Overview

• The Importance of self-monitoring of blood glucose (SMBG) and control solution

• Research

• Results and practice implications / opportunities

Presentation Objectives

• Describe the role of control solution

• Identify 1 pharmacy, patient and provider barrier each to control solution usage

• Discuss provider, pharmacy and patient education opportunities
The Importance of SMBG and Control Solution

Diabetes Standards of Care For Glycemic Control

- **A1c**
  - Normal: 4.0-5.6%
  - General Goal: < 7%
  - Individualize

- SMBG values
  - Normal: 70-100 mg/dL
  - Fasting target: 70-130 mg/dL
  - 2 hour post prandial target: < 180 mg/dL

Therapeutic Decision Making

- SMBG useful for:
  - Evaluating responses to diet, exercise, or medications
  - Preventing or treating hypoglycemia (patient safety)
  - Making adjustments
    - Medication (prandial insulin doses)
    - Medical Nutrition Therapy
    - Physical activity
  - SMBG frequency correlated with lower A1c

Micro- and Macrovascular Complications

- **A1c** < 7%
  - ↓ microvascular complications (retinopathy, nephropathy, neuropathy)
  - DCCT and UKPDS
  - If achieved soon after diagnosis, associated with long-term reduction in macrovascular disease
  - DCCT, UKPDS, ACCORD, ADVANCE, VADT
  - SMBG can facilitate achievement of goal A1c

SMBG Indications and Frequency

- Dictated by patient specific needs / goals
- Patients using multiple-dose insulin or pump
  - Check prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when suspect low, prior to critical tasks (driving)
- Patients using noninsulin regimen or basal
  - Results may be helpful to guide treatment decisions
  - For success, integrate results into clinical and self-management plans

Glucometer Accuracy

- Dependent on both the glucometer and user technique
  - Monitor patient technique
  - Monitor glucometer accuracy

- Glucometers are regulated by the FDA using guidelines from the International Organization for Standardization (ISO)
  - ISO 15197:2003
    - Requires 95% results in range within +/- 20% true value
  - ISO 15197:2013
    - Requires 99% results in range within +/- 15% true value
Glucometer Accuracy

• Many glucometers fall short of the ISO 2003 accuracy standard of 95% +/- 20%.
• 438 reports to FDA regarding glucometer errors*
  • Incorrect display of SMBG results
  • Incorrect glucose readings
• Many manufacturers fail to investigate incorrect glucose readings due to the lack of control solution use by patient / provider.

Role of Control Solution

• When control solution is applied to a test strip, a reading out of range indicates a problem with either the glucometer or the lot of test strips
• Manufacturer recommendations:
  • Use control solution to confirm proper function of glucometer and lot of test strips when there is a suspected error or malfunction of either
  • Use control solution when either a new glucometer or new vial of test strips is used

Is it being used?

• Chaudhry and Klonoff
• **Purpose:** Determine prevalence of control solution use in patients who perform SMBG
• **Methods:**
  • 18 patients with type 1 diabetes surveyed to measure knowledge and usage of control solution
  • Determined availability of control solution in all pharmacies in San Mateo County, California
• **Results:**
  • 82% patients had knowledge of control solution
  • 58% patients never use it (only 26% use it as intended)
  • Only 15% of pharmacies stocked it

Research Objective

• Identify potential barriers to control solution use from multiple perspectives including patient, pharmacy and provider

Primary Outcomes

• **Patient utilization of control solution**
  • Determine whether patient demographic factors influence the use of control solution
• **Barriers to control solution use**
  • Determine availability of control solution in a sampling of community pharmacies
  • Identify whether patient, pharmacist, or prescriber perceptions of control solution use may influence proper use
  • Identify whether the type of clinic or level of provider influences use of control solution
Setting and Sample

**Patients:**
- Type 1 and type 2 diabetes
- Academic health system:
  - Internal Medicine
  - Family Medicine
  - General Pediatrics
  - Specialty Diabetes Pediatrics

**Providers:**
- Physicians (faculty and residents) in the respective clinics

**Pharmacies:**
- Community and independent pharmacies in the Tulsa, OK metropolitan area

Study Design

- Prospective, observational survey design

**Phase 1**
- Pharmacy environmental audit

**Phase 2**
- Pharmacist telephone interview
  - Patient telephone interview

**Phase 3**
- Provider web-based survey

Pharmacy Selection

- **Environmental Audit**
  - Tulsa, OK divided into 5 geographical sections (North, South, East, West, and Central)
  - 4 chain and 1 independent pharmacy randomly selected from a master list of pharmacies located in each geographical section
  - Audit guide:
    - Location of control solution (if visible) and available brands
    - 1 investigator visited each pharmacy for an on-site audit for visible presence of control solution

Pharmacist

- Pharmacist from each of the 25 stores audited were interviewed via telephone
  - Telephone interview script:
    - Knowledge of control solution
    - Perception of use and recommendation habits
    - Availability and brands
    - Location
    - Ordering process
    - Insurance coverage

Patient Selection

- Institution’s electronic medical record system used to generate a report for each clinic identifying patients with type 1 or type 2 diabetes
  - 15 patients randomly selected from each clinic and screened for inclusion eligibility:
    - ‘Active’ patient within the clinic
    - Diabetes diagnosis for at least 1 year
    - Utilize SMBG at least once a week

Patient Telephone Script

- Frequency of SMBG and perception of importance
- Glucometer brand
- Pharmacy
- Control solution knowledge, use / barriers, recommendation and perception
- Received diabetes education
- Works with CDE or specialist
- Medication usage
- Perception of diabetes control and obtaining A1c
- Demographics (age, years diagnosed, insurance, type of diabetes, clinic, and A1c)
Provider Selection
• All faculty and medical residents in each clinic emailed a brief explanation of survey along with the web link with 2-weeks to complete
• Web-based survey created using Qualtrics:
  • Knowledge and perception of control solution
  • Practice habits and frequency of recommendation
  • Clinic
  • Level of provider

Results

Pharmacy Audit

Visual Inspection of Pharmacies

Only 1 of the 25 pharmacies audited had visible control solution

Pharmacist Survey

Control Solution Knowledge, Perception, and Use

100% were familiar with control solution.
61% feel usage should be routine practice
14% always recommend it
43% recommend only in certain situations
43% never recommend

Reasons:
- Not a high priority
- Patients never ask
- Time constraints
- Not stocked

n=23
Stocks Control Solution

- 29% (4) state there is no demand
- 36% (5) don't know or had misunderstanding
- 56% (5) stock it behind the pharmacy counter
- 33% (3) stock it with the OTC diabetes supplies
- 11% (1) didn't know

87% (20) state they can order if the patient asks.

Patient Survey

Demographics
- 15 patients from each of the 4 clinics (n=60)
- 43% (26) type 1 and 57% (34) type 2
- Age range 6-94 (mean 36 yoa)
- 30% (18) patients pediatrics and 70% (42) adults
- Insurance coverage
  - Medicaid / Medicare 62% (37)
  - Private 33% (20)
  - Self-pay 5% (3)

Diabetes History
- Years with diagnosis
  - 1-9 years = 57% patients (34)
  - 10-20 years = 33% patients (20)
  - 21 yrs or longer = 10% patients (6)
- Level of diabetes control
  - < 7% = 28% (17)
  - ≥ 7% = 72% (43)
- 72% of patients (43) received formal diabetes education

Perceived Importance of SMBG

- 2% (1) state yes
- 98% (49) state no

Control Solution Knowledge and Use

- 48% (23) patients use control solution
- 52% (27) use an independent pharmacy
- Only 14 (23%) of the 60 patients use control solution
Patient Characteristics

<table>
<thead>
<tr>
<th>Years with diagnosis</th>
<th>Pediatric</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-8 yrs</td>
<td>26%</td>
<td>31%</td>
</tr>
<tr>
<td>9-20 yrs</td>
<td>17%</td>
<td>39%</td>
</tr>
<tr>
<td>≥ 21 yrs</td>
<td>61%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Formal Diabetes Education

<table>
<thead>
<tr>
<th>Use</th>
<th>Don't Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use</td>
<td>79%</td>
</tr>
<tr>
<td>Don't Use</td>
<td>70%</td>
</tr>
</tbody>
</table>

Years with diagnosis (p=0.9)

Testing Frequency

<table>
<thead>
<tr>
<th>Testing Frequency</th>
<th>Use</th>
<th>Don't Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 time/day</td>
<td>18%</td>
<td>82%</td>
</tr>
<tr>
<td>2-3 times/day</td>
<td>23%</td>
<td>77%</td>
</tr>
<tr>
<td>≥ 4 times/day</td>
<td>26%</td>
<td>74%</td>
</tr>
</tbody>
</table>

Level of Diabetes Control

<table>
<thead>
<tr>
<th>≤ 7%</th>
<th>≥ 7%</th>
<th>No A1c documented</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>30%</td>
<td>40%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use</th>
<th>Don't Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use</td>
<td>20%</td>
</tr>
<tr>
<td>Don't Use</td>
<td>17%</td>
</tr>
</tbody>
</table>

Insurance

<table>
<thead>
<tr>
<th>Medicaid/Medicare</th>
<th>21% use Control Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private</td>
<td>34% use Control Solution</td>
</tr>
<tr>
<td>Self-Pay</td>
<td>4% use Control Solution</td>
</tr>
<tr>
<td></td>
<td>5% use Control Solution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Medicine</td>
</tr>
<tr>
<td>Family Medicine</td>
</tr>
<tr>
<td>Pediatrics</td>
</tr>
<tr>
<td>Diabetes Pediatrics</td>
</tr>
</tbody>
</table>
Control Solution Usage

- 67% (31) don’t use because they don’t know about it (p=0.05)
- 28% (13) lack understanding
- 2% (1) stated pharmacy doesn’t stock

Don’t Use
Use

Type 1 38%
Type 2 15%
P=0.03

Provider Survey

Demographics

Provider Type    Number
Resident         13
Faculty          18
Endocrinologist  1

Clinic    Number
Family Medicine 13
Internal Medicine 8
Pediatrics     8
Pediatric Diabetes 1
Med/Peds       2

Provider Survey

62% were familiar with control solution
50% feel usage should be routine practice

Reasons:
- Not sure needed with new technology
- Use a clinic glucometer to compare against for accuracy
- Don’t think about it

Knowledge and Use by Clinic

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Recommend using CS (p=0.2)</th>
<th>Patient knowledge of CS (p=0.04)*</th>
<th>Patient use of CS (p=0.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Medicine</td>
<td>13% (1)</td>
<td>27% (4)</td>
<td>7% (1)</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>80% (4)</td>
<td>73% (11)</td>
<td>20% (3)</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>25% (1)</td>
<td>40% (6)</td>
<td>27% (4)</td>
</tr>
<tr>
<td>Pediatric Diabetes</td>
<td>100% (1)</td>
<td>67% (4)</td>
<td>40% (6)</td>
</tr>
</tbody>
</table>

Knowledge and Use by Provider

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Recommend using CS (p=0.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resident</td>
<td>15% (2)</td>
</tr>
<tr>
<td>Faculty</td>
<td>27% (4)</td>
</tr>
<tr>
<td>Endocrinologist</td>
<td>100% (1)</td>
</tr>
</tbody>
</table>
Implications

Opportunities for Educators

• Pharmacists may have lack of understanding of importance or 'logistics' of control solution
• Pharmacies are not visibly stocking control solution
• Patients may have lack of understanding of importance or may not know where to purchase
• Providers may have a lack of understanding of importance

• Is there a difference between pediatric vs. adult populations?
• Is there a difference between type1 vs. type 2 patients?

What Ideas Do You Have???

References

• Melker RJ. Test strips for blood glucose monitors are not always accurate. Diabetes Care 2003; 26(11):3190.