
TECHNOLOGY ASSESSMENT REPORT

Consensus statement on self-monitoring in diabetes: Institute of Health Economics, Alberta, Canada, November 14–16, 2006

PROCESS

This consensus statement was prepared by an independent panel of health professionals, academics, and public representatives based on (1) relevant published studies assembled by the Institute of Health Economics, (2) presentations by experts working in areas relevant to the conference questions, (3) presentations by people living with diabetes, (4) questions and comments from conference attendees during open discussion periods, and (5) closed deliberations by the panel. It is an independent report of the panel and is not a policy statement of the Institute of Health Economics or the Government of Alberta. This consensus statement reflects the panel's assessment of scientific knowledge available at the time the statement was written. The objectives of the panel are to develop a consensus statement on the benefits and costs of testing supplies for self-monitoring of blood glucose in diabetes, to inform patients, health policy, and practice.

BACKGROUND

Diabetes is a growing health problem in our society and has been described as an epidemic that will financially burden our healthcare system. More than two million Canadians have diabetes, with an additional one million expected to be diagnosed by 2010 (2006 Canadian Diabetes Association Diabetes Report). Although numerous strategies have been proven to be successful in preventing diabetes (lifestyle modification and various drugs [metformin, acarbose, rosiglitazone]), these approaches are not widely used at this time. Far from diagnosing prediabetes in a timely manner to implement preventive measures, the diagnosis of diabetes itself is usually delayed. It has been estimated that there is an average of 8 years between the onset of diabetes and its diagnosis. Investments in early diagnosis and early treatment of diabetes have been described as leading to long-term savings in costs.

Diabetes leads to numerous chronic complications. Microvascular complications include diabetic retinopathy (the main cause of blindness), diabetic nephropathy (the majority of new cases of dialysis), and diabetic neuropathy (amputations, erectile dysfunction). Macrovascular complications of diabetes include heart attacks, stroke, and peripheral vascular diseases, which are 2 to 5 times more frequent in people with diabetes than in those without.

Type 2 diabetes, which comprises 90 percent of cases, appears mostly in middle-aged overweight people. It is rising rapidly in frequency, as our population is more obese and less active, and appears at a progressively younger age, including in adolescents. This new phenomenon is particularly prevalent in First Nations people and some ethnic groups. Type 2 diabetes is an evolving disease, which is typically treated initially by lifestyle modification (nutrition therapy and physical activity), followed by drugs, and eventually insulin injections are required in a large percentage. Within the medications (metformin, thiazolidinediones, acarbose) used to treat Type 2 diabetes, some do not cause hypoglycemic (low blood sugar) episodes, whereas others need to have their dosages adjusted more carefully as they may cause hypoglycemia (insulin secretagogues, insulin injections). The vast majority of people with Type 2 diabetes are treated by family physicians.

Type 1 diabetes, which comprises 10 percent of cases, appears primarily in young lean people and requires insulin therapy for survival. Insulin therapy is usually delivered as multiple daily injections or by an insulin pump, and needs to be adjusted to diet content, physical activity, or current glucose concentration. People with Type 1 diabetes are more frequently treated by specialists, and when available, with the help of diabetes health teams.

It has been clearly demonstrated that improved glucose control leads to decreased microvascular complications of diabetes in both people with Type 1 (Diabetes Control and Complications Trial [DCCT]) and Type 2 (United Kingdom

Prospective Diabetes Study [UKPDS]) diabetes. The evidence that interventions designed to lower blood glucose levels can prevent adverse cardiovascular outcomes remains to be demonstrated.

Emphasis has been placed on self-management of diabetes, which allows people with this disease to adjust their lifestyles and their medications to optimize health outcomes. Self-management of diabetes requires in-depth and ongoing teaching, usually by a multidisciplinary team, including diabetes educators and peers. Access to diabetes education remains a major concern and is limited by inadequate human resources, geography, and funding.

Question 1: What Is Self-Monitoring of Blood Glucose for Diabetes?

Self-monitoring of blood glucose (SMBG) is the measurement of the concentration of glucose in the blood by people with diabetes in their daily environments. SMBG can include measurements performed fasting in the morning, before and/or after meals, in the middle of the night, or at any other time as required, for example, to detect hypoglycemia.

Although this term describes the action of measuring glucose, it is intimately linked with the concept of self-management of diabetes, whereby these glucose levels are used not only to document the glucose control, but more importantly to adjust lifestyle, diet, physical activity, and therapeutic approaches with the goal of achieving glycemic control.

What Options Are Available for Self-Monitoring?

SMBG is usually performed using glucose meters and test strips. Typically, the test begins by pricking the fingertip, obtaining a small drop of blood (0.3 to 5 microliters), applying this drop of blood to a test strip, and obtaining the result from the meter within 5 to 30 seconds. Some meters allow alternate site testing, allowing blood to be obtained elsewhere, such as from the arm. Approximately 20 brands of meters exist, each using unique test strips. All test strips cost the same, and this cost has remained stable in the past decade (approximately 80 cents to \$1 per strip), without the advent of any generic strips.

Continuous glucose monitoring devices, measuring glucose levels on a continuous basis through an electrode introduced under the skin that needs to be replaced every few days, are becoming available in Canada. These instruments are currently more expensive than meters and strips, but will provide a markedly increased level of information.

It has been demonstrated that patients cannot predict their blood glucose levels with accuracy. Whereas most episodes of hypoglycemia elicit symptoms that people with diabetes can recognize, many of these symptoms are not specific, and over time, some people with diabetes lose these warning symptoms during hypoglycemia.

Urine testing for glucose detects the spillage of glucose in the urine, which occurs when blood glucose levels rise above 10 mmol/L. Because the goals of therapy are now well below this level, urine testing was replaced two decades ago by blood monitoring. Therefore, SMBG is the only method that can reliably assess blood glucose control in the home setting. SMBG should be regarded as a tool in diabetes management, not as an intervention.

Question 2: What Are the Benefits of Self-Monitoring of Blood Glucose for Individuals with Type 1 Diabetes?

Evidence supports self-monitoring as an essential component of appropriate care for people with Type 1 diabetes (Welschen; UK Health Technology Assessment). The DCCT clearly established the benefits of testing for people with Type 1 diabetes. Testing provides information that can enable people with diabetes to make informed changes in diet, exercise, and insulin dose and frequency. The purpose of these changes is to reduce the risk of life-threatening hypoglycemia and more closely approximate normal glycemic levels. Frequency of testing depends on individual need. Appropriate self-monitoring should result in better long-term control, as evidenced by A1C at or below goal levels, thus minimizing the danger of long-term complications. Outcomes in terms of fatal and nonfatal events have been shown to be significantly improved in self-monitoring individuals (Ludwig). Success in self-monitoring with good glycemic control may result in enhanced self-esteem and empowerment. However, the best effects of testing happen in the context of a partnership between the people with diabetes and a healthcare provider or diabetes team, supplemented by effective education.

Question 3: What Are the Benefits of Self-Monitoring of Blood Glucose for Individuals with Type 2 Diabetes?

Research has shown that people with Type 2 diabetes who require insulin benefit from SMBG, as it enhances self-management for better glycemic control. A lower frequency of testing might be required compared with people who have Type 1 diabetes. SMBG is also important to those people with diabetes who are on oral agents that can cause hypoglycemia, that is, insulin secretagogues.

For people with Type 2 diabetes who manage their disease with oral agents and lifestyle modification, or lifestyle and diet modification alone, the research results are unclear on the benefits of self-testing. Benefits can include enhanced glycemic control and a sense of empowerment. SMBG early in disease management may be a useful tool to enable patients to understand relationships among diet, exercise, and glycemic changes. There is conflicting evidence regarding the value of ongoing self-testing in people whose diabetes is controlled by diet and lifestyle. Evidence suggests that some people with diabetes may experience negative results of

testing, including discouragement and feelings of depression. As one person with diabetes noted, “Every test is a reminder of the fact that I have an incurable disease that might affect my life expectancy, my vision, my kidneys, my limbs, etc. This could/should be a motivator to test but as well, at times, it is a motivator not to test.”

Question 4: What Is the Role of Diabetes Self-Management Education in Self-Monitoring of Individuals with Diabetes?

Diabetes education is clearly a mainstay of diabetes self-management. Scientific evidence that would support *specific* diabetes education programming choices is emerging and evolving and increasingly reflects a strong focus on self-efficacy. There are strong diabetes education programs in many regions in the country, and strong beliefs among people with diabetes, health professionals, and groups representing and advocating for people with diabetes and their families in the importance of these programs. However, scientific evidence for specific program models or configurations is lacking.

It is clear that SMBG *in and of itself* does not and cannot affect blood glucose levels or the longer-term consequences of those levels. For SMBG to be effective, it must be accompanied by changes in individual behaviors associated with appropriate blood glucose level targets. For all types of diabetes, these behaviors include (but are not restricted to) lifestyle behaviors such as dietary and activity modification. For insulin-dependent diabetes, these behaviors also include insulin dosage titration. These behavior modifications require people with diabetes to acquire a complex combination of knowledge and skills in a variety of domains.

The goal of diabetes education programs is to foster and enable self-management of diabetes. Such programs should include the following:

- Be multidisciplinary where possible;
- Be delivered in a group context where possible but not exclude other methods (e.g., Web-based) that may fit particular jurisdictions and geographies;
- Support the person with diabetes in targeting the modifications identified as necessary by their SMBG;
- Incorporate individualized feedback (e.g., by maximizing the information from an individual’s SMBG);
- Be tailored to
 - The specific conditions of person with diabetes
 - The identified concerns and issues of the person with diabetes;
- Include proactive follow-up and ongoing contact on an indefinite basis;
- Encompass the principles of partnership and shared care; and
- Reflect a systems approach to education and care in supporting the person with diabetes and their family.

Emerging research suggests a significant change in educational program trends, but these findings have not as yet been effectively evaluated. Those trends can be generally characterized as moving away from didactic (i.e., lecturing) models of education to more collaborative ones that include acquisition of a broader range of life skills (e.g., skills related to increasing self-efficacy and perceptions of empowerment) now recognized as necessary to successful diabetes self-management.

Multifaceted approaches hold promise as being likely to yield optimal results. The specific elements, however, of these multifaceted approaches are not well delineated. Disentangling the relative contributions of these individual elements will be challenging but important if effective and efficient educational strategies are to be identified.

Areas in which we need additional information to enable program choices that are more likely to be *both* effective and efficient include the following:

- Agreement on the key components of the major different educational strategies;
- Information about the *effectiveness* of specific educational strategies that are used either as stand-alone programs or as components of multifaceted strategies;
- Information about the *costs* of these same strategies;
- Information about what *combinations* of these educational programs are most effective in different groups and in different regions; and
- Agreement on common outcomes, so as to enable comparison among programs.

Question 5: How Important Is Self-Monitoring to Individuals with Diabetes?

Self-monitoring is of utmost importance to some people with diabetes and appears to be unimportant to others. Testimony from people with diabetes suggests that testing does influence their behavior and may also be a stimulus to change. Self-monitoring offers a sense of independence and acts as an educational tool. It may serve as a means of expanding options that would otherwise have been limited by the disease. For example, assurance of the ability to prevent hypoglycemia allows expansion of career choices and insurability. Self-monitoring provides a sense of control and empowerment and a means of enhancing lifestyle, and gives a sense of reducing risk. What is not clear from the evidence are the characteristics of people for whom SMBG will be important.

Question 6: What Are the Trends in Utilization and Cost of Testing Supplies for Self-Monitoring of Diabetes Relative to Other Diabetes Expenses in Canada?

The utilization and cost of supplies for SMBG have been steadily increasing in Canada. This increase has been driven

by utilization and not the price of strips which has remained constant. The increased cost has been significant to the extent that, for example, under the Saskatchewan drug plan, testing supplies are now the second most expensive line item after Lipitor, the biggest selling drug in the world. Although the overall expenditures on diabetes care have also increased, the cost of testing supplies has increased disproportionately, with testing supplies used by people with Type 2 diabetes accounting for most of the increase.

It is, however, important to note that costs should not be considered in isolation. Ideally, the cost-effectiveness ratio should be the criterion for judging appropriateness for funding. Whereas some data exist showing that expenditures on diabetes testing supplies lead to better control and leads to lower downstream costs (for example, hospitalization) a proper cost-effectiveness analysis of SMBG within the context of a treatment and management plan among people with Type 1 and Type 2 diabetes is needed.

Question 7: What Is the Role of Public and Private Insurance for Testing Supplies for Self-Monitoring in Blood Glucose for Diabetes?

The impact of insurance coverage of testing supplies is uncertain. For example, the imposition of user fees, such as patient copayments usually leads to reduced utilization. However, observational data-based evidence from a managed care setting in the United States demonstrated that the introduction of cost sharing and subsequent removal of copayments for SMBG test strips did not significantly affect utilization. Similar, albeit weaker results, were shown in a randomized controlled trial performed in Canada. It was noted that the absence of a clear impact of cost sharing may perhaps be due to the relatively small amount of the copayment and/or related to adherence. More importantly, the overall impact of cost sharing is unknown when including utilization of all healthcare services. Given that most healthcare services under Canada's public healthcare system are free of charge, cost sharing or user fees applied solely on testing supplies may have negative impacts elsewhere, such as use of hospital, physician, or other laboratory services. People with diabetes denied access to test strips may seek increased use of more expensive services.

With regard to the use of SMBG in conjunction with regular insulin use, testing and drug use to obtain optimal glycemic control go hand-in-hand. Therefore, it is incumbent upon public or private insurers to provide coverage for both. It appears that use of SMBG is appropriate in the situation of newly diagnosed Type 2 diabetes for a limited period of time for educational purposes, or in cases when regular testing affects the refinement or initiation of new diabetes treatments.

The usefulness of SMBG in people with Type 2 diabetes not on insulin or insulin secretagogues in the absence of a

self-management program has not been proven, as studies are small, have methodological weaknesses, and provided contradictory results. Removal of coverage in this large population may provide immediate large savings, but the impact on long-term outcomes remains unknown. The panel could not reach consensus on two differing approaches: removing funding of test strips in this population because of the absence of evidence of benefit, or requiring further proper studies proving the safety of removing this coverage before such action is taken.

Question 8: What Future Research Is Needed on the Benefits and Costs for Self-Monitoring of Blood Glucose in Diabetes?

While it seems that a wealth of existing research has affirmed the importance of lowering A1C levels in people with diabetes, many potentially useful ideas for further study were raised. Although Type 1 diabetes management could certainly benefit from additional research, the need was perceived to be greater for people not dependent on insulin, where efficacy of SMBG remains uncertain. The panel was persuaded of the usefulness of a "well-designed, prospective, randomized study of 'self-monitoring' versus 'no self-monitoring' as part of an overall treatment plan."

First Nations people are particularly afflicted by Type 2 diabetes, and opportunities for partnering with this population to learn more about the role of self-testing would be helpful. The role of self-testing in gestational diabetes is also worthy of further study. Other useful ideas include studies with different end points than A1C levels, such as those that look at the potential relationships between SMBG and mortality, other morbidities, and quality of life in general.

Additional qualitative studies that look at the experiences and attitudes of people with diabetes and their caregivers would also add to the depth of our knowledge. It would be useful to know more about the reasons why some people with diabetes benefit more than others in self-testing. Understanding the impact of gender, age, education, ethnicity, and other factors that affect responses to testing and treatment would undoubtedly be valuable.

Other research questions might examine more directly the obvious role for prevention in Type 2 diabetes. Before questions of self-testing, attention should be focused on studies that ultimately discover how incentives, or rules, or closer relationships with care providers, might contribute to effecting the lifestyle changes that would so obviously have an enormous impact on the prevention and management of diabetes.

There is certainly room for more work looking at comparative costs and cost-effectiveness of testing, nontesting, and other interventions. In particular, it is vital that such studies look imaginatively at the full range of present costs, opportunity costs, and the potential savings that could accrue

when effective interventions enable people to live 10 or 20 years longer.

The widespread introduction of the current testing regimen seems to have been adopted without extensive research into efficacy. It is prudent that new technology of continuous subcutaneous monitoring be carefully evaluated in the near future.

Finally, self-monitoring, and diabetes management in general, are all part of larger questions around our approach to chronic illnesses. Previously healthy people who are diagnosed with any lifelong condition ought to be nurtured by the healthcare system according to their own needs, wants, and capabilities. Tests and monitoring that serve specific purposes and whose results will dictate specific actions are to be encouraged. Future research that examines the benefits and costs of self-testing for any condition ought to be conducted for its potential to positively motivate Canadians to make healthier choices and to manage chronic conditions more effectively.

CONCLUSIONS

By 2010, three million Canadians will be living with diabetes. Self-monitoring, properly used and properly funded is one of the tools that will assist people living with diabetes.

The panel concludes that the following actions will improve the appropriate utilization of self-monitoring supplies:

- All people with Type 1 or Type 2 diabetes on insulin or insulin secretagogues should be covered in each jurisdiction for self-monitoring supplies on the same basis as medically necessary drugs;
- Educators and healthcare providers should be encouraged to partner with patients to ensure that monitoring results are regularly used to optimize care; and
- Insurance plans providing coverage for self-monitoring supplies should review program criteria to ensure value for money as well as quality of life and quality of care.

DISCLOSURE STATEMENT

All of the panelists who participated in this conference and contributed to the writing of this statement were identified as having no financial or scientific conflict of interest, and all signed forms attesting to this fact. Unlike the expert speakers who present scientific data at the conference, the individuals invited to participate on the Institute of Health Economics consensus panel are reviewed before selection to ensure that they are not proponents of an advocacy position with regard to the topic and are not identified with research that could be used to answer conference questions.

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