To test or not to test...

The value of routine SMBG, especially in patients not on insulin, has come into question, due to uncertain or marginal benefits & significant costs. A possible association with depression & lower quality of life has also been noted. See also:

1) Weighing the Benefits & Risks of Intensive Therapy in online extras
2) Landmark Outcome Trials chart (pg. 49)

Consider cost of SMBG if not using insulin or secretagogues, especially where testing may not change treatment or offer net benefit. Some favours SMBG in most individuals with T2DM. However, SMBG is only worth doing (i.e. time & money) if it results in positive behaviour change.

Highlight Recommendations from the CADTH Review*

1. For most adults with T2DM who are using insulin:
   a. SMBG should be tailored to fine-tune insulin therapy to achieve optimal BG control.
   b. On average, no more than 14 tests each week for most patients on basal insulin (≤2x per day). (Some individuals on multiple daily injections, may benefit from more frequent testing.)

2. For most adults with T2DM taking oral anti-hyperglycemia agent (OAHA):
   a. Routine SMBG is not required.
   b. Periodic testing may be required in some situations, but only if it helps determine a specific course of action. See Other Considerations: Consider testing more often

3. For most adults with T2DM controlled through diet alone: Routine SMBG is not required.

*Note: In gestational & pre-gestational DM, SMBG ≥4x/7x/day (pre & post-prandially) DX, DC

CATH Clinical Analysis: From the Report Summary of Systematic Review of RCTs & observational studies

Patients with diabetes using insulin:
- In general, the COMPU systematic review only identified a few studies that explored the optimal frequency of SMBG in patients with either T1DM, or insulin-treated T2DM. Moreover, the studies identified reported mixed results, and were of low quality. In patients with insulin-treated T2DM, low-quality evidence suggests SMBG is associated with improvements in glycaemic control.

Patients with T2DM not using insulin: *CI= confidence interval, WMD= weighted mean difference
- The COMPU systematic review elicited more robust studies for patients with non-insulin-treated T2DM (most tw with MF, SU, TZD) including several RCTs.
- Pooled results from 7 RCTs showed that SMBG is associated with a statistically significant improvement in glycaemic control (WMD* in AIC [99% CI*] +0.25% [0.15, 0.35]). [However, a change of <0.5% is of questionable clinical significance.]
- In 1 RCT, SMBG was associated with ↓ in symptomatic hypo/hyperglycemic events in patients using sulfonylureas. Another RCT did not show improvements in QOL or AIC.
- For patients not using BG lowering drug tx, improvements in control were less pronounced & not statistically significant. (WMD* in AIC [99% CI*] = -0.05 [0.33, 0.22]).
- Overall, quality of evidence varied, depending on the patient population.

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 up to 6 months, & subside by 12 months.
- Consider factors such as motivation, comprehension level, age, hypoglycemia risk (e.g. 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/feet: portability, speed, dexterity & other needs (e.g. arthritis)
  - Alternate site testing: may be useful if significant pain from finger pokes
  - Simple vs many features, remote reading/transmission etc.
  - Test strip cost: meters compatible with purchase of strips
  - Annual cost: $165 (1 test/day) to $1100-2400 (7 tests/day). Cost/100strips=$75-100.

If testing, when?
- **Diet Only**: occasional testing, esp. of 2 hr post-prandial may be useful to reinforce lifestyle changes. (SK & NHB allows for 3-4 tests/week [200/week])
- **OAHA only**: at staggered times; eg. pre- & 2hr post-prandial, 1 or 2x weekly (↑ or ↓ frequency as necessary; most benefits in 1st 12-12months)
- **OAHA & HS insulin**: 1-2x/day at variable times (≤14 tests/wk); eg. fasting, pre- & 2hr post-prandial
- **Insulin: multiple daily injections +/- OAHA**: individualize CATH, ≥2TD CDA, pre- & 2hr post-prandial;
- **NHB allows for ≤5 tests/day (500/100days) if on insulin. Sk drug plan reimbursement allows for ≤10 tests/day (3650/year) if on insulin.**[Some patients with very intensive regimens may require more meal testing; up to 7 tests/day.]
- **Paired meal testing (AC & PC before & 2hr PC after)**: to match regimen to BG patterns; stagger times and days (see below). Analysis: After 1-3weeks.
- **Day 1: AC & PC breakfast; Day 2: AC & PC lunch; Day 3: AC & PC supper; & HS somewhere. (Provides a good cross-sectional representation of pattern of hypo- & hyperglycemia, with less testing.)
- **Paired HS & AM testing**: for a few nights ~ useful to assess basal control
- **Consider testing more often**: in pregnancy; illness; exercise; prior to o4h 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/smbgregimetionsheet
**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](#)\(^{xxv}\)
  - 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.\(^{xxvi}\) (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.\(^{xxvii}\))
  - Individualization of antihyperglycemic therapy has become a common theme\(^{xxviii}\)\(^{xxix}\)\(^{xxx}\)\(^{xxxi}\)\(^{xxv}\)\(^{xxvi}\)\(^{xxvii}\) 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\(^{xxv}\)\(^{xxvi}\)\(^{xxvii}\)\(^{xxviii}\), in patients randomized to achieve an intensive A1c of 6% vs 7 + 8%; actual A1c achieved was 6.4% vs 7.5%\(^{xxv}\)\(^{xxvi}\)\(^{xxvii}\))
  - 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 Society\(^{xxv}\) 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, PharmaSatG. Public and Private Drug Plans Databases, 2000-2011

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**Growth of Blood Glucose Test Strip Users and Strips**

**Saskatchewan Drug Plan**

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<th>Calendar Year</th>
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</tr>
<tr>
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<tr>
<td>2009</td>
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**Cost of Blood Glucose Test Strips**

(Saskatchewan Drug Plan Paid)

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<th>Metric</th>
<th>2005-06</th>
<th>2006-07</th>
<th>2007-08</th>
<th>2008-09</th>
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<tr>
<td>BOTS $ (use with oral drugs)</td>
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<tr>
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<tr>
<td>BOTS $ (use with no drugs)*</td>
<td>$2,400</td>
<td>$2,450</td>
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<td>$2,550</td>
</tr>
</tbody>
</table>

*No Drugs - may include claims from beneficiaries that received non-benefit insulin or oral prescriptions which were not adjudicated through the Drug Plan system.

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**Acknowledgements:** Contributors & Reviewers: Ann Colbourne, MD, FRCPC, FACCP (Department of Medicine, U of A, Edmonton); Tessa Labuschere (CCFP, College of Medicine, U of S, Saskatoon), M Jin Pharm, CDE (Hamilton), Henry Halapy (PharmD, CDE, SMH, Toronto), Arlene Kuntz (Pharmacist, DES, CDA; Regina); Derek Jorgenson (PharmD, College of Medicine, U of S, Saskatoon), Karen McDermid (Pharmacist CDE, RQH, SK), Kristen Chelak BSc(Pharm), MSc, RPh (COMPUS, Ottawa) & the RxFiles Advisory Committee.

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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 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 fingerstick and point-of-care (POC) blood testing devices.

FDA Aug13/14 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 Nipro Diagnostics initiated a voluntary recall and replacement of a limited number of 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 result measured 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 USA 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 sold or used 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 people 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-BA006A Advacde Redi-Code+ blood glucose test strips lot 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 Jan16 Anhary 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.


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 2013: Introducing restrictions are likely to include the Ontario Diabetes Association, which works with the government to ensure that new 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 (BGTS) have a limited clinical benefit for many patients who don’t take 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 diabetes treatment. Under the new rules, patients managing diabetes with insulin will be allowed 3,000 BGTS a year, while patients managing diabetes with anti-diabetes medication with high risk of hypoglycemia will get 400 BGTS. Patients managing diabetes using anti-diabetes medication with low risk of causing hypoglycaemia and those who are managing diabetes through diet/lifestyle therapy only will be allowed 200 BGTS.

Pickup John C, Freeman Suzanne C, Sutton Alex J. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d5380 (7 July 2011)


Based on type 2 diabetes who are not using insulin is small up to six months after initiation and subsides after 12 months. Further.

References (SMBG)

Cameron C, Coyle D, Ur E, Klarenbach S. Cost-effectiveness of self-monitoring of blood glucose in patients with type 2 diabetes mellitus managed without insulin. CMAJ. 2010 Jan 12;182(1):28-34. (Summary also in DailyPOEMs: 01Apr2010; https://www.essentialevidenceplus.com/content/poem/120401


Majumdar SR. Self-monitoring of blood glucose was not cost-effective in non-insulin-treated type 2 diabetes. ACP J Club. 2008 Nov-Dec;140(4):4-5.


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


