

Implementing PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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Michael M. Davis Lecture

- Michael Marks Davis, Ph.D.: Nov 19, 1879 - August 19, 1971
- Executive Chair of the [Committee for the Nation's Health](#)
- Led the Truman plan for universal health care
- Founding editor **Medical Care**.
- 1970 NEJM Editorial states “one of the great pioneers in American Medicine”
- Last **Medical Care** editorial asserts that we must understand and harness BOTH Medical and Social Forces to achieve universal access to effective and efficient care.

Purpose

- Present the background and design of the PROVEN trial
- Review history of Advance Care Planning from Hospice to the “Conversation Project”
- Describe documenting the implementation of PROVEN in intervention Nursing Homes
- Shifting the emphasis from “pragmatic” to “energetic” implementation assistance
- Implications for future programs & studies

PROVEN: Objective

- To conduct a pragmatic cluster RCT of an Advance Care Planning video intervention in NH patients with advanced comorbid conditions in two NH healthcare systems

Background: Nursing Homes

- NHs are complex health care systems
 - 15,000+ NHs with ~1.5 million beds
 - 3+ million patients admitted annually
 - Less than 1 million long stay residents
 - Increasingly a site of death
- Patients are medically complex with advanced comorbid illness
- Like Hospitals, NHs charged with guiding patient decision making by default

Advance Directives History

- Hospice benefit began in 1983
- Ongoing problem of late hospice referral
- Communication about treatment preferences assailed as inadequate
- Patient Self Determination Act began 1991
- All Medicare/Medicaid institutions had to ask if patients wanted information
- Increased paper Compliance; failed policy

Advance Directives (cont.)

- Hospice use expanded dramatically
- BUT, so did ICU use even among the most frail
- Emphasis on Palliative Care before hospice
- “Conversation Project” and others introduced
- Efforts to train physicians to converse with very sick patients and their families

Background: Traditional ACP

- Failure of mandating Advance Directives led to concept of Advance Care Planning (ACP)
- Problems with traditional ACP
 - Ad hoc
 - Knowledge and communications skills of providers variable
 - Scenarios hard to visualize
 - Health care literacy is a barrier

Background: ACP videos

- Options for care with visual images
- Broad goals of care
 - Life prolongation, limited, comfort
- Specific conditions/treatments
- Adjunct to counseling
- 6-8 minutes
- Multiple languages



Background: Pragmatic Trials

- Traditional Efficacy Trials not often replicated in the real world
 - Staff Skills not adequate
 - Inadequate business case means limited adoption
 - Clinical trials participants differ from population ultimately exposed
- Effectiveness trials measure benefit as implemented in the “real world”
 - Outcome measurements less precise
 - Implementation less complete
 - Still has the advantage of randomization

Background: NIH Common Fund Pragmatic Clinical Trial Collaboratory

- NIH efforts to understand barriers to RCT replication led to support for PCTs
- Cluster based trials with providers/groups being clusters
 - 50 HCA hospitals randomized in ABATE
 - Trauma Centers randomized for PTSD ID and Tx
 - Dialysis Centers randomized for TIME trial
- Interventions implemented by health care system staff following established protocol

PROVEN: Intervention NHs

- 24 month accrual; 12 month follow-up
- Suite of 5 ACP videos
 - Goals of Care, Advanced Dementia, Hospitalization, Hospice, ACP for Healthy Patients
- Offered facility-wide
 - All new admits, at care-planning meetings for long-stay, readmission
- Flexible (who, how, which video)
- Tablet devices, internet via URL and password
- Training: corporate level, webinars, toolkit

PROVEN: Control NHs

- Usual ACP practices
- Other Quality Improvement programs may be introduced (i.e., *INTERACT*; *Rehospitalization reduction efforts*)
- *Subjects to all other contemporaneous changes in clinical practice, policy initiatives and industry responses*

PROVEN: Primary Outcome

- Number of hospital transfers*/person-days alive among fee for service Medicare beneficiaries ≥ 65 years old who are in a NH ≥ 90 days (“long-stay”) and who have EITHER advanced dementia or advanced congestive heart failure/chronic obstructive lung disease
- This is our **target** cohort.

* Transfers include hospital admissions, Observation Stays & ED visits.

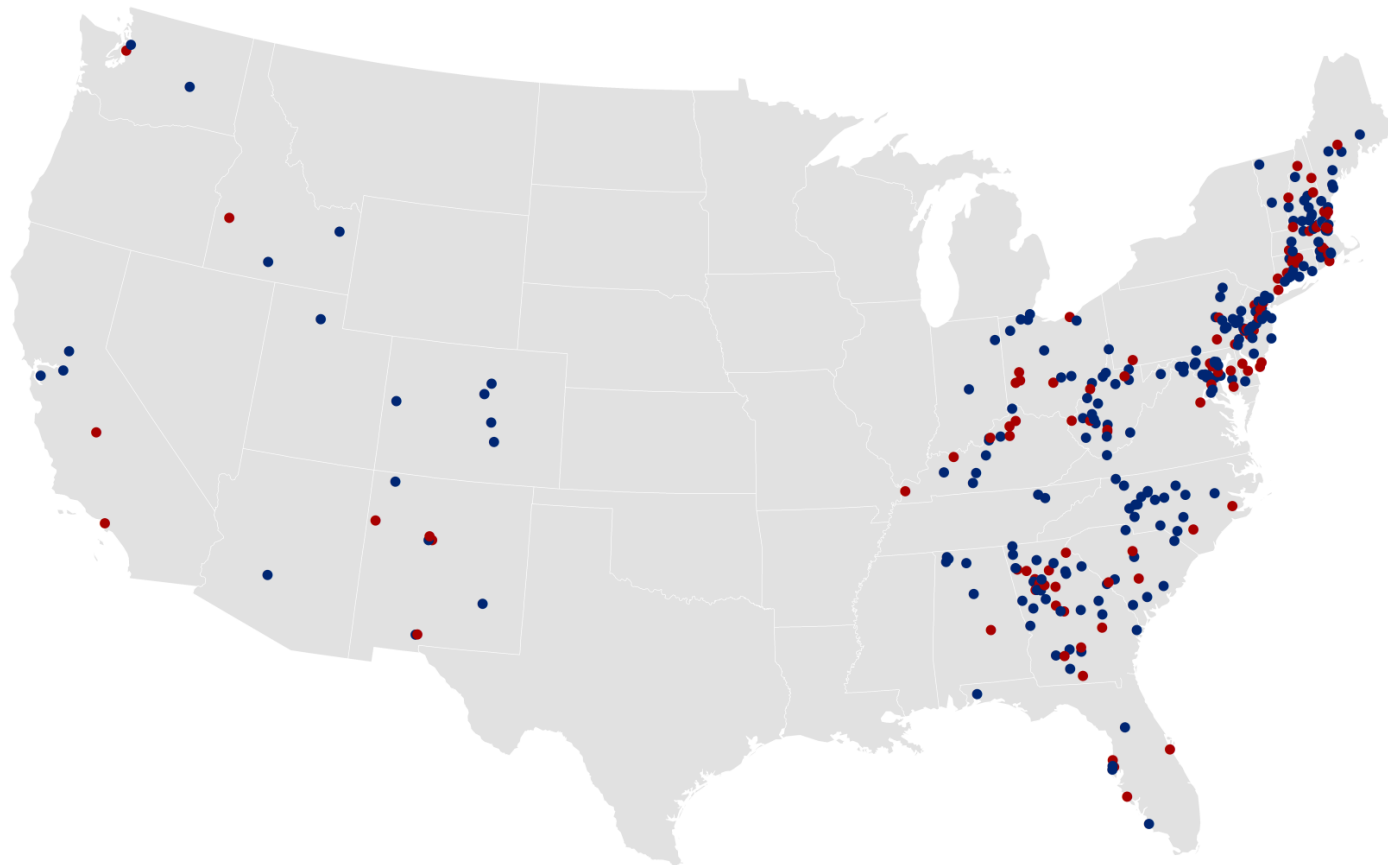
Why Should ACP affect Hospitalizations in Target Cohort?

- Video sensitizes patients and family to poor prognosis of CPR for patients like them
- After video formal ACP discussions may be initiated with physician or NP
- Preferences document in DNR/DNH or other care restriction orders
- Next change in medical condition should not trigger a hospital transfer

PROVEN: Secondary Outcomes

- **Non-target** cohort (for both long- and short stay):
 - Number of hospital transfers/person-days alive (over either 12 months for long stay or 90 days for short stay)
- **Target and non-target** cohorts (for both long- and short stay):
 - Presence of advance directives: Do Not Hospitalize, Do Not Resuscitate, or no tube-feeding (**Available for sub-sample**)
 - Burdensome treatments (feeding tubes, parenteral therapy)
 - Hospice enrollment

Distribution of PROVEN NHs



PROVEN centers
(as of 2/16/2017)

- Intervention
- Control

Data infrastructure in PROVEN

1. Integrated a Video Status Report as a User-Defined Assessment (VSR-UDA) into healthcare systems' EMRs to document offering and showing the ACP Video Program
2. Instituted systems and QA procedures for data transfers between healthcare systems and Brown (MDS, VSR- UDA, MD orders)
3. Monthly “performance” reports for the healthcare systems
4. Data uploaded to CMS Virtual Research Data Center (VRDC) to create finder files to match all Medicare claims, particularly hospitalization (offers “real time” claims data access through the Workbench);

Implementing PROVEN

- Topics for today's presentation:
 - Challenges during implementation
 - Documenting the implementation of the intervention
 - Ongoing challenges & Implications for Estimating the Effect of the intervention as implemented

Challenges during implementation

- Two main challenge areas:

1. **Defining compliance**

2. Changes at healthcare system partners

Defining compliance

- Videos are designed to be offered in six circumstances:

Table 1. Events Triggering when an ACP Video is Offered

1)	ALL PATIENTS: Within One Week of Admission
2)	ALL PATIENTS: Within One Week of Re-admission from Hospital
3)	ALL PATIENTS: Significant Change in Health Care Status
4)	LONG-TERM CARE RESIDENTS: Every 6 months (Align with Scheduled Care Planning Meetings)
5)	FAMILY MEETINGS: About Goals of Care
6)	SPECIFIC DECISIONS: Covered by a Video (e.g., Hospice, Hospitalization)

From ACP Video Program toolkit

Documenting the ACP Video Program

- A Video Status Report User-Defined Assessment (VSR UDA) was programmed in the EMRs of our healthcare system partners.
- Each time a video is offered to a patient or his/her family, a VSR UDA is to be completed – even if a video is not shown.
- Documented each time Staff distribute the Web Site url to families to view at home.
- Intended to document variation in implementation for analytic use

Example VSR UDA data points

- Date video offered
- Which event triggered the video offer?
- Was a video shown?
 - If shown:
 - Date shown
 - Which video(s) shown?
 - Who showed the video?
 - Who viewed the video?
 - Any distress observed?
 - If not shown, why not?

Initial definition of compliance

- ACP Video Program compliance was initially defined as **completion of a VSR UDA** each time a **video was offered**.

Focus on the VSR UDA

- On the regular healthcare system group “check in” calls with NHs and during formal re-training webinars, emphasis was placed on **offering videos**.
- NHs that were compliant with **offering videos** were celebrated and highlighted.

Research Staff-generated compliance reports

1. VSR UDAs completed for new admissions

Total new admissions*

2. VSR UDAs completed for long-stay patients

Total long-stay patients with ≥ 6 months of potential exposure*

- *(from NH MDS data)*

Needed to redefine compliance

- HOWEVER, when we added the proportion of **videos actually shown** to the compliance reports....
- We found that even NHs highly-compliant **offering videos** did not have high rates of **actually showing videos!**

Videos offered vs. videos shown

	Partner 1		Partner 2		Total	
Admissions	15488		2864		18352	
Video Offered	11844	76.50%	1697	59.30%	13541	73.70%
Video Shown	2549	16.5%	1133	39.50%	3882	20.00%

	Partner 1		Partner 2		Total	
Long Stay	9458		2321		11779	
Video Offered	3074	32.50%	595	25.60%	3669	31.10%
Video Shown	618	6.53%	312	13.40%	930	7.90%

Facility Variation in Offer Rates

Facility offer rate only short stay					
	Max	Mean	Median	Min	Standard Deviation
Partner 1	92.2%	68.7%	76.9%	0	22.8
Partner 2	81.8%	50.8%	48.0%	6.9%	23.6

Facility offer rate only long stay					
	Max	Mean	Median	Min	Standard Deviation
Partner 1	100%	46.1%	44.1%	1.6%	41.5
Partner 2	77.9%	40.3%	37.3%	10.7%	17.7

Facility Variation in Show Rates

Facility show rate full sample					
	Max	Mean	Median	Min	Standard deviation
Partner 1	100%	26.8%	17.1%	17.1%	26.6
Partner 2	99.5%	60.7%	62.3%	12.8%	25.6

Facility show rate only short stay					
	Max	Mean	Median	Min	Standard deviation
Partner 1	100%	27.5%	15.7%	0	28.12
Partner 2	78.6%	32.8%	35.6%	0	22.3

Facility show rate only long stay					
	Max	Mean	Median	Min	Standard deviation
Partner 1	100%	25.6%	17.6%	0	24.8
Partner 2	76.5%	24.9%	22.2%	4.0%	18

Change in tune: Show the video

- Compliance reports now include **videos shown**.
- On the regular healthcare system group “check in” calls with NHs and during formal re-training webinars, emphasis is now placed on **showing the video**.
- NHs that are compliant with **showing the video** are celebrated and highlighted as program benchmarks.
- Target set for each center to have a “**video shown**” rate of at least 50%.

Challenges during implementation

- Two main challenge areas:

1. Defining compliance

- 2. Changes at healthcare system partners**

Healthcare system partners

- **CHALLENGE #1: Turnover in key partner staff.**
 - Both of our healthcare system partners experienced turnover (twice) in the system implementation liaison role.
- **SOLUTIONS:**
 - Kept engaged with senior leadership in our healthcare system partners.
 - Provided one-on-one trainings and orientations with newly-hired implementation liaisons.
 - Began including implementation liaisons on our monthly Steering Committee calls.

Healthcare system partners

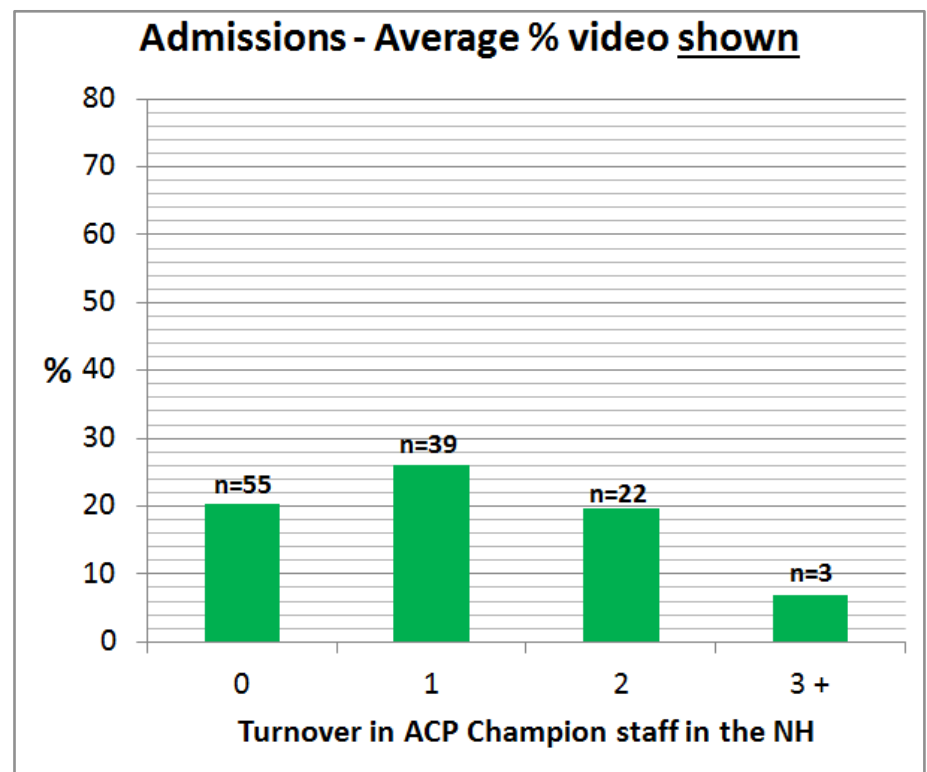
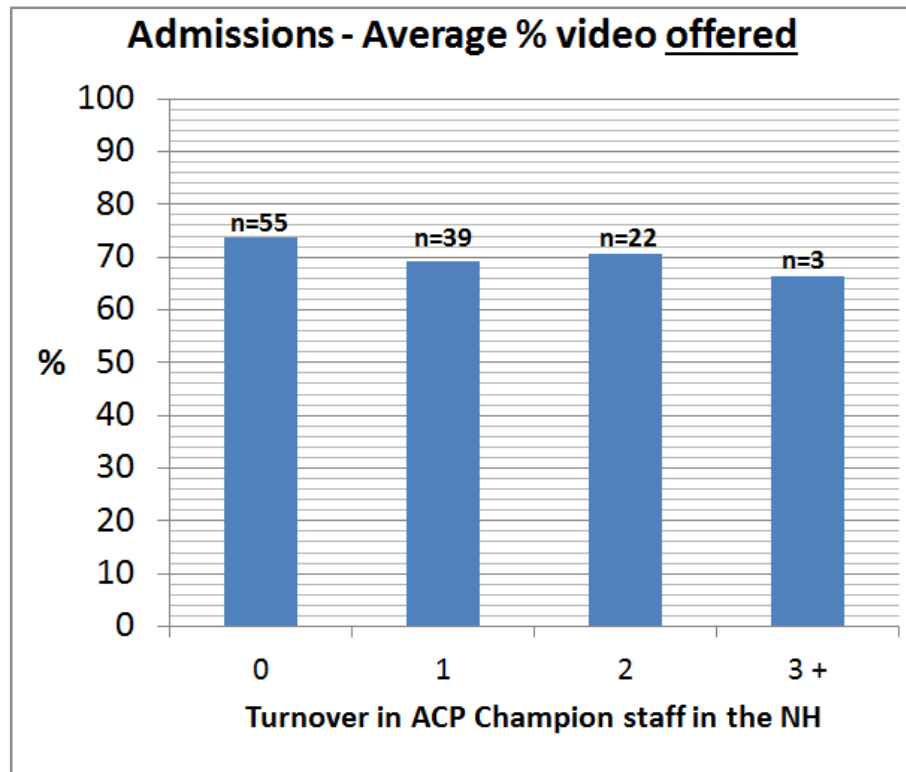
- **CHALLENGE #2: Turnover in ACP Champion staff → More than half of NHs had at least one Champion turnover.**

	# of NHs	% of NHs
No turnover in ACPCs	55	46.22%
1 ACPC loss	39	32.77%
2 ACPC losses	22	18.49%
3 ACPC losses	2	1.68%
5 ACPC losses	1	0.84%

Total intervention NHs 119

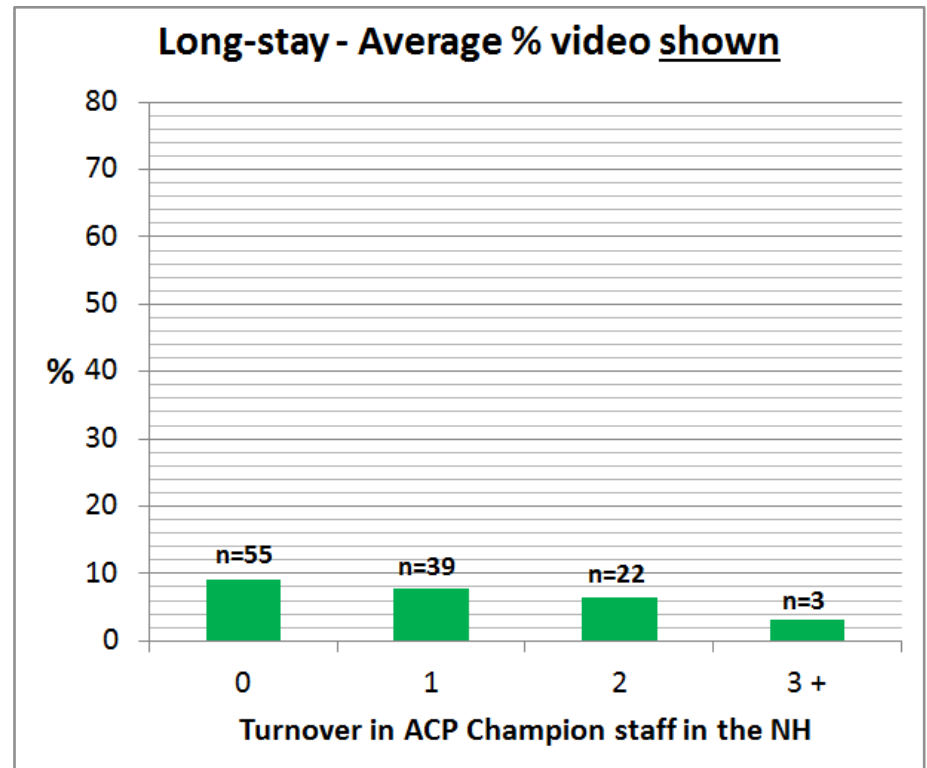
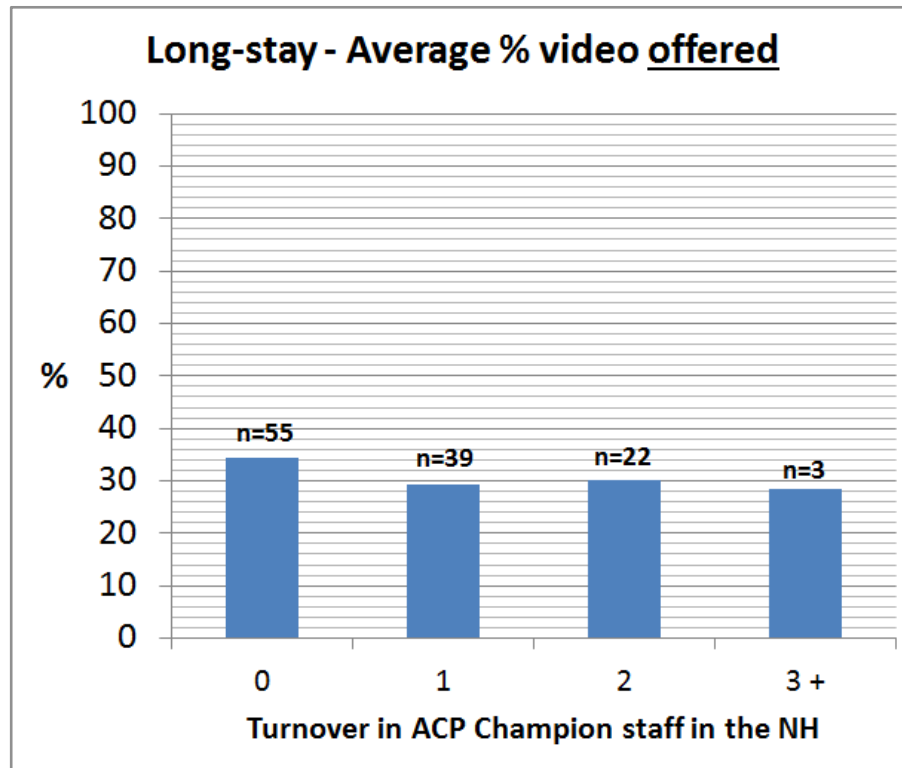
Data as of 2/15/2017

Relationship between turnover and ACP Video Program compliance for admissions



Data as of 12/31/2016

Relationship between turnover and ACP Video Program compliance for long-stay



Data as of 12/31/2016

Healthcare system partners

- **CHALLENGE #3: Divestitures**
 - At one partner, a total of 12 NHs were divested after they were randomized to the study sample.*
 - These divestitures occurred after the ACP Video Program had launched.
 - Intent to treat leaves all “exposed” patients in analysis; exposure stops at time of divestiture.

Healthcare system partners

- **CHALLENGE #3: Divestitures**
- **SOLUTION:**
 - We accrued the cohort of patients in NHs until the date of divestiture.
 - Although we stopped accruing patients in those NHs upon the date of divestiture, we can keep following their patient outcomes for up to 12 months afterward using Medicare files.

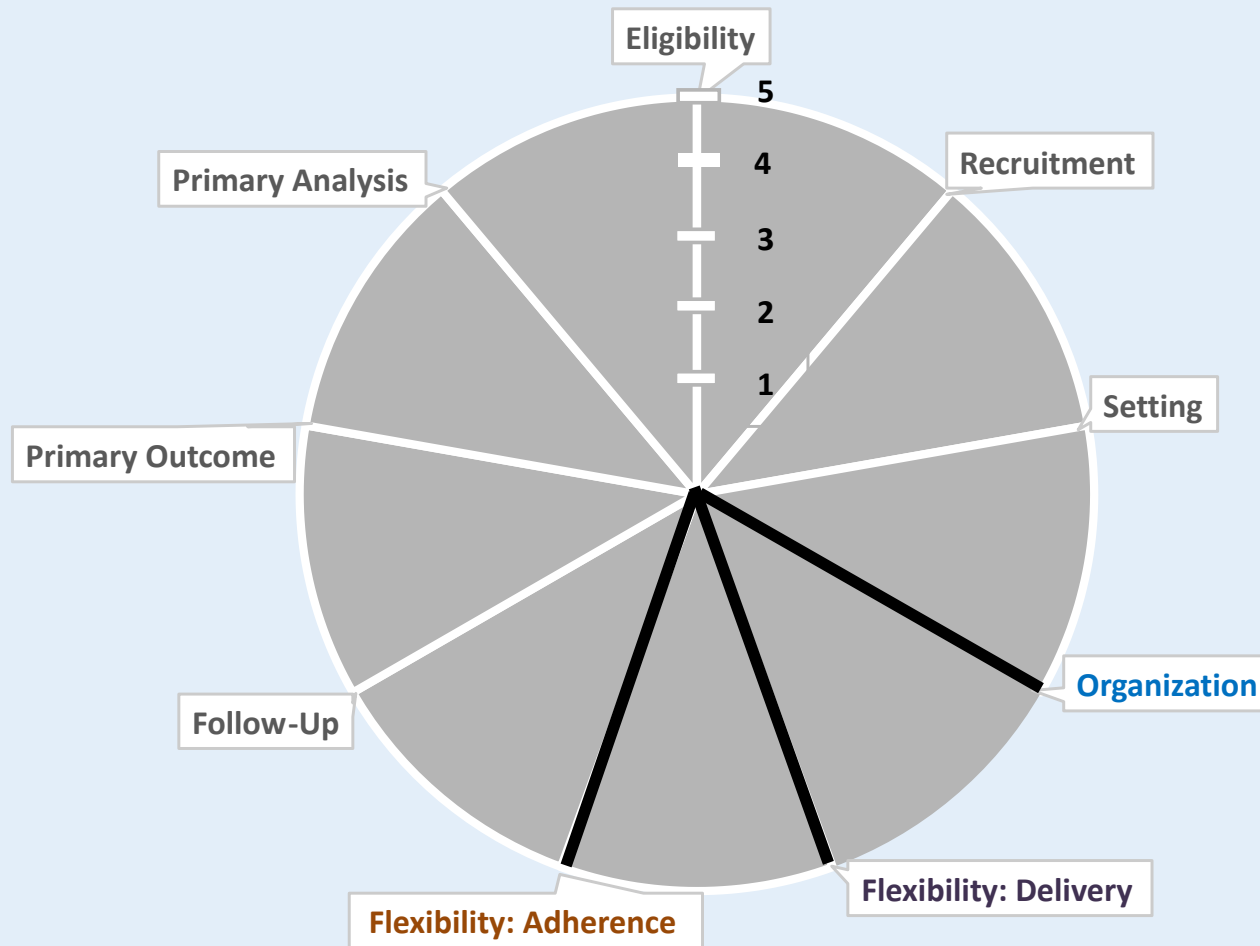
Documenting implementation

- ACP Champions are critical to the success of the ACP Video Program
 - These are key staff (usually Social Workers) appointed by senior leadership to lead the implementation in each NH
 - Each NH has at least two Champions: primary, secondary
- We designed telephone interviews to be conducted with Champions at three timepoints during the 18-month implementation period:
 - Baseline → 4 months after launch
 - Intermediate → 9 months after launch
 - Final → 15 months after launch

So, How Pragmatic is PROVEN now?

- Each Change to the Intervention Implementation model considered in light of PRECIS-2 principles
- Clearly even a multi-facility pilot doesn't uncover all operational implementation impediments
- In “real” world health systems test new programs with pilots as well

PRECIS 2* IMPLEMENTATION DOMAINS



* PRECIS-2 diagram from Loudon et al, BMJ, 2015 with adapted formatting.

Implementation RT vs. HCS:

ORGANIZATION

ASPECT	Approach	Challenges
TRAINING	RT: Developed training materials -e.g., printed toolkit, webinars, laminated card HCS: Leveraged existing corporate infrastructures to do trainings RT & HCS: Co-led trainings	<ul style="list-style-type: none"> HCS' had different preferred modalities: HCS1: Centralized, in-person HCS2: Multiple Webinars Turnover of NH champions required multiple re-trainings
PERSONNEL	RT: Dedicated one PI and one PD HCS: Corporate-level leader appointed to oversee project; Site champion(s) at each NH	<ul style="list-style-type: none"> Turnover of both corporate leaders Extensive champion turnover
RESOURCES	RT: Developed intervention; supplied tablets with videos HCS: Provided training venues; embedded video status report into EMR	<ul style="list-style-type: none"> Two sites had mostly Navajo patients so RT created new videos Tablets stolen at one site so RT replaced them

**RT=research team; HCS=health care system*

Implementation: FLEXIBILITY (DELIVERY)

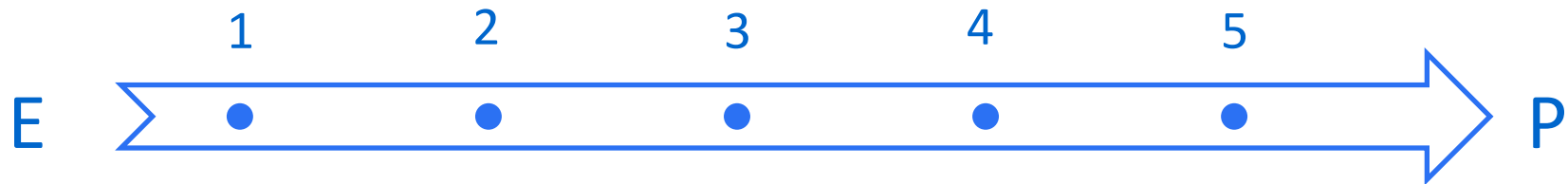
ASPECT	Approach	Challenges
PROTOCOL-DRIVEN	<p>RT: <u>Prescribed</u> guidelines for timing of video OFFERING (7 days from admission, q6 months for long-stay)</p> <p>RT: <u>Flexible</u> guidelines for:</p> <ul style="list-style-type: none"> -which videos to offer which patient -who shows videos (mostly SW) 	<ul style="list-style-type: none"> • Higher adherence for admissions vs. LTC • Competing responsibilities a barrier • LTC-patients hard to find “right time”, family often not at care planning meeting
CO-INTERVENTIONS	<p>RT: Did <u>not</u> dictate how other ACP modalities could be used (e.g., MOLST)</p> <p>HCS: Allowed other ongoing ACP activities to continue in NHs</p>	<ul style="list-style-type: none"> • Other ACP programs highly variable & not easily measured • ++ external initiatives to ↓ hospitalizations (1^o outcome)
MONITORING	<p>RT: Designed Video Status Report (VSR)</p> <p>HCS: Embeds VSR into EMR at all NHs</p> <p>RT & HCS: Instruct VSR completion when video OFFERED (i.e., patient or family could refuse)</p>	<ul style="list-style-type: none"> • Champions interpreted compliance as <u>offering</u> (i.e., VSR completion) vs <u>showing</u> video

*RT=research team; HCS=health care system

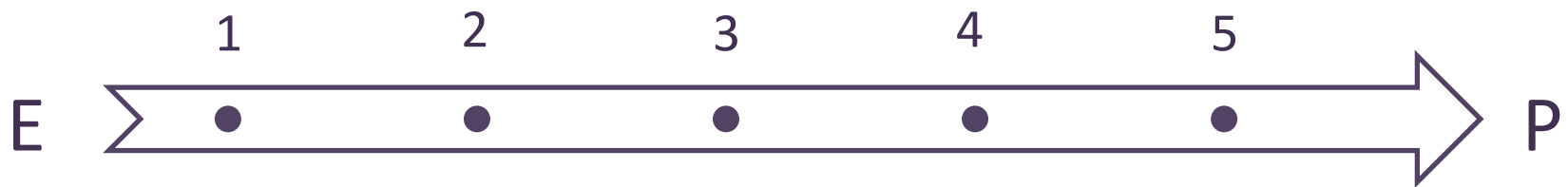
Implementation: FLEXIBILITY (ADHERENCE)

ASPECT	Approach	Challenges
PRE-SCREENING	HCS: Excluded sites with major organizational or regulatory difficulties	<ul style="list-style-type: none"> Determination of ‘dysfunctional’ sites was subjective based on corporate leaders’ assessments
SITE WITH-DRAWAL	RT: NHs with low implementation adherence rates were NOT dropped	<ul style="list-style-type: none"> HCS divested several NHs mid-implementation
SITE MONITOR-ING	<p>HCS: Internal monthly reports for VSR completion for <u>admissions only</u></p> <p>RT: <u>Quarterly reports</u> were completed for admissions and LTC; <u>champion interviews</u> uncovered issues (lack of focus on LTC, champion turnover)</p> <p>RT & HSC: monthly ACP champions calls; problem-solve low performers</p>	<ul style="list-style-type: none"> HCS internal reports for <u>admissions only</u> and based on <u>offering videos</u>, so missed low compliance in LTC and show rate RT reports delayed due to data transfer; 01/17 added ‘show’ rate and increased to monthly

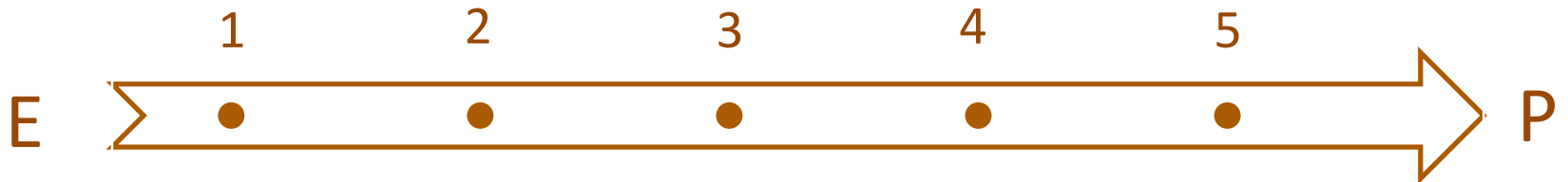
ORGANIZATION:



FLEXIBILITY (Delivery):



FLEXIBILITY (Adherence):

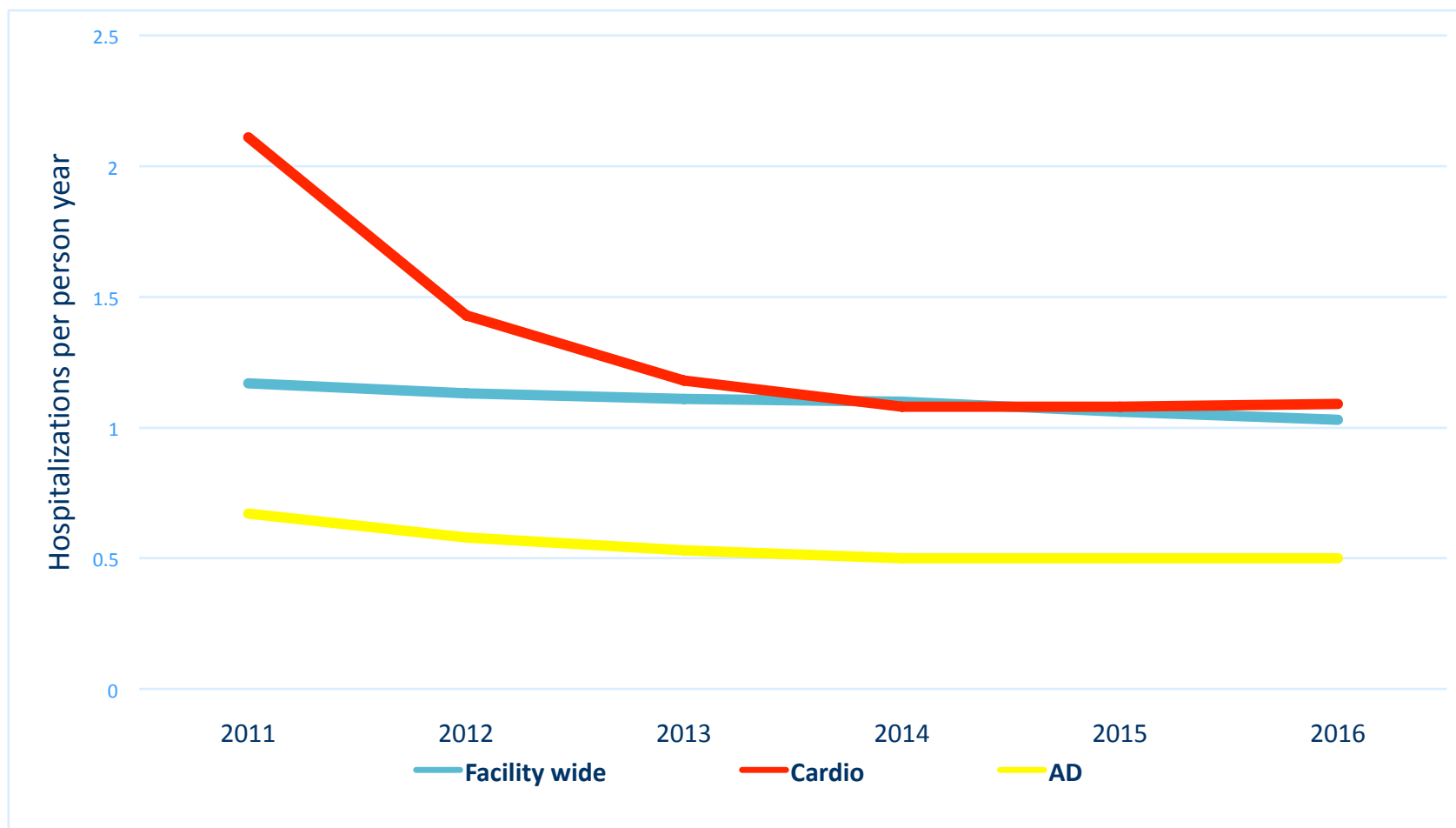


E=Explanatory; P=Pragmatic

Ongoing challenges

- Implementing PROVEN in context of a rapidly evolving medical care environment affecting our primary outcome
- Integrating the video and ACP into centers' standard operating procedures
- Continued market stressors on the NH industry (e.g., reduced Medicare days and higher acuity of patients) that diminish revenue, increase pressure, and reduce staffing levels (including ACP Champions)

Average facility-level Hospitalization/per person year trends



Current Status

- Permitted to extend enrollment from 18 to 24 months (increase sample size)
- Much more intensive exhortation to show the videos and initiate ACP discussions
- Third of facilities not really implementing
- Proposed an “as treated” analysis, BUT
- Primary outcome still as originally stated

Lessons & Implications for ACP

- ACP Videos Selected because standardized and ready for broad implementation
- Unanticipated Complications in the “mechanics” of introducing Videos into daily operations – seemed so simple!
- Just showing video doesn’t mean going to next step of Advance Directives
- Lots of anecdotal stories of families’ resistance to discuss Advance Directives
- Since MDs & NPs can now bill for ACP, perhaps that is best strategy

Lessons and Implications for PCTs

- Integrating interventions into health care systems mean changing Standard Operating Procedures
- Implies a mandate from Management, not a research project
- Continuum of Intervention complexity; easy to change mandated vaccines, hard to change clinical guidelines and practices
- BUT, suggests how tenuous most medical interventions are when broadly implemented