Community Pharmacist Intervention to Close Statin Gaps in Diabetes Care: The GuIDE-S Study

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Disclosure

Dr. Bacci discloses the following financial relationships with companies related to healthcare products or services:

• UCB Pharma (grant or research support)
Learning Objectives

1. Explain the utility of hybrid implementation-effectiveness study designs in pharmacy practice-based research

2. Describe the potential impact of community pharmacists on closing statin gaps in care in people with type 2 diabetes based on the findings of the GuIDE-S study

3. Recall strategies for partnering with community pharmacies on practice-based research
Background

Statin therapy is recommended for people with type 2 diabetes (T2D) to lower cardiovascular risk\(^1\)

Evidence suggests gaps in statin therapy exist

In 2019, 60-75% of eligible patients received statin therapy\(^2\)

Estimates of statin nonadherence range from 18% to 83%\(^3\)

Community pharmacist intervention is potential strategy to increase statin use in people with T2D


Previous Research

Renner et al.\(^4\)

- **Population:**
  - Patients with T2D aged 40 – 75 years

- **Intervention:**
  - Pharmacists identified eligible patients via lists from EQuIPP platform and then contacted providers by phone or fax

- **Results:**
  - 21% (n=46) patients in intervention group vs. 8.5% (n=17) patients in control group prescribed statin (p<0.001)

Drake et al.\(^5\)

- **Population:**
  - Patients with T2D aged 40 – 75 years

- **Intervention:**
  - Pharmacists identified eligible patients screening algorithm in workflow and then contacted providers by fax

- **Results:**
  - 23% (n=7) patients identified by algorithm received statin

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The GuIDE-S Intervention
Objectives

• Primary:
  • To evaluate the impact of a community pharmacist intervention on statin initiation in people with T2D

• Second:
  • To evaluate the impact of the ongoing intervention on statin adherence in new users with T2D
  • To evaluate pharmacists’ self-reported perceptions of the intervention feasibility and fidelity to the intervention
Implementation Strategies

1. Develop educational materials
   • 15-page manual with protocol, guidelines, forms, and documentation templates

2. Conduct educational meetings
   • Required 90-minute computer-based, accredited continuing education program

3. Conduct educational outreach visits
   • Initial visit to each pharmacy within 2 weeks of online training completion; ongoing visits as needed

4. Remind clinicians
   • Electronic alert in dispensing system to identify eligible patients

5. Alter incentive structure
   • Hosted competitions to recognize and award high performers

6. Audit and provide feedback
   • Intervention completion reports monitored every 2 weeks
Methods

Design
Type 1 hybrid effectiveness-implementation study

Setting
9 intervention and 18 control pharmacies within a large community pharmacy chain in Washington State

Timeframe
Patient enrollment conducted August 8, 2018 – December 31, 2019; 12-month follow-up period concluded December 31, 202
Hybrid Effectiveness-Implementation Studies

Translational Research Pipeline


## Hybrid Effectiveness-Implementation Studies

### Types of hybrid designs

<table>
<thead>
<tr>
<th>Hybrid Type 1</th>
<th>Hybrid Type 2</th>
<th>Hybrid Type 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Aim:</strong></td>
<td><strong>Primary Aim:</strong></td>
<td><strong>Primary Aim:</strong></td>
</tr>
<tr>
<td>Determine effectiveness of an intervention</td>
<td>Determine effectiveness of an intervention</td>
<td>Determine impact of an implementation strategy</td>
</tr>
<tr>
<td><strong>Secondary Aim:</strong></td>
<td><em><em>Co-Primary</em> Aim:</em>*</td>
<td><strong>Secondary Aim:</strong></td>
</tr>
<tr>
<td>Better understand context for implementation</td>
<td>Determine feasibility and/or (potential) impact of an implementation strategy</td>
<td>Assess clinical outcomes associated with implementation</td>
</tr>
<tr>
<td>*or Secondary Aim</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### Implementation Outcomes

<table>
<thead>
<tr>
<th>Implementation Outcome</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adoption</td>
<td>The intention, initial decision, or action to try or employ the service (uptake, utilization, initial implementation, intent to try)</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perceived fit, relevance, or compatibility of the service for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem.</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Perceptions that service is agreeable, palatable, or satisfactory</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent to which a service can be successfully used or carried out within a given agency or setting (suitability or practicability)</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Degree to which the service is implemented as intended (includes adherence, dosage, quality of delivery, participant responsiveness, reach, etc.)</td>
</tr>
<tr>
<td>Cost</td>
<td>The financial impact of an implementation effort (refers to cost of implementation)</td>
</tr>
<tr>
<td>Penetration</td>
<td>Integration of a practice within a service setting and its subsystems (spread)</td>
</tr>
<tr>
<td>Sustainability</td>
<td>The extent to which a newly implemented treatment is maintained or institutionalized with a service setting’s ongoing, stable operations</td>
</tr>
</tbody>
</table>

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## Methods: Statin Initiation and Adherence

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Statin Initiation</th>
<th>Statin Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Quasi-experimental</td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>Adult patients with T2D</td>
<td></td>
</tr>
<tr>
<td><strong>Measure(s)</strong></td>
<td>Receipt of any statin within 12-month of a patient-specific index date</td>
<td>Continuous and categorical proportion of days covered (PDC)</td>
</tr>
<tr>
<td><strong>Data Collection</strong></td>
<td>De-identified patient, prescription, and intervention data extracted from pharmacy dispensing system</td>
<td></td>
</tr>
<tr>
<td><strong>Data Analysis</strong></td>
<td>Cox proportional hazards model</td>
<td>Linear and logistic regression</td>
</tr>
</tbody>
</table>
# Methods: Feasibility and Fidelity

| Outcome          | Feasibility                                      | Fidelity                                                       |
|------------------|--------------------------------------------------|                                                               |
| Design           | Repeated cross-sectional                         |                                                               |
| Participants     | Pharmacists practicing at intervention pharmacies |                                                               |
| Measure(s)       | Intervention Outcomes Questionnaire – Feasibility\(^9\) | Adapted Comprehensive Medication Management Patient Care Process Fidelity Assessment\(^10\) |
| Data Collection  | REDCap survey administered at 6- and 12-months post implementation |                                                               |
| Data Analysis    | Descriptive statistics                           |                                                               |

## Results: Statin Initiation

### Demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control (n=3,358)</th>
<th>Intervention (n=1,679)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (sd)</td>
<td>56.6 (14.8)</td>
<td>55.5 (14.1)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>2,032 (60.5)</td>
<td>960 (57.2)</td>
</tr>
<tr>
<td>Insurance, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>1,872 (55.7)</td>
<td>1,160 (69.1)</td>
</tr>
<tr>
<td>Government</td>
<td>1,332 (39.7)</td>
<td>452 (26.9)</td>
</tr>
<tr>
<td>Self-pay</td>
<td>154 (4.6)</td>
<td>67 (4)</td>
</tr>
<tr>
<td>No. unique medications in previous 12 months, mean (sd)</td>
<td>8.4 (6.1)</td>
<td>7.2 (6.5)</td>
</tr>
<tr>
<td>Fill of any cardiovascular medication in previous 12 months, n (%)</td>
<td>3,182 (94.8)</td>
<td>1,277 (76.1)</td>
</tr>
</tbody>
</table>
Results: Statin Initiation

• 26.3% (n=442) of intervention patients vs. 25.4% (n=854) of control patients initiated a statin within 12 months of their index date

• 2.7% intervention patients (n=12) initiated a statin prescribed by a pharmacist via the collaborative practice agreement (CPA)

• Likelihood of statin initiation was not significantly different between intervention and control patients (adjusted HR: 1.00; 95% CI: 0.83, 1.21)
# Results: Statin Adherence

## Demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control (n=370)</th>
<th>Intervention (n=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (sd)</td>
<td>61.7 (11.3)</td>
<td>57.9 (10.7)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>164 (44)</td>
<td>91 (49)</td>
</tr>
<tr>
<td>Insurance, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>188 (51)</td>
<td>144 (78)</td>
</tr>
<tr>
<td>Government</td>
<td>177 (48)</td>
<td>37 (20)</td>
</tr>
<tr>
<td>Self-pay</td>
<td>5 (1)</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>
# Results: Statin Adherence

## Continuous PDC
- Mean statin PDC was 66.1% in the intervention group vs. 64.5% in the control group
- PDC was 3.1% higher in the intervention group (95% CI: -0.037, 0.098)

## Categorical PDC
- 45.5% of intervention patients had PDC \( \geq 80\% \) vs. 44.1% of control patients
- Patients in the intervention groups were 21.2% more likely to have a PDC \( \geq 80\% \) (95% CI: 0.828, 1.774)
## Results: Feasibility

<table>
<thead>
<tr>
<th>Item</th>
<th>6-months post implementation (n=15)</th>
<th>12-months post implementation (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Slightly – Strongly Disagree</td>
<td>Slightly – Strongly Agree</td>
</tr>
<tr>
<td>The amount of <strong>time</strong> to <strong>implement</strong> this service is manageable.</td>
<td>8 (53.3%)</td>
<td>7 (46.7%)</td>
</tr>
<tr>
<td>The <strong>guidance documents</strong> needed to carry out this service are feasible to use.</td>
<td>3 (20%)</td>
<td>12 (80%)</td>
</tr>
<tr>
<td>The <strong>financial resources</strong> needed to carry out this service are reasonable.</td>
<td>5 (33.3%)</td>
<td>10 (66.7%)</td>
</tr>
<tr>
<td>The <strong>staff</strong> needed to carry out this service is reasonable.</td>
<td>8 (53.3%)</td>
<td>7 (46.7%)</td>
</tr>
<tr>
<td>The <strong>space</strong> needed to carry out this service is reasonable.</td>
<td>4 (26.7%)</td>
<td>11 (73.3%)</td>
</tr>
<tr>
<td>The pharmacist(s) responsible is able to dedicate the appropriate <strong>time</strong> to <strong>deliver</strong> this service.</td>
<td>9 (60%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td>The amount of <strong>time</strong> required for <strong>documentation</strong> of this service is reasonable.</td>
<td>7 (46.7%)</td>
<td>8 (53.3%)</td>
</tr>
<tr>
<td><strong>Preparation</strong> for carrying out this service is reasonable.</td>
<td>5 (20%)</td>
<td>10 (80%)</td>
</tr>
</tbody>
</table>
Results: Feasibility

Feasibility Scores

<table>
<thead>
<tr>
<th>Pharmacist Survey</th>
<th>Feasibility Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-months post implementation</td>
<td>4.0</td>
</tr>
<tr>
<td>12-months postimplementation</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Interpretation:

≥ 3.5: Service is highly likely to be feasible to implement at this site
< 3: Service is less likely to be feasible to implement at this site
## Results: Fidelity

Percent of respondents indicating high fidelity (>80%) to intervention protocol at 6- (n=15) and 12- (n=12) months post implementation

<table>
<thead>
<tr>
<th>Activity</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying &amp; engaging eligible patients</td>
<td>45</td>
<td>35</td>
</tr>
<tr>
<td>Collecting &amp; assessing appropriateness</td>
<td>71</td>
<td>43</td>
</tr>
<tr>
<td>Prescribing &amp; communicating</td>
<td>68</td>
<td>52</td>
</tr>
<tr>
<td>Facilitating &amp; communication</td>
<td>46</td>
<td>24</td>
</tr>
<tr>
<td>Following up after statin initiation</td>
<td>46</td>
<td>47</td>
</tr>
</tbody>
</table>

0 20 40 60 80

- 6 months
- 12 months
**Discussion**

- Among 1st studies to evaluate model for community pharmacists initiating statins via a CPA
- Pharmacists prescribed statin via CPA for small percentage of patients (2.7%) in study
- Difference in time and complexity between initiating statin via CPA and acquiring prescription from another prescriber likely influencers
- CPA alone not sufficient to improve statin use in people with T2D; Patients appear to prefer more collaborative approach
Limitations

- May have been systematic differences between intervention and control sites due to lack of randomization.
- Assumptions were required to calculate patient-specific index dates for statin initiation.
- Controlled for insurance type to account for overrepresentation of patients with government-funded insurance in control group.
- Statin fills at other pharmacies not included in PDC calculation using pharmacy-based fill data.
Conclusions

• Community pharmacist-led intervention resulted in more patients initiating statin therapy and higher statin adherence as compared to usual care; however, differences were not statistically significant

• Opportunities to optimize impact of community pharmacist-led intervention to close statin gaps in care include:
  • Increasing awareness of statin therapy availability among patients
  • Integrating pharmacist-physician communication via the electronic health record
  • Implementing intervention in more structured patient care workflow (e.g., appointment-based model, medication synchronization)
Acknowledgements

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• Zach Marcum
• Tricia Rodriguez
• Tara Pfund
• Jenny Kim

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Publications:
Community – Academic Partnerships for Research

Scholarship

Practice Transformation
The Washington State Experience

**1994**
- Immunizations

**1998**
- Hormonal contraception

**2003**
- Emergency contraception

**2015**
- Clinical Community Pharmacist

**2020**
- State-sponsored COVID-19 testing program

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**Immunizations**

**1994**

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**Hormonal contraception**

**1998**

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**Emergency contraception**

**2003**

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**Clinical Community Pharmacist**

**2015**

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**State-sponsored COVID-19 testing program**

**2020**

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Community – Academic Partnerships

• Community pharmacists are interested in research opportunities to: \textsuperscript{11,12}

  • Improve care delivery

  • Increase knowledge and innovation

  • Change patients’ perspectives

  • Increase patient satisfaction and loyalty


Partnership Framework

- Payer and provider interest indicators:
  1. Mission focus
  2. Operational focus
  3. Innovation focus
  4. Consumer (patient) focus
  5. Move to value-based healthcare
  6. Community focus
  7. Advocacy

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My Lessons Learned

- Invest time in community pharmacy partners and their priorities
- Quality partnerships are built over time
- The best research questions come from practice
- Sustainability
Assessment Question #1

Which of the following is a benefit of hybrid effectiveness-implementation study designs?

a. Decreases the time and cost of conducting practice-based research
b. Increases the likelihood of observing an intervention effect if one exists
c. Decreases the time between development of an evidence-based intervention and routine uptake in practice
d. Increases internal validity
Which of the following was a finding of the GuIDE-S study?

a. The community pharmacists prescribed statin therapy for most enrolled patients via the collaborative practice agreement
b. The community pharmacist intervention resulted in more patients initiating statin therapy
c. The community pharmacists perceived the intervention was less likely to be feasible to implement
d. The community pharmacist intervention decreased statin adherence
Assessment Question #3

Which of the following are indicators that researchers can use to determine strength of alignment when partnering with community pharmacies for research?

a. Innovation focus
b. Mission focus
c. Move to value-based healthcare
d. Patient focus
e. All the above