



The Royal Australasian
College of Physicians

From the President

29 November 2012

████████████████████
PBS Post-Market
Department of Health and Ageing
MDP 900
GPO Box 9848
CANBERRA ACT 2601

Via email: PBSpostmarket@health.gov.au

Dear ██████████

Post Market Review of Products Used in the Management of Diabetes

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to provide comments about the Post Market Review of Products Used in the Management of Diabetes.

The RACP supports the review of products and medicines to treat Type 2 diabetes, recognising its potential to provide a nationally consistent approach to treatment.

The RACP would like to make the following comments and general recommendations to the first stage of the review that involves Blood Glucose Test Strips:

1. Guidelines for the use of blood glucose testing be established.
2. All new patients should be taught the use of self-monitoring of blood glucose (SMBG). Self-monitoring translates into self-management and SMBG should be encouraged in all Type 2 diabetic patients.
3. Elevated glucose levels as measured by SMBG should be acted upon by the health care provider to change and improve therapies as required.
4. The frequency of SMBG should be based on the severity of the metabolic disturbance such as HbA1c levels (<6% on no medications, or 6-7% on glucose lowering therapy or >7%) and on the class of glucose lowering medication used, especially insulin and or insulin secretagogues.

With regard to the specific questions raised for stage 1 of the review in the Terms of Reference the RACP would like to make the following comments:

Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people, including children, with Type 2 diabetes;

1. The use of SMBG will provide the following benefits in controlling Type 2 diabetes, for example:
 - identification of hypoglycaemia
 - informing the patient about the appropriateness of the quality and quantity of food choices
 - informing the patient about the need for dosage adjustments
 - identification of changing insulin requirements for changing clinical situations such as intercurrent infections and illnesses, and concomitant drugs that may interfere with diagnostic tests such as corticosteroids.

2. For patients with Type 2 diabetes, managed without insulin, the RACP recommends that:
 - SMBG is used as an essential educational and clinical tool for all people especially when newly diagnosed or when treatment is adjusted. This includes children and adults with type 2 diabetes. Fasting and post-prandial tests are often recommended at diagnosis to determine the effect of dietary changes, exercise and oral glucose lowering medication.
 - hypoglycaemia is identified clearly. For example medications that stimulate insulin release such as the sulphonylurea group.
 - individuals that are in occupations that affect public safety need to be carefully monitored. For example, individuals in transport (truck drivers, train drivers, taxi drivers, bus drivers), individuals in jobs with erratic physical work and eating patterns (building workers, restaurant workers, shift workers). Such individuals should protect themselves against medico-legal issues by implementing an established a pattern of regular SMBG to confirm an absence of hypoglycaemia whilst at work.
 - vulnerable groups, such as pregnant people may also require consideration where hypoglycaemia must be avoided.

Determine the clinical outcomes and benefits (for example, HbA1C) of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with Type 2 diabetes not treated with insulin.

3. HbA1c is an insensitive measure of Type 2 diabetes and does not identify hypoglycaemia. Thus, a low HbA1c in any individual taking medication may fail to identify hypoglycaemia in the individual taking medication. If the individual is not taking medication, or is on metformin alone, then a HbA1c < 7% does not require regular SMBG, except in pregnancy. However, intermittent SMBG may continue to be required during illness, when blood glucose levels typically rise.

4. A trend to deteriorating control will be identified by a rising HbA1c, which needs to be performed with sufficient frequency to identify it (3-6 monthly).

5. At a lower HbA1c, there is more post-prandial hyperglycaemia and at higher HbA1c, there is more fasting and pre-prandial hyperglycaemia, and that the time of testing should reflect these tendencies. If the HbA1c rises (especially over 7%), that the detection of abnormally high glucose values, both fasting and post-prandial, becomes more frequent and, thus more informative. The majority of patients requiring ongoing attention have a HbA1c between 7% and 8.5% and they have combinations of disturbances of both fasting and post-prandial glucose levels.
6. The optimisation of both fasting and post-prandial glucose levels is the most likely to bring about optimisation of the HbA1c in the shortest time.

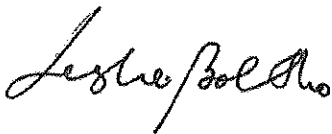
Consider the clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring.

7. To answer this question, more clinical trials are required to compare the validity and reliability of both tests as there is a paucity of data in this regard.

The RACP looks forward to receiving a final version of the stage 1 report and the opportunity to comment on stage 2 of the review.

To discuss any queries, please contact Judith Walker, Senior Policy Officer, on 02 9256 9627 or at Judith.Walker@racp.edu.au

Yours sincerely



Dr Leslie E Bolitho AM