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

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BROWN
School of Public Health
Housekeeping

• All participants will be muted

• Enter all questions in the Zoom Q&A/chat box and send to All Panelists and Attendees

• 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

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• 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 Trials 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

• Doesn’t happen by accident
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
Lower Hospitalization Rate for Patients in HD NHs; 80% - 85%; Vaccination Rates similar in HD and SD facilities and high in almost all facilities
PROVEN

• 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
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 url to families

• Used for feedback reporting
# Offering vs. Showing the Video Intervention

<table>
<thead>
<tr>
<th></th>
<th>Both Systems (N=119) Mean</th>
<th>NH system 1 (N=98) Mean</th>
<th>NH system 2 (N=21) Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome: Offer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admissions</td>
<td>69.55</td>
<td>76.23</td>
<td>38.33</td>
</tr>
<tr>
<td>Long-stay residents</td>
<td>45.06</td>
<td>46.97</td>
<td>42.45</td>
</tr>
<tr>
<td><strong>Outcome: Show</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New admissions</td>
<td>19.68</td>
<td>18.32</td>
<td>25.98</td>
</tr>
<tr>
<td>Long-stay residents</td>
<td>14.36</td>
<td>11.66</td>
<td>26.95</td>
</tr>
</tbody>
</table>
Fidelity

- 55.6% advanced illness residents (or proxies) offered a video
- 21.6% advanced illness residents (or proxies) shown a video
- Only 20% of NHs had 40% or more of their Residents Shown the Video
## Results: Outcomes – No Differences

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Intervention N=4171</th>
<th>Control N=8308</th>
<th>Marginal Rate Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital transfers/1000 person-days alive alive</td>
<td>3.7 (0.2)</td>
<td>3.9 (0.3)</td>
<td>-0.2 (0.3) (-0.5,0.2)</td>
</tr>
<tr>
<td></td>
<td>(3.4-4.0)</td>
<td>(3.6-4.1)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Percent (SE) (95% confidence interval)</th>
<th>Marginal Risk Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1 hospital transfer</td>
<td>40.9 (1.2) (38.4-43.2)</td>
<td>-0.7 (1.5) (-3.7, 2.3)</td>
</tr>
<tr>
<td>≥ 1 burdensome treatment</td>
<td>9.6 (0.8) (8.0-11.3)</td>
<td>-1.1 (1.1) (-3.2, 1.1)</td>
</tr>
<tr>
<td>Enrolled in hospice*</td>
<td>24.9 (1.2) (22.6, 27.2)</td>
<td>-0.6 (1.5) (-3.4, 2.4)</td>
</tr>
</tbody>
</table>

*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

![Bar chart showing the number of residents exposed per nursing home intervention. The x-axis represents Intervention Nursing Homes, ranging from 1 to 27, and the y-axis represents the number of residents exposed, ranging from 0 to 20.]
METRIcAL: Proportion of residents using music at least weekly
METRIcAL: Median minutes of music per resident exposed day
## Music & Memory: Outcomes by Intervention Fidelity

<table>
<thead>
<tr>
<th></th>
<th>Total n=976</th>
<th>Intervention, n=483</th>
<th>Control, n=493</th>
<th>Adjusted Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Sample –Agitated Behavior Scale</td>
<td>0.432</td>
<td>0.349</td>
<td>0.460</td>
<td>-0.110 NS</td>
</tr>
<tr>
<td>Proportion of Residents with any anti-psychotic use in past week</td>
<td>28.1</td>
<td>26.2</td>
<td>29.6</td>
<td>-3.61 NS</td>
</tr>
<tr>
<td>Proportion of residents with any anti-anxiety med use in past week</td>
<td>22.6</td>
<td>20.8</td>
<td>24.3</td>
<td>-3.47 NS</td>
</tr>
</tbody>
</table>
Summary: METRICAL

- Customizing music to residents’ preferences was more complicated than anticipated
- Transferring 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.
Hospitalization and AHRQ avoidable hospitalization rate per 1,000 person days over time among INTERACT CLCs

Pre Period

Intervention Period

Post Period

Control CLC Hospitalizations

Control CLC AHRQ Avoidable Hospitalizations

Experimental CLC Hospitalizations

Experimental CLC AHRQ Avoidable Hospitalizations
Differences in CLCs Hospitalization Rates

Adjusted hospitalization rate per 1,000 CLC days over time among INTERACT CLCs

Experimental CLCs
Control CLCs
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 avoidable 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

Figure 1. The hidden complexity of long-term care.
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
Summary

• 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?