Clinical Pearls

- Goal of blood glucose (BG) testing: Inform therapy decisions to help assess the effectiveness of glucose lowering interventions, prevent hypoglycemia and provide feedback to patients on lifestyle interventions.
- For individuals using insulin ≥1 time/day, SMBG should be used as an essential part of diabetes self-management for T1DM and T2DM.
- If not using insulin or secretagogues, consider if cost of SMBG (>50% expenditure for BG strips) comes from these patients; may result in improved treatment or behavioral change.
- Increasing use of flash glucose monitoring (FGM) & continuous glucose monitoring (CGM)

<table>
<thead>
<tr>
<th>Type 2 Diabetes</th>
<th>Evidence Summary for SMBG</th>
<th>Bottom Line</th>
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</thead>
<tbody>
<tr>
<td>Diet alone or prediabetes</td>
<td>SMBG vs no SMBG: Improvements in glycemic control were less pronounced (ΔA1c= 0.05%) and not statistically significant.</td>
<td>Routine SMBG is not required. May be considered for feedback to new patients on the effects of lifestyle interventions.</td>
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</tbody>
</table>
| Not using insulin | - Self-testing (>7 times per week) is associated with a statistically significant, but not clinically relevant, improvement (ΔA1c = 0.25%).
- Benefits are small up to 6 mos (ΔA1c = 0.3%) & subside by 12 mos. 
- No studies have determined whether SMBG shows benefit for hard diabetes endpoints such as reduction in blindness, kidney damage, MI or mortality. 
- An association with depression and lower quality of life has also been noted. | Routine SMBG is not required. 
- The small reduction in A1c does not translate to better glycemic control or quality of life. 
- Periodic testing in some situations (see Table 3), but only if it helps to determine a specific course of action (e.g. self-directed dose adjustments). |
| Using insulin | Low quality evidence suggests the use of SMBG appears to be associated with improvements in glycemic control. 
- There is insufficient evidence to determine the optimal frequency and this should be individualized. Preformed SMBG at least as often as insulin is being given. | Basal insulin ≤2 times per day; Individualize frequency, usually not more than 14 times per week (e.g. SMBG 2x per day). 
- Basal-prandial insulin: Individualize frequency to guide adjustments in insulin therapy (see Table 2). |

Table 1: Recommendations for Self-Monitoring Blood Glucose (SMBG) in People with Type 2 Diabetes

<table>
<thead>
<tr>
<th>Situation</th>
<th>SMBG Frequency Recommendation</th>
<th>Test Strip &amp; Lancet Coverage (SKH/NIH)</th>
<th>Cost of strips</th>
<th>Number of strips</th>
</tr>
</thead>
</table>
| Non-insulin pharmacotherapy | If achieving targets or using medications not associated with hypoglycemia: 
- In frequent SMBG is appropriate 
- If glycemic control not achieved: Non-Insulin 
- Consider at testing staggering times (e.g. period pre- & post-prandial) | SKH: 3,650 per year (10 per day) 
NIBH: 800 per 100 days (8 per day) | SS: $50-100 per 100 strips | |
| Basal (typically on GS) | At least as often as insulin is being given. | Hypoglycemia risk: 
- ↑ risk = 400 per year; 
- ↓ risk = 200 per year | |
| Premixed (typically ac, breakfast & supper) | At least as often as insulin is being given. | | |
| Basal-prandial/multiple daily injections (QID) (bolus ac & basal HS) | QID: pre meals and at bedtime, to assess previous dose and to adjust the next dose (post-prandial or paired meal BG checking can also be helpful, see chart page 51) | | |

Table 2: If self-monitoring blood glucose, when?

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<td>Situation</td>
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<td>Diabetic Canada SMBG Recommendation Tool (HCP): SMBG Tool (pdf)</td>
<td>SMBG Interactive Tool</td>
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Table 3: Consider More Frequent SMBG

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ONLINE EXTRAS: SELF-MONITORING OF BLOOD GLUCOSE IN TYPE 2 DIABETES

Acknowledgements: Written by T Trischuk, L Regier, C Lee. Updated by Marlys LeBras. Thanks to our reviewers: Henry Halapay, Monica Lawrence, Kerry Mansell.

Disclosures: No conflicts of interest are reported.

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Background considerations:

- **Weighing the benefits & risks of intensive therapy:** [See also Diabetes - Landmark Outcome Trials Chart]
  - The results of clinical trials evaluating outcomes of intensive glycemic control have been somewhat disappointing. Achieving an A1c of less than 6.5% may ↓ microvascular endpoints, but over 100,000 patient years of RCT data have failed to show a benefit on CV endpoints.¹ (The 10 year observational follow-up to the UKPDS suggests CV benefit of intensive glycemic control (FBG <6; mean baseline A1c 7.9% vs 8.5%) especially with metformin.²)
  - Individualization of antihyperglycemic therapy has become a common theme³⁴ as some evidence & experience suggests that some patients may do worse with more intensive regimens (e.g. ↘ mortality (NNH=95/3.5yrs) in patients randomized to achieve an intensive A1c of 6% vs 7 - 8%; actual A1c achieved was 6.4% vs 7.5%)⁵.
  - 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 Society⁶ 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.⁷

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, PharmaStat®, Public and Private Drug Plans Databases, 2000-2011]
References for SMBG meters:


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.)


Additional articles for SMBG meters:


Canadian Diabetes Association (CDA) plans to launch a compassionate batch of test strips later this year to help cover the costs of blood glucose monitoring supplies. http://www.diabetescanada.ca/


FDA Aug10 and CDC have noted a progressive increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from shared use of fingertips and point-of-care [POC] blood testing devices.

FDA Aug13/Nov13 Diabetes Care initiated a voluntary recall of 21 lots of the Nova Max Glucose Test Strips distributed both in the USA and outside the continental USA.

FDA Jan14/Nov14 Diagsinics initiated a voluntary recall and replacement of a limited number of TRUEbalance and TRUEtrack Blood Glucose Meters distributed both in the USA 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 mmol/L rather than mg/dL. If a consumer were not to notice the incorrect unit of measure, it is possible that the meter result could be read as a lower than expected blood glucose result. These TRUEtrack meters were distributed in the United States from September 2008 to May 2013. The company is sending notifications to pharmacies, durable medical equipment providers, order medical device distributors and customers and distributors where the TRUEbalance and TRUEtrack Blood Glucose Meters are recommended or sold in the United States.

FDA Mar14 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 Apr14 is advising patients with diabetes and health care professionals to stop using GenStrip Blood Glucose Test Strips because the strips may report incorrect blood glucose levels.

FDA Jun14 Diabetic Supply of Suncoast, Inc. initiated a nationwide voluntary recall of all BMB-BAA906 Advocate Redi-Code+ blood glucose test strips manufactured by BroadMaster Bio-Tech Corp due to a labeling error which could result in confusion about which meter models the Redi-Code+ BMB-BAA906A blood glucose test strips are designed to be used with. In the incorrect labeling, the test strips model (BMB-BAA906A) was omitted.

FDA Jan16/Arkay is recalling the SPOTCHEM II Basic PANEL-1 Reagent Test Strip and SPOTCHEM II Reagent Test Strip because they may report falsely low blood glucose levels.


Health Canada Mar14: Informing Canadians that when Abbott FreeStyle glucose test strips are used with certain devices, there is a potential for users to receive a lower-than-actual blood sugar reading.


Also article in CPJ, Sep 2010 at: http://www.cjpodjournal.ca/pdf/10.3821/1913-701X-143.5.218


MHRAS 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 2013: introducing limitations in funding for diabetes test strips. And these new restrictions are ok with the Canadian Diabetes Association, which worked with the government to ensure that new self-management of diabetes reflects 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 (BGSTs) have a limited clinical benefit for many patients who don’t take insulin. Based on this evidence, Ontario will restrict the number of BGSTs allowed in a 365-day period, while ensuring continued access to those who need test strips to manage their blood sugar. The province’s Health Network System (HNS) will track and determine the reimbursement level based on each patient’s insulin. Based on this evidence, Ontario will restrict the number of BGTS allowed in a 365-day period, while ensuring continued access to those who need test strips to manage their blood sugar. The province’s Health Network System (HNS) will track and determine the reimbursement level based on each patient’s insulin. Based on this evidence, Ontario will restrict the number of BGTS allowed in a 365-day period, while ensuring continued access to those who need test strips to manage their blood sugar. The province’s Health Network System (HNS) will track and determine the reimbursement level based on each patient’s insulin.


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