Investigators & Collaborators

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  – Pedro Gozalo PhD
  – Joan Teno MD,

• Statistical Consultant
  – Allan Donner PhD

• Partners
  – Barbara Yody (Genesis)
  – Sherry Johnson (Pruitt)
Background: Nursing Homes

- NHs are complex health care systems
  - 3 million patients admitted annually
  - Rapidly growing % post-acute care
- Patients medically complex with advanced comorbid illness
- NHs charged with guiding patient decisions by default
Background: ACP

• Advance care planning (ACP)
  – Process of communication
  – Care consistent with preferences
  – Leads to advance directives (e.g., DNR, DNH)

• Better ACP associated with improved outcomes

• ACP suboptimal in NHs
  – Not standardized
  – Low advance directive completion rates
  – Not reimbursed
  – Regional and racial/ethnic disparities
Background

- Need to align care with preferences
- ACP reduces hospitalization rates and burdensome treatments
- Focus on hospitalization
  - 15% die in hospital
  - 30-day re-hospitalization rates ~30%
  - Traumatic for patient, costly
  - 23-60% avoidable
Background

• Problems with traditional ACP
  – Ad hoc
  – Knowledge and communications skills of providers variable
  – Scenarios hard to visualize
  – Health care literacy is a barrier
Background: ACP videos

- Presents options for care
- Visual images of options
- Broad goals of care
  - Life prolongation, limited, comfort
- Specific conditions/treatments
  - Metastatic cancer, advanced dementia, CHF, dialysis, hospice, CPR
- Adjunct to counseling
- 6-8 minutes
- Multiple languages
Background: ACP videos

• Completed ‘explanatory’ RCTs
  – Advanced dementia (hypothetical)
    • *BMJ* 2009
  – Advanced cancer (actual patients)
    • *J Clin Onc* 2010; *J Clin Onc* 2013
  – Skilled nursing facility
    • *J Palliat Med*, 2012

• Ongoing ‘explanatory’ RCTs
  – Advanced Dementia (EVINCE); NIH-NIA R01
  – CHF; NIH-NHLBI R01
Background: ACP videos

- Hawaii state-wide implementation
- 11 hospitals, 50 NHs, 9 hospices, 14 out-patient
- Suite of ACP videos, flexible
- “Real-world experience”
  - training materials and program
  - electronic platforms
  - widespread dissemination (not disease specific)
- Evaluations very positive but...
  - Lack of consistent infrastructure
  - No formal evaluation
Background: NH Research

- Electronic Data Sources *(Brown)*
  - Minimum DataSet
  - Medicare linkage
  - Residential History File
  - Facility (OSCAR)
  - Electronic Medical Records in nursing homes

- Generated large body of health services literature

- Emergence of cluster trials
  - Small *(EVINCE)*
  - Large *(e.g., high vs. standard dose influenza vaccine)*
UH 2 Aims

1. Establish organizational structure
2. Establish procedures and infrastructure
3. Pilot 4 intervention NHs (2/chain)
PROVEN: UH3 Aims

Compare patient-level outcomes: intervention vs control NHs

- Hospital transfers, burdensome treatments, Hospice election

TARGET populations:

1. Patients & Residents with advanced comorbid conditions (dementia, CHF, COPD) over 18-months
   \[1^\circ \text{TRIAL OUTCOME} = \text{hospitalization in long stay}\]

2. Long-stay and post-acute patients without advanced comorbid conditions; “Generalized Effect on non-target population”
PROVEN: Setting

<table>
<thead>
<tr>
<th>Characteristics of partner NH Health Systems</th>
<th>Genesis</th>
<th>PruittHealth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities, No.</td>
<td>406</td>
<td>86</td>
</tr>
<tr>
<td>States, No.</td>
<td>28</td>
<td>4</td>
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<tr>
<td>EMR system</td>
<td>PointClickCare™</td>
<td>American Health Tech</td>
</tr>
<tr>
<td>Training Resources</td>
<td>Adobe® Connect™</td>
<td>UHS-Pruitt University</td>
</tr>
</tbody>
</table>
PROVEN: Population

- Intervention facility-wide, all patients are population
- Characterized with existing (2012-13) MDS data

<table>
<thead>
<tr>
<th>Characteristics of total NH population (Genesis/Pruitt)</th>
<th>Genesis</th>
<th>Pruitt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td>Female</td>
<td>61%</td>
<td>61%</td>
</tr>
<tr>
<td>White</td>
<td>78%</td>
<td>69%</td>
</tr>
<tr>
<td>Medicaid*</td>
<td>63%</td>
<td>70%</td>
</tr>
<tr>
<td>Heart failure</td>
<td>23%</td>
<td>26%</td>
</tr>
<tr>
<td>Dementia</td>
<td>27%</td>
<td>33%</td>
</tr>
<tr>
<td>COPD</td>
<td>26%</td>
<td>26%</td>
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</tbody>
</table>

*Percent Medicaid from most recent OSCAR data available
PROVEN: Target Populations

• Advanced comorbid illness patients estimated to accrue by System over 18 months:
  
  **Advanced dementia:** advanced cognitive impairment, Alzheimer’s or non-Alzheimer’s dementia, assistance to eat and transfer
  **Advanced CHF/COPD:** CHF, COPD, breathless with minimal exertion, assistance to ambulate and assistance with at least one other ADL
  **PLUS:** At least one other medical diagnosis.

<table>
<thead>
<tr>
<th>Estimated Target populations (Genesis/Pruitt)</th>
<th>Genesis</th>
<th>PruittHealth</th>
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<tbody>
<tr>
<td>Total No.</td>
<td>317424</td>
<td>47982</td>
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<tr>
<td>Advanced Dementia</td>
<td>21641 (6.8%)</td>
<td>4932 (10.3%)</td>
</tr>
<tr>
<td>Advanced CHF or COPD</td>
<td>18260 (5.8%)</td>
<td>3431 (7.2%)</td>
</tr>
</tbody>
</table>
PROVEN: Proposed Random Assignment Strata

• **Eligibility**: > 50 beds, mixture of short & long-term patients

• **Random Assignment:**

```
Health Care System 1

Low Hospitalization Rate
  - Randomize
    - Intervention
    - Control

High Hospitalization Rate
  - Randomize
    - Intervention
    - Control
```
PROVEN: Intervention

• 18 month intervention period
• Suite of six ACP videos
  – Goals of Care, Advanced Dementia, Hospitalization, Dialysis, Hospice, CPR/MV
• Offered facility-wide
  – All new admits, at care-planning meetings for long-stay and upon readmission from hospital
• Flexible (who, how, which video)
• Tablet devices, internet, corporate websites
• Training: corporate level, webinars, toolkit
PROVEN: Intervention

• New Video Status Report in EMR
  – When was video shown
  – By whom
  – Which Video
PROVEN: Control

• Usual ACP practices
• Recognize programs may be going on in background (i.e., INTERACT)
• Non-differential between arms
PROVEN: Human Subjects

• Seek waiver of individual consent (HHS 45 CFR 46:116)
  – NH unit of random Assignment
  – NH administrators are gatekeepers
  – Facility-wide intervention
  – Minimal risk, cannot be carried out without waiver, patients welfare not adversely affected by waiver
  – Possibility that Brown IRB will NOT consider this to be human subjects research

• DSMB appointed by NIA
PROVEN: Data Flow

- **MDS**: hospitalization, Discharge Dead
- **EMR**
- **Physician Orders**: AD/DNR/DNH
- **Video Status Report**

**Monthly Transmission**

**Project Data Base**

**18 Month Lag**

**CMS Data**: Enrollment Record Fee for Service Claims Hospital, SNF, MD, Drugs, Outpatient

**Bi-Weekly**
UH2 UPDATES
Update: General Structure

- **Meetings**
  - Executive: Weekly
  - Steering: Monthly
  - Working Groups: q2 weeks

- Kick-off meeting October 2 at Brown

- Presentations to corporate leaderships

- Standard Operating Procedures in process
Update: Intervention Group

- Completed suite of six videos
- Completed training materials
  - Toolkit
  - Webinar
  - Quick Reference Guide
- Began pilot study
# Update: Intervention Group

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Update: Pilot Study

• 4 Facilities (2/health care system)
• Intervention implementation
• Data
  – Define analytic cohorts
  – Data exchange
  – Cohort and outcome definition validation
  – Preliminary analysis
• Exit Interviews
Pilot Study Timeline:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
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<tr>
<td>Recruit four facilities</td>
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<td></td>
<td>X</td>
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<tr>
<td>Implementation set up</td>
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<td>X</td>
<td>X</td>
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<td>Staff Training</td>
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<tr>
<td>Intervention Implementation</td>
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<td>X</td>
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<tr>
<td>Program database</td>
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<td></td>
<td>X</td>
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<tr>
<td>Data extraction, merging, and cleaning</td>
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<td>X</td>
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<td>X</td>
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<td>Measurement validation</td>
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<td>Preliminary analyses</td>
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<td>Exit interviews</td>
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</table>
Update: Statistics Group

• How big a difference?
• 1° outcome: hospitalizations among long term care NH residents
• Assumptions
  – Proportion of target patients hospitalized ~ 0.44
  – # of residents per facilities varies between 50 and 200
  – Intra-Class Correlation of outcome across facilities =.06
  – Want to detect a .06 percentage point reduction in probability of Hospitalization
  – Desired Power =.90 and two sided Alpha = .05
• Conservative Sample Size Estimate ~125 facilities/arm
Update: Statistics Group

• Sample Size estimates based on proportion hospitalized, HOWEVER

• Operational outcome is hospitalizations per person month alive in target group
  – Over dispersed Poisson Distribution to account for multiple hospitalizations per person and informative censoring due to death
# Hospitalizations per Person-Year among Target Groups

- **Cardio-Respiratory**:
  - PruittHealth: 3.5
  - Genesis: 2.8

- **Dementia**:
  - PruittHealth: 1.7
  - Genesis: 1.4
Update: Measurement Group

• Cohort Definitions: complete & Coded
• Data Transfer: Arrangements for regular transmission of “warehouse” data
• Prepare for Pilot to identify “target” population
• IRB application scheduled for submission in February following pilot project results
## Update: Human Subjects

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<th>Goal</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
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<td>IRB approval for pilot</td>
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<td>Prepare and Submit IRB for RCT</td>
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<td>Convene DSMB &amp; charter</td>
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## Update: Stakeholder Group

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<tr>
<th>Stakeholder</th>
<th>Group</th>
<th>Representative</th>
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<tbody>
<tr>
<td>Center to Advance Palliative Care</td>
<td>Care delivery</td>
<td>Diane Meier, MD</td>
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<td>Scientific Community</td>
<td>Investigator</td>
<td>Joseph Ouslander, MD</td>
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<td>Patient Quality of Life Coalition</td>
<td>Patient</td>
<td>Daniel Smith, JD</td>
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<tr>
<td>Natl LTC Ombudsman Resource Center/Consumer Voice</td>
<td>Patient</td>
<td>Amity Overall Laib, MS</td>
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<tr>
<td>Excellus BlueCross BlueShield &amp; MedAmerica Insurance Company</td>
<td>Payor</td>
<td>Patricia Bomba, MD</td>
</tr>
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<td>American Health Care Association</td>
<td>Policy</td>
<td>David Gifford, MD, MPH</td>
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<td>National Hospice and Palliative Care Organization</td>
<td>Provider-Hospice</td>
<td>Carol Spence, PhD, RN</td>
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<td>American Medical Directors Association</td>
<td>Providers-MD</td>
<td>Paul Katz, MD, CMD</td>
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<td>National Association Directors of Nursing Administration</td>
<td>Providers-Nurses</td>
<td>Sherrie Dornberger, RN</td>
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<td>American Geriatric Society</td>
<td>Providers/Policy</td>
<td>Jennie Chin Hansen, CEO</td>
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<td>Coalition to Transform Advanced Care</td>
<td>Mixed Coalition</td>
<td>Charlie Sabatino</td>
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<tr>
<td>Family Caregiver Alliance</td>
<td>Family/Patient</td>
<td>Kathy Kelly, Executive Director</td>
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</table>
Challenges

• Academic “Detailing” in pilot study training
• Advance directive ascertainment
• Corporate business agreements (contracting)
• IRB ---determining best approach
• Delay in Medicare Claims Availability