly, both Polonsky et al. (2011) and Parkin et al. (2012) stated that SMBG was underutilised. Likewise, the International Diabetes Federation (IDF) (2009) indicated effective SMBG contributes to education, diabetes management and tailored support, but recommended SMBG be used for people with non-insulin treated T2DM who are willing to use the BG patterns to adjust their diabetes management regimen.

People with T2DM will be at different stages of the condition, have different comorbidities, different capabilities including health literacy, varying interest in self-management, different medicine-related risks including hypoglycaemia, be on different medicine regimens, and have different lifestyles. Therefore, SMBG needs to be individualised. Having clearer guidelines about when to test, how often to test and what to do with the results, is important. These factors could be encompassed in structured SMBG programs.

Follow up SMBG education that includes how to use SMBG results improves outcomes. Documented benefits of structured approach to SMBG include:

- Improved understanding of the factors that affect individual's BGLs leading to a greater sense of control/self-efficacy.

• Information about the impact of specific foods, exercise and medicines, including diabetogenic medicines such as corticosteroids and atypical antipsychotic medicines on BGLs. People prescribed corticosteroids or antipsychotic medicines who have diabetes risk factors are likely to develop hyperglycaemia. SMBG provides the individual and health professionals with a greater understanding of how these medicines affect BGLs. BGLs tend to increase later in the day depending on the particular corticosteroid used, the dose form and the duration of use.

• Thus, SMBG is an important teaching/learning tool for all people with diabetes and can help people adjust their diet, physical activity and medicines to increase the likelihood they will meet management targets.

4. Summary

There is little sound evidence to recommend SMBG testing frequency for non-insulin-treated people with T2DM. However, there is good evidence that 'structured' monitoring combined with education that teaches the individual to use his or her SMBG pattern to adjust their treatment is beneficial. Both the person with diabetes and the health practitioner need to know how to interpret SMBG patterns and relate them to HBA1c and other pathology tests such as lipids, and discuss these issues within consultations to plan changes that could improve BGLs.

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References

The ACCORD Study Group. (2011). Long term effects of intensive glucose lowering on cardiovascular outcomes. *New England Journal of Medicine 364*, 818–828.

American Diabetes Association. (2010). Standards of Medical Care in Diabetes. *Diabetes Care 33*(1) S11–S61.

Australian Institute of Health and Welfare. (2010). *Australia's Health*. (pp. 157-159). Canberra: AIHW.

Australian Diabetes Society. (2009). *Position statement: Individualisation of HbA1c Targets for Adults with Diabetes Mellitus*. Retrieved from http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/cpl102.pdf

Clar, C., Barnard, K., Cummins, E., Royle, P., Waugh, N. (2010). Aberdeen Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: Systematic review. *Health Technology Assessment 14*, 1-140.

Cohen, R., Snieder, H., Lindsell, C., Beyan, H., Hawa, M., Blinko, S., Edwards, R., Spector, T., Leslie, R. (2006). Evidence for independent heritability of the glycation gap (glycosylation gap) fraction of HbA1C in nondiabetic twins. *Diabetes Care, 29,* 1739-1744.

Davis, W., Bruce, D., Davis, T. (2007). Is self-monitoring of blood glucose appropriate for all type 2 diabetic patients: The Fremantle Diabetes Study. *Diabetes Care, 30*(1), 184-185.

Dunning, T., Martin, M. (1997). Using a Focus Group to Explore Perceptions of Diabetes Severity. *Practical Diabetes International*, *14*(7), 185–188.

Dunning, T., Martin, M. (1998). Type 2 diabetes: is it serious? *Journal of Diabetes Nursing, 2*(3), 70–76.

Dyce, P., Wallymahmed, M. (2012). Long term complications of cystic fibrosis-related diabetes. *Journal of Diabetes Research, 16*(6) 240–246.

Faas, A., Schellevais, F., Van Eijk, J. (1997). The efficacy of self-monitoring of blood glucose in NIDDM subjects: a criterion-based literature review. *Diabetes Care, 20*(9) 1482-1486.

Farmer, A. J., Perera, R., Ward, A., Heneghan, C., Oke, J., Barnett, A. H., Davidson, M. B., Guerci, B., Coates, V., Schwedes, U., O'Malley, S. (2012). Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *British Medical Journal*, *344*, e486.

Gale, E. (2010). Diabetes in the UK: time for a reality check. *Diabetic Medicine, 27,* 973-976.

Giusasola, A., Mavros, P., Nocea, G., Alemao, E., Alexander, C., Yin, D. (2008). Glycaemic control among patients with type 2 diabetes mellitus in seven European countries: findings from the Real-Life Effectiveness and Care Patterns of Diabetes Management (RECAP-DM) Study. *Diabetes Obesity and Metabolism, 10*(1) 8–15.

Herman, W. (2009). Do race and ethnicity impact on haemoglobin A1c independent of glycaemia? *Journal Diabetes Science and Technology, 3*(4) 656–660.

International Diabetes Federation (IDF). (2009). *Guideline on Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes.* Brussels: IDF.

International Expert Committee. (2009). Report on the role of the HbA1c assay in the diagnosis of diabetes. *Diabetes Care,* 32, 1327–1334.

National Collaborating Centre for Chronic Conditions. Type 2 diabetes. (2009). The management of type 2 diabetes. London: National Institute for Health and Clinical Excellence (NICE).

Parkin, C. G., Buskirk, A., Hinnen, D. A., Axel-Schweitzer, M. (2012). Results that matter: structured v s unstructured self-monitoring of blood glucose in type 2 diabetes, *Diabetes Research & Clinical Practice 97,* 6-15.

Polonsky, W., Fisher, l., Schikman, C., Hinnen, D., Parkin, C., Jelovsky, Z. (2011). Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled noninsulin treated type 2 diabetes from the Structured testing Program study. *Diabetes Care 34*(2), 262-267.

SIGN 116. (2010). *Management of Diabetes; A National Clinical Guideline.* Edinburgh: SIGN.

Schweitzer, M., Cavan, D., Ziegler, R., Cranston, I., Barnard, K., Ryder, J., Vogel, C., Parkin, C., Koehler, W., Vesper, I., Petersen, B., Wagner, R. (2012). Is HbA1c a reliable measure for assessing glycaemic control. Paper session presented at the European Association for the Study of Diabetes, Berlin.

United Kingdom Prospective Study. (1998). *The Lancet*, *352,* 837–853.

World Health Organisation (WHO). (2011). Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus. Abbreviated report of WHO consultation. Geneva: WHO.