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School of Public Health

Center for Long-Term Care Quality & Innovation

Using a Pilot to Test and Refine Your Measurement Strategy

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Acknowledgements & Disclaimer

- METRICaL: Music & MEmory: A Pragmatic TRial for Nursing Home Residents with ALzheimer's Disease
 - NIA R21AG057451 (PI: Vincent Mor)
 - NIA R33AG057451 (PI: Vincent Mor)
- METRICaL Team: Rosa Baier, James Rudolph, Kali Thomas, Roe Gutman, Renee Shield, Tingting Zhang, Jeff Hiris, Jessica Ogarek, Faye Dvorchak, Rebecca Uth, Laura Dionne, Esme Zediker, Miranda Olson, Natalie Davoodi
- The views and opinions expressed in this presentation are those of the presenter and do not necessarily reflect the official policy or position of the funder.

Key Points

- Using existing data to evaluate study outcomes is a key feature of embedded pragmatic trials (ePCTs)
- Administrative and system-generated data were not designed to evaluate your study
- It is important to determine if existing data are “good enough” to detect a real change in response to your intervention (if one exists)
- Piloting is a great way to test the sensitivity of existing measures
- If you know you have under-detection or a lack of sensitivity to change in existing measures, there are options to address these limitations in your full trial

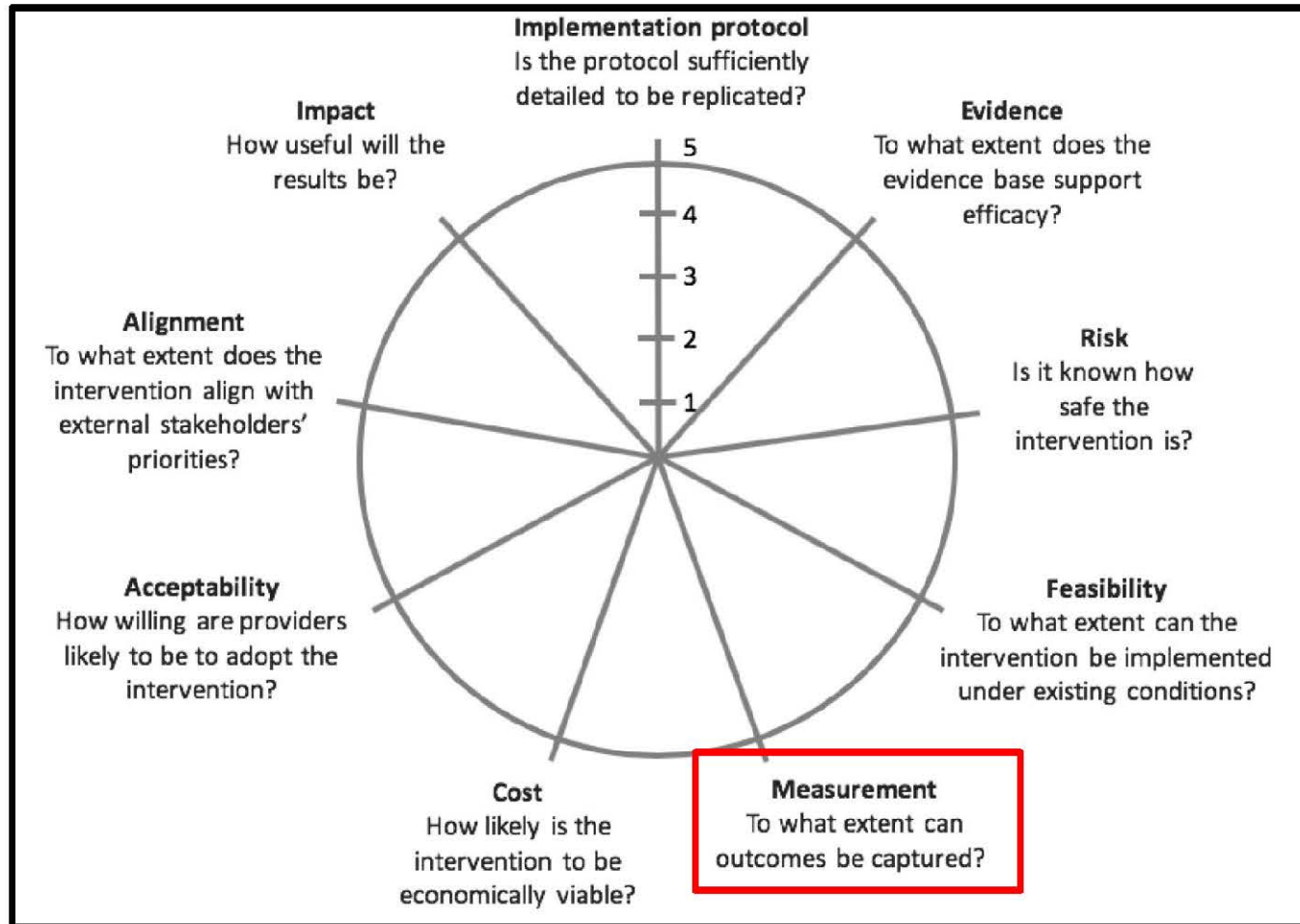
Embedded Pragmatic Trials (ePCTs)



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- Understand barriers to implementation in real-world settings
- Establish effectiveness evidence for interventions in complex populations and systems
- No more follow-up than is normal in usual care and minimal additional data collection (use data obtained from administrative or clinical record systems)

Using Existing Data Improves ePCT Readiness





Using your pilot to determine if the existing administrative data is “good enough”



Case Study: Music & Memory Pilot (R21)

- Music & Memory is a non-drug approach for managing dementia-related behaviors in nursing home residents
- Music a resident preferred when s/he was young is put on a personalized music device (mp3 player) and used at early signs of agitation
- May reduce agitation resulting from boredom, social isolation, or sensory deprivation
- Despite its popularity, there is no effectiveness evidence for the intervention

Case Study: Music & Memory Pilot (R21)

- The primary study outcome of interest is agitated and reactive aggressive behaviors
- Agitated and reactive aggressive behaviors are reported in the existing administrative data
- Preliminary analyses suggested potential under-detection of behaviors in the existing data

Look at the data before you propose!

- **Minimum Data Set (MDS)**
 - Comprehensive assessment of all nursing home residents at standardized intervals
 - Resident cognitive and physical functioning over time
- **LTCFocus (access for free at ltcfocus.org)**
 - Facility-level data from nursing home surveys, aggregated resident assessments, market characteristics
- **Electronic Health Record (EHR)**
 - Ability to customize modules to capture intervention adherence
 - Medications and other physician orders
- **Claims**
 - Great for (re)hospitalization outcomes
 - Can be linked to other data sources to understand resident and nursing home characteristics associated with outcomes

Agitated / Reactive Aggressive Behaviors in MDS

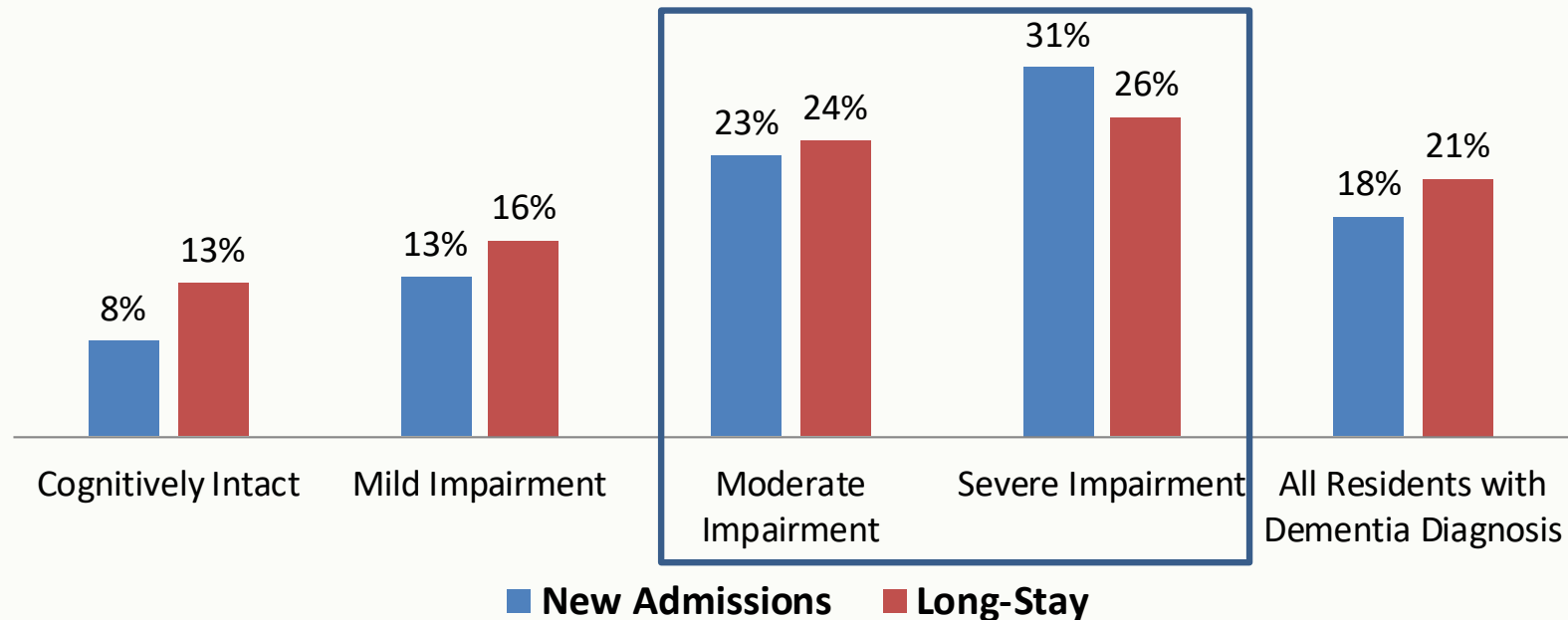
- Frequency of following behaviors in past week (MDS 3.0, Section E)
 - Physical behavioral symptoms directed towards others
 - Verbal behavioral symptoms directed towards others
 - Other behavioral symptoms not directed toward others
 - Rejection of needed care

- Response categories for items:
 - behavior was not exhibited in the last week (0),
 - behavior occurred 1-3 days (1),
 - behavior occurred 4-6 days (2), or
 - behavior occurred daily (3)

- Items combined to create Minimum Data Set - Agitated and Reactive Behavior Scale (MDS-ARBS)

We knew we had potential under-detection

National MDS Data: Residents with Dementia and Any Behaviors in Past Week
(1.3 Million Residents, 15,300 NHs, 2016)



McCreedy E, Ogarek JA, Thomas KS, Mor V. The Minimum Data Set Agitated and Reactive Behavior Scale: Measuring Behaviors in Nursing Home Residents With Dementia. Journal of the American Medical Directors Association. 2019 Dec 1;20(12):1548-52.

Behaviors not fully captured in available data

- 25% of residents with advanced dementia had any agitated behaviors in past week based on MDS
- 50-70% of similar residents had any agitated behaviors in past week based on gold standard interviews.^{1,2}
- Normalization of behaviors
- MDS nurse may not know resident, depend on charted behaviors
- Intervention designed to target routine behaviors



Use pilot to test measurement strategy

Available Administrative Data (Minimum Data Set, MDS)



Gold Standard Staff Interview (Cohen-Mansfield Agitation Inventory, CMAI)



Link data at the
person-level to
understand
missingness and
sensitivity to
change

- Proposed collecting gold standard data in the pilot
- Link gold standard data to available administrative data at the person-level
- If similarly sensitive to change, use available administrative data for full trial (R33)

While on-site collect additional data

- iPod play data to capture person-level adherence to intervention (dose)
- Direct observations of residents when using and not using the music (real-world efficacy data)
- Standardized assessments of intervention protocol adherence



Sumner Place Local Press Release
(accessed www.1011now.com, 1/21/20)



Bowling Green Manor Press Release
(accessed www.toledoblade.com, 1/21/20)



Journal of the American Geriatrics Society



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Measuring Effects of Nondrug Interventions on Behaviors: Music & Memory Pilot Study

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Pilot Results: Primary data collection and attrition

45 Residents were identified by nursing home staff at baseline data collection visit as targets for the intervention. Baseline staff interviews and direct observations were conducted.

5 Residents died in the nursing home before follow-up data collection visit

6 Residents were never exposed to intervention (staff decided to offer the intervention to different residents)

34 Residents were exposed to the intervention and were alive at the follow-up data collection visit. Follow-up staff interviews were conducted.

3 Residents were unable to be observed when using and not using the intervention:

- **1** resident was hospitalized
- **1** resident was deemed inappropriate for observation by staff
- **1** resident had been exposed to the intervention, but music player could not be located during follow-up visit

31 Residents were exposed to the intervention, were alive at the follow-up data collection visit, and were able to be observed when using and not using the music. Follow-up direct observations were conducted.

Pilot Results: Available administrative data may not be sensitive to change

	Behavioral score at baseline visit	Behavioral score at follow-up visit	Average within-person difference in behaviors	Average within-person change in behaviors	P-value
	Mean (SE)	Mean (SE)	Mean (SE)		
Available Administrative Data (MDS)	0.7 (1.5)	0.6 (1.6)	-0.1 (1.2)	-14%	.54
Gold Standard Staff Interview (CMAI)	61.2 (16.3)	51.2 (16.1)	-10.0(18.9)*	-16%	<.01
Direct observations of residents (ABMI)	4.1 (3.0)	4.4 (2.3)‡ 1.6 (1.5)§	-2.8 (2.3)*	-60%	<.01

*paired t-test with continuity correction

‡Frequency of behaviors when not using the music

§Frequency of behaviors when using the music

What now?!?

- Collecting primary data is expensive, time consuming and not pragmatic
- Available secondary data *may* not be sensitive to “real” changes in response to intervention
- If we end up with a 4-year, null finding ePCT, we want to be able to disentangle the following:
 - The intervention was not effective
 - The intervention was effective when used, but adherence unknown
 - **The intervention was effective but outcomes were not adequately captured by existing data sources**



Revise your ePCT measurement strategy based on your pilot findings



R33: Revising ePCT design based on pilot

- 81 nursing homes from 4 geographically diverse nursing home corporations participating in ePCT
- Originally proposed a stepped-wedge design in which all primary and secondary outcomes were assessed using available administrative data (behaviors from MDS and antipsychotic use from EHR)

R33: Originally proposed ePCT design

	<u>Wave 1</u> Nursing homes (NHs) randomized to receive intervention in Year 1 (n=27)	<u>Wave 2</u> Nursing homes (NHs) randomized to receive intervention in Year 2 (n=27)	<u>Wave 3</u> Nursing homes (NHs) randomized to receive intervention in Year 3 (n=27)
Study Year 1	Intervention Launches in Wave 1 NHs		
Study Year 2		Intervention launches in Wave 2 NHs	
Study Year 3			Intervention launches in Wave 3 NHs

Administrative data obtained monthly for all 81 NHs

R33: Designing a trial with missingness in mind

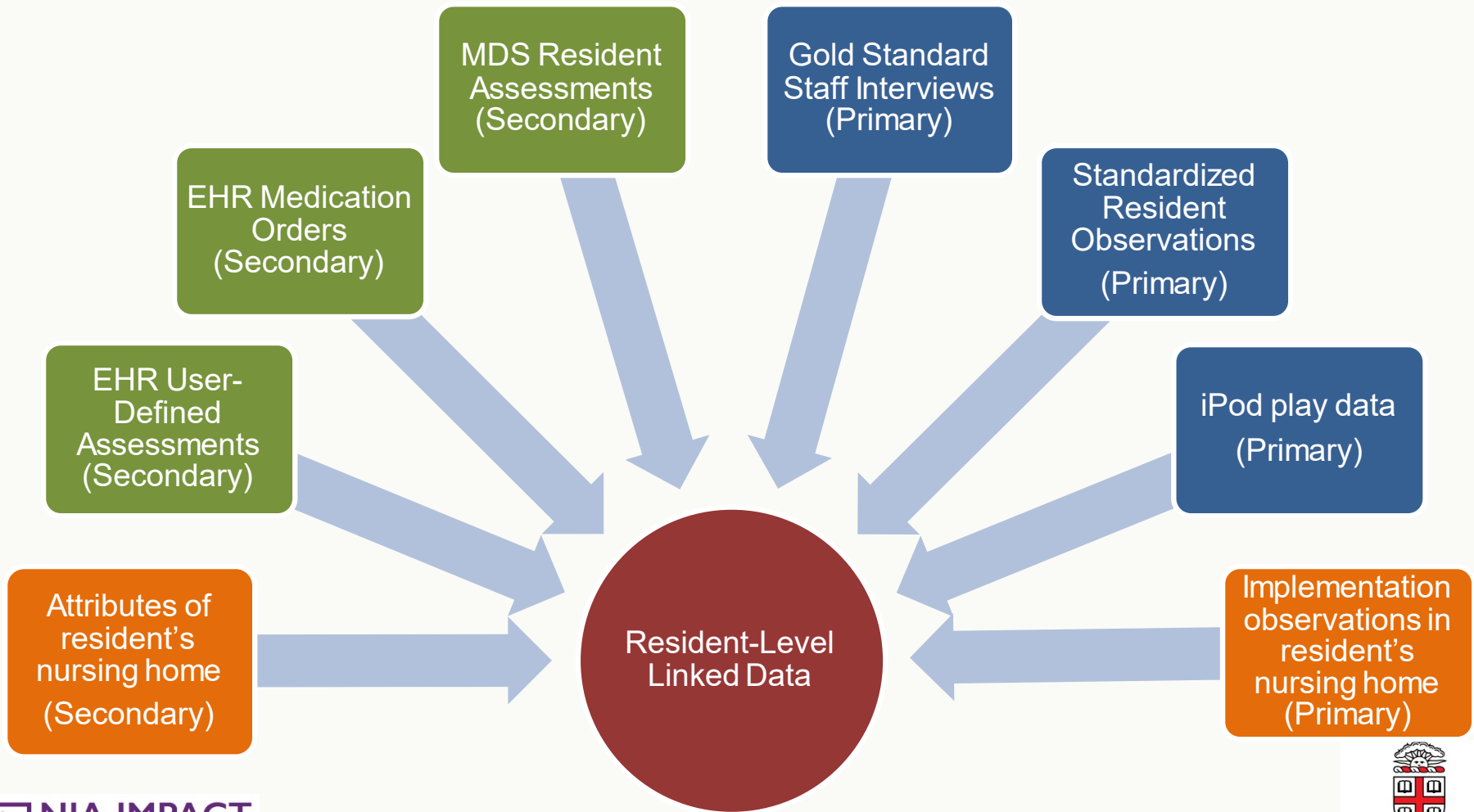
- 81 nursing homes from 4 geographically diverse nursing home corporations participating in the trial
- Originally proposed a stepped-wedge design in which all primary and secondary outcomes were assessed using available administrative data (behaviors from MDS and medication orders from EHR)
- Based on pilot findings, knew that we needed to account for under-detection and potential lack of sensitivity to change in administrative data
- Collected gold standard staff interview measure on randomly selected subset of treatment and control nursing homes during the first year of ePCT (parallel design)

R33: Originally proposed ePCT design

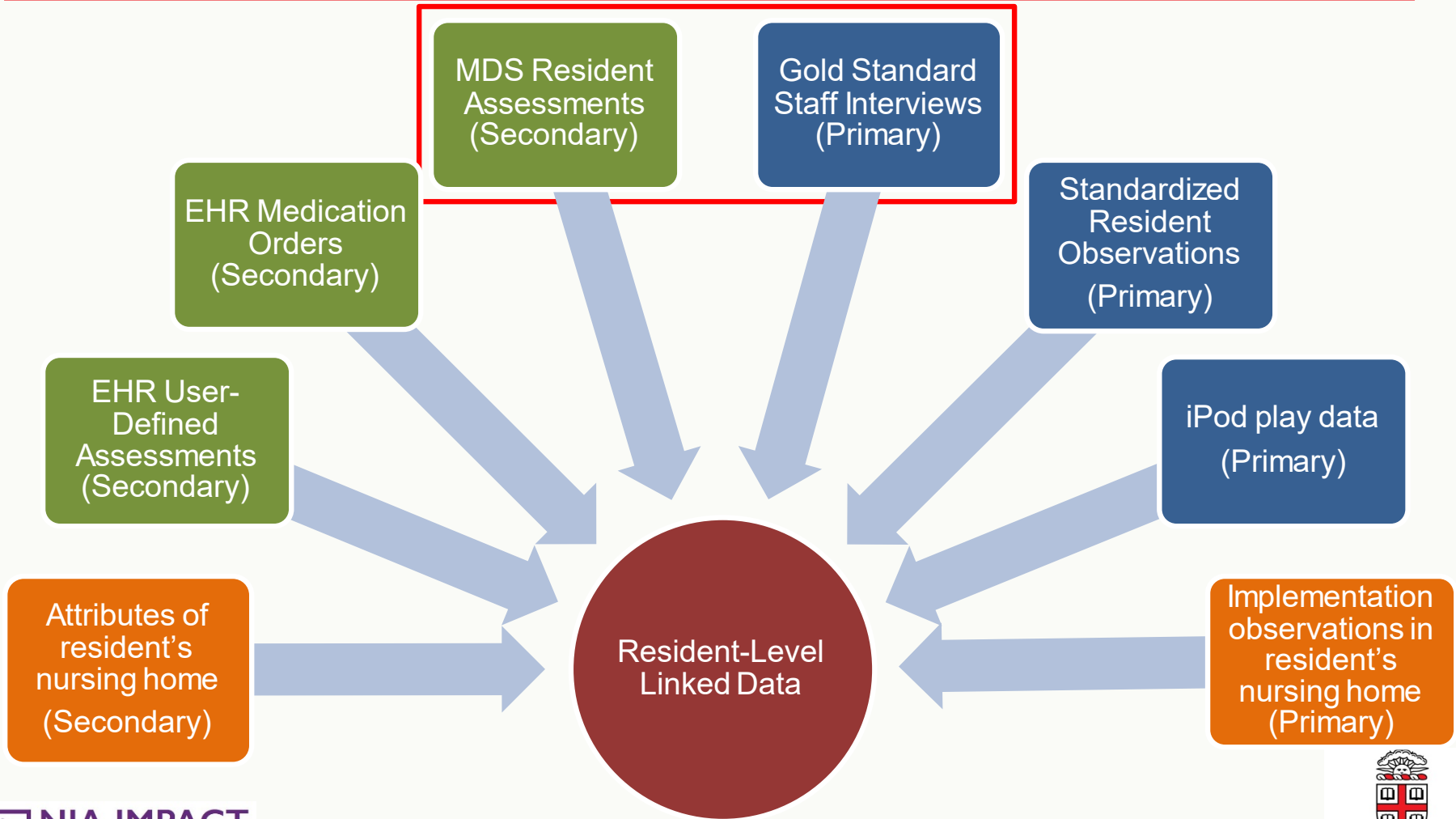
	<u>Wave 1</u> Nursing homes (NHs) randomized to receive intervention in Year 1 (n=27)	<u>Wave 2</u> Nursing homes (NHs) randomized to receive intervention in Year 2 (n=27)	<u>Wave 3</u> Nursing homes (NHs) randomized to receive intervention in Year 3 (n=27)
Study Year 1	On-site Data Collection	On-site Data Collection	
	Intervention Launches in Wave 1 NHs		
	On-site Data Collection	On-site Data Collection	
	On-site Data Collection	On-site Data Collection	
Study Year 2		Intervention launches in Wave 2 NHs	
Study Year 3			Intervention launches in Wave 3 NHs

Administrative data obtained monthly for all 81 NHs

R33: Resident-level data linking



R33: Resident-level data linking



R33: Resident-level data linking and imputation

- All residents in wave 1 and wave 2 nursing homes (n=54 nursing homes) will have administrative and gold standard measurements of their behaviors
- For these residents, we will equate these measures to understand potential under-detection or missingness (and resident and nursing home characteristics associated with under-detection)
- We will use what we learn about this relationship to statistically impute missing behavioral data for residents who never had gold standard interviews

R33: Ongoing challenges and caveats

- Data linking at the person-level requires secure infrastructure accessible by on-site data collectors, nursing home staff, and researchers
- Primary data collection is especially sensitive to attrition because of limited time and resources
- Challenges linking data across time/ varying follow-up
- Imputation models become complex and you need a good biostatistician



Key Takeaways

- Use available data before you propose
- When possible, use your pilot phase to test under-detection and/or possible lack of sensitivity to change in available measures by comparing to gold standard
- Design your full trial to address weakness in available data identified during pilot
- Person-level linking and statistical imputation may allow for large scale, cost-effective evaluations when under-detection is a problem

Questions?

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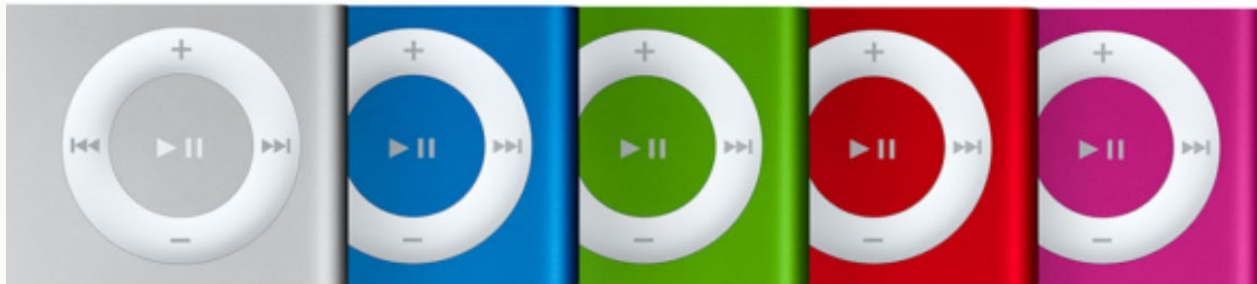
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Music & Memory Trial: Corporations

	Corporations			
	A	B	C	D
Characteristics of Participating Corporations				
Eligible nursing homes (#)	69	15	24	76
Geographic region	Mid-West	Mid-West	Mid-Atlantic	South
Ownership type	Non-Profit	Non-Profit	For-Profit	For-Profit
Characteristics of Eligible Nursing Homes	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
African American residents (%)	.5 (0.9)	0 (0.0)	42.0 (20.4)	40.0 (27.4)
Quality star rating (Range 1-5)	3.6 (1.1)	4.0 (1.1)	3.0 (1.5)	3.4 (1.3)
Residents with antipsychotics in past 7 days (%)	16.3 (6.7)	12.2 (6.6)	25.2 (13.6)	17.3 (8.5)
Residents with any behaviors in past 7 days (%)	11.2 (7.2)	9.4 (6.9)	21.6 (15.3)	11.6 (11.7)

Music & Memory Trial: Post-Randomization

	Randomized to Year 1 (n=27 Nursing Homes)	Randomized to Year 2 (n=27 Nursing Homes)	Randomized to Year 3 (n=27 Nursing Homes)
	Mean (SD)	Mean (SD)	Mean (SD)
Resident Composition and Acuity			
Female (%)	65.4 (10.9)	64.9 (12.0)	65.5 (9.1)
African American (%)	22.3 (25.7)	23.1 (26.2)	21.0 (26.3)
Moderate or severe cognitive impairment (%)	64.1 (11.8)	64.9 (9.1)	66.1 (11.8)
Potentially eligible residents (#)	44.8 (24.8)	44.7 (20.5)	45.3 (14.8)
Potentially eligible residents with agitated/aggressive behaviors (%)	20.1 (11.3)	20.5 (13.3)	20.5 (9.7)
Any antipsychotic use (%)	17.9 (8.6)	18.0 (8.3)	17.5 (12.0)
ADLs requiring extensive / complete assistance (#)	16.7 (1.7)	16.5 (2.0)	16.9 (2.0)

Music & Memory Trial: Post-Randomization

	Randomized to Year 1 (n=27 Nursing Homes)	Randomized to Year 2 (n=27 Nursing Homes)	Randomized to Year 3 (n=27 Nursing Homes)
	Mean (SD)	Mean (SD)	Mean (SD)
Nursing Home Quality, Payment, and Staffing			
Total beds (#)	101.5 (42.3)	107.3 (40.0)	103.6 (33.0)
Quality star rating	3.5 (1.4)	3.6 (1.2)	3.5 (1.2)
Medicaid as primary payer (%)	58.8 (25.6)	58.6 (27.6)	55.4 (26.1)
Medicare as primary payer (%)	11.2 (7.0)	11.5 (9.5)	11.1 (7.5)
Self-pay (%)	30.1 (26.4)	30.0 (24.7)	33.5 (28.5)
RN hours per resident day (#)	0.3 (0.2)	0.3 (0.2)	0.3 (0.2)
LPN hours per resident day (#)	0.9 (0.3)	0.9 (0.3)	0.8 (0.3)

Music & Memory Trial: Data Sources and Outcomes

Study Data Sources	Agitation / Aggression	Antipsychotics	Anxiolytics	Antidepressants	Hypnotics	Observed Emotion	Intervention Characteristics	Implementation Adherence
Evaluating Study Outcomes								
Standardized Assessments (MDS)	X	X	X	X	X	X		
Resident Observation	X					X	X	
Staff Interview	X							X
Medication Order Records (EHR)		X	X	X	X			
Evaluating Implementation								
User Defined Assessment (EHR)							X	X
iPod Play Data							X	X
Key Informant Interviews							X	
Environmental Scan							X	

Red = secondary data

Blue = primary data

MDS = Minimum Data Set

EHR = Electronic Health Record

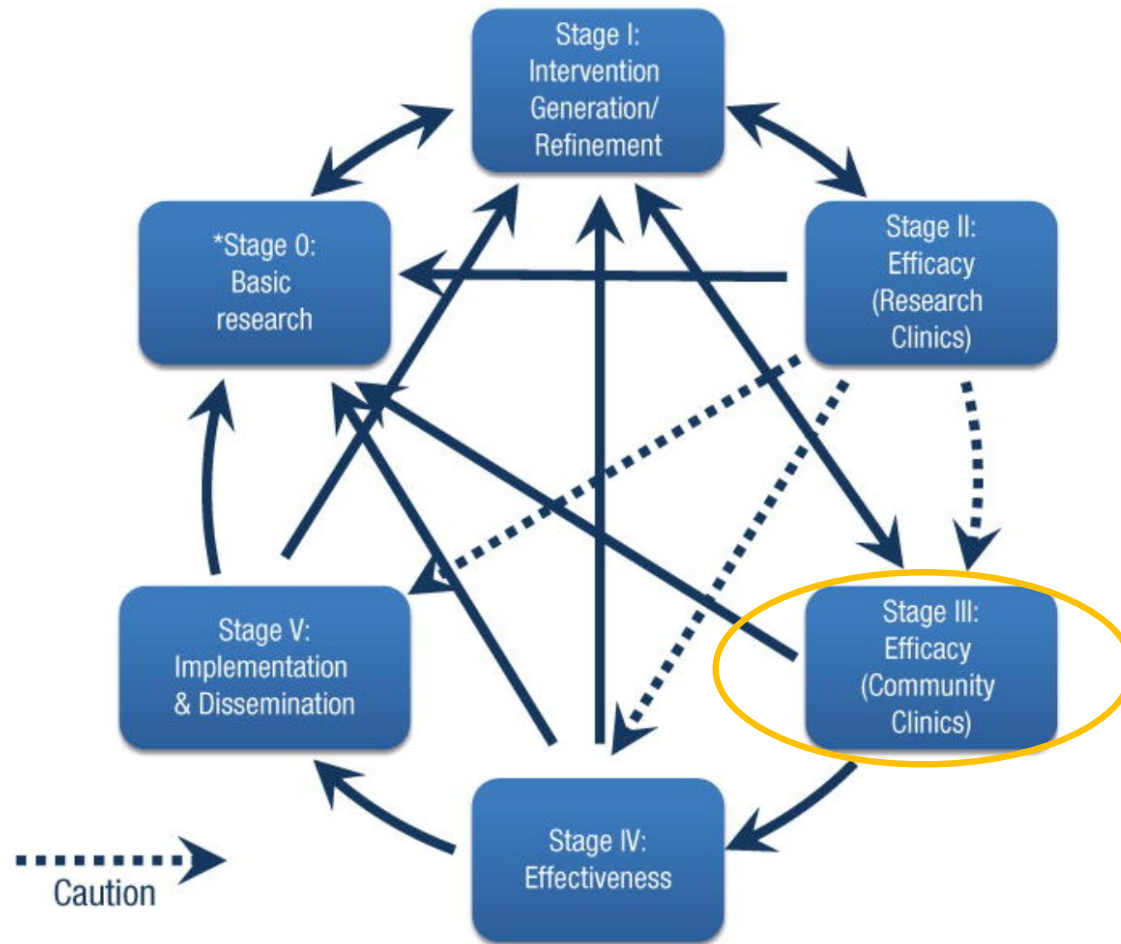
Under-Detection of Behaviors in MDS

- Percent of residents with any behaviors in past week on MDS compared to the Cohen-Mansfield Agitation Inventory
- CMAI = gold standard

Behavioral Domain	MDS 3.0 (418 long-stay residents, study nurses)	CMAI (418 long-stay residents, study nurses)
Physical	5%	6%
Verbal	7%	12%
Other	6%	14%

*Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. RAND Health Corporation. 2008 Apr

NIH Stage Model for Behavioral Intervention Development



Music & Memory Pilot: Measuring Agitated Behaviors Nursing Home Residents with Dementia

Administrative Data = MDS



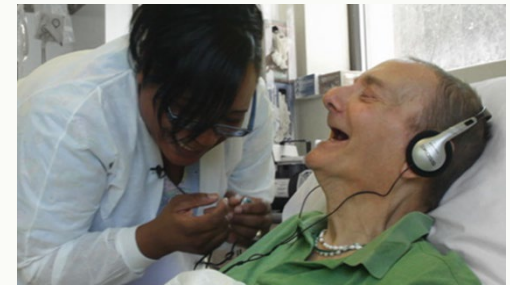
- + Routinely collected by NH staff on all NH residents
- + No on-site data collection required
- Likely under-detection
- Does not assess real-world efficacy
- Not subject to desirability bias

Staff Interview = CMAI



- Not routinely collected by NH staff
- Requires on-site data collection
- + Gold standard measure for assessing agitation in population
- Does not assess real-world efficacy
- Somewhat subject to desirability bias

Structured Resident Observations = ABMI



- Not routinely collected by NH staff
- Requires on-site data collection
- + Assesses real-world efficacy

Photo courtesy of Michael Rossato-Bennett
(musicandmemory.org)