Pharmaceutical Society of Australia

Submission

Review of self-monitored blood glucose test strips for people with type 2 diabetes mellitus

NOV
2012

Purpose

The Pharmaceutical Society of Australia (PSA) understands the Australian Government, through the Pharmaceutical Benefits Advisory Committee, is undertaking a review of products and medicines used in the treatment of diabetes. The PSA makes this submission in relation to phase one of the review which focuses on the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) and the clinical outcomes and benefits of SMBG for people with type 2 diabetes mellitus (T2DM) not treated with insulin.

The clauses in the terms of reference relevant to this phase of the review are:

- describe the utilisation and patterns of use of SMBG for people with T2DM;
- determine the clinical outcomes and benefits of SMBG relative to HbA_{1C} monitoring alone for people with T2DM not treated with insulin; and
- consider the clinical criteria for eligibility for subsidised access to blood glucose (BG) test strips under the Pharmaceutical Benefits Scheme (PBS) and National Diabetes Services Scheme (NDSS).

Recommendations

PSA provides the following four recommendations to this review:

1. Regular SMBG appears to offer clinical benefit over the use of glycated haemoglobin (HbA_{1C}) measurement alone provided consumer factors have been assessed and is subject to ongoing monitoring and assistance. Examples of relevant factors for consumers with non-insulin T2DM include an ability to perform SMBG correctly, a good understanding of the results and outcomes of SMBG, and a positive approach to responsible self-management.

2. Current subsidisation of medicines and devices through the PBS and NDSS is fundamental to the provision of timely and affordable care for consumers with diabetes. These subsidies must be maintained to continue to support the 'regular' health care of people with diabetes. In the longer term they will also help to lower health care costs by preventing or minimising diabetic complications.

3. For consumers with T2DM not treated with insulin, access to subsidised BG test strips should be linked to an annual assessment of the consumer's ability and need to perform SMBG. The annual assessment could be conducted as part of a GP consultation (including as a component of an annual cycle of care), a consultation session with a diabetes educator, a pharmacist-conducted in-pharmacy Diabetes MedsCheck or a Home Medicines Review (HMR).

4. In-pharmacy Diabetes MedsCheck services are likely to be of benefit to many more consumers with T2DM than what current funding allows. An investment in this quality use of medicines service is likely to impact positively on wider health care system costs. Consideration should be given to widening consumer eligibility and access as well as alternative models of funding.

Background

The International Diabetes Federation states that diabetes mellitus is one of the most common non-communicable diseases globally and is the fourth or fifth leading cause of death in most high income countries.[1] The most common form of diabetes is 'type 2' which accounts for a high majority of all cases.

A snapshot of some statistics relevant to Australia is provided below.[2,3,4,5,6,7,8]

Prevalence	• Approximately 4% of Australians have been diagnosed to have diabetes. • Death rates associated with diabetes have remained stable between 1997 and 2006 at around 45 deaths per 100,000 people living in outer regional, remote and very remote areas of Australia. This is despite a rate decline for people living in major cities from 38 to 30 deaths per 100,000 people over the same period. • T2DM accounts for 88% of all people with diabetes. • Occurrence of T2DM is mostly in people aged 50 years and over. It is still uncommon in childhood although becoming increasingly recognised in this group. • Proportion of Indigenous Australians with diabetes is three times that of non-Indigenous Australians and is mostly attributed to T2DM. • It is expected that T2DM will become the leading cause of disease burden by 2023.

1 International Diabetes Federation, *www.idf.org*

2 Australian Institute of Health and Welfare, *www.aihw.gov.au/diabetes*

3 Australian Institute of Health and Welfare. Australia's health 2010. Australia's health series no. 12. Cat. no. AUS 122. Canberra: AIHW; 2010.

4 Figures at 31 January 2012 sourced from the NDSS web site, *www.ndss.com.au*

5 Australian Institute of Health and Welfare. Diabetes: Australian facts 2008. Diabetes series no. 8. Cat. no. CVD 40. Canberra: AIHW; 2008.

6 Britt H, Miller GC, Charles J, et al. General practice activity in Australia 2010–11. General practice series no. 29. Sydney: Sydney University Press; 2011.

7 NPS Better choices Better health, *www.nps.org.au/diabetes*

8 National Rural Health Alliance. Diabetes: protect our rural future [media release]. 14 Nov 2012.

Risk factors	• Genetic: family history of the condition, ethnicity • Biomedical: age, impaired glucose regulation, overweight, high blood pressure, high levels of cholesterol and triglycerides, history of gestational diabetes • Behavioural: physical inactivity, alcohol misuse, poor nutrition, tobacco smoking • Environmental: socioeconomic position (education, employment status, income), geographical location
Comorbidities	• Around 60% of people with T2DM have cardiovascular disease. Close to two-thirds of all cardiovascular disease deaths occur in people with diabetes. • Over half a million hospitalisations were recorded in 2004-05 of individuals with diabetes and coronary heart disease, stroke or peripheral vascular disease. • Cardiovascular disease, diabetes and chronic kidney disease share many risk factors, are risk factors for each other and often co-exist.
Complications	• Cardiovascular disease: coronary heart disease, stroke, peripheral vascular disease • Eye disease: diabetic retinopathy, cataracts, glaucoma • Kidney disease: diabetic nephropathy, chronic kidney failure • Nerve damage: peripheral neuropathy, autonomic neuropathy • Foot complications: foot ulcer, lower extremity amputation • Oral complications: periodontal disease, dental caries • Complications in pregnancy
Medical services	• Hypertension and diabetes were the equal third most common reason for the provision of clinical treatment by general practitioners (GPs). • In general practice, diabetes was one of four most common conditions for referral to a specialist and one of three most common reasons for referral to an allied health service. • Diabetes was the most common condition/reason for a pathology test order by a GP. • The rate of referral of people with diabetes to a specialist is more than two and a half times the referral rate of people without diabetes. Specialists consulted are in medical fields such as endocrinology, cardiology, nephrology, obstetrics and ophthalmology.
NDSS	• Total expenditure for all products and services reported for 2009-10 was $156.8 million representing a 50% increase since 2005-6 and a ten-fold jump from 1992-93. • Over one million people diagnosed with diabetes were registered on the NDSS database at 31 January 2012. Two-thirds of registrants (or approximately 715,000 people) were classified as ‘type 2, non-insulin’. • More than 3.2 million packs of BG test strips were distributed during 2005–6. In the six months to 31 January 2012, close to 2.0 million units (packs of 100 strips) had been supplied. • The supply of BG test strips far outweighs the volume of supply of other products which include sharps, insulin pump consumables, reservoir and urine testing strips and products.
PBS and RPBS	• According to available Medicare Australia statistics based on PBS and RPBS claims presented by approved pharmacies, in the 2011 calendar year, $15.8 million of benefits were paid for pharmaceutical items listed under ‘glucose indicator (blood) test strips’. For the same items, $13.9 million has been paid to September in the 2012 calendar year.

Introduction

The impact of T2DM on individuals is well established and is associated with reduced life expectancy, significant morbidity and therefore reduced quality of life. Apart from premature death, T2DM results in irreversible long term complications including myocardial infarction, stroke, retinopathy and blindness, renal disease requiring dialysis or transplantation, neuropathy, foot ulcer, amputation and erectile dysfunction.

While general practitioners are the central point of contact for people with diabetes, the complexity and ongoing nature of the disease means that a multidisciplinary approach to care is essential. Controlling modifiable risk factors is a priority in the prevention, early detection and referral, and reduction in deterioration of T2DM. In this regard, pharmacists have an integral role in providing direct support to consumers and carers, and working as an active member of the diabetes care team.

Contribution of pharmacists to diabetes care

Pharmacists have a strong primary health care role and, due to their accessibility and regular contact with health consumers, they are well placed to provide information and support to people with diabetes at all stages of the disease. This includes the provision of health promotion activities to people who have yet to be diagnosed (including recognition of symptoms which may suggest the onset of diabetes), education and support of people in the stages immediately after initial diagnosis, monitoring and supporting medication management, and assisting lifestyle decisions to minimise progression of the disease and to reduce the incidence of complications.

The positive contribution of diabetes disease state management services delivered by pharmacists has been clearly established by research in both the clinic[9,10,11] and community pharmacy settings[12,13,14] for example in the USA and Australia. Specific services offered by pharmacists have included the following elements:

- providing diabetes education and coaching to assist in empowerment of the consumer;
- monitoring and promoting adherence with medication and other components of self-management;

---

[9] Irons BK, Lenz RJ, Anderson SL, Wharton BL, Habeger B, Anderson HGJ. A retrospective cohort analysis of the clinical effectiveness of a physician-pharmacist collaborative drug therapy management diabetes clinic. Pharmacother 2002; 22:1294–300.

[10] Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management [comment]. Ann Pharmacother 1996; 30:238–43.

[11] Clifford RM, Davis WA, Batty KT, Davis TME. Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: The Fremantle Diabetes Study. Diabetes Care 2005; 28:771–6.

[12] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc 2003; 43:173–84.

[13] Armour C, Taylor S, Hourihan F, Smith C, Krass I. Implementation and evaluation of Australian pharmacists' diabetes care services. J Am Pharm Assoc 2004; 44:455–66.

[14] Krass I, Armour C, Taylor S, Hughes J, Peterson G, Stewart K, Clark P. The Pharmacy Diabetes Care Program. Final report, April 2005.

- ensuring evidence-based use of medications in the complete management of the consumer's diabetes, including the prevention of diabetic complications;

- assisting with monitoring and documenting key clinical indicators such as BG levels, HbA_{1c}, blood pressure, urinary albumin excretion and lipid levels; and

- reminding consumers of the importance of regular examinations for the presence of any diabetic complications (e.g. examinations of eyes and feet).

Diabetes is a complex disease requiring consideration of many aspects of health and coordination of appropriate health services involving many health practitioners. As indicated, pharmacists have a range of roles to fulfil in the care of people with diabetes. Medication management is clearly a key area of pharmacists' expertise within their scope of safe and appropriate use of medicines. However, PSA would advocate that there are greater synergies and benefits in health literacy and quality use of medicines for consumers with diabetes when pharmacists can contribute their expertise through a collaborative team-based environment.

Diabetes MedsCheck service

In Australia, several research studies and a pilot program were previously funded through Community Pharmacy Agreements between the Australian Government and the Pharmacy Guild of Australia. As a result, under the Fifth Community Pharmacy Agreement (5CPA), a Diabetes Medication Management Service Program, known as Diabetes MedsCheck, is currently available.[15]

A Diabetes MedsCheck provides an in-pharmacy review of medications with a focus on the consumer's type 2 diabetes medicines management, monitoring devices, education and self-management. The service is targeted at consumers who are unable to gain timely access to other diabetes education or health services in their community and aims to:

- optimise a consumer's effective use of medicine through improving understanding of, and compliance with, their diabetes medication therapy;

- improve a consumer's effective use of BG monitoring devices through training and education;

- improve BG control; and

- reduce the risk of the consumer developing complications associated with type 2 diabetes.

As Diabetes MedsCheck services are funded under the 5CPA, a targeted list of criteria for consumer eligibility[16] is necessary to meet the conditions of the allocated funding which is capped and for a limited period. Therefore, some consumers with T2DM who may benefit clinically from a Diabetes MedsCheck may not currently be eligible to be considered for this service.

---

[15] Further information is available at: *www.5cpa.com.au/sites/5CPA/Initiatives/Medication_Management/MedsCheck_and_Diabetes_MedsCheck/About%20MedsCheck.page*

[16] Further information is available at: *www.5cpa.com.au/sites/5CPA/Initiatives/Medication_Management/MedsCheck_and_Diabetes_MedsCheck/Eligibility.page*

Home Medicines Review

Another medication management service funded through the 5CPA is Home Medicines Review (HMR).[17] This service is not specifically targeted for people with T2DM and, once again, there are strict consumer eligibility criteria. The aim of this service is to prevent medication-related problems and to maximise the benefits of medicines for consumers in the community. The consumer's GP must determine that there is a clinical need for an HMR to help optimise the quality use of medicines and to address the consumer's needs.

Where a person with T2DM is on a number of medicines for diabetes as well as other chronic disease conditions, the GP may refer the consumer for an HMR. While the scope of this service covers broader medication management issues, the accredited pharmacist conducting an HMR would also be able to assess the consumer's knowledge and technique around SMBG and provide information and assistance as needed. The outcomes of such an assessment would be provided to the consumer's GP through the HMR report from the accredited pharmacist.

National Diabetes Services Scheme

The NDSS is an Australian Government initiative administered by Diabetes Australia. The core objective of the NDSS is to improve health outcomes for people with diabetes across Australia. Information and support services, including subsidised products (e.g. blood and urine testing strips, syringes and needles), are provided to consumers who have registered with the NDSS. Registrants obtain the products and services through Access Points, the majority of which are community pharmacies. Other entities eligible to apply to be an Access Point include general practices, hospitals, Aboriginal health services and Medicare Locals.

To apply to become an NDSS Access Point, PSA notes that the requirements are different for pharmacies and non-pharmacy entities. For Pharmacy applications, one of the requirements is to register the pharmacy in the "Diabetes MedsCheck Program". However, there does not appear to be any process to evaluate how many or how widely Diabetes MedsCheck services are being delivered through Access Point pharmacies.

Since the majority of NDSS Access Points are currently community pharmacies, PSA believes this is an important opportunity for better integration of pharmacists' contribution to the care of people with diabetes.

Blood glucose control

In Australia, national recommendations and supporting evidence on BG control for T2DM include the following.[18]

- Measurement of HbA_{1C} should be used to assess long term BG control. It should be performed at least twice a year in people with T2DM and stable BG control. More frequent

---

[17] Further information is available at: *www.5cpa.com.au/5CPA/Initiatives/Medication_Management/Home_Medicines_Review/About+HMR.page*?

[18] Colagiuri S, Dickinson S, Girgis S, Colagiuri R. National evidence based guideline for blood glucose control in type 2 diabetes. Canberra: Diabetes Australia and NHMRC; 2009.

testing is required in people with sub-optimal control and following changes to therapy. Levels of HbA_{1C} correlate with diabetes complications and outcomes.

- SMBG is a useful method for assessing real time BG levels and day-to-day management of diabetes. It should be considered in all people with T2DM but the decision to perform SMBG, and the frequency and timing of testing, should be individualised.

General advice within these recommendations further elaborates that SMBG:

- complements HbA_{1C} data through real time feedback;
- allows detection of hypoglycaemia and hyperglycaemia which can improve safety and also helps to motivate people with diabetes to make appropriate treatment changes;
- is an educational tool to inform consumers and health care professionals about the effects of lifestyle, behavioural and/or medication changes; and
- to be fully effective requires ongoing education and reinforcement about the use of the data.

These Australian recommendations are consistent with PSA's view that SMBG with tailored support provides one of the tools to enhance self-management of T2DM. Anecdotal reports from pharmacists indicate that, provided there is appropriate assessment of the consumer's ability and desire to perform regular SMBG, consumers generally benefit from this activity. Not only does it enable more timely discussion and consideration of any required changes to therapy, pharmacists also frequently observe a positive reflection in the consumer's behaviour such as greater motivation and confidence to self-management. For ongoing benefit, regular assessment and support, and provision of information about the consumer's medicines, diabetes and other chronic diseases are essential. Through these activities, pharmacists can contribute to diabetes care which is tailored to the consumer, in collaboration with the other members of the health care team.

The Australian recommendations reflect an assessment of published evidence on the clinical benefits of regular SMBG which were available to the authors of the national guidelines published in 2009. PSA is aware that there have been conflicting reports[19,20] more recently regarding the value of SMBG in people with non-insulin treated T2DM. Conducting a thorough review of these recent reports and publications is beyond the scope of this submission. Therefore PSA's views presented in this submission are generally based on the body of evidence supporting the current national guidelines (published in 2009) as well as feedback we receive from practising pharmacists who are engaged in assisting consumers with diabetes and associated chronic diseases with medication management issues and improving health and well being.

---

[19] Farmer AJ, Perera R, Ward A et al. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. BMJ 344:e486 (2012).

[20] Canadian Agency for Drugs and Technologies in Health. Systematic review of use of blood glucose test strips for the management of diabetes mellitus (Optimal therapy report; vol. 3 no. 2). Ottawa: CADTH; 2009.

Better outcomes for consumers

As mentioned earlier in this submission, pharmacists have an important role in the delivery of care for people with diabetes particularly where advice and assistance is required to tailor the care for individuals and to help achieve optimal outcomes.

The Diabetes MedsCheck service and HMRs are two pharmacist-delivered services that could benefit people with non-insulin T2DM. Both are quality use of medicines initiatives and are available in the community setting (although currently they are subject to specific 5CPA business rules). The services also integrate communication and collaboration with other health professionals, in particular, the consumer's GP.

Both services cover many elements, however, in relation to supporting the consumer with SMBG, pharmacists are able to:

- provide feedback to the consumer's GP about the consumer's willingness and readiness to perform SMBG to help inform decisions on frequency and timing of measurements;
- provide education and training to the consumer on the management and effective use of devices to measure BG levels;
- assist consumers with the interpretation of results of SMBG and suggest appropriate actions;
- assist the consumer with medication management issues which may impact on the outcomes of SMBG;
- encourage the consumer to participate in shared decision making around lifestyle factors and choices; and
- provide feedback to the consumer's GP about the outcomes of the Diabetes MedsCheck or HMR service.

Specifically with regards to the use of BG test strips, pharmacists are able to provide advice to consumers about the correct use of test strips and the measuring device and may assist with detecting inappropriate use or unnecessary overuse of the test strips. Education can also be provided about the storage of test strips, expiry of test strips and cleaning and maintenance of the measuring device. The pharmacist can also provide feedback to the consumer's GP about how the consumer is managing with regular, ongoing SMBG.

As indicated in this submission, SMBG may not be required by all consumers with non-insulin T2DM. Further, where SMBG is indicated, it is recommended that frequency and timing of testing should be individualised based on shared decision making between the consumer and the health care team.

Recognising these factors and to maximise the benefits from SMBG, PSA suggests that consumer access to subsidised BG test strips should be linked, for example, to an annual assessment of the consumer's ability and need to perform SMBG. The annual assessment could be conducted as part of a regular GP consultation (including as a component of an annual cycle of care), a consultation session with a diabetes educator, a pharmacist-conducted in-pharmacy Diabetes MedsCheck service or an HMR.

PSA believes such a strategy will continue to provide for the needs of consumers with non-insulin treated T2DM but will lead to more appropriate use of subsidised BG test strips. Through the annual health practitioner assessment these individuals are also likely to experience enhanced support for their overall diabetes care thereby contributing to better health outcomes.

Conclusion

For people with diabetes, self-management is an important contributor to a better quality of life and a reduction of the possibility of irreversible complications which are often costly to the individual as well as the Australian health system.

While the consumer's desire or ability to undertake SMBG can be variable, where SMBG is indicated, PSA believes ongoing support on a regular basis (or as required) by pharmacists is of benefit to the consumer and their carer, and will complement the regular care provided by the GP, specialist, diabetes educator and other health practitioners.

PSA would suggest that the Diabetes MedsCheck and HMRs are key services through which pharmacists can provide optimal care for consumers with diabetes including activities around SMBG. PSA believes that through these services, pharmacists can contribute to informed decision making around the appropriate and judicious use of BG test strips in collaboration with other health practitioners. PSA is aware that consumer eligibility criteria for these services are currently limited to those specifically approved under the 5CPA.

Current subsidisation of medicines, devices and related products through the PBS and NDSS is fundamental for Australian consumers with diabetes to access and afford quality care and treatment in a timely manner. These subsidies not only contribute to the current 'regular' care of people with diabetes, in the longer term they also help to lower costs associated with hospitalisation from diabetic complications and treatment needed from avoidable progression of the disease.

For consumers with T2DM not treated with insulin however, it is PSA's view that access to PBS and NDSS subsidised BG test strips should be linked to an annual assessment by a health practitioner. Such an assessment could be conducted by a GP, diabetes educator or pharmacist and in a manner that promotes holistic diabetes care for the consumer.

Given the current prevalence and likely future upward trend of T2DM, PSA believes urgent consideration is needed around the future availability of services such as Diabetes MedsCheck. The contribution of pharmacists in assisting consumers with T2DM to maintain stable BG levels and to understand appropriate management of diabetes is key to better health outcomes and lower health expenditure.

While understanding the basis for capped funding and therefore limited availability of Diabetes MedsCheck services, PSA is also cognisant of those consumers who may be missing out on valuable health care services. Consideration of equity of access to Diabetes MedsCheck services through a review of consumer eligibility or dedication of alternative funds (e.g. supporting the roll-out of Diabetes MedsCheck through Medicare Locals with high T2DM population) must now be a priority.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

Liesel Wett
Chief Executive Officer

Kay Sorimachi
Director Policy and Regulatory Affairs