PROVEN
PRagmatic Trial of Video Education in Nursing Homes

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Investigators & Collaborators

- Co-Investigators
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  - Pedro Gozalo PhD
  - Joan Teno MD,
- Statistical Consultant
  - Allan Donner PhD

- Partners
  - Barbara Yody (Genesis)
  - Sherry Johnson (Pruitt)

Background: Nursing Homes

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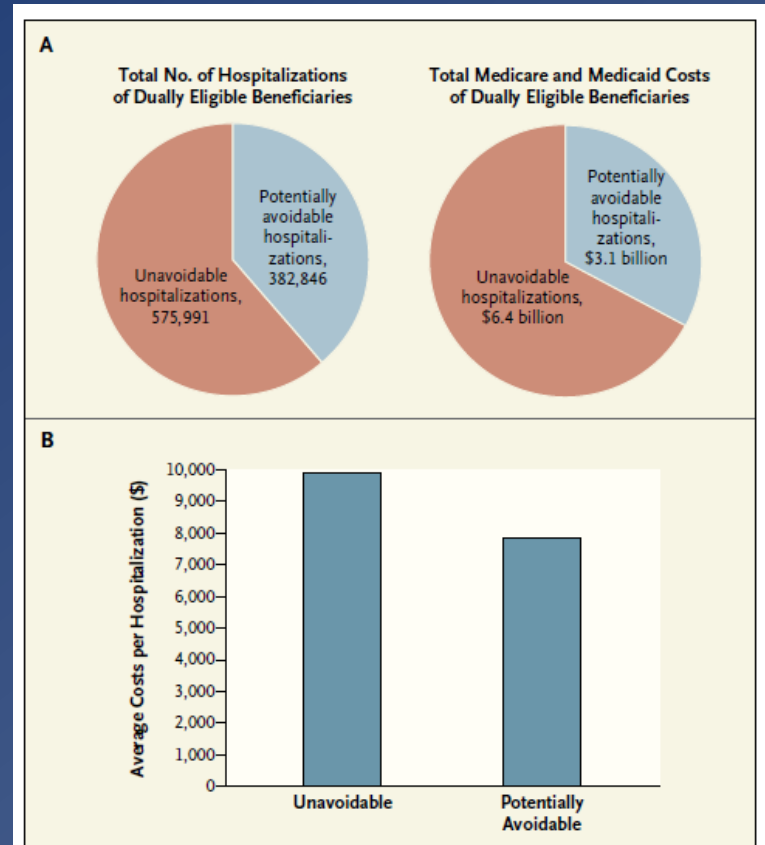
Background: ACP

- **Advance care planning (ACP)**
  - *Process* of communication
  - Care consistent with preferences
  - Leads to advance directives (e.g., DNR, DNH)
- **Better ACP associated with improved outcomes**
- **ACP suboptimal in NHs**
  - 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

The NEW ENGLAND JOURNAL of MEDICINE

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**

Advance Care Planning

Making Decisions for People with Advanced Dementia

Intensive Medical Care

Basic Medical Care

Comfort Care

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**
- **11 hospitals, 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

PROVEN

PRagmatic Trial of Video Education in Nursing Homes
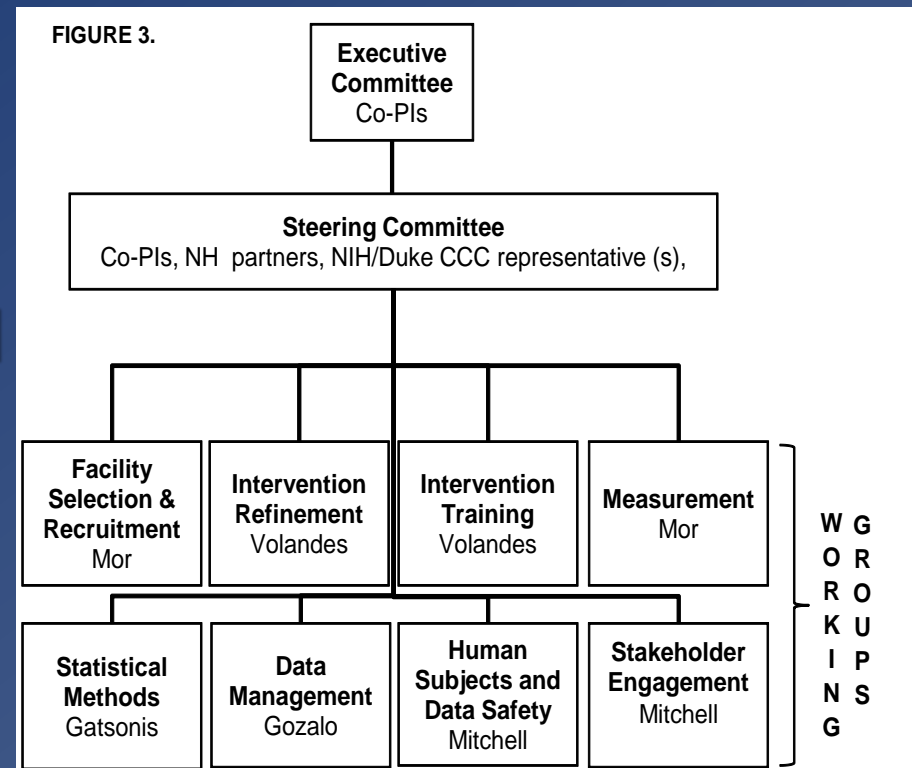
Background: NH Research

- **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)*

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)

FIGURE 3.

Executive Committee
Co-PIs

Steering Committee
Co-PIs, NH partners, NIH/Duke CCC representative (s),

Facility Selection & Recruitment Mor	Intervention Refinement Volandes	Intervention Training Volandes	Measurement Mor
Statistical Methods Gatsonis	Data Management Gozalo	Human Subjects and Data Safety Mitchell	Stakeholder Engagement Mitchell

WORKING GROUPS

PROVEN: UH3 Aims

Compare patient-level outcomes: intervention vs control NHs

➢ Hospital transfers , burdensome treatments, Hospice election

TARGET populations:

1. <u>Patients & Residents</u> with advanced comorbid conditions (dementia, CHF, COPD) over 18-months
1° **TRIAL OUTCOME = hospitalization in long stay**

1. Long-stay and post-acute patients <u>without advanced comorbid conditions</u>; *"Generalized Effect on non-target population"*

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: Population

- **Intervention facility-wide, all patients are population**
- **Characterized with existing (2012-13) MDS data**

Characteristics of total NH population (Genesis/Pruitt)		
	Genesis	Pruitt
Age, mean	76	76
Female	61%	61%
White	78%	69%
Medicaid*	63%	70%
Heart failure	23%	26%
Dementia	27%	33%
COPD	26%	26%

*Percent Medicaid from most recent OSCAR data available

PROVEN: Target Populations

- **Advanced comorbid illness patients estimated to accrue by System over 18 months:**
  - **Advanced dementia**: advanced cognitive impairment, Alzheimer's or non-Alzheimer's dementia, assistance to eat and transfer
 - **Advanced CHF/COPD**: CHF, COPD, breathless with minimal exertion, assistance to ambulate and assistance with at least one other ADL
  - **PLUS**: At least one other medical diagnosis.

Estimated Target populations (Genesis/Pruitt)		
	Genesis	PruittHealth
Total No.	317424	47982
Advanced Dementia	21641 (6.8%)	4932(10.3%)
Advanced CHF or COPD	18260 (5.8)	3431 (7.2%)

PROVEN: Proposed Random Assignment Strata

- **<u>Eligibility</u>**: > 50 beds, mixture of short & long-term patients
- **<u>Random Assignment:</u>**
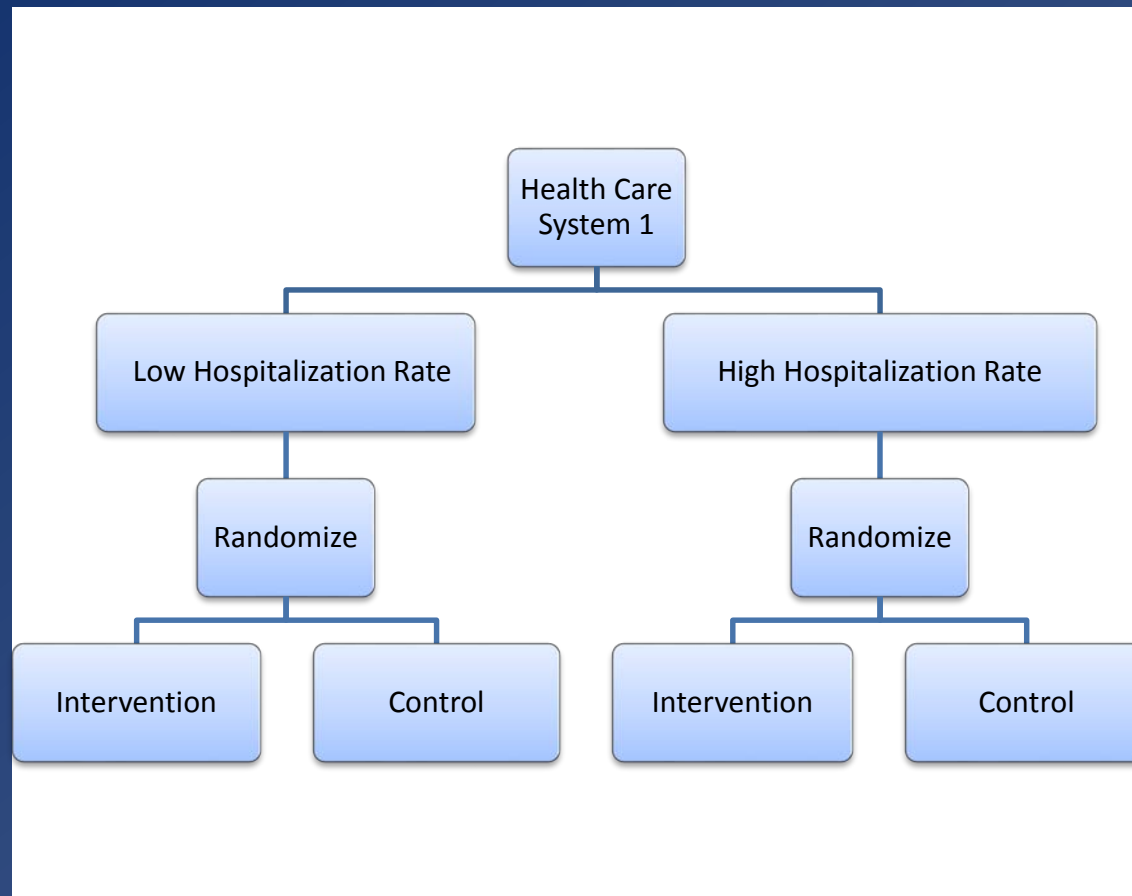
PROVEN: Intervention

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

PROVEN: Intervention

- **New Video Status Report in EMR**
  - When was video shown
  - By whom
  - Which Video

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
    - Possibility that Brown IRB will NOT consider this to be human subjects research
- **DSMB appointed by NIA**

PROVEN: Data Flow

MDS:
hospitalization,
Discharge Dead

EMR

Physician Orders;
AD/DNR/DNH

Video Status Report

Monthly
Transmission

Bi-Weekly

Project Data Base

18
Month
Lag

CMS Data
Enrollment Record
Fee for Service Claims
Hospital, SNF, MD,
Drugs, Outpatient
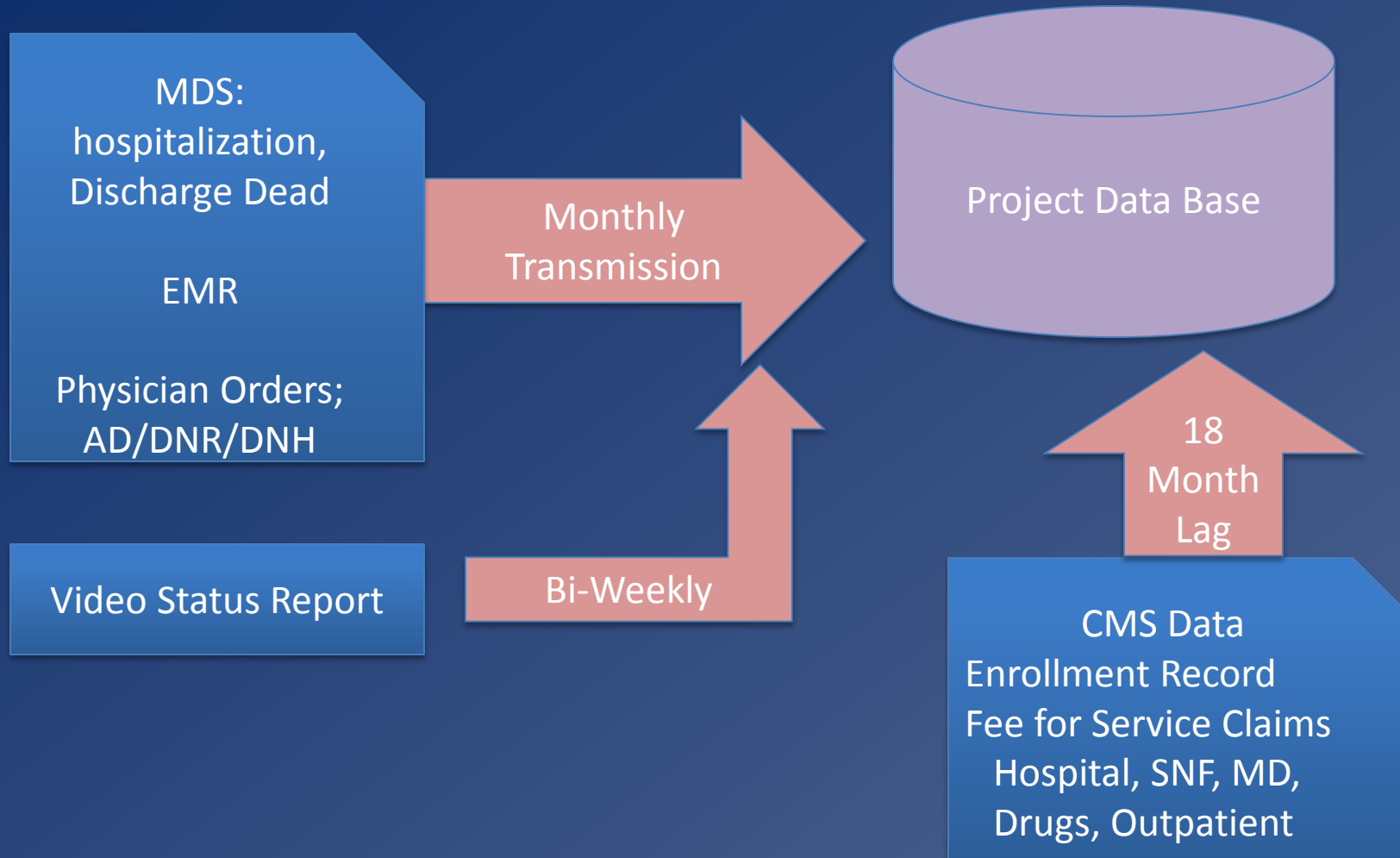
UH2 UPDATES

Update: General Structure

- Meetings
  - Executive: Weekly
  - Steering: Monthly
  - Working Groups: q2 weeks
- Kick-off meeting October 2 at Brown
- Presentations to corporate leaderships
- Standard Operating Procedures in process

Update: Intervention Group

- Completed suite of six videos
- Completed training materials
  - Toolkit
  - Webinar
  - Quick Reference Guide
- Began pilot study

Update: Intervention Group

Table of Contents

Update: Pilot Study

- 4 Facilities (2/health care system)
- Intervention implementation
- Data
  – Define analytic cohorts
  – Data exchange
  – Cohort and outcome definition validation
  – Preliminary analysis
- Exit Interviews

Pilot Study Timeline:

|	Month of UH2 phase				
Timeline for Pilot Testing (UH2 Aim 3)					
Activity	Oct	Nov	Dec	Jan	Feb
Recruit four facilities	X				
Implementation set up		X	X		
Staff Training		X	X	X	
Intervention Implementation				X	
Program database				X	
Data extraction, merging, and cleaning				X	X
Measurement validation					X
Preliminary analyses					X
Exit interviews					X

Update: Statistics Group

- How big a difference?
- 1^0 outcome: hospitalizations among long term care NH residents
- Assumptions
  - Proportion of target patients hospitalized ~ 0.44
  - # of residents per facilities varies between 50 and 200
  - Intra-Class Correlation of outcome across facilities =.06
  - Want to detect a .06 percentage point reduction in probability of Hospitalization
  - Desired Power =.90 and two sided Alpha = .05
- Conservative Sample Size Estimate ~125 facilities/arm

Update: Statistics Group

- Sample Size estimates based on proportion hospitalized, HOWEVER

- Operational outcome is hospitalizations per person month alive in target group
  - Over dispersed Poisson Distribution to account for multiple hospitalizations per person and informative censoring due to death

Hospitalizations per Person-Year among Target Groups
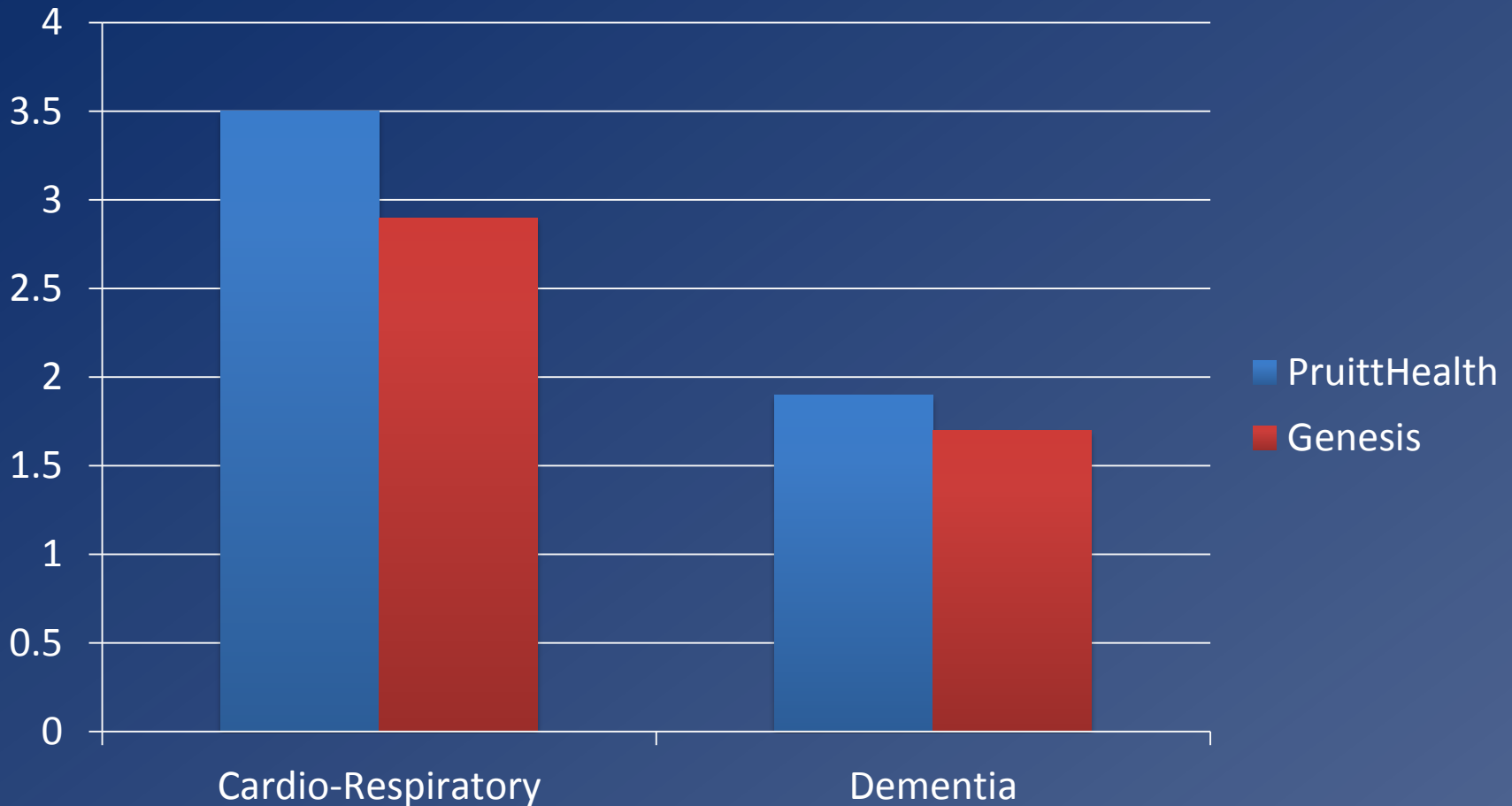
Update: Measurement Group

- Cohort Definitions: complete & Coded
- Data Transfer: Arrangements for regular transmission of "warehouse" data
- Prepare for Pilot to identify "target" population
- IRB application scheduled for submission in February following pilot project results

Update: Human Subjects

Goal	Aug	Sep	Oct	Nov	Jan	Feb	Mar	Apr	May	Jun
IRB approval for pilot	■	■								
Prepare and Submit IRB for RCT			■	■	■					
Submit DUAs						■	■	■		
Convene DSMB & charter					■	■	■	■	■	■
Register ClinicalTrials.gov									■	

Update: Stakeholder Group

Stakeholder	Group	Representative
Center to Advance Palliative Care	Care delivery	Diane Meier, MD
Scientific Community	Investigator	Joseph Ouslander, MD
Patient Quality of Life Coalition	Patient	Daniel Smith, JD
Natl LTC Ombudsman Resource Center/Consumer Voice	Patient	Amity Overall Laib, MS
Excellus BlueCross BlueShield & MedAmerica Insurance Company	Payor	Patricia Bomba, MD
American Health Care Association	Policy	David Gifford, MD, MPH
National Hospice and Palliative Care Organization	Provider-Hospice	Carol Spence, PhD, RN
American Medical Directors Association	Providers-MD	Paul Katz, MD, CMD
National Association Directors of Nursing Administration	Providers-Nurses	Sherrie Dornberger, RN
American Geriatric Society	Providers/Policy	Jennie Chin Hansen, CEO
Coalition to Transform Advanced Care	Mixed Coalition	Charlie Sabatino
Family Caregiver Alliance	Family/Patient	Kathy Kelly, Executive Director

Challenges

- Academic "Detailing" in pilot study training
- Advance directive ascertainment
- Corporate business agreements (contracting)
- IRB ---determining best approach
- Delay in Medicare Claims Availability