

Challenges Implementing Innovative Programs in Long Term Care: Examples from Pragmatic Trials



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Housekeeping

- All participants will be muted
- Enter all questions in the Zoom Q&A/chat box and send to All Panelists and <u>Attendees</u>
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
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Grant Support

- NIA U54AG063546
- NIA 5R33AG057451
- NIH 5UH34G049619
- VHA CRE 12-025





Conflicts of Interest

- Chair Scientific Advisory Committee for naviHealth, a post-acute care care coordination company
- Board membership of HopeHealth Hospice in Providence, RI





Learning Objectives

Upon completion of this presentation, you should be able to:

- Understand the complexities of Making Changes in Health Care Systems
- Understand the kinds of Implementation Challenges that arise in conducting ePCTs in nursing homes
- Understand the Implications of how difficult it is to Change Care Practices to improve Dementia care





Statement of the Problem

- Care interventions designed to help people living with dementia are tested in controlled environments using research staff to implement the treatment – nothing like the real world in which such successful interventions might be implemented;
- Need to combine knowledge of what works with knowledge of how to institutionalize changes in care processes embedded in fully functioning health care systems designed to achieve the intended goals of novel interventions.





Clinical Trial Problems Today

- Many interventions implemented by researchers show positive effects
- They are done as proof of concept
- BUT, rarely consider whether and how they would be adopted in functioning health systems
- Implementing interventions in the real world requires we understand how current care processes can be changed





Translating Efficacy Trials into Effectiveness Research

- Pragmatic Clinical Trails test interventions super-imposed on existing systems in hospitals, ED, SNFs or home
- Like traditional biomedical studies, need to connect the dots to be "translated" into advances in clinical medicine
- Health Care Systems must be active players in study design as is true for clinicians and even important stakeholders like patients and care partners
- <u>Doesn't happen by accident</u>





Embedded Pragmatic Randomized Clinical Trials

- Emulate how the intervention/treatment would be done in "real world"
- Often randomized at the area, hospital or nursing home (NH) level
- Since not drug trials, intervention could be considered "standard of care," able to waive consent and intervene with all eligible patients
- Like doing Quality Improvement with random assignment





How Does Change Happen in Health Care Systems?

- What happens when a new clinical care protocol is adopted? How is work reassigned? How is task sequencing re-engineered?
- What happens when nursing homes mandate universal 2 person lifts to transfer patients? Do staff comply? Do they use the Hoya lift?
- How were new infection control protocols and PPE use promulgated? How variable was adoption? Between or Within provider?
- How are such changes in practice sustained, reinforced?





Four Pragmatic Trials: Simpler Interventions Easier to Implement

- Experience suggests the following proposition:
 - *Easy*: Substitute one vaccine for another (e.g. high dose influenza vs Standard dose)
 - Surprisingly Complicated: PROVEN -- Video Assisted Advance Care Planning for ALL in NH
 - *Multi-pronged:* Music & Memory implemented in a nursing home
 - *Multi-pronged Complexity:* INTERACT, DCM-Dementia Care Mapping, Staff Training
- Logarithmic increase in complexity as more Departments and types of workers involved





Substituting High Dose Influenza Vaccine for Standard

- High-dose Influenza vaccine FDA approved based on traditional clinical trial
- BUT, never tested in NH population, even though approved for use
- Recruited hundreds of NHs
- Randomly assigned to HD or SD
- Outcome was hospitalization for Influenza like Illness





HD vs SD Participating NHs by State (n=823)







High Dose vs Low Dose (Unadjusted) Stratified by Patient Vaccination Status



Lower Hospitalization Rate for Patients in HD NHs; 80% - 85%; Vaccination Rates similar in HD and SD facilities and high in almost all facilities







- A pragmatic cluster RCT of an advance care planning (ACP) video intervention embedded within two NH healthcare systems
- Introduced in 2 large nursing home companies in US; 119 facilities trained in how to implement the intervention
- Outcome of interest monitored using Medicare Claims:
 - Hospital transfers (including ED visits) per 1000 person days





Intervention

- Suite of 5 videos
- Tablet (2/NH) or on-line
- 2 Champions/NH
 - Social Worker
- Offer video to resident or proxy:
 - Baseline
 - Admission
 - Q6months
 - Ad hoc
- Could choose video
- English or Spanish



Goals of Care for Any Patient*

This video helps patients understand and make decisions about their goals of care.



Goals of Care for Patients with Advanced Dementia

This video helps family members understand and make decisions for patients with advanced dementia.



Decisions about Hospice*

This video helps patients and their families understand and make decisions about hospice care.



Decisions about Hospitalization*

This video helps patients understand and make decisions about hospitalization.



General Information about Advance Care Planning for Healthy Adults*

This video helps generally healthy patients understand and make decisions about their long-term health goals.



Australian Dementia Forum Keynote



Measuring Fidelity

- Video Status Report User-Defined Assessment programmed into EMR
- Each time a video is offered, a form completed even if a video is not shown
- If shown: who watched, which video... etc
- Staff distribute the Web Site <u>url</u> to families
- Used for feedback reporting





Offering vs. Showing the Video Intervention

	Both Systems (N=119) Mean	NH system 1 (N=98) Mean	NH system 2 (N=21) Mean	
Outcome: Offer				
Admissions	69.55	76.23	38.33	
Long-stay residents	45.06	46.97	42.45	
Outcome: Show				
New admissions	19.68	18.32	25.98	
Long-stay residents	14.36	11.66	26.95	







- 55.6% advanced illness residents (or proxies) <u>offered</u> a video
- 21.6% advanced illness residents (or proxies) <u>shown</u> a video
- Only 20% of NHs had 40% or more of their Residents Shown the Video







Results: Outcomes – No Differences

	Intervention N=4171	Control N=8308	Marginal Rate					
Primary Outcome	Rate ((95%	SE) CI)	(95% CI)					
Hospital transfers/1000 person-days alive	3.7 (0.2) (3.4-4.0)	3.9 (0.3) (3.6-4.1)	-0.2 (0.3) (-0.5,0.2)					
Secondary Outcomes	Percent (SE) (95% confidence interval)		Marginal Risk Difference (SE) (95% Cl)					
≥ 1 hospital transfer	40.9 (1.2) (38.4-43.2)	41.6 (0.9) (39.7,43.3)	-0.7 (1.5) (-3.7, 2.3)					
≥ 1 burdensome treatment	9.6 (0.8)	10.7 (0.7)	-1.1 (1.1)					
	(8.0,11.3)	(9.4,12.1)	(-3.2,1.1)					



*Excluded residents enrolled in hospice at baseline



PROVEN- Summary

- Introducing the video as part of the admission process was just "one more thing" for busy social service staff
- Incorporating videos into routine care planning process was more difficult to do than suggested during the pilots
- High turnover among "champions"; new intervention activities were not incorporated into standard operating procedures for replacement staff





METRICAL (Music & Memory) Overview

- METRICAL was a parallel, cluster randomized pragmatic trial of a personalized music intervention targeting agitated behaviors in NH residents living with ADRD
- 27 implementation facilities from 4 healthcare systems (nursing home companies) differing in size, geographical location, residents' racial composition, and ownership
- Recruitment and randomization completed in February, 2019
- Trial ran from June, 2019 through February, 2020





Music and Memory (M&M) program

- Personalized music; favorite tunes as a young adult
- Activities staff personalize and load music on device
- NH staff chose 20 residents with ADRD & behavior outbursts
- A guide for M&M implementation was developed in the pilot phase of this study and used to train NH staff
- Nurses and Aides instructed to use the music at times of day when behaviors were likely or at early signs of agitation
- Recommended dose was 30 minutes per day





METRICAL: Number of Residents Exposed per NH







METRICAL: Proportion of residents using music at least weekly







METRICAL: Median minutes of music per resident exposed day







Music & Memory: Outcomes by Intervention Fidelity

	Total n=976	Intervention, n=483	Control, n=493	Adjusted Difference
Full Sample – Agitated Behavior Scale	0.432	0.349	0.460	-0.110 NS
Proportion of Residents with any anti-psychotic use in past week	28.1	26.2	29.6	-3.61 NS
Proportion of residents with any anti-anxiety med use in past week	22.6	20.8	24.3	-3.47 NS





Summary: METRICAL

- Customizing music to residents' preferences was more complicated than anticipated
- Transferring the the music between Departments was a barrier to wide use
- Some NHs didn't implement at all; some implemented fully
- Overall intervention was NOT effective





INTERACT (Interventions to Reduce Acute Care Transfers)

- Quality Improvement (QI) Program designed to assist nursing home (NH) staff in managing acute changes in residents' condition.
- Designed to help nursing staff identify subtle changes in patients' condition and assess the need for intervention and physician communication
- includes tools and processes
- Past Studies show NHs using these tools had reduction in hospital transfers
- But most compliant NHs probably had better management; (effect may not be INTERACT)





Implementing INTERACT in VA Community Living Centers

 We examined the adaptation and implementation of *INTERACT* in VA Community Living Centers (CLCs) voluntarily participating in an HSR&D funded pair-matched cluster RCT of the impact of INTERACT on hospitalizations from CLCs.





Critical INTERACT Components

- Two INTERACT tools used; Stop & Watch Early for aides and SBAR, a change in condition progress note; essential INTERACT components.
- These tools encompass the *INTERACT* QI program's core goal by prompting CLC staff to detect problems early, identify and communicate changes, to potentially manage the change in the CLC without hospital transfer when safe and feasible.





Nurse Tool Use by CLCs over Intervention Period



NIA IMPACT COLLABORATORY TRANSFORMING DEMENTIA CARE









Differences in CLCs Hospitalization Rates







Why INTERACT Wasn't Effective?

- VA CLCs have higher hospital transfers per 1000 (~5 vs. ~3) than outside NHs
- But, only ~15% of VA CLC hospital transfers are <u>avoidable</u> while ~33% in community NH
- VA CLCs have sicker residents, BUT, there is greater MD involvement, higher RN staffing ratio and lower staff turnover.
- Not all VA nursing staff felt there was a need to adopt INTERACT



Long-term care context is complex and unique

- Each of these organizational characteristics may differ between NHs or individual wards within the same NH
- These organizational differences lead to variations in intervention implementation







What do these studies tell us about Changing Health Systems Behavior?

- Complex interventions are hard to implement
- Commitment by leadership is a necessary but not sufficient condition
- Even agreement in advance doesn't guarantee implementation success
- Health Systems Leadership responds to market exigencies long before study end date



Lessons and Implications for PCTs

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





Implications for Studies of Health Systems Change

- Need replication of efficacy studies as embedded interventions
- Need to consider how to translate interventions to scale from the outset
- Must understand dose response; how much implementation is enough?
- As part of intervention adaptation need to know which components are critical
- Multiple pilots embedded in Health Systems may be needed to get implementation right





- Not enough for researchers to test interventions to change health systems
- To be useful, health systems must be willing to introduce interventions system wide
- Requires evidence of feasibility AND effectiveness in a fully functioning HCS
- Researchers must partner with HCS to implement the most salient features of researchers' interventions







Questions?

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