Clinical Practice Guidelines

Monitoring Glycemic Control

Canadian Diabetes Association Clinical Practice Guidelines Expert Committee

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KEY MESSAGES

- Glycated hemoglobin (A1C) is a valuable indicator of treatment effectiveness and should be measured every 3 months when glycemic targets are not being met and when diabetes therapy is being adjusted.
- Awareness of both measures of glycemia, self-monitoring of blood glucose (SMBG) results and A1C, provide the best information to assess glycemic control.
- SMBG should not be viewed as an intervention but rather as an aid to assess interventions and hypoglycemia.
- Timing and frequency of SMBG should be determined individually based on the type of diabetes, the treatment prescribed, the need for information about blood glucose (BG) levels and the individual's capacity to use the information from testing to modify behaviours or adjust medications.
- SMBG and continuous glucose monitoring (CGM) should be linked with a structured educational and therapeutic program designed to facilitate behaviour change for improving BG levels.

Glycated Hemoglobin Testing

Glycated hemoglobin (A1C) is a reliable estimate of mean plasma glucose (PG) levels over the previous 3 to 4 months for most individuals (1). The mean level of blood glucose (BG) in the 30 days immediately preceding the blood sampling (days 0 to 30) contributes 50% of the result and the prior 90 to 120 days contributes 10% (2,3). In uncommon circumstances, where the rate of red blood cell turnover is significantly shortened or extended, or the structure of hemoglobin is altered, A1C may not accurately reflect glycemic status (Table 1).

A1C is the preferred standard for assessing glycated hemoglobin, and laboratories are encouraged to use assay methods for this test that are standardized to the Diabetes Control and Complications Trial (DCCT) reference (4–6). A1C is a valuable indicator of treatment effectiveness and should be measured every 3 months when glycemic targets are not being met and when diabetes therapy is being adjusted. Testing at 6-month intervals may be considered in situations where glycemic targets are consistently achieved (4). A1C is now also being used for diagnosis of diabetes (see Screening for Type 1 and Type 2 Diabetes chapter, p. S12).

In Canada, the A1C continues to be reported using the National Glycohemoglobin Standardization Program (NGSP) units (%). In 2007, a consensus statement from the American Diabetes Association, European Association for the Study of Diabetes and the International Diabetes Federation called for A1C reporting worldwide to change to dual reporting of A1C with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) SI units (mmol/mol) and derived NGSP units (%) with the hope of fully converting to exclusive reporting in SI units (7). However, this has not been adopted worldwide, with both Canada and the United States still using the NGSP units (%) (8). Although there are some advantages to reporting in SI units, the most notable disadvantage is the massive education effort that would be required to ensure recognition and adoption of the new units. At this time, Canada is not performing dual reporting. Therefore, throughout this document, the A1C will still be written in NGSP units (%). For those who wish to convert NGSP units to SI units, the following equation can be used: $IFCC = 10.93(NGSP) - 23.50$ (9) (see Appendix 11 for conversion of A1C from NGSP units to IFCC SI units).

Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) can serve as a useful adjunct to other measures of glycemia, including A1C. Most people with diabetes will benefit from SMBG for a variety of individual reasons (10,11). SMBG is the only way to confirm, and appropriately treat, hypoglycemia. It can provide feedback on the results of lifestyle and pharmacological treatments, and increase patient empowerment and adherence to treatment. It can provide information to both the patient and healthcare professionals to facilitate longer-term treatment modifications and titrations as well as shorter-term treatment decisions, such as insulin dosing for people with type 1 or type 2 diabetes. In situations where A1C does not accurately reflect glycemia (Table 1), SMBG is essential (12).

SMBG is most effective when combined with an educational program that incorporates behavioural changes (lifestyle modification and/or oral hypoglycemic agents) in response to BG values (13–17). As part of this education, patients should receive instruction on (1) how and when to perform SMBG, (2) how to record the results in an organized fashion, (3) the meaning of various BG levels, and (4) how behaviour and actions affect SMBG results.

Frequency of SMBG

The recommended frequency of SMBG must be individualized to each person's unique circumstances. Factors influencing this recommendation will include type of diabetes, type of therapy, adequacy of glycemic control, literacy and numeracy skills, propensity to hypoglycemia, awareness of hypoglycemia, occupational requirements and acute illness.

Table 1
Factors that can affect A1C (74)

Factor	Increased A1C	Decreased A1C	Variable Change in A1C
Erythropoiesis	Iron deficiency B12 deficiency Decreased erythropoiesis	Use of erythropoietin, iron or B12 Reticulocytosis Chronic liver disease	
Altered hemoglobin			Fetal hemoglobin Hemoglobinopathies Methemoglobin Genetic determinants
Altered glycation	Alcoholism Chronic renal failure Decreased erythrocyte pH	Ingestion of aspirin, vitamin C or vitamin E Hemoglobinopathies Increased erythrocyte pH	

Erythrocyte destruction	Increased erythrocyte lifespan:
	    Splenectomy
		Decreased erythrocyte lifespan:
		    Chronic renal failure
		    Hemoglobinopathies
		    Splenomegaly
		    Rheumatoid arthritis
		    Antiretrovirals
		    Ribavirin
		    Dapsone	

Assays	Hyperbilirubinemia Carbamylated hemoglobin Alcoholism Large doses of aspirin Chronic opiate use	Hypertriglyceridemia	Hemoglobinopathies

A1C, glycated hemoglobin.

Type 1 and type 2 treated with insulin

For people with type 1 diabetes, SMBG is an essential daily activity. In a large cohort study, performance of ≥3 self-tests per day was associated with a statistically and clinically significant 1.0% absolute reduction in A1C (7). The evidence is less certain in people with type 2 diabetes treated with insulin, although the above principles likely apply (7). In a large, nonrandomized study of individuals with stable type 2 diabetes using insulin, testing at least 3 times a day was associated with improved glycemic control (18).

More frequent testing, including preprandial and 2-hour post-prandial PG (18,19) and occasional nocturnal BG measurements, is often required to provide the information needed to reduce hypoglycemia risk, including unrecognized nocturnal hypoglycemia (20–24).

Type 2 diabetes not treated with insulin

For people with type 2 diabetes treated with lifestyle management, with or without oral antihyperglycemic agents, the effectiveness of SMBG in terms of improving glycemic control, as well as the optimal frequency, is less clear (10,11,25–34). However, a series of recent meta-analyses, all using different methodologies and inclusion criteria, have generally shown a small benefit to reducing A1C in those individuals performing SMBG compared to those who did not (35–41). The magnitude of the benefit was small, with (absolute) A1C reductions in these meta-analyses ranging from 0.2% to 0.5%. These analyses demonstrated greater A1C reductions in those performing SMBG when the baseline A1C was >8% (17,35,38,42). SMBG has been demonstrated to be most effective in persons with type 2 diabetes within the first 6 months after diagnosis (43). Also of significance, there is no evidence that SMBG affects patient satisfaction, general well-being or general health-related quality of life (43).

It is important to recognize that most trials in non-insulin-treated patients with type 2 diabetes are of limited value as baseline A1C levels were typically <8.0%, and these trials did not include a component of educational and therapeutic intervention in response to BG values. Several recent, well-designed randomized controlled trials that have included this component have demonstrated reductions in A1C (17,44,45). In the STeP trial, 483 poorly controlled subjects, not on insulin (mean A1C >8.9%), were randomized to either an active control group with enhanced usual care or a structured testing group with enhanced usual care and at least quarterly use of structured SMBG (17). At 1 year, there was a significantly greater reduction in mean A1C in the structured testing group compared with the active control group (-0.3%, p=0.04). Significantly, more structured testing group subjects received a treatment change recommendation compared with active control group subjects. In the ROSES (Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin) trial, subjects were randomly allocated to either a self-monitoring-based disease management strategy with education on how to modify lifestyle according to SMBG readings or to usual care (44). Results of SMBG were discussed during monthly telephone contact. After 6 months, significantly greater reductions in mean A1C (-0.5%, p=0.04) and body weight (-4.0 kg, p=0.02) were observed in the SMBG group compared with the usual care group. In the St. Carlos trial, newly diagnosed patients with type 2 diabetes were randomized to either an SMBG-based intervention or an A1C-based intervention (45). In the SMBG intervention group, SMBG results were used as both an educational tool to adhere to lifestyle changes as well as a therapeutic tool for adjustment of pharmacologic therapy. Treatment decisions for the A1C cohort were based strictly on A1C test results. After 1 year of follow-up, the median A1C level and body mass index (BMI) were significantly reduced in patients in the SMBG intervention group (from 6.6% to 6.1%, p<0.05; and from 29.6 to 27.9 kg/m^2, p<0.01). In the A1C group, there was no change in median A1C or BMI.

The evidence is less clear about how often, once recommended, SMBG should be performed by persons with type 2 diabetes not treated with insulin. Separate from one's ability to use SMBG in order to lower A1C, SMBG should be considered for the prevention, recognition and treatment of hypoglycemia in persons whose regimens include an insulin secretagogue due to the higher risk of hypoglycemia with this class of agents (46). On the other hand, for patients with type 2 diabetes who are managed with lifestyle, with or without oral antihyperglycemic agents associated with low risk of hypoglycemia, and who are meeting glycemic targets, very infrequent checking may be needed.

The Canadian Diabetes Association has published the "Self-Monitoring of Blood Glucose (SMBG) Recommendation Tool for Healthcare Providers," which defines basic SMBG requirements to provide guidance to healthcare professionals regarding appropriate utilization of SMBG (Appendix 4) (available at: (http://www.diabetes.ca/documents/for-professionals/SMBG_HCP_Tool_9.pdf).

Verification of accuracy of SMBG performance and results

Variability can exist between BG results obtained using SMBG devices and laboratory testing of PG. At BG levels >4.2 mmol/L, a difference of <20% between SMBG and simultaneous venous FPG is considered acceptable (47). In order to ensure accuracy of SMBG, results should be compared with a laboratory measurement of FPG at least annually or when indicators of glycemic control (A1C) do not match SMBG readings. Periodic re-education on correct SMBG technique may improve the accuracy of SMBG results (48,49). In rare situations, therapeutic interventions may interfere with the accuracy of some SMBG devices. For example, icodextrin-containing peritoneal dialysis solutions may cause falsely high readings in meters utilizing glucose dehydrogenase. Care should be taken to select an appropriate meter in such situations.

Alternate site testing

Meters are available that allow SMBG using blood samples from sites other than the fingertip (forearm, palm of the hand, thigh). Accuracy of results over a wide range of BG levels and during periods of rapid change in BG levels is variable across sites. During periods of rapid change in BG levels (e.g. after meals, after exercise and during hypoglycemia), fingertip testing has been shown to more accurately reflect glycemic status than forearm or thigh testing (50,51). In comparison, blood samples taken from the palm near the base of the thumb (the thenar area) demonstrate a closer correlation to fingertip samples at all times of day and during periods of rapid change in BG levels (52,53).

Ketone Testing

Ketone testing is recommended for all individuals with type 1 diabetes during periods of acute illness accompanied by elevated BG, when preprandial BG levels remain elevated (>14.0 mmol/L), or when symptoms of diabetic ketoacidosis (DKA), such as nausea, vomiting or abdominal pain, are present (4). If all of these conditions are present in type 2 diabetes, ketone testing should be considered, as DKA also can occur in these individuals.

During DKA, the equilibrium that is usually present between ketone bodies shifts toward formation of beta-hydroxybutyric acid (beta-OHB). As a result, testing methods that measure blood beta-OHB levels may provide more clinically useful information than those that measure urine acetoacetate or acetone levels. Assays that measure acetoacetate through urine testing may not identify the onset and resolution of ketosis as quickly as those that quantify beta-OHB levels in blood, since acetoacetate or acetone can increase as beta-OHB decreases with effective treatment (47). Meters that quantify beta-OHB from capillary sampling may be preferred for self-monitoring of ketones, as they have been associated with earlier detection of ketosis and may provide information required to prevent progression to DKA (54–56). This may be especially useful for individuals with type 1 diabetes using continuous subcutaneous insulin infusion, as interruption of insulin delivery can result in rapid onset of DKA (54).

Continuous Glucose Monitoring Systems

Continuous glucose monitoring systems (CGMSs) measure glucose concentrations in the interstitial fluid. Two types of devices are available. The "real time" (also called "personal") CGMS provides information directly to the user by displaying moment-to-moment absolute glucose levels and trending arrows, and by providing alarm notifications in the event that the glucose level is above or below a preset limit. A "blinded" (sometimes referred to as "professional") CGMS captures, but does not display, the glucose readings, which are then downloaded onto a computer for viewing and retrospective analysis by the healthcare provider (typically in conjunction with the user).

Continuous glucose monitoring (CGM) technology incorporates a subcutaneously inserted sensor, an attached transmitter and, in the case of real-time CGM, a display unit (which may be a stand-alone unit or be integrated into an insulin pump). In professional

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RECOMMENDATIONS

1. For most individuals with diabetes, A1C should be measured every 3 months to ensure that glycemic goals are being met or maintained. Testing at least every 6 months should be performed in adults during periods of treatment and lifestyle stability when glycemic targets have been consistently achieved [Grade D, Consensus].

2. For individuals using insulin more than once a day, SMBG should be used as an essential part of diabetes self-management [Grade A, Level 1 (21), for type 1 diabetes; Grade C, Level 3 (10), for type 2 diabetes] and should be undertaken at least 3 times per day [Grade C, Level 3 (10,18)] and include both pre- and postprandial measurements [Grade C, Level 3 (18,19,73)]. In those with type 2 diabetes on once-daily insulin in addition to oral anti-hyperglycemic agents, testing at least once a day at variable times is recommended [Grade D, Consensus].

3. For individuals with type 2 diabetes not receiving insulin therapy, SMBG recommendations should be individualized depending on type of anti-hyperglycemic agents, level of glycemic control and risk of hypoglycemia [Grade D, Consensus].
   - When glycemic control is not being achieved, SMBG should be instituted [Grade B, Level 2 (33,38)] and should include periodic pre- and postprandial measurements and training of healthcare providers and patients on methods to modify lifestyle and medications in response to SMBG values [Grade B, Level 2 (17)].
   - If achieving glycemic targets or receiving medications not associated with hypoglycemia, infrequent SMBG is appropriate [Grade D, Consensus].

4. In many situations, for all individuals with diabetes, more frequent testing should be undertaken to provide information needed to make behavioural or treatment adjustments required to achieve desired glycemic targets and avoid risk of hypoglycemia [Grade D, Consensus].

5. In people with type 1 diabetes, real-time continuous glucose monitoring may be used to improve glycemic control [Grade B, Level 2 (58)] and reduce hypoglycemia [Grade B, Level 2 (65,69)].

6. In order to ensure accuracy of BG meter readings, meter results should be compared with laboratory measurement of simultaneous venous FPG at least annually and when indicators of glycemic control do not match meter readings [Grade D, Consensus].

7. Individuals with type 1 diabetes should be instructed to perform ketone testing during periods of acute illness accompanied by elevated BG, when preprandial BG levels remain >14.0 mmol/L or in the presence of symptoms of DKA [Grade D, Consensus]. Blood ketone testing methods may be preferred over urine ketone testing, as they have been associated with earlier detection of ketosis and response to treatment [Grade B, Level 2 (55)].

Abbreviations:
BG, blood glucose; *DKA*, diabetic ketoacidosis; *FPG*, fasting plasma glucose; *SMBG*, self-monitoring of blood glucose.

CGM, the "transmitter" captures and retains the data. In Canada, one real-time CGMS and two professional CGMSs are available. Real-time CGM has been consistently shown to reduce A1C in both adults (57–66) and children (58,60,62,63,65–67) with type 1 diabetes, and to reduce A1C in adults with type 2 diabetes (68). Real-time CGM also has been shown to reduce the time spent in hypoglycemia (65,69). Professional CGM has been shown to reduce A1C in adults with type 2 diabetes (70) and in pregnant women with type 1 or type 2 diabetes (71).

Successful use of CGM is, unsurprisingly, dependent on adherence with using the CGMS; the greater the time wearing the device, typically the better the A1C (59,60,63,64,67,72). Like SMBG, CGM provides the best outcomes if it is associated with structured educational and therapeutic programs. CGM is not a replacement for SMBG because SMBG is still required for calibration of the CGM device and, for real-time CGM, to confirm interstitial measurements prior to making therapeutic changes or treating suspected hypoglycemia.

Other Relevant Guidelines

Self-Management Education, p. S26
Targets for Glycemic Control, p. S31
Hypoglycemia, p. S69
Type 1 Diabetes in Children and Adolescents, p. S153
Type 2 Diabetes in Children and Adolescents, p. S163
Diabetes and Pregnancy, p. S168

Relevant Appendix

Appendix 4. Self-Monitoring of Blood Glucose (SMBG) Recommendation Tool for Healthcare Providers
Appendix 11. A1C Conversion

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