

PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Vince Mor, PhD

Susan L Mitchell MD, MPH

Angelo Volandes MD, MPH



Investigators & Collaborators

- Co-Investigators
 - Constantine Gatsonis PhD
 - Roe Gutman PhD
 - Pedro Gozalo PhD
 - Joan Teno MD
- Statistical Consultant
 - Allan Donner PhD
- NIH
 - Dr. Marcel Salive (NIA)
 - Dr. Jeri Miller (NINR)
- Partners
 - Barbara Yody (Genesis)
 - Sherry Johnson (Pruitt)

PROVEN: Objective

- To conduct a pragmatic cluster RCT of Advance Care Planning video intervention in NH patients with advanced comorbid conditions in 2 NH health systems (Genesis, PruittHealth) (230 NHs)

PROVEN: UH₂

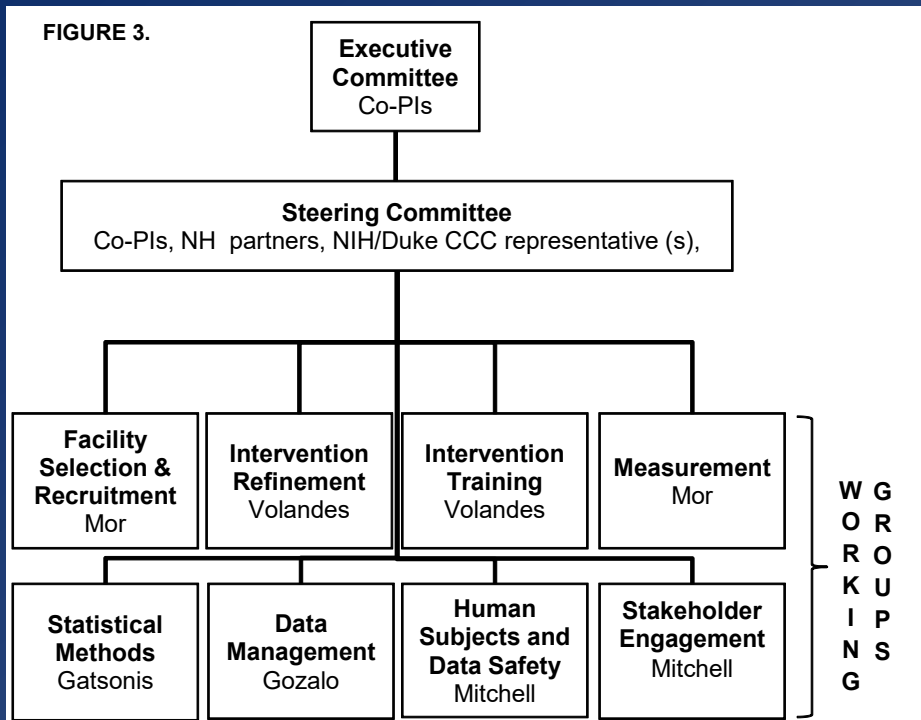
Working with NIH Collaboratory...

UH 2 Aims

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

PROVEN UH₂: Aim 1

➤ Establish Organizational Structure



- ✓ Executive: Weekly
- ✓ Steering: Monthly
- ✓ Working: q1-2 weeks
- ✓ Two special meetings
 - October 2014
 - February 2015
- ✓ Collaboratory integration

PROVEN UH₂: Aim 2

Component	1m	2m	3m	4m	5m	6m	7m	8m	9m	10m	11m	12m	
EXECUTIVE & STEERING COMMITTEES	Oversee all planning activities and coordinate with												
	Compile manual of standard operating procedures							Direct pilot testing		Prepare final report & UH3 transition request including budget			
FACILITY RECRUITMENT	Finalize eligibility criteria	Identify candidate NHs with existing datasources			Prepare recruitment materials and process			Recruit 4 pilot NHs					
INTERVENTION REFINEMENT	Align videos with corporate preferences		Edit existing and create new videos		Program videos on devices			Pilot test intervention					
INTERVENTION TRAINING IMPLEMENTATION	Environmental scan of training infrastructures			Refine and create new training materials				Intervention training	Pilot implementation				
MEASUREMENT	Refine measurement definitions			Finalize data collection protocol				Pilot protocol		Validate measures			
DATA MANAGEMENT	Obtain all data use agreements				Create system of data download from NH EMRs				Create merged file with EMR, MDS, Medicare claims & OSCAR			Extract, merge and clean pilot data	
STATISTICAL METHODS	Finalize randomization scheme		Finalize analytic plan and sample size estimates				Program pilot dataset			Pilot analysis			
HUMAN SUBJECTS	Review criteria for consent /HIPAA waivers			Create procedures for data safety		Prepare/submit IRB materials				Register Clinical Trials.gov			
	Obtain all data use agreements				Set up DSMB								
STAKEHOLDER ENGAGEMENT	Meet with Collaboratory's External Stakeholder Advisory Group			Convene an internal stakeholder advisory group		Engage with key stakeholders at existing venues						Engage with key stakeholders at specially arranged meetings	

PROVEN UH₂: Leadership

- **Executive and steering committees**
 - ✓ Major decisions
 - ✓ Coordinated working groups
 - ✓ Coordinated pilot
 - ✓ Prepared
 - Protocol
 - Manual of operations
 - Transition request

PROVEN UH2: Intervention

- **Intervention**

- ✓ Refined videos (6 total)

- Goals of care, advanced dementia, MV, hospice, dialysis, hospitalization

- **Training and Implementation**

- ✓ Prepared training material (*for pilot*)

- Toolkit, webinar, quick reference guides

- ✓ Decided on implementation procedures

- **Adherence**

- ✓ Designed Video Status Report (which, when, to whom, by whom)

- ✓ Loaded in to EMR

Training Toolkit



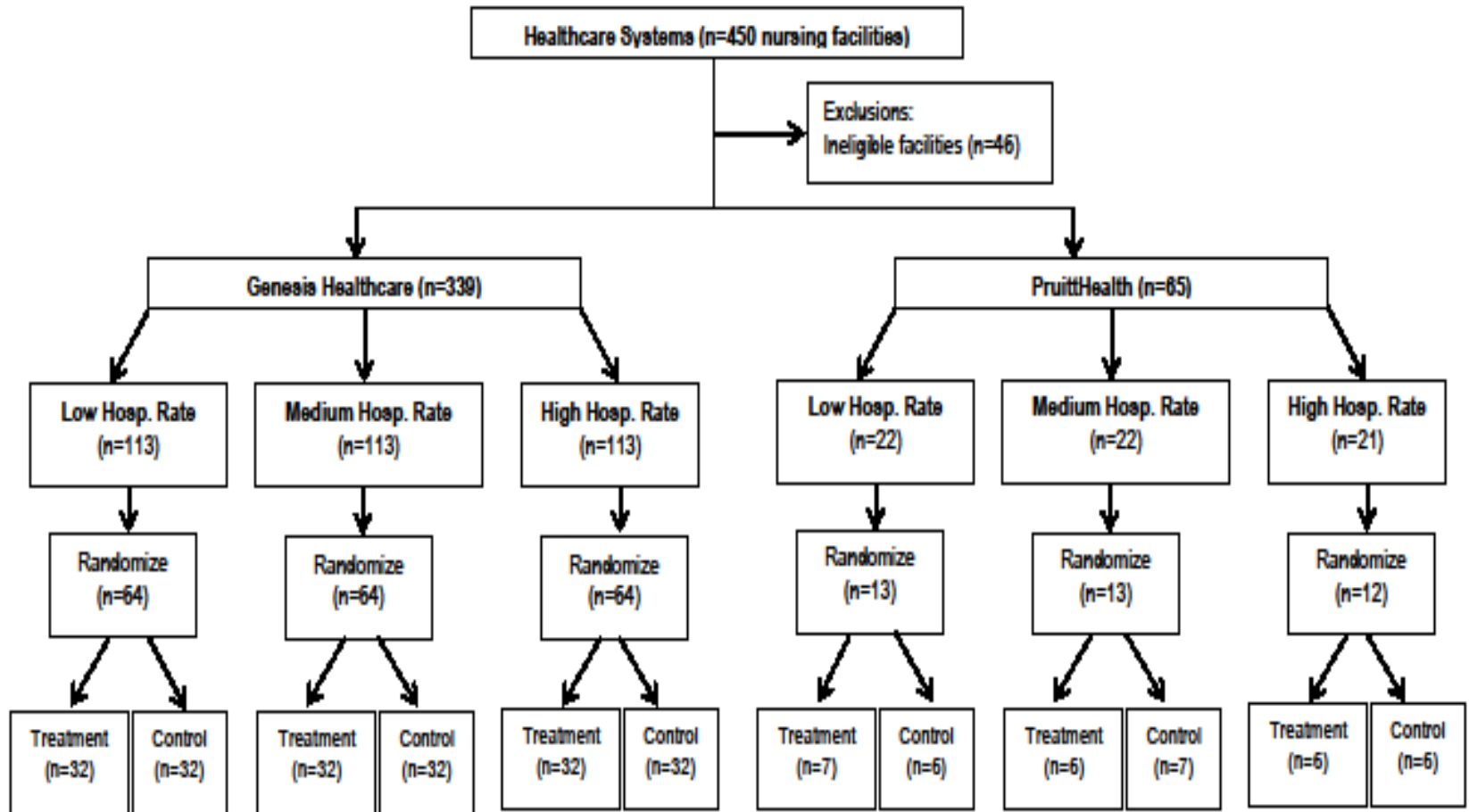
Table of Contents

Purpose of this Toolkit	3
I. Introduction	4
II. The Advance Care Planning (ACP) Videos	5
III. Using the ACP Videos	7
A. When to Show ACP Videos	7
B. Choosing an ACP Video	8
C. Starting the Conversation	8
D. Showing an ACP Video	9
E. Continuing the Conversation	10
F. Documentation and Translating Preferences into Advance Directives	10
IV. Implementing an ACP Video Program at Your Skilled Nursing Facility	12
A. Get the Right People on Board	12
B. Set Goals & Timelines	12
C. Key Elements of Implementation	12
C.1. Who will show the videos?	12
C.2. When will videos be offered?	13
C.3. How will videos be shown?	13
C.4. How will the ACP Video Program be documented?	13
C.5. How will your staff be trained?	14
C.6. How will you evaluate your success?	15
V. Getting Help	16
Appendices	17

PROVEN UH₂: Facility

- **Facility Recruitment/Randomization**
 - ✓ **Finalized eligibility criteria and protocol**
 - > 50 beds, mixture of short & long-term, stable organization structure
 - Used existing data : 404/450 NHs
 - ✓ **Pre-randomization assignment**
 - Actively recruit only those assigned to intervention
 - Strong corporate endorsement (~90% participation)
 - Unfair to rescind offer of videos to control
 - ✓ **Two stratification levels**
 - NH system
 - Hospitalization rates in prior year in target groups

PROVEN UH₂: Facility



PROVEN: Measurement

- ✓ Refined target group definition with MDS 3.0
 - Advanced dementia, COPD, or CHF
- ✓ Refined 1^o Outcome
 - Hospitalizations/person day-alive over 12 months in long-stay with advanced disease
- ✓ Estimated with 2012-13 data

Target population in Genesis and Pruitt Facilities		
	Long-stay	Short-stay
Total	35738	159197
Advanced Disease	15017 (42%)	19024 (12%)

PROVEN: Data Management

- ✓ Written contracts between Brown and Health Systems
- ✓ Created secure file transfer procedures
- ✓ Successfully transferred data in pilot
- ✓ Plan for q2-4 data “dumps” from NHs during trial
- Linkage to Medicare claims at Brown

PROVEN: Statistical Methods

- ✓ Refined stratification scheme
- ✓ Refined analysis of primary outcome
 - Hospitalization/person-year alive in target group
 - Zero-inflated Poisson distribution
 - Two part assumption for primary hypothesis
 - Probability of ANY hospitalization will be lower
 - Number of hospitalizations will lower if ever hospitalized

PROVEN: Statistical Methods

- ✓ Finalized power calculations
 - 103 NHs per arm; recruit 115 to intervention (ITT)

Number of NHs Required Per Arm				
Initial Hospitalization rates/year	Effect Size			
	0.20	0.225	0.25	0.275
1.06	81	63	50	41
1.51	165	129	103	84
2.12	351	275	220	180

PROVEN: Human Subjects

- IRB at Brown
 - ✓ IRB approval for pilot
 - IRB for trial: *submitted and pending*
 - Minimal Risk
 - Waiver of consent
 - OHRP review April 22
- Data Safety and Monitoring Board
 - ✓ Assembled, first meeting April 16
- Data Use Agreements
 - ✓ Contracts with health care partners
 - Preparing reuse for CMS
- ClinicalTrials.gov

PROVEN: Stakeholders

✓ Established External Advisory Group

- ✓ kick-off meeting February, intro, established mission, review study
- next meeting in May

Members of PROVEN External Stakeholder Advisory Group		
Stakeholder	Perspective	Representative
Center to Advance Palliative Care	Patient/Provider	D. Meier, MD
Scientific Community	Investigator	J. Ouslander, MD
Patient Quality of Life Coalition	Patient	D. Smith, JD
National LTC Ombudsman Resource Ctr	Patient	A. Overall Laib, MS
Excellus BlueCross BlueShield & MedAmerica	Payor	P. Bomba, MD
American Health Care Association	Policy	D. Gifford, MD, MPH
National Council of Hospice and Palliative	Providers-Hospice	Carol Spence, PhD
American Medical Directors Association	Providers-MD	P. Katz, MD
National Association Directors of Nursing Admin.	Providers-Nurses	S. Dornberger, RN
American Geriatric Society	Providers/Policy	J. Chin Hansen, RN
Coalition to Transform Advanced Care	Mixed Coalition	C. Sabatino, JD
Family Caregiver Alliance	Patient	K. Kelly, MPA

PROVEN: Pilot study

- 4 intervention NHs (2/site)
- Two-month training; one-month intervention; one-month evaluation
- Training:
 - Toolkit, webinars, on-site Pruitt only, calls
 - Mostly by research team
- Two-IPads, NH loaded with videos
- Data transfer
- Exit interviews

PROVEN: Pilot study

- **What went well**
 - LOVED the videos, request to keep using
 - No adverse reactions
 - Data transfer successful
 - Video status report: 130 (60 Genesis/70 Pruitt)

Patients Features (No.)	All Facilities (N=4)	Genesis Facilities (N=2)	Pruitt Facilities (N=2)
Met criteria for advanced dementia	34	24	10
Met criteria for advanced CHF/COPD	21	2	19
Met criteria advanced dementia or CHF/COPD	55	26	29

PROVEN: Pilot study

- Lessons Learned/Modifications
 - Training: Led by corporations
 - Intervention: Videos modified, add “healthy patient”
 - Implementation:
 - Expand window to 7 days of admission
 - Video status report completed when shown
 - Tablets instead of iPads
 - Two champions/home

PROVEN: Ongoing activities

- Transition Progress Report
- Manual of Procedures
- IRB
- DSMB
- “Planning”