PROVEN: PRagmatic Trial Of Video Education in Nursing Homes

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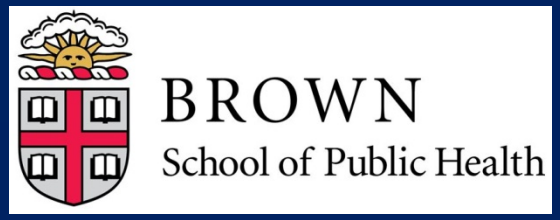

Background: Nursing Homes

- NHs are complex health care systems
  - 3 million patients annually
  - Rapidly growing % post-acute care
- Patients medically complex with advanced comorbid illness
- NHs charged with guiding patient decisions by default

Background: ACP

- Advance care planning (ACP)
  - *Process* of communication
  - Ensures care consistent with preferences
  - Leads to advance directives (e.g., DNR, DNH)
- Better ACP associated with improved outcomes
  - Fewer terminal hospitalizations, less burdensome interventions, lower costs, greater family satisfaction
- ACP suboptimal in NHs
  - Process is not standardized
  - Low advance directive completion rates
  - Not reimbursed
  - Regional and racial/ethnic disparities

Background

- Need to align care with preferences
- ACP reduces hospitalization rates and burdensome treatments
- Focus on hospitalization
  - 15% die in hospital
  - 30-day re-hospitalization rates ~30%
  - Traumatic for patient, costly
  - 23-60% avoidable

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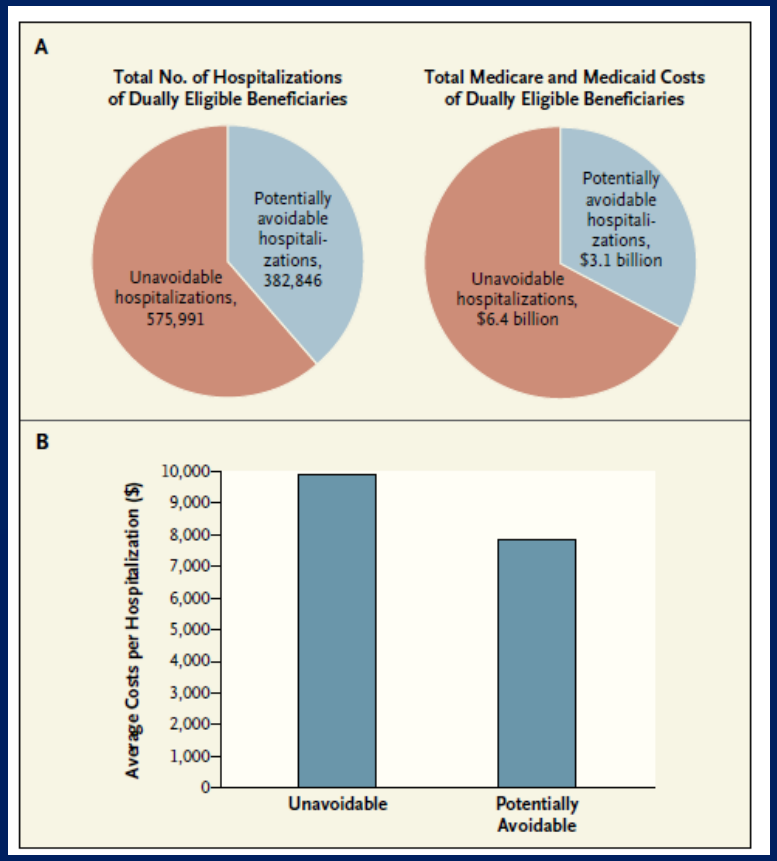
Reducing Unnecessary Hospitalizations of Nursing Home Residents



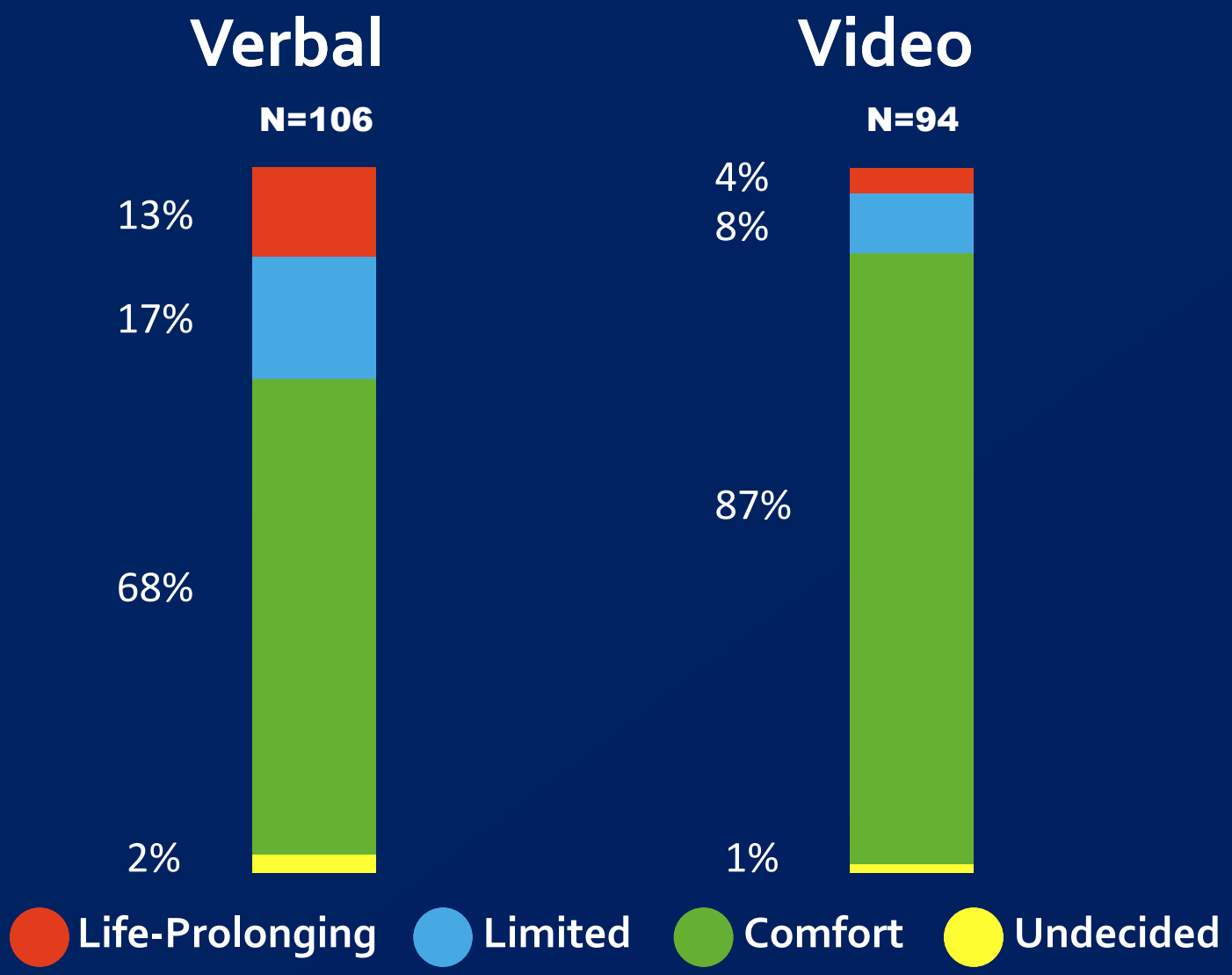
Background

- 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

- Presents options for care
- Visual images of options
- Broad goals of care
  - Life prolongation, limited, comfort
- Specific conditions/treatments
  - Metastatic cancer, advanced dementia, CHF, dialysis, hospice, CPR
- Adjunct to counseling
- 6-8 minutes
- Multiple languages

Advanced dementia video (RCT)



Volandes, A BMJ;2009

Background: ACP videos

- Completed 'explanatory' RCTs
  - Advanced dementia *(hypothetical)*
    - *BMJ 2009*
  - Advanced cancer *(actual patients)*
    - *J Clin Onc 2010; J Clin Onc 2013*
  - Skilled nursing facility
    - *J Palliat Med, 2012*
- Ongoing 'explanatory' RCTs
  - Advanced Dementia (EVINCE); NIH-NIA R01
  - CHF; NIH-NHLBI R01

Background: ACP videos

- Hawaii state-wide implementation
- 11hospitals, 50 NHs, 9 hospices, 14 out-patient
- Suite of ACP videos, flexible
- "Real-world experience"
  - training materials and program
  - electronic platforms
  - widespread dissemination (not disease specific)
- Evaluations very positive but…
  - Lack of consistent infrastructure
  - No formal evaluation

Background: NH Research

- Electronic Data Sources *(Brown)*
  - Minimum DataSet
  - Medicare linkage
  - Residential History File
  - Facility (OSCAR)
  - Electronic Medical Records in nursing homes
- Generated large body of health services literature
- Emergence of cluster trials
  - Small *(EVINCE)*
  - Large *(e.g., high vs. standard dose influenza vaccine)*

Background: Pragmatic trial

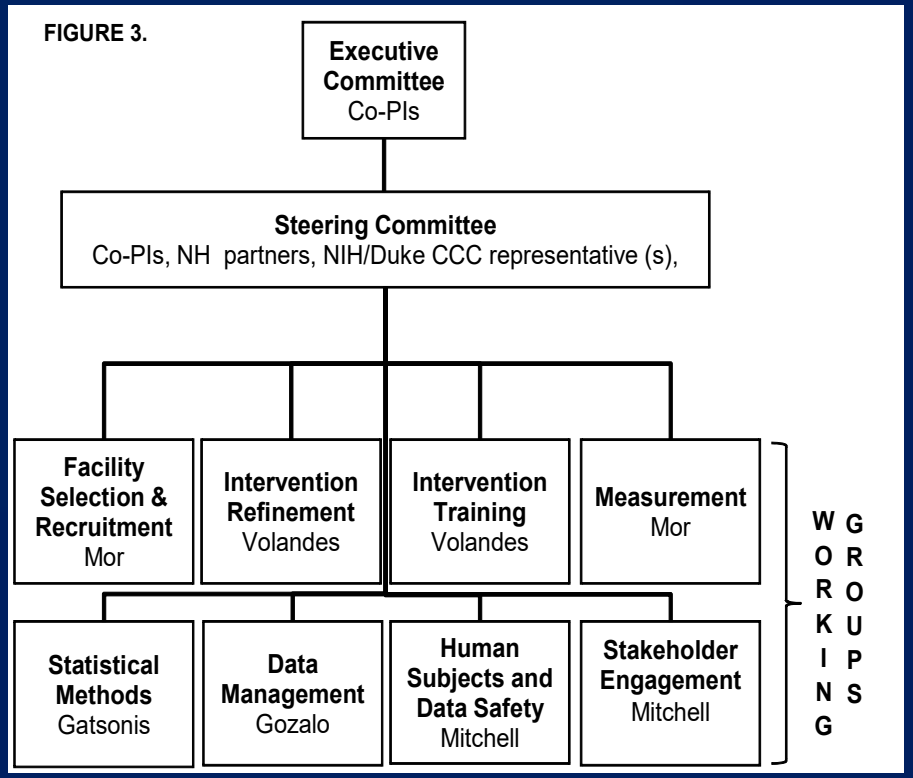
- NHs engage ALL patients in ACP
- Facility level implementation, patient level outcomes (i.e., cluster design)
- Practical, standardized, feasible intervention
- Corporate ownership of NHs chains; infrastructure for training and implementation
- Electronic data sources; cohort identification and outcome measurement

PROVEN

Pragmatic cluster RCT of ACP video intervention in NH patients with advanced comorbid conditions in 2 NH health systems (Genesis, PruittHealth) (492 NHs)

UH 2 Aims

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



PROVEN: UH3 Aims

Compare patient-level outcomes: intervention vs control NHs

- Hospital transfers , advance directives, burdensome treatments, Hospice election

TARGET populations:

1. Long-stay residents with advanced comorbid conditions (dementia, CHF, COPD) over 12-months
   1° TRIAL OUTCOME = hospitalization in long stay

2. Post-acute care (short-stay) patients with advanced comorbid conditions

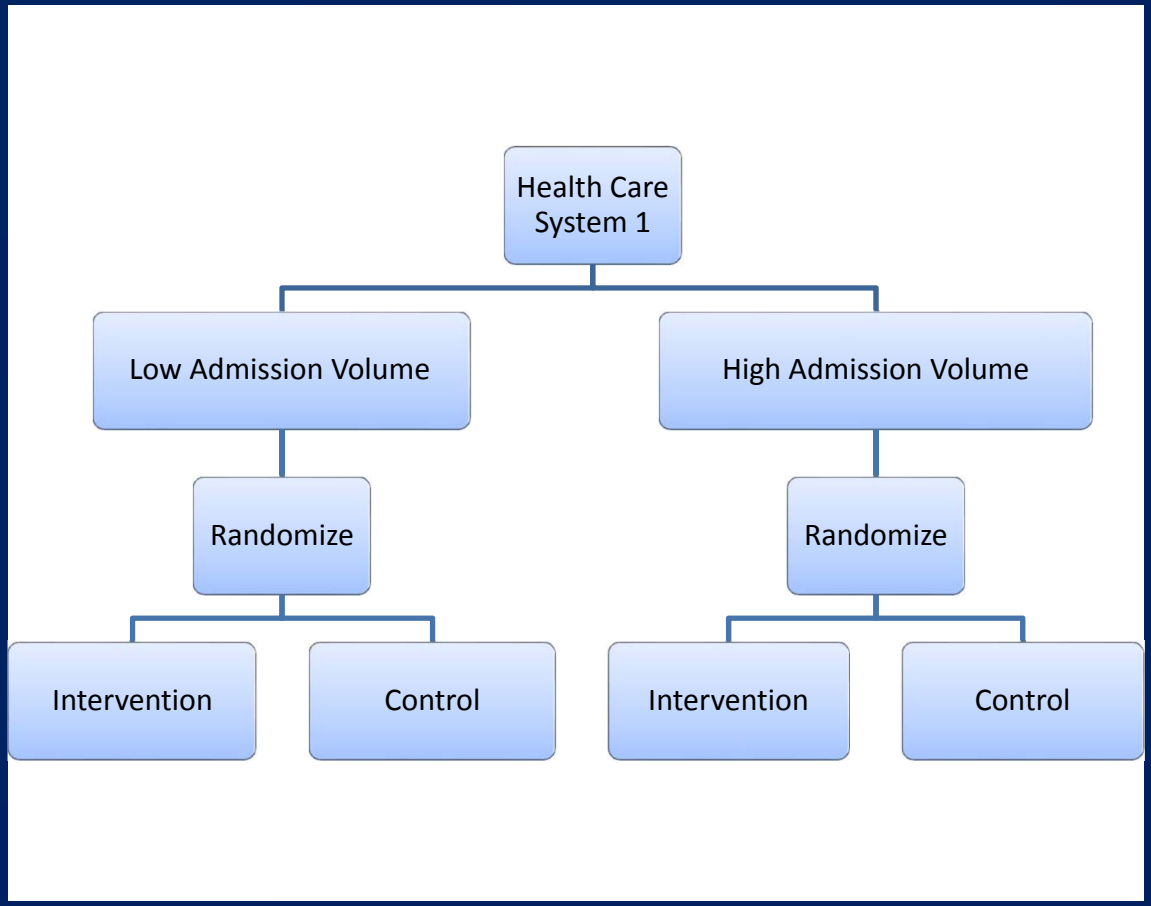
3. Long-stay and post-acute patients without advanced comorbid conditions; *"SPILLOVER"*

PROVEN: Setting

Characteristics of partner NH Health Systems		
Characteristic	Genesis	PruittHealth
Facilities, No.	406	86
States, No.	28	4
EMR system	PointClickCare™	American Health Tech
Training Resources	Adobe® Connect™	UHS-Pruitt University

PROVEN: Facilities

- **Eligibility**: > 50 beds, short & long-term
- **Randomization:**



PROVEN: Population

- Intervention facility-wide, all patients are population
- Characterized with existing MDS data

Characteristics of total NH population (Genesis/Pruitt)		
	Long-stay	Post-Acute Care
Age, mean	82	79
Female	72%	62%
White	83%	86%
Medicaid	75%	27%
Heart failure	21%	21%
Dementia	63%	25%
COPD	18%	24%

PROVEN: Target Populations

- Advanced comorbid illness, identify with MDS data
  - Advanced dementia: advanced cognitive impairment, dependent in eating
  - Advanced CHF/COPD: CHF or COPD, breathless with minimal exertion, assistance to ambulate

PLUS: diabetes, stroke, CVD, arthritis , hip fx, or other neuro

Estimated Target populations (Genesis/Pruitt)		
	Long-stay	Post-Acute
Total No.	54702	136905
Advanced Dementia, CHF, or COPD No. (%)	20144 (37%)	21712 (17%)

PROVEN: Intervention

- 18 month intervention period
- Suite of six ACP videos *(already exist)*
  - Goals of Care, Advanced Dementia, Hospitalization, Dialysis, Hospice, CPR/MV
- Offered facility-wide
  - All new admits, at care-planning long-stay
- Flexible (who, how, which video)
- Tablet devices, internet, corporate websites
- Training: corporate level, webinars, toolkit

PROVEN: Intervention

- How close to monitor fidelity?
- New Video Status Report in EMR
  - When was video shown
  - By whom
  - Which Video
- Ongoing discussion
  - Only when a video is shown vs. offered
  - More pragmatic vs. more prescriptive

PROVEN: Control

- Usual ACP practices
- Recognize programs may be going on in background (i.e., *INTERACT)*
- Non-differential between arms

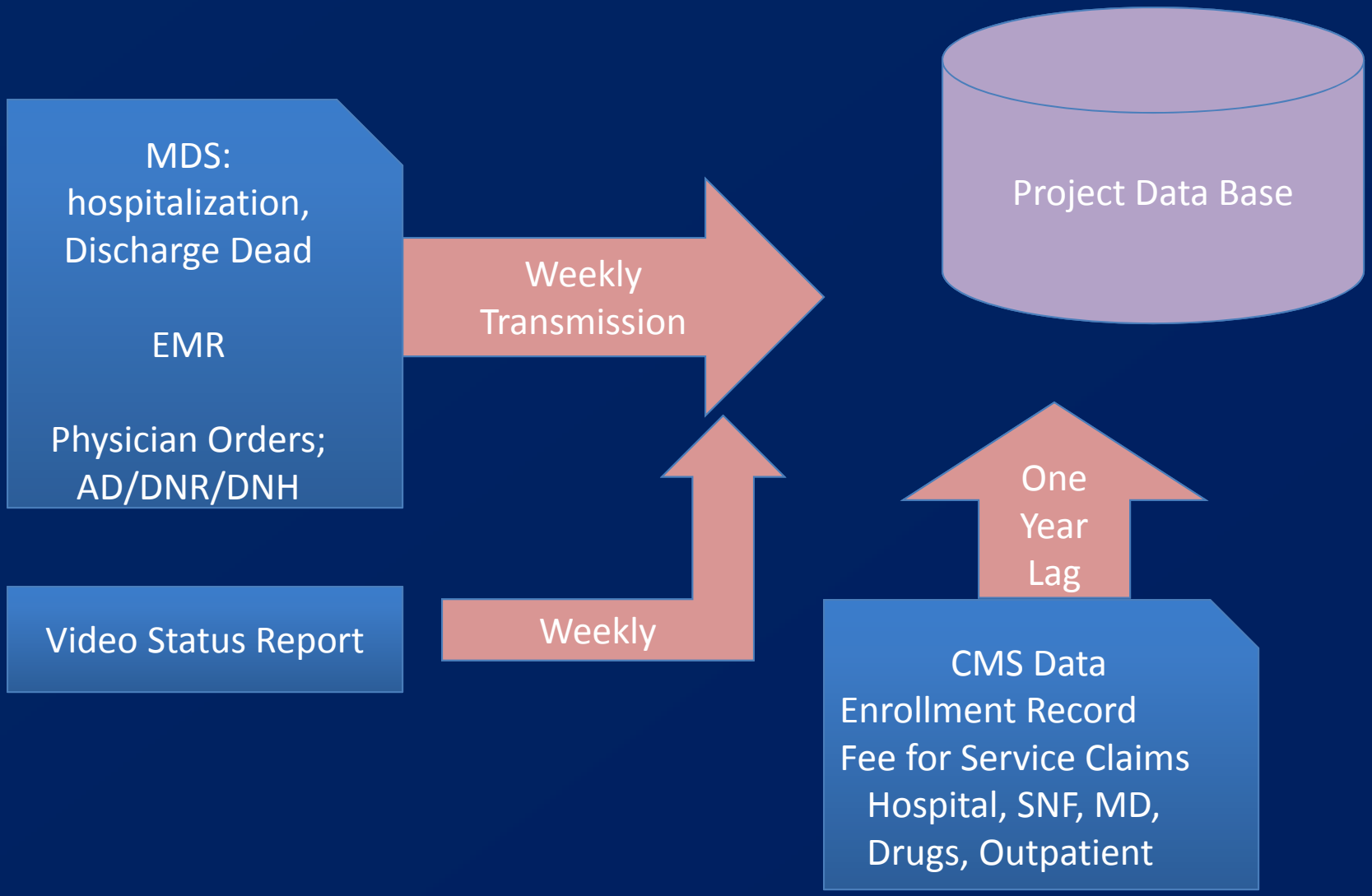
PROVEN: Human Subjects

- Seek waiver of individual consent (HHS 45 CFR 46:116)
  - NH unit of random Assignment
  - NH administrators are gatekeepers
  - Facility-wide intervention
  - Minimal risk, cannot be carried out without waiver, patients welfare not adversely affected by waiver
- DSMB

PROVEN: Data Sources

Data Element	Purpose	SOURCE		
		EMR	MDS	Medicare
Facility-Level				
Case-mix	recruitment		X	
Admission volume	randomization		X	
Patient-Level				
Demographic	covariate	X	X	
Long vs. short-stay	cohort definition		X	
Functional status	sub-population identification		X	
Cognitive status	sub-population identification		X	
Medical condition	sub-population identification	X	X	
Insurance	covariate			X
Advance directives	2° outcome	X		
Health services use	1° and 2° outcome	X	X	X
Burdensome treatments	2° outcome	X	X	X
Death	description, competing risk	X		X
Video implementation	monitoring fidelity	X		

PROVEN: Data Flow



PROVEN: Power Estimates

- 1^0 outcome: hospitalizations among long term care NH residents
- Assumptions
  - Hospitalization rate per person year = .25
  - Intra-class correlation of outcome across facilities = .10
  - Power >.90
  - # of residents per facilities varies between 10 and 75
  - Effect size of .075; alpha = .05
- 3341 Residents per arm in ~ 81 NHs

PROVEN: Outcome Analysis

- **Outcome: Number of hospitalizations per person per month alive.**
- **Hypothesis testing will be performed using randomization test[1] with the test statistic $r_T - r_C$, where**

$$r_t = \sum_{j=1}^{J} \sum_{i=1}^{I_j} d_{ij} / m_{ij} \qquad t \in \{C, T\}$$

- **d_{ij} – # of events for person i in facility j**
- **m_{ij} – # of months alive for person i in facility j**

[1] Gail MH, Byar D, Pechacek TF, Corle D. Aspects of statistical design for the Community Intervention Trial for Smoking Cessation (COMMIT). Control Clin Trials. 1992;13:6–21.

PROVEN: Outcome Analysis

- Confidence interval will be obtained using multilevel hierarchical log-linear model for person level hospitalization rates with facility level random effect.

$$r_{ij} \sim Poisson(\lambda_{ij})$$

$$\log(\lambda_{ij}) = \mathbf{X_{ij}}\beta + \beta_T \delta(T_{ij} = 1) + \grave{o}_j$$

$$\grave{o}_j \sim N(0, \sigma^2)$$

- The conditional treatment effect will be with $\hat{\beta}_T$ appropriate confidence interval
- Similar models with different link functions (e.g logit) will be used for secondary outcomes.

Issues & Questions

- Documenting the intervention; all who are offered video or only those shown the video?
- How prescriptive should we be?
- Informing residents in intervention arm
- Is the competing risk of death merely a statistical issue since death is not an outcome?