Hit the Pharmacy Easy Button: Driving Ease, Effectiveness and Safety through Innovation

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Financial Disclosure

Owner of Mobile Pharmacy Solutions
Moving Toward a Golden Era

Advanced Primary Care Structures

Nutritionists
Diabetes Educators
Pharmacists
Nurses

Endocrinologists
Monitoring Technology
Pump Technology
Safe & Effective Meds

Continuum of Care
Consensus Goals
A Walk Through Time

1922: 1st Gen Sulfonylureas
1957: Regular / NPH Insulin
1982: 2nd Gen Sulfonylureas
1984: Insulin Discovered
1994: Metformin
1995: α-glucosidase inhibitor
1996: Rapid Acting Insulin
1997: Meglitinides
1999: Thiazolidinediones
2000: Basal Insulin
2005: DPP-IV Inhibitors
2006: Amylinomimetics
2008: Rapid acting GLP-1
2009: Bile Acid Sequestrants
2010: Dopamine Agonist
2014: SGLT2 Inhibitors
Strategizing Diabetes Management
Manage Glucose, Have Common Goals

- Help with weight loss or at least not put more weight on
- Avoid hypoglycemia
- Minimal daily administration times
- Minimal or tolerable side effects
- Cost sustainable
Strategizing Diabetes Management
Avoiding Hypoglycemia and Weight Gain

Hypoglycemia & Weight Gain
- Sulfonylureas (glyburide, glipizide, glimepiride)
- Thiazolidinediones (pioglitazone, rosiglitazone)
- Basal Insulin (degludec, detemir, glargine)
- Bolus Insulin (aspart, glulisine, lispro)
- Mixed Insulins (75/25, 75/30, 50/50; aspart and lispro protamine)

No Hypoglycemia, No Weight Gain
- Wt loss: Biguanide (metformin)
- Wt neutral: Meglitinides (netaglinide, repaglinide)
- Wt neutral: DPP-IV Inhibitors (alogliptin, linagliptin, saxagliptin, sitagliptin)
- Wt loss: SG LT-2 Inhibitors (canagliflozin, dapagliflozin, empagliflozin)
- Wt loss: GLP-1 agonists (albiglutide, dulaglutide, exenatide, liraglutide)
Metformin

A great drug is a terrible thing to waste

- **GI Side Effects: Nausea (25%), Diarrhea (53%)**
  - 50% of Type 2 diabetics are NOT on Metformin
  - Dose related side effects at \( \geq 1000 \) mg per day
  - Reintroduce 500 mg x 1-week, escalate 500 mg weekly to reach 2g
  - Conversion to ER vs. IR tablet may improve tolerability

- **Kidney Clearance “Contraindication”**
  - Lactic Acidosis: Indistinguishable v. T2DM (3/100,000 pt years)
  - GFR > 60 ml/min: Normal use
  - 45-60 ml/min = 2000 mg daily
  - 30-44 ml/min = 1000 mg daily (continuation only; do NOT initiate)

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1 Levy J. Diabetol Metab Syndr. 2010;2:16.
GLP-1 Receptor Agonists

Mechanism of Action
1. Increases insulin secretion (β-cell – predominantly 1st phase)
2. Suppresses post-prandial glucagon secretion (α-cell)
3. Delays gastric emptying
4. Centrally regulates food intake and satiety (hypothalamus)

Pharmacologic Nuances
- Fasting and prandial coverage without risk of hypoglycemia
- Daily and weekly injections may be taken without regard to food
- No renal or hepatic impairment concern (no exenatide <30 ml/min)
- Liraglutide steady state is 2-3 days; all others 2-6 weeks
**SGLT-2 Inhibitors**

**Mechanism of Action**
- Inhibition of the Sodium Glucose co-transporter-2 (SGLT-2) responsible for reabsorbing majority of glucose filtered by kidney. Increases excretion of urinary glucose up to 50-100 g daily.

**Pharmacologic Nuances**
- Fasting and prandial coverage without risk of hypoglycemia
- Once a day tablet may be taken without regard to food
- Renal dose adjustments at EGFR 45-60; NOT to be used <45ml/min
- DKA has been observed at glucose <200 mg/dl
  - Risk factors: Low carb intake, T1DM, Reduced insulin dose, dehydration
  - Recommendation: Reduce insulin dose gradually (new start: max 25%)
Strategizing Diabetes Management

Consider the Emerging Opportunity

- Metformin (once or twice a day - HbA1C reduction 1.0-1.5%)
- GLP-1 analogs (once a day or week - HbA1C reduction 1.0-1.5%)
- SGLT-2 Inhibitors (once a day - HbA1C reduction 0.8-1.0%)

- Multi-target approach (brain, liver, pancreas, kidney)
- No hypoglycemia for any agent
- Weight loss profile for all agents
- Cardiovascular favorable data for all agents

Strong Foundation Regimen to ADD Secretagogues or Targeted Insulin
Secretagogues
Sulfonylurea (Glipizide) v. Meglitinides (Nateglinide)

Carroll M. Diabetes Care 2002.
Activating Pharmacy

Innovative and Team-based Care Models
A Profession Evolving
“The 2011 Report provides rationale and compelling discussion to support health reform through pharmacists delivering expanded patient care services. In collaboration with other providers, this is an existing, accepted, and additional model of improved health care delivery that meets growing health care demands in the United States.”

Long History of Pharmacy in Diabetes

- **Asheville Diabetes Project (2003)**  
  - Community Pharmacy-led diabetes intervention
  - Statistically significant reductions in HbA$_1$C over 5-years
  - Increased drug costs with reduced total costs of care

- **Diabetes Ten City Challenge (2009)**  
  Fera T. J Am Pharm Assoc. 2009;49:e52–e60
  - Extension of the Asheville Project to 10 cities across the U.S.
  - Increased vaccination, foot and eye exam rates
  - Increased drug costs with 7.25% reduction of predicted total costs

- **Dozens of studies in ambulatory and inpatient settings**
  - HbA$_1$C improvement
  - Reduced emergency room use, hospitalizations and readmissions
  - Favorable Benefit:Cost
  - Improved quality of life
Clinical and economic impact of a diabetes clinical pharmacy service program in a university and primary care–based collaboration model

Scott V. Monte, Erin M. Slazak, Nicole Paolini Albanese, Martin Adelman, Gauri Rao, and Joseph A. Paladino

Abstract

Objective: To provide program methodology and outcomes data identifying the impact of clinical pharmacy services (CPs) in patients with type 2 diabetes.

Design: Longitudinal pre–post cohort study.


Patients: Patients with type 2 diabetes identified by their primary care providers were referred to the MedSense program; a pharmacist-led, patient-centered pharmacotherapy management program developed through university collaboration with a regional primary care physician group.

Interventions: Education, clinical assessments, provider recommendations, and longitudinal follow-up of treatment goals provided by MedSense pharmacists.

Main outcome measures: Clinical outcomes were followed for 1 year from the index date for primary diabetes endpoints (glycosylated hemoglobin and fasting plasma glucose) and accompanying metabolic parameters (body mass index, blood pressure, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides). Economic endpoints from the payer perspective were also followed for 1 year from the index date for medical and prescription-related costs.
MedSense Pharmacy Program

- University-Group Model HMO Collaborative Care Effort
- Physician, pharmacist, or patient initiated diabetes management program (direct medical practice integration).
- 30-60 minute initial in-person patient interview followed by an unlimited number of follow-up encounters (phone or in-person)
- Diabetes and metabolic history, pharmacotherapy review, disease state education, nutrition counseling, blood pressure evaluation, blood glucose monitoring, laboratory review, provider consultations
- No patient oriented financial incentives
# Medsense: Benchmarking Asheville

<table>
<thead>
<tr>
<th></th>
<th>Asheville&lt;sup&gt;a&lt;/sup&gt; Mean ± SD</th>
<th>MedSense&lt;sup&gt;a&lt;/sup&gt; Mean ± SD</th>
<th>Asheville&lt;sup&gt;b&lt;/sup&gt; Mean ± SD</th>
<th>MedSense&lt;sup&gt;b&lt;/sup&gt; Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C (%)</td>
<td>-1.1 ± 1.9</td>
<td>-1.1 ± 2.1</td>
<td>-1.1 ± 1.9</td>
<td>-1.1 ± 2.2</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>-4.2 ± 32.2</td>
<td>-3.9 ± 28.1</td>
<td>-6.5 ± 34.8</td>
<td>+4.4 ± 49.7</td>
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<tr>
<td>HDL (mg/dL)</td>
<td>+1.1 ± 7.9</td>
<td>-0.2 ± 6.2</td>
<td>+1.5 ± 7.8</td>
<td>-0.8 ± 6.9</td>
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<tr>
<td>Prescription: antidiabetic medications ($)</td>
<td>—</td>
<td>+76 ± 438</td>
<td>+408 ± 828</td>
<td>+125 ± 872</td>
</tr>
<tr>
<td>Prescription: total ($)</td>
<td>—</td>
<td>+208 ± 1,070</td>
<td>+656 ± 1,199</td>
<td>+304 ± 1,755</td>
</tr>
<tr>
<td>Total costs ($)</td>
<td>—</td>
<td>-1,250 ± 10,608</td>
<td>-2,704 ± 13,056</td>
<td>-2,547 ± 21,184</td>
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</table>
Community Pharmacy
Innovating to Identify Barriers and Solve Problems with Medication Use
Mobile Pharmacy Solutions
Community Pharmacy Services

**Prescription delivery:**
- Medications can be delivered by vehicle or mailed to patient home

**Adherence reminder calls:**
- Pharmacy dispensing system creates automated queues for staff to initiate and prioritize outbound adherence reminder phone calls
- Reminder systems includes (3) phone calls in the 7-10 day period before a chronic medication comes due
- Caregiver or provider can be contacted to check on the patient
Medication Synchronization:

- Pharmacist and technical staff reconcile all chronic medications.
- Updated prescription information and refills are obtained from all of the patient’s providers.
- Prescription refills are aligned to occur at a regular intervals to permit for consistent insurance billing and single delivery (i.e. monthly) to achieve synchronization and adherence.
Community Pharmacy Services

Adherence Packaging:
- Advanced medication synchronization process
- Distinct from blister packs (ONE card = ONE drug)
  - Commingle **MULTIPLE** medications in one card
- Organize the daily medication regimen
  - 4 Weekly packages (pillbox feel)
  - Monthly packages (morning, evening, bedtime etc.)
- Building care plans by scheduling regimen
EXPERIENCE

Pharmacist home visits: A 1-year experience from a community pharmacy

Scott V. Monte*, Sarah N. Passafiume, Wesley D. Kufel, Patrick Comerford Jr, Dean P. Trzewieczynski, Kenneth Andrus, Peter M. Brody
Residency Training Program

Residencies are postgraduate training programs that provide essential clinical training for advancement within the
Bariatric Surgery

Giant leaps forward over the past decade
Bariatric Surgery Options

Which is the most common surgery being performed in the U.S.???
Debunking Myths

#1: Bariatric Surgery is a last line therapy for people incapable of self-discipline
Gastric Bypass vs. Sleeve: GLP-1

Gastric Bypass vs. Sleeve: PYY

![Graph showing PYY levels after meal in LRYGB and LSG procedures.](image)

Gastric Bypass vs. Sleeve: Ghrelin

Debunking Myths

Myth #2: Weight will just be regained and the diabetes will return
STAMPEDE TRIAL

- Mean Age = 49, BMI = 36 kg/m², Female = 66%
- Diabetes Duration = 8.5 years, ≥3 diabetes medications, 50% on insulin
- Lifestyle + Medications + Nutritionists + Endocrinologists + Psychologists
- Target HbA1C <6.0%
# STAMPEDE: 5-year Diabetes Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Medical therapy, n=38 (%)</th>
<th>Gastric bypass, n=49 (%)</th>
<th>Sleeve gastrectomy, n=47 (%)</th>
<th>P, gastric bypass vs medical therapy</th>
<th>P, sleeve gastrectomy vs medical therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA$_1c$ $\leq$ 6%</td>
<td>5</td>
<td>29</td>
<td>23</td>
<td>0.005</td>
<td>0.02</td>
</tr>
<tr>
<td>HbA$_1c$ $\leq$ 6% without diabetes meds</td>
<td>0</td>
<td>22</td>
<td>15</td>
<td>0.002</td>
<td>0.02</td>
</tr>
<tr>
<td>HbA$_1c$ $\leq$ 7%</td>
<td>21</td>
<td>51</td>
<td>49</td>
<td>0.004</td>
<td>0.008</td>
</tr>
</tbody>
</table>
STAMPEDE: 5-year Outcome Highlights

- **HbA1C Target <7.0%**
  - Medical = 25% vs. Surgery = 50%

- **Diabetes remission (HbA1C w/ no medication)**
  - Medical = 0% vs. Surgery = 20%

- **Insulin Requirement**
  - Medical = 40% vs. Surgery = 12%

- **Weight regain >5%**
  - Medical = 19% vs. Surgical = 0%

- **No deaths in the perioperative period**

Debunking Myths

#3: Surgeons cut and send back to the PCP
Bariatric Surgery Patient Care Continuum

- Surgeon
- Nutritionist
- Pharmacist
- Physical Trainer
- Nurse
- Eating Behavior Specialist

Primary Care