NIH Collaboratory Case Study: PROVEN

- Pragmatic cluster RCT of an Advance Care Planning (ACP) video intervention in NH patients with advanced comorbid conditions in two NH healthcare systems
- Video overcomes barriers of traditional ACP; ad hoc & perceived to take too long
- Randomize 360 NHs; 119 to intervention
- Primary Outcome: hospital transfers of target, multi-morbid residents with ~50% one year mortality

PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Video Assisted Advance Care Planning

- Visualize treatments such as CPR
- Broad goals of care
 - Life prolongation, limited, comfort
- Specific conditions/treatments
- Adjunct to counseling
- 6-8 minutes
- Multiple languages
- Trained Health Care System staff to train facility champions and jointly monitored implementation over 18 months of recruitment and 12 months of followup

Health Care Systems Research Collaboratory



Advance Care Planning

Making Decisions for People with Advanced Dementia



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

Documenting the ACP Video Program

- A Video Status Report (VSR) 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; documents whether shown or refused
- # patients offered video/# of eligible to be offered
- Monthly Reports generated for ALL intervention facilities
- Intended to identify limited implementation for re-training
- Documenting Implementation has important lessons for future dissemination efforts

VARIATION IN FACILITY VIDEO SHOW RATE



FACILITIES IN THE INTERVENTION GROUP

PROVEN: Implementation Challenges

- Turnover of facility champions
- VSR record becomes one more "check box"
- High "offer rates" unrelated to high "show" rates
- Transfer of facility ownership
- ACP video program added on to staff responsibilities
- Program became low priority at times of facility crisis
- Goal of lowering hospital transfers is long term; daily operating demands always a priority in an industry constantly in flux



Plan for:

How the trial addresses sustainable implementation

How the trial addresses effectiveness

How the healthcare system learns

Key policy or practice changes needed to enhance sustainable implementation

Designing With Implementation and Dissemination in Mind

Visit the Living Textbook of Pragmatic Clinical Trials at

rethinkingclinicaltrials.org



Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of

the typical cost and time needed to conduct a traditional clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate highGET STARTED

What is the

NIH COLLABORATORY? >>

What is a

PRAGMATIC CLINICAL TRIAL? ⊗

ENGAGING STAKEHOLDERS ③