Implementing

PROVEN

PRagmatic Trial of Video Education in Nursing Homes

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Embedding Pragmatic Clinical Trials in Health Care Systems: Trials and Tribulations

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Purpose

- Describe the PROVEN intervention and trial

- Why Nursing Home Partners wanted PROVEN

- Documenting and implementing PROVEN

- Implementation Challenges

- 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

- To test the impact of video assisted Advance Care Planning on seriously ill residents' transfer to hospital (inpatient, ED or Obs Stays)

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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

Advance Care Planning

Making Decisions for People with Advanced Dementia

Intensive Medical Care

Basic Medical Care

Comfort Care

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

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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

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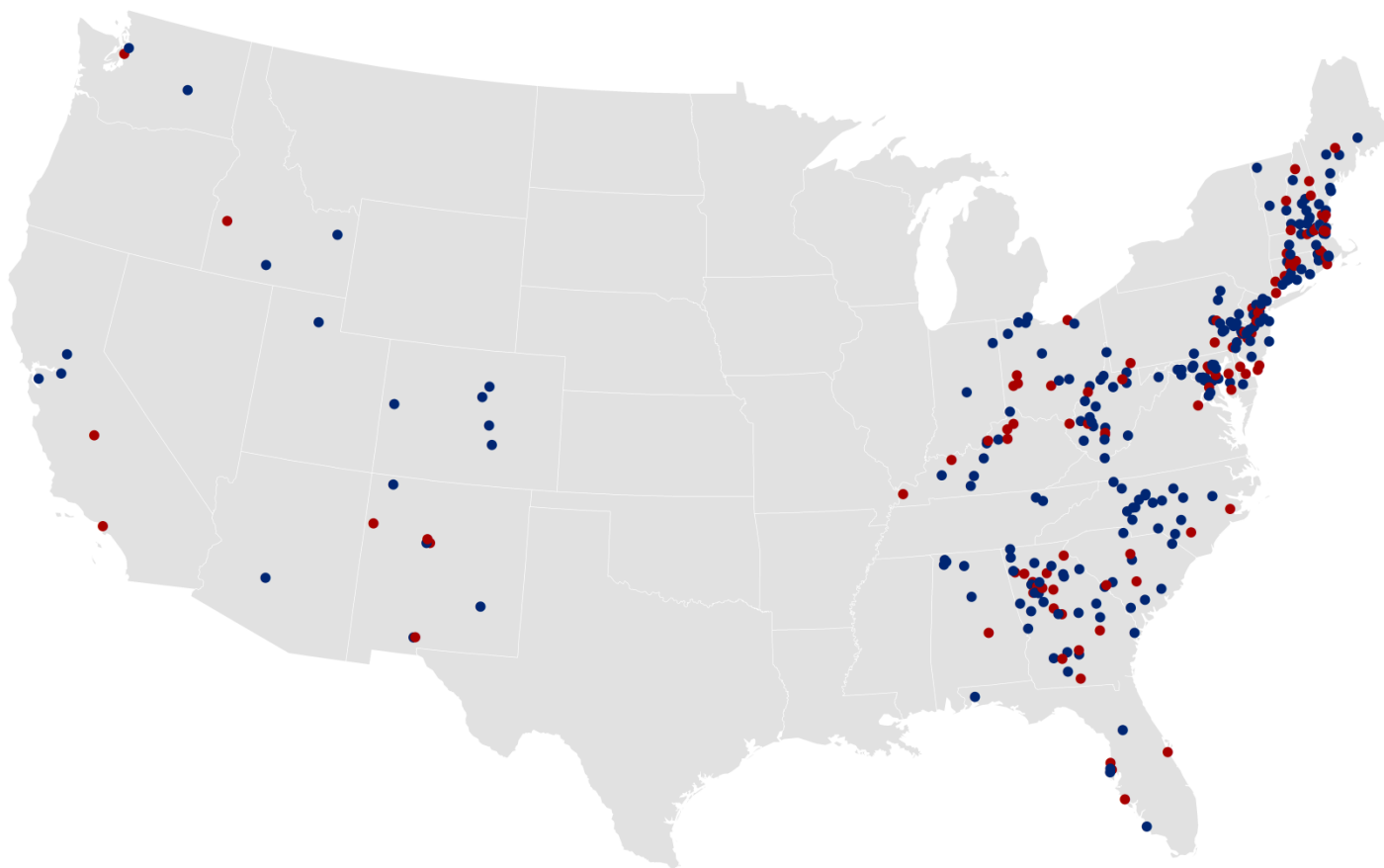
PROVEN: Intervention NHs

- 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*

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Distribution of PROVEN NHs

PROVEN centers
(as of 2/16/2017)

- Intervention
- Control

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Why Should Nursing Home Systems want to participate in PROVEN?

- Medicare rehospitalization penalty prompted hospitals to build networks of low rehospitalization providers

- ACOs trying to control post-acute spending

- CMS implementing a re-hospitalization penalty to apply to SNFs in 2018

- Leadership views goal to reduce transfers that are inconsistent with patient preferences

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);

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Challenges during implementation

- Changes at Healthcare System Partners
  - Changes in Corporate Office
  - Changes in Participating Facilities

- Changes In Health Care Environment

- Changes in Regulatory Environment

Healthcare system partners

- **CHALLENGE #1: Turnover in key partner staff.**

  – Both of our healthcare system partners experienced turnover (<u>twice</u>) 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.

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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

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Relationship between turnover and ACP Video Program compliance: admissions

Data as of 12/31/2016

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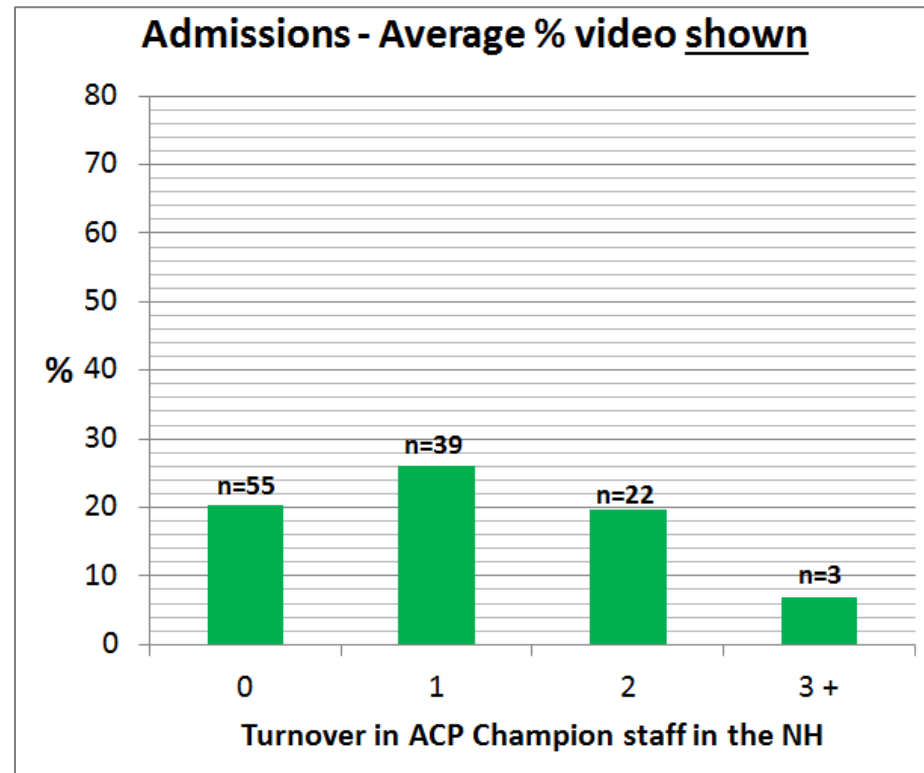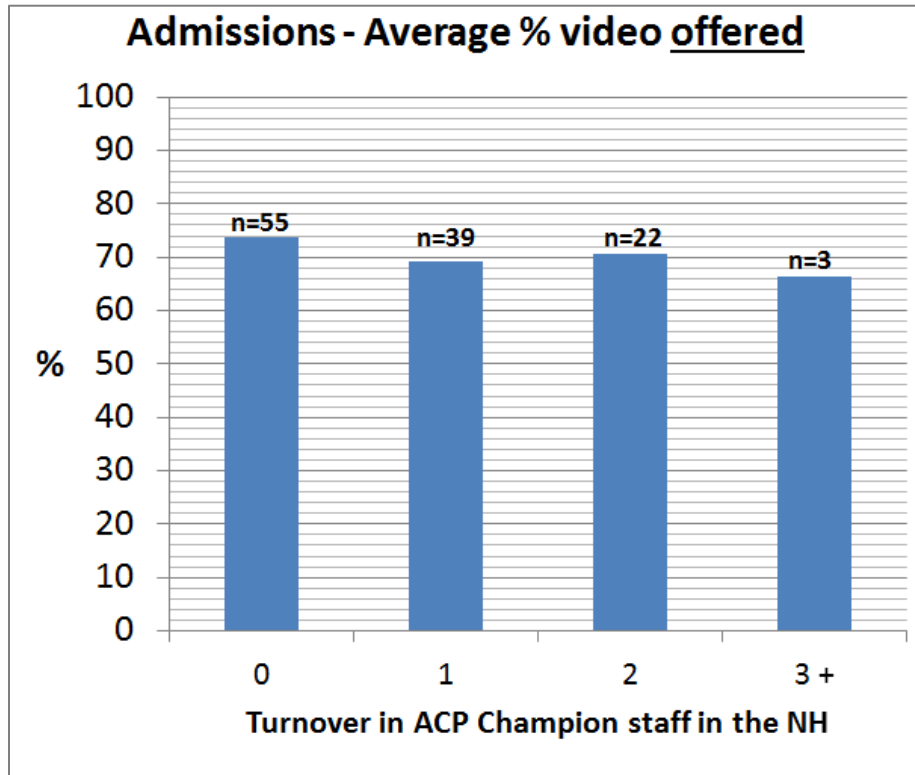
Healthcare system partners

- **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.

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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.

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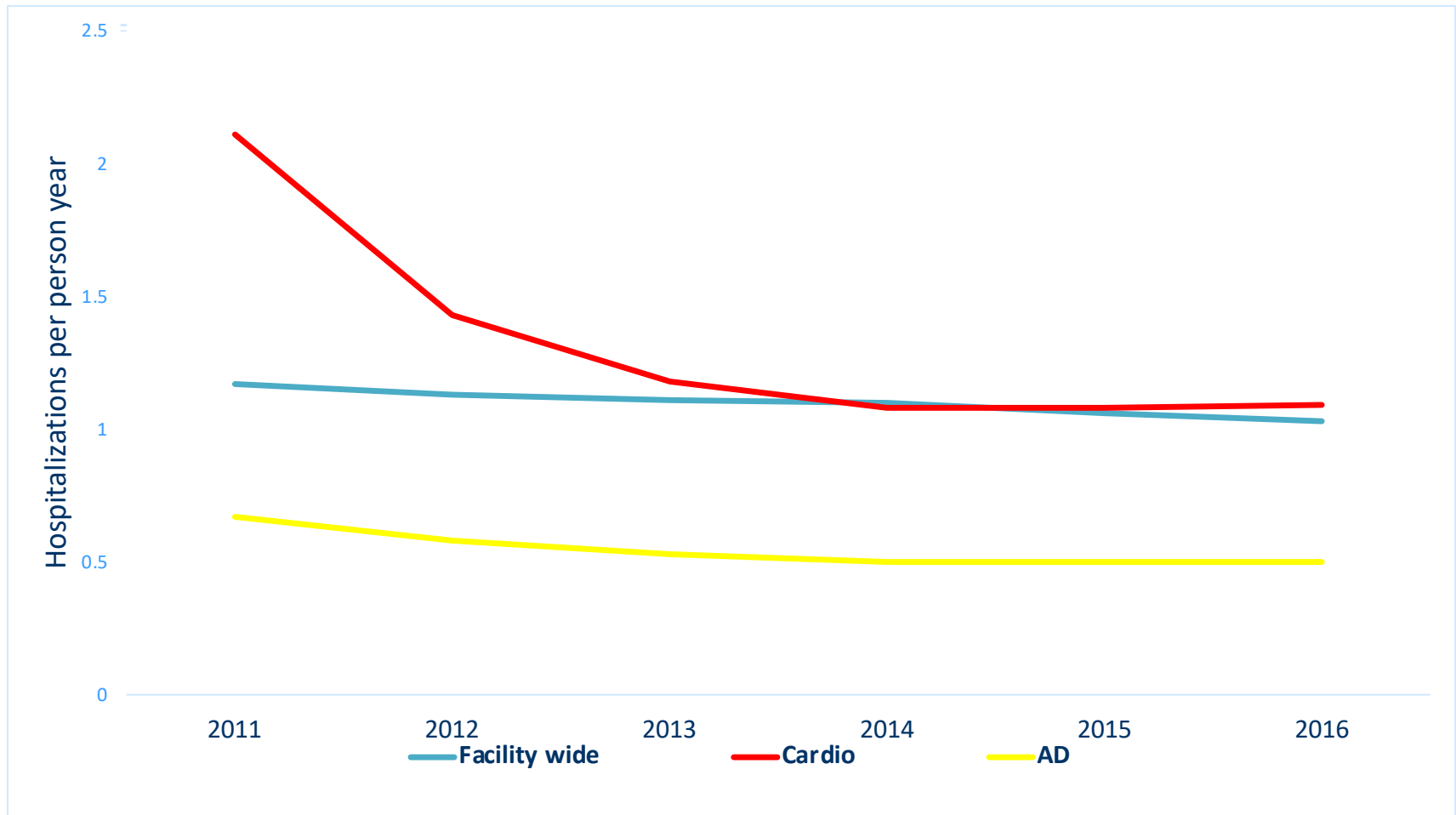PRagmatic Trial of Video Education in Nursing Homes

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 <u>three timepoints</u> during the 18-month implementation period:

  - Baseline → 4 months after launch
  - Intermediate → 9 months after launch
  - Final → 15 months after launch

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Changes in Industry and Regulatory Environment

- Medicare SNF Length of Stay declined rapidly; dropping ~5 days over 3 years resulting in revenue shock

- Contemporaneous presures to reduce re-hospitalizations resulted in large declines in hospital admissions from NH

- 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)

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Average facility-level Hospitalization/per person year trends

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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

- Quarter of facilities not really implementing

- In spite of external stressors Health Care System partners still committed

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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' resistence to discuss Advance Directives

- Since MDs & NPs can now bill for ACP, perhaps that is best strategy

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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

- Essential to have fully engaged health care system partners

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