### SELF-MONITORING OF BLOOD GLUCOSE (SMBG) IN TYPE 2 DIABETES (T2DM)

<table>
<thead>
<tr>
<th>Devices</th>
<th>Accu-Chek</th>
<th>Mobile</th>
<th>Next</th>
<th>Next ONE</th>
<th>Next EZ</th>
<th>Next LINK &amp; 2.4</th>
<th>Precision Neo</th>
<th>InsuLinx</th>
<th>Lite</th>
<th>Libre</th>
<th>Verio &amp; Flex</th>
<th>Ultra 2</th>
<th>Reflect</th>
<th>Dario</th>
<th>Sanofi-Aventis</th>
</tr>
</thead>
<tbody>
<tr>
<td>7, 14, 30, 90 day averaging</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Second-chance sampling: may apply more blood</td>
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<td>Consider cost of SMBG</td>
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<tr>
<td>For most adults with T2DM taking &quot;Diabetes treated&quot;</td>
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<tr>
<td>Few studies compared different frequencies of SMBG</td>
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<tr>
<td>Amanda et al, 2012</td>
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<tr>
<td>To test or not to test...</td>
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</tr>
<tr>
<td>AST= alternate site testing; may be less accurate when blood glucose is fluctuating (e.g. following a meal, after exercise, signs of hypoglycemia)</td>
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</tbody>
</table>

### The Value of SMBG (especially if not on insulin) has come into question due to uncertain or marginal benefits & significant costs

This change in the evidence has led to a review of the value of SMBG in T2DM management. A recent Cochrane review found that for those not on insulin, benefits of SMBG on glycemic control are small, and there is no clear evidence of a benefit in glycemic control for adults with T2DM. However, SMBG is important for those on insulin or other treatments that require frequent testing.

### Consideration of SMBG in T2DM

- SMBG should be used in T2DM to achieve optimal blood glucose control.
- SMBG is important for those on insulin or other treatments that require frequent testing.
- SMBG is not recommended for general use in T2DM management.

### CADDTh Clinical Analysis

Optimal Therapy Report: Systematic Review of Use of Blood Glucose Test Strips for the Management of Diabetes

Within the limitations of available evidence, the report concluded:

1. **Insulin treated T2DM:** Use of SMBG appears to be associated with improvements in glycemic control.
2. **Few studies compared different frequencies of SMBG for patients with either T1DM or insulin-treated T2DM:** and the evidence from these studies was low quality.
3. **T2DM not using insulin:** Use of SMBG is associated with a statistically significant, albeit clinically modest, improvement in glycemic control.
4. **Long-term studies are needed to determine whether or not SMBG reduces DM related clinical endpoints (e.g., blindness, reduction in MI, ESRD) or mortality.
5. **Studies of specific subgroups within this population who may be more likely to benefit from SMBG are also warranted.
6. **The effect of using SMBG in women with gestational diabetes requires further investigation.

### Other Considerations

- **SMBG is often used to provide feedback to new patients regarding effects of lifestyle & dietary choices on BG levels.** One Cochrane review found that for those not on insulin, benefits of SMBG on glycemic control are small, and there is no clear evidence of a benefit in glycemic control for adults with T2DM.
- **Consider factors:** such as motivation, comprehension level, age, hypoglycemia risk (especially when on insulin or secretagogues), exercise, illness, drug dose adjustments.
- **Choice of meter** should accommodate individual needs.
- **Vision impairment:** consider display size or voice option
- **Size/Feel:** portability, speed, dexterity & other needs (e.g. arthritis)
- **Alternate site testing:** may be useful if significant pain from finger pokes
- **SMBG in people with T2DM:** Use of SMBG is recommended for those on insulin or secretagogues. SMBG is less likely to be required in people not on insulin or secretagogues. SMBG is not required for people with gestational diabetes.
- **Cost of meter:** complimentary with purchase of strips; **Cost of strips:** $75-100 per 100 strips

### If testing, when?

- **Diet only:** occasional testing, esp. if 2 hr post-prandial may be useful to reinforce lifestyle changes. (SK & NIDDM allows for 3-4 tests/week (200/year))
- **OAHA only:** at staggered times; eg. pre- & 2hr post-prandial, 1 or 2 weekly (1 tool or 3 tests/week as necessary; most benefits in 1st - 6 months)
- **OAHA & HS insulin:** at 2400 (7 tests/d)
- **Insulin: multiple daily injections +/- OAHA:** individualize CADDTh; ≥2TID ≥1TID; pre- & 2hr post-prandial; **OAHA allows for ≤8 tests/day (800/1000days) if on insulin.**
- **Pair meal testing (AC before & 2hr PC after):** to match regimen to BG patterns; stagger times and days (see below). Analyze after 1-3 weeks.
- **Day 1:** AC & PC breakfast; **Day 2:** AC & PC lunch; **Day 3:** AC & PC supper & & HS periodically.
- **Provides a good cross-sectional representation of pattern of hypoglycemia & hyperglycemia, with less testing.

- **Pair HS & AM testing:** for a few nights ~ useful to assess basal control
- **Consider testing more often:** in pregnancy; illness; exercise; prior to o2h4h while driving if on insulin to detect & tx hypoglycemia; changes in diet &/or activity; after adjusting diabetes regimen (insulin/pills) over 1-2 weeks; adding medication may ↑ blood glucose; if hypoglycemic unawareness.

### SMBG DECISION TOOLS

- **http://guidelines.diabetes.ca/bloodglucoselowering/smbgrecommendationsheet**
- **http://diabetecare.nihshealth.ca/sites/default/files/files/SMBGDecisionTool.pdf**


Online Extras: Self-Monitoring of Blood Glucose in Type 2 Diabetes

Background Considerations:

- **Weighing the Benefits & Risks of Intensive Therapy:** [See also Diabetes - Landmark Outcome Trials Chart xxiv]
  - The results of clinical trials evaluating outcomes of intensive glycemic control have been somewhat disappointing. Achieving an A1C of less than 6.5% may decrease microvascular endpoints, but over 100,000 patient years of RCT data have failed to show a benefit on CV endpoints.xxii (The 10 year observational follow-up to the UKPDS suggests CV benefit of intensive glycemic control (FBG <6; mean baseline A1Cs 7.9% vs 8.5%) especially with metformin.xxiii)
  - Individualization of antihyperglycemic therapy has become a common themexxiv,xxv as some evidence & experience suggests that some patients may do worse with more intensive regimens (e.g. ↑ mortality (NNH=95/3.5yrs) in the ACCORD RCT xxv,xxvi in patients randomized to achieve an intensive A1c of 6% vs 7 to 8%, actual A1c achieved was 6.4% vs 7.5%xxv).
  - Although an A1C of <7% is suggested for most, individual patient & treatment regimen factors may result in acceptance of less aggressive targets. For example the American Geriatric Societyxxv noted that an A1c of 8% may be more suitable in frail elderly & those with a life expectancy <5yrs.
  - A recent observational cohort trial found a “U” shaped curve for mortality related to A1C. An A1C of 7.5% was associated with the lowest mortality, with higher mortality seen at higher and lower A1C values.xxv.

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If practice changes to reflect the evidence, $450 million to $1.2 billion* could be freed up between 2012 and 2015 for spending on antidiabetes interventions that are proven effective. Patient health would not be affected negatively.

[These results were prepared using data from Brogan Inc., a unit of IMS, PharmacySure. Public and Private Drug Plans Databases, 2000-2011]

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A1c = hemoglobin A1c  
Ac = before meals  
AST = Alternate Site Testing  
BG = blood glucose  
CADTH = Canadian Agency for Drugs & Technologies in Health  
CI = confidence interval  
COMPUS = Canadian Optimal Medication Prescribing and Utilization Service  
CV = cardiovascular  
Eng/Fre = English and French  
Exp = Expiration  
Fx(s) = Function(s)  
Gl = glucose  
IFR = infrared data transfer  
P = insulin pump  
Ket = ketones  
OAHA = oral anti-hyperglycemic agent  
RCT = randomized controlled trial  
SMBG = self-monitor blood glucose  
T2DM = Type 2 diabetes  
TS = Touch Screen  
WMD = weighted mean difference

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Data provided from Saskatchewan Health; used by permission.
Additional articles SMBG meters:


Canadian Diabetes Association (CDA) plans to launch a compassionate use program to assist people with diabetes who have difficulty covering the costs of blood glucose monitoring supplies http://www.diabetes.ca/


FDA Aug/10 and CDC June/16 TRUEyou blood glucose test strips

Medical Letter.


FDA Jan/14 Nipro Diagnostics initiated a voluntary recall and replacement of a limited number of TRUEbalance and TRUEtrack Blood Glucose Meters distributed both in the United States and outside the United States. The company determined that certain isolated TRUEbalance and TRUEtrack Blood Glucose Meters have an incorrect factory-set unit of measure that displays the glucose result in mmoi/L rather than mg/dl. If a consumer were not to notice the incorrect unit of measure, it is possible that the meter could be read as a lower than expected blood glucose result. BACKGROUND: There are 501 affected TRUEbalance meters and 105 affected TRUEtrack meters that were distributed in the US from September 2008 to May 2013. The company is sending notifications to pharmacies, durable medical equipment providers, mail order companies and distributors where the TRUEbalance and TRUEtrack meters are recommended or sold in the United States.

FDA Mar/14 Abbott is conducting a recall for the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter. When used with the Abbott FreeStyle test strips, the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter may produce mistakenly low blood glucose results.

FDA Apr/14 is advising people with diabetes and healthcare professionals to stop using GenStrip Blood Glucose Test Strips because the strips may report incorrect blood glucose levels.

FDA Jun/14 Diabetic Supply of Suncoast, Inc. initiated a nationwide voluntary recall of all BMB-BA006A Advoca Redi-Code+ blood glucose test strip lots manufactured by BroadMaster Bio-Tech Corp due to a labeling error which could result in confusion about which meter models the Redi-Code+ BMB-BA006A blood glucose test strips are designed to be used with. In the incorrect labeling, the test strips model (BMB-BA006A) was omitted.

FDA Jan/16 Arkray is recalling the SPOTCHEM II Basic PANEL-1 Reagent Test Strip and SPOTCHEM II Glucose Reagent Test Strip because they may report falsely low blood glucose levels.


Health Canada Mar/14: Informing Canadians that when Abbott FreeStyle glucose test strips are used, there are certain devices, there is a potential for users to receive a lower-than-actual blood sugar reading.


MHRA June/16 TRUEyou blood glucose test strips - certain lots of test strips may give incorrect low blood glucose results that could lead to undetected hyperglycaemia.

Ontario Aug/13: Introducing limitations in funding for diabetes test strips. And these new restrictions are aimed at the Canadian Diabetes Association, which worked with the government to ensure that the provision of continuous monitoring of blood glucose doesn’t take the best evidence and clinical experience available. According to a notice posted on the Ontario Public Drug Programs (ODP) website, research indicates that Blood Glucose Test Strips (BPTS) have a limited clinical benefit for many patients who don’t take insulin. Based on this evidence, Ontario will restrict the number of BPTS allowed in a 365-day period, while ensuring continued access to those who need test strips to manage their blood sugar.


References (SMBG)


12. Malanda UL, Welschen LM, 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 Jan 18;1:CD005060. [From this review, we conclude that when diabetes duration is over one year, the overall effect of self-monitoring of blood glucose on glycaemic control in patients with type 2 diabetes who are not using insulin is small up to six months after initiation and subsides after 12 months. Furthermore, based on a best-evidence synthesis, there is no evidence that SMBG affects patient satisfaction, general well-being or general health-related quality of life. More research is needed to explore the psychological impact of SMBG and its impact on diabetes specific quality of life and well-being, as well as the impact of SMBG on hypoglycaemia and diabetic complications.]


Note: see Diabetes and Pregnancy Recommendations, page s170 and s174


