Submission to the PBS Review of Products and Medicines Used in the Management of Diabetes

Phase 1 - Self-Monitored Blood Glucose Test Strips for people with Type 2 Diabetes Mellitus not treated with insulin.

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Executive Summary

IVD Australia is pleased to provide comment on Stage 1 of the PBS Review of Products and Medicines used in the Treatment of Diabetes - "*Self-Monitored Blood Glucose Test Strips for people with Type 2 Diabetes Mellitus not treated with insulin"*

IVD Australia believes that the data on whether or not there are specific benefits to the use of self monitoring of blood glucose (SMBG) by patients who have been diagnosed with type 2 Diabetes mellitus (T2DM) is still inconclusive. There have been numerous trials over the years but many of these have either not been well controlled or have failed to show a dramatic effect either way on the use of SMBG by T2DM patients. Many of the trials have focused on the effect on glycated haemoglobin A1c (HbA1c) levels as an endpoint and they have often used random SMBG measurements. Recent discussion has also focused on the value of blood glucose excursion as a better endpoint for patient management; in other words less fluctuation in the BG levels through the day.

SMBG is valuable to T2DM patients for a number of other qualitative reasons as well as for the specific detection of acute hypo- or hyper-glycaemia. Regular SMBG measurement allows patients and clinicians to detect BG excursions facilitating therapeutic adjustments or patients on oral medication. In addition the use of a planned regime of SMBG provides immediate feedback on how lifestyle affects BG levels and motivates patients towards healthier behaviour Use of rapidly evolving wi-fi and internet technology also facilitates patient education about T2DM and its management as well as enabling reliable recording and assessment of data concerning blood glucose levels.

Certainly, there is evidence that, for lower income patients, better outcomes are achieved through the use of subsidised blood glucose strips.

IVD Australia accepts that the cost of SMBG is a considerable burden on the overall health budget. However patients who are non - insulin dependent use less than one strip per day on average at a cost of around $0.50 per day. This would appear to be a small cost to manage the increasing incidence of T2DM within the Australia community and to assist in reducing the expenditure of nearly $420 million on oral medication used to treat diabetes.

IVD Australia recommends that T2DM patients who are not on insulin therapy continue to access SMBG strips through the National Diabetes Services Scheme (NDSS). Use of HbA1c to diagnose and manage T2DM is complimentary to SMBG and both should be available for patients.

IVD Australia however also recommends there be a well designed program of patient education and control so that the continued use of SMBG for T2DM patients who are on oral therapy leads to improved outcomes for the growing number of T2DM patients in the Australia community. This education and control should be directed towards reducing the impact of diabetes morbidity and the level of expenditure on pharmaceuticals used to treat T2DM.

IVD Australia looks forward to working with the Government, and the Department of Health and Ageing, in implementing the recommendations of the Review in order to continue to deliver world class management of Type 2 diabetes for all affected Australians.

About IVD Australia

IVD Australia is the peak body representing sponsors and manufacturers of *in vitro* diagnostics based in Australia.

In vitro, literally "*in glass*", diagnostics (IVDs) comprises the instruments, reagents and consumables that are used to perform pathology tests requested by General Practitioners (GPs), specialist Physicians (specialists) or other healthcare professionals (HCPs), or those undertaken as part of a screening program. These pathology tests are generally performed in accredited Public and Private pathology laboratories across Australia, but IVDs also include over-the-counter tests such as blood glucose meters for diabetes testing, home pregnancy test kits and point of care (PoCT) devices used in general practice and healthcare clinics to measure INR or HbA1c levels. Supply of these products in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

IVD Australia was formed in July 2009 and currently represents Australian manufacturers, multi-national and local distributors of IVDs, as well as regulatory consultants working in the IVD sector. Our 50 members supply *in vitro* diagnostic products in Australia valued at over $750,000,000 per annum and they employ around 2000 people across Australia.

IVD Australia members supply the bulk of blood glucose meters and strips used for SMBG as well as instrumentation for HbA1c testing for both professional laboratory use and point of care (PoCT) use.

General Comments on the Review

IVD Australia thanks the Department and the Pharmaceutical Benefits Advisory Committee (PBAC) for the opportunity to comment on Stage 1 of the Review of Products and Medicines Used for Diabetes Management - ***Review of self-monitored blood glucose tests strips for people with type 2 diabetes mellitus.***

Diabetes has become an epidemic

Diabetes is a rapidly growing disease both in Australia and across both the developed and less-developed world. In Australia it is one of the fastest growing diagnoses.

The most recent data from Australian Institute of Health and Welfare (AIHW) indicates that in 2007–08, an estimated 898,800 Australians had been told by a doctor or a nurse that they had diabetes at some time in their lives. Of these around 87,100 people (10%) had Type 1 diabetes, and around 787,500 people (87%) had Type 2 diabetes[1].

AIHW also indicates that the prevalence of the disease has also increased to over 4% of the Australian population. It is generally accepted that this cohort probably only represents about half of the real population as there are many patients with undiagnosed T2DM and many more with glucose intolerance or resistance.

The prevalence is also growing rapidly; in 1989 -90 the prevalence was calculated to be 1.5%. It is not clear whether the dramatic rise (nearly 3x) over this 20 year period is due to better awareness, better diagnosis, or to the fact that the baby boomer generation particularly seems to be developing diabetes at a highly increased rate.

Diabetes is also one of the most common causes of morbidity and mortality in the indigenous population. In 2004–05, 6.3% (29,874) of indigenous Australians had diabetes[2] and diabetes among indigenous Australians was 3 times as common as in non-Indigenous Australians according to the 2004–05 National Aboriginal and Torres Strait Islander Health Survey. Indigenous Australians were 7 times as likely as non-Indigenous Australians to have diabetes recorded on their death certificate for the period 2003–2007. Hence any programs that attempt to manage the treatment of diabetes or changes to programs must take into account the special need of the indigenous population.

[1] Australian Institute of Health and Welfare (AIHW) - http://www.aihw.gov.au/how-common-is-diabetes/#all - accessed on 05/11/2012

[2] Ibid - http://www.aihw.gov.au/diabetes/populations-of-interest/#atsi - accessed on 05/11/2012

Cost to the community of diabetes and SMBG

There are considerable costs to the community of this epidemic of type 2 diabetes; these include;

- The increasing costs of treatment with pharmaceuticals;
- The increasing number of visits to general practitioners related to diabetes; and
- The increase in co-morbidities associated with diabetes, including cardiovascular disease, vision loss, end-stage kidney disease and peripheral vascular disease resulting in amputations.

In the United Kingdom the House of Commons has recently published its 17th Report of Sessions which examined the management of diabetes in the NHS[3]. This concluded that over 24,000 patients die each year in the UK because their diabetes has not been effectively managed and many more develop avoidable complications such as blindness or kidney disease. It estimates that over 80% of the STG 3.9 billion per year spent on diabetes services goes to treating avoidable complications.

These complications all add dramatically to the cost and morbidity of chronic disease. The Government has a focus on tackling the issue of chronic disease in the community and given that many of them such as diabetes, cardiovascular disease and obesity are inextricably linked efforts to improve diabetes care will result in improvements in other chronic disease areas.

Finally there is the cost of monitoring using SMBG. Currently the NDSS spends about $44 million per year on providing BG strips to the 363,000 patients who are diagnosed as T2DM but who are not treated with insulin or insulin analogues. This equates to about 1.1 million boxes of BG strips per year or an average of 3 boxes per year. Hence each T2DM patient uses an average of slightly less than 1 strip per patient per day at a cost of around $120 per patient per year[4].

In addition there are BG strips supplied through the PBS. However the volume of strips used is about 10% of the use through NDSS. The pattern of usage is also equivalent; T2DM patients not on insulin use less than 1 strip per patient per day.

However the cost of the strips supplied through the NDSS and PBS is not the only cost in managing diabetes. The Federal Government for example currently spends nearly $420 million on pharmaceuticals (excluding insulin) to manage diabetes[5].

[3] UK Public accounts Committee - accessed as http://www.publications.parliament.uk/pa/cm201213/cmselect/cmpubacc/289/28902.htm on 05/11/2012

[4] Dr G. Koumantakis, personal communication, October 2012

[5] PBS statistics for 2012, accessed as http://www.health.gov.au

Benefits of SMBG to Patients and the Community

What then are the benefits to patients of the use of SMBG?

Evidence from a large number of trials is still inconclusive. A number of recent reviews have indicated that there seems to be modest or little change in the levels of HbA1c measured in patients who undertook SMBG versus those who did not[6].

Part of the problem is that the studies have had different designs, populations and interventions. Many have used random glucose measurements during the trials rather than structured measurement of blood glucose at controlled times.

A number of the studies also used well controlled populations meaning that the possible effects that could have been expected were constrained, especially those that were looking for changes in HbA1c values great than 0.5%

Additionally these studies tended to focus on the longer term goal of glycemic control through HbA1c reduction. This may mean that effects that are not related to HbA1c measurements or that occur on a shorter time frame than 3-4 months may have been overlooked.

The data from recent randomized controlled trials seems to indicate that SMBG is likely to be an effective self-management tool however when the results are reviewed and acted upon by T2DM patients and healthcare providers to actively modify behaviour and / or adjust treatment[7].

Recent studies such as that by Polonsky et al[8] have indicated that appropriate use of structured SMBG significantly improves glycemic control and facilitates treatment changes in non insulin treated T2DM patients.

[6] International Diabetes Federation " Self-Monitoring of Blood Glucose in Non-insulin treated Type 2 Diabetes", 2009,

[7] Ibid - p4

[8] Polonsky, W. H et al., Diabetes Care, 2011, 34(2): 262-267

Alternatives to SMBG

Given the cost to the community of providing SMBG test strips through the NDSS or PBS, and the inconclusive evidence that SMBG makes a difference in T2DM, what then are the alternatives to SMBG for T2DM patients who are not insulin treated?

Firstly, there is measurement of HbA1c. This provides a good marker of long term glycemic control but for many patients it requires several visits to the GP or clinic to obtain the level. In addition MBS data suggests that there is poor compliance with the recommended quarterly guideline for HbA1c measurement with patients having an average of less than 2 HbA1c tests per year.

At present there is an MSAC application for a new MBS item number for measurement of HbA1c for the diagnosis of diabetes[9]. As the measurement of HbA1c levels is currently not rebated for point-of-care testing, if this application is accepted, then the sample must be sent to a laboratory for processing and the result returned to the GP or clinic for review. In rural and remote Australia this adds a significant additional burden to patients resulting in significant non-compliance. Given that it is already difficult to treat indigenous T2DM patients, removal or restriction of SMBG may make the problem of diabetes in indigenous Australia far worse than it already is.

Measurement of HbA1c is also not a replacement for measurement of blood glucose. It is appropriate as a measure of glycemic control but does not replace measurement of glucose for the determination of hypo- or hyper-glycemia. It is little value in the short term when commencing or changing therapy. If HbA1c is adopted for diagnosis as proposed then this may mean a significant decrease in the use of SMBG in newly diagnosed T2DM patients; perhaps to the detriment of their ongoing health.

Secondly, there is the alternative of urine glucose measurements via dipsticks which is considerable cheaper than SMBG. However, numerous studies have shown that patients greatly prefer the convenience of a finger-prick over urine specimen collection, as well as the ability to store the reading within the BG meter and then review the reading with their GP or diabetes clinic. Finally reading of the urine glucose measurements can be very subjective and give little reassurance during a hypo- or hyper-glycemic episode, and in many countries this test has been discontinued.

Finally there is the alternative of restricting the supply of strips under the NDSS to T1DM or T2DM patients on insulin only.

This would of course save a considerable sum (~$50 million per annum) but runs the risk of poor management of patients who are newly diagnosed as T2DM, those who are having dosage adjustment, and those that are undergoing change to their medication. In all these situations the ability to measure BG levels is critical.

[9] Medical Services Advisory Committee - accessed as http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1267 on 07/11/2012

Changes in Technology for SMBG

A further aspect to be considered in any decision regarding the use of SMBG in non -insulin T2DM patients is the changes to technology that are taking place.

There has been a steady improvement in the quality of both blood glucose meters and test strips over the last 10 year. Modern meters and strips suffer from far less interference from other substances (both endogenous and exogenous) than in the past. The ISO international standard for Blood Glucose meters (ISO 15197) has recently been revised to tighten the acceptable range of accuracy. Similarly, test methodology has been greatly improved and the number and type of interfering substances has been greatly reduced.

This means that the results from modern SMBG meters using finger-stick can be relied upon to produce results that are very similar to those obtained from laboratory measurements requiring venipuncture.

Additionally, modern meters are small and take measurements within a convenient timeframe, generally 5 -20 seconds. This added patient convenience means that readings can be taken anytime, anywhere and the results relied upon to inform dietary or other lifestyle decisions.

Finally modern SMBG meters have greatly increased connectivity. Most modern meters allow for the results to be downloaded to a computer or tablet device. These data can then be provided to a GP or HCP or indeed, as in some modern meters, collected directly by the tablet device and transmitted remotely to the GP's computer. This trend towards increasing technological involvement in healthcare will mean that programs that seek to manage interventions based on SMBG levels will be better informed and be able to do so with reliable data taken directly from the patient's meter.

The advent of the personally controlled electronic health record (PCEHR), a key initiative of the Australian Government, will also enable better sharing of SMBG measurements amongst health care professionals. The inclusion of SMBG readings in the PCEHR will mean that patient interventions can be reviewed not only by a GP but also by a specialist endocrinologist or cardiologist or other HCPs involved in the patient's management.

This ability to obtain reliable, accurate SMBG measurements, transmit them automatically into a patient's record and then make rational interventions based on these will revolutionise the management of T2DM patients.

Changes to the role of Patients in their own diabetes management

In general, patients in the 21st Century are much more participative in their personal health care than they have been in the past.

Given the advent of the internet, and the enormous amount of information that patients can access, many people for the first time are taking an active role in managing their own health and assisting more generally in the interventions that are proposed.

This is borne out, for example, by the number of patients that are using PoCT technology to manage their anticoagulant status via personal INR measurements. For these patients getting the correct level is critical to their health, and the ability to measure and then modify (dosage) is essential. This use of PoCT for this application is well accepted around the world and has led to dramatic improvements in control and convenience.

For people with T2DM it is not proposed that SMBG measurements be used by patients to self adjust therap. However measurement of blood glucose levels can be of great benefit for patients in managing their lifestyle decisions that influence their diabetes. The ability to use modern technology such as PoCT blood glucose measurements can facilitate and remind patients of the changes in lifestyle required.

There are significant other benefits accruing to regular SMBG measurement[10]. Besides the ability to detect gross hypo- or hyper-glycemic episodes these include;

- Patients and clinicians can detect BG excursions facilitating therapeutic adjustments;
- The technology facilitates patient education about T2DM and its management; and
- SMBG immediately motivates patients towards healthier behaviour as opposed to quarterly review of HbA1c levels.

The reassurance given to patients who undertake regular SMBG measurements in itself cannot be underestimated. This instills a regime into patients who become accustomed to the levels that they expect under a well structured plan, and means that changes in SMBG levels or in the range of levels can alert patients to changes in their underlying diabetes. This information can be assessed regularly by the patient, who then does not need to wait up 3-4 months before their next HbA1c level to discuss their diabetes with their GP or HCP.

[10] Klonoff, D, *"Benefits and Limitations of self-monitoring of Blood Glucose"*, J. Diabetes Science and Technology, 2007, 1(1), 130-132

List of Abbreviations and Acronyms

AIHW	Australian Institute of Health and Welfare
GP	General Practitioner
HCP	Healthcare Professional
IVD	*In vitro* Diagnostic
INR	International Normalised Ratio (for blood clotting)
MBS	Medical Benefits Schedule
MSAC	Medical Services Advisory Committee
NDSS	National Diabetes Services Scheme
NHS	National Health Scheme (UK)
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally controlled electronic health record
SMBG	Self monitoring of Blood Glucose
TGA	Therapeutic Goods Administration
T2DM	Type 2 Diabetes mellitus