PROVEN: PRagmatic Trial Of Video Education in Nursing Homes

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Background: Nursing Homes

• NHs are complex health care systems
  – 3 million patients 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
  – Ensures care consistent with preferences
  – Leads to advance directives (e.g., DNR, DNH)

• Better ACP associated with improved outcomes
  – Fewer terminal hospitalizations, less burdensome interventions, lower costs, greater family satisfaction

• ACP suboptimal in NHs
  – Process is 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
Advanced dementia video (RCT)

<table>
<thead>
<tr>
<th></th>
<th>Verbal</th>
<th>Video</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=106</td>
<td>N=94</td>
<td></td>
</tr>
<tr>
<td>Life-Prolonging</td>
<td>13%</td>
<td>4%</td>
</tr>
<tr>
<td>Limited</td>
<td>17%</td>
<td>8%</td>
</tr>
<tr>
<td>Comfort</td>
<td>68%</td>
<td>87%</td>
</tr>
<tr>
<td>Undecided</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Volandes, A BMJ;2009
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*)
Background: Pragmatic trial

- NHs engage ALL patients in ACP
- Facility level implementation, patient level outcomes (i.e., cluster design)
- Practical, standardized, feasible intervention
- Corporate ownership of NHs chains; infrastructure for training and implementation
- Electronic data sources; cohort identification and outcome measurement
Proven

Pragmatic cluster RCT of ACP video intervention in NH patients with advanced comorbid conditions in 2 NH health systems (Genesis, PruittHealth) (492 NHs)

UH 2 Aims

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

FIGURE 3.
PROVEN: UH3 Aims

Compare patient-level outcomes: intervention vs control NHs

- Hospital transfers, advance directives, burdensome treatments, Hospice election

TARGET populations:

1. **Long-stay residents** with advanced comorbid conditions (dementia, CHF, COPD) over 12-months
   \[1^\text{o} \text{TRIAL OUTCOME} = \text{hospitalization in long stay}\]

2. **Post-acute care (short-stay) patients** with advanced comorbid conditions

3. **Long-stay and post-acute patients** without advanced comorbid conditions; “**SPILLOVER**”
## 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>
</tr>
<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: Facilities

- **Eligibility:** > 50 beds, short & long-term
- **Randomization:**

![Diagram showing randomization process in Health Care System 1, with subcategories for low and high admission volume, and subsequent randomization and intervention/control assignments.](diagram.png)
PROVEN: Population

- Intervention facility-wide, all patients are population
- Characterized with existing MDS data

<table>
<thead>
<tr>
<th>Characteristics of total NH population (Genesis/Pruitt)</th>
<th>Long-stay</th>
<th>Post-Acute Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean</td>
<td>82</td>
<td>79</td>
</tr>
<tr>
<td>Female</td>
<td>72%</td>
<td>62%</td>
</tr>
<tr>
<td>White</td>
<td>83%</td>
<td>86%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>75%</td>
<td>27%</td>
</tr>
<tr>
<td>Heart failure</td>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td>Dementia</td>
<td>63%</td>
<td>25%</td>
</tr>
<tr>
<td>COPD</td>
<td>18%</td>
<td>24%</td>
</tr>
</tbody>
</table>
PROVEN: Target Populations

• Advanced comorbid illness, identify with MDS data
  Advanced dementia: advanced cognitive impairment, dependent in eating
  Advanced CHF/COPD: CHF or COPD, breathless with minimal exertion, assistance to ambulate
PLUS: diabetes, stroke, CVD, arthritis, hip fx, or other neuro

<table>
<thead>
<tr>
<th>Estimated Target populations (Genesis/Pruitt)</th>
<th>Long-stay</th>
<th>Post-Acute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No.</td>
<td>54702</td>
<td>136905</td>
</tr>
<tr>
<td>Advanced Dementia, CHF, or COPD No. (%)</td>
<td>20144 (37%)</td>
<td>21712 (17%)</td>
</tr>
</tbody>
</table>
PROVEN: Intervention

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

• How close to monitor fidelity?
• New Video Status Report in EMR
  – When was video shown
  – By whom
  – Which Video
• Ongoing discussion
  – Only when a video is shown vs. offered
  – More pragmatic vs. more prescriptive
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

- DSMB
## PROVEN: Data Sources

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Purpose</th>
<th>SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facility-Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case-mix</td>
<td>recruitment</td>
<td></td>
</tr>
<tr>
<td>Admission volume</td>
<td>randomization</td>
<td>X</td>
</tr>
<tr>
<td><strong>Patient-Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic</td>
<td>covariate</td>
<td>X</td>
</tr>
<tr>
<td>Long vs. short-stay</td>
<td>cohort definition</td>
<td></td>
</tr>
<tr>
<td>Functional status</td>
<td>sub-population identification</td>
<td></td>
</tr>
<tr>
<td>Cognitive status</td>
<td>sub-population identification</td>
<td></td>
</tr>
<tr>
<td>Medical condition</td>
<td>sub-population identification</td>
<td>X</td>
</tr>
<tr>
<td>Insurance</td>
<td>covariate</td>
<td>X</td>
</tr>
<tr>
<td>Advance directives</td>
<td>2° outcome</td>
<td>X</td>
</tr>
<tr>
<td>Health services use</td>
<td>1° and 2° outcome</td>
<td></td>
</tr>
<tr>
<td>Burdensome treatments</td>
<td>2° outcome</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>description, competing risk</td>
<td>X</td>
</tr>
<tr>
<td>Video implementation</td>
<td>monitoring fidelity</td>
<td>X</td>
</tr>
</tbody>
</table>
PROVEN: Data Flow

MDS: hospitalization, Discharge Dead
EMR
Physician Orders; AD/DNR/DNH

Video Status Report

Weekly Transmission

Weekly

Project Data Base

One Year Lag

CMS Data Enrollment Record Fee for Service Claims Hospital, SNF, MD, Drugs, Outpatient
PROVEN: Power Estimates

- ¹⁰ outcome: hospitalizations among long term care NH residents

- Assumptions
  - Hospitalization rate per person year = 0.25
  - Intra-class correlation of outcome across facilities = 0.10
  - Power > 0.90
  - # of residents per facilities varies between 10 and 75
  - Effect size of 0.075; alpha = 0.05

- 3341 Residents per arm in ~ 81 NHs
PROVEN: Outcome Analysis

- **Outcome:** Number of hospitalizations per person per month alive.
- **Hypothesis testing** will be performed using randomization test\(^1\) with the test statistic

\[
R_T - R_C, \quad \text{where} \\
R_t = \sum_{j=1}^{J} \sum_{i=1}^{I_j} \frac{d_{ij}}{m_{ij}} \quad t \in \{C, T\}
\]

- \(d_{ij}\) – # of events for person \(i\) in facility \(j\)
- \(m_{ij}\) – # of months alive for person \(i\) in facility \(j\)

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PROVEND: Outcome Analysis

- Confidence interval will be obtained using multilevel hierarchical log-linear model for person level hospitalization rates with facility level random effect.
  \[ r_{ij} \sim \text{Poisson}(\lambda_{ij}) \]
  \[ \log(\lambda_{ij}) = X_{ij}\beta + \beta_T \delta(T_{ij} = 1) + \delta_j \]
  \[ \delta_j \sim N(0, \sigma^2) \]
- The conditional treatment effect will be with \( \hat{\beta}_T \) appropriate confidence interval.
- Similar models with different link functions (e.g. logit) will be used for secondary outcomes.
Issues & Questions

• Documenting the intervention; all who are offered video or only those shown the video?
• How prescriptive should we be?
• Informing residents in intervention arm
• Is the competing risk of death merely a statistical issue since death is not an outcome?