

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



PRagmatic Trial of Video Education in Nursing Homes

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Grand Rounds: A Shared Forum of the NIH HCS Collaboratory and PCORnet
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Objectives

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

PROVEN

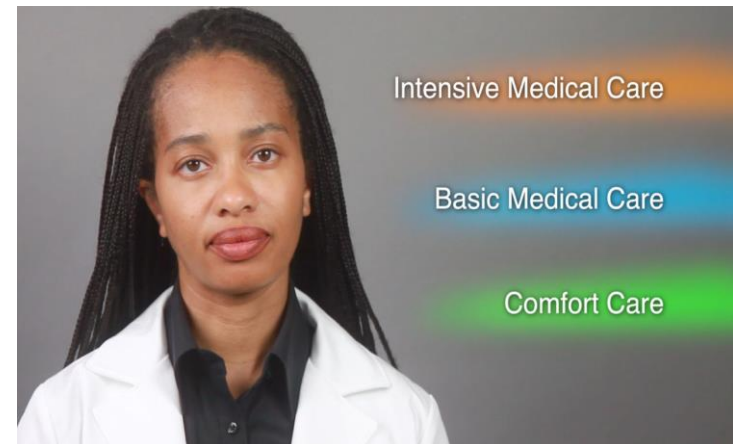
- A pragmatic cluster RCT of an advance care planning (ACP) video intervention embedded within two NH healthcare systems

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

	Life Prolonging	Limited	Comfort
Goal	Prolong life	Return to level of functioning prior to illness	Maximize Comfort
Treatment types	All available e.g., CPR, ventilation, ICU care	Conservative treatments for potentially reversible conditions, e.g., antibiotics, IV fluids	Only treatments to reduce suffering, e.g., analgesics, O ₂
Setting	Hospital	NH or hospital	Usually NH
Visual Images	Simulated CPR Ventilated patient Tube-fed advanced dementia patient	Patient in regular hospital bed getting IV therapy	Patient on O ₂ in NH bed & getting help with self-care

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

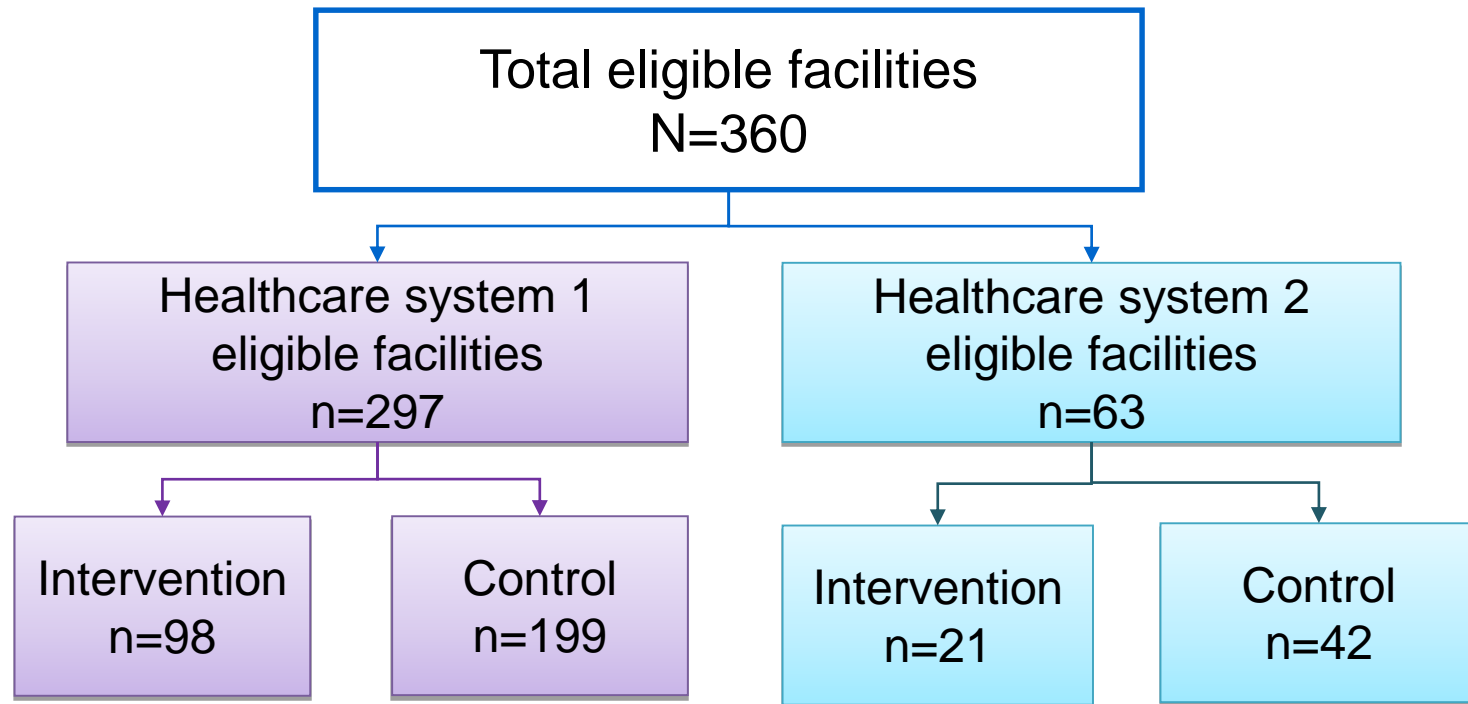
Regulatory and Data Safety

- 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



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**

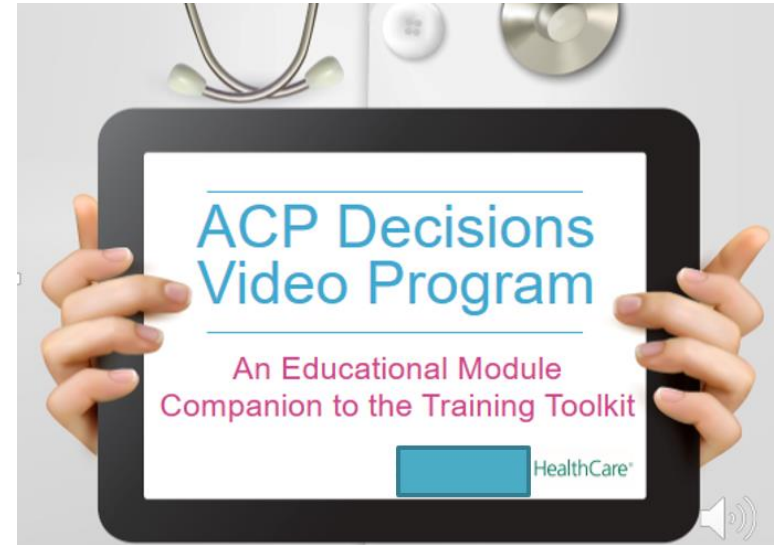
This video helps generally healthy patients understand and make decisions about their long-term health goals.

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



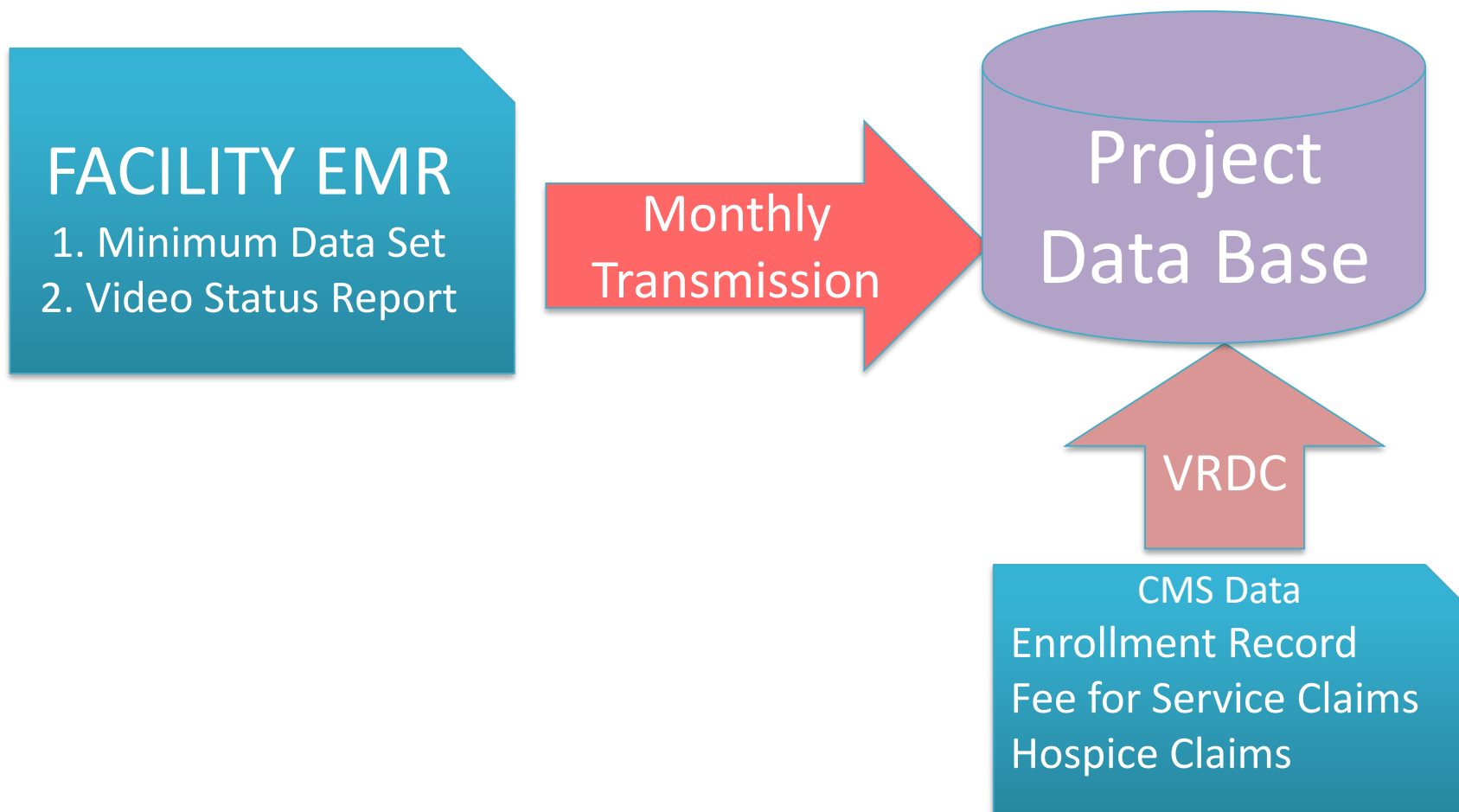
Measuring Fidelity

- 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



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)

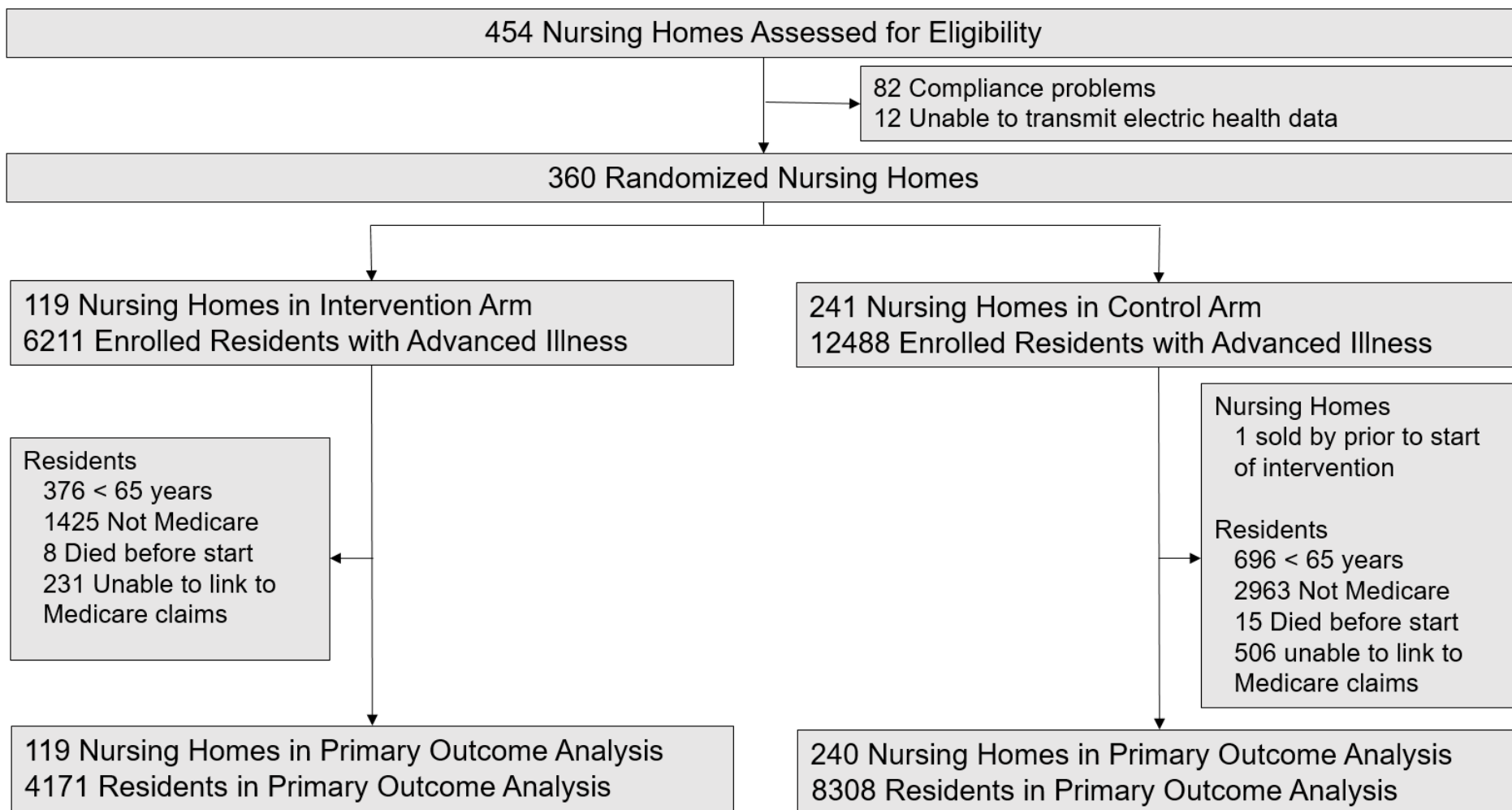
Analysis

- 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
- ~1.5 hospital transfers/person-year in control
- 90% power
- 0.25 rate reduction (16% relative reduction)
- 119 NHs/arm; 4998 subjects/arm (~42/NH)
- 360 NHs available; 2 (control):1(intervention)
 - NHs: Control, N=241; Intervention, N=119
 - Subjects: Control, N=10122; Intervention, N=4998

Results: Consort



Results: Subject Characteristics

Characteristic	Intervention (N=4172)	Control (N=8307)
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)

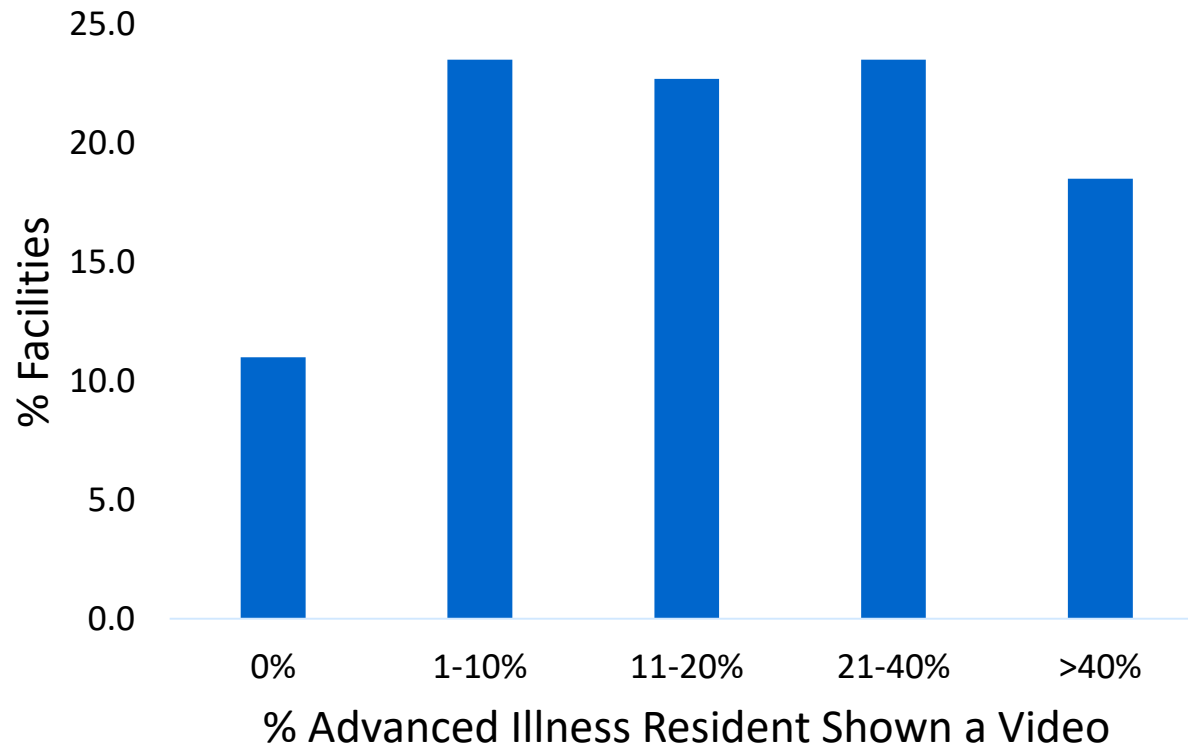
Results: Outcomes

Primary Outcome	Intervention N=4171	Control N=8308	Marginal Rate Difference (SE) (95% CI)
	Rate (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% CI)		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
- Emerging evidence during conduct of PROVEN

Interpretation: Efficacy

JAMA Internal Medicine | Original Investigation

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

Published online June 4, 2018.

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

Interpretation: EVINCE Trial

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

- 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”

The NEW ENGLAND JOURNAL of MEDICINE

STATISTICS IN MEDICINE

Per-Protocol Analyses of Pragmatic Trials

Miguel A. Hernán, M.D., Dr.P.H., and James M. Robins, M.D.

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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