


| Clinical Pearls | Table 1: Recommendations for Self-Monitoring Blood Glucose (SMBG) in People with Type 2 Diabetes <small>CADTH '16,'09</small> | |
|--|---|---|
| | Type 2 Diabetes | Evidence Summary for SMBG |
| <p>Clinical Pearls</p> <ul style="list-style-type: none"> • 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 ^{DC(A,1)} and T2DM. ^{DC(C,3)} • If not using insulin or secretagogues, consider if cost of SMBG (>50% expenditure for BG strips comes from these patients ^{CADTH'16}) will result in improved treatment or behavioral change. • Increasing use of flash glucose monitoring (FGM) & continuous glucose monitoring (CGM). | Diet alone or prediabetes | SMBG vs no SMBG: Improvements in glycemic control were less pronounced (↓A1c= 0.05%) and not statistically significant. |
| | Not using insulin | <ul style="list-style-type: none"> ➢ Self-testing (>7 times per week) is associated with a statistically significant, <u>but not clinically relevant</u>, improvement (↓A1c = 0.25%), ^{DC'18, Young '17} ➢ Benefits are small up to 6 mos (↓A1c = 0.3%) & subside by 12 mos. ^{Cochrane: Malanda et al '12} ➢ 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. ^{ESMON, DIGEM} |
| | Using insulin | <p>Low quality evidence suggests the use of SMBG appears to be associated with improvements in glycemic control.</p> <ul style="list-style-type: none"> ➢ 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. |
| | <p>Bottom Line Diabetes Canada Tool for SMBG</p> <p>Routine SMBG is not required. May be considered for feedback to new patients on the effects of lifestyle interventions.</p> <p>Routine SMBG is not required.</p> <ul style="list-style-type: none"> ➢ 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). <p>Basal insulin (≤2 times per day): Individualize frequency, usually not more than 14 times per week (e.g. SMBG 2x per day).</p> <p>Basal-prandial insulin: Individualize frequency to guide adjustments in insulin therapy (see Table 2).</p> | |

| Table 2: If self-monitoring blood glucose, when? ^{DC'18} There is no gold standard, reassess often. | | | Table 3: Consider More Frequent SMBG | |
|--|--|--|--|--|
| Situation | SMBG Frequency Recommendation | Test Strip & Lancet Coverage ^{SKH/NIHB} | | |
| Diet/lifestyle only | Occasional testing; 2hr post-prandial may be useful to reinforce diet changes | 200 per year (3-4/week) | <ul style="list-style-type: none"> ➢ unstable glucose levels; SMBG ≥ 2 times per day until targets are met ➢ medications with ↑ risk of hypoglycemia (e.g. insulin or insulin secretagogues) ➢ hypoglycemia unawareness due to decreased counter regulatory hormones ➢ nocturnal hypoglycemia (night sweats, nightmares): intensive insulin regimens; occasionally monitor overnight BG levels at peak action time of HS insulin ^{DC'18} <ul style="list-style-type: none"> • more info on assessment and management of hypoglycemia, see page 53 & link ➢ medication changes, major changes in diet/activity (e.g. ↑SMBG for 1-2 weeks) ➢ acute illness or hospitalization (e.g. risk of hyperglycemia with infection) ➢ prolonged exercise with ↑HR; check BG before & after exercise, monitor for sx ➢ occupation where hypoglycemia poses safety concerns (e.g. machinery, driving) ➢ SMBG when symptoms of hypoglycemia occur or have previously occurred ➢ starting medications known to cause hyperglycemia (e.g. corticosteroids, see pg 52) ➢ peri-pregnancy and gestational diabetes: see RxFiles Peri-Pregnancy Chart pg 173 ➢ newly diagnosed (<6 mos): SMBG ≥ 1 time per day (at different times of day) to learn the effects of meals, exercise and medications ^{DC'18} | |
| Non-insulin pharmacotherapy | <p>If achieving targets or using medications not associated with hypoglycemia: ^{DC(Consensus)}</p> <ul style="list-style-type: none"> • Infrequent SMBG is appropriate <p>If glycemic control not achieved: ^{DC(B,2)}</p> <ul style="list-style-type: none"> • Consider testing at staggering times (e.g. periodic pre- & 2hr post-prandial) | Hypoglycemia risk: ↑ risk = 400 per year; ↓ risk = 200 per year | | |
| Insulin | Basal (typically given HS) | <p>At least as often as insulin is being given. T2DM: daily at variable times. ^{DC(D,Consensus)}</p> <ul style="list-style-type: none"> • ≤14 times per week at variable times (e.g. fasting, pre- & 2hr post prandial) • Paired HS & am fasting testing: may be useful to assess basal control | | <p>SKH: 3,650 per year (10 per day)</p> <p>NIHB: 800 per 100 days (8 per day)</p> |
| | Premixed (typically ac; breakfast & supper) | <p>At least as often as insulin is being given.</p> <ul style="list-style-type: none"> • QID until targets are met, then BID (alternating times) once targets met | | <p>Cost of strips: \$50-100 per 100 strips</p>  |
| | Basal-prandial/multiple daily injections (QID) (bolus ac & basal HS) | <p>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)</p> <ul style="list-style-type: none"> • Intensive regimens: may require 6-10 tests/day (ac, pc, HS, night) | | |

| DEVICES | Accu-Chek | | Ascensia - Contour | | | | FreeStyle | | | | One-Touch | | | Dario | Dexcom |
|----------|--|---|--|--|---|---|---|--|---|---|--|---|--|--|---|
| | Aviva & Connect, Combo | Mobile | Next | Next ONE | Next EZ | Next LINK & 2.4 | Precision Neo | InsuLinx | Lite | Libre & 2 | Verio Flex | Ultra 2 | Verio Reflect | Dario | Dexcom G6 |
| FEATURES | <ul style="list-style-type: none"> • 7, 14, 30, 90 day averaging • Others: Accu-Chek Guide (App avail) <p>Ergonomic</p> <p>AST: palm, upper arm, forearm</p> <p>Connect: ✓ App & online resource</p> <p>Combo: ✓ For insulin users- calculates bolus dose. No AST.</p> | <ul style="list-style-type: none"> • No strip handling (50 tests on a strip) • Integrated lancing device (preloaded) • Acoustic mode for visually impaired • AST: thumb, palm, upper arm, calf, thigh | <ul style="list-style-type: none"> • Large buttons & simple language messages • 14-language options • AST: palm | <ul style="list-style-type: none"> • Contour Diabetes App: trends, reminders, log diet & meds, share results • AST: palm | <ul style="list-style-type: none"> • Large display • Easy to use tech-savvy but messages are in symbols/code • AST: none | <ul style="list-style-type: none"> • For use with Medtronic MiniMed Veo insulin pump • Link 2.4: ✓ Send bolus dose to insulin pump • AST: palm | <ul style="list-style-type: none"> • Suggests insulin dose • E-ink screen • Measures BG and ketones • Slim/ultra-light weight • No AST | <ul style="list-style-type: none"> • For insulin users; touch screen • Calculates bolus insulin dose with calculator set up by HCP • No AST | <ul style="list-style-type: none"> • Small, portable • AST: palm, upper arm • Freedom Lite: larger display | <ul style="list-style-type: none"> • Flash BG and ketone monitor • LibreLink App: sensor readings under of clothes (no lancets) • Sensor on for up to 14 days, water resistant | <ul style="list-style-type: none"> • Good option for tech-savvy • All info on one screen • Flex: ✓ Bluetooth, OneTouch Reveal App | <ul style="list-style-type: none"> • Easy to use • Results are linked to meals: shows link between food and results • AST: palm, forearm | <ul style="list-style-type: none"> • Reveal App: graphs, log diet & insulin, share results • Blood Sugar Mentor: analyzes info and provides guidance | <ul style="list-style-type: none"> • All-in-one: integrated lancing device, 25 strip cartridge • No battery, plugs into smart phone • Connects to smart phones: Dario App | <p>CGM</p> <p>Dexcom App: continuous data/sensor readings (no scanner)</p> <ul style="list-style-type: none"> • Sensor on for up to 10 days • Real-time low & high BG alerts |

To ensure accuracy of meters: Results should be compared with lab measurements of simultaneous venous FBG (8-hour fast) at least annually and when A1c does not match glucose meter readings. ^{DC(D,Consensus)} Variability <15% acceptable.

Cost of BG meter: FREE with purchase of test strips (covered by SKH, NIHB and many 3rd party plans); **CGM/FGM** e.g. **FreeStyle Libre, Dexcom G6:** NIHB ⚡ >2-19yrs if on ≥ 3 rapid acting insulin inj/day criteria is met; SKH: <18yrs who meet criteria.

Annual cost of test strips: \$200-365 (1 test/day) to \$1300-2500 (7 tests/day); **Annual cost of sensor (Libre):** \$2400/year; **Choice:** consider patient factors and preferences (e.g. vision impairment, dexterity, AST if finger poke pain, smart phone compatibility, need for CGM); Alcohol swab for skin not required; just soap & water is adequate. Also available but not commonly used: **Oracle** talking meter.

A1c= glycosylated hemoglobin ac= before meals am= morning AST= alternate site testing BG= blood glucose CGM= continuous glucose monitoring d= day DC= Diabetes Canada DM= diabetes mellitus FBG= fasting blood glucose FGM= flash glucose monitoring HS= bedtime NIHB= non-insured health benefits program pt= patient QID= four times per day sec= seconds SKH= Saskatchewan Health SMBG= self-monitoring blood glucose SU= sulfonylurea sx= symptoms T1DM= type 1 diabetes mellitus T2DM= type 2 diabetes mellitus tx= treatment wk= week

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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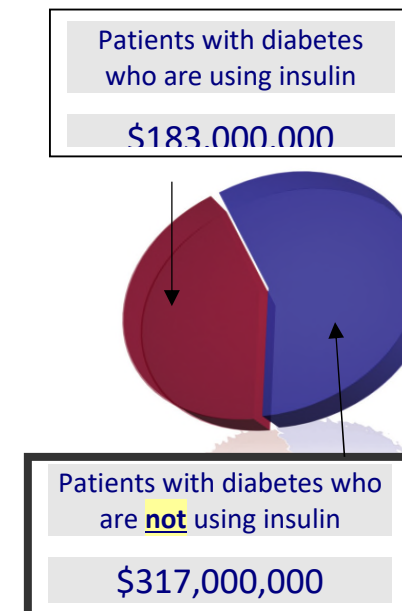
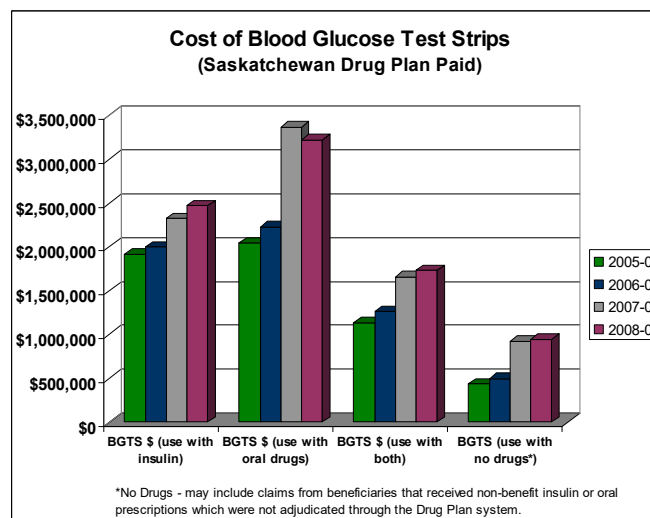
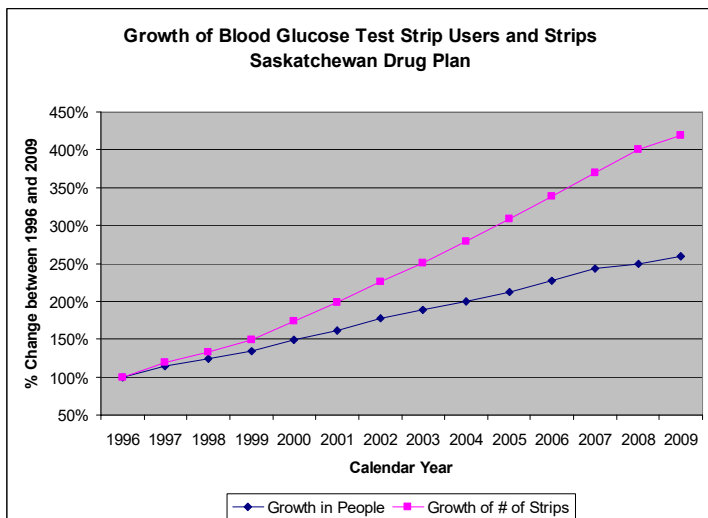
Background considerations:

- **Weighing the benefits & risks of intensive therapy:** [See also Diabetes - Landmark Outcome Trials Chartⁱ]
 - 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.ⁱⁱ {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.ⁱⁱⁱ}
 - Individualization of antihyperglycemic therapy has become a common theme^{iv,v} 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^{n=10,251} in patients randomized to achieve an intensive A1c of 6% vs 7 - 8%; actual A1c achieved was 6.4% vs 7.5%)^{vi}.
 - 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^{vii} 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.^{viii}

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]

- Cost to drug plans public+private = \$330 million 2006 ^{Canadian data}
- Cost per QALY (quality adjusted life year) is estimated at \$113,643 for routine use of SMBG (at least 1 strip each day on average).
- Annual cost per patient: \$165 - \$2,400 (see Table below).



A1c=hemoglobin A1c **ac**=before meals **Alternate Site Testing (AST)**: Most newer meters allow for testing from forearm, upper arm, palm, thigh or abdomen as well as usual fingertip, **Automatic Coding**= all meters are automatically coded unless otherwise specified **ave**=averaging **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) **Glu**= glucose **IFR**=infrared data transfer **IP**=Insulin Pump **Ket**=ketones **OAHA**=oral anti-hyperglycemic agent **RCT**=randomized controlled trial **SMBG**=self-monitor blood glucose **pc**=after meals **T2DM**=Type 2 diabetes **TS**=Touch Screen **WMD**=weighted mean difference {ReliOn Micro & ReliOn Ultima are low strip cost options but only available at Walmart in the USA (Not in Canada) }

Thanks to CADTH-COMPUS for assistance the development of this document.

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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/>

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FDA Aug/10 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 Aug/13 Nova 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 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 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. BACKGROUND: There are 501 affected TRUEbalance meters and 105 affected TRUEtrack meters that were distributed in the United States 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 health care 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 Advocate 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.

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Ontario Aug 2013: introducing limitations in funding for diabetes test strips. And these new restrictions are okay 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 (OPDP) 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 causing hypoglycemia will get 400 BGTS. Patients managing diabetes using anti-diabetes medication with low risk of causing hypoglycemia and those who are managing diabetes through diet/lifestyle therapy only will be allowed 200 BGTS.

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