Design of an Ongoing Randomized Controlled Trial

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Overview

- Cluster randomized controlled trial
- 3 insurers (Kaiser Permanente Mid-Atlantic States, Medicare FFS, US Family Health Plan/Tricare)
- 3 medical systems (Kaiser Permanent Mid-Atlantic States, Johns Hopkins Community Physicians, Medstar Physician Partners)
- 8 physician practices in the Baltimore/Washington area
- 49 physicians
- 904 participants and 308 caregivers
Selection of Providers

Practice requirements

• Located in the Baltimore/Washington metropolitan area
• At least 2 teams of physicians that could be matched for randomization
• Each team would have no more then 5 physicians and a total panel of 600 patients or more 65+ years of age
• Interested in participating
• Adequate office space for GCN
Complex Recruitment

• Not enough practices within one medical system (JHCP) to meet requirements
  - not enough older patients
  - no space for nurse
• Extended study to include Kaiser Permanente and Medstar Physician Partners
• Advantages- enriches study sample; study the effects across multiple systems
• Disadvantages- 3 different IRBs, 3 different insurers
# Selection of Providers

<table>
<thead>
<tr>
<th>Sites</th>
<th>Total</th>
<th>Met Eligibility</th>
<th>Selected to Participate</th>
<th># of MDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>JHCP</td>
<td>17</td>
<td>9</td>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td>Kaiser</td>
<td>14</td>
<td>7</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Medstar</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>17</td>
<td>8</td>
<td>49</td>
</tr>
</tbody>
</table>

Physician groups within sites were randomized to either receive Guided Care or Usual Care.
Selection of Participants

Inclusion Criteria

- Age 65+
- Patients of a participating physician with at least one visit in preceding 12 months
- Hierarchical Condition Categories (HCC) score of 1.20 (top 25% highest risk)
  - Diagnoses from previous years’ insurance claims
Selection of Participants

Exclusion Criteria

• Have cognitive impairment with no legal representative

• Would be unable to participate in the baseline or follow-up interviews (e.g., because of communication barrier, inability to be contacted by telephone, or plans for extended travel out of the area)

• Non-English speaking
Recruiting Participants

- Nurse case load of 50-60 patients
- Target recruitment of 65+ participants at each site to enable replenishment during the first year of the study
- Three waves of recruitment
  - Lower the HCC threshold in one insurer to include adequate number of patients
  - Differential consent rates across sites
  - Attrition
13,534 Screened

3,692 Eligible

3,035 Non-Opt Outs

217 Deaths  830 Refused  302 Ineligible  753 Lost to Follow up

933 Consented

8 Administrative Withdrawals

904 Participants Randomized

485 Guided Care

419 Usual Care

21 Administrative Withdrawals
Identifying Caregivers

- Identified during patient baseline interview
- Relatives or unpaid friends who assist patients with health related tasks regardless of intensity or specific types of assistance provided
- Of the 449 caregivers identified, 68.6% (308) were consented to participate in the study
Patient Outcomes

Physical and Mental Health
- SF36 physical and mental component

Quality and Satisfaction with Care
- Patient Assessment of Chronic Illness Care (PACIC)
- Primary Care Assessment Survey (PCAS)

Health Care Utilization
- Claims and encounter data from all 3 insurers
Caregiver Outcomes

Caregiver burden, cost, health and satisfaction with care

- Modified Caregiver Strain Index (CSI)
- EUROQOL
- Work Productivity and Activity Impairment (WPAI)
- Center for Epi Studies Depression Scale (CES-D)
- Modified PACIC
Physician Outcomes & Practice Environment

Physician satisfaction with care provided to older, chronically ill patients
- Managing and coordinating care
- Primary Care Assessment Tool (PCAT)

Practice Environment
- Characterize infrastructure at each site
## Data Collection

<table>
<thead>
<tr>
<th></th>
<th>Completed Data Collection</th>
<th>Future Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient/Caregiver</strong></td>
<td>BL interview</td>
<td>18 month interview (6/08)</td>
</tr>
<tr>
<td></td>
<td>6 month interview</td>
<td></td>
</tr>
<tr>
<td><strong>Physician &amp; Practice Staff</strong></td>
<td>BL survey</td>
<td>2 yr practice staff &amp; PCP survey</td>
</tr>
<tr>
<td></td>
<td>1 yr PCP survey</td>
<td></td>
</tr>
<tr>
<td><strong>Claims</strong></td>
<td>-------</td>
<td>6 month (thru 6/07)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18 month (thru 6/08)</td>
</tr>
</tbody>
</table>
6 Month Follow-up

904 Participants Randomized

485 Guided Care
- 28 Deaths
- 13 Rescinded Consent
- 22 Ineligible
- 5 Declined Interview
- 9 Lost to Follow-up
  → 408 Completed 6 m Interview

419 Usual Care
- 24 Deaths
- 4 Rescinded Consent
- 10 Ineligible
- 5 Declined Interview
- 17 Lost to Follow-up
  → 359 Completed 6 m Interview
## Baseline Socio-Demographics

<table>
<thead>
<tr>
<th></th>
<th>Guided Care (n=485)</th>
<th>Usual Care (n=419)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean yr (range)</td>
<td>77.2 (66-106)</td>
<td>78.1 (66-96)</td>
</tr>
<tr>
<td>% female</td>
<td>54.2</td>
<td>55.4</td>
</tr>
<tr>
<td>% Minority</td>
<td>48.9</td>
<td>51.1</td>
</tr>
<tr>
<td>% Married</td>
<td>46.0</td>
<td>48.5</td>
</tr>
<tr>
<td>Education (% 12+ yrs)</td>
<td>46.4</td>
<td>43.4</td>
</tr>
<tr>
<td>% with just enough or not enough money left over at the end of the month</td>
<td>42.1</td>
<td>48.9</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FFS Medicare</td>
<td>31.7</td>
<td>36.5</td>
</tr>
<tr>
<td>MO 1</td>
<td>26.2</td>
<td>16.0</td>
</tr>
<tr>
<td>MO 2</td>
<td>42.1</td>
<td>47.5</td>
</tr>
</tbody>
</table>
## Baseline Health Status and Function

<table>
<thead>
<tr>
<th></th>
<th>Guided Care (n=485)</th>
<th>Usual Care (n=419)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCC score, mean (95% CI)</strong></td>
<td>2.1 (2.0, 2.1)</td>
<td>2.0 (1.9, 2.0)</td>
</tr>
<tr>
<td><strong>% rated health as fair or poor</strong></td>
<td>39.8</td>
<td>46.8</td>
</tr>
<tr>
<td><strong>Self-reported conditions, mean (out of 14)</strong></td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td><strong>SF36 score, mean (95% CI)</strong></td>
<td>38.7 (38.3, 39.1)</td>
<td>38.1 (37.6, 38.5)</td>
</tr>
<tr>
<td>Physical component</td>
<td>50.3 (49.8, 50.7)</td>
<td>48.7 (48.2, 49.2)</td>
</tr>
<tr>
<td>Mental Component</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Difficulty with 1+ ADL (%)</strong></td>
<td>30.9</td>
<td>29.3</td>
</tr>
<tr>
<td><strong>Difficulty with 2+ IADL (%)</strong></td>
<td>19.6</td>
<td>27.6</td>
</tr>
<tr>
<td><strong>Cognition, mean SPMS</strong></td>
<td>9.1</td>
<td>9.0</td>
</tr>
</tbody>
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