Post-Market Review of Products Used in the Management of Diabetes

Report to the Pharmaceutical Benefits Advisory Committee

Part 1: Blood Glucose Test Strips

July 2013

Contents

Structure of the Report

This Report is presented in six 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 background information on diabetes, including 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 Pharmaceutical Benefits Scheme (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 and Stakeholder Forum, and Working Group and Diabetes Review Reference Group (Reference Group) advice to the Review are also provided.

Part 4 – Summarises the findings of the Review.

Part 5 – Outlines a number of options for consideration based on the outcomes of the Review and issues identified.

Part 6 – Provides an overview of the Reference Group consideration of the Review findings and commentary for consideration by the Pharmaceutical Benefits Advisory Committee (PBAC).

Abbreviations

ACRRM	Australian College of Rural and Remote Medicine
ADEA	Australian Diabetes Educators Association
ADS	Australian Diabetes Society
AIHW	Australian Institute of Health and Welfare
BGTS	Blood Glucose Test Strips
CADTH	Canadian Agency for Drugs and Technologies in Health
CHD	Coronary Heart Disease
DHS	Department of Human Services
DoH	Department of Health
DTSQ	Diabetes Treatment Satisfaction Questionnaire
DVA	Department of Veterans' Affairs
ESC	Economics Sub-Committee (of the PBAC)
HbA_{1c}	Haemoglobin A_{1C} or glycated haemoglobin
HTA	Health Technology Assessment
IDF	International Diabetes Federation
IVD	In Vitro Diagnostic Device
MATES	Medicines Advice and Therapeutics Education Services
MNT	Medical Nutrition Therapy
NDSS	National Diabetes Services Scheme
NICE	National Institute for Health and Clinical Excellence
NHMRC	National Health and Medical Research Council
NMP	National Medicines Policy
NPS MedicineWise	National Prescribing Service MedicineWise
NZGG	New Zealand Guidelines Group

PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBD	Pharmaceutical Benefits Division
PIN	Patient Identifier
PPB	Pharmaceutical Policy Branch
PVD	Peripheral Vascular Disease
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
RCT	Randomised Control Trial
Reference Group	Diabetes Review Reference Group
RPBS	Repatriation Pharmaceutical Benefits Scheme
SIGN	Scottish Intercollegiate Guidelines Network
SMBG	Self-Monitoring of Blood Glucose
SMUG	Self-Monitoring of Urine Glucose
TGA	Therapeutic Goods Administration
The Department	The Department of Health
ToR	Terms of Reference
WHO	World Health Organization

Executive Summary

Diabetes is a major health issue, as recognised by its status as a National Health Priority Area. Due to the considerable recent changes in diabetes management, including the Pharmaceutical Benefits Scheme (PBS) listing of a number of new medicines for the treatment of diabetes, the Pharmaceutical Benefits Advisory Committee (PBAC) agreed to a Post-Market Review of Products Used in the Management of Diabetes in August 2012. The Review encompasses three aspects of diabetes management and is being undertaken in stages: Stage 1 – blood glucose test strips (test strips); Stage 2 – insulin pumps; and Stage 3 – medicines used in the management of type 2 diabetes mellitus.

This component of the Review focuses on the clinical benefit of self-monitoring of blood glucose (SMBG) with test strips for people with type 2 diabetes not using insulin. The objective was to systematically evaluate the body of clinical evidence to ensure the most appropriate management of diabetes in clinical practice.

Diabetes requires a multidisciplinary approach involving a wide range of healthcare professionals. A number of Australian and international clinical practice guidelines on blood glucose control in type 2 diabetes are available. In people with type 2 diabetes not using insulin, guidelines generally recommend individualisation of the frequency and timing of SMBG testing in line with the patient's goals, as part of a broader educational intervention that promotes patient behavioural changes and treatment adjustments.

Recent literature, including a Cochrane Collaboration Review (2012) and Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) report (2009), found limited evidence of the benefit and effectiveness of regular use of test strips in people with type 2 diabetes not using insulin. Such reports have indicated that there is little evidence that self-monitoring improves health-related quality of life, patient satisfaction, long-term complications and associated mortality for this population.

This Report examines current evidence and guidelines on the role of test strips in the ongoing management of people with type 2 diabetes not using insulin. Based on the vast body of information available, the Review examined how to better target information about effective monitoring regimens for diabetes and ensure access arrangements for test strips are consistent with the best use of these products in this patient group.

The main findings of the Review are:

- Ongoing SMBG in people with type 2 diabetes not using insulin does produce statistically significant changes in HbA_{1c}. The size of this benefit is often very small (0.25–0.3% reduction in HbA_{1c} levels) and unlikely to be clinically significant;
- Quality of life, patient satisfaction or patient wellbeing outcomes were not significantly different between those on SMBG and those not on SMBG;

- In some circumstances where patients are prescribed medicines that can cause hypoglycaemia (e.g. sulfonylureas) there is some benefit of ongoing SMBG;
- Self-monitoring should occur only where determined in consultation with a healthcare professional, in a structured format, to guide treatment;
- Total test strip utilisation grew approximately 6.2% per year over the past four years (2008–2011), but has remained relatively stable on a per person basis over time for people with type 2 diabetes not using insulin;
- Around 35% of all test strips dispensed were to people with type 2 diabetes not using insulin in both NDSS and PBS datasets;
- In both NDSS and PBS datasets, people with type 2 diabetes not using insulin receive on average 3 dispensings per year (300 strips); and
- Just under a third (29%) of people with type 2 diabetes not using insulin use four or more packs (400 test strips) in a year. There are a small number of people receiving more than 13 packs per year.

It is clear from the Review findings, and consultation with stakeholders and the Reference Group, that people with type 2 diabetes in the following categories may benefit from regular SMBG in conjunction with healthcare professional advice:

- People using insulin;
- People with gestational diabetes;
- People co-prescribed medicines that may adversely affect blood glucose control (e.g. sulfonylureas and corticosteroids); and
- People with inter-current illness that may cause fluctuations in blood glucose control.

The options for subsidised access through the PBS provided in Section 5 of this Report maintain the current level of access to test strips for the above categories of people. For those people with type 2 diabetes not included above, the Review has identified that there may be ongoing use of test strips in patients stabilised on therapy that is beyond clinical need. These patients may be undertaking painful testing procedures for limited clinical benefit. Section 5 of this Report proposes two main options to address this use on the PBS.

Option 1 provides access to up to 3 months' supply of test strips (100 strips, max qty 1, repeats 2) for people with type 2 diabetes not using insulin who are initiating or require changes to existing diabetes management (e.g. lifestyle change or new medication regimen), and is designed to encourage frequent prescriber review.

Option 2, the preferred option by the Diabetes Review Reference Group, provides access to up to 12 months' supply of test strips. People with type 2 diabetes not using insulin who are initiating or require changes to existing diabetes management will be able to access up to 6 months' supply (100 strips, max qty 1, repeats 5). The prescriber will

then have the discretion to prescribe up to an additional 6 months' supply of test strips if they determine that the patient would benefit from further monitoring. This is consistent with the findings of the Cochrane Review (2012) that indicate a minimal clinical benefit in improved blood glucose control at 6 months, which disappears after 12 months follow-up.

The Reference Group considered that Option 2 appropriately balanced clinical need with the findings of the Review. The Reference Group favoured an Authority Required (STREAMLINED) restriction, to balance compliance with administrative burden. The restriction aims to guide access to these products, encouraging prescribers to review patients' SMBG following changes to diabetes management, including lifestyle changes, and conveying consistent messages about self-monitoring to people with type 2 diabetes. The restriction is not expected to affect the frequency of patient visits to healthcare professionals, as people with type 2 diabetes are recommended to undertake HbA_{1c} testing at least every six months. The Group considered that the availability of smaller pack sizes (e.g. 50 strips) may also assist in ensuring efficient use.

The Review also notes that optimally, any changes to the current PBS restrictions should be reflected in access arrangements through the NDSS to align clinical practice. This is likely to require system and technology changes, which may take longer to implement than any changes to the PBS. To avoid prescriber and patient confusion, any changes to the PBS and NDSS will need to be communicated via updates to the clinical guidelines, and a multi-media approach through a range of organisations, including NPS MedicineWise, Diabetes Australia and the Royal Australian College of General Practitioners (RACGP).

In summary, this Review provides options for more structured access to test strips in line with clinical evidence for people with type 2 diabetes not using insulin. It is important to note that prescribers continue to have access to blood glucose monitoring with HbA_{1c} for all patients if they want an indication of blood glucose control. The PBS restrictions only address access to test strips for self-monitoring.

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, p. 3). The PBAC's role also involves ongoing monitoring of the use of PBS listed medicines, to ensure they are used in the way that was intended when originally recommended, and to ensure ongoing safe and cost-effective use.

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-effective use of the medicines and products used to manage diabetes, a Post-Market Review of Products Used in the Management of Diabetes (the Review) is being undertaken in the context of Australia's NMP.

The overarching Review 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 people with type 2 diabetes not using insulin; and

- Insulin Pumps: the clinical benefits of insulin pump therapy for type 1 diabetes mellitus across age groups.

The objective of this Review is to systematically evaluate the body of clinical evidence 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 Review will focus on the management of the condition overall and how medicines and products are being used to benefit patients, alongside other aspects of diabetes management. The groups of medicines and products under review include type 2 diabetes medicines, insulin pumps, and 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 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 these aspects of diabetes management are considered comprehensively.

At its August 2012 special meeting, the PBAC endorsed the following Terms of Reference for the overarching Diabetes Review.

Purpose: To examine and characterise the complexity and heterogeneity of PBS listings for drugs used in type 2 diabetes; and to review self-monitored blood glucose testing for people with type 2 diabetes and insulin pumps for people with type 1 diabetes 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 type 2 diabetes, 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 type 2 diabetes 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. HbA_{1c}) of SMBG relative to HbA_{1c} 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 HbA_{1c} monitoring;**

8. Determine the clinical outcomes (e.g. HbA_{1c}, 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 Programme which is funded by the Australian Government;
9. Investigate the effectiveness and costs of different insulin pumps available under the Insulin Pump Programme; and
10. Consider the clinical criteria and eligibility under the Insulin Pump Programme, 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 regarding the ongoing use of regular SMBG with test strips in people with type 2 diabetes not using insulin.

Open public consultation processes were undertaken for all components of the Review to ensure that stakeholders were provided with the opportunity to contribute.

Input from stakeholders was sought by directly inviting submissions to address the Review's Terms of Reference relating to test strips and by placing information and a call for submissions on the PBS website. The call for submissions was open between 2 October and 15 November 2012. A summary of these submissions is included in Part 3.6 of this Report.

A Stakeholder Forum was convened on 19 November 2012 to provide a further opportunity for stakeholders to input to the Review.

A small Working Group consisting of key government agencies was formed to provide a forum to discuss potential implications with other government programmes and priorities. A Reference Group was also established to provide consumer, clinical, and technical advice to inform the 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 test strips. A separate external research group from the University of South Australia was engaged under the Department of Veterans' Affairs (DVA) Veterans' Medicines Advice and Therapeutics Education Services (MATES) programme to undertake a utilisation analysis of PBS data provided by the Department. In addition, an analysis of estimates of supply of test strip packs per patient on the NDSS and the PBS was undertaken for comparison purposes.

2. Diabetes Mellitus

2.1 Diabetes Mellitus

Diabetes Mellitus (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 (WHO) 2012).

Without insulin, or if insulin production or action are ineffective, the body cannot turn glucose into energy and this results in glucose remaining in the blood, causing high blood glucose levels. This can result in a number of complications, including serious damage to the nerves and blood vessels (Australian Institute of Health and Welfare (AIHW) 2013).

Diabetes was endorsed as a National Health Priority Area 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 programmes.

2.2 Criteria for Diagnosis

The current WHO (2006) diagnostic criteria for diabetes include:

- Fasting plasma glucose ≥ 7.0mmol/L (126mg/dL); or
- 2 h plasma glucose ≥ 11.1mmol/L (200mg/dL).

HbA_{1c} 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 (WHO 2011).

An HbA_{1c} of 6.5% (48 mmol/mol) is recommended as the cut-off point for diagnosing diabetes. A value less than 6.5% does not exclude diabetes diagnosed using glucose tests (WHO 2011).

HbA_{1c} is a laboratory test that shows the average level of blood glucose over the previous 3 months (Diabetes Australia 2009). It is a test used to provide an indication of how well a patient's diabetes is being controlled. High levels of HbA_{1c} 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 HbA_{1c} increases, the risk of microvascular and macrovascular complications of diabetes increases. HbA_{1c} thus gives a measure of an individual's risk of the long-term complications of diabetes.

HbA_{1c} testing provides clinicians with a reliable indication that therapy is working appropriately and that 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 may 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 diabetes and type 2 diabetes. The Australian Diabetes Society (ADS) recommends a general target HbA_{1c} of ≤7.0% for most patients. However, HbA_{1c} targets need to be individualised. For example, targets may need to be higher for some people including children and the elderly (Diabetes Australia 2009).

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 HbA_{1c}, independent of glycaemia (Saudek & Brick 2009). In people with conditions associated with shortened red blood cell survival where HbA_{1c} is less reliable (e.g. thalassemia, portal hypertension, haemolytic anaemia), measured HbA_{1c} will be lower. Conversely, if the average age of circulating erythrocytes is older, then the older red blood cell population would have higher HbA_{1c} levels (Saudek & Brick 2009). In these patients, HbA_{1c} is less reliable and SMBG 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 mellitus: type 1 diabetes, type 2 diabetes, and gestational diabetes (WHO 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 affects women in about 3–8% of pregnancies (Diabetes Australia 2012). Additionally, certain populations including people of Aboriginal or Torres Strait Islander, Indian, Vietnamese, Chinese, Middle Eastern or Polynesian descent 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 diabetes affects about 10% of people with diabetes (AIHW 2013).

2.3.2 Type 2 Diabetes

People with type 2 diabetes produce insulin, but may not produce enough of it, or cannot use it effectively (insulin resistance)(AIHW 2013). 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 medicines 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 becoming increasingly prevalent in younger age groups. About 83% of self-reported cases of diagnosed diabetes in 2004–05 were type 2 diabetes (AIHW 2008).

2.4 Prevalence of Diabetes in Australia

According to the Australian Health Survey (2011–12), the total number of people in Australia that have been diagnosed with diabetes is 986,900. This figure has increased by 9.8% since the 2007–08 survey, when 898,000 Australians were estimated to have ever been diagnosed with diabetes (Australian Bureau of Statistics (ABS) 2012).

Furthermore, the Australian Health Survey (2011-12) showed that, 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%) (ABS 2012).

Type 2 diabetes is over-represented among people of Aboriginal and/or Torres Strait Island descent and a number of other populations including people of 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 (ABS 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 (ABS 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 coronary heart disease (CHD) (47%), while hypertensive and cerebrovascular diseases accounted for 30% and 20% of diabetes deaths, respectively (AIHW 2013).

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

2.6 Guidelines for the Management of Type 2 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 practising health professional.

A complete list of national best practice guidelines for the prevention, diagnosis and management of diabetes can be found at **Appendix A**.

Diabetes Australia (NHMRC-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 Guideline is 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 Guideline was designed to provide information to assist decision-making and was 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);
- HbA_{1c} measurement should be used to assess long term blood glucose control (Grade A);
- 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 HbA_{1c} target in people with type 2 diabetes is ≤ 7%. Adjustment to diabetes treatment should be considered when HbA_{1c} 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 HbA_{1c} should begin with lifestyle modification followed by pharmacological options selected on the basis of individual clinical circumstances, side effects and contraindications (Grade A); and
- 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 test strips to allow for an assessment of their comparative differences. A comparison of differences between the Australian guidelines is given at **Appendix A**.

Australia

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 RACGP on diabetes management in general practice (2011), recommend SMBG for those on agents that can cause hypoglycaemia (e.g. sulfonylureas 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 (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, ADS, ADEA, RACGP, 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 SMBG 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 support clinically optimal practice.

United Kingdom

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

The National Institute for Health and Clinical Excellence (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 produced a position statement that refers to the NICE Guideline and supports individualised decisions and not the blanket removal of test 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 statement from the NZGG Diabetes Advisory Group (New Zealand Guidelines Group 2011). In New Zealand, the number of test strips available on a prescription is restricted to 50 for patients with type 2 diabetes, unless the patient has also been prescribed insulin or a sulfonylurea, 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 diabetes medicines (without insulin) or no diabetes medicines, the routine use of 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 commissioned as part of this Report indicated that most guidelines recognised the lack of strong evidence supporting the use of SMBG in terms of HbA_{1c} improvement.

2.8 NPS MedicineWise Programmes and Publications on Diabetes

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

2.8.1 Programmes

Academic detailing programmes

NPS MedicineWise has developed and implemented four academic detailing programmes focusing on type 2 diabetes, since its conception in 1998. Details of these four programmes are outlined below:

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

NPS MedicineWise Facilitators were up skilled in August 2012 and delivery of this programme will be completed by December 2013. As of 27 November 2012, a total of 2407 health professionals had been actively engaged, including 1890 general practitioners (GPs).

Key messages of the programme:

- Address blood pressure (BP) and lipids as a priority;
- Treat according to cardiovascular risk;
- Controlling BP and lipids appears more effective in reducing cardiovascular disease than tightening blood glucose levels;
- Individualise blood glucose targets based on patient factors and duration of disease;
- Lowering blood glucose levels reduces microvascular complications; and
- Use the ADS position statement to individualise HbA_{1c} targets.

Messages that relate to SMBG:

- Identify patients who may benefit from SMBG;
- Defined purpose for testing is necessary;
- Recommended for people using insulin; and
- Potential benefit where modifying treatment, to help identify or treat hyper/hypoglycaemia and to encourage self-management.

2. ***Early use of insulin and oral diabetes medicines (2008)***

NPS MedicineWise Facilitators were up skilled in February/March 2008 and delivery of this programme was completed in July 2009. At the completion of this programme, a total of 11,197 health professionals had been actively engaged, including 8745 GPs.

Key messages/features of programme:

- Early and continuing lifestyle interventions decrease disease progression;
- Initiate insulin early by adding night-time basal insulin to oral diabetes medicines;
- Ensure metformin is part of ongoing therapy and use of thiazolidinediones does not delay progression to insulin; and
- 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 (HbA_{1c}, LFT and adverse effects).

3. Reducing risk in Type 2 Diabetes (2005)

NPS MedicineWise Facilitators were up skilled from May 2005 onwards and delivery of this programme was completed by December 2006. At the completion of this programme, a total of 6749 health professionals had been actively engaged, including 5742 GPs.

Key messages/features of programme

- 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; and
- 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 therapy.

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

NPS MedicineWise Facilitators were up skilled from November 2001 onwards and delivery of this programme was completed in early 2003. At the completion of this programme, a total of 5763 health professionals had been actively engaged, including 5552 GPs.

Key messages/features of programme

- 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 ; and
- Individualise lifestyle interventions, targets, monitoring and drug therapy.

2.8.2 NPS MedicineWise 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

3. Blood Glucose Test Strips

3.1 Background

SMBG is one tool that can assist in the management of diabetes. In patients with type 1 diabetes, SMBG is used to guide insulin dose adjustments, improving glycaemic control (Cochrane 2012). HbA_{1c} is measured to identify the average blood glucose concentration over prolonged periods of time. High levels of HbA_{1c} 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 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. A wide variety of diabetes test strips are available on the Australian market.

Patients with diabetes who require insulin may monitor their blood glucose by finger-prick (capillary) testing up to three to four times or more a day along with their one to five 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 (Australian Prescriber 2010).

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

A Cochrane Collaboration Review (2012), a 2009 Canadian study (COMPUS) and a 2010 German study questioned the evidence of the benefit and effectiveness of regular (trained, systematically used, etc.) use of 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 Australia in people with type 2 diabetes not using insulin.

3.1.1 Access to Test Strips in Australia

Access to test strips in Australia occurs through two main government-subsidised channels (outside of the private market): the PBS and the NDSS. Patients must be assessed by an eligible healthcare practitioner (prescriber) in order to access test strips through the PBS and, in the case of access through the NDSS, must be registered on the scheme, the requirements for which are outlined in Section 3.1.1.2. Through the PBS, a maximum quantity of 100 test strips plus five repeats can be prescribed. For those people receiving treatment under a GP Management Plan or Team Care Arrangement, a maximum quantity of 100 test strips plus 11 repeats is available. Another visit to the prescriber and another prescription would then be required.

Through the NDSS, in any 180-day period, registrants can purchase up to 900 (nine packs of 100) test strips.

3.1.1.1 PBS 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 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 restricted to patients on insulin therapy.

Test strips 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 1953* 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 (dependent on brand). The current PBS co-payment of $36.10 for general patients and $5.90 for concessional patients applies to 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 for products priced between $30.01 and $45.00, and 10% for products priced between $45.01 and $180); and
- Dispensing fees ($6.63).

3.1.1.2 National Diabetes Services Scheme

The NDSS is an initiative of the Australian Government administered by Diabetes Australia. The NDSS delivers diabetes-related products, including syringes and needles, test strips, urine ketone test strips and insulin pump consumables at subsidised prices. The NDSS also 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 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 and the following co-payment arrangements currently apply:

- For general registrants, the current co-payment is $7.80 for a box of 50 strips and $15.50 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.

3.1.2 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 and the IVD Australia Code of Conduct (2010) regulate the professional conduct of manufacturers for advertising that is directed exclusively to healthcare professionals.

The IVD Australia Code of Conduct covers the advertising of in vitro diagnostic devices (IVDs), such as test strips, to health professionals. In promoting or advertising their products and services to healthcare professionals, sponsors of IVDs must ensure that the following principles are adhered to:

a. Advertisements (excluding brand name reminders) must contain the following information:

i. The brand name of the IVD (where appropriate);

ii. The name and address of the sponsor; and

iii. Any other information as may be required by law or as a condition of a licence.

b. Where claims are made, these must be consistent with the intended purpose of the IVD;

c. The term "safe" should not be used unless clearly qualified;

d. The term "new" may only be used in the first 12 months of promotion;

e. Products and services of other companies or the medical or scientific opinions of healthcare professionals should not be disparaged, compared unfairly or treated with disrespect, either directly or by implication. Comparison must be in the context of peer-reviewed publications available in the public domain. Members must be able to substantiate all claims made through reliable, readily available, medical or scientific evidence;

f. Promotional activities must not be designed such that they reflect poorly upon or reduce confidence in the IVD industry; and

g. Company-commissioned articles must be clearly identified as such.

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

A Cochrane Collaboration Review published in January 2012 found limited evidence of the benefit and effectiveness of regular use of 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."

In addition, 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.

Such evidence suggests that there is some initial benefit gained from blood glucose monitoring when a person is first diagnosed with type 2 diabetes. However, over time, that benefit is reduced as a person's diabetes stabilises. Further, while regular testing may assist in identifying hyperglycaemia, regular engagement with healthcare

professionals and periodic testing of a patient's HbA_{1c} is of greater benefit for people with type 2 diabetes not using insulin.

These studies put forward that ongoing support for other targeted interventions to improve a person's glycaemic control may be 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 HbA_{1c} to inform overall glycaemic management. It should be noted that such education and support activities may come at an additional cost.

As a result of evidence such as that outlined above, 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 test strips and ongoing SMBG 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 SMBG 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 SMBG (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 insulin dependent?

HbA_{1c}

Seven meta-analyses found that the use of SMBG was associated with a small decrease in HbA_{1c} 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 of around -0.25%. This benefit is less than the change in HbA_{1c} of 0.5% usually considered clinically significant, although this is acknowledged as a somewhat arbitrary figure (Clar, Barnard et al. 2010). However, the reduction may 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. It is noted that blood glucose meters can show variability in accuracy at the lower (and upper) ends of the glucose spectrum.

Long-term health outcomes (microvascular and macrovascular complications)

Quality observational studies have not demonstrated positive effects. The Fremantle diabetes study involved 1280 participants with type 2 diabetes 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 regard 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 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 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 ADEA (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 programme including the training of doctors to consider SMBG results in treatment adjustment, there was a significantly greater reduction in mean HbA_{1c} 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 HbA_{1c}

The results were not consistent between the four meta-analyses that examined the efficacy of SMBG depending on patients' baseline HbA_{1c} level. Three meta-analyses found a greater decrease in HbA_{1c} in people with higher HbA_{1c} levels, and one meta-analysis of individual patient data found 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 HbA_{1c} 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 diabetes treatments) on the HbA_{1c} 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 insulin dependent?

Three older trials (1989–1997) and one recent trial (2011) showed no significant difference between SMBG and SMUG in terms of blood glucose control (HbA_{1c}). The literature review did not find any other studies that met the inclusion criteria for this research topic.

What is the evidence that SMBG improves outcomes compared to no SMBG in patients with type 2 diabetes who are not insulin dependent 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, and 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 HbA_{1c} 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 European and North American countries with populations and health care standards similar to Australia. All trials included patients with type 2 diabetes, 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 applicable to the Australian population and health care setting.

This literature review demonstrated that ongoing SMBG levels in people with type 2 diabetes not using insulin does produce statistically significant changes, but the size of this benefit is often very small.

The literature review does highlight that in some instances, such as where people are prescribed agents which could cause hypoglycaemia such as sulfonylureas, 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, to guide treatment.

3.3 Additional Research Projects and Recent Studies

The Reference Group was asked for advice on any additional research not included in the literature review on the use of test strips in Australia that could be provided to the PBAC.

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 PBS Dataset on Blood Glucose Test Strips

As stated previously, subsidised 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' MATES research group, University of South Australia.

Main Findings

- **Total utilisation of test strips is growing at a rate of approximately 6.2% per year.**
- **Total government expenditure on test strips reached approximately $143.5 million in 2011–12.**
- **Approximately 35% of all test strips dispensed are for people with type 2 diabetes not using insulin.**
- **50% of people registered with the NDSS and 12% of people in PBS data with type 2 diabetes not using insulin received test strips in 2011–12.**
- **People with type 2 diabetes 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 Test Strips

Total test strip utilisation grew by approximately 6.2% per year over the past four years (2008–2011). 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 fell during the same period (Table 1).

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

	2008	**2009**	**2010**	**2011**
NDSS	2,553,974	2,775,183	2,968,484	3,221,231
PBS	435,434	407,239	379,164	361,581
Total	**2,989,408**	**3,182,422**	**3,347,648**	**3,582,812**
% Growth		6.5%	5.2%	7.0%

In 2011–12, the Australian Government spent approximately $143.5 million subsidising test strips for people 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 Test Strips in PBS Data

A ten year PBS dataset that included all unique patient identifiers (PINs) that were supplied a diabetes 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 of 875,000 from the 2011–12 National Health Survey. 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 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 people with type 2 diabetes not using insulin was estimated by analysing related supplies of oral diabetes medicines and insulin in de-identified patient level data. Because some oral diabetes 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 type 2 diabetes not using insulin grew annually in the NDSS data and declining slightly in the PBS data (refer to Figure 1 below).

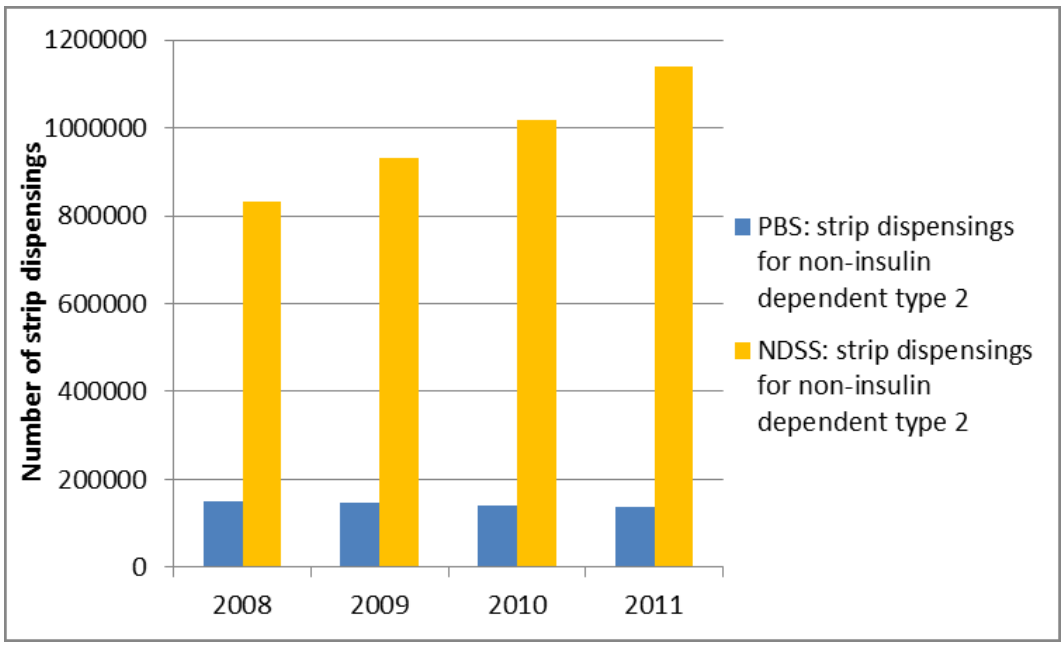


Figure 1. Number of test strip dispensings for people with type 2 diabetes not using insulin via the PBS and NDSS.

In 2011, 12% of people with type 2 diabetes not using insulin received at least one test strip dispensing during the year via the PBS. In contrast, approximately 50% of people with type 2 diabetes not using insulin received test strips via the NDSS. This data indicates that a significant proportion (up to 50%) of people with type 2 diabetes not using insulin did not access any test strips in a 12 month period.

When analysing PBS subsidised use of test strips by medicine class, people dispensed glitazones and sulfonylureas received more test strips than those on metformin. This is consistent with the 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 people with type 2 diabetes not using insulin in both NDSS and PBS data (Figure 2). Thus the majority (65%) of test strips supplied in Australia are used in insulin dependent and other forms of diabetes.

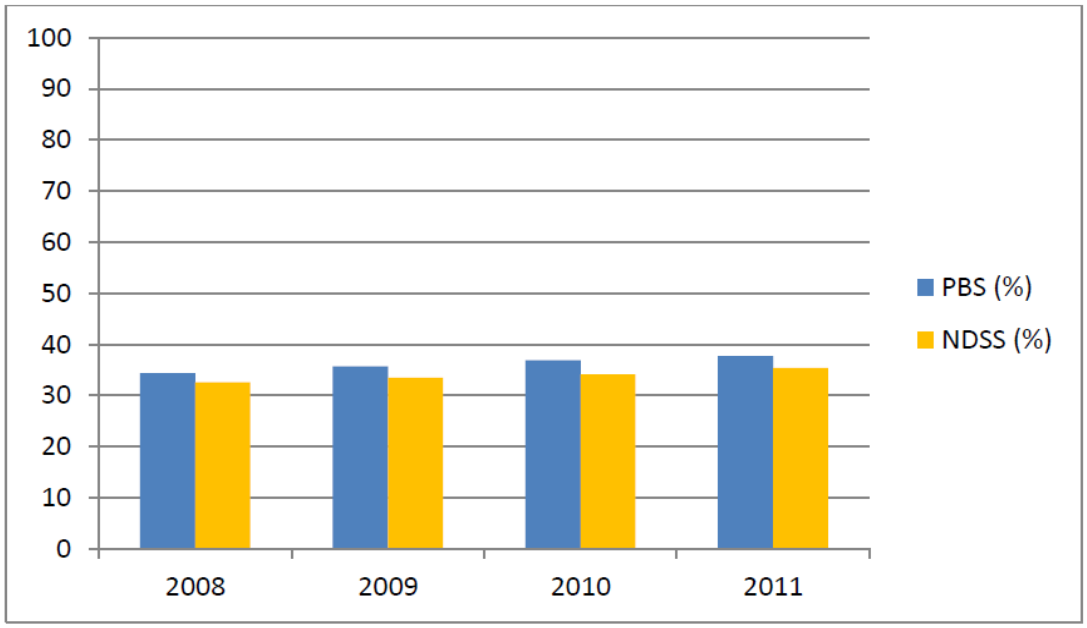


Figure 2. Percentage of test strips dispensed to people with type 2 diabetes not using insulin as a proportion of total test strip dispensing.

3.4.4 Utilisation of Test Strips Per Person

Figures 3 and 4 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 type 1 diabetes were receiving twice as many dispensings for test strips compared to those with type 2 diabetes using insulin, and 3–4 times as many as people with type 2 diabetes not using insulin. Type 1 diabetes patients averaged 11 dispensings a year (1100 strips), suggesting regular multiple daily use of test strips.

People with type 2 diabetes using insulin received on average 6 dispensings per year (600 strips), which is sufficient for twice daily use. In both NDSS and PBS data, people with type 2 diabetes not using insulin receive on average 3 dispensings per year (300 strips). The use of test strips in people with type 2 diabetes using insulin and type 1 diabetes is much higher in the NDSS dataset than the PBS dataset. The reason for this is unknown.

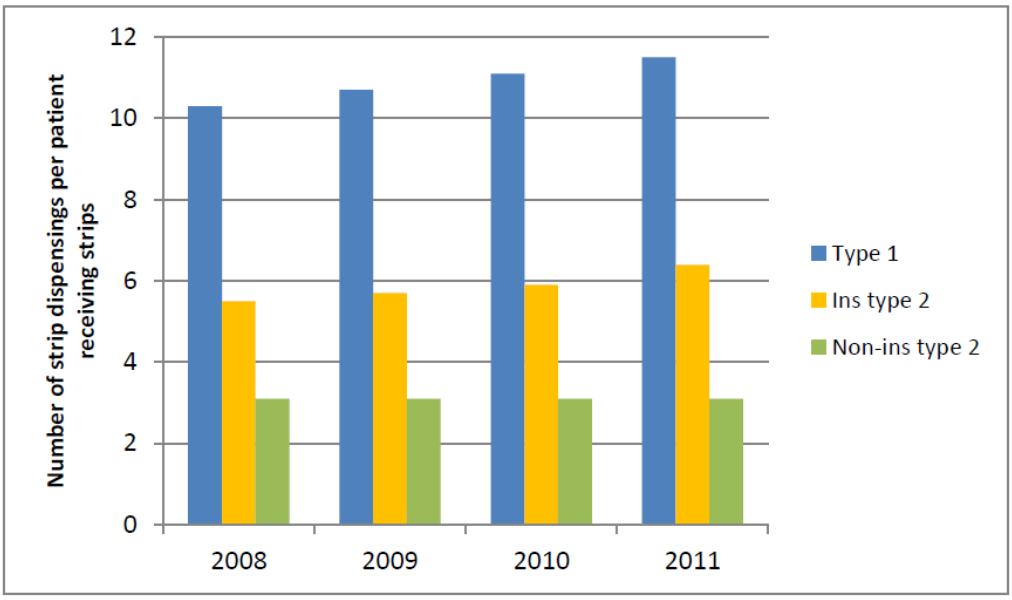


Figure 3. Average number of test strip dispensings (packs of 100) per patient receiving any test strips (NDSS data).

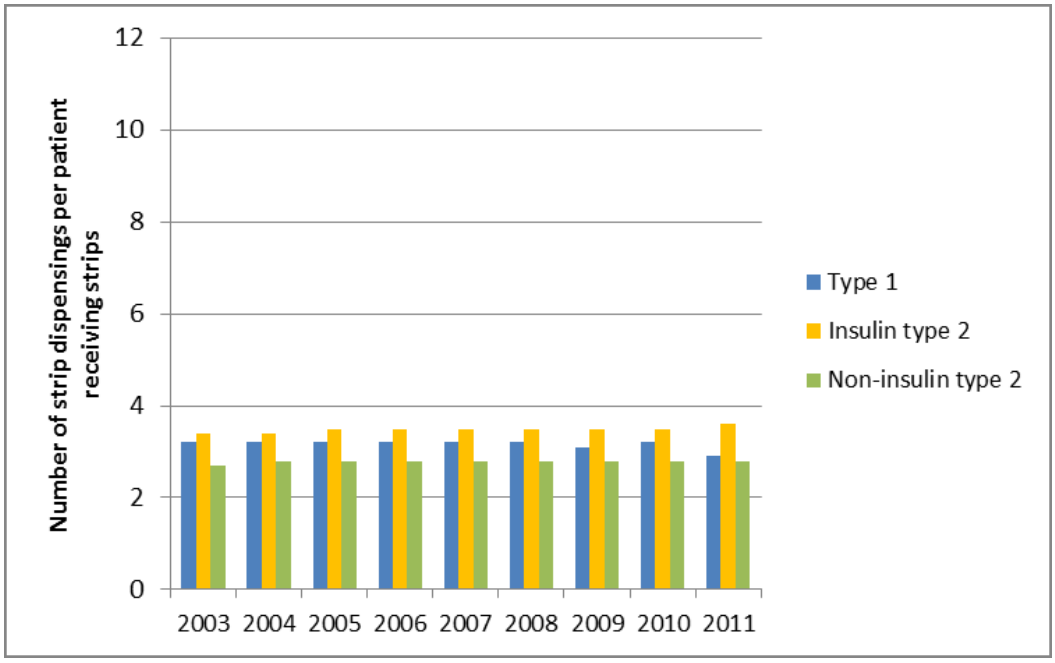


Figure 4. Average number of test strip dispensings (packs of 100) per patient receiving any test strips (PBS data).

3.4.5 New Users (Type 2 Diabetes Not Using Insulin) of Test Strips – 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 diabetes medicine 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 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 type 2 diabetes 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 1–2 strips per day, and one fifth received a supply of strips that would have enabled the use of three or 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 underestimate the total use per patient.

3.5 Utilisation Review of NDSS Dataset on Test Strips

In response to the Reference Group's and the PBAC's requests, and to construct a comprehensive perspective on the use of test strips in clinical practice, the Department sought further utilisation data from the NDSS. The analysis of this data was conducted by the PBS Information Section of the Department.

The NDSS database captures two data sets: SALES data and REGISTRANT data. In the first instance, these two data sets were combined by matching on 'registrant number', 'insulin requiring' and 'diabetes type' fields.

This resulted in a combined dataset of prevalent registrants. From this dataset, those with type 2 diabetes not using insulin were identified and data was captured in discrete financial years from 2008–09 to 2011–12. Prevalent users were analysed as new users of medicines or test strips could not be accurately identified in this dataset.

Main Findings

- **The average number of packs supplied per year per person with type 2 diabetes not using insulin was 3.06 in 2008–09, 3.08 in 2009–10, 3.09 in 2010–11 and 3.11 in 2011–12 (Figure 5).**
- **Of those people with type 2 diabetes not using insulin in the NDSS dataset who receive any packs of test strips, the majority receive less than four packs of test strips per year (Figure 6).**

- **The proportion in the NDSS dataset of people with type 2 diabetes and not using insulin receiving less than four packs of test strips per year (less than 400 strips per year) was consistent at approximately 71% in each of the four financial years from 2008–09 to 2011–12 (Figure 7).**
- **In 2011–12, 29% of people with type 2 diabetes not using insulin were supplied with four or more packs of test strips (400 or more test strips), and a small number of these people received between 13 and 50 packs (Figure 6).**
- **No major differences in baseline characteristics were found to contribute to this pattern, although there was a trend towards higher use of test strips in older age groups (Figure 8).**

3.5.1 Number of Packs of Test Strips Supplied Per Person on an Annual Basis

Figure 5 shows the average number of packs of test strips supplied per person with type 2 diabetes not using insulin in each financial year analysed for the NDSS dataset.

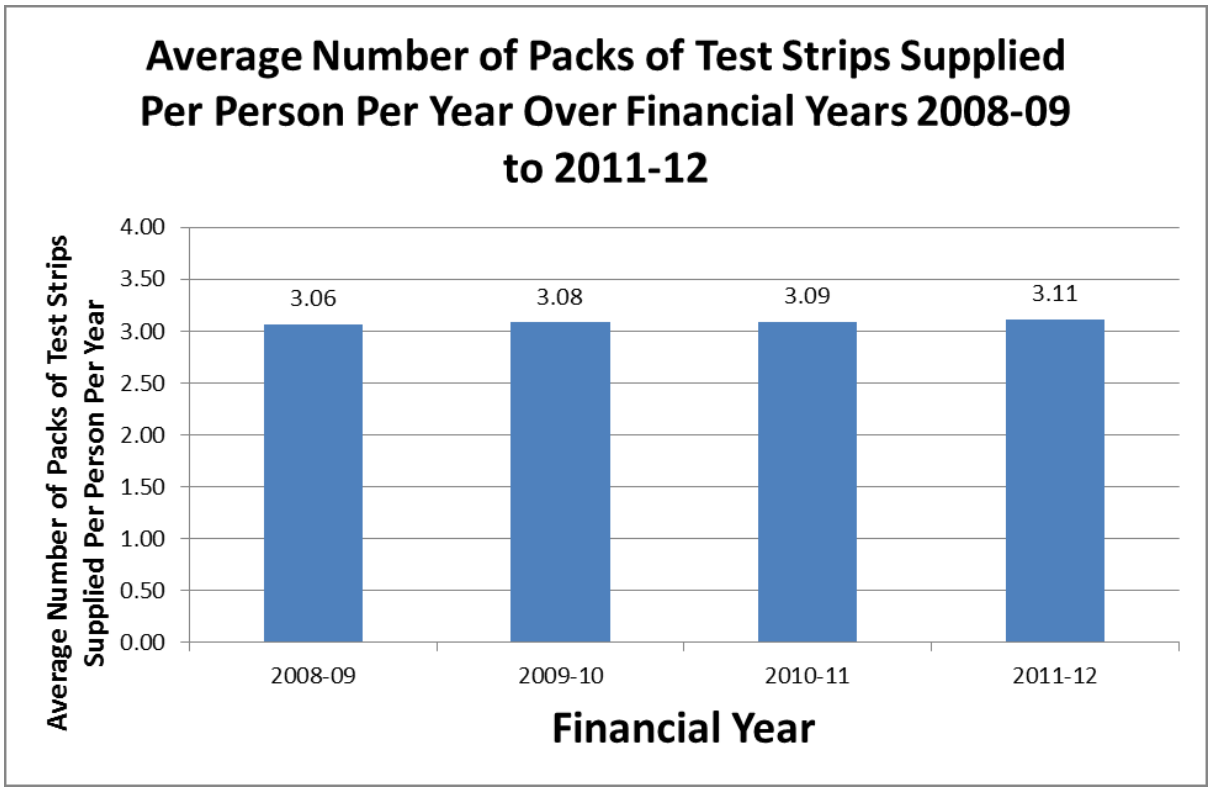


Figure 5. Average number of test strip dispensings (packs of 100) per person with type 2 diabetes not using insulin per year over four financial years (NDSS data).

From this, it can be seen that the total average number of packs supplied to individuals yearly has remained stable over time.

3.5.2 Frequency Distribution of Packs of Test Strips Supplied to People with Type 2 Diabetes Not Using Insulin per Year

Figure 6 provides a frequency distribution of NDSS registrants identified as having type 2 diabetes not using insulin supplied 1–50 packs of test strips per year, over the four financial years. This shows that the vast majority of registrants are supplied 1–3 packs of test strips per year. This result is consistent in each of the four financial years analysed.

There is a small proportion of patients receiving more than 13 and up to 50 packs of test strips per year. The clinical need or benefit for this number of test strips for an individual in a one year period is questionable. The cut-off point or appropriate rate of testing has not been determined and individual fluctuations in disease may need to be accounted for. For example, periods of hypoglycaemia would necessitate more testing. However, more than nine packs per year approximates testing on average three times per day.

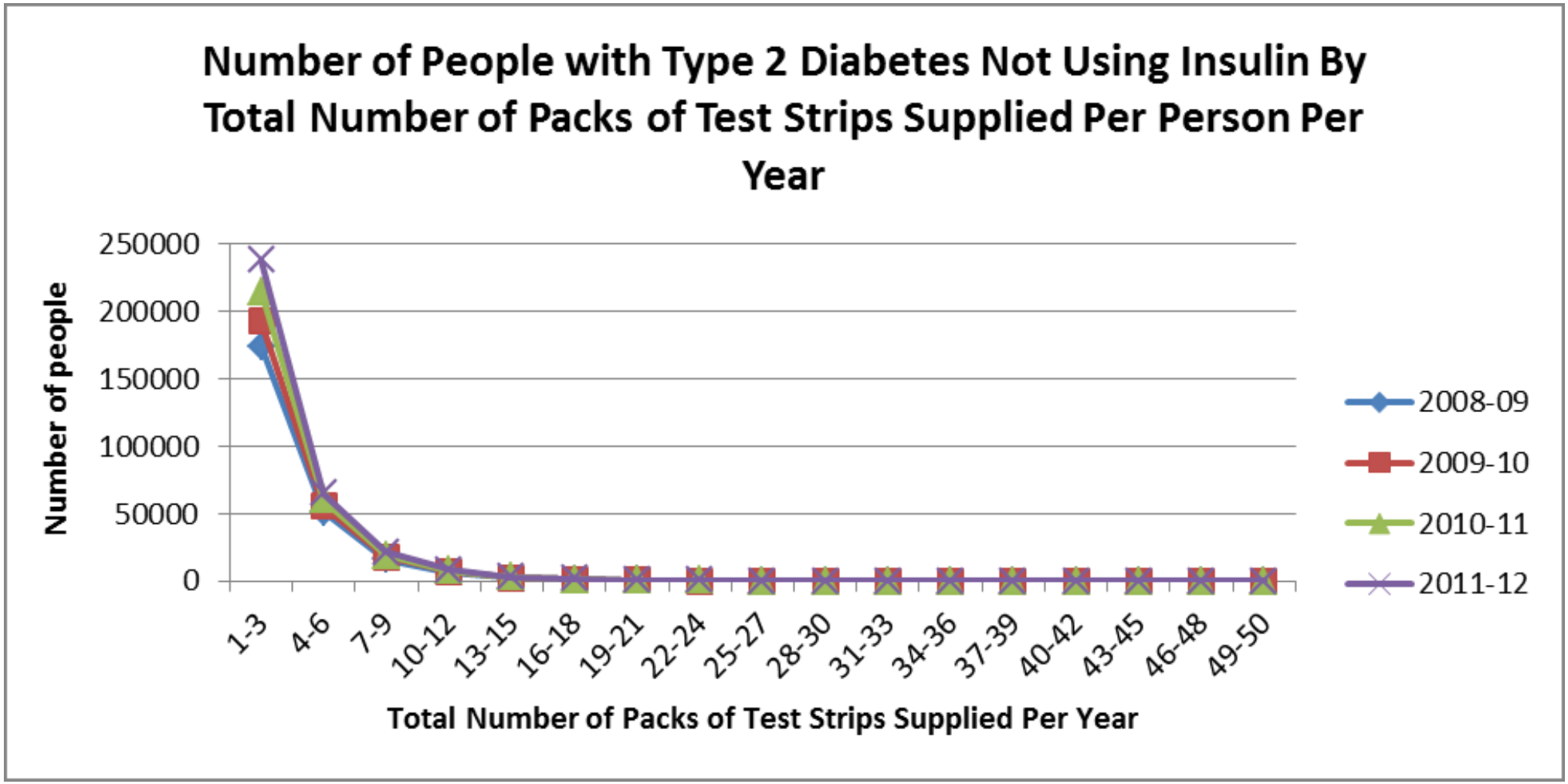


Figure 6. Total number of people with type 2 diabetes not using insulin supplied with test strip dispensings (packs of 100) by total number of dispensings in one year (NDSS data).

3.5.3 Proportion of People with Type 2 Diabetes Not Using Insulin Supplied With Less Than Four Packs of Test Strips per Year

Figure 7 shows that the proportion of people with type 2 diabetes not using insulin supplied with less than four packs of test strips per year has remained stable in the four financial years 2008–09 to 2011–12 at approximately 69–70% of the total population. Accordingly, approximately 30–31% of this population are supplied with four or more packs of test strips per year.

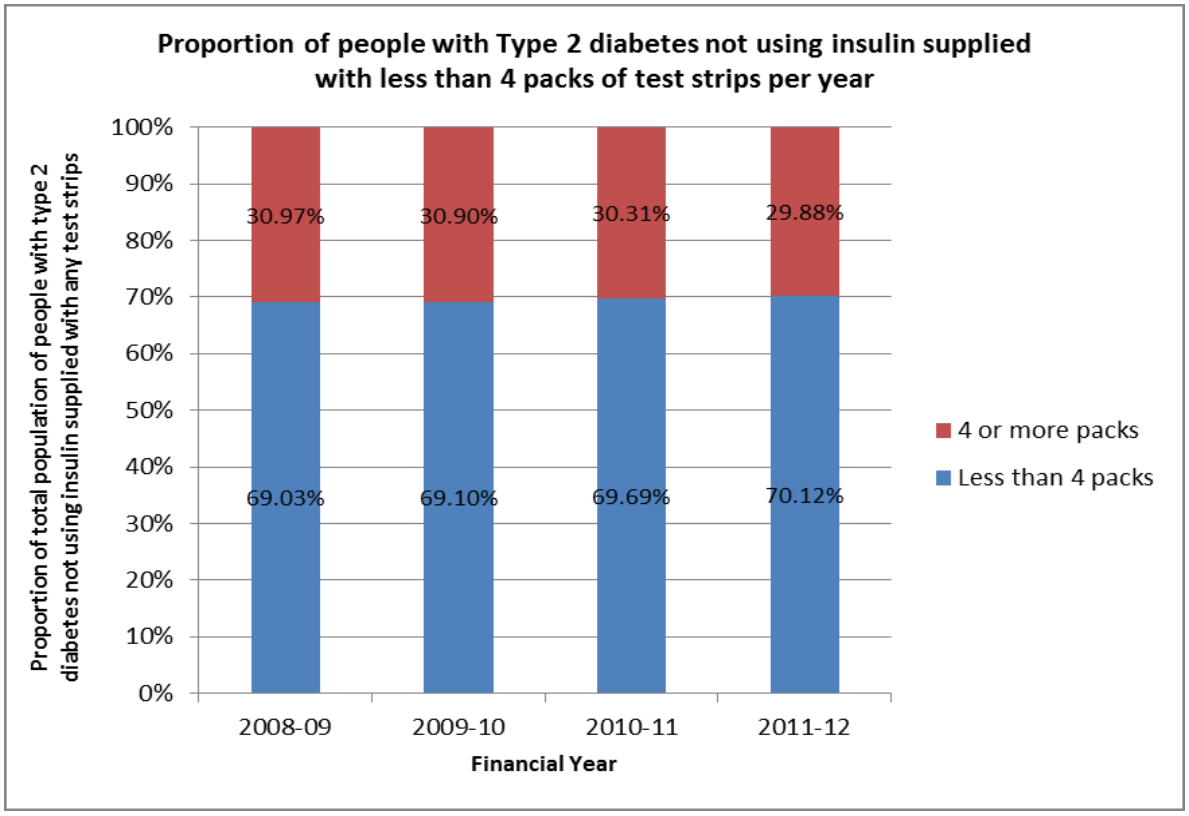


Figure 7. Proportion of the total number of people with type 2 diabetes not using insulin supplied with any test strips that are supplied with less than four test strip dispensings (packs of 100) in one year (NDSS data).

3.5.4 Baseline Characteristics of People with Type 2 Diabetes Not Using Insulin Supplied with Less Than Four or Four or More Packs per Year

Table 2 shows the total number of people with type 2 diabetes not using insulin in the NDSS dataset over the four financial years from 2008–09 to 2011–12. It can be seen from this table that this population has increased over time at a rate of approximately 10% each year.

Table 2. Total number of people with type 2 diabetes not using insulin supplied with test strip dispensings (packs of 100) (NDSS data).

	2008–09	2009–10	2010–11	2011–12
Total in dataset	252,705	278,439	307,995	339,639

Tables 3–7 show baseline characteristics of the 2011–12 dataset of people with type 2 diabetes not using insulin. Columns 3 and 4 show the proportion of people in each sub-category of baseline characteristic supplied with either less than four (column 3) or four or more (column 4) packs of test strips in the one year. Column 5 indicates the proportion of the total 2011–12 NDSS dataset in each sub-category of baseline characteristic.

Time since diagnosis was unable to be examined as this dataset. Almost 90% of this dataset was incomplete.

3.5.4.1 Age

Table 3 shows the proportion of people with type 2 diabetes not using insulin supplied with less than four, or four or more packs of test strips per year by age.

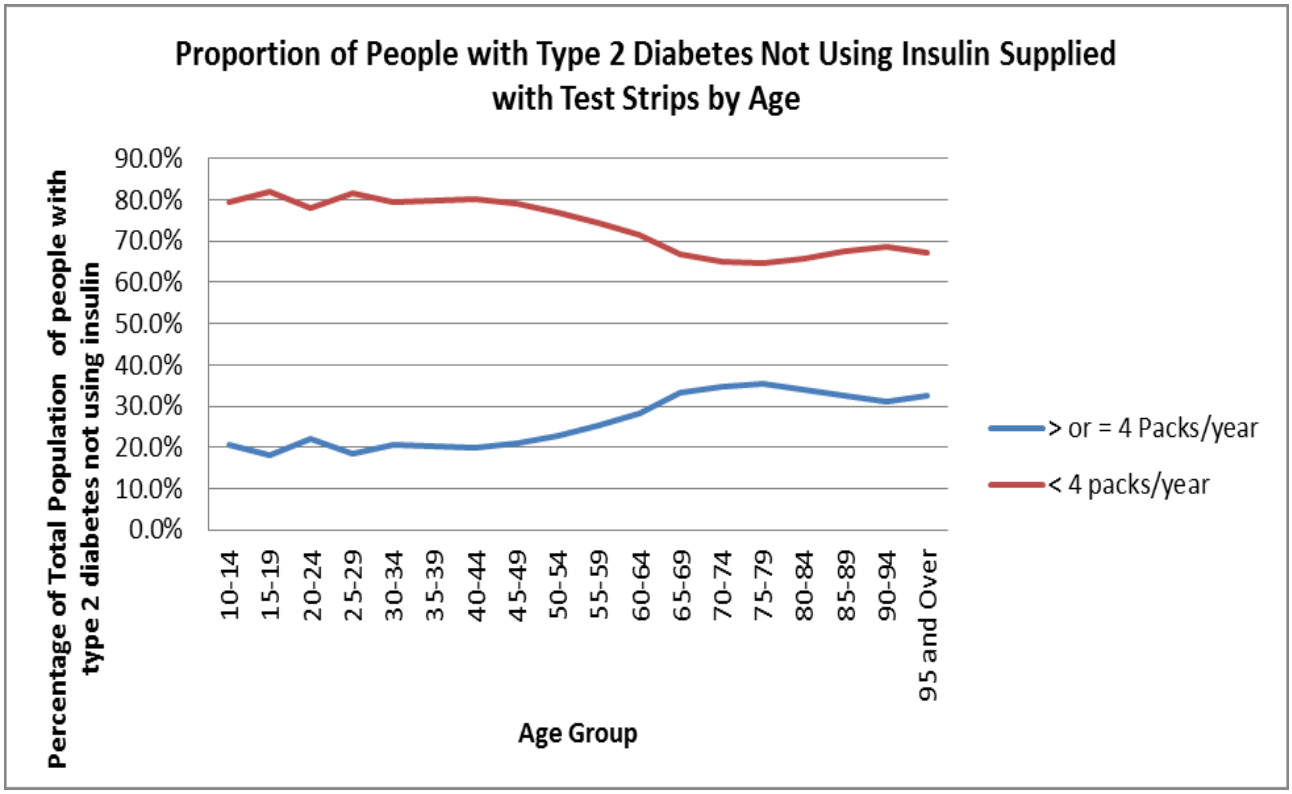
As a proportion of the total population, 65–69 year olds were the largest age group (15.96%) followed closely by 60–64 year olds (15.01%). Less than 0.5% were under 30 years of age.

Table 3. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by age.

Characteristic	**Sub-Categories**	**Proportion supplied less than four packs in 2011–12**	**Proportion supplied four or more packs in 2011–12**	**Proportion of total 2011–12 dataset N= 339,639**
Age	5 – 9	50.00%	50.00%	0.00%
	10 – 14	79.55%	20.45%	0.01%
	15 – 19	81.88%	18.12%	0.05%
	20 – 24	77.99%	22.01%	0.09%
	25 – 29	81.66%	18.34%	0.27%
	30 – 34	79.50%	20.50%	0.68%
	35 – 39	79.73%	24.27%	1.47%
	40 – 44	80.21%	19.79%	2.94%
	45 – 49	79.05%	20.95%	5.14%
	50 – 54	77.13%	22.87%	8.05%
	55 – 59	74.61%	25.38%	11.39%
	60 – 64	71.72%	28.28%	15.01%
	65 – 69	66.90%	33.10%	15.96%
	70 – 74	65.15%	34.85%	14.31%
	75 – 79	64.46%	35.54%	11.56%
	80 – 84	65.89%	34.11%	8.01%
	85 – 89	67.53%	32.47%	3.85%
	90 – 94	68.81%	31.19%	1.03%
	95 and Over	67.35%	32.65%	0.19%
	Total	**70.12%**	**29.88%**	**100%**

As shown in Figure 8, there is a trend towards higher use of test strips in older age groups, peaking at 75–79 year olds, where 35.5% use four or more packs of test strips per year.

Figure 8. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by age.



3.5.4.2 Sex

Table 4 shows the proportion of the 2011–12 dataset of NDSS registrants with type 2 diabetes not using insulin supplied with less than four packs of test strips by sex. There were more males than females (56% compared to 44%, respectively) accessing test strips. The proportion of males and females supplied with less than four packs was similar (72% and 68%, respectively).

Table 4. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by sex.

1. Characteristic	2. Sub-Categories	3. Proportion supplied less than four packs in 2011–12	4. Proportion supplied four or more packs in 2011–12	5. Proportion of total 2011–12 dataset N= 339,639
Sex	Male	71.51%	28.49%	56.31%
	Female	68.32%	31.68%	43.69%
	Total	**70.12%**	**29.88%**	**100%**

3.5.4.3 Aboriginal and Torres Strait Islander Status

Table 5 shows the Aboriginal and Torres Strait Islander status of NDSS registrants with type 2 diabetes not using insulin in the 2011–12 dataset. This table shows that the majority of people in this group were not of Aboriginal or Torres Strait Islander origin (86.98%), and a further 12% did not specify Aboriginal or Torres Strait Islander status. Less than 1% of this dataset identified as being of either Aboriginal or Torres Strait Islander origin, or both (0.84%, 0.09% and 0.04%, respectively).

Table 5 further shows that in all sub-categories of Aboriginal and Torres Strait Islander status, the majority of people were supplied with less than four packs of test strips in the 2011–12 financial year. Similar to results obtained in other baseline characteristic groups discussed above, approximately 70–78% of each sub-category was supplied with less than four packs of test strips in the year.

It is noted that identification and recording of Aboriginal and Torres Strait Islander status in the NDSS is low and so caution is warranted in the interpretation of this data.

Remote Area Aboriginal Health Services (RAAHS) and the PBS

An examination of Indigenous status of people with type 2 diabetes supplied with test strips in the PBS dataset may have complemented this evaluation; however, the PBS data uses an identifier known as the Voluntary Indigenous Identifier. This is only a sample of the Indigenous population accessing the PBS and is not a complete representation of this population. Further, the use of this identifier requires express permission from the Office for Aboriginal and Torres Strait Islander Health. For these reasons, PBS data on Indigenous status is not presented.

Special arrangements exist for approved RAAHS to supply PBS medicines to patients. Under the provisions of section 100 of the *National Health Act 1953*, patients of approved RAAHS can receive free PBS medicines from the Aboriginal Health Services (AHS) without a prescription.

Information about the utilisation of test strips through AHS in Australia has not been reported as the data is limited to summary level data of the total number of supplies ordered through AHS. Patient-level information is not available. Descriptive data about the person or their type of diabetes is also not available.

Table 5. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by Aboriginal or Torres Strait Islander status.

1. Characteristic	2. Sub-Categories	3. Proportion supplied less than four packs in 2011–12	4. Proportion supplied four or more packs in 2011–12	5. Proportion of total 2011–12 dataset N= 339,639
Indigenous status	Neither Aboriginal nor Torres Strait Islander	69.71%	30.29%	86.98%
	Aboriginal but not Torres Strait Islander origin	78.49%	21.51%	0.84%
	Torres Strait Islander but not Aboriginal origin	77.00%	23.00%	0.09%
	Both Aboriginal and Torres Strait Islander origin	78.17%	21.83%	0.04%
	Inadequate/ Not stated	72.38%	27.62%	11.97%
	Total	**70.12%**	**29.88%**	**100%**

3.5.4.4 State/ Territory of Residence

Table 6 shows the proportion of people in the 2011–12 NDSS dataset supplied with less than four packs of test strips by their state/ territory of residence. Consistent with the overall pattern of supply, in which approximately 70% of the overall dataset are supplied with less than four packs of test strips, the proportion of people supplied with less than four packs in the different states and territories is in the range of 65–80%. Western Australia and the Northern Territory have the lowest percentage (approximately 20%) supplied with four or more packs per year and Victoria had the highest at 35%.

In terms of the distribution of test strips supplied in each state or territory as a proportion of the overall total, the larger states of New South Wales and Victoria represented the largest proportion of overall test strips supplied (29.71% and 27.11%, respectively).

The total number of people in each state or territory was assessed on a per capita basis (total number of people with type 2 diabetes not using insulin supplied with test strips by state or territory divided by the total population in that state or territory). These analyses showed that the number of people with type 2 diabetes not using insulin supplied with test strips in each state or territory was lowest in the Northern Territory at 0.73% and highest in South Australia at 1.94%. The apparent lower use of NDSS test strips in the Northern Territory may be due to the supply of test strips through RAAHS.

Table 6. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by state of residence.

1. Characteristic	2. Sub-Categories	3. Proportion supplied less than four packs in 2011–12	4. Proportion supplied four or more packs in 2011–12	5. Proportion of total 2011–12 dataset N= 339,639
State/ Territory (usual residence)	ACT	76.30%	23.70%	1.54%
	#Per capita			*1.38%*
	NSW	69.07%	30.93%	29.71%
	#Per capita			*1.37%*
	NT	79.59%	20.41%	0.51%
	#Per capita			*0.73%*
	QLD	72.27%	27.73%	18.21%
	#Per capita			*1.34%*
	SA	69.96%	30.04%	9.48%
	#Per capita			*1.94%*
	TAS	69.89%	30.11%	2.53%
	#Per capita			*1.67%*
	VIC	65.43%	34.57%	27.11%
	#Per capita			*1.62%*
	WA	79.87%	20.13%	10.92%
	#Per capita			*1.50%*
	Inadequate/ Not stated	75.00%	25.00%	0.00%
	Total	**70.12%**	**29.88%**	**100%**

Based on *Australian Bureau of Statistics,* 'Australian Demographic Statistics, Dec 2012', Population at end of December quarter 2012 (latest) for states and territories; http://www.abs.gov.au/ausstats/abs@.nsf/mf/3101.0/

3.5.4.5 Concessional Status

Table 7 shows the proportion of people with type 2 diabetes not using insulin in the 2011–12 NDSS dataset by concession card type. It should be noted that during the period, some used more than one type of concession card when supplied with test strips, therefore the overall percentage of the total dataset is greater than 100% (110.15%). Most of this cohort held a pensioner concession (over 50%).

Of those included in the analysis, over 35% of this dataset was incomplete. Therefore, limited conclusions can be made about the results. What can be seen is that, similar to results obtained for other baseline characteristics, most (68–83%) of the people in this dataset were supplied with less than four packs of test strips in the 2011–12 financial year.

Table 7. Proportion of people with type 2 diabetes not using insulin supplied with less than four test strip dispensings (packs of 100) in the 2011–2012 dataset by concession card type.

1. Characteristic	2. Sub-Categories	3. Proportion supplied less than four packs in 2011–12	4. Proportion supplied four or more packs in 2011–12	5. Proportion of total 2011–12 dataset N= 339,639
^*Concession card type*	CN	69.62%	30.38%	1.79%
	DVACSHC	71.91%	28.09%	0.12%
	DVAG	67.24%	32.76%	1.88%
	DVAPCC	72.52%	27.48%	2.24%
	DVAW	76.34%	23.66%	0.03%
	HC	74.61%	25.39%	4.77%
	PEN	68.11%	31.89%	51.38%
	SN	73.29%	26.71%	11.01%
	Inadequate/ Not stated	83.20%	16.80%	35.31%
	Total	**73.95%**	**26.05%**	**110.15%***

* Total of concession card type dataset is more than 100% (N=339,639) as a patient could have used more than one card type during the year.

^ Type of Concession card used at time of purchase: CN - Safety Net Concession; DVACSHC – DVA Commonwealth Seniors Health Care; DVAG – DVA Gold; DVAPCC – DVA Pensioner Concession; DVAW – DVA White; HC - Health Care; PEN – Pension; SN - Safety Net

Appendix B describes the different concession card types, their administration and the benefits provided to cardholders.

The test strips results presented here are based on NDSS data. It is also possible for people to buy these strips through the PBS, and this data is provided in Section 3.4. Without linking the two data sources it is difficult to ascertain a complete picture of the supply patterns of test strips given that some people may be accessing test strips through both schemes. The Department is aware that the AIHW, as an accredited national data integrating authority, is currently undertaking such a project through its National Centre for Monitoring Diabetes. This work is part of a project that is examining more broadly the use of medications by people with diabetes, and which will also take into account diabetes type and duration of disease. The database linkage will allow the purchases of individuals through both schemes to be quantified. The Department will continue to work with the AIHW to ensure that it is aware of progress in this project. It is anticipated that this work will be publicly released during 2014.

3.6 Public Consultation Process

3.6.1 Submissions to Terms of Reference

Submissions addressing the Terms of Reference relating to test strips were invited from interested organisations and individuals. This consultation process focused on the utilisation and patterns of use of SMBG and the clinical outcomes and benefits of SMBG for people with type 2 diabetes not treated with insulin (Terms of Reference 5–7).

Thirty-three submissions were received: 10 from industry organisations, 10 from professional peak bodies, 4 from professional individuals, 8 from non-government organisations and one from a government organisation. Unless otherwise requested, submissions were made publicly available on the PBS website.

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 achieve a better understanding of diabetes and provide means to actively and effectively participate in its control and management;
- 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 stakeholders believe this provides individuals assistance to manage their condition;
- Concern was expressed about the impact to consumers of any restriction to accessing test strips;
- 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, that regardless of how test strips should be used, SMBG 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.

3.6.2 Submissions to Draft Report

The draft Report for Stage 1 of the Diabetes Review focusing on the use of test strips in people with type 2 diabetes not using insulin was submitted to the PBAC for comment and feedback in December 2012.

Further, in December 2012, interested organisations and individuals were invited to review the draft Report and suggest any additional evidence that they feel should be considered.

A total of nine submissions were received:

- Three state offices of Diabetes Australia (Tasmania, Western Australia and Victoria), as well as the Australian Diabetes Educators Association provided the same submission, which raised concern about potential implications of any restrictions to access, including the fundamental change to universal access rights it would present to Australians with diabetes;
- Roche Diagnostics, Abbott Diabetes Care and IVD Australia also provided submissions, which raised similar concerns;
- AIHW identified further information and projects it is undertaking in this area; and
- Consumer Health Forum supported the draft Report in full and provided no further comment.

The final Report incorporates the comments of stakeholder feedback and PBAC advice received during these consultation periods.

3.7 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 to the Review.

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

- Better contextualise the use of test strips in type 2 diabetes; and
- Encourage open discussion in addressing the most clinically effective use of these test strips in improving outcomes for people with type 2 diabetes not using insulin.

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 test strips?

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 initiating medical assistance. If there is a change in access to test strips, health professionals and patients will need to be supported.
- Over the past 10 years test strips have been treated as an intervention, or a diagnostic tool to inform intervention.
- Test strips give patients control over their own health, and if used in conjunction with the HbA_{1c} test, patients are better able to manage their type 2 diabetes, which they value.
- Although the HbA_{1c} 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 test strips was an important part of providing greater patient control over the self-management of their condition.
- If patients believe their diabetes is well controlled they see little need to visit their GP and this has implications for ensuring the most effective use of test strips.
- Patients with longer term maintenance issues associated with their type 2 diabetes benefit from using test strips; whereas they are less relevant for more stable patients.
- Test strips 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 therapy.
- Evidence and data is critical.
- There is a need to better understand test strips data and patient patterns of use. Current data is available through:
    - Professor Tim Davies, WA;
    - Fremantle Cohort; and
    - Cochrane Collaboration Review.
- Representatives responsible for the administration of the NDSS indicated that, at a population level, there was little evidence to indicate over-use of test strips. Data suggests that on average, people with type 2 diabetes not using insulin use one test strip per day. However, this is at the population level and an average rate. 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:
    - NHMRC Guidelines;

- RACGP/Diabetes Australia Handbook;
- International Diabetes Federation;
- NDSS; and
- Diabetes Educators Guidelines.

- There is a need for clarity and consistency in messages to patients and health professionals in relation to test strips. The core Guidelines at this point in time are the NHMRC Guidelines and these may need updating in recognition that use of test strips for type 2 diabetes is only one element of broader diabetes management. These Guidelines are presented in plain English and have relevance across the breadth of health professions. They should indicate a minimum standard of care.
- Patient education in the best practice use of test strips needs to occur in a structured manner and should be viewed as part of a collaborative package of care or a patient care agreement. Information and education enable informed decisions and more effective self-management and action.

Summary of Responses to Focus Questions

Focus Question One: How can test strips be most appropriately used for self-management of type 2 diabetes?

- Currently there is open access to test strips for eligible people. A key issue consistently identified during the forum was the need for test strips to form part of an integrated and holistic structured programme that ensures the use of test strips feeds into and informs appropriate clinical, lifestyle and treatment decisions. Such a structured programme would likely improve the clinical benefit of testing.
- Clinical conditions and glycaemic variability needs to be accounted for when creating structure around test strips use.
- Test strips should not be limited, particularly for those people where they will have the greatest 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.
- Patients require reassurance and two-way communication with their health professional 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. Test strips 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 test strip use needs to be consistent across health professions. There should not be rigidity in this structure to allow for points of incongruity.

Focus Question Two: How do people access test strips and what facilitates clinically optimal use?

- Patient episodes (e.g. illness exacerbation, hospitalisation or other events) can trigger test strip use.
- Health professionals are the primary entry point for accessing test strips. Other providers, including community pharmacy for example, offer structured programmes and interventions (such as Diabetes MedsCheck) that support understanding of appropriate medication management, including test strips.
- 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 test strips through the NDSS and PBS is good, with remote areas catered for through a postal service.
- Although Australia has relatively unlimited access to test strips 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 test strips, but may not currently access them.

Focus Question Three: How can education and support better inform self-management of type 2 diabetes (including test strips)?

- There is a need for a structured but flexible programme that provides consistent messages, allows for common elements of sub-services, and incorporates Care Plans, while accounting for the risks associated with GP only updates without including the perspectives of other health professionals.
- The use of test strips should be tied to a multidisciplinary education and training programme where all health professionals provide a consistent message supported by guidelines.
- Pharmacists are a key dispensing point for test strips 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 test strips.
- Education strategies should convey that all treatment approaches are equally valid.

Final Perspectives

<u>Clinicians</u>

- Test strips should be available under conditions that include informed, structured approaches (self-management). Could limit use to be more targeted. However, there was a level of discomfort with the notion that test strips would only be available under certain conditions and this would impact universal access.
- If universal access was limited this would need structure, education and clinical utility.
- Any education strategy must take into account cross-cultural considerations.

Health Professionals

- Review size of test strip 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.

Consumers

- Test strips are empowering, restricting access may bear risk (dieticians).
- Co-ordinated and consistent approach across health professionals.

Industry

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

3.8 Internal Working Group

The first meeting of the Working Group was held on 23 October 2012, to provide information to agencies that may have an interest in the outcomes of the Review and to discuss strategies to manage possible impacts on these agencies. It was emphasised that a two-way flow of advice between the Working Group and the Reference Group would assist the Review, with the two groups working in parallel to steer the Review.

Specific agency issues

Working Group members were invited to provide a brief summary of the perceived implications of the Review for their agencies. Some issues raised include:

DoH (Pharmaceutical Benefits Division) – Emphasised the importance of the Working Group's role in informing agencies of the progress of the Review, and in engaging a range of stakeholders, including manufacturers, educators, consumer groups and health professionals in the Review process.

DoH (Population Health Division) – Noted the importance of maintaining involvement in the Review process, as a stakeholder with interests in funding and monitoring of diabetes management programmes, including funding for guidelines production.

Therapeutic Goods Administration (TGA) – Focused on safety issues of medicines, rather than devices.

NHMRC – Agreed that there needs to be consistency between guidelines and clinical practice in the management of diabetes.

Department of Veterans' Affairs (DVA) - Veterans' MATES programme focused on quality use of medicines through providing tailored information for veterans and health professionals based on data from prescription claims.

Department of Human Services (DHS) – Interested in any significant changes affecting the PBS, and will work with DoH through this process.

3.9 Reference Group

A Reference Group was established to provide a platform for experts to advise on issues for the Diabetes Review. The Reference Group consists of experts in a range of fields relating to the management of diabetes such as endocrinologists, pharmacists, nurse practitioners, GPs, dieticians, diabetes educators, consumers and psychologists.

The purpose of the Reference Group is to provide expert advice to the Review and the 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.

The first meeting of the Reference Group was held on 22 November 2012 in Canberra. Advice from the Reference Group contextualised stakeholder submissions and findings from the utilisation analysis, and provided further support for a more structured approach to blood glucose testing. The Reference Group identified the risk that universal access has the potential to promote use of limited clinical benefit. The Group considered that more regular inclusion of health professionals in the management of diabetes would support clinically appropriate use of test strips, including better integration with patient education and use as a tool to inform diabetes management.

Further, the Reference Group 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 programme aimed at delivering a structured approach to SMBG using test strips, including quarterly Hb1AC testing and a 12 monthly review by a health professional; and
- Growth in the NDSS appears to be due to better and easier access for patients through more Access Points and less expensive co-payments.

The Reference Group advised that the Department may wish to consider:

- Including other research projects in 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 advertising of test strips and related diagnostic devices, and how that may affect patients using test strips to self-monitor their blood glucose levels.

The Reference Group noted that unsupported open access may not send a consistent message to consumers about appropriate use. Similar to New Zealand guidelines, patients could be given a 3–6 month supply with additional supplies available under special conditions, such as those listed in the SIGN Guideline (2010), including access for certain populations, with the ability to be flexible. It was noted that the SIGN Guideline (2010) listed in the literature review provided a good example of possible eligibility criteria to support more appropriately targeted access.

The Reference Group agreed that guidelines relating to the use of test strips 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.

It was noted that the cost-effectiveness of SMBG remains uncertain, for people with type 2 diabetes not using insulin, in Australia.

The second Reference Group meeting was held on 17 April 2013.

4. Summary

The focus of this component of the Review is on the clinical benefit of blood glucose testing to facilitate 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 analyses; and
- Input from the Reference Group.

The main results of these analyses were that:

- Ongoing SMBG in people with type 2 diabetes not using insulin produces statistically significant changes in HbA_{1c}, although the size of this benefit is often very small;
- 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, there may be benefits to ongoing self-monitoring, such as where agents that could cause hypoglycaemia (e.g. sulfonylureas) are prescribed;
- Any self-monitoring should occur only where determined in consultation with a healthcare professional, in a structured format, to guide treatment;
- Total test strip utilisation has been growing at approximately 6.2% per year over the past four years (2008–2011). This is due to an increasing number of supplies provided through the NDSS;
- Around 35% of all test strips were dispensed to people with type 2 diabetes not using insulin, in both NDSS and PBS data; and
- In both NDSS and PBS data, people with non-insulin dependent type 2 diabetes 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. Some of the key recommendations of the guidelines are:

- 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 SIGN Guideline (2010) states that routine SMBG in people with type 2 diabetes who are using oral glucose-lowering drugs (with the exception of sulfonylureas) 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, SMBG 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 SMBG levels in terms of HbA_{1c} improvement. However, the guidelines were generally in agreement that, to be effective, SMBG needs to be part of a complex educational intervention that promotes 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 people with type 2 diabetes not using insulin. Therefore, it is important to ensure that access to test strips in this population is clinically appropriate.

Considering potential changes to access arrangements must factor in the range of potential costs and benefits. This is made difficult by the fact that potential benefits and costs are not always explicit. Through the consultation processes and examination of available literature, it is evident that there are benefits of using test strips that are not easily measured, particularly patient-valued outcomes such as self-empowerment.

HbA_{1c} provides a measure of an individual's risk of the long-term complications of diabetes. Regular blood glucose testing with strips provides valuable information about short-term fluctuations in blood glucose levels and informs patients about how best to modify their behaviour in response to acute fluctuations. Better self-management of type 2 diabetes has the potential to reduce complications of the disease and use of other healthcare resources. Blood glucose testing plays a valuable role in informing treatment regimens for people with diabetes, in particular for those recently diagnosed.

This Review has identified that in some people with type 2 diabetes not using insulin, there may be some use of test strips that is beyond clinical need and providing limited benefit.

It should be emphasised that changing access arrangements to require more regular inclusion of a health professional may have an impact on health care resourcing for health services. In better targeting information about effective treatment regimens for diabetes, access arrangements should reflect the best use of these products taking into account all potential implicit and explicit factors.

5. Options

In December 2012, the PBAC noted the draft Report on Stage 1 of the Review focusing on the ongoing regular use of test strips in people with type 2 diabetes not using insulin. The PBAC noted the outcome of the utilisation analysis and agreed that greater involvement by a healthcare professional to ensure meaningful monitoring could be of benefit.

The PBAC agreed that test strips should remain unrestricted for type 2 diabetes patients using insulin and those with gestational diabetes. The PBAC considered that if the use of these products were to be limited in some populations of people with diabetes, then consideration would need to be given to the basis of any such restriction to access, such as drafting restrictions based on the treatment plan; patient; prescriber/dispenser; and/or the volume prescribed.

It is evident from the findings of the Review, including the advice of the Reference Group, clinicians represented at the Stakeholder Forum and the PBAC, that the following special categories of diabetes patients should be excluded from changes to access arrangements for test strips:

- People with diabetes on insulin therapy;
- People with diabetes on concomitant medicines (e.g. sulfonylureas and corticosteroids); and
- Gestational diabetes.

As such, the following options take into consideration these patient groups.

It is important to note that prescribers continue to have access to blood glucose monitoring with HbA_{1c} for all patients if they want an indication of blood glucose control. The PBS restrictions only address access to test strips for self-monitoring.

Two potential options for amending the current PBS restrictions (including the maximum quantity and number of repeats) are provided as follows. These options aim to guide access to these products, and thus convey consistent messages to people with type 2 diabetes not using insulin about self-monitoring with test strips.

5.1 Option 1 – Restricted Benefit

The intent of this potential listing structure provides for:

- Special categories of people with diabetes that are recommended to be excluded from changes to access arrangements: people with diabetes using insulin, people with gestational diabetes, people with inter-current illness or treatment with a concomitant medicine that may adversely affect blood glucose control. It is not proposed the current access arrangements for these patients be amended.

- People with non-insulin dependent diabetes outside of the categories above, will be entitled to access one supply of test strips (pack size of 100) with two repeats to monitor blood glucose levels if they are initiating therapy or have had recent changes to their diabetes management. This will include people that have had a change in a treatment regimen or where the prescriber has recommended lifestyle interventions to improve blood glucose control. The benefit of this option is that the restriction will require the patient to see the prescriber more regularly than the current PBS restrictions and encourage more structured use of test strips in line with the evidence-based best practice identified in the Review. If blood glucose control has stabilised after three months and no more interventions have been made to the treatment regimen, these patients will no longer have access an ongoing supply of test strips on the PBS.

Overall, the proposed changes to the current PBS listing will remove the unrestricted listing for test strips and provide more guidance to the prescriber on targeted use in specific groups of patients.

The following table outlines the general intent for the potential restriction for these categories of patients and the reasons for each category.

Restriction text option	**Explanation and other matters to consider**
Restricted benefit (100 strips, max qty 1, rpts 5) For use in patients with diabetes on insulin therapy.	A person receiving insulin is subject to greater diurnal fluctuations of blood glucose (and their associated harms) than a person receiving other diabetes treatments such as oral hypoglycaemics. Such a person should not be excluded. The aetiology of the diabetes as type 1 diabetes or type 2 diabetes is not important. This is consistent with the current listings accessed by this group of patients, which are for 100 test strips as a maximum quantity, and 5 repeats for the unrestricted listings. It is not proposed that the maximum quantity and number of repeats be amended in this group. The only proposed change is to specify this arrangement as applicable to patients on insulin therapy.

Restricted benefit (100 strips, max qty 1, rpts 11) For use in patients with diabetes on insulin therapy who are receiving treatment under a GP Management Plan or Team Care Arrangement where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	The current listings are for 100 test strips as a maximum quantity, and 11 repeats for the restricted benefit of '*For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements*'. It is not proposed that the maximum quantity and number of repeats be amended.
Restricted benefit (100 strips, max qty 1, rpts 5) For use in patients not on insulin therapy with gestational diabetes, inter-current illness or treatment with a concomitant medicine that may adversely affect blood glucose control.	A person with gestational diabetes, inter-current illness or those treated with a concomitant medicine that may affect blood glucose control (e.g. sulfonylureas or corticosteroids), may be subject to greater fluctuations of blood glucose (and its associated harms) and for the sake of any unintended consequences, the current access arrangements for these categories of people with diabetes should not be amended. In order to retain current access arrangements in this group, the only proposed change is to specify this arrangement as applicable to these patients.
Restricted benefit/ Authority Required (STREAMLINED) (100 strips, max qty 1, rpts 2) For use in patients with diabetes not on insulin therapy, initiating or requiring changes to existing diabetes management within the previous three months.	The maximum quantity and number of repeats should be for up to three months for the average eligible patient. This is intended to promote a three-monthly review by the prescriber. As discussed in the Cochrane Review (2012), a three-monthly visit to a GP or diabetes nurse is generally recommended. Consideration may be given to the use of an Authority Required (STREAMLINED) listing, which provides an additional check by the prescriber for eligibility against the PBS restriction criteria. The prescriber is required to write the streamlined authority code on the prescription. This provides an additional compliance check without the administrative burden of an Authority Required listing which would require the prescriber to obtain a telephone authority approval from DHS or DVA.

5.2 Option 2 – Initiating and Continuing Restriction

The intent of this potential listing structure provides for:

- Special categories of people with diabetes that are recommended to be excluded from changes to access arrangements: people with diabetes using insulin, people with gestational diabetes, people with inter-current illness, or those receiving treatment with a concomitant medicine that may adversely affect blood glucose control (e.g. corticosteroids, sulfonylureas). It is not proposed that the current access arrangements for these patients be amended.
- Unlike Option 1, people with non-insulin dependent diabetes outside of the categories above, will be entitled to up to 12 months' supply of test strips. Under an 'initial' restriction, the patient will be able to access up to six months' supply. A 'continuing' supply for another six months would be available if the prescriber determines that the person would benefit from further monitoring.
- After 12 months' supply, only people requiring additional SMBG when further changes to diabetes management are made, would be eligible to access test strips through the 'initial' restriction pathway. This is consistent with the findings of the Cochrane Review (2012) that indicate a minimal clinical benefit in improving blood glucose control at six months, which disappears after 12 months follow-up.

The following table outlines the general intent for the potential restriction for these categories of patients and the reasons for each category.

Restriction text option	**Explanation and other matters to consider**
Restricted benefit (100 strips, max qty 1, rpts 5) For use in patients with diabetes on insulin therapy.	A person receiving insulin is subject to greater diurnal fluctuations of blood glucose (and their associated harms) than a person receiving other diabetes treatments such as oral hypoglycaemics. The aetiology of the diabetes as type 1 diabetes or type 2 diabetes is not important. The current listings are for 100 test strips as a maximum quantity, and 5 repeats for the unrestricted listings. It is not proposed that the maximum quantity and number of repeats be amended in this group. The only proposed change is to specify this arrangement as applicable to patients on insulin therapy.
Restricted benefit (100 strips, max qty 1, rpts 11) For use in patients with diabetes on insulin therapy who are receiving treatment under a GP	The current listings are for 100 test strips as a maximum quantity, and 11 repeats for the restricted benefit of '*For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements*'. It is not proposed that the maximum quantity and number of

Management Plan or Team Care Arrangement where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	repeats be amended in this group.
Restricted benefit (100 strips, max qty 1, rpts 5) For use in patients not on insulin therapy with gestational diabetes, inter-current illness or treatment with a concomitant medicine that may adversely affect blood glucose control.	A person with gestational diabetes, inter-current illness or those treated with a concomitant medicine that may affect blood glucose control (e.g. sulfonylureas or corticosteroids), may be subject to greater fluctuations of blood glucose (and its associated harms) and for the sake of any unintended consequences, the current access arrangements for these categories of people with diabetes should not be amended. In order to retain current access arrangements in this group, the only proposed change is to specify this arrangement as applicable to these patients.
Restricted benefit / Authority Required (STREAMLINED) (100 strips, max qty 1, rpts 5) (Initial) For use in patients with diabetes not on insulin therapy, initiating or requiring changes to existing diabetes management within the previous three months. (Continuing) For use in patients with diabetes not on insulin therapy, where diabetes control is inadequate or where continued monitoring for up to 12 months from initial use is required.	The Cochrane Review (2012) found that for people with type 2 diabetes not using insulin: "…results of studies including people 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." This initial and continuing restriction is proposed to complement these findings. Consideration may be given to the use of an Authority Required (STREAMLINED) listing, which provides an additional check by the prescriber for eligibility against the PBS restriction criteria. The prescriber is required to write the streamlined authority code on the prescription. This provides an additional compliance check without the administrative burden of an Authority required listing which would require the prescriber to obtain a phone or telephone authority approval from DHS or DVA.

5.2 Maximum Quantity, Number of Repeats and/or Pack size

The maximum quantity and number of repeats applicable to each restriction option will need to be considered as set out above, and whether the Note '*No applications for increased maximum quantities and/or repeats*' should still apply to each of the recommended restriction options.

Consideration may also need to be given to making available test strips in smaller pack sizes to support access for short-term use, such as during periods of intercurrent or acute illness.

5.3 Further Considerations

5.3.1 Implications for Other Programmes – 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 at subsidised prices and provides information and support services to people with diabetes. Registration is free and open to all Australians diagnosed with diabetes.

Further information about the NDSS programme is provided at section 3.1.1.2 above.

As the NDSS currently reflects, but operates differently to the PBS, there will be complexities in the NDSS programme which may affect how quickly any recommended changes can be implemented. Importantly, a central issue will be how any changes to current PBS access arrangements could be reflected in the NDSS, given that the NDSS does not operate on authorities or prescriptions. Such complexities include:

- Introduction of authority systems, with broader implications for the Scheme.
- Information technology changes to Diabetes Australia, Agent and Access Point systems.
- Revised product monitoring, inventory and supply systems.

This will have both implications on the administration of the NDSS as well as cost implications in upgrading information systems to undertake these tasks.

5.3.2 Guidelines

As discussed throughout this Report, there are a number of Australian guidelines relating to the use of ongoing self-monitoring in type 2 diabetes. See **Appendix A** for a comparative analysis of relevant Australian guidelines on this topic. Ensuring consistency in these guidelines as well as consistency with the advice provided in these guidelines and the PBS restrictions are key objectives in implementing the outcomes of this Review.

For example, the National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes, developed by Diabetes Australia and approved by the NHMRC, states that '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'. The proposed restrictions provide more guidance for selecting patients where SMBG would be of benefit. Any differences with clinical guidelines may create confusion for prescribers and patients.

5.3.3 Education

Any changes to current access arrangements for test strips will need to be communicated to consumers and health professionals. Consideration may need to be given to engaging an organisation to undertake such an education campaign. Education about better targeted access for ongoing regular monitoring with test strips in people with type 2 diabetes will help to ensure consistency in the appropriate management of these patients.

NPS MedicineWise is one organisation that could undertake such a campaign. NPS MedicineWise works with consumers, healthcare professionals, government and industry to improve the health of all Australians through targeted educational campaigns, professional development activities and publications. Their programmes are subject to rigorous evaluation to ensure that they are providing the services required to meet their goals (NPS MedicineWise 2012).

6. Reference Group Commentary on Report Options

This Report was considered by the Diabetes Review Reference Group on 17 July 2013. The Reference Group generally preferred Option 2 for the proposed restriction changes. The Group considered that this option would balance the findings of the Review with the clinical need for access to test strips in a range of sub-groups and circumstances, and allow flexibility for prescribers to provide patients with monitoring tools during necessary periods of diabetes management.

PBS restrictions

Consideration was given to the appropriate level of authority required for the restrictions. The Reference Group favoured a streamlined Authority Required (STREAMLINED) listing, noting that this may not achieve the level of compliance intended. This is evident for some medicines, including diabetes medicines, where use outside the PBS restrictions has been observed despite the streamlined authority restrictions placed on these items. The Reference Group considered that changing the restriction to Authority Required, which requires prescribers to phone DHS for an authority approval number, would create substantial administrative burden for DHS and prescribers, given the volume of prescriptions.

NDSS implications and alignment

In order to align the NDSS with PBS restriction changes, the NDSS software systems will need to be updated as they do not have a mechanism to apply an authority system. This could take up to 12 months and there would be initial set-up and maintenance costs to implement the system changes. There would be need to further explore the capacity of the NDSS access points to administer the changes, for example, asking questions of patients regarding their disease status and treatment plan prior to supplying test strips. The Reference Group agreed that any changes to PBS access arrangements should coincide with changes to the NDSS.

Access implications

The Reference Group discussed the possibility of making available test strips in smaller pack sizes (e.g. 50 strips) to support access for short-term use, such as during periods of inter-current illness.

The Reference Group discussed the potential for unintended consequences of changing access arrangements, specifically regarding consumers not purchasing a blood glucose meter because they think it will only be useful for six months. It was noted that blood glucose meters are often available at no charge through endocrinologists and diabetes educators, and cheaply from manufacturers via pharmacy or direct-to-consumer promotions. Further, blood glucose meters are usually inexpensive due to the profit made from test strips sales, as the test strip brands are only compatible with specific

blood glucose meters. If a particular patient group is limited in terms of prolonged access to test strips, companies may implement changes to the cost of blood glucose meters to recoup potential losses, which, in turn, may further increase consumer barriers to purchasing a blood glucose meter.

Change implementation and education

The Reference Group emphasised the importance of education programmes to occur alongside any changes to access arrangements for test strips. This programme delivery would require collaboration between The RACGP, the Australian College of Rural and Remote Medicine (ACRRM), ADEA, and ADS. NPS MedicineWise would be instrumental in informing key groups including patients and prescribers. The Reference Group noted that education must extend to Aboriginal and Torres Strait Islander populations and be delivered in a culturally appropriate manner that addresses differing literacy levels in the community.

The Reference Group suggested that the Department consider whether a media release or other form of communication should accompany the implementation of any access changes. With regard to informing consumers, it was suggested that it may be possible to contact registrants of the NDSS directly, which would form part of a multi-media approach.

Key education messages

The Reference Group discussed the need to clearly communicate key messages regarding changes to access arrangements, and suggested messages that emphasise:

- There is no change in access to test strips for people using insulin.
- Access to test strips is not being restricted for any patients with diabetes who need them.
- Changes are being implemented to encourage better practice and direct more attention to appropriate use of test strips.
- You still need a blood glucose meter for future use, such as when you change therapy or if you are unwell.
- Just because you've stopped using test strips, it doesn't mean that you're cured.

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Appendices

Appendix A

Current diabetes management guidelines hosted by the National Health and Medical Research Council Clinical Guidelines Portal

Title	Publication year	Primary developer	Recommendations for use of test strips (SMBG)	Comparative analysis – quantitative guidelines
Australian Diabetes Society position statement. Individualisation of HbA1c targets for adults with diabetes mellitus	2009	Australian Diabetes Society	General target HbA_{1c} ≤7.0, based on United Kingdom Prospective Diabetes Study (UKPDS) demonstrated improved outcomes with median HbA_{1c} ≤7%, supported by NHMRC systematic review. This target will vary with specific clinical situations. Practitioners need to individualise the HbA_{1c} target for people with type 2 diabetes, taking into consideration the presence of CVD, diabetes duration, diabetes medication(s) taken, comorbidities, and problems with severe hypoglycaemia . Prevention of hypoglycaemia does not rely purely on adjustment of medication, but also on patient education, including blood glucose monitoring.	General target HbA_{1c} ≤7.0. However, HbA_{1c} targets however, need to be individualised to a tighter or lesser degree, with a recommended target HbA_{1c} level of ≤6.0% in some people, or up to ≤8.0% in others.
Diabetes management in general practice. Guidelines for type 2 diabetes (17th edition) 2011/12	2011	Diabetes Australia	Self-monitoring is recommended for those on agents that can cause hypoglycaemia (e.g. sulfonylureas and insulin). Home blood glucose monitoring is the method of choice in most patients. The method and frequency of testing needs to reflect therapeutic aims. Initially close supervision is recommended. A suggested initial schedule of testing is 3 to 4 blood glucose tests daily (early morning, plus other tests	Targets for self-monitored blood glucose levels are 6–8 mmol/L fasting and pre-prandial, and 6–10 mmol/L 2 hours post prandial An HbA_{1c} target >7% may be appropriate in people with type 2 diabetes who have a history of severe hypoglycaemia, a limited life expectancy, co-morbidities or who are elderly.

			before and after meals). Frequent consultation with health care professionals is important. Monitoring in type 2 diabetes need not be as intensive as with type 1 diabetes except when the normal pattern is broken (e.g. travelling, the festive season, intercurrent illness, changes to medication and diet). The ideal would be blood glucose estimation before and after meals. A reasonable approach in a patient with stable glycaemic control would include blood glucose estimation at different times of the day on 2–3 days each week. The IDF suggests that an HbAlc >7% should prompt more active hypoglycaemic treatment. The general HbA_{1C} target in people with type 2 diabetes is ≤7%. An HbA_{1C} target >7% may be appropriate in people with type 2 diabetes who have a history of severe hypoglycaemia, a limited life expectancy, co-morbidities or who are elderly. The ADS Position Statement discusses individualisation of HbA_{1C} targets for adults with diabetes mellitus Working toward the target level is important but any significant reduction in HbA_{1C} will improve patient outcomes.	
Dietary management in diabetes	2010	Collaborating Authors	*No specific guidance on SMBG.*	
Exercise prescription for patients with type 2 diabetes and pre-diabetes. A position statement from Exercise and Sport Science	2012	Exercise and Sports Science Australia	Prevention of hypoglycaemia centres around SMBG levels and consultation with the patient's doctor. Important considerations are timing of medications, meals, and exercise. Given the risk of post-prandial hyperglycaemia, a good strategy is to take advantage of the acute glucose-lowering effect of exercise by timing the session for approximately one hour after a meal (to coincide with peak post-prandial rise in glucose).	

Australia				
Guidelines for the management of diabetic retinopathy	2008	Australian Diabetes Society	The Guidelines recognise that the mainstay of current treatment involves risk factor reduction by controlling blood glucose, blood pressure and serum lipids	
National evidence based guideline for blood glucose control in type 2 diabetes	2009	Diabetes Australia	Blood glucose control should be optimised because of its beneficial effects on the development and progression of microvascular complications (Grade A, see Note 2). 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). HbA_{1c} measurement should be used to assess long term blood glucose control (Grade A). 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 HbA_{1c} target in people with type 2 diabetes is ≤ 7%. Adjustment to diabetes treatment should be considered when HbA_{1c} 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).	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) General HbA_{1c} target in people with type 2 diabetes is ≤ 7%.

			Routine care of people with type 2 diabetes should address disparities associated with socio-economic status and ethnicity (Grade C).	
National evidence based guideline for diagnosis, prevention and management of chronic kidney disease in type 2 diabetes	2009	Diabetes Australia	Blood glucose control should be optimised aiming for a general HbA_{1c} target ≤ 7% (GRADE A), noting that the HbA_{1c} target may need to be individualised taking in to account history of hypoglycaemia and co morbidities.	General HbA_{1c} target ≤ 7%
National evidence based guideline for patient education in type 2 diabetes	2009	Diabetes Australia	Diabetes patient education has long been recognised as a vital and integral component of successful diabetes care. However, complex and daily requirements such as medication taking and adjustment and SMBG place a psychological and financial burden on people with diabetes. Evidence statement: Diabetes education has a positive short-term effect on SMBG.	
National evidence based guideline for the primary prevention of type 2 diabetes	2009	Diabetes Australia	Guideline recognises that, particularly in the initial years following diagnosis, type 2 diabetes can be successfully managed with dietary and general lifestyle modification alone or in combination with oral diabetes medications. Insulin therapy may be required if and when oral medication becomes ineffective in lowering and maintaining the blood glucose within an acceptable range. Using therapeutic interventions to lower blood glucose and achieve optimal HbA_{1c} levels is critical in preventing diabetes complications and improving the quality of life.	

National evidence based guidelines for case detection and diagnosis of type 2 diabetes	2009	Diabetes Australia	Blood glucose testing only excludes diabetes at a particular point in time. Therefore, those people who have risk factors but have a negative screening or diagnostic blood test require ongoing surveillance and testing for the future development of type 2 diabetes. Guidelines conclude that it is difficult to justify glucose-based community screening in low risk populations.	
Prediabetes. A position statement from the Australian Diabetes Society and Australian Diabetes Educators Association	2007	Collaborating Authors	Testing generally not required in the absence of specific clinical indications in an individual. There is no role for routine home capillary blood glucose measurement (particularly as measurements using portable monitors have significant attendant error of > 10%). Also, in the absence of specific clinical indications in an individual, there is no role for routine HbA_{1c} testing in people who have prediabetes, as no data exist to define the utility of measurement of HbA_{1c} in monitoring prediabetes.	
Therapeutic guidelines endocrinology version 4	2009		Various studies cited, see Note 2. A number of conclusions from studies (published in 2007-2008), including: Evidence is not convincing of an effect of self-monitoring blood glucose, with or without instruction on incorporating findings into self-care, or improving glycaemic control compared with usual care in reasonably well controlled non-insulin treated patients with type 2 diabetes. Regular medical feedback of the monitored HbA_{1c} levels is important. Furthermore, SMBG is likely to be more effective than self-monitoring of urine glucose. In patients with newly diagnosed type 2 diabetes, SMBG	

			concentration has no effect on glycaemic control but is associated with higher scores on a depression subscale.	
Type 1 diabetes in children - emergency management	2010			
Type 2 diabetes - controlling hyperglycaemia with early insulin use	2010		Report describes when and how to initiate insulin therapy for patients with type 2 diabetes in the primary care setting.	
Type 2 diabetes - kidney disease	2010		Blood glucose control should be optimised aiming for a general HbA_{1c} target ≤7% (Grade A).	
Type 2 diabetes in children and adolescents. Model of care and clinical practice guideline for Western Australia	2009		The HbA_{1c} target may need to be individualised taking in to account history of hypoglycaemia and co-morbidities.	Blood glucose control should be optimised aiming for a general HbA_{1c} target ≤7%, but may need to be individualised.

Note 1

Definition of NHMRC grades of recommendations

A Body of evidence can be trusted to guide practice
B Body of evidence can be trusted to guide practice in most situations
C Body of evidence provides some support for recommendation(s) but care should be taken in its application
D Body of evidence is weak and recommendation must be applied with caution

Note 2

Therapeutic Guidelines, Key references for Endocrinology, version 4

Self-monitoring of blood glucose and ketones

Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, et al. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. BMJ 2007;335(7611):132.
International Diabetes Federation. Guideline for management of postmeal glucose. Brussells: IDF; 2007. Note that this Guideline was updated in 2011, with recommendations of: • *Postmeal plasma glucose should be measured 1-2 hours after a meal;* • *The target for postmeal glucose is 9.0 mmol/l (160 mg/dl) as long as hypoglycaemia is avoided; and* • *SMBG should be considered because it is currently the most practical method for monitoring postmeal glycaemia.* Studies cited in the Guideline support the view that control of fasting hyperglycaemia is necessary but usually insufficient for achieving HbA_{1c} goals <7% and that control of postmeal hyperglycaemia is an important consideration for achieving recommended HbA_{1c} goals.

Appendix B

Details of different concession card types and benefits provided

Card Type	Card Benefits
PEN - Pension	Issued by Medicare to people aged over 60 receiving certain types of Government payments (i.e. Age or Disability Support Pension) Includes: - reduced-cost medicines under the PBS. Also MAY include concessions for: - bulk billing for GP appointments (at doctor's discretion); - more refunds for medical expenses through Medicare Safety Net; and - assistance with hearing services through the Office of Hearing Services.
HC - Health Care Card	Issued by Medicare to people receiving certain types of Government payments (e.g. Youth Allowance) Includes: - reduced-cost medicines under the PBS. Also MAY include concessions for: - bulk billing for GP appointments (at doctor's discretion); - more refunds for medical expenses through Medicare Safety Net; and - assistance with hearing services through the Office of Hearing Services.
DVAG – Department of Veterans' Affairs (DVA) Gold	Issued by DVA to veterans of the Australian Defence Force, their widows and dependants. Includes: - treatment for all medical conditions; - access to the Repatriation Pharmaceutical Benefits Scheme; and - assessment for services through Veterans Home Care.
DVAW - Department of Veterans' Affairs (DVA) White	Issued by DVA to eligible veterans for the care and treatment of accepted (war/service related) injuries. Includes: - treatment for all medical conditions; - access to the Repatriation Pharmaceutical Benefits Schemes; and - assessment for services through Veterans Home Care.
DVAPCC - Department of Veterans' Affairs (DVA) Pensioner Concession Card	Issued by DVA to all service and age pensioners who receive their pension through DVA and war widows receiving an income support supplement. Includes access to: - reduced-cost medicines under the PBS; - cheaper out-of-hospital medical expenses through the Medicare Safety Net; - bulk billed GP appointments (at doctor's discretion) - National Diabetes Services; and - Hearing Services.

DVACSHC - Department of Veterans' Affairs (DVA) Commonwealth Seniors Health Care	Issued by DVA to people of pensioner age (60+ years) who do not qualify for a payment by DHA or DVA and meet income test requirements. Includes: - bulk-billed GP appointments (at doctor's discretion) - cheaper out-of-hospital medical expenses through the Medicare Safety Net; and - additional state related concessions (varies between states and territories).
CN - Safety Net Concession Card	Issued to concessional patients who have reached the current threshold ($354 - concession card holders) for purchased medicines under the PBS for the calendar year. It entitles the card holder and their family to free PBS medicines for the remainder of the calendar year.
SN - Safety Net Entitlement Card	Issued to general patients who have reached the current threshold ($1,390.60 - general patients) of costs relating to patient co-payments for medicines. It entitles the card holder and their family to PBS medicines at a concessional price ($5.90 contribution per purchased) for the remainder of the calendar year.