Investigators & Collaborators

• Co-Investigators
  – Constantine Gatsonis PhD
  – Roee Gutman PhD
  – Pedro Gozalo PhD
  – Joan Teno MD

• Statistical Consultant
  – Allan Donner PhD

• NIH
  – Dr. Marcel Salive (NIA)
  – Dr. Jeri Miller (NINR)

• Partners
  – Barbara Yody (Genesis)
  – Sherry Johnson (Pruitt)
PROVEND: Objective

- To conduct a pragmatic cluster RCT of Advance Care Planning video intervention in NH patients with advanced comorbid conditions in 2 NH health systems (Genesis, PruittHealth) (230 NHs)
PROVEN: UH$_2$

Working with NIH Collaboratory...

**UH 2 Aims**

1. Establish organizational structure
2. Establish procedures and infrastructure
3. Pilot 4 intervention NHs (2/chain)
Establish Organizational Structure

- Executive: Weekly
- Steering: Monthly
- Working: q1-2 weeks
- Two special meetings
  - October 2014
  - February 2015
- Collaboratory integration
# PROVEN UH2: Aim 2

## Executive & Steering Committees
- 1m: Oversee all planning activities and coordinate with Executive & Steering Committees.
- 2m: Direct pilot testing.
- 3m: Compile manual of standard operating procedures.
- 4m: Prepare final report & UH3 transition request including budget.

## Facility Recruitment
- 1m: Finalize eligibility criteria.
- 2m: Identify candidate NHs with existing datasources.
- 3m: Prepare recruitment materials and process.
- 4m: Recruit 4 pilot NHs.

## Intervention Refinement
- 1m: Align videos with corporate preferences.
- 2m: Edit existing and create new videos.
- 3m: Program videos on devices.
- 4m: Pilot test intervention.

## Intervention Training Implementation
- 1m: Environmental scan of training infrastructures.
- 2m: Refine and create new training materials.
- 3m: Intervenion training.
- 4m: Pilot implementation.

## Measurement
- 1m: Refine measurement definitions.
- 2m: Finalize data collection protocol.
- 3m: Pilot protocol.
- 4m: Validate measures.

## Data Management
- 1m: Obtain all data use agreements.
- 2m: Create system of data download from NH EMRs.
- 3m: Create merged file with EMR, MDS, Medicare claims & OSCAR.
- 4m: Extract, merge and clean pilot data.

## Statistical Methods
- 1m: Finalize randomization scheme.
- 2m: Finalize analytic plan and sample size estimates.
- 3m: Program pilot dataset.
- 4m: Pilot analysis.

## Human Subjects
- 1m: Review criteria for consent/HIPAA waivers.
- 2m: Create procedures for data safety.
- 3m: Prepare-submit IRB materials.
- 4m: Register Clinical Trials.gov.

## Stakeholder Engagement
- 1m: Meet with Collaboratory's External Stakeholder Advisory Group.
- 2m: Convene an internal stakeholder advisory group.
- 3m: Engage with key stakeholders at existing venues.
- 4m: Engage with key stakeholders at specially arranged meetings.

## Timeline
<table>
<thead>
<tr>
<th>Component</th>
<th>1m</th>
<th>2m</th>
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<th>5m</th>
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PROVEn UH2: Leadership

• Executive and steering committees
  ✔ Major decisions
  ✔ Coordinated working groups
  ✔ Coordinated pilot
  ✔ Prepared
    – Protocol
      ○ Manual of operations
      ○ Transition request
PROVEN UH2: Intervention

• Intervention
  ✓ Refined videos (6 total)
    • Goals of care, advanced dementia, MV, hospice, dialysis, hospitalization

• Training and Implementation
  ✓ Prepared training material (*for pilot*)
    • Toolkit, webinar, quick reference guides
  ✓ Decided on implementation procedures

• Adherence
  ✓ Designed Video Status Report (which, when, to whom, by whom)
  ✓ Loaded in to EMR
Training Toolkit

Table of Contents

Purpose of this Toolkit
I. Introduction
II. The Advance Care Planning (ACP) Videos
III. Using the ACP Videos
   A. When to Show ACP Videos
   B. Choosing an ACP Video
   C. Starting the Conversation
   D. Showing an ACP Video
   E. Continuing the Conversation
   F. Documentation and Translating Preferences into Advance Directives
IV. Implementing an ACP Video Program at Your Skilled Nursing Facility
   A. Get the Right People on Board
   B. Set Goals & Timelines
   C. Key Elements of Implementation
      C.1. Who will show the videos?
      C.2. When will videos be offered?
      C.3. How will videos be shown?
      C.4. How will the ACP Video Program be documented?
      C.5. How will your staff be trained?
      C.6. How will you evaluate your success?
V. Getting Help
Appendices
PROVEN UH2: Facility

• Facility Recruitment/Randomization
  ✓ Finalized eligibility criteria and protocol
    • > 50 beds, mixture of short & long-term, stable organization structure
    • Used existing data: 404/450 NHs
  ✓ Pre-randomization assignment
    • Actively recruit only those assigned to intervention
    • Strong corporate endorsement (~90% participation)
    • Unfair to rescind offer of videos to control
  ✓ Two stratification levels
    • NH system
    • Hospitalization rates in prior year in target groups
PROVEN UH2: Facility

Healthcare Systems (n=450 nursing facilities)

Exclusions: Ineligible facilities (n=46)

Genesis Healthcare (n=339)

Low Hosp. Rate (n=113)
- Randomize (n=64)
  - Treatment (n=32) Control (n=32)

Medium Hosp. Rate (n=113)
- Randomize (n=64)
  - Treatment (n=32) Control (n=32)

High Hosp. Rate (n=113)
- Randomize (n=64)
  - Treatment (n=32) Control (n=32)

PruittHealth (n=85)

Low Hosp. Rate (n=22)
- Randomize (n=13)
  - Treatment (n=7) Control (n=6)

Medium Hosp. Rate (n=22)
- Randomize (n=13)
  - Treatment (n=6) Control (n=7)

High Hosp. Rate (n=21)
- Randomize (n=12)
  - Treatment (n=6) Control (n=6)
PROVEN: Measurement

✓ Refined target group definition with MDS 3.0
  – Advanced dementia, COPD, or CHF

✓ Refined 1º Outcome
  – Hospitalizations/person day-alive over 12 months in long-stay with advanced disease

✓ Estimated with 2012-13 data

<table>
<thead>
<tr>
<th>Target population in Genesis and Pruitt Facilities</th>
<th>Long-stay</th>
<th>Short-stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>35738</td>
<td>159197</td>
</tr>
<tr>
<td>Advanced Disease</td>
<td>15017 (42%)</td>
<td>19024 (12%)</td>
</tr>
</tbody>
</table>
PROVEN: Data Management

- Written contracts between Brown and Health Systems
- Created secure file transfer procedures
- Successfully transferred data in pilot
- Plan for q2-4 data “dumps” from NHs during trial
  - Linkage to Medicare claims at Brown
PROVEN: Statistical Methods

✓ Refined stratification scheme
✓ Refined analysis of primary outcome
  – Hospitalization/person-year alive in target group
  – Zero-inflated Poisson distribution
  – Two part assumption for primary hypothesis
    • Probability of ANY hospitalization will be lower
    • Number of hospitalizations will lower if ever hospitalized
Finalized power calculations

- 103 NHs per arm; recruit 115 to intervention (ITT)

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<thead>
<tr>
<th>Initial Hospitalization rates/year</th>
<th>Effect Size</th>
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<tr>
<td></td>
<td>0.20</td>
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<tr>
<td>1.06</td>
<td>81</td>
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<tr>
<td>1.51</td>
<td>165</td>
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<tr>
<td>2.12</td>
<td>351</td>
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</tbody>
</table>
PROVEN: Human Subjects

• IRB at Brown
  ✓ IRB approval for pilot
  ○ IRB for trial: submitted and pending
    • Minimal Risk
    • Waiver of consent
    • OHRP review April 22

• Data Safety and Monitoring Board
  ✓ Assembled, first meeting April 16

• Data Use Agreements
  ✓ Contracts with health care partners
  ○ Preparing reuse for CMS
  ○ ClinicalTrials.gov
PROVEN: Stakeholders

✓ Established External Advisory Group
  ✓ kick-off meeting February, intro, established mission, review study
    ○ next meeting in May

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Perspective</th>
<th>Representative</th>
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<tbody>
<tr>
<td>Center to Advance Palliative Care</td>
<td>Patient/Provider</td>
<td>D. Meier, MD</td>
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<tr>
<td>Scientific Community</td>
<td>Investigator</td>
<td>J. Ouslander, MD</td>
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<td>Patient Quality of Life Coalition</td>
<td>Patient</td>
<td>D. Smith, JD</td>
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<td>National LTC Ombudsman Resource Ctr</td>
<td>Patient</td>
<td>A. Overall Laib, MS</td>
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<td>Excellus BlueCross BlueShield &amp; MedAmerica</td>
<td>Payor</td>
<td>P. Bomba, MD</td>
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<td>American Health Care Association</td>
<td>Policy</td>
<td>D. Gifford, MD, MPH</td>
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<tr>
<td>National Council of Hospice and Palliative</td>
<td>Providers-Hospice</td>
<td>Carol Spence, PhD</td>
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<td>American Medical Directors Association</td>
<td>Providers-MD</td>
<td>P. Katz, MD</td>
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<td>National Association Directors of Nursing Admin.</td>
<td>Providers-Nurses</td>
<td>S. Dornberger, RN</td>
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<td>American Geriatric Society</td>
<td>Providers/Policy</td>
<td>J. Chin Hansen, RN</td>
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<td>Coalition to Transform Advanced Care</td>
<td>Mixed Coalition</td>
<td>C. Sabatino, JD</td>
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<tr>
<td>Family Caregiver Alliance</td>
<td>Patient</td>
<td>K. Kelly, MPA</td>
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</tbody>
</table>
PROVEN: Pilot study

- 4 intervention NHs (2/site)
- Two-month training; one-month intervention; one-month evaluation
- Training:
  - Toolkit, webinars, on-site Pruitt only, calls
  - Mostly by research team
- Two-IPads, NH loaded with videos
- Data transfer
- Exit interviews
PROVEN: Pilot study

• What went well
  – LOVED the videos, request to keep using
  – No adverse reactions
  – Data transfer successful
  – Video status report: 130 (60 Genesis/70 Pruitt)

<table>
<thead>
<tr>
<th>Patients Features (No.)</th>
<th>All Facilities (N=4)</th>
<th>Genesis Facilities (N=2)</th>
<th>Pruitt Facilities (N=2)</th>
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</thead>
<tbody>
<tr>
<td>Met criteria for advanced dementia</td>
<td>34</td>
<td>24</td>
<td>10</td>
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<tr>
<td>Met criteria for advanced CHF/COPD</td>
<td>21</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>Met criteria advanced dementia or CHF/COPD</td>
<td>55</td>
<td>26</td>
<td>29</td>
</tr>
</tbody>
</table>
PROVEN: Pilot study

• Lessons Learned/Modifications
  – **Training**: Led by corporations
  – **Intervention**: Videos modified, add “healthy patient”
  – **Implementation**:
    – Expand window to 7 days of admission
    – Video status report completed when shown
    – Tablets instead of IPads
    – Two champions/home
PROVEN: Ongoing activities

- Transition Progress Report
- Manual of Procedures
- IRB
- DSMB
- “Planning”