



To Test or Not to Test: The Role of Glucose Self-Monitoring in Primary Care Patients with Non-Insulin Type 2 Diabetes

Katrina Donahue, MD, MPH

Professor, UNC –Chapel Hill Department of Family Medicine

North Carolina Diabetes Advisory Council Meeting

February 9, 2018

Investigative team

- Laura Young, MD, PhD
- John Buse, MD, PhD
- Mark Weaver, PhD
- Maihan Vu, DrPH
- C. Madeline Mitchell, MURP
- Tamara Blakeney, BS
- Kimberlea Grimm, BA
- Jennifer Rees, RN, CPF
- Franklin Niblock, BS, MS4
- Katrina Donahue, MD, MPH

MONITOR trial Group

- April Reese, BSW, MPH
- Joanne Rinker, MS, RD, CDE, LD
- Jan Hutchins, RN
- Melvin Dubose, DD
- Michael Pfeifer, MD, MS
- Nellie Lewis, RN
- Paula LeClair, MBA
- Val Atkinson
- Jim Straight, BA
- Students-Kamaara Lucas, BA, Rachel Fuchs, MS, Alexa Waters, BS, Paul Alvarez, BS, Caroline Grandis, BS, Sara Kowitt, MPH
- 15 Participating Primary Care Practices and key clinicians and staff



Support

- Patient-Centered Outcomes Research Institute (PCORI) Contact Award (CE-12-11-4980). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.
- National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001111. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.



COI Disclosures

Dr. Donahue: UNC has licensed its interest in copyright works to Telcare of a glucose messaging and treatment algorithm for the purposes of commercialization.

Objectives

- Review and Interpret findings from the MONITOR SMBG trial
- Apply findings from the MONITOR trial in primary care patients with non-insulin treated type 2 diabetes



Background

- Guidelines are inconsistent regarding the role of glucose self monitoring (SMBG) in patients with non-insulin treated type 2 diabetes
- Recommendations from health care providers vary widely
- Numerous stakeholders have an interest in this debate

SMBG

(Self Monitoring of Blood Glucose)

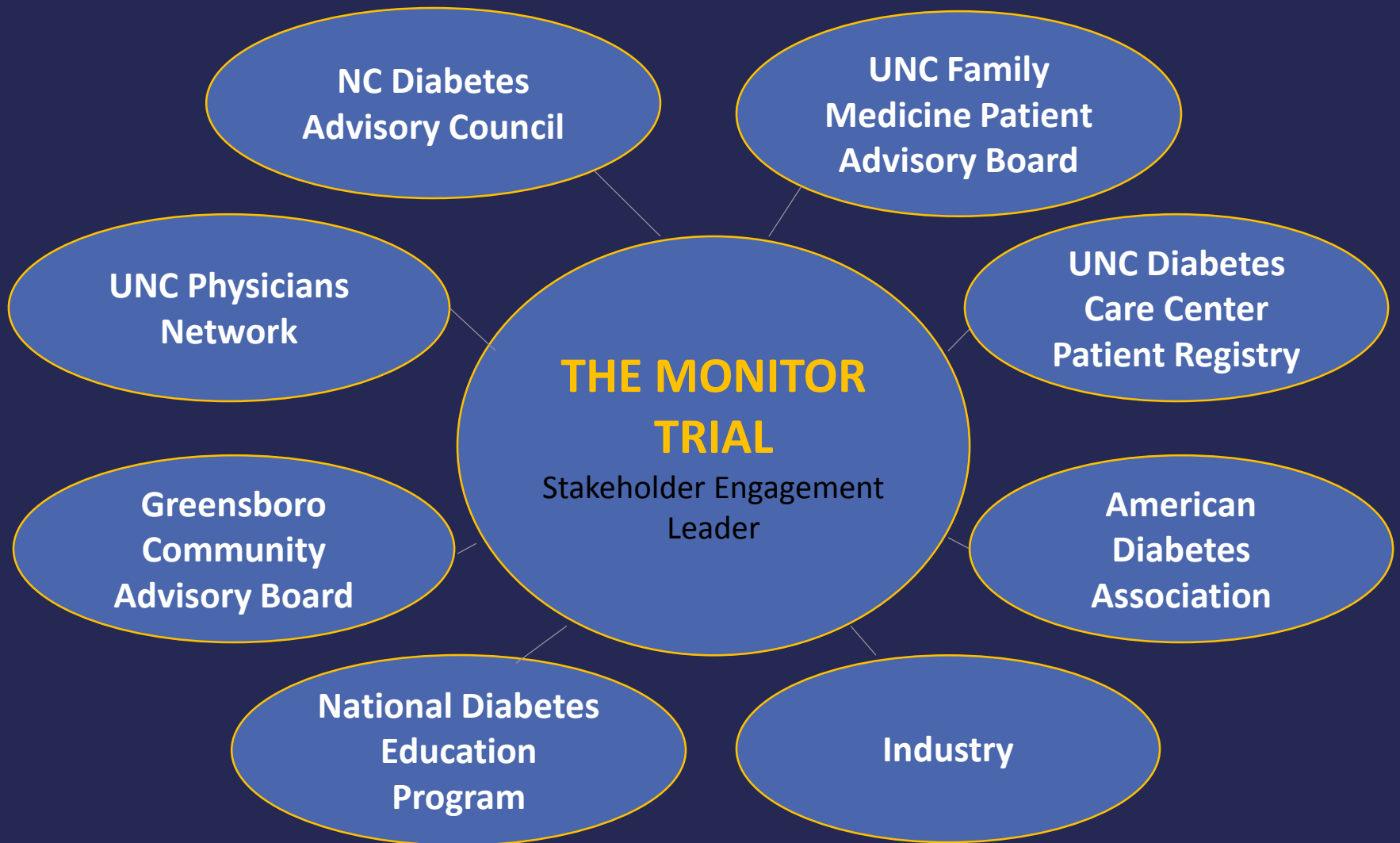
- Widely practiced in patients with diabetes
- Conducted since 1980s
- Benefits well-established in Type 1 diabetes and Type 2 diabetes on insulin



To test or not to test



Stakeholders



Project Overview

Assess impact of 3 SMBG testing approaches over 1 year

- 450 patients with non-insulin treated T2DM
- 15 primary care practice sites

Group 1: No SMBG Testing

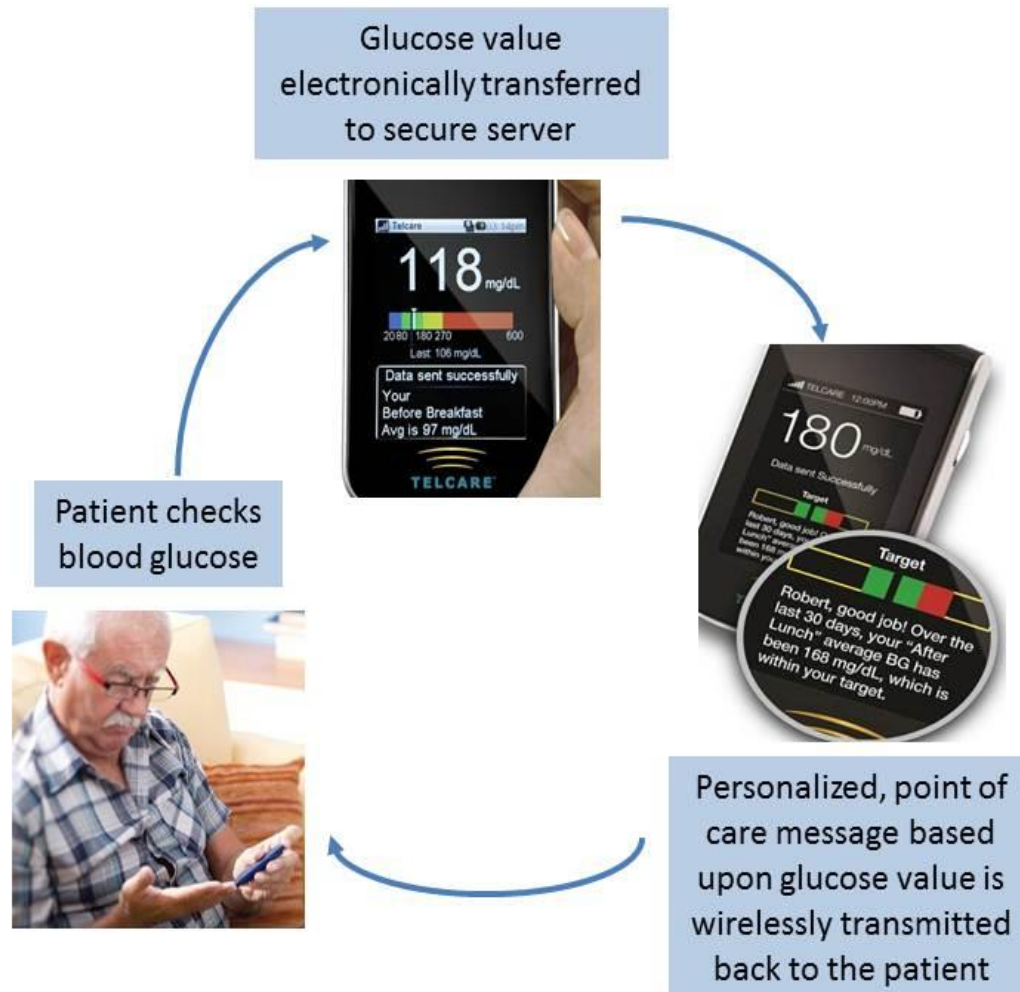
Group 2: Once daily SMBG Testing with standard patient feedback

- Glucose values reported on monitor

Group 3: Once daily SMBG Testing with enhanced patient feedback

- Glucose values reported on monitor plus a tailored feedback message delivered to the patient through the monitor

Tailored Messaging



Study Population

- Age 30 and over
- Type 2 diabetes, not on insulin
- Health provider at practice is primary provider of diabetes care
- A1c 6.5%-9.5%
- English speaking
- Non pregnant

Outcomes

Primary

- Change in A1c from baseline to 52 weeks (venipuncture)
- Health Related Quality of life (HRQOL-SF-36, Mental and Physical)

Secondary

- Diabetes Related Quality of Life (DSC-R, PAID, DES-SF)
- Diabetes Self-Care (SDSCA)
- Diabetes Treatment Satisfaction (DTS)
- Patient-Provider Communication (CAT)
- Health Care Utilization (Inpatient, Outpatient and ED visits via EMR and self-report)
- Treatment Modification (change in DM meds)
- Hypoglycemia frequency (self report, EHR)

Analysis

- Change in A1c levels from baseline to 52 wks using ANCOVA
 - Controlled for site, baseline A1c levels, use of SMBG at baseline, duration of diabetes, baseline use of antihyperglycemic treatment, age, race/ethnicity, health literacy, number of comorbidities
- ANCOVA similar models used to compare groups for change in HRQOL as well as secondary outcomes
- Prespecified sensitivity analyses for A1c; repeated ITT analyses with a per protocol population
- Linear mixed models including A1c values captured in EHR

Baseline Characteristics

	No Testing n=152	Testing, No Messaging n=150	Testing, with Messaging n=148
Age, years (SD)	60.9 (11.6)	59.9 (11.4)	60.7 (11.5)
Sex, male, %	48.7	44.7	44.6
Race, %			
Black	27.6	36.7	34.5
White	68.4	59.3	58.1
Other	3.9	4.0	7.4
Ethnicity, Non-Latino Hispanic, %	97.4	98.7	98.6
BMI, mean (SD)	33.8 (7.3)	34.1 (7.2)	35 (8.5)
Years with diabetes, mean (SD)	7.7 (6.9)	8.3 (8.0)	8.6 (7.8)
Current use of SMBG testing, %	75.0	72.0	78.4

Primary Outcomes: A1c

Summary of 52 week Outcomes by Randomization Group (ITT)					
	Randomization group				
	No testing	Testing No Messaging	Testing with Messaging	Overall Pvalue	Contrast Pvalue
	Means				
Hemoglobin A1c					
Baseline	7.52	7.55	7.61		
Follow-up	7.55	7.49	7.51		
Change	0.04	-0.05	-0.10	0.740	0.483

Primary Outcomes: Quality of Life

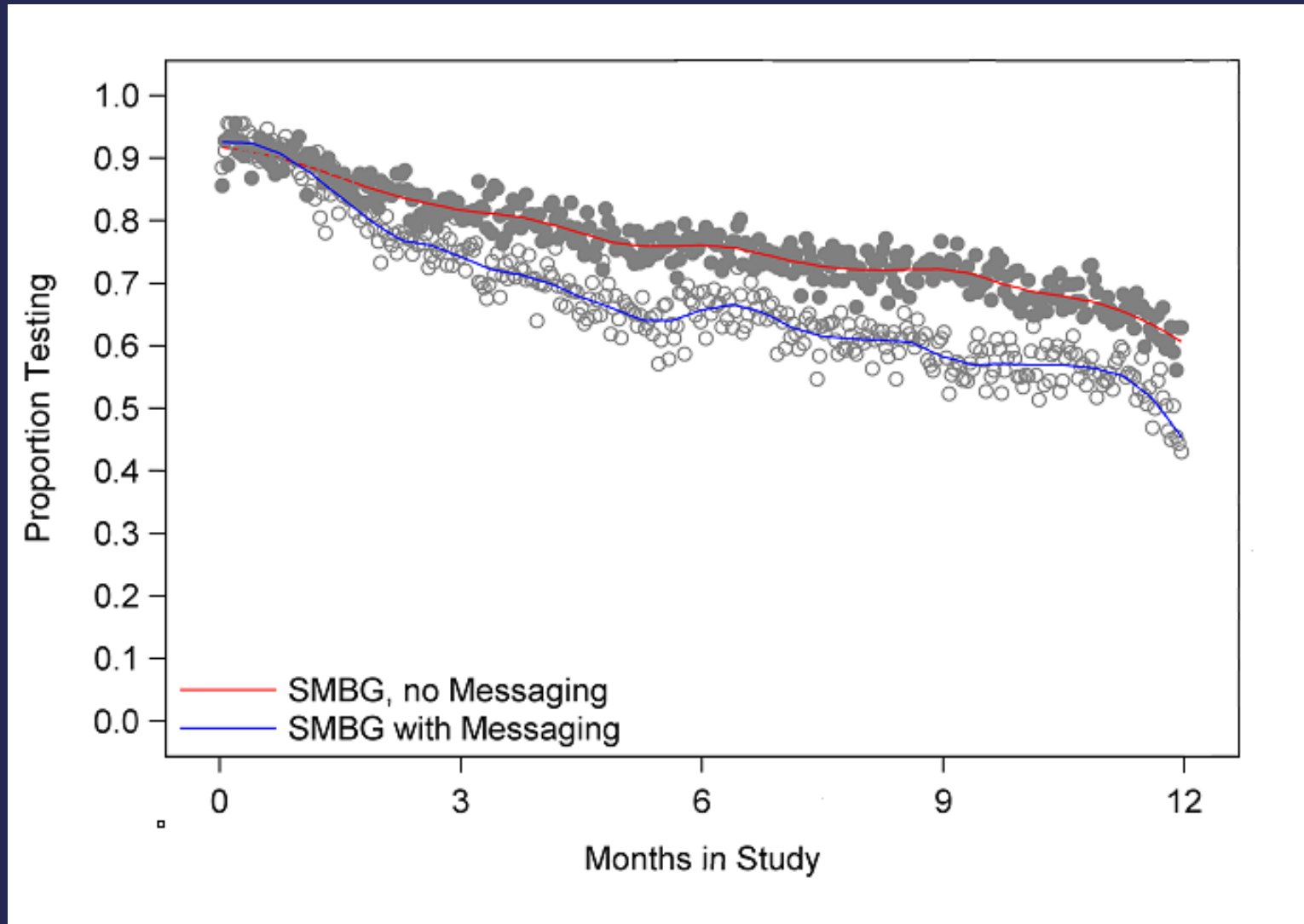
Summary of 52 week Outcomes by Randomization Group (ITT)

	Randomization group				
	No testing	Testing No Messaging	Testing with Messaging	Overall P value	Contrast P value
	Means				
Health-related quality of life, SF-36					
Physical score					
Change	-0.43	0.07	-0.35	0.481	0.504
Mental score					
Change	-0.94	-0.71	-1.39	0.899	1.000

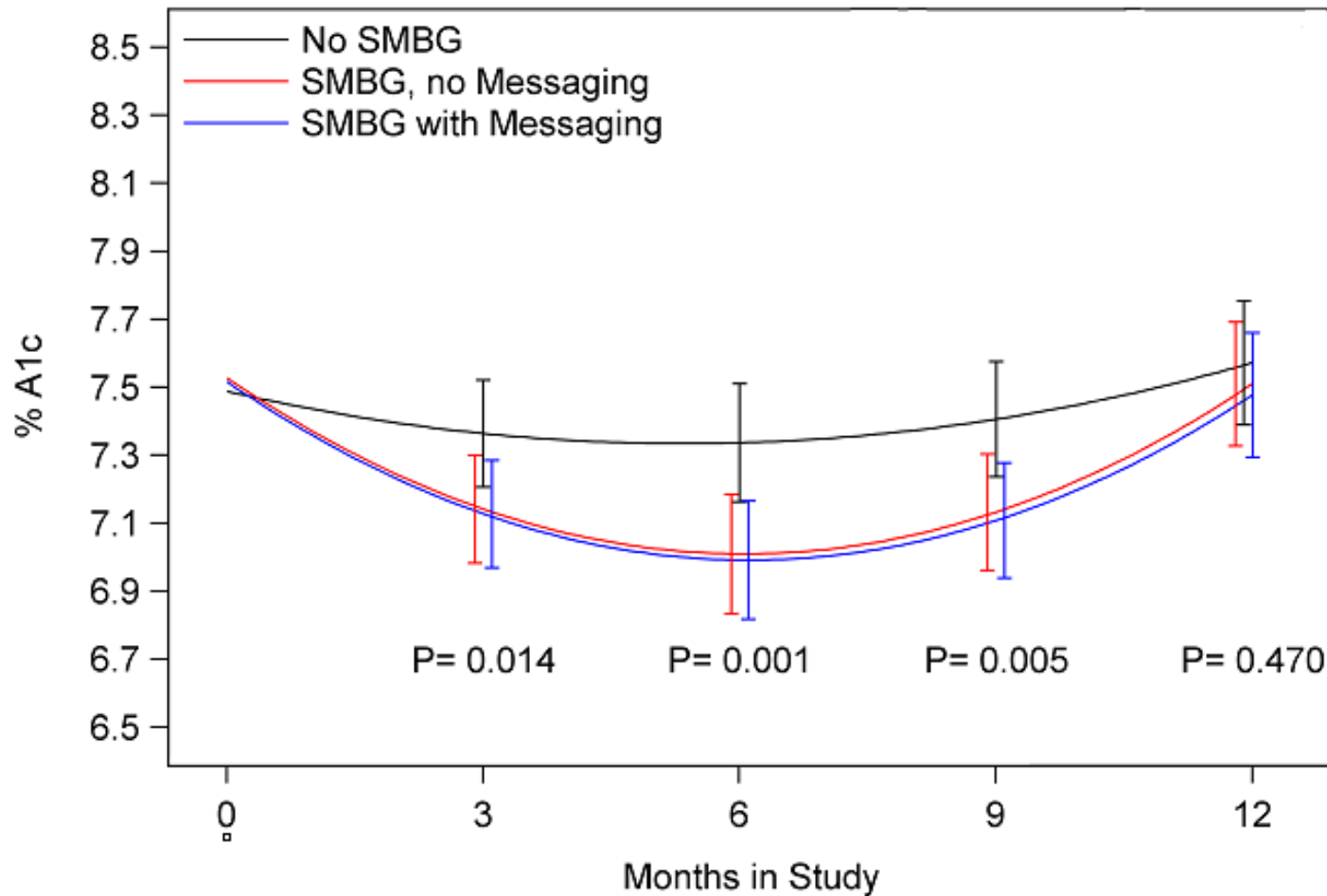
Secondary Outcomes

- No significant differences for
 - Problem Areas In Diabetes (PAID)
 - Diabetes Symptoms Checklist (DSC)
 - Diabetes Empowerment Scale (DES-SF)
 - Diabetes Treatment Satisfaction
- Communication Assessment Tool
- Summary of Diabetes Self-Care Activities was significant (but related to the blood sugar testing scale)

Glucose monitoring data: Daily Proportions of Patients testing in the SMBG groups



EHR data: Mean A1c levels by study arm over time



Safety and Adverse Events

- 1 severe hypoglycemia (secondary to bladder CA and urosepsis)
- 62 hospitalizations (no difference by arm)
- 2 deaths (1-cardiac surgery, 1-ALS)
- NONE of the events were study related

Limitations

- Test of continuing monitoring rather than initiating monitoring
- Not all patients adhered to the group assigned; however no difference in ITT and per-protocol analyses
- Patients belonged to one health care system
- Findings do not apply to patients on insulin

Conclusions

- Over the course of one year, there were no clinically or statistically significant differences in glycemic control or quality of life between patients with non insulin treated DM who perform SMBG compared to those who do not perform SMBG.
- The addition of tailored feedback provided through messaging via a glucometer did not provide any advantage in glycemic control.

Research

JAMA Internal Medicine | Original Investigation

Glucose Self-Monitoring in Non-Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings: A Randomized Trial

Laura A. Young, MD, PhD; John B. Buse, MD, PhD; Mark A. Weaver, PhD; Mahan B. Vu, DrPH, MPH; C. Madeline Mitchell, MJRP; Tamara Blakeney, BS; Kimberlea Grimm, BAS; Jennifer Rees, RN, CPF; Franklin Niblock, BS; Katrina E. Donahue, MD, MPH; for the Monitor Trial Group

IMPORTANCE The value of self-monitoring of blood glucose (SMBG) levels in patients with non-insulin-treated type 2 diabetes has been debated.

OBJECTIVE To compare 3 approaches of SMBG for effects on hemoglobin A_{1c} levels and health-related quality of life (HRQOL) among people with non-insulin-treated type 2 diabetes in primary care practice.

DESIGN, SETTING, AND PARTICIPANTS The Monitor Trial study was a pragmatic, open-label randomized trial conducted in 15 primary care practices in central North Carolina. Participants were randomized between January 2014 and July 2015. Eligible patients with type 2 non-insulin-treated diabetes were: older than 30 years, established with a primary care physician at a participating practice, had glycemic control (hemoglobin A_{1c}) levels higher than 6.5% but lower than 9.5% within the 6 months preceding screening, as obtained from the electronic medical record, and willing to comply with the results of random assignment into a study group. Of the 1032 assessed for eligibility, 450 were randomized.

INTERVENTIONS No SMBG, once-daily SMBG, and once-daily SMBG with enhanced patient feedback including automatic tailored messages delivered via the meter.

MAIN OUTCOMES AND MEASURES Coprimary outcomes included hemoglobin A_{1c} levels and HRQOL at 52 weeks.


RESULTS A total of 450 patients were randomized and 418 (92.9%) completed the final visit. There were no significant differences in hemoglobin A_{1c} levels across all 3 groups ($P = .74$; estimated adjusted mean hemoglobin A_{1c} difference, SMBG with messaging vs no SMBG, -0.09% ; 95% CI, -0.31% to 0.14% ; SMBG vs no SMBG, -0.05% ; 95% CI, -0.27% to 0.17%). There were also no significant differences found in HRQOL. There were no notable differences in key adverse events including hypoglycemia frequency, health care utilization, or insulin initiation.


CONCLUSIONS AND RELEVANCE In patients with non-insulin-treated type 2 diabetes, we observed no clinically or statistically significant differences at 1 year in glycemic control or HRQOL between patients who performed SMBG compared with those who did not perform SMBG. The addition of this type of tailored feedback provided through messaging via a meter did not provide any advantage in glycemic control.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT02033499

JAMA Intern Med. doi:10.1001/jamainternmed.2017.1233
Published online June 10, 2017.

 Editor's Note

 Author Video Interview and JAMA Report Video

 Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: A complete list of the Monitor Trial Group members is provided in at the end of the article.

Corresponding Author: Katrina Donahue, MD, MPH, Department of Family Medicine, School of Medicine, University of North Carolina at Chapel Hill, CB #7595, 590 Manning Dr, Chapel Hill, NC 27599-7595 (kdonahue@med.unc.edu).

JAMA Internal Medicine

Young LA, Buse JB, Weaver MA, et al.

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Published online June 10, 2017

Available at jama.com and on The JAMA Network Reader at mobile.jamanetwork.com

Thank You!

