Testing times! Choosing Wisely when it comes to monitoring type 2 diabetes

Harnessing the value of self-monitoring of blood glucose among people with non-insulin-treated type 2 diabetes

Affecting over one million Australians, type 2 diabetes (T2D) costs our country an unsustainable $15 billion annually,[1] and is predicted to be the nation's leading cause of disease burden by 2017.[2] It is therefore essential to engage people with this condition in cost-effective therapy to reduce these costs, which arise mostly from treating the long-term complications (eg, blindness, stroke, amputation).

Self-monitoring of blood glucose levels (by means of a finger-prick blood sample analysed with an ambulatory blood glucose meter) is an essential part of managing type 1 diabetes and insulin-treated T2D; however, the clinical benefit for people with T2D who are not using insulin is, and we believe remains, a matter of debate.

The Government decides ...

On 29 May 2015, the Australian federal government announced that access to testing strips for self-monitoring of blood glucose (SMBG) would be limited for most people with T2D. This announcement followed a much anticipated 2-year review process and extensive consultation. The Pharmaceutical Benefits Scheme (PBS) now stipulates that:

- unrestricted access to SMBG strips will continue for people with T2D who are using insulin or other medicines (eg, corticosteroids, sulfonylureas) to detect asymptomatic hypoglycaemia, or during illness that may cause fluctuations in blood glucose level;[3] and
- access will now be restricted for those with T2D "who are not using insulin and who have their blood glucose level under control. The PBAC [Pharmaceutical Benefits Advisory Committee] recommended that these patients be limited to a six month supply [100 strips] following changes to their diabetes management, with a further six months' supply available at the prescriber's discretion."[3]

This second stipulation is more specific but consistent with another recommendation released just a month earlier.

Choosing Wisely Australia recommends ...

Among its 25 recommendations published on 29 April 2015, Choosing Wisely Australia (an initiative of NPS MedicineWise), in collaboration with the Royal Australian College of General Practitioners, made only one about diabetes. This was: "Don't advocate routine self-monitoring of blood glucose for people with type 2 diabetes who are on oral medication only."[4]

"Choosing Wisely Australia should positively advocate structured [self-monitoring of blood glucose levels] for all people with T2D"

Originating in the United States, Choosing Wisely is a laudable global movement encouraging clinicians and consumers to question the use of unnecessary medical tests, treatments and procedures.

In the US and Canada, Choosing Wisely recommendations for diabetes have focused similarly on restricting SMBG strips for people with non-insulin-treated T2D; in the United Kingdom, recommendations are expected in late 2015.

Despite nuances of language in these international recommendations, SMBG among people with non-insulin-treated T2D is clearly a "hot topic".

The evidence base indicates ...

In 2012, two highly influential systematic reviews — a Cochrane review and a meta-analysis — were published.[5,6] Based largely on the same set of randomised controlled trials (RCTs), their conclusions were comparable: "clinical benefit is limited" for SMBG in people with non-insulin-treated T2D.

The Cochrane review[5] included 12 RCTs (3249 participants). Among these, nine trials of 6 months' duration found that glycated haemoglobin (HbA_{1c}) levels were reduced on average by 0.3% (a statistically, but not clinically, significant improvement).[5] There was no significant reduction in HbA_{1c} levels in trials with 12 months of follow-up. Overall, no benefit was shown for patient satisfaction, emotional wellbeing or health-related quality of life, and SMBG was considered unlikely to be cost-effective.[5]

Challenging the evidence and assumptions

Our own critical appraisal revealed too much variation in trial methods and populations to draw firm conclusions about the value of SMBG overall.[7] In particular, in some trials, participants were not given instructions about when or how often to check their blood glucose level (or this was not reported). Among trials where frequency was reported, it varied enormously — from four times per month to six times per day, 7 days per week. In most cases, the SMBG conducted was insufficient to provide interpretable blood glucose patterns that could inform

Jane Speight
PhD, CPSychol, AFBPsS[1,2]

Jessica L Browne
BPsych(Hons), PhD[1,2]

John S Furler
MB BS, FRACGP, PhD[3]

1 Australian Centre for Behavioural Research in Diabetes, Diabetes Victoria, Melbourne, VIC.
2 Deakin University, Melbourne, VIC.
3 University of Melbourne, Melbourne, VIC.

jspeight@acbrd.org.au

doi: 10.5694/mja15.00639

diabetes self-management and lifestyle choices (eg, food intake or physical activity). Some studies incorporated feedback and education about self-management, but others did not.

We refer to this random, low frequency, routine SMBG as "unstructured", and suggest it is ineffective because it does not enable people with T2D or health professionals to detect blood glucose level patterns or act upon them. Indeed, people with non-insulin-treated T2D reported that their GPs rarely refer to their glucose diary data, and perceive this to mean that SMBG is worthless.[7] They experience SMBG as "frustrating", "painful", "inconvenient" and "expensive", they lack motivation for it, and report "feelings of failure or anxiety in response to high blood glucose readings".[7]

However, in studies where the protocol for a "structured" approach to SMBG was clearer, the findings were more positive — reduced HbA_{1c} levels, less glycaemic variability overall, less time spent in hyperglycaemia.[5,7]

Structured monitoring is effective, economical and engaging

After the systematic reviews were concluded, an RCT of structured SMBG was published.[8] In the STeP study, structured SMBG was defined as seven checks per day over 3 consecutive days in the week before their consultation with a doctor about their diabetes.[8] STeP showed that structured SMBG was associated with a statistically significant reduction in HbA_{1c} level (− 0.3%; $P < 0.001$; intention-to-treat analysis), and a per protocol analysis (focused on those who conducted structured SMBG as intended) showed a clinically significant reduction in HbA_{1c} level (− 0.5%).[8]

Notably, trials of structured SMBG have also shown important psychological benefits — increased satisfaction with treatment, reduced diabetes-related distress, improved general emotional wellbeing and greater confidence in, and motivation for, diabetes self-care.[7-9]

The findings of the STeP study suggest that SMBG does not have, as such, a dose-related response, and needs to be viewed, rather, in terms of quality rather than quantity of monitoring.[8] The protocol suggests that a person with non-insulin-treated T2D using structured SMBG could use as few as 84 test strips per year (ie, 21 in the week before each quarterly general practitioner visit). This, in fact, compares very favourably with the current Australian average of 300 strips per annum per person with non-insulin-treated T2D, and suggests great potential for the federal government's restricted access policy (100 strips over 6 months) to be applied sensibly.

Our recent observational study, STeP-IT-UP, (involving 98 people with non-insulin-treated T2D attending 22 general practices across our eastern seaboard), showed that structured SMBG is feasible in Australia.[10] Furthermore, our findings support US and European evidence showing significant reductions in HbA_{1c} levels (without increasing hypoglycaemia) and diabetes-related distress.

What is structured SMBG?

Structured SMBG is more than just 21 finger pricks. It involves meaningful (rather than random) glucose checks at set times (eg, pre-meal and 2 hours post-meal, and before bedtime) to generate a pattern over at least 3 consecutive days. The person with T2D also notes their meal sizes and energy levels to provide context for the readings. While most trials have evaluated SMBG as though it were an active agent, it is actually just one aspect of a complex intervention, requiring:

- agreement between the person with T2D and their health professional on glucose targets and the timing and frequency of SMBG;
- a supportive and enthusiastic health professional trained in the interpretation of SMBG data;
- appropriate feedback to, and education for, the person with T2D;
- collaborative review of the SMBG pattern to determine areas for improvement and to discuss what contributed to low, high or within-target glucose levels;
- a plan for how to change diet, activity levels or medication to improve glucose levels;
- action (ie, actual change in diet, activity levels or medication); and
- motivation on the part of the person with T2D, which is likely to be contingent on much of the above being in place.

A closer look at the Choosing Wisely Australia recommendation

We take issue with Choosing Wisely's initial statement, that there "is no evidence that self-monitoring of blood glucose (SMBG) affects patient satisfaction, general well-being or general health-related quality of life."[4] There is compelling evidence on both sides of this debate, depending on whether SMBG is structured or unstructured.[7]

Choosing Wisely claimed that Australian Government spending on glucose monitoring strips was $143 million in 2012.[4] This is true, but misleading. Only 35% of this spending was for people with non-insulin-treated T2D.[3] Most of this funding was for SMBG essential for informing insulin dosing and detecting hypoglycaemia in people with type 1 diabetes and those with T2D using insulin or sulphonylureas. Substantial cost savings therefore seem unlikely.

The most positive aspects of the Choosing Wisely recommendation are the exceptions, in particular the usefulness of SMBG for "short-term education about

diet influencing blood sugar", although we would expand this to include physical activity.

Choosing *more* Wisely Australia

We appreciate absolutely the need for evidence-based medicine — and have described the complexity of this evidence base. Nevertheless, we remain concerned that restricting access to glucose monitoring strips conveys the wrong message philosophically. At face value, it implies that some forms of diabetes require less monitoring and are, therefore, less serious than others. Yet all diabetes is serious and all diabetes leads to complications if not monitored and managed appropriately: conveying any other message is confusing, inaccurate and potentially dangerous.

As with most behaviour, if individuals do not value it, or perceive more costs than benefits, they are unlikely to instigate or maintain the behaviour. This applies not only to people with non-insulin-treated T2D, but also to health professionals. While the government is undoubtedly interested in potential costs savings, the PBS final report also recognises the need to emphasise to clinicians and people with T2D that "changes are being implemented to encourage better practice and direct more attention to appropriate use of test strips".[3]

Podcast with Professor Jane Speight is available at mja.com.au/multimedia/podcasts and from iTunes.

Far from recommending against routine SMBG, which may unintentionally deter *any* SMBG in people with non-insulin-treated T2D, we believe Choosing Wisely Australia should positively advocate structured SMBG for all people with T2D not using insulin or other hypoglycaemia-inducing medications. This would be more consistent with its mission not only to reduce unnecessary medical tests, but also to promote evidence-based clinical practice. Structured SMBG offers an evidence-based model for effective blood glucose monitoring and engagement in diabetes self-management.

Competing interests: Jane Speight and Jessica Browne are funded by the collaboration between Diabetes Victoria and Deakin University that supports the Australian Centre for Behavioural Research in Diabetes. Jane Speight is a member of the Accu-Chek Advisory Board (Roche Diagnostics Australia). Her research group has received unrestricted educational grants from Medtronic and Sanofi Diabetes; sponsorship to host or attend educational meetings from Lilly, Medtronic, MSD, Novo Nordisk, Roche Diagnostics Australia, and Sanofi Diabetes; consultancy income from Abbott Diabetes Care, Roche Diagnostics Australia and Sanofi Diabetes. Jessica Browne has received consultancy income from Roche Diagnostics Australia and Sanofi Diabetes. John Furler received fellowship support from the National Health and Medical Research Council (NHMRC) Centre of Clinical Research Excellence in Diabetes Science and is supported by an NHMRC Primary Health Care Research, Evaluation and Development Career Development Fellowship. He has received unrestricted educational grants for research support from Roche, Sanofi and Medtronic. ■

References are available online at www.mja.com.au.

1 Lee CM, Colagiuri R, Magliano DJ, et al. The cost of diabetes in adults in Australia. *Diabetes Res Clin Pract* 2013; 99: 385-390.

2 Australian Institute of Health and Welfare. Australia's health 2010. Canberra: AIHW, 2010. (AIHW Cat. No. AUS 122.) http://www.aihw.gov.au/publication-detail/?id=6442468376 (accessed Sep 2015).

3 Australian Government Department of Health. The Pharmaceutical Benefits Scheme: post-market review of products used in the management of diabetes. Canberra: DoH, 2013. http://www.pbs.gov.au/info/reviews/diabetes#Final-Report-Stage-1 (accessed Jun 2015).

4 Choosing Wisely Australia and Royal Australian College of General Practitioners. 5 things clinicians and consumers should question. 2015. http://www.choosingwisely.org.au/getmedia/cafaec2c-d407-4997-b1a4-1d5dccf0f393/RACGP-Choosing-Wisely-recommendations-270415.pdf.aspx (accessed Jun 2015).

5 Malanda UL, Welschen LMC, Riphagen II, et al. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database Syst Rev* 2012; (1): CD005060. doi: 10.1002/14651858.CD005060.pub3.

6 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* 2012; 344: e486. doi: 10.1136/bmj.e486.

7 Speight J, Browne JL, Furler J. Challenging evidence and assumptions: is there a role for self-monitoring of blood glucose in people with type 2 diabetes not using insulin? *Curr Med Res Opin* 2013; 29: 161-168.

8 Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, non-insulin-treated type 2 diabetes. *Diabetes Care* 2011; 34: 262-267.

9 Fisher L, Polonsky WH, Parkin CG, et al. The impact of structured blood glucose testing on attitudes toward self-management among poorly controlled, insulin-naïve patients with type 2 diabetes. *Diabetes Res Clin Pract* 2012; 96: 149-155.

10 Speight J, Browne JL, Barclay AW, et al. Use of structured self-monitoring of blood glucose improves glycemic control in Australians with non-insulin-treated type 2 diabetes: first results of the STeP IT UP Trial [abstract]. 74th Scientific Sessions of the American Diabetes Association; 2014 Jun 13-17; San Francisco, Ca. http://app.core-apps.com/tristar_ada14/abstract/e3048dedfd3d5fbcc516bc86383e12b3 (accessed Sep 2015). ■