SMBG Frequency & Titration Guidelines for Insulin Treated Patients

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QUESTION 1

What is the guideline and evidence for SMBG use for insulin-requiring patients?

Current ADA Recommendations

- **SMBG should be carried out 3 or more times daily for patients using multiple injections or insulin pump therapy (A)**
- **For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy and physical activity alone, SMBG may be useful as a guide to the success of therapy (E)**

Diabetes Care 32 (Suppl. 1): S14-61, 2009

MDI and CSII

- **The most common study quoted suggesting the positive impact of SMBG on outcomes?**
  - **DCCT**
    - **BUT, this study used SMBG in a comprehensive program of diabetes care (the control group was encouraged not to do <u>any</u> SMBG)**
      - **It is impossible to single out SMBG's impact on the DCCT since it was only one of many tools utilized in the DCCT intensive therapy group**

Main Use of SMBG

- Prior to insulin doses, especially prandial dosing at time of meal
- Preventing hypoglycemia
- Guide need to change carbohydrate intake

But what does “3 or more times daily” mean?

My question: Is 3 enough?

Experience From Atlanta

- **N = 378 c-peptide negative type 1 patients using CSII**

HbA1c= 5.99+5.32/tests per day+1.39

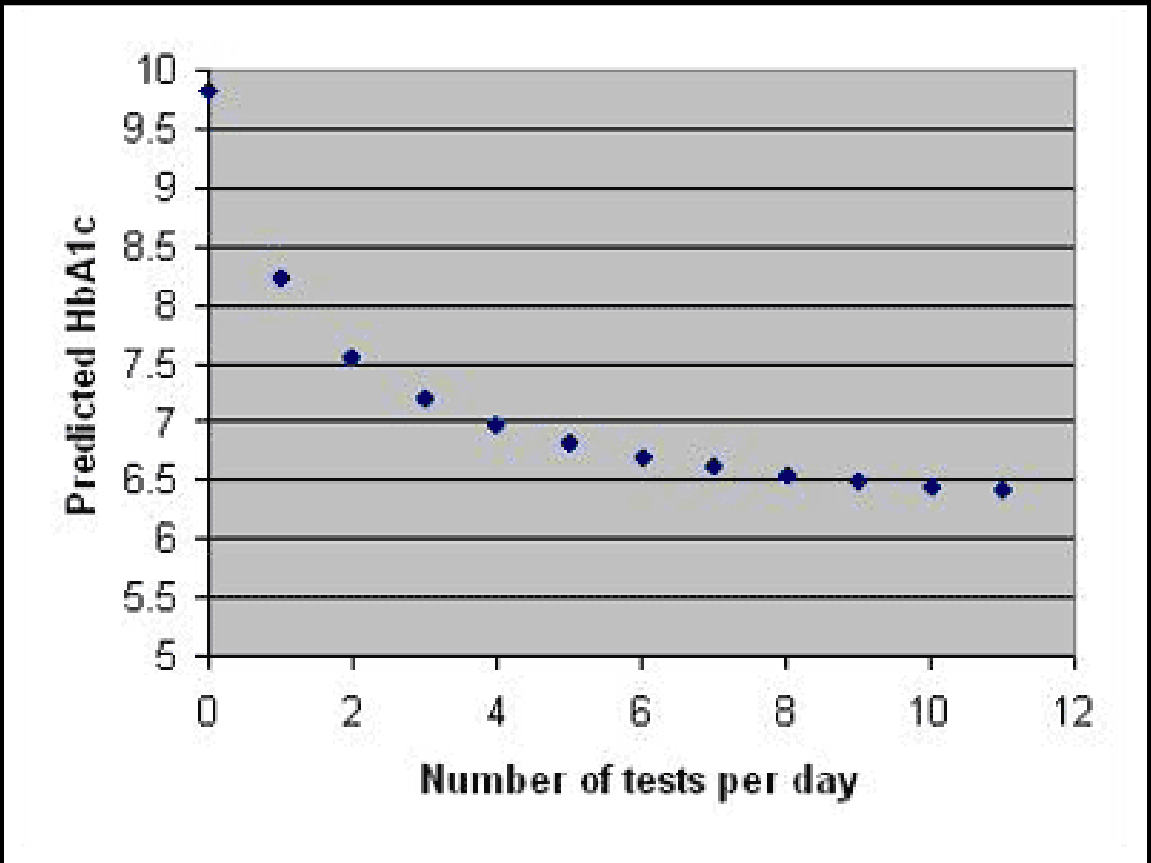
What does this mean exactly?

Diabetes. 2004;52:A101. Abstract 430-P.

Using the Formula…

TESTS/DAY	A1C
1	8.2%
2	7.6%
3	7.2%
4	7.0%
5	6.8%
6	6.7%
7	6.6%
8	6.6%
9	6.5%
10	6.5%
11	6.5%

SMBG: Little Benefit with > 8 Tests/Day?



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Limitations of These Data

- **Single Center Assessment**
- **Retrospective**
- **Risk of severe hypoglycemia based on A1C and frequency SMBG?**
- **Cannot extrapolate any data (frequency of SMBG as it relates to A1C or hypoglycemia) with CGM**

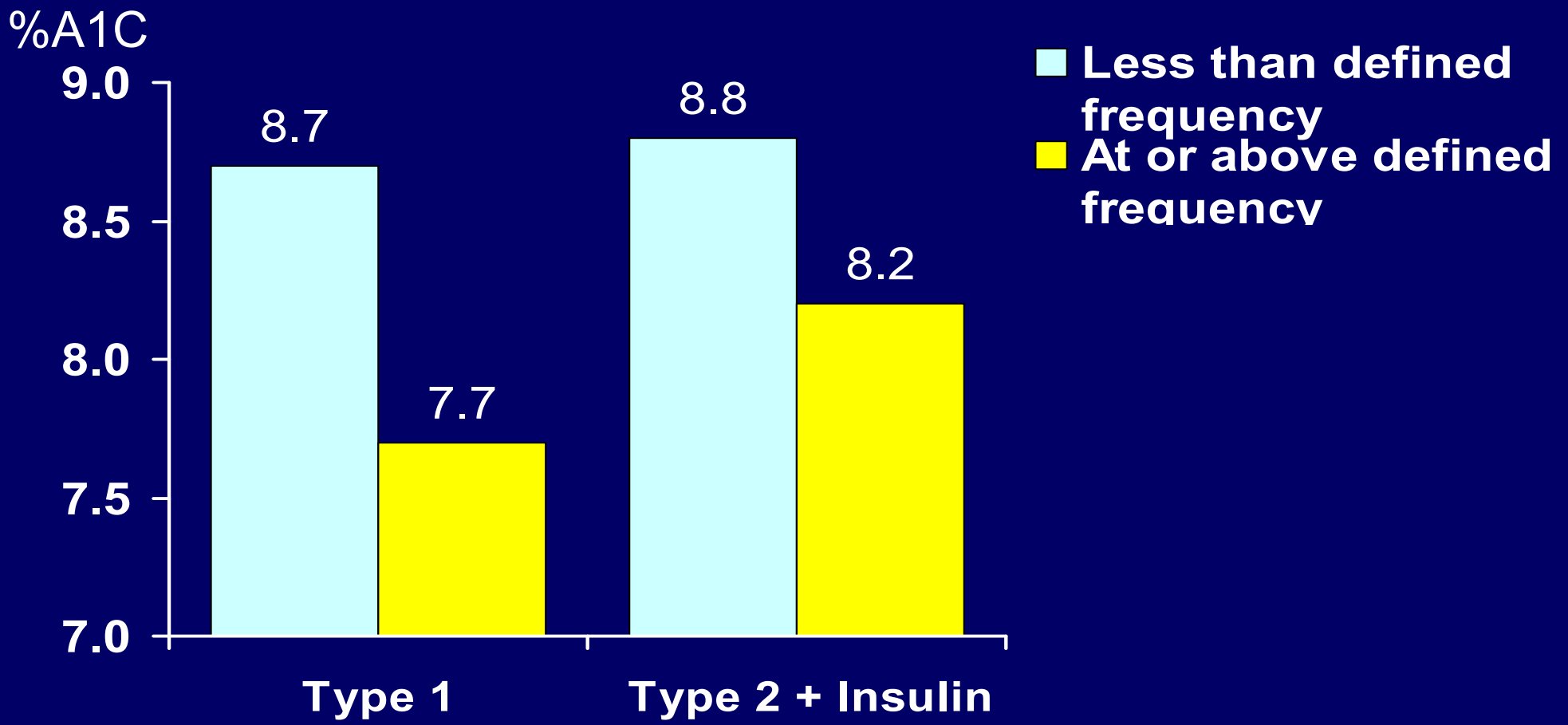
Association Between SMBG Frequency and Glycemic Control

- Large cohort study (N=24,312) of the Northern California Kaiser Permanente Diabetes Registry
- Compared A1C in patients testing at or above a defined SMBG frequency vs below the defined frequency

	Defined frequency
Type 1	≥3 times daily
Type 2 + insulin	Daily

Karter AJ et al. *Am J Med*. 2001;111:1-9.

SMBG Testing At or Above Defined Frequencies Associated With Better Glycemic Control



Karter AJ et al. *Am J Med*. 2001;111:1-9

What About Insulin-Rx'ed T2DM?

- N=201 insulin-Rx'ed T2DM, baseline A1C 8.1%
- Asked 4X/day SMBG X 8 weeks
- Baseline A1C decreased by 0.36% at 8 weeks
- At 52 weeks, A1C continued reduced for those with baseline A1C > 8% or those with > 75% testing compliance
- "SMBG provided a strong stimulus for improved self-care resulting in clinically important and sustained reductions in A1C."

Diabetes Care 26:1759, 2003

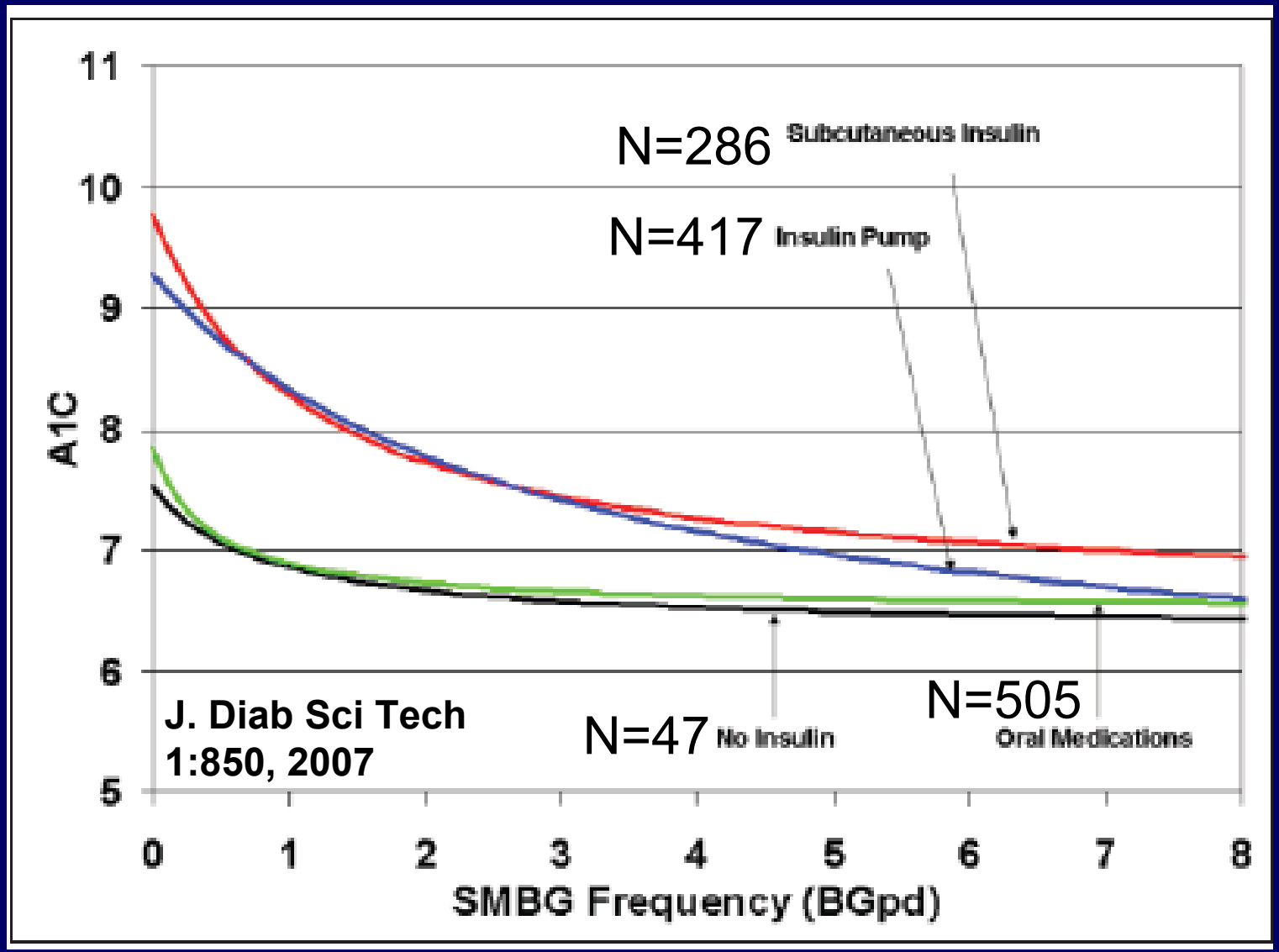
What About T1DM and Insulin-Rx'ed T2DM in Scotland?

- Early observational study (1993) in Tayside, Scotland
- T1DM (N=258): range A1C 4.2-17.4% (mean/median not provided)
  - Frequency of SMBG related to A1C reduction-for every 180 strips there was a decrease in A1C by 0.7%
- T2DM receiving insulin (N=290): range A1C 4.2 to 14.3%
  - NO relationship between frequency of SMBG and A1C

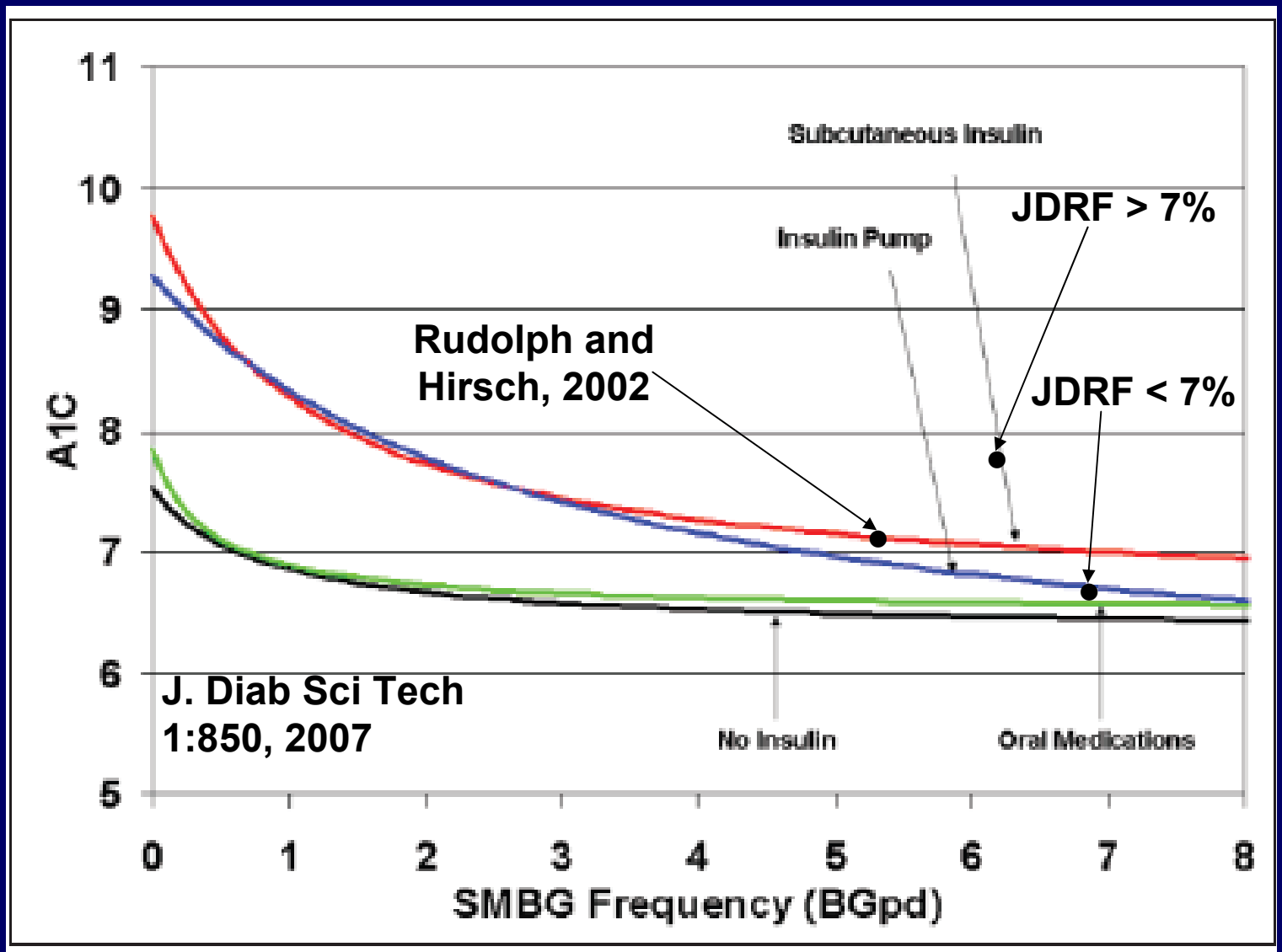
SMBG Frequency: Observations

- **Rudolph JW and Hirsch IB:**
  - **5.5 tests/day MDI to CSII, A1C 7.1% (N=107, T1DM) Endo Pract 8:401, 2002**
- **JDRF CGM Research Group:**
  - **5.6-7.0 tests/day A1C 7.6-8.0% (85% CSII, N = 322, T1DM) NEJM 359:1464, 2008**
  - **6.8 to 7.3 tests/day, A1C 6.4-6.5%, (86% CSII, N = 129, T1DM) Diabetes Care, in press**

A1C vs. SMBG in Atlanta, GA



A1C vs. SMBG in Atlanta, GA



Important Points About These Trials

- **These are all observations and are not really even observational trials since SMBG per se was not studied**
  - **These are type 1 trials with different study outcomes and SMBG is simply a reported descriptor of the population! (not true for the Atlanta trial)**
- **These types of trials do not meet the basic criteria needed for our current "evidenced-based medicine" culture**

Bottom Line

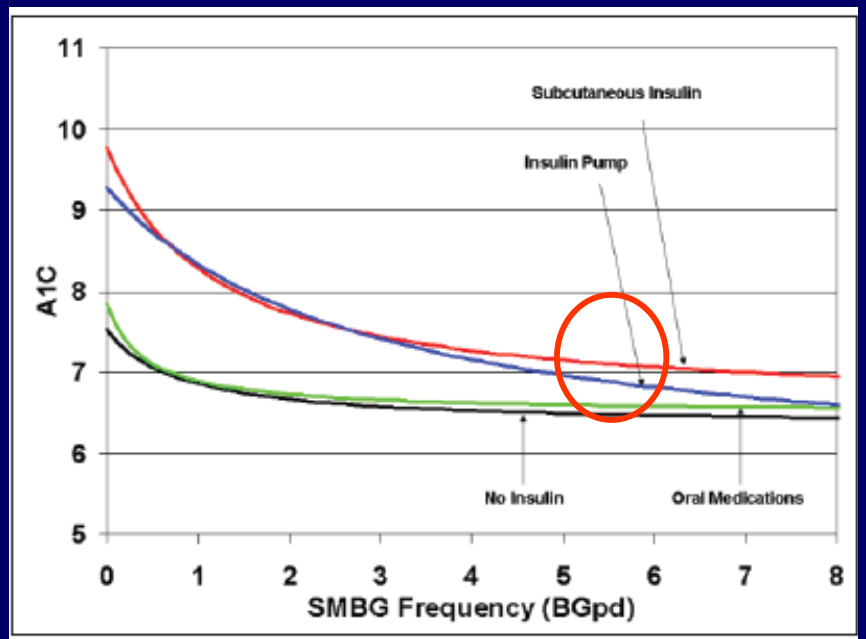
The actual evidence for desired frequency of SMBG in insulin-treated patients is limited!

Thinking About This Another Way…

- SMBG frequency for ***insulin-requiring*** patients needs to be individualized based on
  - Type 1 DM
    - With or without CGM
    - History of severe hypoglycemia
  - Type 2 DM
    - Basal-bolus therapy (including CSII) vs. pre-mix vs. “basal plus” vs. basal alone
    - History of severe hypoglycemia

SMBG: T1DM

- Without CGM (assuming target A1C < 7%)
  - Most patients require *a minimum* of 5 to 6 daily, meaning once or twice between meals to "fine-tune". If history (especially recent) of severe hypoglycemia, more are required



Even though this is just my opinion, at least it loosely agrees with the Atlanta group's data

SMBG: T1DM

- USING CGM
  - Theoretically, shouldn't have an impact but we know that isn't the case
  - N = 33 consecutive CGM patients June 22 to July 10
    - 61% CSII, 9% in JDRF trial
    - Mean duration on CGM 14.4 ± 9.4 months
    - Mean A1c initial: 7.3 ± 0.99%
    - Mean A1C final: 6.8 ± 0.87%
    - Mean SMBG frequency before CGM: 6.1 ± 1.5/d
    - Mean SMBG frequency after CGM: 5.0 ± 1.1/d

SMBG: Insulin-Requiring T2DM

- Even less data-much more heterogeneous group!
- For MDI (or CSII) patients, I still ask for before-meal and HS measurements
  - If problems with hypoglycemia or not near A1C target, between meal testing can be extremely helpful
  - Major problem:

Medicare Headaches!

Steve and Ingrid Edelman

SMBG: Insulin-Requiring T2DM

- Insulin-requiring T2DM
  - Pre-mix: need to individualize. At the very least, prefer 2-3/day before meals or at bedtime. If not at target needs more
  - Basal insulin alone: key tests are fasting at bedtime numbers. If not at target most frequent problem is high bedtime number. Measuring fasting BG alone in this population is the most common mistake make with insulin therapy

SMBG: Why Even More Attention in 2009?

Brand A	$1.04/strip*
Brand B	$1.04/strip
Brand C	$0.62/strip
Brand D	$1.12/strip
Brand E	$1.07/strip
Brand F	$1.04/strip
Brand G	$0.44/strip**

- Accessed June 21, 2009 at drugstore.com

** Accessed June 21, 2009 at Amazon.com

Summary

- Data for ideal frequency of SMBG in insulin-requiring patients are lacking
- The correct frequency needs to be individualized based on diabetes-type, A1C target, frequency, risk of severe hypoglycemia, and cost
- As CGM accuracy improves, frequency of SMBG use, especially in T1DM may decrease


THANK YOU