Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-insulin Treated Diabetes
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"To Test or Not to Test?"
... evaluating the impact of glucose monitoring on the control of Type-2 Diabetes

Disclosure to Participants
- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
- Conflict of Interest (COI) and Financial Relationship Disclosures:
  - UNC received financial support from the following companies for research (Dr. Young is PI/co PI on the studies): Eli Lilly, BMS, GI Dynamics, PhaseBio, Medtronics, Sanofi, Takeda, Halozyme, J&J, Andromeda, QSK, Bi, Intarcia, Lexicon, Orexigen, Scion Neurostim, Takeda, Theracos, Novo Nordisk
  - Dr. Young serves on Medical Advisory Board/Steering Committees for: PGPs Diabetes, DEXCOM
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What is PCORI?
Patient Centered Outcomes Research Institute

Mission:
PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

Vision:
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.

What is PCORI?
- PCORI was created by the Affordable Care Act of 2010 as an independent, non-profit, non-governmental organization.
- Funding is provided by the general fund of the US Treasury and by an annual $2 fee per individual assessed on Medicare, private health insurance and self-insured plans.
- PCORI is interested in funding research that is directly relevant to patients
Stakeholder Engagement

- Meetings (Stakeholders and Team)
  - Year 1
    - Kickoff (Stakeholders and Team ) on August 28th Today!
    - ~8 calls, 1 hour with Team
  - Year 2
    - ~4 calls, 1 hour with Team
  - Year 3
    - Review of Results
    - ~8 calls, 1 hour with Team

Input given during study design

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Input Provided</th>
<th>How it shaped our design</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Carolina Diabetes Advisory Council</td>
<td>Consider health literacy and subgroup would be useful to engage for this work.</td>
<td>Shaped the Center for Diabetes Translation and Research Literacy to assist with message tailoring and algorithm that could be used in office.</td>
</tr>
<tr>
<td>Greensboro Community Advisory Board</td>
<td>Important outcomes: quality of life, hypoglycemia, health care service use, patient empowerment.</td>
<td>Hypoglycemia added as an outcome measure. CME for providers.</td>
</tr>
<tr>
<td>Diabetes Center Patient Registry</td>
<td>Testing is quite variable in real world settings.</td>
<td>Designed three arm plan to address real world variability and better align to improved patient issues.</td>
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<tr>
<td>UNCPhysicians Network</td>
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“To Test or Not To Test”

For SMBG to be an effective self-management tool in NIT DM, the patient and the health care provider must both actively engage in performing, interpreting, and acting upon the SMBG values.

Project Overview

Assess the impact of 3 SMBG testing approaches over one year on patient-centered outcomes in 450 patients with non-insulin treated T2DM with the real-world, clinic setting

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
  (Standard plus automated tailored feedback messaging following each SMBG testing event delivered to the patient through the monitor)

AIM 1

Assess SMBG effectiveness on two primary patient-centered outcomes, glycemic control and quality of life, over 52 weeks in 450 non-insulin treated patients with T2DM

a) Compare 3 different SMBG testing approaches
b) Assess glycemic and quality of life across the following subgroups: prior experience using SMBG, duration of T2DM, baseline degree of glycemic control, anti-hyperglycemic treatment, age, race/ethnicity and health literacy
AIM 2
Evaluate the SMBG impact on several secondary patient-centered outcomes over 52 weeks including:

a) Diabetes treatment satisfaction, diabetes symptoms, diabetes self-efficacy, diabetes related distress, and diabetes self-care activities

b) Patient-provider communication

Study Design

Sample Messages

Testing Algorithm Overview

Who Will Guide SMBG Timing
Study Population

- 15 Primary Care Practices in Central NC Practices
- Patients
  - T2DM diagnosed after age 30 not on insulin
  - Established patient at a participating UNCPN practice who identifies a UNCPN health care provider as their primary provider of diabetes care
  - A1C 6.5%-9.5%
  - English speaking
  - Non pregnant
  - Not seeing or planning to see Endocrine

Outcomes

- Primary Outcomes
  1. Change in A1c from baseline to 52 weeks
  2. Quality of life (measured by SF-36)

- Secondary Outcomes
  1. Diabetes Related Quality of Life (PAID, DM Symptom CL)
  2. Diabetes Self-Care (SDSCA)
  3. Diabetes Treatment Satisfaction
  4. Patient-Provider Communication (CAT)

Potential Moderating Variables

- Prior experience using SMBG
- Age, race, ethnicity
- Other co-morbidities
- DM-related complications
- Duration of DM
- Prior experience with SMBG
- Health literacy (Newest Vital Sign)
Limitations

- Primary care
- Did not explicitly engage other support staff (CDEs, nutritionists)
- Unable to enforce health care providers’ compliance with recommendations

Conclusions

- 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.