Post Market Review

Pharmaceutical Benefits Scheme Products Used in the Treatment of Diabetes

Report to the Pharmaceutical Benefits Advisory Committee

Part 1: Blood Glucose Test Strips

Date: December 2012

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Contents

Structure of the Report

This report is presented in four separate parts, as briefly outlined below. The report has been structured in this way to address the Terms of Reference of the Review.

Part 1– Provides the background and context for the Review.

Part 2 – Provides the background regarding the condition, diabetes, and its prevalence and impact in Australia. This part also provides a synopsis of the current National guidelines for self-monitoring of blood glucose in type 2 diabetes.

Part 3 – Provides the analysis of current research on blood glucose test strips used in the treatment of diabetes including their history of PBS listing, costs and restrictions. A systematic literature review, analysis of the utilisation of blood glucose test strips in Australia, summaries of the stakeholder submissions, stakeholder forum, Working Group and Expert Advisory Group advice to the Review are also provided.

Part 4 – Provides a summary of the findings of the Review.

Acronyms

ADEA	Australian Diabetes Educators Association
AIHW	Australian Institute of Health and Welfare
CADTH	Canadian Agency for Drugs and Technologies in Health
CHD	Coronary Heart Disease
DHS	Department of Human Services
DoHA	Department of Health and Ageing
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DVA	Department of Veterans' Affairs
ESC	Economics Sub-Committee (of the PBAC)
HTA	Health Technology Assessment
MNT	Medical Nutrition Therapy
NDSS	National Diabetes Services Scheme
NICE	National Institute for Health and Clinical Excellence
NHMRC	National Health and Medical Research Council
NHPA	National Health Priority Area
NMP	National Medicines Policy
NPS	National Prescribing Service
NZGG	New Zealand Guidelines Group
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBD	Pharmaceutical Benefits Division
PIN	Patient Identifier
PMM	Post Market Monitoring
PPB	Pharmaceutical Policy Branch

PVD	Peripheral Vascular Disease
QUM	Quality Use of Medicines
RCT	Randomised Control Trial
RPBS	Repatriation Pharmaceutical Benefits Scheme
SIGN	Scottish Intercollegiate Guidelines Network
SMBG	Self-Monitoring of Blood Glucose
SMUG	Self-Monitoring of Urine Glucose
TGA	The Therapeutic Goods Administration
The Department	The Department of Health and Ageing
ToR	Terms of Reference
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization

1. Background

1.1 Context for the Review

1.1.1 The Pharmaceutical Benefits Scheme (PBS)

The PBS provides reliable, timely and affordable access to a wide range of medicines for all Australians. Under the PBS, the Australian Government subsidises medicine costs to help people pay for prescription medicines for most medical conditions.

1.1.2 The Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC is the independent, expert advisory body comprising doctors, other health professionals and a consumer representative, which makes recommendations to the Australian Government about PBS listings. This Committee examines applications for PBS subsidy on the basis of a medicine's clinical effectiveness and value-for-money for the intended use, in comparison with other available treatments. In accordance with the *National Health Act 1953 (the Act)*, the PBAC must consider both the effectiveness and cost of proposed medicines when making a recommendation to the Government to list a medicine on the PBS (PBAC Guidelines V 4.3, p3). The PBAC's role also involves ongoing monitoring of the use of PBS-listed medicines, to ensure they continue to be used in the way that was intended when originally recommended, and to ensure ongoing safe and cost effective use that continues to provide value for money.

1.1.3 Post-Market Monitoring

The 2011-12 Budget measure *Improving sustainability of the PBS through enhanced post-market surveillance* provides funding for reviews aimed at improving patient safety, quality use of medicines and the cost effective use of PBS listed medicines. This is in line with the Australian Government's broader National Medicines Policy (NMP) and the role of the PBAC to monitor ongoing utilisation of PBS-listed medicines.

1.2 About the Review

Aimed at assisting the overall management of diabetes including the clinical and cost effectiveness of the medicines and products used to treat diabetes, a Post Market Monitoring (PMM) review on products used in the treatment of diabetes is being undertaken within the context of Australia's NMP.

The overarching post-market review of products and medicines to treat diabetes consists of a number of different projects, including:

- Drug utilisation including safety and analysis of utilisation of type 2 diabetes medicines, and listing review;
- Drug restrictions pertaining to type 2 diabetes medicines reviewed against current guidelines;

- Blood glucose test strips in persons with type 2 diabetes not using insulin; and
- Insulin Pumps: the clinical benefits of insulin pump therapy for type 1 diabetes across age groups.

Other Government programs and activities relating to diabetes, such as supply of blood glucose test strips through the National diabetes Services Scheme (NDSS), and the Diabetes MedsCheck, an in-pharmacy, patient centred service that provides a review of the patient's diabetes medication and monitoring management will be considered in the context of the overarching review of diabetes management to ensure a comprehensive approach to this review is achieved.

The objective of this review is to systematically evaluate the body of clinical evidence regarding diabetes interventions to ensure the most appropriate management of diabetes in clinical practice. This review aims to ensure that patients are using the most appropriate medicines and products, effectively and safely, to achieve optimal health outcomes and support quality use of medicines.

The diabetes review will focus on the management of the condition overall and how all medicines and products are being used to benefit patients, alongside other aspects of diabetes management. The groups of medicines and products under review include anti-hyperglycaemic agents, insulin pumps, and blood glucose test strips.

1.2.1 Terms of Reference of the Review

Given the scope of the Review and the significant health issue that diabetes represents, the review is being progressed in a staged approach. The first component under consideration in this Report focuses on blood glucose test strips given that they are a precursor to other medicines and aspects of diabetes management (Terms of Reference 5 – 7 below). That is, testing is intended to be used to achieve stability and better inform the best therapeutic approach. The Review is being staged to ensure all aspects of diabetes management are considered comprehensively.

At its August 2012 special meeting, the PBAC endorsed the following terms of reference for the overarching PMM review of diabetes.

Purpose: To examine and characterise the complexity and heterogeneity of PBS listings for drugs used in type 2 diabetes mellitus (T2DM); and to review self-monitored blood glucose testing for people with T2DM and insulin pumps for people with type 1 diabetes mellitus (T1DM) to inform an assessment of their effectiveness in terms of clinical outcomes and cost.

1. Describe the utilisation and patterns of treatment of PBS listed drugs for T2DM, and compare these with PBS restrictions;
2. Consider if the utilisation of PBS listed drugs in current clinical practice represents expected cost-effective use;
3. Consolidate the clinical trial evidence used to support PBS listings of diabetes medicines listed since 2002;

4. Collate and evaluate any additional clinical studies or meta-analyses for drugs currently PBS listed for T2DM that the Pharmaceutical Benefits Advisory Committee (PBAC) has not seen and that would inform their consideration;

5. **Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with Type 2 diabetes;**
6. **Determine the clinical outcomes and benefits (e.g. HbA1C) of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with Type 2 diabetes not treated with insulin;**
7. **Consider the clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring;**

8. Determine the clinical outcomes (e.g. HbA1C, health-related quality of life, and other potential benefits and harms) for people with Type 1 diabetes) of insulin pump therapy. In this, consideration should be given to different age groups, with a particular reference to those under 18 who may be eligible for the Insulin Pump Program which is funded by the Australian Government;
9. Investigate the effectiveness and costs of different insulin pumps available under the Insulin Pump Program; and
10. Consider the clinical criteria and eligibility under the Insulin Pump Program, to ensure those who would most benefit from insulin pump therapy receive support to assist in their care.

1.2.2 Overview of the Review Process

This component of the Review aims to evaluate the clinical evidence to support the ongoing use of regular self-monitoring of blood glucose using test strips in people with type 2 diabetes not using insulin.

Open public consultation processes will be undertaken for all components of the review to ensure that all stakeholders are provided with the opportunity to contribute. This will be carried out in stages with the first stage being blood glucose test strips.

Input from stakeholders was sought by directly inviting submissions to address the Review's Terms of Reference relating to blood glucose test strips and by placing information and a call for submissions on the pbs.gov.au website. The call for submissions was open between 2 October and 15 November 2012. A summary of these submissions is included in Part 3.5 of this report.

A stakeholder forum was convened on 19 November 2012 to provide a further opportunity for stakeholders to input into the Review. This forum was supported by an external facilitator and a contractor was employed to summarise the outcomes.

A small working group consisting of key government agencies was formed to provide a forum for communication to discuss potential flow-on implications on agencies. An Expert Advisory Group was also established to provide consumer, clinical, and technical advice to inform this review.

An external Research group from the University of South Australia was engaged to conduct the literature searches and evaluation of more recent clinical evidence on these products. A separate external research group from the University of South Australia, the Department of Veterans' Affairs (DVA) Veterans' Medicines Advice and Therapeutics Education Services (MATES) project, was engaged to undertake an utilisation analysis of data sourced from PBS data provided by the Department. In addition, an analysis of estimates of supply of prescriptions per patient on the NDSS and the PBS was undertaken for comparison purposes.

2. Diabetes

2.1 Diabetes

Diabetes is a chronic disease characterised by high levels of glucose in the blood. Blood glucose levels are controlled by insulin, a hormone produced by the pancreas. Diabetes occurs when the pancreas is unable to produce enough insulin, or the body becomes resistant to insulin, or both (World Health Organization 2012).

Without insulin or if insulin production or action are ineffective, the body cannot turn glucose into energy and results in glucose remaining in the blood, causing blood glucose levels to become high. This can result in a number of complications, including serious damage to the nerves and blood vessels (AIHW 2008).

Diabetes mellitus was endorsed as a National Health Priority Area (NHPA) at the Australian Health Minister's Conference in 1996 in recognition of the high prevalence of the disease in Australia, its impact on morbidity and mortality, and its potential for health improvements through prevention and treatment programs.

2.2 Criteria for diagnosis

The current World Health Organization (2006) diagnostic criteria for diabetes include:

- Fasting plasma glucose ≥ 7.0mmol/l (126mg/dl); or
- 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).

HbA1c has recently been accepted as an additional test to diagnose diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement (World Health Organization 2011).

An HbA1c of 6.5% (48 mmol/mol) is recommended as the cut point for diagnosing diabetes. A value less than 6.5% does not exclude diabetes diagnosed using glucose tests (World Health Organization 2011).

HbA1c (glycated haemoglobin) is a laboratory test that shows the average level of blood glucose (glucose) over the previous 3 months (Diabetes Australia 2009). It is another test used to provide an indication of how well a patient's diabetes is being controlled. High levels of HbA1c indicate poor glycaemic control. The Diabetes Control and Complications Trial (DCCT) in Type 1 diabetes and the UK Prospective Diabetes Study (UKPDS) in Type 2 diabetes both showed that, as HbA1c increases, the risk of microvascular and macrovascular complications of diabetes increases. HbA1c thus gives a measure of an individual's risk of the long-term complications of diabetes.

HbA1c testing provides clinicians with a reliable indication that therapy is working appropriately and the risk of long-term complications, particularly microvascular complications is reduced (Saudek & Brick 2009). The test doesn't show the highs and lows that regular self-testing show and therefore does not replace, but is an added tool, in giving the overall picture of blood glucose management (Diabetes Australia 2010).

Tight glycaemic control reduces the risk of development and progression of organ complications in people with both type 1 and type 2 diabetes. The Australian Diabetes Society recommends a general target HbA1c of ≤7.0% for most patients. HbA1c targets however, need to be individualised for example, this may need to be higher for some people including children and the elderly (Diabetes Australia 2009).

However it should be noted that glycation of haemoglobin occurs only as the erythrocyte circulates in serum, therefore anything that alters red blood cell survival will influence HbA1c independent of glycaemia (Saudek & Brick 2009). In people with conditions associated with shortened red cell survival where HbA1c is less reliable (e.g. thalassemia, portal hypertension, haemolytic anaemia), then measured HbA1c will be lower, independent of glycaemia. Conversely, if the average age of circulating erythrocytes is older, then the older red cell population would have higher HbA1c levels (Saudek & Brick 2009). In these patients, HbA1c is less reliable and self-monitoring of blood glucose and fructosamine, which measures the glycation of all serum proteins, may be of more value (Saudek & Brick 2009).

2.3 Types of diabetes

There are three main types of diabetes, Type I, Type II and gestational diabetes (World Health Organization 2012). Gestational diabetes occurs during pregnancy and usually disappears once the baby is born. However, a history of gestational diabetes increases a woman's risk of developing type 2 diabetes later in life. It is estimated that gestational diabetes mellitus affects women in about 3 - 8% of pregnancies (Diabetes Australia 2012). Additionally, certain populations including Aboriginal or Torres Strait Islander, Indian, Vietnamese, Chinese, Middle Eastern or Polynesian cultural backgrounds are at increased risk of gestational diabetes (Diabetes Australia 2012).

2.3.1 Type 1 diabetes

Type 1 diabetes is an auto-immune disease where the body's immune system attacks the insulin producing cells of the pancreas. People with type 1 diabetes cannot produce insulin and require lifelong insulin injections for survival (WHO 2012).

Without insulin, the body cannot convert glucose into energy and instead burns its own fats as a substitute. Unless treated with insulin, people with type 1 diabetes accumulate dangerous chemicals in their blood from the burning of fat, causing a condition known as ketoacidosis. This condition is potentially life-threatening if not treated. Type 1 diabetes can occur at any age, although it mostly occurs in children and young adults.

Type 1 diabetes is sometimes referred to as juvenile onset diabetes or insulin dependent diabetes. Type 1 affects 10%–15% of people with diabetes (AIHW 2008).

2.3.2 Type 2 diabetes

Type 2 diabetes is marked by the inability of the body to use insulin properly (insulin resistance) and reduced levels of insulin (AIHW 2008). It is associated with hereditary factors and lifestyle risk factors including poor diet, insufficient physical activity and overweight or obesity (Shaw & Chisholm 2003). People with type 2 diabetes may be able to manage their condition through lifestyle changes; however, diabetes medications or insulin injections may also be required to control blood glucose levels. Type 2 diabetes occurs mostly in people aged over 40 years old. However, the disease is also becoming increasingly prevalent in younger age groups. About 83% of self-reported cases of diagnosed diabetes in 2004-05 were Type 2 (AIHW 2008).

2.4 Prevalence of Diabetes in Australia

According to the Australian Health Survey, in 2011-12, 4.0% of the Australian population (875,400 people) reported having some type of diabetes (excluding gestational diabetes). The Australian Diabetes, Obesity and Lifestyle (AusDiab) study (2005), the largest Australian longitudinal population-based study examining the natural history of diabetes, pre-diabetes (in which glucose metabolism is impaired but not to the level to cause diabetes), heart disease and kidney disease reported that 0.8% of Australian adults developed diabetes every year.

The prevalence of diabetes in Australia has more than doubled since 1995 (407,900 people). This substantial increase has been attributed to more people developing the disease, but also people with diabetes living longer and improved detection of the disease. However, the prevalence of diabetes has remained stable between 2007-08 and 2011-12 (both 4.0%) (Australian Bureau of Statistics 2012).

Of persons who reported having diabetes, the majority had Type 2 diabetes (85.3%), while 12.4% had Type 1 diabetes and the remainder had an unspecified type of diabetes (2.3%). More men reported having diabetes than women (4.3% of all men compared with 3.6% of all women) and as with many health conditions, the rate of diabetes increased with age. People aged 65-74 years had the highest rate of diabetes (16.0%) (Australian Bureau of Statistics 2012).

Type 2 diabetes is over-represented among Indigenous Australian persons and a number of other populations including Chinese, Vietnamese, Indian, and Maltese heritage (International Diabetes Federation 2012). In the 2004-05 Australian National Aboriginal and Torres Strait Islander Health Survey, the self-reported prevalence of diabetes among Aboriginal and Torres Strait Islander people was 6%. After adjusting for differences in age structure, Aboriginal and Torres Strait Islander people were 3 times as likely as other Australians to report diabetes as a long-term health condition. However, among those aged 45–54 years, they were 5 times as likely.

2.5 Impact of Diabetes in Australia

Diabetes significantly affects the health of many Australians and can result in a range of complications. Untreated or poorly managed diabetes can lead to complications involving many parts of the body, including coronary heart disease, stroke, kidney failure, limb amputations or blindness (Australian Bureau of Statistics 2012).

In 2004, diabetes was among the top ten leading causes of death being the direct cause of 2.7% of deaths in Australia, and being associated with another 6% of deaths (Australian Bureau of Statistics, 2006). Cardiovascular disease is the major cause of death in people with diabetes, accounting for approximately 50% of all fatalities (International Diabetes Federation 2011). In 2005, diabetes was associated with cause of death in nearly 11,900 Australian deaths or 9% of all deaths that year. Approximately half of these deaths involved CHD (48%), stroke (16%), and PVD in 6% of diabetes deaths (AIHW 2008).

7.2 million pharmaceutical prescriptions were claimed for diabetes medicines in 2011. The number of prescriptions claimed per year has been increasing (Australian Bureau of Statistics 2012). $990 million was spent on treating diabetes in 2004–05, which represented 1.9% of all health expenditure. This is the current figure considered in the most recent Australian Bureau of Statistics (ABS) Australian Health Survey (2011-12).

2.6 Guidelines for the Management of Diabetes

The following section summarises best-practice guidelines relating to blood glucose control in type 2 diabetes that have been developed for health professionals by medical experts and researchers. These are aimed at the practicing health professional.

Diabetes Australia (National Health and Medical Research Council-Approved) National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes

This Guideline addresses the topic of blood glucose control in people with type 2 diabetes and provides guidance on a number of issues relating to the assessment and management of blood glucose levels in people with type 2 diabetes.

The Guidelines are a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case. The guidelines are designed to provide information to assist decision-making and are based on the best evidence available at the time of development.

Key recommendations of the Guideline, and their level of evidence, include:

- Blood glucose control should be optimised because of its beneficial effects on the development and progression of microvascular complications (retinopathy, neuropathy, nephropathy) (Grade A);
- The potential harmful effects of optimising blood glucose control in people with type 2 diabetes should be considered when setting individual glycaemic targets(Grade A);
- Glycated haemoglobin (HbA1c) measurement should be used to assess long term blood glucose control (Grade A);
- Self-monitoring of blood glucose (SMBG) should be considered in all people with type 2 diabetes but the decision to perform SMBG, and the frequency and timing of testing, should be individualised (Grade C);
- The general HbA1c target in people with type 2 diabetes is ≤ 7%. Adjustment to diabetes treatment should be considered when HbA1c is above this level (Grade A);
- Targets for self-monitored blood glucose levels are 6–8 mmol/L fasting and preprandial, and 6–10 mmol/L 2 h postprandial (Grade C);
- Interventions to achieve target glycated haemoglobin should begin with lifestyle modification followed by pharmacological options selected on the basis of individual clinical circumstances, side effects and contraindications (Grade A);
- Routine care of people with type 2 diabetes should address disparities associated with socio-economic status and ethnicity (Grade C).

2.7 Australian and International Guidelines on SMBG for People with Type 2 Diabetes

The following is a summary of Australian and international guidelines on the use of BGTS to allow for an assessment of their comparative differences.

Australia

Australia is unique in that access to blood glucose test strips is universal and virtually unlimited, as described below at sections 3.1.1 and 3.1.2. The following discussion of Australian and international best practice guidelines must be considered with respect to their applicability to the Australian context and its unique health care system.

Although consideration of international practices must be given, they cannot necessarily be directly compared and applied to the Australian context.

The guidelines adopted by Diabetes Australia and the Royal Australian College of General Practitioners on diabetes management in general practice (2011) do recommend SMBG for those on agents that can cause hypoglycaemia (e.g. sulphonylureas and insulin). They do not provide references to support their recommendations.

They state 'despite some recent controversial studies, the current view is that blood glucose monitoring is recommended….A suggested initial schedule of testing is 3 to 4 blood glucose tests daily (early morning, plus other tests before and/or after meals). Frequent consultation with health care professionals is important. Self-monitoring needs to be individualised and assist people with diabetes to understand the impact of medication, food and physical activity on blood glucose control. Frequency of monitoring can be determined according to the individual's self-management goals'.

The Australian Diabetes Educators Association (ADEA) provides a 2010 position statement that does not include definitive recommendations for use of SMBG in patients with type 2 diabetes. They state that 'there is still debate as to the utility of self-monitoring in people with type 2 diabetes who do not use insulin therapy. Therefore the decision to self-monitor blood glucose should be determined by the individual in consultation with their health care professional' (Australian Diabetes Educators Association 2010).

The ADEA has also commissioned a review assessed earlier in this report (Baker IDI 2011) that includes a list of recommendations for practice that are more in favour of SMBG including, 'the use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment'.

The guideline for Blood Glucose Control in Type 2 Diabetes undertaken for the Diabetes Australia Guideline Development Consortium (Diabetes Australia, Australian Diabetes Society, the Australian Diabetes Educators' Association, the Royal Australian College of General Practitioners and the University of Sydney) and approved by the NHMRC states that 'SMBG should be considered in all people with type 2 diabetes but the decision to perform SMBG, and the frequency and timing of testing, should be individualised" (grade C evidence) (Colagiuri, Dickinson et al. 2009).

This Guideline further notes that self-monitoring of blood glucose provides 'real time feedback to people with diabetes, their carers and health professionals…. [and in addition to improving safety, it] is an educational tool to inform both patient and health care professionals about the effects of lifestyle, behavioural and/or medication changes'.

In Australia, a patient can access test strips through the NDSS regardless of their disease state, level of glycaemic control or current medication regimen. It is therefore important to consider whether current access arrangements may be inadvertently promoting inappropriate or less than clinically optimal practice.

United Kingdom

The Scottish Intercollegiate Guidelines Network (SIGN) guidelines state that 'routine self-monitoring of blood glucose in people with type 2 diabetes who are using oral glucose-lowering drugs (with the exception of sulphonylureas) is not recommended' (Scottish Intercollegiate Guidelines Network 2010).

The NICE guideline that relied on older evidence than SIGN recommended 'offer self-monitoring of plasma glucose to a person newly diagnosed with Type 2 diabetes only as an integral part of his or her self-management education' (National Collaborating Centre for Chronic Conditions 2008).

Diabetes UK produces a position statement that refers to the NICE guidelines and support individualised decisions and not the blanket removal of strips from prescriptions (Diabetes UK 2009).

New Zealand

The New Zealand guidelines developed by the New Zealand Guidelines Group (NZGG) and endorsed by the New Zealand Society for the Study of Diabetes refers to the SIGN guideline and a position from the NZGG Diabetes advisory group (New Zealand Guidelines Group 2011). In New Zealand, the number of blood glucose test strips available on a prescription is restricted to 50 for patients with T2DM, unless the patient has also been prescribed insulin or a sulphonylurea, or is pregnant.

United States

The American Diabetes Association recommends that 'for patients using less-frequent insulin injections, non-insulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to management' (American Diabetes Association 2012).

Canada

The Canadian Agency for Drugs and Technologies in Health (CADTH) Recommendations on Self-Monitoring of Blood Glucose Using Test Strips state that for most adults with type 2 diabetes using oral anti-diabetes drugs (without insulin) or no anti-diabetes drugs, the routine use of blood glucose test strips for SMBG is not recommended.

International

The Coalition for Clinical Research—Self-Monitoring of Blood Glucose Scientific Board published recommendations after a meeting of 12 physician panel members from the United States, Brazil, Canada, France, Germany, Italy, and the United Kingdom in San Francisco in 2011 (Klonoff, Blonde et al. 2011). It stated that 'to be most effective, it should be performed in a structured format where information obtained from this measurement is used to guide treatment'.

The International Diabetes Federation adopted recommendations based on a workshop of the International Diabetes Federation Clinical Guidelines Taskforce in collaboration with the SMBG International Working Group (International Diabetes Federation 2009). It states that 'SMBG should be used only when individuals with diabetes (and/or their caregivers) and/or their healthcare providers have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals'.

In considering guidelines and recommendations from the main professional and health technology organisations, the literature review indicated that most guidelines recognised the lack of strong evidence supporting the use of self-monitoring of blood glucose levels in terms of HbA1c improvement.

2.8 National Prescribing Service (NPS) Programs and Publications on Diabetes

The information that follows is a brief summary of diabetes programs conducted by the NPS and publications in which diabetes is the main focus.

2.8.1 Programs

Academic detailing programs

NPS has developed and implemented four academic detailing programs focusing on Type 2 Diabetes, since its conception in 1998. Details of these four programs are outlined below:

1. ***Type 2 Diabetes: Priorities and targets (2012)***

NPS Facilitators were up skilled in August 2012 and delivery of this program will be completed by December 2013. As of 27 November 2012, a total of 2407 health professionals had been actively engaged. Of these 1890 were general practitioners.

Key messages of the program:

- Address blood pressure (BP) and lipids as a priority;
- Treat according to cardiovascular risk;
- Controlling BP and lipids appears more effective in reducing CVD than tightening blood glucose levels;
- Individualise blood glucose targets based on patient factors and duration of disease;
- Lowering blood glucose levels reduces microvascular complications;
- Use Australia Diabetes Society position statement to individualise HbA1c targets

Messages that relate to self-monitoring of blood glucose:

- Identify patients who may benefit from self-monitoring blood glucose;
- Defined purpose for testing is necessary;

- Recommended for people using insulin;
- Potential benefit where modifying treatment, to help identify or treat hyper/hypoglycaemia and to encourage self-management.

2. Early use of insulin and oral anti-diabetic agents (2008)

NPS Facilitators were up skilled in February/March 2008 and delivery of this program was completed in July 2009. At the completion of this program, a total of 11197 health professional had been actively engaged. Of these 8745 were general practitioners.

Key messages/features of program:

- Early and continuing lifestyle interventions decrease disease progression;
- Initiate insulin early by adding night-time basal insulin to oral antidiabetic agents;
- Ensure metformin is part of ongoing therapy and use of thiazolidinediones does not delay progression to insulin;
- Review use of thiazolidinediones in heart failure and ischaemic heart disease
    - Safety concerns of glitazones
    - Use glitazones only when the risks are acceptable
    - Monitor patient (HbA1c, LFT and adverse effects)

3. Reducing risk in Type 2 Diabetes (2005)

NPS Facilitators were up skilled from May 2005 onwards and delivery of this program was completed by December 2006. At the completion of this program, a total of 6749 health professionals had been actively engaged. Of these 5742 were general practitioners.

Key messages/features of program

- Encourage intensive lifestyle change to slow progression to diabetes and prevent complications
    - Focus on diet, weight loss and exercise to slow the progression to diabetes
    - Emphasis on the importance of maintaining lifestyle change in the long term
    - Impact of lifestyle change on glycaemic control and complications of diabetes
- Assess and manage overall cardiovascular risk early
    - Focus on multifactorial intervention
    - Attention to blood pressure control and treatment of dyslipidaemia
    - The role of aspirin for patients with diabetes

- Metformin remains the drug of choice in type 2 diabetes, especially in overweight people
- Role of the thiazolidinediones in therapy
- Consider insulin early when blood glucose control fails with maximal oral therapy
    - Focus on identifying the need for insulin in individual patients, and responding to the need without delay
    - Benefits of insulin therapy
    - Pros and cons of progressing to triple oral therapy and introducing insulin to dual oral therapeutic regimen

4. ***Management of Type 2 diabetes mellitus in general practice (2001)***

NPS Facilitators were up skilled from November 2001 onwards and delivery of this program was completed in early 2003. At the completion of this program, a total of 5763 health professional had been actively engaged. Of these 5552 were general practitioners.

Key messages/features of program

- Metformin is the preferred initial drug therapy unless contraindicated
- Metformin and sulfonylureas remain the drugs of choice in Type 2 diabetes
- Assess and manage all cardiovascular risk factors
    - Optimise blood pressure control
- Individualise lifestyle interventions, targets, monitoring and drug therapy

2.8.2 NPS Articles on Diabetes

Self-monitoring of blood glucose in type 2 diabetes
http://www.australianprescriber.com/magazine/33/5/138/40

Drugs for gestational diabetes
http://www.australianprescriber.com/magazine/33/5/141/4

'How low to go with glucose control'
http://www.australianprescriber.com/magazine/32/2/30/1

Experimental and clinical pharmacology - 'Incretin mimetics and enhancers: mechanisms of action'
http://www.australianprescriber.com/magazine/31/4/102/4

Experimental and clinical pharmacology - 'Incretin mimetics and enhancers: clinical applications' http://www.australianprescriber.com/magazine/31/4/104/8

'Have glitazones lost their sparkle?'
http://www.australianprescriber.com/magazine/31/3/58/9

Prescribing exercise for diabetes
http://www.australianprescriber.com/magazine/30/5/130/3

Metformin in pregnancy and lactation
http://www.australianprescriber.com/magazine/30/3/68/9

Managing foot infections in patients with diabetes
http://www.australianprescriber.com/magazine/30/1/21/4

Insulin prescribing: http://www.australianprescriber.com/magazine/33/5/artid/1134

A number of other publications including recent articles on diabetes medicines can be found on the NPS website at www.nps.org.au.

3. Blood Glucose Test Strips

3.1 Background

Self-monitoring of blood glucose (SMBG) is one tool which can assist in the management of diabetes mellitus. In patients with type 1 diabetes, SMBG is used to guide insulin dose adjustments, thereby improving glycaemic control (Cochrane 2012). Glycated haemoglobin (HbA1c) is measured to identify the average blood glucose concentration over prolonged periods of time. High levels of HbA1c indicate poor glycaemic control and have been associated with increased risk of diabetes-related complications (Saudek & Brick 2009).

Blood glucose levels can be monitored through the use of a self-monitoring test administered through the use of a blood glucose test strip. A small amount of blood is applied to the test strip, and glucose concentration is determined by inserting the strip into a reflectance photometer, or an electrochemical sensor (Canadian Agency for Drugs and Technologies in Health 2010). Results of the test are available almost immediately.

Blood glucose test strips (test strips) are used in conjunction with a blood glucose monitor to detect how much glucose is present in the blood. A wide variety of diabetes test strips are available on the Australian market.

Patients with diabetes who require insulin have to monitor their blood glucose by finger-prick (capillary) testing up to 3–4 times or more a day along with their 1–5 insulin injections or use of continuous subcutaneous insulin infusion pump. The need for this is widely accepted, but the principle of frequent daily monitoring is also currently being applied to people who are not on insulin (Aust Prescr 2010).

There is still much debate about the use and effectiveness of SMBG in patients with type 2 diabetes who are not using insulin (Cochrane 2012). SMBG can be used to guide patients to adjust physical activity or food intake and heath care providers to start or titrate blood glucose-lowering agents during periodical consultation with patients.

There is more information being published including a Cochrane Collaboration Review published in January 2012, a 2009 Canadian study (COMPUS) and a 2010 German study questioning evidence of the benefit and effectiveness of regular (trained, systematically used, etc.) use of glucose test strips in people with type 2 diabetes not using insulin (Schwedes et al 2002). This changing perspective has instigated the present review of SMBG in people with type 2 diabetes not using insulin in Australia.

3.1.1 Pharmaceutical Benefits Scheme subsidisation of test strips

Access to affordable and effective monitoring equipment and medicines is essential in the management of diabetes. Currently, all Australians regardless of disease state are eligible to access test strips through the PBS on prescription from a medical practitioner. Access to test strips is only restricted in the following two circumstances:

1. In order to access more than the standard five repeats, patients must be treated under a GP Management Plan or Team Care Arrangement; and
2. One brand of test strips, Accu-Chek Mobile, is only available to patients on insulin therapy.

BGTS were first listed on the PBS in December 1969. These first test strips were paper reagent strips that had an outer semipermeable membrane to trap red blood cells whilst allowing soluble glucose to pass through to react with the dry reagents (Clarke & Foster 2012). The first blood glucose meters, instruments that could produce quantitative blood glucose results using test strips, became available in the 1970s.

The introduction of test strips on the PBS occurred prior to the Government's adoption of the comparative effectiveness and cost evaluation framework and their listings have not since been reviewed. The introduction of comparative cost-effectiveness was undertaken by the PBAC through an amendment to the National Health Act in 1987. From 1991, submissions by sponsors began to include an economic analysis and from January 1993 this was made mandatory.

Test strips are available under the PBS in pack sizes of 50 or 100 strips. The current PBS co-payments of $35.40 for general patients and $5.80 for concessional patients apply to blood glucose test strips obtained through the PBS. The dispensed price for maximum quantity (two boxes of 50 or one box of 100 strips) ranges from $46 to $53.28. The PBS dispensed price consists of:

- The approved price to pharmacist (ex-manufacturer price + 7.52% wholesaler mark-up);
- Mark-up by the pharmacist ($4.50); and
- Dispensing fees ($6.52).

3.1.2 National Diabetes Services Scheme

The National Diabetes Services Scheme (NDSS) is an initiative of the Australian Government administered by Diabetes Australia. The NDSS delivers diabetes-related products, including syringes and needles, blood glucose test strips, urine ketone test strips and insulin pump consumables at subsidised prices and provides information and support services to people with diabetes. Registration is free and open to all Australians diagnosed with diabetes.

All Australians with a diagnosis of diabetes, of any type, are eligible to access test strips through the NDSS without a prescription provided they are registered under the scheme.

On average, the cost price for blood glucose test strips is $19.65 for a box of 50 and $39.29 for a box of 100 according to the NDSS. This cost is subsidised through the NDSS scheme and the following co-payment arrangements currently apply:

- For general registrants, the current co-payment is $7.60 for a box of 50 strips and $15.20 for a box of 100 strips;
- For concessional registrants, the current co-payment is $1.20 for a box of 50 strips and $2.40 for a box of 100 strips; and
- For pensioners, the current co-payment is $0.60 for a box of 50 strips and $1.20 for a box of 100 strips.

3.1.3 Regulation of Medical Device Advertising

In Australia, medical devices may be advertised directly to consumers. All advertisements for therapeutic goods are subject to the Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, the Competition and Consumer Act 2010 and other relevant laws. Advertisements for therapeutic goods directed to consumers must comply with the Therapeutic Goods Advertising Code 2007 (the Code).

The purpose of the Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

The regulatory requirements for direct-to-consumer advertising of medical devices are similar to those applying to direct-to-consumer advertising of non-prescription medicines. However there is no requirement for prior approval of these advertisements.

Industry self-regulation, such as the Medical Technology Association of Australia (MTAA) Code of Practice regulates the professional conduct of manufacturers for advertising that is directed exclusively to healthcare professionals. Such advertisements must:

a. comply with the Code and relevant Laws and Regulations;

b. not be misleading or deceptive, or likely to mislead or deceive;

c. reflect a high standard of social responsibility and conform to generally accepted standards of good taste;

d. be readily recognisable by the target audience as an Advertisement;

e. not claim that a Medical Technology is unique or has some special merit, quality or property unless the claim can be substantiated;

f. not use the term "safe" without appropriate qualification;

g. not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse;

h. not use, the term "new", or any other term having the same connotation in an Advertisement to describe a Medical Technology after one year from the date of the product's launch, unless appropriately qualified;

i. comply with the laws and regulations for both Medical Devices and Scheduled Medicines where the Medical Technology consists of both a Medical Device and a Scheduled Medicine; and

j. conform with all requirements of the Code, except to the extent that any such requirement may be in conflict with any provision of the Advertising Code.

In addition, the advertisement must contain the following mandatory information:

(i) the brand name of the Medical Technology (where appropriate);

(ii) the name and contact details of the Sponsor;

(iii) claims consistent with the intended purpose of the Medical Technology; and

(iv) all such other information as may be required by law or as a condition of grant of a licence.

3.2 Literature review of the use and clinical effectiveness of blood glucose test strips and ongoing self-monitoring in people with type 2 diabetes not using insulin

Studies and other recent evidence suggest that there is some initial benefit gained from blood glucose monitoring when a person is first diagnosed with type 2 diabetes. However, they suggest that over time, that benefit is reduced as a person's diabetes stabilises. Further, that while regular testing may assist in identifying hyperglycaemia, regular engagement with healthcare professionals and periodic testing of a patient's HbA1c is of greater benefit for patients not using insulin.

For example, a Cochrane Collaboration Review published in January 2012 found limited evidence of the benefit and effectiveness of regular use of glucose test strips in people with type 2 diabetes not using insulin. This review found that for people not using insulin: "…results of studies including patients diagnosed with type 2 diabetes for at least one year show that self-monitoring of blood glucose has a minimal effect in improving glucose control at six months, which disappears after 12 months follow-up" and that "the clinical benefit resulting from this effect is limited."

A 2009 Canadian study (COMPUS) and a 2010 German study also highlighted that there was little evidence that self-monitoring improved health-related quality of life, patient satisfaction, long-term complications and associated mortality.

These studies further suggested that ongoing support for other targeted interventions to improve a person's glycaemic control is more effective. This may include targeted education and interventions by healthcare professionals that seek to support healthy lifestyle choices (for example, diet and other risk factors such as alcohol) and regular periodic testing of HbA1c (which gives an average of blood glucose levels over three months) to inform overall glycaemic management. It should be noted that education and support activities may come at an additional cost.

As a result of such evidence, in June 2012 the Department commissioned the University of South Australia to undertake a literature review to further examine the use of and clinical benefits associated with blood glucose test strips and ongoing self-monitoring of blood glucose (SMBG) levels in people with type 2 diabetes who are not using insulin.

The brief for the literature review was to consider only literature and evidence related to the clinical effectiveness of self-monitoring of blood glucose in people with type 2 diabetes not using insulin.

The literature search included all systematic reviews and meta-analyses on this topic published since 2000, as well as randomized controlled trials (RCTs) and large observational studies (500 participants or more) that had not been included in the systematic reviews (published up to June 2012). It also identified current position statements and guidelines by professional organisations that made recommendations on the use of Self-Monitoring of Blood Glucose (2009 up to June 2012).

Nine systematic reviews were included, as well as two recent trials and one recent observational study that had not been included in previous reviews.

In response to the research questions, the findings of the literature review are summarised below.

What is the evidence that SMBG improves outcomes compared to no SMBG in patients with type 2 diabetes who are not using insulin?

HbA1c

Seven meta-analyses found that the use of SMBG was associated with a small decrease in HbA1c ranging between -0.10% to -0.31%, which was statistically significant in most cases (Allemann, Houriet et al. 2009; Poolsup, Suksomboon et al. 2009; McIntosh, Yu et al. 2010; St John, Davis et al. 2010; Baker IDI 2011; Farmer, Perera et al. 2012; Malanda, Welschen et al. 2012). Most meta-analyses showed an average decrease around -0.25%. This benefit is less than the 0.5% change in HbA1c usually considered clinically significant, however, it might be considered important from a public health perspective.

Hypoglycaemias

Six clinical trials identified in the systematic reviews investigated hypoglycaemia in relation with SMBG use. In one trial, there was a significantly higher frequency of hypoglycaemia in the SMBG group (p=0.00) explained by a between-group difference in patients reporting asymptomatic hypoglycaemia only (p=0.001) (Guerci, Drouin et al. 2003). In one trial, there was an increased frequency of hypoglycaemia in self-monitoring individuals (mild symptomatic hypoglycaemia: intense SMBG 28.5%, less intense SMBG: 22%. No SMBG 9.2%) (Farmer, Wade et al. 2007). It was unclear whether this difference resulted from biochemical differences or greater awareness of hypoglycaemia as a cause of symptoms. Further, blood glucose meters can show variability in accuracy at the lower (and upper) ends of the glucose spectrum. Self-reported low levels of glucose (e.g. 3 mmol/L) may be of no real significance as the true result may be 4 or 4.5 mmol/L).

Long-term health outcomes (microvascular and macrovascular complications)

Quality observational studies have not demonstrated positive effects. The Fremantle diabetes study involved 1280 type 2 diabetic participants in Western Australia. The mean follow-up period was 9.8 ± 3.5 years (Davis, Bruce et al. 2007). It found that SMBG was not independently associated with all-cause mortality, but was associated with a 79% increased risk of cardiovascular mortality in patients not treated with insulin. It was suggested that this unexpected finding could be explained by the attempt to improve glycaemic control in patients with cardiovascular symptoms. However, given the observational nature of this data, the interpretation of these results is limited.

The Self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (ROSSO) study in Germany, while reporting a positive effect, was subject to immortal time bias (Martin, Schneider et al. 2006; Hoffmann and Andersohn 2011). Immortal time refers to a period of follow-up during which, by design, death or the study outcome cannot occur and thus, the results were not likely to be reliable (Lévesque et al 2010). This period is considered immortal because individuals in the treatment group must 'survive' (be alive and event free) until the treatment definition is fulfilled. If not, they will be in the untreated group. Bias is introduced when this survival period is either misclassified with regards to treatment status or excluded from the analysis (Lévesque et al 2010).

Quality of life, wellbeing and satisfaction

Seven trials compared quality of life, patient satisfaction or patient wellbeing in those on SMBG and those who were not on SMBG. None of the four trials reporting outcomes on treatment satisfaction using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) found significant differences between groups. None of the five trials that assessed patient well-being with the Well-being questionnaire or the WHO-5 Well-Being Index found a significant difference between groups.

Three trials assessed the quality of life using the EuroQol 5 dimensions (EQ-5D), the Diabetes Quality-of-Life inventory or the Short-Form 36 Health Survey Questionnaire (SF-36). Quality of life was significantly lower with the enhanced SMBG compared with no SMBG (-0.072, 95% CI -0.127 to -0.017, $p < 0.05$) in the EQ-5D trial due to the higher level of anxiety and depression compared to the baseline. In one trial, scores on the subscales of the SF-36 showed a small and non-significant worsening in the SMBG group compared to the non SMBG group. There was no difference in quality of life in the trial using the Diabetes Quality-of-Life inventory.

What is the evidence that intensive SMBG (e.g. more frequent, enhanced by educational activities) improves outcomes compared to less intensive SMBG?

Studies of SMBG incorporating educational interventions and studies incorporating different SMBG regimens varied across the RCTs and the interventions were often poorly articulated in the published articles. Therefore, the interventions were difficult to summarise and classify into meaningful and homogeneous categories for the purpose of meta-analysis.

A subgroup analysis in one systematic review indicated that results from three RCTs that provided patients with education regarding application of SMBG results were similar to those from five RCTs that did not provide education with SMBG (McIntosh, Yu et al. 2010). Although difficult to ascertain the exact intervention used in these studies, in implementing such a recommendation into clinical practice it will be important to define the type of education of most benefit in this population. According to a literature review of SMBG in people with type 2 diabetes not using insulin commissioned by the Australian Diabetes Educators Association (2011), 'education should include the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimise glycaemic control'.

A recent trial not included in the previous meta-analyses found that, when SMBG was associated with a structured education program including the training of doctors to consider SMBG results in treatment adjustment, there was a significantly greater reduction in mean HbA1c in the intervention SMBG group compared to the usual care SMBG group (-0.3%; P = 0.04). Further, the reduction was even greater in the subgroup of patients adherent to the protocol (-0.5%; P < 0.003) (Polonsky, Fisher et al. 2011).

Does the evidence demonstrate sub-groups of patients who are more likely to benefit from SMBG (e.g. patients on diet only, patients treated with oral medications only)?

Baseline HbA1c

The results were not consistent between the four meta-analyses that examined the efficacy of SMBG depending on the baseline HbA1c level with 3 meta-analyses finding a greater decrease in HbA1c in people with higher HbA1c levels and one meta-analysis of individual patient data finding no evidence of a differing effect.

Duration of diabetes

The results were not consistent between the three meta-analyses that examined the efficacy of SMBG depending on the duration of diabetes. One meta-analysis found a greater HbA1c decrease in patients with newly diagnosed diabetes, one meta-analysis did not find a significant difference between SMBG and non SMBG groups based on a single trial with newly diagnosed patients, and one meta-analysis found no difference with varied durations of diabetes. These analyses were limited by the small number of trials including patients with newly diagnosed diabetes.

Type of diabetes treatment

No meta-analysis examined the impact of diabetes treatment (diet only, oral anti-diabetic treatments) on the HbA1c differences between SMBG groups and non SMBG groups.

What is the evidence that SMBG improves outcomes compared to Self-Monitoring of Urine Glucose (SMUG) in patients with type 2 diabetes who are not using insulin?

Three older trials (1989-1997) and one recent trial (2011) showed no significant difference between SMBG and SMUG in terms of blood glucose control (HbA1c). The literature review did not find any other studies that met the inclusion criteria on this research topic.

What is the evidence that SMBG improves outcomes compared to no SMBG in patients with type 2 diabetes who are not using insulin and who are managing their diabetes with non-insulin injectable medicines (e.g. exenatide)?

There was no study that examined the use of SMBG in patients who were managing their diabetes with non-insulin injectable medicines (e.g. exenatide).

What are the recommendations of the main professional and HTA organisations for SMBG?

Eleven guidelines or position statements on use of SMBG or SMUG were identified in Australia, United Kingdom, New Zealand, the United States or were published by international organisations. Most guidelines acknowledged the lack of strong quantitative evidence supporting the use of SMBG in terms of HbA1c improvement, and some guidelines also considered qualitative studies where SMBG had been shown to facilitate effective diabetes self-management (Baker IDI 2011).

The guidelines were generally in agreement that, to be effective, SMBG needed to be part of a complex educational intervention that promoted patient behavioural changes and therapeutic medication adjustments more tightly aligned to the results obtained from SMBG.

Recommendations varied with some guidelines recommending the use of SMBG in specific subgroups such as patients on agents that can cause hypoglycaemia, or those with poor glycaemic control, or as part of ongoing diabetes self-management education.

Applicability of the results to the Australian context

No RCTs were undertaken in Australia but most RCTs were done in the European and North American countries with populations and health care standards similar to Australia. All trials included patients with type 2 diabetes and generally with no age exclusions. The differences between RCTs in the way that SMBG was integrated in the management of diabetes complicated direct comparisons between studies. However, a recent meta-analysis of individual patient data concluded that the differences in the effect size observed between individual trials did not suggest that differences in the way SMBG has been used to date or the characteristics of trial participants might contribute to important differences in the observed effect (Farmer, Perera et al. 2012). This suggests the results are likely to be generalisable to the Australian population and health care setting.

This literature review demonstrated that ongoing self-monitoring of blood glucose levels in people with type 2 diabetes not using insulin does produce statistically significant changes, with a 0.25 to 0.3 per cent reduction in HbA1c levels. However, self-monitoring does not produce the clinically significant change of 0.5 per cent for the majority of the identified population (Clar, Barnard et al. 2010).

The literature review does highlight that in some instances, such as where prescribed agents which could cause hypoglycaemia such as sulphonylureas, there is some benefit from ongoing self-monitoring. It further suggests that any self-monitoring should occur only where determined in consultation with a healthcare professional, in a structured format as a guide to treatment.

3.3 Additional Research Projects and Recent Studies Not Included in the Literature Review

The Expert Advisory Group to the Review was asked to advise of any additional research on the use of blood glucose test strips in Australia that could be provided to the PBAC for consideration.

A list of these studies is presented as follows:

- **The 45 and Up Study** - The Sax Institute
- **The Diabetes MILES Study** – The Australian Centre for Behavioural Research in Diabetes
- **Self-Monitoring of Blood Glucose as Part of a Multi-Component Therapy Among Non-Insulin Requiring Type 2 Diabetes Patients: A Meta-Analysis (1966-2004)** – Sarol et al (2005)
- **Self-Monitoring of Blood Glucose in Type 2 Diabetes: Longitudinal Qualitative Study of Patients' Perspectives** – Peel (2007)
- **ROSSO-in-Praxi Follow-Up: Long-Term Effects of Self-Monitoring of Blood Glucose on Weight, Hemoglobin A1c, and Quality of Life in Patients with Type 2 Diabetes Mellitus** – Kempf et al. (2012)
- **Lasting Effects of a 2-Year Diabetes Self-Management Support Intervention: Outcomes at 1-Year Follow-Up** – Tang et al (2012)
- **Self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes on oral anti-diabetes drugs: cost-effectiveness in France, Germany, Italy, and Spain – Tunis et al** (2010)
- **Self-monitoring of blood glucose (SMBG) for type 2 diabetes patients treated with oral anti-diabetes drugs and with a recent history of monitoring: cost-effectiveness in the US** – Tunis and Minshall (2010)

- **Cost-effectiveness of self-monitoring of blood glucose in patients with type 2 diabetes mellitus managed without insulin** – Cameron et al (2010)
- **Randomised controlled trial of an automated, interactive telephone intervention to improve type 2 diabetes self-management (Telephone-Linked Care Diabetes Project): study protocol** – Bird et al (2010)
- **An evaluation of diabetes self-management applications for Android smartphones** – Demidowich et al (2012)

3.4 Utilisation Review of Blood Glucose Test Strips

As stated previously, subsidised blood glucose test strips are supplied through the NDSS and the PBS to Australians with diabetes. Both data sources have been included in this report. This is a brief summary of findings from a report prepared by the Veterans Medicines Advice and Therapeutic Education Services, University of South Australia.

Main Findings

- **Total utilisation of blood glucose test strips is growing at a rate of approximately 6.3% per annum.**
- **Total government expenditure on blood glucose test strips reached approximately $143.5 million in 2011/12.**
- **Approximately 35% of all blood glucose test strips dispensed are for people with T2DM not using insulin.**
- **50% of people registered with the NDSS and 12% of people in PBS data with T2DM not using insulin received test strips in 2011/12**
- **People with T2DM not using insulin who received at least one test strip dispensing in 2011/12, received on average 300 test strips per year.**

3.4.1. Total utilisation of blood glucose test strips

Total test strip utilisation is growing at approximately 6.3% per year over the past four financial years. This is due to an increasing number of supplies provided through the NDSS. Total supply of test strips through the PBS is much lower and has been falling during the same period (Table 1).

Table 1: Total Prescriptions (and NDSS equivalent supplies) for blood glucose test strips.

	2008-2009	2009-2010	2010-2011	2011-2012
NDSS	2,553,974	2,775,183	2,968,484	3,221,231
PBS	423,339	394,672	368,097	352,630
Total	**2,977,313**	**3,169,855**	**3,336,581**	**3,573,861**
% Growth		6.5%	5.3%	7.1%

In 2011-12, the Australian Government spent approximately $143.5 million subsidising glucose test strips for people living with diabetes, through both the PBS ($17 million) (Medicare Australia 2012) and the NDSS ($126.5 million) (Diabetes Australia 2012).

3.4.2 Utilisation of blood glucose test strips in PBS data

A ten year PBS dataset that included all unique patient identifiers (PINs) that were supplied a diabetic medicine over the period July 2002 to June 2012 was analysed. In 2011, there were 558,000 people with claims for diabetes medicines who are concession card beneficiaries and an estimated 223,000 general beneficiaries (781,000 in total). This is slightly lower than the total estimate of prevalence for any type of diabetes in the recent 2011/12 National Health Survey of 875,000. The difference may be accounted for by those who use diet alone to control their diabetes. The concession cohort (71%) was further analysed to determine type of diabetes and associated blood glucose test strip utilisation.

3.4.3 Utilisation of blood glucose test strips in people with type 2 diabetes not using insulin

Data on utilisation of test strips by type of diabetes is available in NDSS data. In PBS data the supply of test strips to patients with T2DM not using insulin was estimated by analysing related supplies of oral diabetic medicines and insulin in de-identified patient level data. Because some oral diabetic medicines are priced below the general PBS co-payment only concession card holders could be accurately accounted for in this analysis.

As with the total utilisation, the number of test strips supplied to people with T2DM not using insulin is growing annually in the NDSS data and declining slightly in the PBS data (refer to Figure 1 below).

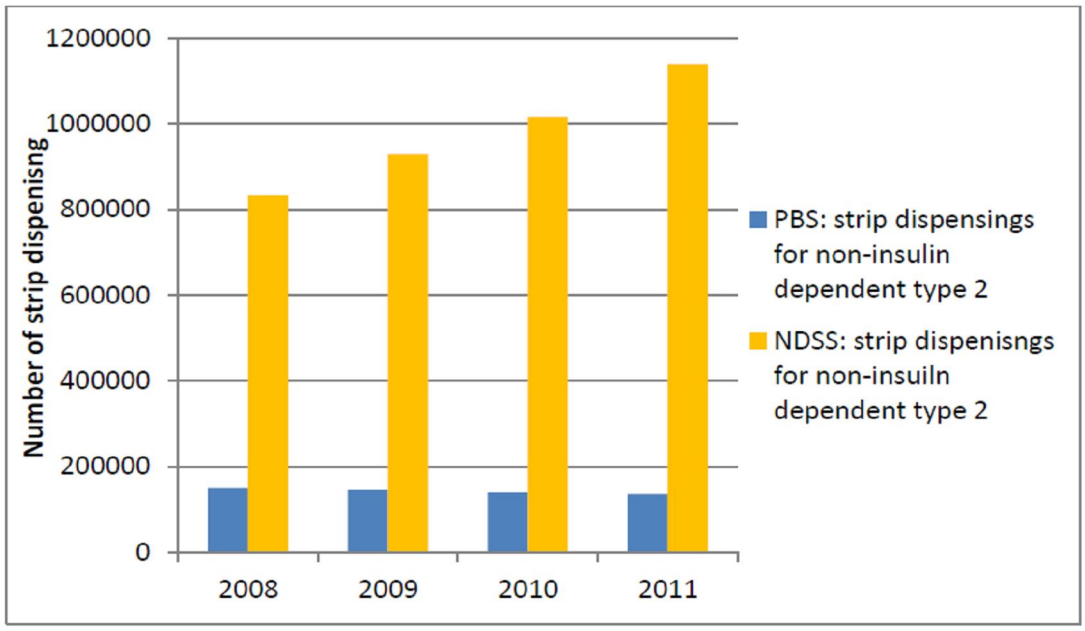

Figure 1. Number of blood glucose test strip dispensings for people with type 2 diabetes not using insulin via the PBS and NDSS

In 2011, 12% of those with T2DM not using insulin received at least one test strip dispensing during the year via the PBS. In contrast, approximately 50% of those with T2DM not using insulin received blood glucose test strips via the NDSS. This data would indicate that a significant proportion (up to 50%) of people with T2DM not using insulin did not access any test strips in a 12 month period.

When analysing PBS subsidised use of blood glucose test strips by medicine class, people dispensed glitazones and sulfonylureas received more blood glucose test strips than those on metformin. This is consistent with 2009 Canadian HTA report recommending that people on sulfonylurea (either alone or in combination with other oral therapy) may need to test their blood glucose periodically because of an increased risk of hypoglycaemia.

Around 35% of all test strips dispensed were to patients with T2DM not using insulin in both NDSS and PBS datasets (refer to figure 2). Thus the majority (65%) of blood glucose test strips supplied in Australia are used in insulin dependent and other forms of diabetes.

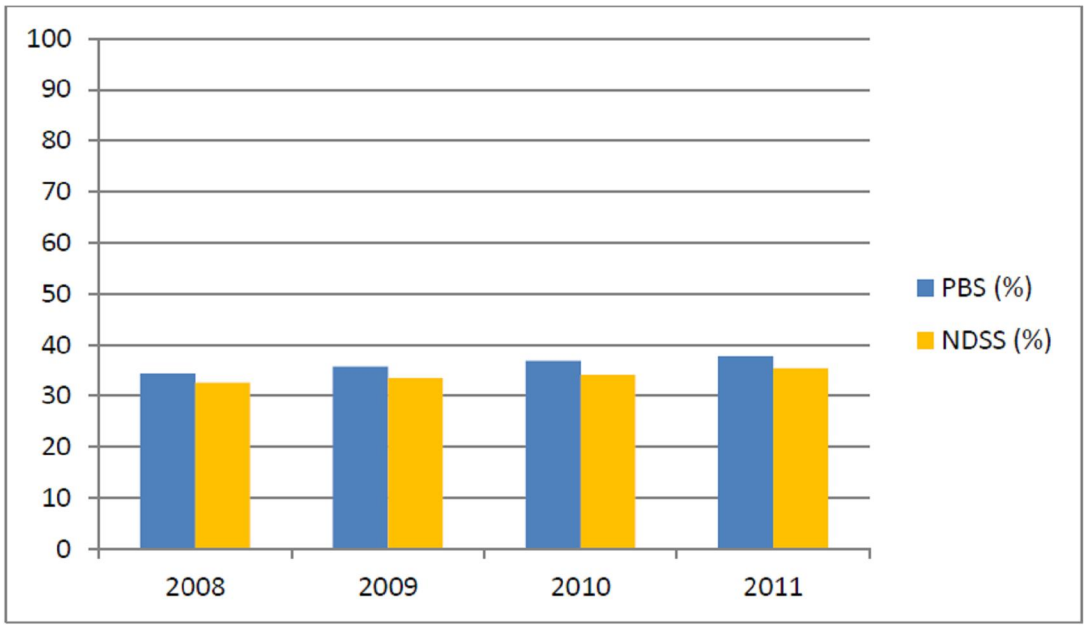

Figure 2. Percentage of blood glucose test strips dispensed to people with type 2 diabetes not using insulin as a proportion of total blood glucose test strip dispensing

3.4.4 Utilisation of test strips per person

The following two graphs show the average number of supplies per person in both PBS and NDSS data according to type of diabetes. Analysis of NDSS data showed people with T1DM were receiving twice as many dispensing for test strips compared to those with T2DM using insulin, and 3-4 times those with T2DM not using insulin. T1DM patients averaged 11 dispensing's a year (1100 strips), suggesting regular multiple daily use of blood glucose test strips. People with type 2 diabetes using insulin received on average 6 dispensing's per year (600 strips), which is sufficient for twice daily use. In both NDSS and PBS datasets, people with T2DM not using insulin receive on average 3 dispensing per year (300 strips). The use of test strips in insulin dependent type 1 and type 2 diabetics is much higher in the NDSS dataset than the PBS dataset. The reason for this is unknown. It is not possible to link these datasets, therefore patients accessing supplies through both programs cannot be identified and reporting supplies per patient (as above) may underestimate individual use.

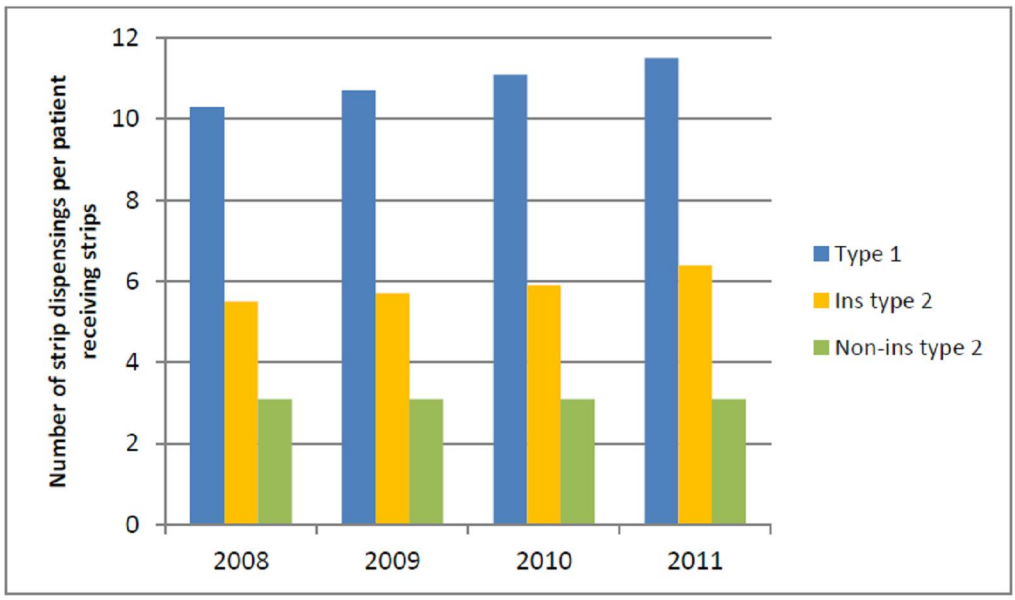

Figure 3. Average number of blood glucose test strip dispensings (packs of 100) per patient receiving any test strips (NDSS data).

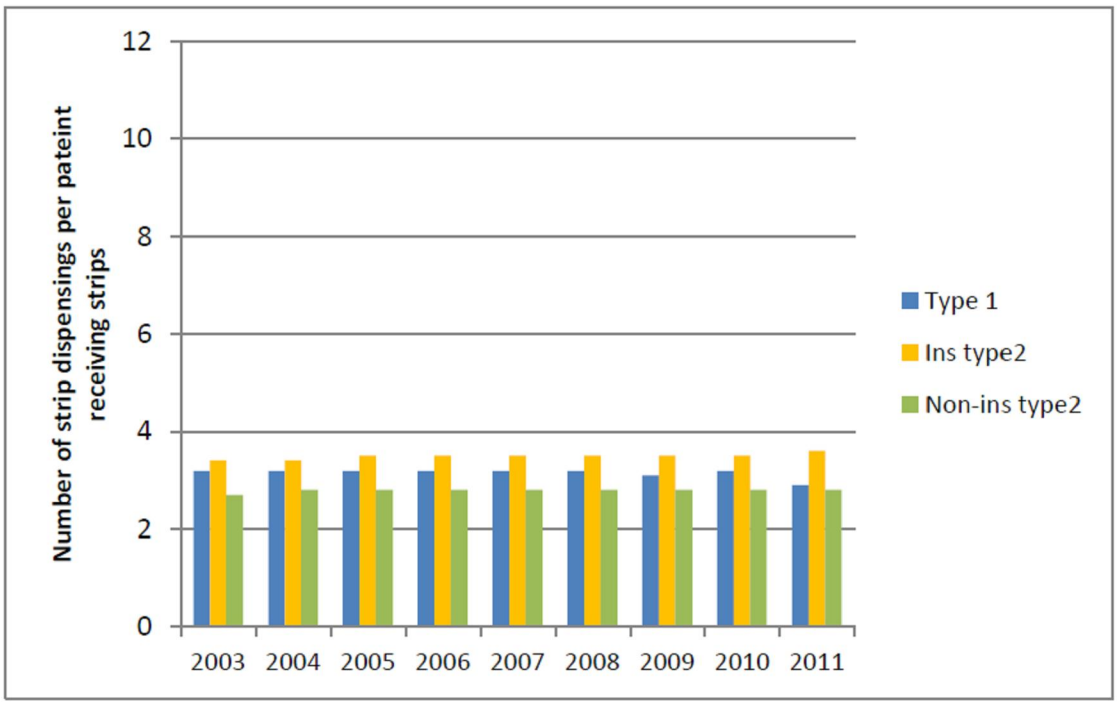

Figure 4. Average number of blood glucose test strip dispensings (packs of 100) per patient receiving any test strips (PBS data).

3.4.5 New Users (NID Type 2) of test strips according to PBS data

A cohort of concession patients were selected from PBS data in 2008 and followed for a maximum of four years. Only those who had their first ever dispensing of an oral anti-diabetic agent in 2008 were included in the cohort. Patients were followed until their last oral dispensing and contributed person time in any month that they filled a prescription for oral treatment. The monthly proportion receiving at least one blood glucose test strip dispensing was stratified according to age, gender, location and state of residence. The results for this analysis showed no differences in the utilisation of test strips in people with T2DM not using insulin according to age, gender or state of residence.

People living in major cities seemed to receive slightly more test strips than those living in regional and rural areas. Around half the patients were provided with sufficient supply to be using less than one strip per day, one third received between 1 and 2 strips per day and one fifth received supply of strips that would have enabled three of more test strips per day. Again, it is not possible to determine whether or not patients are receiving test strips via the PBS alone, therefore this analysis may under estimate the total use per patient.

3.5 Public consultation process

Submissions addressing the Terms of Reference relating to blood glucose test strips were invited from interested organisations and individuals. This consultation process focused on 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 using insulin (terms of reference 5 -7).

32 submissions were received including 10 from industry organisations, 10 from professional peak bodies, 4 from professional individuals, 7 from non-government organisations and one from a government organisation. Unless otherwise requested, submissions will be made publicly available on the Pharmaceutical Benefits Scheme website at www.pbs.gov.au.

In general, stakeholders were supportive of the need for clinically appropriate use of test strips and for consistent guidance and education of healthcare professionals to support such use.

Key viewpoints expressed through the public consultation process include:

- SMBG should be considered as part of ongoing self-management to assist people to a better understanding of diabetes and provide means to actively and effectively participate in its control and treatment;

- The use of SMBG in diabetes self-management has assisted in the control and treatment of patients' through providing the individual the ability to monitor glucose levels. Additionally they believe this provides individuals assistance to manage treatment of their condition;
- Concern was expressed about the impact to consumers of any restriction to accessing BGTS;
- SMBG should be used only when people with diabetes and/or their healthcare providers have the knowledge, skills and desire to incorporate SMBG and therapy adjustments into their diabetes care plan;
- There is consensus, however, that regardless of how blood glucose test strips should be used, self-monitoring of blood glucose needs to be supported by better access to support and education from relevant health professionals, including diabetes educators;
- Many of the submissions acknowledge the uncertainty in this area quoting recent research on SMBG both in Australia and internationally.

3.6 Stakeholder forum

The Stakeholder forum was convened on 19 November 2012 to provide a further opportunity for interested stakeholders including industry, health professional bodies and consumers to provide input into the Review.

This Stakeholder Consultation Forum was aimed at gaining a range of stakeholder perspectives to:

- Better contextualise the use of Blood Glucose Test Strips (BGTS) in type 2 diabetes; and
- Encourage open discussion in addressing the most clinically effective use of these BGTS in improving outcomes for people with type 2 diabetes not using insulin.

These views will then be forwarded to the PBAC for their consideration in the broader management of this condition. The review will be progressed in a staged approach, with BGTS being addressed initially as they are a precursor to other medicines and aspects of diabetes management. Three focus questions were posed to draw out stakeholder views:

- How should Blood Glucose Test Strips be most appropriately used in supporting self-management for people with type 2 diabetes not using insulin?
- How people access Blood Glucose Test Strips now – what works and what does not?
- How can education and support from relevant health care professionals and others be used to better inform the self-management of type 2 diabetes, including the ongoing use of blood glucose test strips?

As diabetes is a national health priority area, the objective of the review is to systematically evaluate the clinical evidence available regarding diabetes interventions which will help ensure that patients are using the most appropriate medicines and products, effectively and safely, to achieve optimal health outcomes and support quality use of medicines.

The Department of Health and Ageing received 32 written public submissions, representative of a cross section of interests– individuals, consumer advocates, peak bodies and industry. These submissions demonstrate an awareness of issues associated with the use of BGTS in type 2 diabetes and recognise uncertainties that need to be addressed so that best clinical practice can be reflected in access arrangements

Summary of Discussion Points

Critical Issues on Blood Glucose Testing

Participants presented a range of views and opinions, including:

- Health professionals identify blood glucose testing as part of clinical practice, particularly in initialising medical assistance. If there is a change in access to BGTS, health professionals and patients will need to be supported.
- Over the past 10 years BGTS have been treated as an intervention, or a diagnostic tool to inform intervention.
- BGTS give patients control over their own health, and if used in conjunction with the HbA1C test, patients are better able to manage their type 2 diabetes which they value.
- Patient education in the best practice usage of BGTS needs to occur in a structured manner and should be viewed as part of a collaborative package of care or patient care agreement. Information and education enable informed decisions and more effective self-management and action.
- Although the HbA1C and blood glucose testing are independent measures of glycaemic control, they should be viewed as complementary measurements of blood glucose levels.
- Some stakeholders expressed that universal access to BGTS was an important part of providing greater patient control over the self-management of their condition.
- There is need for clarity and consistency in messages conveyed in relation to BGTS to both patients and health professionals.
- If patients believe their diabetes is well controlled they see little need to visit their General Practitioner (GP) and this has implications for ensuring the most effective use of BGTS.
- Patients with longer term maintenance issues associated with their type 2 diabetes benefit from use of BGTS whereas they are less relevant for more stable patients.

- BGTS results are clinically significant for newly diagnosed patients, patients with gestational diabetes, people with glycaemic instability (such as periods of acute illness) and prior to initiation of insulin.
- Evidence and data is critical.
- There is a need to better understand BGTS data and patient patterns of use. Current data is available through:
    - Professor Tim Davies, WA
    - Fremantle Cohort
    - Cochrane Collaboration Review
- Representatives responsible for the administration of the National Diabetes Services Scheme (NDSS) indicated that, at a population level, there was little evidence to indicate over-usage of BGTS. Data suggests that on average, patients with type 2 diabetes not using insulin use one BGTS per day. It was however noted that this is at the population level and therefore an average rate, and further investigation is required to determine individual patterns of use.
- A key point is quality of monitoring not quantity.
- A number of guidelines currently exist including:
    - National Health and Medical Research Council (NHMRC) Guidelines
    - RACGP/DA Handbook
    - IDF
    - NDSS
    - Diabetes Educators Guidelines.
- There is a need for consistent approaches and messages across health professionals and community of care. The core Guidelines at this point in time are the NHMRC Guidelines and these may need updating in recognition that usage of BGTS for type 2 diabetes is only one element of broader diabetes management. These guidelines are to be presented in plain English and have relevance across the breadth of health professions. They should indicate a minimum standard of care.

Focus Question One:

Summary of How BGTS can be most appropriately used for self-management of type 2 diabetes.

- Currently there is open access to BGTS for eligible people. A key issue consistently identified during the forum was the need for BGTS to form part of an integrated and holistic structured program ensures the use of BGTS feeds into and informs appropriate clinical, lifestyle and treatment decisions.
- Such a structured program would likely improve the clinical benefit of testing.
- Clinical conditions and glycaemic variability needs to be accounted for when creating structure around BGTS usage.

- It is vital to ensure BGTS remains completely accessible for those people where they will have the greatest clinical impact. Consideration should be given to clinical indicators, such as initiation, periods of instability (e.g. changes to medication regimen, medication initiation) and illness exacerbation.
- Blood glucose testing is important for detection and monitoring of pre-diabetes.
- Patients require reassurance and two-way communication with their health professional so as to more effectively self-manage their condition. They need to understand their blood glucose readings so that they can better engage with their GP and take action as necessary. BGTS readings can inform these conversations and actions. Specific patient factors can impact on the need for increased monitoring such as during acute periods of illness.
- Patients require initial and intermittent information along their journey with type 2 diabetes.
- Structure and education surrounding BGTS usage needs to be consistent across health professions. There should not be rigidity in this structure to allow for points of incongruity.

Focus Question Two:

Summary of how people access BGTS and what facilitates clinically optimal use?

- Patient episodes (e.g. illness exacerbation, hospitalisation or other events) can trigger BGTS usage.
- Health Professionals are the primary entry point for accessing BGTS. Other providers, including community pharmacy for example, offer structured programs and interventions (such as Diabetes MedsCheck) that support understanding of appropriate medication management, including BGTS.
- The quality of information requested by clinician or health professional is vital in appropriately addressing a patient's needs at time of consultation.
- Current access to BGTS is good through the NDSS and PBS, with remote areas catered for through a postal service and community pharmacies.
- Although Australia has relatively unlimited access to BGTS there is a question as to whether this current access actually improves clinical outcomes.
- It was noted that it is unclear whether there is a cohort of patients that could benefit from BGTS but may not currently access them.

Focus Question Three:

Summary on How Can Education and Support Better Inform Self-Management of Type 2 Diabetes (including BGTS)

- There is a need for a structured Program (not rigid) that provides consistent messages, allows for common elements of sub-services, incorporates Care Plans, accounting for the risks associated with GP only updates without the inclusion of the perspectives of other health professionals.

- The use of BGTS should be tied to a multidisciplinary education and training program where all health professionals provide a consistent message supported by guidelines.
- Pharmacists are a key dispensing point for BGTS and could be well placed to take on an educative role.
- Education strategies need to be broader than just the provision of an information leaflet at time of dispensing the BGTS.
- Education strategies should convey that all treatment approaches are equally valid.

Final Perspectives

Clinicians

- BGTS be available under conditions that include informed, structured approaches (self-management). Could limit use to be more targeted. There was however a level of discomfort with the notion that BGTS would only be available under certain conditions and this would impact universal access.
- If universal access was limited this would need structured education linked to clinical utility across a range of health professionals.
- Any education strategy must take into account cross-cultural considerations.

Health Professionals

- Review size of BGTS packs. Questions were raised as to whether the current pack sizes and quantities available reflected best use or promoted wastage.
- Need to better understand what enables appropriate patient/consumer use.
- The use of BGTS empower clients to manage their T2DM and universal access is equitable. BGTS allow particularly useful feedback to both clients and their treating dietitian regarding appropriate food intake.

Consumers

- Supportive of suggestions that access to subsidised BGTS could be linked to or associated with a 'mandatory' education component.
- Co-ordinated and consistent approach to management of illness across health professionals.

Industry

- Evidence should inform decisions; need to recognise emerging therapies and technologies.
- Recognise that targeted approaches involve multiple factors.
- BGTS can ensure a monitoring regime for a disease that may otherwise not be monitored.
- Monitoring (lipids and blood pressure) is also critical.

3.7 Expert Advisory Group

An Expert Advisory Group (EAG) has been convened to provide a platform for experts to provide advice on arising issues for the diabetes review. The Group consists of experts in a range of fields relating to the management of diabetes such as endocrinologists, nurse practitioners and general practitioners.

The purpose of this Group is to provide expert advice into the Review and its Report to the PBAC. The Review aims to provide a comprehensive assessment of the clinical evidence to support the management of diabetes and assess its applicability to the Australian context. This Group will provide advice on the Report to the PBAC**.**

The first meeting of the EAG was held on 22 November 2012 in Canberra. Advice from the EAG contextualised stakeholder submissions and findings from the utilisation analysis and provided further support for the need for a more structured approach to blood glucose testing. The EAG identified the risk that universal access may be promoting inappropriate use and that more regular inclusion of health professionals in the management of diabetes would support more clinically appropriate use.

Further, the EAG advised that:

- From a clinical point of view, the goal is to ensure that where possible access and use support best clinical practice;
- Health professionals and patients would benefit from a structured program aimed at delivering a structured approach to SMBG using BGTS, including quarterly Hb1AC testing and a 12 monthly review by a health professional
- Growth in the NDSS appears to be due to better and easier access for patients through more access points at less expensive co-payments;

- The Department may wish to consider:
  - Including other research projects into the Report, if available and relevant including the 45&Up study and the MILES Report;
  - Seeking further NDSS data from Diabetes Australia for inclusion in the report for the PBAC; and
  - Including information in the report on how industry self-regulate with regards to BGTS and related diagnostic devices advertising that may affect how patients are using BGTS with their SMBG.

The EAG further noted that universal access does not appear to be sending the right message to consumers with regards to appropriate usage. Similar to New Zealand guidelines, patients could be given a three to six month supply and receive extras under special conditions listed under the SIGN guidelines, including access for certain populations, with the ability to be flexible.

It was also noted that the Scottish Intercollegiate Guidelines Network 2010 (SIGN) guidelines referred to in the Literature Review provided a good example of possible eligibility criteria to support more appropriate access.

The EAG agreed that guidelines relating to the use of BGTS need to be consistent and that a structured approach including support by the health professionals would assist in realising the potential benefits of self-monitoring and improve appropriate use.

Further, it was noted that the cost-effectiveness of blood glucose test strip monitoring remains uncertain, for people with Type II diabetes not using insulin, in Australia.

4. Summary

The objective of this review is to systematically evaluate the body of clinical evidence regarding diabetes interventions. This will help to ensure that patients are using the most appropriate medicines and products, effectively, and safely, to achieve optimal health outcomes and support quality use of medicines.

Diabetes is a major health issue, as recognised by its status as a National Health priority. As such the current review will take time to properly assess all relevant components.

The focus of this component of the Review is on the clinical benefit and how the use of blood glucose testing facilitates improved outcomes for people with type 2 diabetes not using insulin.

This review has been informed by relevant research and evidence, including:

- Relevant guidelines;
- International experience;
- Public consultation;
- Literature review;
- Utilisation analysis; and
- Input by an Expert Advisory Group.

Given their virtually unrestricted availability and wide use in Australia, the Department of Health and Ageing engaged the University of South Australia to undertake a literature review and utilisation analysis to further investigate the clinical evidence and data to support the use of SMBG in people with type 2 diabetes not using insulin. The main results of these analyses were that:

- Ongoing self-monitoring of blood glucose levels in people with type 2 diabetes not using insulin does produce statistically significant changes, with a 0.25 to 0.3 per cent reduction in HbA1c levels. However, self-monitoring does not produce the clinically significant change of 0.5 per cent for the majority of the identified population;

- Quality of life, patient satisfaction or patient wellbeing outcomes were not significantly different in those on SMBG and those who were not on SMBG;
- In some circumstances, such as where prescribed agents which could cause hypoglycaemia such as sulphonylureas, there is some benefit from ongoing self-monitoring; Any self-monitoring should occur only where determined in consultation with a healthcare professional, in a structured format as a guide to treatment, and if the person is prescribed agents which could cause hypoglycaemia;
- Total test strip utilisation is growing at approximately 6.3% per year over the past four financial years. This is due to an increasing number of supplies provided through the NDSS. Total supply of test strips through the PBS is much lower and has been falling during the same period;
- Around 35% of all test strips dispensed were to patients with type 2 diabetes not using insulin in both NDSS and PBS datasets; and
- In both NDSS and PBS datasets, people with type 2 diabetes not using insulin receive on average 3 dispensings per year (300 strips).

A number of Australian and international clinical practice guidelines regarding blood glucose control in type 2 diabetes are available. However, there is currently no consensus view regarding the use of regular blood glucose testing in type 2 diabetes not using insulin. Some of these key recommendations include:

- Australian guidelines recommend that SMBG should be considered in all people with type 2 diabetes but the decision to perform SMBG, and the frequency and timing of testing, should be individualised;
- The Scottish Intercollegiate Guidelines Network (SIGN) guidelines state that routine self-monitoring of blood glucose in people with type 2 diabetes who are using oral glucose-lowering drugs (with the exception of sulphonylureas) is not recommended;
- The American Diabetes Association recommends that for patients using less-frequent insulin injections, non-insulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to management; and
- The Coalition for Clinical Research—Self-Monitoring of Blood Glucose Scientific Board recommendations state that to be most effective, it should be performed in a structured format where information obtained from this measurement is used to guide treatment.

In considering guidelines and recommendations from the main professional and health technology organisations, the literature review indicated that most guidelines recognised the lack of strong evidence to support the use of self-monitoring of blood glucose levels in terms of HbA1c improvement.

However, the guidelines were generally in agreement that, to be effective, SMBG needed to be part of a complex educational intervention that promoted patient behavioural changes and therapeutic medication adjustments more tightly aligned to the results obtained from SMBG.

In 2011-12, the Australian Government spent approximately $143.5 million subsidising glucose test strips for people living with diabetes, through both the PBS ($17 million) and the NDSS ($126.5 million). Approximately 35% of all test strips were dispensed to patients with type 2 diabetes not using insulin.

Given the above information, it is important to ensure that access to blood glucose test strips in this population is clinically appropriate and does not have the potential to inadvertently promote their inappropriate use in this population.

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