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

PROVEN
PRagmatic Trial of Video Education in Nursing Homes

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Presentation to Pruitt Health Care Leadership
Wednesday, July 15, 2020 — 10:30 a.m. Eastern Time
Objectives

- Present main findings of PROVEN trial
- Interpret findings
- Discuss implications for Dissemination of Advance Care Planning in Pruitt facilities
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>Life Prolonging Care</th>
<th>Limited Medical Care</th>
<th>Comfort Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Goal to prolong life</td>
<td>• Goal is to return to prior level of physical functioning before illness</td>
<td>• Goal is to maximize comfort</td>
</tr>
<tr>
<td>• Wants all available treatments including: cardiopulmonary resuscitation (CPR), Mechanical Ventilation, and Intensive Care Unit (ICU)</td>
<td>• Treat reversible conditions</td>
<td>• Only treatments to relieve suffering, such as oxygen and analgesics</td>
</tr>
<tr>
<td>• Care can only be provided in hospital</td>
<td>• May include hospitalization, intravenous fluids, antibiotics</td>
<td>• NO CPR, ICU, Mechanical Ventilation or intravenous fluids</td>
</tr>
<tr>
<td></td>
<td>• NO CPR, ICU, or Mechanical Ventilation</td>
<td>• Usually cared for at skilled nursing center; hospitalize only if needed for comfort</td>
</tr>
</tbody>
</table>
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
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

Goals of Care for Any Patient*
This video helps patients understand and make decisions about their goals of care.

Goals of Care for Patients with Advanced Dementia
This video helps family members understand and make decisions for patients with advanced dementia.

Decisions about Hospice*
This video helps patients and their families understand and make decisions about hospice care.

Decisions about Hospitalization*
This video helps patients understand and make decisions about hospitalization.

General Information about Advance Care Planning for Healthy Adults*
This video helps generally healthy patients understand and make decisions about their long-term health goals.
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

VDRC

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, emergency room visits

• Up to 12-month follow-up

• Switch to MA: last date of FFS Medicare coverage
Facility & Patient Selection Results

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
- 1424 Not Medicare
- 8 Died before start
- 231 Unable to link to Medicare claims

119 Nursing Homes in Primary Outcome Analysis
- 4172 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
- 2964 Not Medicare
- 15 Died before start
- 506 unable to link to Medicare claims

240 Nursing Homes in Primary Outcome Analysis
- 8307 Residents in Primary Outcome Analysis
### Results: Subject Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N=4171)</th>
<th>Control (N=8308)</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

*Excluded residents enrolled in hospice at baseline

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Intervention N=4171 Rate (SE) (95% CI)</th>
<th>Control N=8308 Rate (SE) (95% CI)</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% confidence interval)</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>
Fidelity

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

![Diagram showing percentage of advanced illness residents shown videos across facilities]
Summary

• In this pragmatic cluster RCT, an 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

• Studies emerged during conduct of PROVEN
EVINCE Trial (not pragmatic)

<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 orders</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 (videos shown by research staff)
  - 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

Mitchell SL, JAMA IM 2018
PROVEN: Fidelity

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

• Hard to introduce and sustain new programs
  – Very little bandwidth
  – Staff turnover
  – Variability in managerial ability and quality

• We found 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 measure
Implications for Researchers

• Results are sobering
• Consider from stakeholder perspectives
• Clinicians, patients, families
  – Widely adoptable, effective NH interventions to improve ACP is elusive
• Pragmatic trialists/Implementation scientists in NHs
  – Leadership endorsement is not enough; front line staff buy in needed
Implications for PRUITT Healthcare

• Subset of Genesis NHs had workable MD orders on advance directives
• Did find that DNR/DNH more likely to be there for patients in intervention homes
• Pruitt ISNP program has incentive to reduce hospital transfers
• Can use MDS/EMR to target long stay cases to have focused discussion with NP/MD
• Would Results be the same?
Thank You

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