Statement of Problem

- Medication harm of frail elders: major public health challenge.
- Potentially Inappropriate Medications (PIMs) harm older adults: still used at very high rates.
- Response to these challenges has little cross-system impact: including Medication Therapy Management (MTM) programs not connected to primary care.
- Medication Reconciliation not effective at de-prescribing harmful drugs: may actually perpetuate PIMs.
- System fragmentation endangers frail elders: lack of integration/collaboration persists between patient, caregiver, primary care provider, pharmacy, payer, and health information exchange (HIE).

Objective

Pilot Study aims are:
1. Manualize study design aspects for a future multi-site pragmatic clinical trial;
2. Generate preliminary data to assess study feasibility;
3. Estimate the effect size.

Materials and Methods

- Design: Pragmatic clinical trial – patients randomized to Collaborative Drug Safety Management (CDSM) vs Usual Care
- Setting: Patient Centered Medical Home (PCMH) – A suburban family practice
- Participants: Medicare recipients aged 65+ Goal: 100 To date: 32
- Intervention: CDSM intervention utilizes a pharmacist in the PCMH to make medication safety assessments during the annual wellness visit, with recommendations for deprescribing made in partnership with the patient/caregiver and shared with the provider (future goal of sharing this information across the system)
- Expected Outcome Measures:
  - Rates of deprescribing
  - Rates of unplanned emergency department visits and hospitalization

Results (August 18, 2017 through November 3, 2017)

![View Figure 1 - Eligible Subject Disposition](image)

Table 1 - Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n=15)</th>
<th>Control (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean, range)</td>
<td>77 (66-87)</td>
<td>76 (66-90)</td>
</tr>
<tr>
<td>Sex – Female</td>
<td>9 (60%)</td>
<td>7 (41.2%)</td>
</tr>
<tr>
<td>Meds – mean(SD)</td>
<td>9.6 (3.2)</td>
<td>8.6 (6.1)</td>
</tr>
<tr>
<td>Rx</td>
<td>5.2 (3.2)</td>
<td>5.3 (4.9)</td>
</tr>
<tr>
<td>OTC</td>
<td>4.4 (2.4)</td>
<td>3.4 (2.3)</td>
</tr>
<tr>
<td>Beers’ Meds – mean (range)</td>
<td>1.3 (0-4)</td>
<td>1.4 (0-6)</td>
</tr>
<tr>
<td>Subjects with Beers’ Med</td>
<td>9 (60%)</td>
<td>10 (58.8%)</td>
</tr>
<tr>
<td>Beers (2) – PIM</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Beers (3) – PIM Drug/Disease</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Beers (4) – Caution</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Beers (5) – Drug Interaction</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Beers (6) – Kidney function</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Recommendations Made</td>
<td>5</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Table 2 - Pharmacist’s Time Mean ± SD (minutes)

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>5.3 (1.3)</td>
</tr>
<tr>
<td>Consultation</td>
<td>15.9 (4.3)</td>
</tr>
<tr>
<td>Provider Communication</td>
<td>4.0 (1.7)</td>
</tr>
<tr>
<td>Follow-up &amp; Documentation</td>
<td>5.3 (1.3)</td>
</tr>
<tr>
<td>Total</td>
<td>30.9 (5.8)</td>
</tr>
</tbody>
</table>

Observational data:

- Critical for research team to meet with the care team multiple times to convey study details and confer regarding workflow, in order to:
  1. Minimize research team disruption to the clinical practice workflow.
  2. Enhance care team engagement
- Research team members should provide daily updates and reminders to care team to maximize successful patient study enrollment.

Patient-Pharmacist Interactions

- Patient concern over the high cost of medications, suggesting a potential determinant of non-adherence.
- Patients cited informal caregivers (e.g. a spouse) as more knowledgeable about patient medication lists.

Conclusion

Study Aim status:
1. Manualize study design - Achieved
   - Study workflow integrated into PCMH family practice site.
   - Follow-up data
     - Accessible through practice’s EHR and local HIE.
2. Generate preliminary data - Partially Achieved
   - Baseline Beers list and pharmacist time.
3. Estimate Effect size – Pending

Future Study Plans

A larger pragmatic cluster-randomized trial of primary care practices:
- Practices randomized to CDSM vs usual care.

Enhance CDSM intervention –
- Empower pharmacist integration in primary care (Collaborative Practice)
- Patient/caregiver medication hard stop tools (Empowerment for Successful Aging)
- Electronic systems (Health System Alerts) to disseminate de-prescribing of harmful drugs across the system.

References


Faculty Disclosure

Monte SV discloses ownership in Mobile Pharmacy Solutions. [www.buffalo.edu](http://www.buffalo.edu)
Figure 2 – Beers List Meds by Group

- Testosterone
- Dabigatran
- Bupropion
- Insulin, sliding scale
- Non-benzodiazepine hypnotic
- Diphenhydramine
- Hydralazine
- Aspirin (>80 yo)
- Diltiazem
- Paroxetine
- Alpha blocker
- Bladder anticholinergic
- Amiodarone
- Colchicine
- Warfarin
- NSAID/COX-2
- SSRI
- H2-receptor antagonist
- Opioid
- Benzodiazepine
- Anticonvulsant
- Diuretics
- Proton Pump Inhibitor

Legend: 
- Control
- Intervention