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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MGH 1811

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

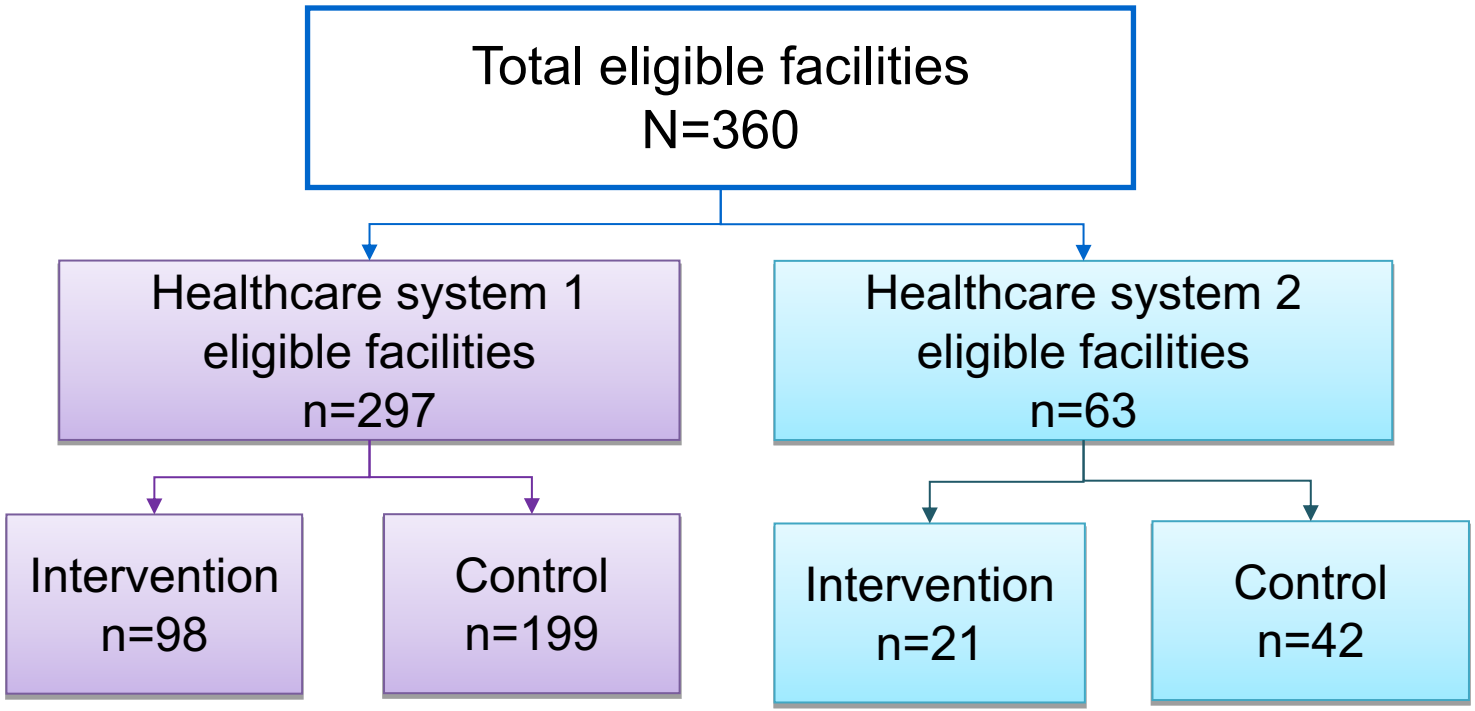
ACP Videos

Life Prolonging Care	Limited Medical Care	Comfort Care
• Goal to prolong life • Wants all available treatments including: cardiopulmonary resuscitation (CPR), Mechanical Ventilation, and Intensive Care Unit (ICU) • Care can only be provided in hospital	• Goal is to return to prior level of physical functioning before illness • Treat reversible conditions • May include hospitalization, intravenous fluids, antibiotics • **NO** CPR, ICU, or Mechanical Ventilation • Care may be provided in skilled nursing center or hospital	• Goal is to maximize comfort • Only treatments to relieve suffering, such as oxygen and analgesics • NO CPR, ICU, Mechanical Ventilation or intravenous fluids • Usually cared for at skilled nursing center; hospitalize only if needed for comfort

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



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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 on-line
- 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**

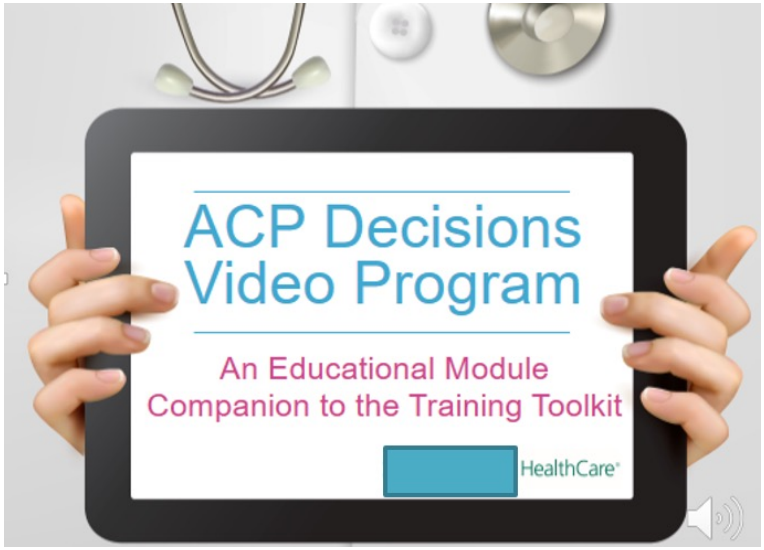
This video helps patients understand and make decisions about hospitalization.

*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



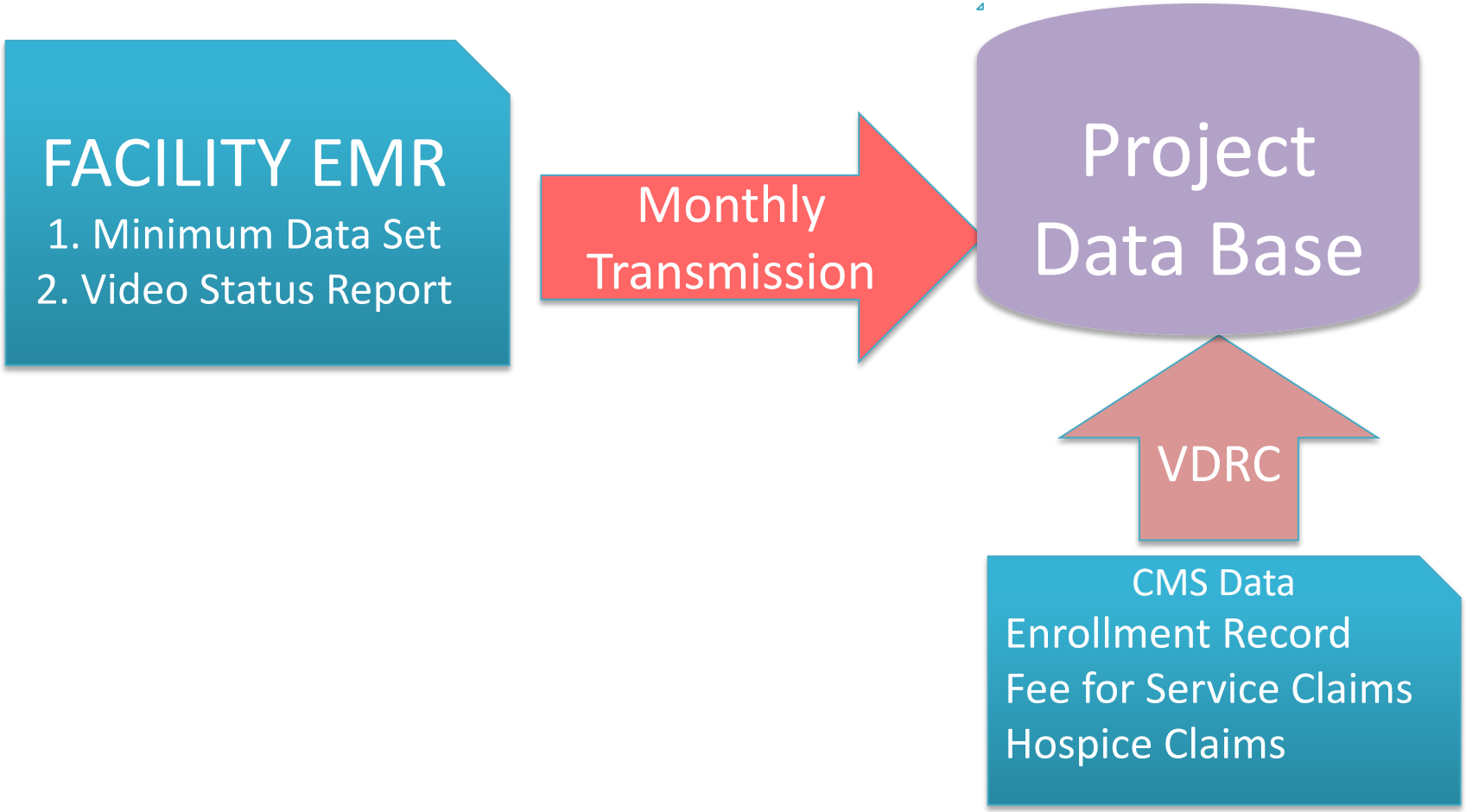
Measuring Fidelity

- 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

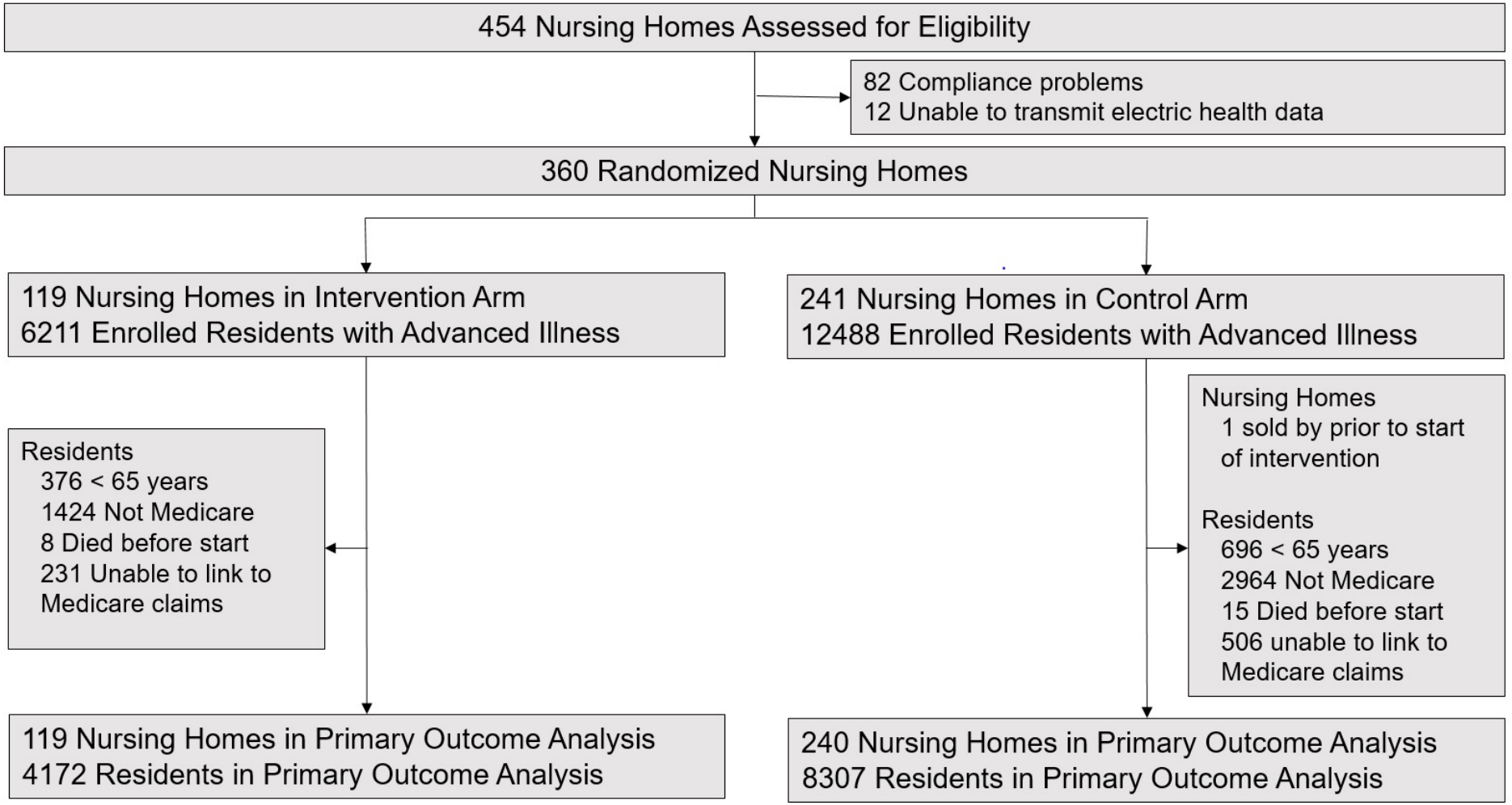
Data Sources and Flow



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



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Results: Subject Characteristics

Characteristic	Intervention (N=4171)	Control (N=8308)
Age, mean (SD)	83.6 (9.1)	83.6 (8.9)
Female, %	71.2	70.5
White, %	78.4	81.5
Advanced dementia, %	68.6	70.1
Advanced CHF/COPD, %	35.4	33.4
Hospice at baseline, %	34.2	34.6
Activities of daily living score (0-28), mean (SD)	21.8 (3.8)	21.9 (3.8)
Mortality risk score (0-39), mean (SD)	7.6 (2.9)	7.6 (2.8)
Died during follow-up, %	**43.8**	**45.3**
Days of follow-up, mean (SD)	253.1 (136.2)	252.6 (135.1)

Results: Outcomes

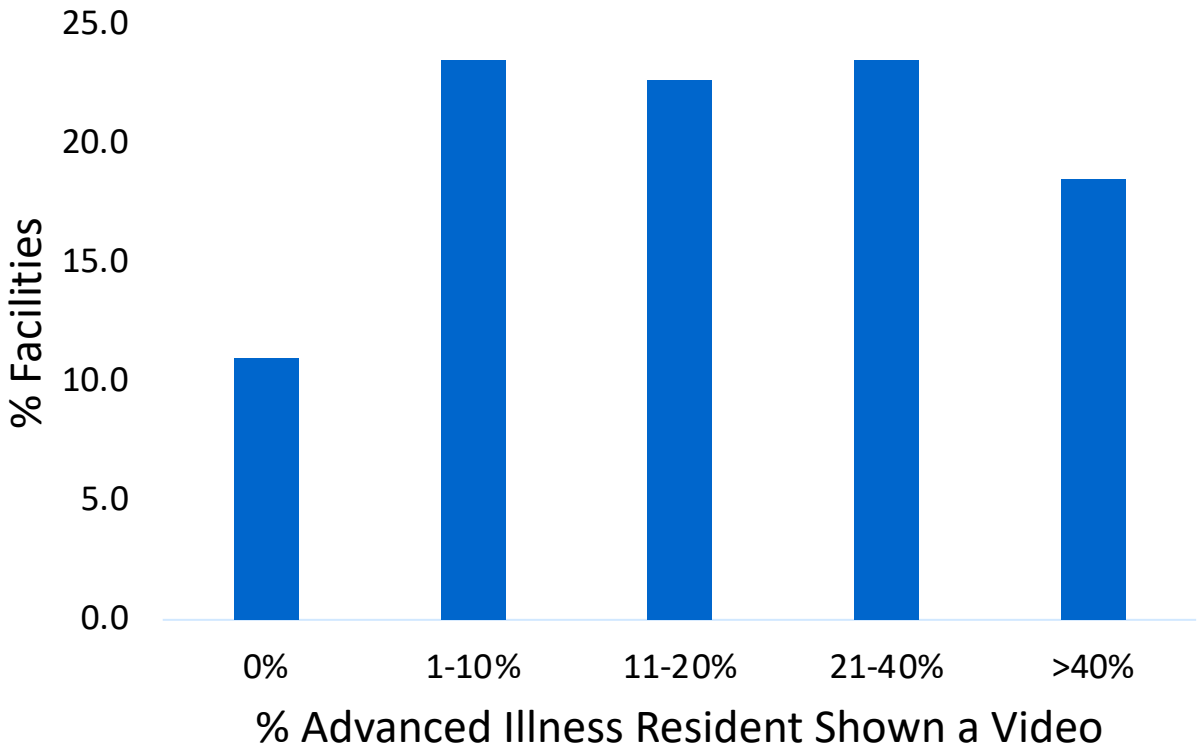
Primary Outcome	Intervention N=4171 Rate (SE) (95% CI)	Control N=8308 Rate (SE) (95% CI)	Marginal Rate Difference (SE) (95% CI)
Hospital transfers/1000 person-days alive	3.7 (0.2) (3.4-4.0)	3.9 (0.3) (3.6-4.1)	-0.2 (0.3) (-0.5,0.2)

Secondary Outcomes	Percent (SE) (95% confidence interval)		Marginal Risk Difference (SE) (95% CI)
≥ 1 hospital transfer	40.9 (1.2) (38.4-43.2)	41.6 (0.9) (39.7,43.3)	-0.7 (1.5) (-3.7, 2.3)
≥ 1 burdensome treatment	9.6 (0.8) (8.0,11.3)	10.7 (0.7) (9.4,12.1)	-1.1 (1.1) (-3.2,1.1)
Enrolled in hospice*	24.9 (1.2) (22.6, 27.2)	25.5 (0.9) (23.3,27.2)	-0.6 (1.5) (-3.4, 2.4)

**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
- Studies emerged during conduct of PROVEN

EVINCE Trial (not pragmatic)

6-Month Outcome	Intervention N=211	Control N=189	Adjusted Odds ratio (95% CI)
Comfort Care orders	73%	77%	0.96 (0.58-1.58)
Do-not-hospitalize order	63%	63%	1.08 (0.69-1.69)

- 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

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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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