A Cluster Randomized Pragmatic Trial of an Advance Care Planning Video Intervention in Long-Stay Nursing Home Residents with Advanced Illness: Main findings from the PROVEN Trial

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Grand Rounds: A Shared Forum of the NIH HCS Collaboratory and PCORnet
Friday, June 12, 2020 — 1-2 p.m. Eastern Time
Objectives

- Present main findings of PROVEN trial
- Interpret findings
- Discuss implications for pragmatic trials in nursing homes (NHs)
PROVEN

• A pragmatic cluster RCT of an advance care planning (ACP) video intervention embedded within two NH healthcare systems
Rationale

- 1.5 million NH residents with advanced illness
- Burdensome interventions, particularly hospital transfers, are common but often inconsistent with preferences and of little clinical benefit
- ACP modifiable factor but often inadequate
- Video ACP decision support tools address shortcomings of traditional ACP
Rationale: ACP Videos

• Goals of care options with visual images
  – Life prolongation, basic, comfort
• Specific conditions or treatments
• Adjunct to counseling
• 6-8 minutes
# ACP Videos

<table>
<thead>
<tr>
<th></th>
<th>Life Prolonging</th>
<th>Limited</th>
<th>Comfort</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal</strong></td>
<td>Prolong life</td>
<td>Return to level of functioning prior to illness</td>
<td>Maximize Comfort</td>
</tr>
<tr>
<td><strong>Treatment types</strong></td>
<td>All available e.g., CPR, ventilation, ICU care</td>
<td>Conservative treatments for potentially reversible conditions, e.g., antibiotics, IV fluids</td>
<td>Only treatments to reduce suffering, e.g., analgesics, O₂</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Hospital</td>
<td>NH or hospital</td>
<td>Usually NH</td>
</tr>
<tr>
<td><strong>Visual Images</strong></td>
<td>Simulated CPR Ventilated patient Tube-fed advanced dementia patient</td>
<td>Patient in regular hospital bed getting IV therapy</td>
<td>Patient on O₂ in NH bed &amp; getting help with self-care</td>
</tr>
</tbody>
</table>
Rationale: State-of-the Evidence

• PROVEN conceived late 2013
• Several small efficacy RCTs
  – Various populations
  – Video vs. verbal narrative delivered by research team
  – Greater preference for comfort care in video arm
• One pilot RCT in clinical setting
  – Cancer patients shown video by clinicians
  – Increase ACP documentation
• Adopted in clinical care since 2012
HCS-Research Partnership

Health Care Systems Team

- Corporate Leaders: Endorse project, Recruit facilities
- Senior Project Leader: Roll-out system-wide, Design/conduct training, Monitor/motivate fidelity, Liaise with research team
- Facility Champions: Deliver Intervention
- Informatics Lead: Transfer facility data, Insert report in EMR

Research Team

- MPIs: Design trial, Obtain funding, Oversee research, 2/3Masked
- Implementation Team (PD/1 PI): Design & assist with training, Monitor/motivate fidelity, Unmasked
- Data Managers: Receive facility data, Link to CMS data
Regulatory and Data Safety

• Brown Institutional Review Board
  – Minimal risk
  – Waiver of consent
  – NH staff not engaged in research
• Full Data Safety Monitoring Board
• Adverse Event
  – Extreme distress by resident/family
  – None
Facilities

• 360 facilities owned by 2 for-profit NH health care systems

• Eligibility:
  – National survey (OSCAR) and MDS data
    • > 50 beds, short and long stay patients
  – Review by corporate leaders
    • Stable, able to transfer EMR data

• Random assignment at facility level
  – Two levels of stratification:
    • NH chain
      • Prior year hospital transfer rates (terciles)
  – 2:1; control:intervention

• Recruitment
  – Post random assignment
  – Corporate leader ‘informs’ intervention NH administrators
  – No recruitment in control arm
  – Facility administration & staff unaware of trial
Facilities

Total eligible facilities
N=360

Healthcare system 1
eligible facilities
n=297

Intervention
n=98
Control
n=199

Healthcare system 2
eligible facilities
n=63

Intervention
n=21
Control
n=42
Participants

• Enrollment: 02/02/16-05/31/18
• 12-month f/u each resident; ends 06/01/19
• Population
  – All patients in NH during enrollment period
• Target population with advanced illness
  – Greatest opportunity to benefit from ACP
  – Medicare beneficiaries
  – > 65, long-stay (>100 days)
  – Advanced dementia, CHF or COPD based on MDS
  – Met criteria at start or during enrollment period
Intervention

- Suite of 5 videos
- Tablet (2/NH) or online
- 2 Champions/NH
  - Social Worker
- Offer video to resident or proxy:
  - Baseline
  - Admission
  - Q6months
  - Ad hoc
- Could choose video
- English or Spanish
Control

• Usual advance care planning practice
• Allowed other programs targeting improved ACP or reduced hospital transfers
Implementation and Training

• Began 01/16
• 4 waves, 30 NHs/wave
• 1-month training
  – Webinars
  – Printed Toolkit
  – Pocket Cards
• Modality
  – HCS 1, Webinar
  – HCS 2, In-person
Measuring Fidelity

• Video Status Report User-Defined Assessment (VSR UDA) programmed in EMR
• Each time a video is offered a VSR completed – even if a video is not shown.
• If shown: who watched, which video... etc
• Each time staff distribute the Web Site url to families
• Used for feedback reporting
Monitoring Fidelity and Adaptations

• VSR linked to resident-level MDS data
• Create facility reports
  – % targeted residents offered/shown a video
• Q2month calls with ACP champion, HCS senior project manager, implementation team
• January 2017 steps take to increase fidelity
  – Calls increased to q1month and made 1:1
  – List of actual residents not offered video reviewed
  – Site visits by senior project manager
Data Sources and Flow

FACILITY EMR
1. Minimum Data Set
2. Video Status Report

Monthly Transmission

Project Data Base

VRDC

CMS Data
Enrollment Record
Fee for Service Claims
Hospice Claims
PROVEN: Primary Outcome

• No. hospital transfers/1000 person-days alive among long-stay (> 100 days) Medicare beneficiaries ≥ 65 with advanced dementia, CHF or COPD
• Medicare Claims
• Transfers = admissions, observation stays, or emergency room visits
• Up to 12-month follow-up
• Switch to MA: last date of FFS Medicare coverage
Secondary Outcomes

• Over 12 months
• % residents with ≥ 1 hospital transfer (Medicare claims)
• ≥ 1 burdensome intervention (Medicare claims & MDS)
  – Tube-feeding
  – Parenteral Therapy
  – Mechanical Ventilation
  – Intensive Care Unit Admission
• Hospice enrollment (Medicare Claims)
• (Death: not an outcome, descriptive only, Medicare vital status file)
Analysis

• Intention-to-treat
• Hierarchical models adjust for clustering
• Hospital transfers/1000 person-days
  – Multi-level zero inflated Poisson distribution
  – 2-sided test of difference in marginal means with SEs
  – Marginal rate differences with 95% CIs
• Binary outcomes
  – Logistic regression
  – Marginal risk differences with 95% CIs
Sample Size & Power Estimates

- Based on primary outcome
- Assumed Poisson distribution
- \( \sim 1.5 \) hospital transfers/person-year in control
- 90% power
- 0.25 rate reduction (16% relative reduction)
- 119 NHs/arm; 4998 subjects/arm (\( \sim 42/\text{NH} \))
- 360 NHs available; 2 (control) : 1 (intervention)
  - NHs: Control, \( N=241 \); Intervention, \( N=119 \)
  - Subjects: Control, \( N=10122 \); Intervention, \( N=4998 \)
Results: Consort

454 Nursing Homes Assessed for Eligibility

- 82 Compliance problems
- 12 Unable to transmit electric health data

360 Randomized Nursing Homes

119 Nursing Homes in Intervention Arm
6211 Enrolled Residents with Advanced Illness

Residents
- 376 < 65 years
- 1425 Not Medicare
- 8 Died before start
- 231 Unable to link to Medicare claims

119 Nursing Homes in Primary Outcome Analysis
4171 Residents in Primary Outcome Analysis

241 Nursing Homes in Control Arm
12488 Enrolled Residents with Advanced Illness

Nursing Homes
- 1 sold by prior to start of intervention

Residents
- 696 < 65 years
- 2963 Not Medicare
- 15 Died before start
- 506 unable to link to Medicare claims

240 Nursing Homes in Primary Outcome Analysis
8308 Residents in Primary Outcome Analysis
## Results: Subject Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N=4172)</th>
<th>Control (N=8307)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>83.6 (9.1)</td>
<td>83.6 (8.9)</td>
</tr>
<tr>
<td>Female, %</td>
<td>71.2</td>
<td>70.5</td>
</tr>
<tr>
<td>White, %</td>
<td>78.4</td>
<td>81.5</td>
</tr>
<tr>
<td>Advanced dementia, %</td>
<td>68.6</td>
<td>70.1</td>
</tr>
<tr>
<td>Advanced CHF/COPD, %</td>
<td>35.4</td>
<td>33.4</td>
</tr>
<tr>
<td>Hospice at baseline, %</td>
<td>34.2</td>
<td>34.6</td>
</tr>
<tr>
<td>Activities of daily living score (0-28), mean (SD)</td>
<td>21.8 (3.8)</td>
<td>21.9 (3.8)</td>
</tr>
<tr>
<td>Mortality risk score (0-39), mean (SD)</td>
<td>7.6 (2.9)</td>
<td>7.6 (2.8)</td>
</tr>
<tr>
<td>Died during follow-up, %</td>
<td>43.8</td>
<td>45.3</td>
</tr>
<tr>
<td>Days of follow-up, mean (SD)</td>
<td>253.1 (136.2)</td>
<td>252.6 (135.1)</td>
</tr>
</tbody>
</table>
# Results: Outcomes

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Intervention N=4171</th>
<th>Control N=8308</th>
<th>Marginal Rate Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital transfers/1000 person-days alive</td>
<td>3.7 (0.2) (3.4-4.0)</td>
<td>3.9 (0.3) (3.6-4.1)</td>
<td>-0.2 (0.3) (-0.5,0.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Percent (SE) (95% CI)</th>
<th>Marginal Risk Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1 hospital transfer</td>
<td>40.9 (1.2) (38.4-43.2)</td>
<td>-0.7 (1.5) (-3.7, 2.3)</td>
</tr>
<tr>
<td>≥ 1 burdensome treatment</td>
<td>9.6 (0.8) (8.0,11.3)</td>
<td>-1.1 (1.1) (-3.2,1.1)</td>
</tr>
<tr>
<td>Enrolled in hospice*</td>
<td>24.9 (1.2) (22.6, 27.2)</td>
<td>-0.6 (1.5) (-3.4, 2.4)</td>
</tr>
</tbody>
</table>

*Excluded residents enrolled in hospice at baseline*
Fidelity

- 55.6% advanced illness residents (or proxies) offered a video
- 21.6% advanced illness residents (or proxies) shown a video
- Variability across facilities
Summary

• In this pragmatic cluster RCT, a ACP video intervention was not effective in significantly:
  – Reducing hospital transfers
  – Reducing burdensome interventions
  – Increasing hospice enrollment

• Fidelity
  – Low
  – Variable across facilities
Interpretation

• Three main points to consider
  – Efficacy of videos
  – Intervention fidelity
  – Outcome selection
Interpretation: Efficacy

• State of evidence when PROVEN was designed
  – Small traditional RCTs demonstrate increase in preference for comfort care
  – Only small pilot in actual clinical care setting
  – Little downstream known about outcomes or integration in care

• Emerging evidence during conduct of PROVEN
## Interpretation: Efficacy

**An Advance Care Planning Video Decision Support Tool for Nursing Home Residents With Advanced Dementia: A Cluster Randomized Clinical Trial**

<table>
<thead>
<tr>
<th>Domain</th>
<th>EVINCE</th>
<th>PROVEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage</td>
<td>Efficacy</td>
<td>Effectiveness</td>
</tr>
<tr>
<td>Setting</td>
<td>64 Boston-area NHs</td>
<td>360 NHs in 2 HCS</td>
</tr>
<tr>
<td>Randomization</td>
<td>Cluster; NH-level</td>
<td>Cluster; NH-level</td>
</tr>
<tr>
<td>Participants</td>
<td>Advanced dementia pts with consent</td>
<td>All patients w/ advanced illness</td>
</tr>
<tr>
<td>Intervention</td>
<td>Single video shown by research staff</td>
<td>Suite of videos embedded in workflow</td>
</tr>
<tr>
<td>Delivery/Adherence</td>
<td>Tightly controlled</td>
<td>Up to NH Champion</td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Outcome</td>
<td>Do-not-hospitalize order</td>
<td>Hospitalizations</td>
</tr>
<tr>
<td>Data collection</td>
<td>By research staff</td>
<td>Existing data</td>
</tr>
</tbody>
</table>

*Published online June 4, 2018.*

*Mitchell SL, JAMA IM 2018*
Interpretation: EVINCE Trial

<table>
<thead>
<tr>
<th>6-Month Outcome</th>
<th>Intervention N=211</th>
<th>Control N=189</th>
<th>Adjusted Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort Care</td>
<td>73%</td>
<td>77%</td>
<td>0.96 (0.58-1.58)</td>
</tr>
<tr>
<td>Do-not-hospitalize order</td>
<td>63%</td>
<td>63%</td>
<td>1.08 (0.69-1.69)</td>
</tr>
</tbody>
</table>

- **Intervention**
  - Not integrated into clinical care
  - Fundamentally difference that PROVEN
- **Population**
  - 60% wanted comfort care at beginning
  - Too late in disease course
  - Only those that consented
- **Outcome**
  - Did not capture not most important effect of enhanced ACP
Interpretation: Fidelity

• Only 1/5 targeted residents shown a video
• “Implementation error”
• Per-protocol analysis
  – Not straightforward
  – Intention-to-treat better captures “real world messiness”
Interpretation: Fidelity

• New program uptake in NHs is very challenging
  – Very little bandwidth
  – A lot of turnover
  – Highly variable in quality

• Early PROVEN papers, higher show rate in NHs with...
  – Better quality rating
  – Less turnover
  – Great champion engagement (e.g., meeting attendance)
Interpretation: Outcome

• Hospital transfer rate
  – Important to stakeholders
  – Ascertainable with secondary data

• ‘Care consistent with goals’
  – Most important according to palliative care experts
  – Very hard to ascertain pragmatically

Goal-Concordant Care — Searching for the Holy Grail

Scott D. Halpern, M.D., Ph.D.  N ENGL J MED 381;17  NEJM.ORG  OCTOBER 24, 2019
Limitations

• Secular decline in hospital transfer rate
  – Acceptable in pragmatic trial
  – Non-differential between arms

• Inadequate power
  – Control (8307 vs 10222); Intervention (4171 vs 4998)
  – High mortality and MA plan enrollment

• No information on videos impact on decision-making
  – Advance directive data not consistently available
Implications

• Results are sobering
• Consider from stakeholder perspectives
• Clinicians, patients, families
  – Widely adoptable, effective interventions to improve ACP in NHs is elusive
• Palliative care researchers
  – How to capture goal concordant care
• Pragmatic trialists/implementation scientists in NHs
  – High level of endorsement from c-suite to front-line needed prior to embarking on ePCT
Thank You

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