Structured Self-Monitoring of Blood Glucose (SMBG)

***What's the Point?* -**

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Disclosures

- I have no relevant financial relationships with the manufacturers(s) of any commercial products(s) and/or provider of commercial services discussed in this CME activity.
- I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Is SBGM even useful or effective in management of T2DM?

- There is uncertainty in the literature as to whether SMBG use is efficacious in insulin-naïve type 2 diabetic patients.
- Current evidence in this population is mixed:
  - some studies pointing to significant glycemic benefits resulting from SMBG use
  - others have shown no significant benefits
- Given the growing cost of current type 2 diabetic care, it is important to determine whether resources devoted to SMBG in the insulin-naïve population are justified and are *effectively applied*.

The MONITOR Trial

July 2017

- **Glucose Self-monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings: A Randomized Trial**
- Laura A. Young, MD, PhD1,2; John B. Buse, MD, PhD1; Mark A. Weaver, PhD3; et al Maihan B. Vu, DrPH, MPH4; C. Madeline Mitchell, MURP2; Tamara Blakeney, BS2; Kimberlea Grimm, BAS2; Jennifer Rees, RN, CPF2; Franklin Niblock, BS5; Katrina E. Donahue, MD, MPH2,6; for the Monitor Trial Group
- JAMA Intern Med. 2017;177(7):920-929. doi:10.1001/jamainternmed.2017.1233

The MONITOR Trial – Key Points

- Question: Is [**routine, daily] self-monitoring blood glucose levels** effective for people with **non–insulin-treated type 2 diabetes** in terms of improving either hemoglobin A1c levels or health-related quality of life (HRQOL) in primary care practice?

- Findings: In this pragmatic randomized clinical trial that included 450 patients randomized to 1 of 3 groups:
  - no self-monitoring of blood glucose (SMBG)
  - once-daily SMBG
  - once-daily SMBG with enhanced patient feedback.

  There were no significant differences in glycemic control across all groups, nor were there significant differences found in HRQOL.

- Meaning: *Routine* self-monitoring of blood glucose levels does not significantly improve hemoglobin A1c levels or HRQOL for most patients with non–insulin-treated type 2 diabetes; patients and clinicians should consider the specifics of each clinical situation as they decide

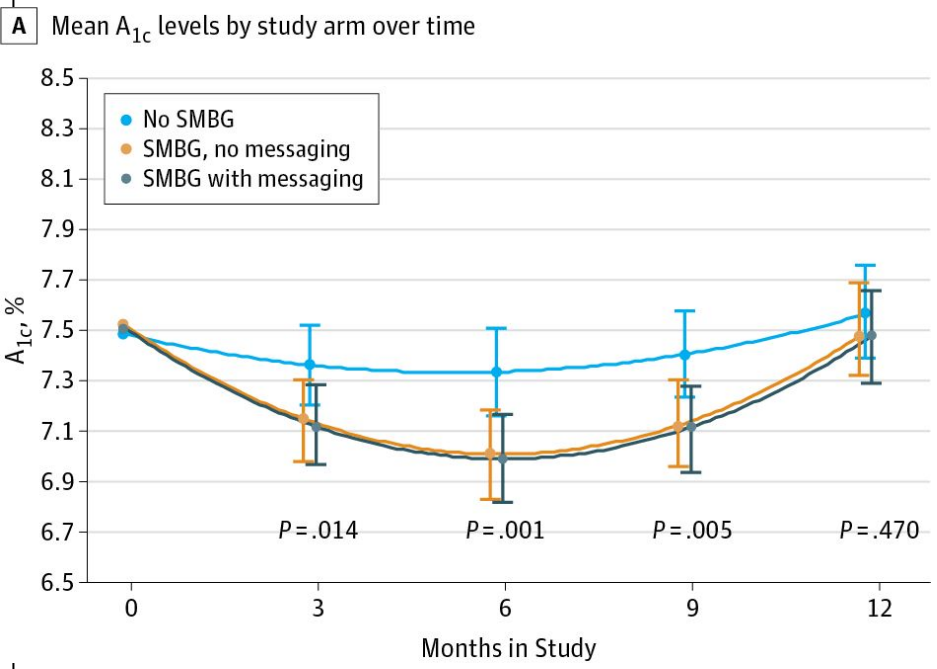
Table 2. Summary of Primary Outcomes by Randomization Group

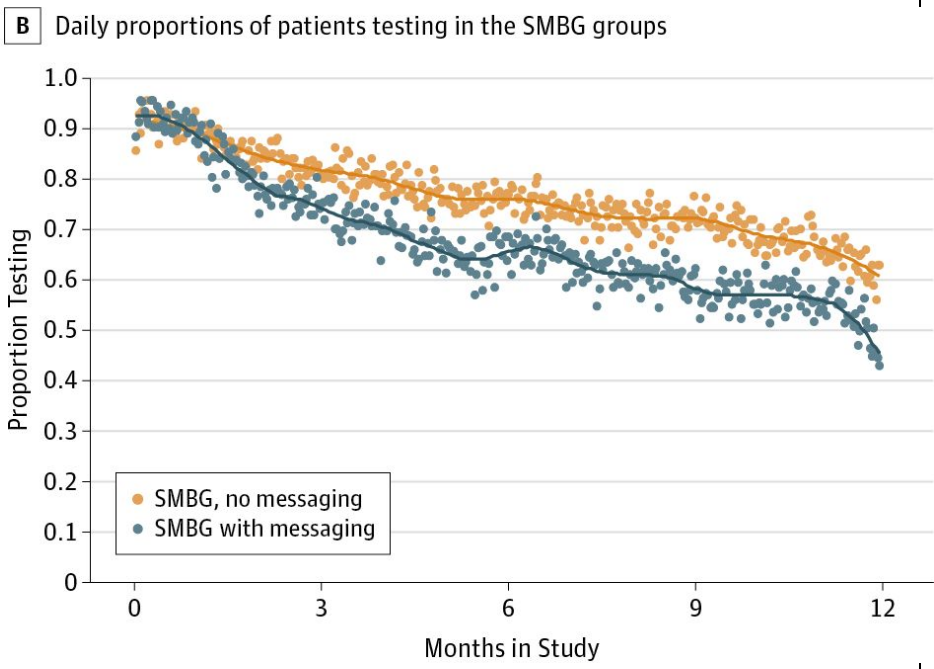
Variable	Randomization Group					
	No SMBG		SMBG, No Messaging		SMBG With Messaging	
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)
Hemoglobin A_{1c}, %[c]						
Baseline	152	7.52 (1.12) (58.70 [12.24] mmol/mol)	150	7.55 (1.10) (59.06 [12.07] mmol/mol)	148	7.61 (0.97) (59.65 [10.64] mmol/mol)
Follow-up	147	7.55 (1.24) (59.01 [13.56] mmol/mol)	141	7.49 (1.12) (58.41 [12.23] mmol/mol)	139	7.51 (1.13) (58.55 [12.34] mmol/mol)
Change	147	0.04 (1.12) (0.41 [12.27] mmol/mol)	141	−0.05 (1.00) (−0.57 [10.89] mmol/mol)	139	−0.10 (1.14) (−1.04 [12.42] mmol/mol)
Health-Related Quality of Life, SF-36						
Physical score						
Baseline	152	48.72 (8.00)	150	47.27 (8.40)	148	46.22 (10.13)
Follow-up	143	48.47 (7.21)	142	47.42 (9.03)	135	46.44 (9.68)
Change	143	−0.43 (6.86)	142	0.07 (6.77)	135	−0.35 (6.95)
Mental score						
Baseline	152	53.52 (9.29)	150	52.94 (8.77)	148	53.43 (9.58)
Follow-up	143	53.39 (10.55)	142	52.04 (9.57)	135	52.57 (10.39)
Change	143	−0.94 (7.46)	142	−0.71 (7.72)	135	−1.39 (6.85)

The MONITOR Trial - Considerations

- Based on these findings, patients and clinicians should ***engage in dialogue regarding SMBG*** with the ***current evidence suggesting that SMBG should not be*** **routine** ***for most patients with non–insulin-treated T2DM.***
- [This] study was not powered to determine effectiveness in certain clinical situations, such *as initiation of new medication or medication dose changes*. Patients and clinicians should ***consider each situation as they determine whether to test or not to test.***
- In addition, *compliance with testing showed progressive attrition* in both SMBG monitoring groups.
  - This *may explain the statistically significant improvements in hemoglobin A1c levels initially seen between the testing and non-testing arms in the early months, but no*

MONITOR Trial – quarterly data





Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study.

Polonsky WH et al. Diabetes Care. 2011 Feb;34(2):262-7.

OBJECTIVE: To assess the effectiveness of structured blood glucose testing in poorly controlled, **noninsulin-treated type 2 diabetes**.

RESEARCH DESIGN AND METHODS: 12-month randomized study - 483 poorly controlled (A1C ≥ 7.5%), insulin-naïve type 2 diabetic subjects - randomized to

- an active control group (ACG) with enhanced usual care or
- a structured testing group (STG) with enhanced usual care and at least quarterly use of structured self-monitoring of blood glucose (SMBG).

RESULTS:

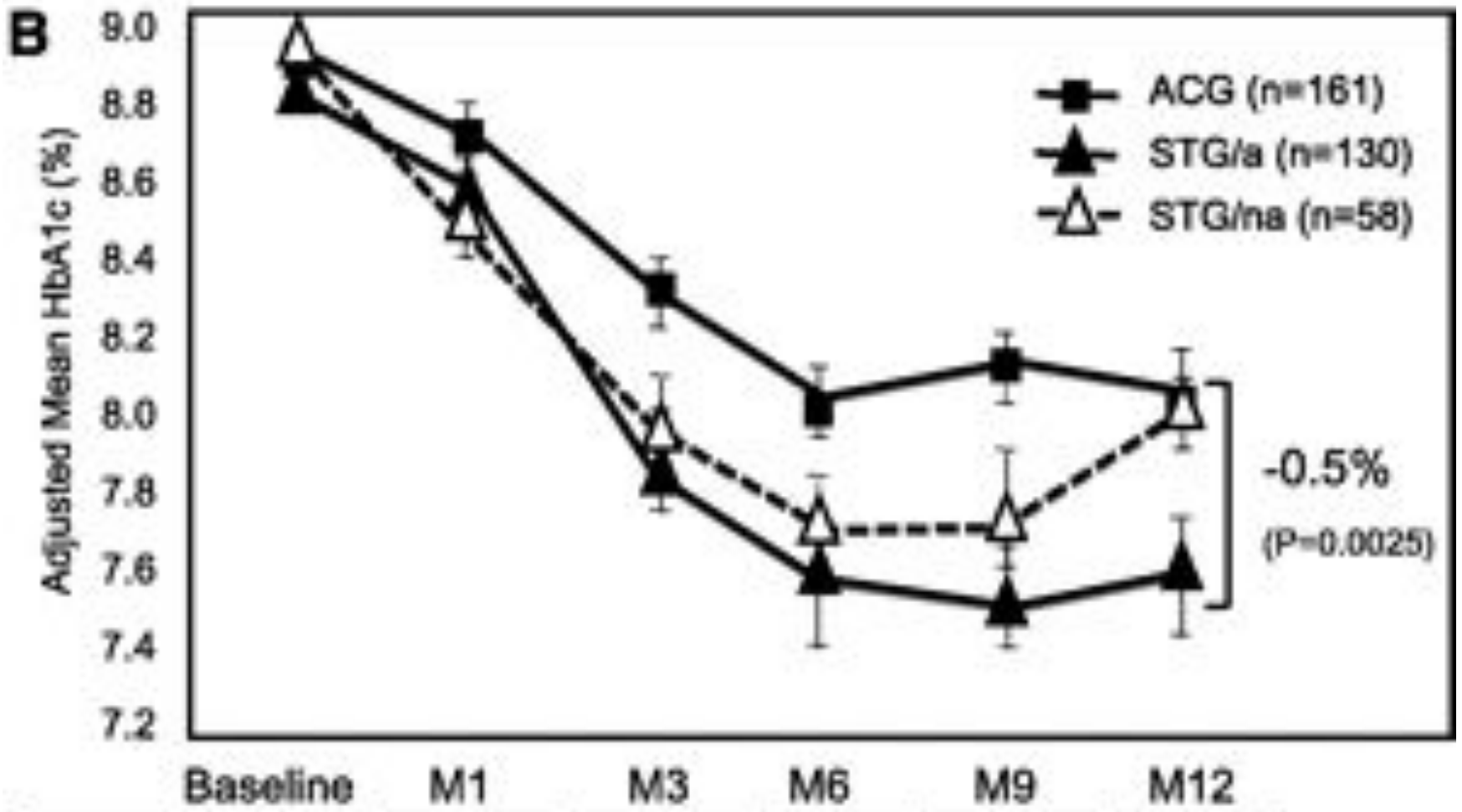
- significantly greater reductions in mean A1C in the STG compared with the ACG: -1.2% (0.09) vs. -0.9% (0.10); Δ = -0.3%; P = 0.04.
- Per protocol analysis showed even greater mean A1C reductions in the STG compared with the ACG: -1.3% (0.11) vs. -0.8% (0.11); Δ = -0.5%; P < 0.003.
- Significantly more STG patients received a treatment change recommendation at the month 1 visit compared with ACG patients, regardless of the patient's initial baseline A1C level;

Structured Self-Monitoring of Blood Glucose Significantly Reduces A1C Levels in Poorly Controlled, Noninsulin-Treated Type 2 Diabetes

Results from the Structured Testing Program study

William H. Polonsky, PHD, et al Diabetes Care 2011 Feb; 34(2): 262-267

- Our findings demonstrate ***that appropriate use of [structured] SMBG in poorly controlled, insulin-naïve type 2 diabetic patients can be efficacious and clinically meaningful.***
  - STG patients – used **7-point SMBG profile** (fasting, preprandial/2-h postprandial at each meal, bedtime) on **3 consecutive days prior to each scheduled study visit**
  - ACG subjects - instructed to use their meter following their physicians' recommendations but received no additional SMBG prompting, training, or instruction.


B
Adjusted Mean HbA1c (%)
9.0
8.8
8.6
8.4
8.2
8.0
7.8
7.6
7.4
7.2
Baseline
M1
M3
M6
M9
M12
ACG (n=161)
STG/a (n=130)
STG/na (n=58)
-0.5%
(P=0.0025)

International Diabetes Federation guidelines:

- Recommend that **structured SMBG** be performed initially and periodically in order to obtain glucose information from BG profiles that are representative of ***daily glucose excursions***.
- Emphasize the need for strong ***collaboration between patients and their healthcare team*** in **reviewing, interpreting, and appropriately acting upon the data** obtained through ***structured*** **SMBG .**
  - Prior studies have demonstrated SMBG to ***be beneficial when patients receive feedback*** regarding the impact of their behaviors on SMBG results.

IHS Best Practices -Recommendations for Self-Monitoring of Blood Glucose

- ***All insulin-treated patients should perform SMBG.*** If on multiple daily injections or an insulin pump, SMBG should be performed ≥ 3 times/day.
- The decision as to whether and how often to prescribe ***SMBG in non-insulin treated patients should be individualized.*** Providers are encouraged to ***consider SMBG when needed***, such as when medication therapy is initiated or changed, in patients with any indication that their diabetes control is not stable (e.g., recent history of hypoglycemia), or in medically complex patients on multiple glucose-lowering medications.
- People with diabetes perform ***SMBG as a tool to help improve glycemic control***.
  - Since SMBG is expensive and can be burdensome for patients, research has been conducted to see if its effectiveness is worth its cost and inconvenience.

IHS Best Practices -Recommendations for Self-Monitoring of Blood Glucose

- ***Prescribe*** the SMBG schedule ***so as to collect the information needed*** to adjust a patient's meal plan and medications, particularly insulin (e.g., check pre-supper values to see if the morning NPH insulin dose needs to be adjusted).
- ***Instruct*** patients clearly as to ***when and how often*** to check their blood glucose, and **what to do with the results.**
- ***Review SMBG data and A1C results with the patient at each diabetes visit, and take them into consideration when making therapeutic management decisions.***
- Patients need ***hands-on instruction*** in how to use their glucose meter, including quality control. Training is more effective when ***patients are asked to demonstrate*** the correct procedure for checking blood glucose at the time of initial SMBG training

Ideas for Utilizing Structured SMBG

- **Paired glucose testing**
  - Before and after exercise
  - Before and after meals – staggered Paired glucose testing
    - Target peak glucose values < 180 mg/dl (ADA) (<220-250 depending on risk)
    - Rise of 50 or less from Pre-prandial
    - Favorite food – see if can eat smaller amount without BG going too high
  - Before and after stressful event (job stress) or stress reduction activity
- **7-point glucose profile**
  - Collect for 2-3 days before appointment
  - Before and after new medication or adjustment in dosage

Examples of Structured SBGM

7-Point Glucose Profile

	Pre-Breakfast	Post-Breakfast	Pre-Lunch	Post-Lunch	Pre-Supper	Post-Supper	Bedtime
Monday	X	X	X	X	X	X	X
Tuesday	X	X	X	X	X	X	X
Wednesday	X	X	X	X	X	X	X
Thursday	X	X	X	X	X	X	X
Friday	X	X	X	X	X	X	X
Saturday	X	X	X	X	X	X	X
Sunday	X	X	X	X	X	X	X

Staggered SMBG Regimen

	Pre-Breakfast	Post-Breakfast	Pre-Lunch	Post-Lunch	Pre-Supper	Post-Supper	Bedtime
Monday	X	X					
Tuesday			X	X			
Wednesday					X	X	
Thursday	X	X					
Friday			X	X			
Saturday					X	X	
Sunday	X	X					

Sometimes 2-3 AM BG instead especially if evening meal is later

Use glucose log sheet or meter download

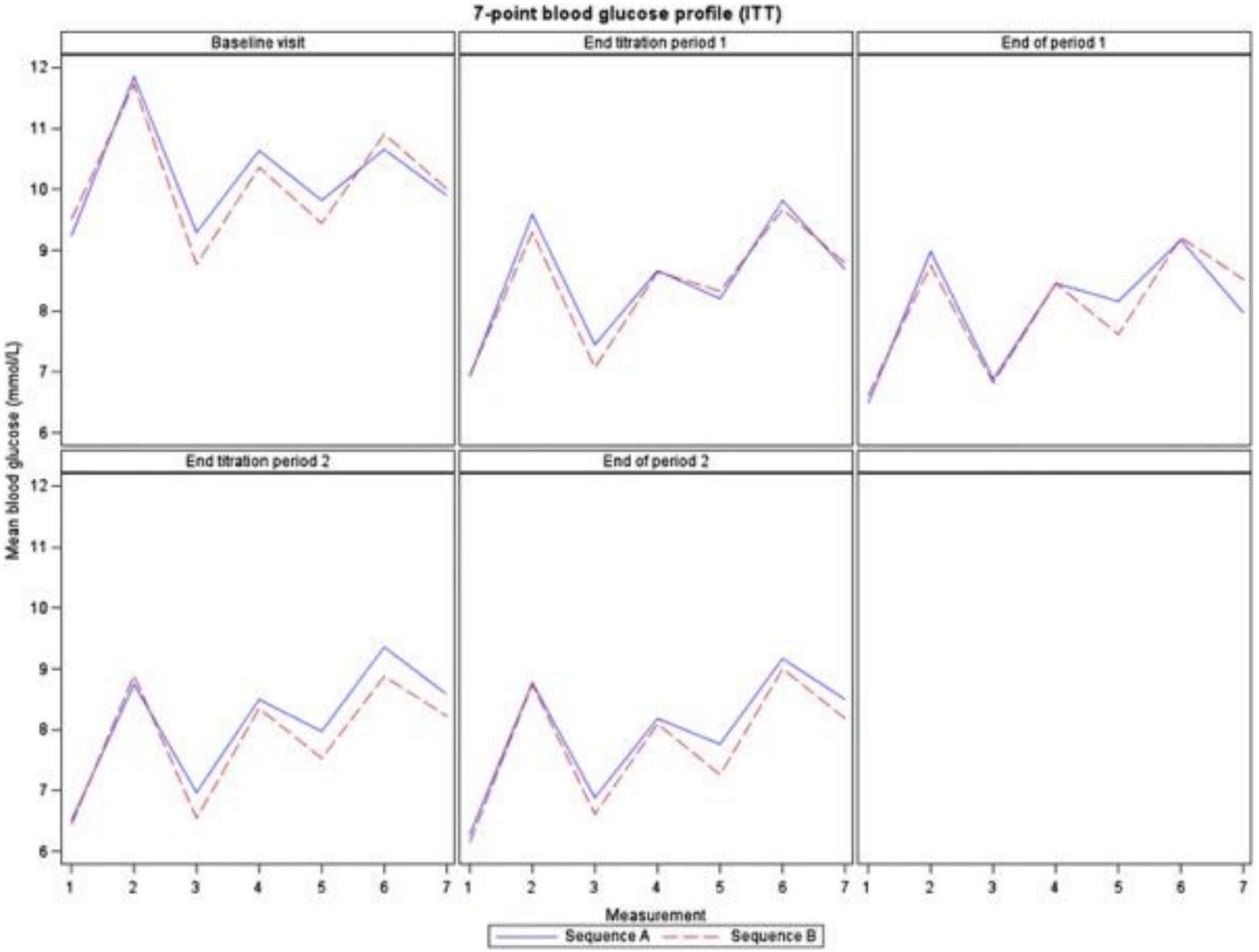
DATE	Fasting or Pre - Breakfast	2hrs Post - Breakfast	Pre - Lunch	2 hrs Post - Lunch	Pre - Dinner	2hrs Post - Dinner	3.00 AM	Comments

- Not an every day expectation
- Do for 2-3 days before appointment [or after appointment

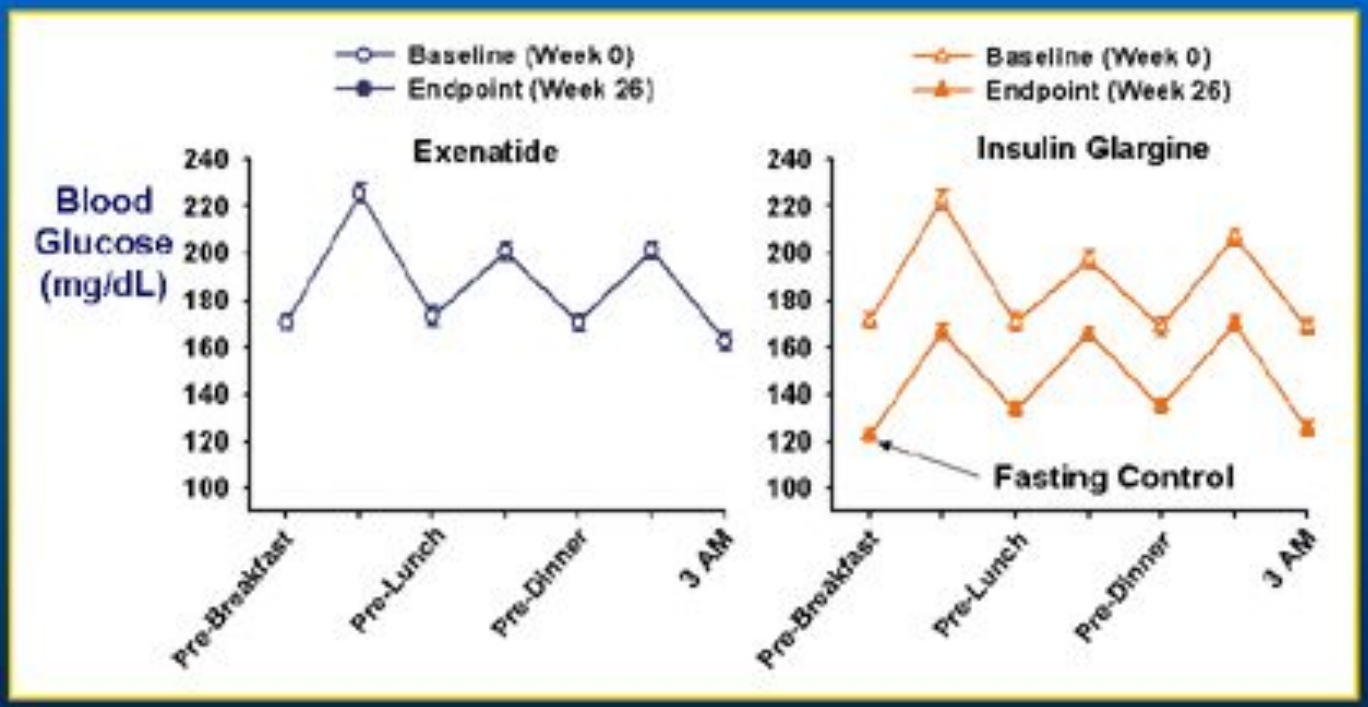
with A1c showing not at desired target (or concerns about excursions/variability)]

- Repeat x 2-3 days after Rx change

(for years this method was used in major trials on diabetes medication efficacy)

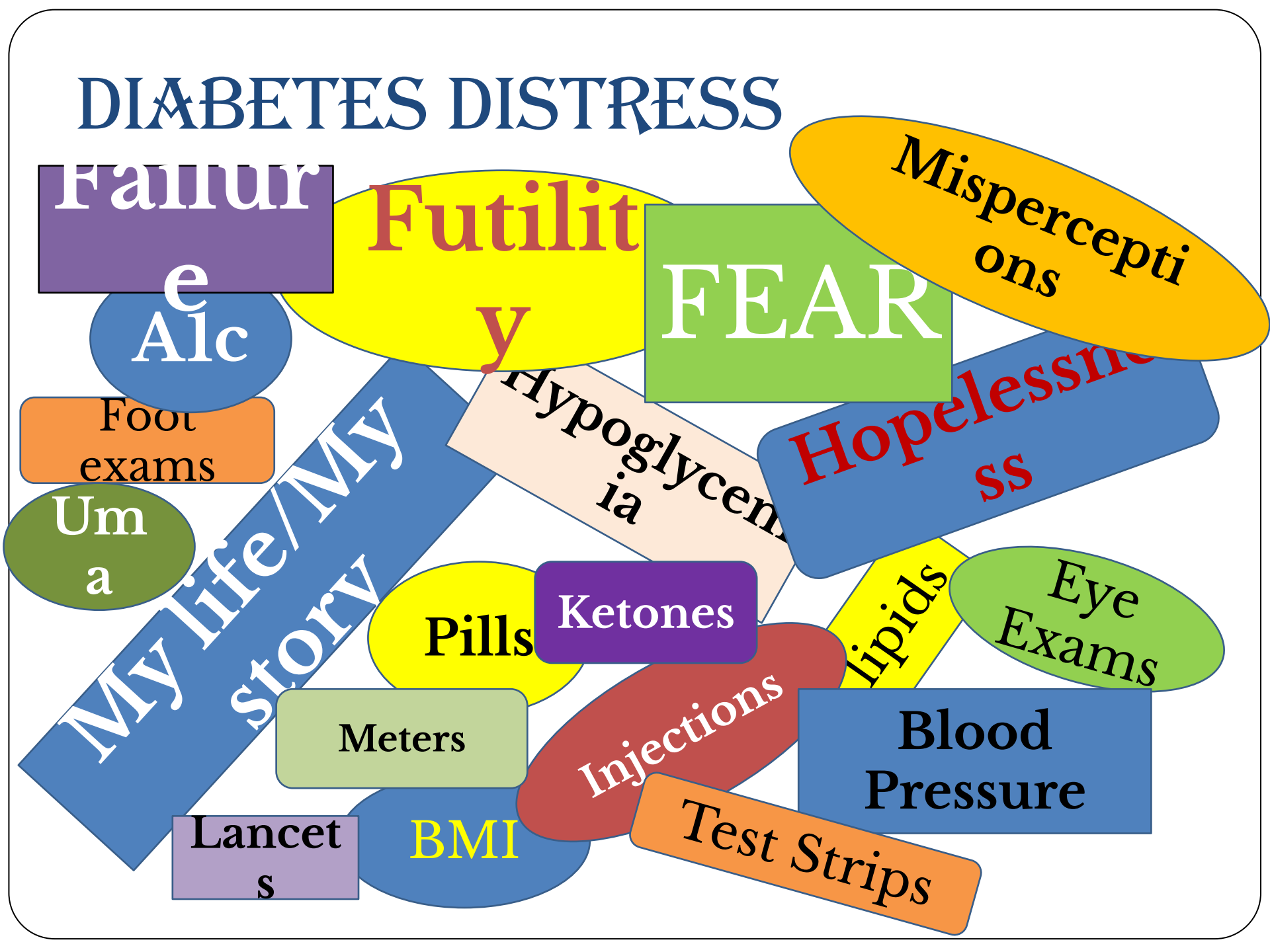

7-point blood glucose profile (ITT)
Baseline visit
End titration period 1
End of period 1
End titration period 2
End of period 2
Mean blood glucose (mmol/L)
12
11
10
9
8
7
6
1
2
3
4
5
6
7
Measurement
Sequence A
Sequence B

7-Point Self-Monitored Blood Glucose Profiles



ITT sample shown
Mean ± SE shown

Heine et al. Presented at the ADA Scientific Sessions, 2005.


DIABETES DISTRESS
Failure
Futility
FEAR
Misperceptions
Alc
Foot exams
Hypoglycemia
Hopelessness
Uma
My life/My story
Pills
Ketones
lipids
Eye Exams
Meters
Injections
Blood Pressure
Lancets
BMI
Test Strips

Need to Provide: (WHP)

- **Evidence-Based HOPE**
  - *"With good care, odds are pretty good you can live a long and healthy life with diabetes"*

- **Tangible Sense that their efforts make a difference**
  - Establish *Treatment Efficacy*
    - ***Discovery Learning*** *(paired or structured BG testing)*

  (helps with Ownership vs Buy-in)

Need to Provide a Tangible sense that their efforts make a difference (discovery learning):

- **7-point Blood Glucose Profile or Paired Glucose Testing**
  - **Before and After exercise**
    - *"I just want you to test to see if it makes any difference"*
  - **Before and After various foods**
    - *"See what happens when you eat it, maybe you can find an amount that works for you"*
  - **Watch responses after medication changes**
    - *"I need you to check to see if the new medication is working or not" (explain not every med works for every person(*Response Heterogeneity*)) (teach them to use data)*

Help them prove their case is not hopeless – care is

Summary

- Routine daily SMBG in people with T2DM not on insulin therapy did not/may not contribute to improved glycemic control as indicated in several studies
  - ***Daily*** SMBG not necessary in people not on insulin therapy (unless hypoglycemia on sulfonylureas – adjust meds/meals)
- Structured SMBG designed to provide useful, meaningful information has been shown improve glycemic control
- It is important to review and act on the SMBG data –
  - patients can learn how to act on the results
  - also needs to be part of the care planning with their diabetes team care
- Patients get weary of doing SMBG and it appears that control worsens (A1c rises) as people fade

Comparison of **Continuous Glucose Monitoring and 7-Point Blood Glucose Profile** for the Assessment of Glucose Variability in ***Type 2 Diabetics on Diet and Metformin Therapy 2009 ADA G. Freckmann***

- This study aimed to ***evaluate glucose variability in type 2 diabetic patients on diet alone and under therapy with metformin.***
  - Low and high blood glucose indices (LBGI/HBGI) were calculated from continuous glucose monitoring (CGM) profiles and 7-point self monitoring blood glucose (7pSMBG) profiles.
- **Calculation of LBGI and HBGI based on CGM or 7pSMBG** profiles yielded **nearly identical risk** category assignment.

In patients on diet alone or metformin therapy, 7-point SMBG provides similar info to CGM and