I Want YOU in Pharmacotherapy Clinic!
Predictors of Response to Pharmacist-Delivered Diabetes Care

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**Learning Objectives:**
1. Describe the need for ambulatory care pharmacists in today’s healthcare landscape
2. Explain the roles and responsibilities of pharmacists in the ambulatory care setting
3. Evaluate the impact of pharmacists on diabetes outcomes in a diverse population
4. Analyze a study designed to determine which patients are most likely to benefit from these services
Current Healthcare Landscape

I. Health burden in the United States (U.S.)
   a. Several chronic diseases are the leading cause of deaths in the U.S.\(^1\)
      i. Some include heart disease, cancer, chronic lower respiratory disease, and diabetes mellitus
      ii. Chronic disease is a “disease that lasts a year or more and requires ongoing medical attention or limits activities of daily living or both”
      iii. Increases in number of adults with diagnosed diabetes\(^2\)
          1. About 12 million cases in 2000 (4.4% of population) compared to more than 23 million cases in 2015 (7.4% of population)
          2. Major risk factor for a variety of chronic diseases including heart disease and cancer
      iv. Patients with more chronic conditions have an increased healthcare burden (Figure 1)\(^3\)

![Figure 1: Health Care Spending by Number of Chronic Conditions (2014)](image)

II. Aging population in the U.S.
   a. Chronic diseases disproportionately affect older adults ≥65 years old\(^3,5\)
      i. Prevalence of multiple chronic diseases stratified by age\(^3\)
          1. ≥65 years: 81%
          2. 45-64 years: 50%
          3. 18-44 years: 18%
   b. Adults ≥65 years old are expected to more than double in population from 46 million to 98 million by 2060 vs. population <18 years old with expected growth of 3%\(^6\)
      i. Elderly support ratio = number of working-age adults (18-64 years old) for every person ≥65 years old
          1. The elderly support ratio will continue to decrease by 2060
          2. Elderly support ratio past values and future projections\(^6\)
3. This decrease illustrates declining resources to care for an aging population

I. Primary care & primary care physician (PCP) shortage
   a. Primary care
      i. Foundation of the U.S. healthcare system and serves as access point for patients
      ii. Accessible and integrated into the community
      iii. Promotes wellness, disease prevention, and health maintenance
      iv. Responsible for the long-term management of many chronic diseases
   b. Primary care shortage (Figure 2)
      i. Projected shortfall for all physicians by 2030: 42,600 to 121,300
      ii. Projected shortfall for primary care physicians by 2030: -25,300 to 74,100
         1. This range depends on several factors including the supply & demand of mid-level practitioners including nurse practitioners, physician assistants, and pharmacists

![Graph showing projected shortfall range for primary care physicians, 2016-2030](image)

**Figure 2: Projected Shortfall Range for Primary Care Physicians, 2016-2030**

iii. Shortfall driven by many factors including
   1. Aging & growing population
   2. Physician retirement
      a. >33% of all active physicians will be ≥65 years old within the next 10 years
   3. Increasing complexity of patients’ healthcare needs
II. Shift towards value-based care
   a. Since the Patient Protection and Affordable Care Act (ACA) of 2010 healthcare delivery has shifted towards value-based care vs. fee-for service\textsuperscript{8,10}
      i. Value-based care includes “triple aims” of reduced cost, improved care, and improved population health
      ii. Reimbursement dependent on quality and value of healthcare received

III. Pharmacists in ambulatory care are important resources to assist in today’s healthcare environment and can help fill void

**Pharmacists in Ambulatory Care**

I. Growing and important area of specialization
   a. Increasing number of ambulatory care pharmacists: >3,800 Board Certified Ambulatory Care Pharmacists (BCACPs) in 2018 or a >17% increase from 2017\textsuperscript{11}
   b. Improves access to care
   c. Management and prevention of chronic diseases
      i. Similar resource utilization compared to usual care\textsuperscript{12}
   d. Proven contributions to value-based care and including cost containment and achievement of quality measures
      i. Cost-effectiveness shown for disease state management including diabetes and hypertension\textsuperscript{13,14}
      ii. Proven positive effects on hypertension, heart failure, diabetes, and anticoagulation management\textsuperscript{15-19}
      iii. Beneficial effects of medication therapy management programs\textsuperscript{20-22}
      iv. Promotion of public health through vaccination and education

II. Role of the ambulatory care pharmacist
   a. Medication optimization\textsuperscript{23}
      i. Appropriate medication selection
      ii. Proper dosing and adjustment
      iii. Comprehensive medication reviews
   b. Medication monitoring including physical assessment and labs\textsuperscript{23}
      i. Assess medication effectiveness and safety
   c. Improvement metrics\textsuperscript{23}
      i. Influenza & pneumococcal vaccination
      ii. A1C control (<8%)
      iii. Blood pressure control (<140/90 mm Hg)
      iv. Low density lipoprotein control (<100 mg/dL)
      v. Medication reconciliation
   d. Patient education and goal setting
   e. Documentation in electronic medical record
   f. Referral to other healthcare providers as needed
   g. Adherence barrier identification
      i. Increase access to therapy
   h. Patient advocacy
      i. Support patient-centered decision making
      ii. Promote overall health and wellness
III. Pharmacist structures and place in primary care

a. Independent prescribing

b. Collaborative practice agreement

i. Formal relationship between pharmacist and provider
ii. Physician-initiated and requires supervision
iii. Outlines pharmacist’s roles and responsibilities
   1. Adjustment of current therapy
   2. Initiation of new therapy
   3. Ordering of pertinent labs
iv. Lists disease states that may be managed
v. Shared responsibility for patient outcomes

c. Other collaborative care models

i. Shared appointments with provider
ii. Pharmacist available for recommendations & patient education

d. Annual wellness visit (AWV)

i. Once yearly free Medicare Part B benefit
ii. Focuses on patient’s overall wellbeing, screening, and disease prevention
iii. Required components include
   1. Medical and family histories
   2. Vital signs
   3. List of medical providers
   4. Cognitive impairment and depression screenings
   5. Personalized prevention plan
iv. Generates substantial revenue for the health organization
v. Can be managed by pharmacists, physician assistants, or nurses working under supervision of a physician
vi. Pharmacists have shown to be effective in AWVs
   1. Decreased risk of polypharmacy, underprescribing, and adverse drug events
   2. Improve achievement of Medicare quality metrics

Pharmacists and Diabetes Care

I. Diabetes in the U.S.

a. Prevalence
   i. >30 million (9.4% of population)
      1. 25% of those ≥65 years old
      2. Texas: >2.9 million (14.6% of population)
   ii. >84 million have prediabetes

b. Costs
   i. Direct costs = $237 billion
      1. Texas ~ $18.9 billion
   ii. Indirect costs = $90 billion
   iii. Total costs = $327 billion
iv. Care for people with diabetes account for 1 in 4 healthcare dollars spent in the U.S.
v. $13,240 annual burden per person with diagnosed diabetes
vi. Overall economic burden of $1,240 for each citizen in 2017

c. Complications of uncontrolled diabetes\textsuperscript{31}
   i. Neurological
      1. Loss of protective sensation
      2. Gastroparesis
      3. Sexual dysfunction
   ii. Retinopathy
   iii. Cardiovascular
      1. Myocardial infarction (MI)
      2. Stroke/transient ischemic attack (TIA)
      3. Hypertension
      4. Hyperlipidemia
   iv. Kidney disease
      1. Albuminuria
      2. End-stage renal disease
   v. Peripheral vascular
      1. Intermittent claudication
      2. Ulceration
   vi. Diabetic ketoacidosis
   vii. Hypoglycemic unawareness

II. Challenges with treating diabetes
   a. Demanding for patient and requires lifestyle modifications
   b. Chronic disease condition that must be managed long-term
   c. High medical costs
      i. Estimated that a person with diabetes spends 2.3 times more on medical costs compared to a person without diabetes\textsuperscript{31}
   d. Complicated and complex pharmacotherapy
      i. Many new therapies for diabetes especially since the early 2000s
      ii. More than 7 drug classes available (Table 1)\textsuperscript{33-35}
<table>
<thead>
<tr>
<th>Medication Class</th>
<th>Specific Agents</th>
<th>Expected A1C Reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biguanide</td>
<td>Metformin</td>
<td>1-2</td>
</tr>
<tr>
<td>Sulfonylureas</td>
<td>Glimepiride&lt;br&gt;Glipizide&lt;br&gt;Glyburide</td>
<td>1-2</td>
</tr>
<tr>
<td>Sodium-glucose cotransporter-2 inhibitors</td>
<td>Canagliflozin&lt;br&gt;Dapagliflozin&lt;br&gt;Empagliflozin&lt;br&gt;Ertugliflozin</td>
<td>0.5-1</td>
</tr>
<tr>
<td>Dipeptidyl peptidase-4 inhibitors</td>
<td>Sitagliptin&lt;br&gt;Saxagliptin&lt;br&gt;Linagliptin&lt;br&gt;Alogliptin</td>
<td>0.5-0.8</td>
</tr>
<tr>
<td>Glucagon-like peptide-1 receptor agonists</td>
<td>Liraglutide&lt;br&gt;Exenatide&lt;br&gt;Dulaglutide&lt;br&gt;Semaglutide&lt;br&gt;Lixisenatide</td>
<td>0.5-1.5</td>
</tr>
<tr>
<td>Thiazolidinediones</td>
<td>Pioglitazone</td>
<td>0.5-1.4</td>
</tr>
<tr>
<td>Insulin</td>
<td>Insulin lispro&lt;br&gt;Insulin aspart&lt;br&gt;Regular insulin (R)&lt;br&gt;Intermediate insulin (N)&lt;br&gt;Insulin glargine&lt;br&gt;Insulin degludec&lt;br&gt;Insulin detemir</td>
<td>&gt;1</td>
</tr>
</tbody>
</table>

a. Complex treatment algorithm with many considerations (Figure 3)
   i. Contraindications
   ii. Tolerability & safety
   iii. Comorbidities
   iv. Cost
   v. Patient preference
Figure 3: Diabetes Treatment Algorithm

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b. Drug costs
   i. Represents 43% of the total direct costs of diabetes
   ii. High prices especially for insulin, sodium-glucose transporter-2 (SGLT-2) inhibitors, and glucagon-like peptide-1 (GLP-1) agonists

III. Ambulatory care pharmacists are uniquely positioned and have required knowledge and skills to help manage diabetes
   a. Medication management including safety, dosing, cost minimization, and counseling
   b. Education on lifestyle modification
   c. Monitoring pertinent labs and for adverse drug effects

Effectiveness of Pharmacist Impact in Diabetes Care

I. Ambulatory Care Pharmacists and Diabetes Outcomes
   a. Pharmacists have been shown to improve important diabetes outcomes including hemoglobin A1c
      i. Systematic review & meta-analysis illustrating proven effectiveness in a diverse population (Table 2)19
   b. Pharmacists also benefit major cardiovascular risk factors in this population including lowering cholesterol and blood pressure19,26,36

PALKA
Impact of Diabetes Care by Pharmacists as Part of Health Care Team in Ambulatory Settings: A Systemic Review and Meta-analysis

### Objective
To evaluate the impact of pharmacists in ambulatory settings on diabetes outcomes

### Methods

#### Study Design
Systemic review & meta-analysis including studies with one of the following comparative designs:
- Randomized controlled trials (RCT)
- Non-randomized controlled trials (NRCT)
- Prospective pretest-posttest (pre-post)
- Retrospective pre-post

#### Inclusion
- Studies with patients ≥18 years old with type 1 or 2 diabetes

#### Exclusion
- Studies with patients diagnosed with gestational diabetes

#### Intervention
- Studies must have direct patient care by pharmacist in an ambulatory care setting
- Patient care could be clinical, educational, or both (with or without collaborative practice agreement or independent prescribing privileges)
- Compared to usual care without pharmacist intervention

#### Setting
- Hospital-based clinics
- Community pharmacies
- Private physician offices
- Federally qualified and community clinics

#### Outcomes
- Absolute A1C lowering from baseline
- Systolic blood pressure & low-density lipoprotein cholesterol lowering from baseline
- Standardized mean difference (SMD)

#### Data Analysis
- Random effects model
- Fail-safe N
- Sensitivity analyses for study design, baseline A1C, & age

### Results

#### Study Characteristics
- 1908 studies were screened
- 42 included in systemic review
- 35 included in meta-analysis
- Duration ranged from 3 to 60 months

#### Patient Population
- Included in systemic review: 10,860
- Included in meta-analysis: 7,417
- Sample size: 23-1,667
- Mean age: 42-73 years

#### Outcomes
- Overall SMD: 0.56 (p<0.001)
- Expressed as difference in A1C: 1.1% (95% CI, 0.88-1.27)
### SMD Based on Study Design

<table>
<thead>
<tr>
<th>Design</th>
<th>SMD</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCTs</td>
<td>0.59</td>
<td>0.35-0.83</td>
</tr>
<tr>
<td>NRCTs</td>
<td>0.48</td>
<td>0.31-0.64</td>
</tr>
<tr>
<td>Pre-post</td>
<td>0.73</td>
<td>0.44-1.03</td>
</tr>
<tr>
<td>Retrospective pre-post</td>
<td>0.61</td>
<td>0.37-0.86</td>
</tr>
</tbody>
</table>

- P-value for difference between study designs = 0.48

### SMD Based on Baseline A1C

<table>
<thead>
<tr>
<th>Baseline A1C</th>
<th>SMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;8.5% (low)</td>
<td>0.49</td>
</tr>
<tr>
<td>≥8.5%-&lt;10% (medium)</td>
<td>0.52</td>
</tr>
<tr>
<td>≥10% (high)</td>
<td>1.08</td>
</tr>
</tbody>
</table>

P=0.18

- No significant differences when stratified by age <59 or >59 years (P=0.75)
- Fail-safe N = 7,148

### Conclusion

- Pharmacist involvement demonstrated a beneficial effect on diabetes outcomes in a variety of settings and did not differ based on 3 ranges of A1C values at baseline or between study designs.
Predictors of Success in Pharmacist-Led Diabetes Care

I. Who is most likely to benefit?
   a. Unclear who is most likely to benefit from pharmacist-led diabetes management
   b. One study has assessed predictors of response in diabetes care to clinical pharmacy interventions (Table 3)\textsuperscript{37}

### Table 3: Lam, et al. 2017\textsuperscript{37}

<table>
<thead>
<tr>
<th>Objective</th>
<th>To develop a prediction model using patient factors to assist in selecting patients with diabetes most likely to benefit from pharmacy interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Design</td>
<td>• Retrospective, case-control study</td>
</tr>
<tr>
<td>Setting</td>
<td>• Three outpatient treatment facilities in an integrated healthcare system in Cleveland, OH • Collaborative practice agreement in place</td>
</tr>
</tbody>
</table>
| Patient Population | **Inclusion**
   • >18 years old with diabetes mellitus
   • Baseline A1C ≥9%
   • Referral to pharmacist between July 2009 & July 2014
| Cases (Success) & Controls (Failure) | • Success = decrease in A1C by ≥2% or an A1C <8% 1 year after initial visit
   • Failure = failure to meet A1C goals or lost to follow-up |
| Data Collection | • EMR data 1 year before & after date of initial consult |
| **Variables Collected at Baseline** | • Demographics (gender, race, age, weight, body mass index (BMI))
   • Insurance type
   • Comorbidities
   • Relevant labs (e.g., A1C, cholesterol panel, & serum creatinine)
   • Other healthcare providers
   • Number of diabetes-related admissions or emergency room visits
   • Outpatient medications |
| Statistical Analysis | • Univariable analyses conducted on nominal, ordinal, and continuous data
   • P<0.20 on univariable analysis → covariate used in regression model
   • All tests were 2-tailed
   • Multivariable logistic regression → determine independent predictors of success
   • P-value <0.05 = significant |
## Results

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Failure (Control) (n=301)</th>
<th>Success (Case) (n=243)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>57 ± 12</td>
<td>58 ± 12</td>
<td>0.15</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>99 ± 27</td>
<td>99 ± 26</td>
<td>0.84</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>34 ± 8.7</td>
<td>34 ± 7.9</td>
<td>0.66</td>
</tr>
<tr>
<td>A1C (%), mean ± SD</td>
<td>11.0 ± 1.7</td>
<td>11.5 ± 1.9</td>
<td>0.001</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>219 (73)</td>
<td>189 (79)</td>
<td>0.78</td>
</tr>
<tr>
<td>White</td>
<td>70 (23)</td>
<td>46 (19)</td>
<td>0.22</td>
</tr>
<tr>
<td>Other</td>
<td>12 (4)</td>
<td>8 (2)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>143 (48)</td>
<td>114 (47)</td>
<td>0.89</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>15 (5)</td>
<td>11 (5)</td>
<td>0.10</td>
</tr>
<tr>
<td>Medicare</td>
<td>59 (20)</td>
<td>33 (14)</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>101 (34)</td>
<td>102 (42)</td>
<td></td>
</tr>
<tr>
<td>Self-pay</td>
<td>27 (9)</td>
<td>29 (12)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>99 (33)</td>
<td>68 (28)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>33 (11)</td>
<td>32 (13)</td>
<td>0.43</td>
</tr>
<tr>
<td>CHF</td>
<td>30 (10)</td>
<td>37 (15)</td>
<td>0.06</td>
</tr>
<tr>
<td>COPD</td>
<td>24 (8)</td>
<td>14 (6)</td>
<td>0.31</td>
</tr>
<tr>
<td>CVA</td>
<td>11 (4)</td>
<td>20 (8)</td>
<td>0.02</td>
</tr>
<tr>
<td>Dementia</td>
<td>1 (0.3)</td>
<td>1 (0.4)</td>
<td>0.87</td>
</tr>
<tr>
<td>Connective tissue disorder</td>
<td>2 (0.7)</td>
<td>1 (0.4)</td>
<td>0.69</td>
</tr>
<tr>
<td>Liver disease</td>
<td>14 (5)</td>
<td>12 (5)</td>
<td>0.87</td>
</tr>
<tr>
<td>Malignancy</td>
<td>86 (29)</td>
<td>75 (31)</td>
<td>0.56</td>
</tr>
<tr>
<td>CAD</td>
<td>60 (20)</td>
<td>52 (21)</td>
<td>0.67</td>
</tr>
<tr>
<td>Renal disease</td>
<td>33 (11)</td>
<td>41 (17)</td>
<td>0.05</td>
</tr>
<tr>
<td>PVD</td>
<td>35 (12)</td>
<td>22 (9)</td>
<td>0.33</td>
</tr>
<tr>
<td>Number of comorbidities, mean ± SD</td>
<td>1.1 ± 1.2</td>
<td>1.3 ± 1.3</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Abbreviations: CHF, congestive heart failure; COPD, chronic obstructive pulmonary disorder; CVA, cerebral vascular accident; CAD, coronary artery disease; PVD, peripheral vascular disease
All data presented as n (%) unless otherwise noted
## Baseline Diabetes Care

<table>
<thead>
<tr>
<th></th>
<th>Failure (Control) (n=301)</th>
<th>Success (Case) (n=243)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geriatrics</td>
<td>10 (3)</td>
<td>7 (3)</td>
<td>0.77</td>
</tr>
<tr>
<td>Endocrine</td>
<td>56 (19)</td>
<td>38 (16)</td>
<td>0.36</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>27 (9)</td>
<td>12 (5)</td>
<td>0.07</td>
</tr>
<tr>
<td>Diabetes educator</td>
<td>12 (4)</td>
<td>12 (5)</td>
<td>0.59</td>
</tr>
<tr>
<td>Dietician</td>
<td>14 (5)</td>
<td>18 (7)</td>
<td>0.17</td>
</tr>
<tr>
<td>Any DM specialties</td>
<td>99 (33)</td>
<td>68 (28)</td>
<td>0.21</td>
</tr>
<tr>
<td>Any hospital admissions</td>
<td>73 (24)</td>
<td>60 (24)</td>
<td>0.91</td>
</tr>
<tr>
<td>DM related admissions</td>
<td>21 (7)</td>
<td>23 (9.5)</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metformin</td>
<td>179 (60)</td>
<td>146 (60)</td>
<td>0.89</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>122 (41)</td>
<td>99 (41)</td>
<td>0.96</td>
</tr>
<tr>
<td>TZD</td>
<td>16 (5)</td>
<td>11 (5)</td>
<td>0.67</td>
</tr>
<tr>
<td>GLP-RA</td>
<td>9 (3)</td>
<td>11 (5)</td>
<td>0.34</td>
</tr>
<tr>
<td>DPP-IV Inhib.</td>
<td>39 (13)</td>
<td>31 (13)</td>
<td>0.95</td>
</tr>
<tr>
<td>Basal insulin</td>
<td>219 (73)</td>
<td>166 (68)</td>
<td>0.26</td>
</tr>
<tr>
<td>Bolus insulin</td>
<td>152 (51)</td>
<td>86 (35)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>Number of classes</strong></td>
<td><strong>of DM medications, mean ± SD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5 ± 0.9</td>
<td>2.3 ± 0.9</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Abbreviations: DM, diabetes mellitus; TZD, thiazolidinedione; GLP-RA, glucagon-like peptide-1 receptor agonist; DPP-IV inhib, dipeptidyl peptidase-4 inhibitor

All data presented as n (%) unless otherwise noted

## Multivariable Logistic Regression

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVA</td>
<td>2.7</td>
<td>1.2-5.9</td>
<td>0.013</td>
</tr>
<tr>
<td>Bolus insulin</td>
<td>0.5</td>
<td>0.4-0.8</td>
<td>0.001</td>
</tr>
<tr>
<td>A1C (per percentage point &gt;9%)</td>
<td>1.2</td>
<td>1.1-1.3</td>
<td>0.001</td>
</tr>
</tbody>
</table>

## Conclusions

### Strengths
- First study to assess predictors of response to pharmacist-led diabetes care interventions
- Definition of success was meaningful and clinically significant
### Limitations
- Failure to include pharmacist interventions made during the study period
- Retrospective nature → missing data (e.g., insurance type)
- Excluded 536 patients with A1C ≤9%
- Does not reflect current practice with lack of SGLT-2 inhibitor use due to timing of approval

### Conclusions
- Strong predictors of success appear to be higher baseline A1C, a history of CVA, and lack of bolus insulin at baseline
- Limited generalizability based on patients excluded, lack of intervention information, and absent diabetes drug therapy (e.g., SGLT2-Inhibitors)

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**Designing a Prediction Study**

I. Thesis project: determining predictors of response to ambulatory pharmacist-managed diabetes care (Table 4)
   a. Research rationale
      i. By determining who is most likely to benefit, several goals may be reached:
         1. Identification of patients who may not otherwise be referred to the pharmacist and therefore increase patient referrals
         2. Assistance with PCP patient workload especially in setting of PCP shortage and aging population
         3. Increase growth of ambulatory care pharmacist specialty
         4. Improve health outcomes
**Table 4: Thesis Project**

<table>
<thead>
<tr>
<th><strong>Objective</strong></th>
<th>To identify baseline &amp; interventional predictors of response to pharmacist-led diabetes care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hypotheses</strong></td>
<td>Responders will have higher baseline A1C and zero missed appointments with the pharmacist</td>
</tr>
</tbody>
</table>

### Methods

<table>
<thead>
<tr>
<th><strong>Study Design</strong></th>
<th>Observational retrospective &amp; prospective cohort study</th>
</tr>
</thead>
</table>

![Diagram showing observational, retrospective, and prospective cohort study with timelines]

<table>
<thead>
<tr>
<th><strong>Setting</strong></th>
<th>San Antonio, TX</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>University Health System Family Health Clinic</td>
</tr>
<tr>
<td></td>
<td>University of Texas Medical Drive Primary Care Center</td>
</tr>
<tr>
<td></td>
<td>University of Texas Medical Arts &amp; Research Center (MARC) Primary Care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Participants</strong></th>
<th>Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age ≥18 with diagnosis of type 2 diabetes</td>
</tr>
<tr>
<td></td>
<td>First visit to pharmacotherapy clinic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Participants</strong></th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent A1C value at 3 months</td>
</tr>
<tr>
<td></td>
<td>Diagnosis of gestational or type 1 diabetes</td>
</tr>
<tr>
<td></td>
<td>Visit to endocrinologist during study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Outcomes</strong></th>
<th>Responder = ≥0.5% reduction in A1C after 3 months of initial pharmacist visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-responder = &lt;0.5% reduction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>A1C</strong></th>
<th>Minimum expected decrease from any drug at 13-18 weeks is 0.5% in the A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reducing A1C will reduce future complications</td>
</tr>
<tr>
<td></td>
<td>25% reduction of microvascular complications at 10 years for A1C 7% vs. 7.9%</td>
</tr>
<tr>
<td></td>
<td>Clinically meaningful A1C reduction per FDA is at least -0.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Data Sources</strong></th>
<th>UHS: Sunrise electronic medical record</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UT Health: Epic electronic medical record</td>
</tr>
</tbody>
</table>

---

**PALKA**
## Data Collection

**Baseline**
- Age, sex, race/ethnicity
- Weight & BMI
- Preferred language
- Baseline A1C
- Outpatient medications
- Duration of diabetes
- Comorbidities (Charlson Comorbidity Index)
- Insurance Type
- Estimated glomerular filtration rate (eGFR) & serum creatine (Scr)
- Microalbuminuria
- Employment
- Clinic location

**During Study Period**
- ≥1 missed pharmacist appointment
- # of appointments with pharmacist
- # of appointments with PCP
- Hospital admission
- New diabetic medications
- Dose intensification

## Analysis

**Study Diagram**

- Multivariable logistic regression analysis
- Covariates will include all independent variables collected
- P-value <0.05 considered significant

## Advantages

- Multiple clinic sites increases generalizability
- Short timeframe limits loss to follow-up
- Observational aspect gives “real-world” data
- Prospective study arm → limits misclassification bias & reflects current practice
- No exclusion of patients based on baseline A1C
- Baseline & interventional data included in logistic regression model
c. Limitations
   i. Observational aspect may lead to missing data
   ii. Selection bias of patient referred to the pharmacist
   iii. Non-randomized study

II. Summary
   a. Need for ambulatory care pharmacists
      i. High prevalence of chronic diseases and aging population
      ii. Older adults disproportionately affected by chronic disease
      iii. Patients with chronic disease utilize more health resources
      iv. Decreased PCP supply to manage growing health needs
   b. Diabetes management
      i. Highly prevalent especially in Texas
      ii. Treatment is complex and patient-specific
      iii. Pharmacists proven to be effective
   c. Future research
      i. Identify patients most likely to benefit to help increase patient referral
      ii. Improve health outcomes for more patients
References