Panel 2: Managing Behavioral Symptoms of AD/ADRD

Michelle Dionne-Vahalik
Laura Gitlin

Panel Discussion

Helen Kales, MD, University of Michigan, Ann Arbor
Ellen McCreedy, PhD, Brown University

Moderator: Laura Gitlin

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Moving evidence-informed assessment and management of behavioral symptoms out of the ivory tower and into the real world: *The DICE Approach and the WeCareAdvisor*

Helen C. Kales MD

Professor of Psychiatry

Director, Program for Positive Aging

University of Michigan

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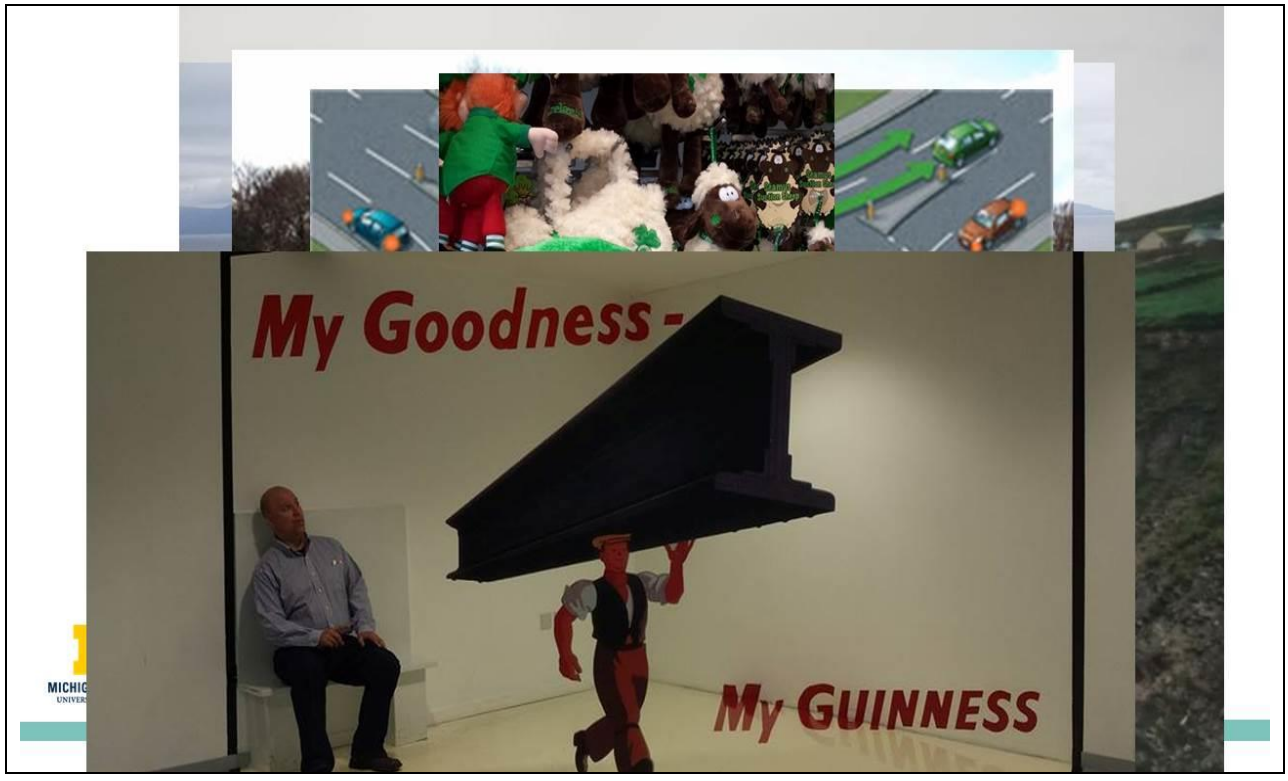

What made the difference?

- ABILITY TO ACCESS RELEVANT RESOURCES PRECISELY WHEN NEEDED=Technology ("Sat Nav"; AirBnB; Google for walking maps and hours of operation)
- PERSONALIZATION=Trip included something for everyone (shopping, kitschy hats, Guinness factory)
- TRAINING=Knew what to expect (roundabouts; driving on left side of road; guest house ladies don't like check-ins after tea time)

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Currently, the **5 million** people with dementia and their **15 million** family caregivers find themselves navigating without resources, personalization or training

Spheres that people with dementia and their families must navigate

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Dementia behaviors (BPSD) and their consequences

- Depression
- Anxiety
- Apathy
- Psychosis
- Agitation
- Aggression
- And many more

→

- Greater functional impairment
- Worsened quality of life
- Excess morbidity and hospitalizations
- Earlier nursing home placement
- Major source of caregiver burden and reduced caregiver income
- $10,000/year additional care costs
- Shorter time to severe dementia
- Accelerated mortality

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Dementia Care for BPSD: Big problem #1

- **Big problem #1=Inability to access relevant resources precisely when needed**
  - Few specialists, concentrated in academic centers
  - Primary care physicians with too little training
  - Dementia is more than a "medical" illness, there are multiple other spheres it impacts (legal, financial, functional, social)
  - Resources are available but can be hard for caregivers to find and access

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Lack of resources impacts on family caregivers and people with dementia

Caregiver themselves:

- Stress
- Burden
- Depression
- Burnout
- Lost income

To the person with dementia:

- Unoptimized health and function
- Limited social engagement
- Lack of tailored activities

Within the dyad:

- Lack of understanding about dementia ("he's doing this on purpose")
- Poor communication (yelling, negative communications)
- Expecting too much for the person's dementia stage

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Dementia Care for BPSD: Big problem #2

- Personalized medicine=treatment focusing on patients based upon their individual clinical characterization
- Precision medicine=focus on identifying which treatment approaches will be effective for which patients

- **Big problem #2=Current dementia care is neither personalized nor precise**
  - Given the lack of a cure for dementia, the current focus is on day to day management
  - Much of that management is focused on the ubiquitous and extremely challenging behaviors that accompany dementia
  - Current real-world care (community or NH) for behaviors is largely centered on medicating/sedating people with dementia

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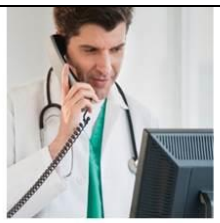
Current "Assessment"/Treatment of Physical vs. Behavioral Symptoms



- Family caregiver dealing with a behavior:
  - "Joe is agitated"
  - "I need something to calm Joe down"
  - "Can we get an order for Risperdal 0.5 BID?"
- PCP
  - "I'll write for the Risperdal now"

- Family caregiver dealing with "physical" symptom:
  - "Jo[illegible] sh[illegible]ss of breath"
- PCP
  - "I'll w[illegible]he antibiotic now"

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Dementia Care: Big problem #3

- Medications not very effective (1950's treatment for 21st century patients)
- In most cases, medications do not treat the underlying problem, but cover it over (e.g. sedate)
- Medications are associated with significant side effects including mortality
- Efforts by national policy bodies to limit use of one medication (e.g. antipsychotics) drive up use of others (e.g. anticonvulsants)
- Behavioral and environmental treatment strategies if selected appropriately (precision medicine) are more effective

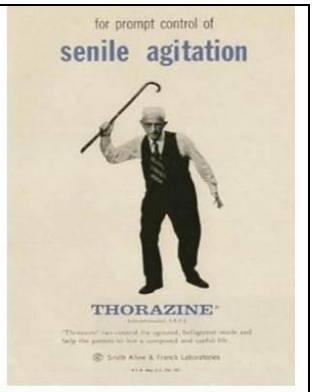

Table 3. Adjusted Mortality Risk Differences in Death Rates During the 180-Day Observation Period Between Medication Users and Antidepressant Users[a]

Medication	Risk Difference, % (95% CI)	NNH (95% CI)
Antidepressant	[Reference]	NA
Haloperidol	12.3 (8.6-16.0)[b]	8 (6-12)
Olanzapine	7.0 (4.2-9.8)[b]	14 (10-24)
Quetiapine	3.2 (1.6-4.9)[b]	31 (21-62)
Risperidone	6.1 (4.1-8.2)[b]	16 (12-25)
Valproic acid	5.1 (1.8-8.4)[b]	20 (12-56)

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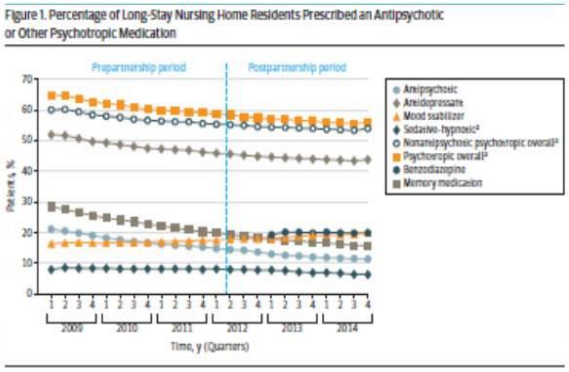
Antipsychotic use HAS declined—but does that mean that fewer people with dementia are being medicated with psychiatric drugs?

- Programs such as CMS' National Partnership have driven down nursing home AP use
- Unintended consequences?: Shift to other psychotropics with less evidence of benefit and similar risks?



Maust, Kales et al
JAMA Internal Med
2018

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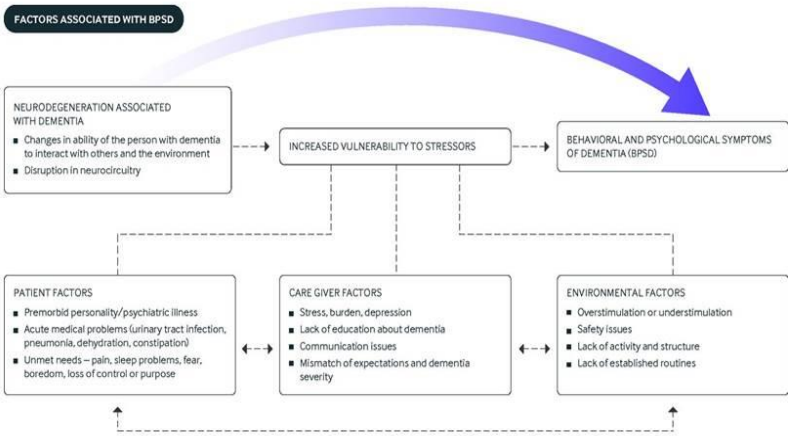
BMJ Conceptual Model

- Consequence of neurodegeneration associated with dementia
- Creates an increased vulnerability to stressors
- Stressors include patient, caregiver and environmental factors
- No one-size-fits all solution



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Kales, Gitlin, Lyketsos BMJ 2015

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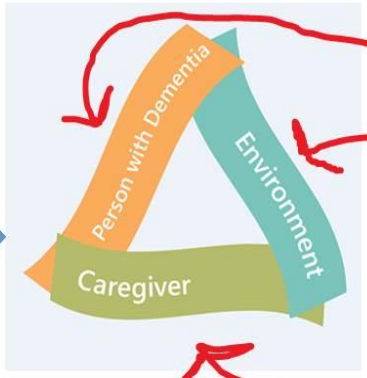
Does how we treat behaviors currently make sense?

Brain disease

Behavior



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Non-pharmacologic treatment

- Numerous expert bodies recommend as first-line
- May be better stated as **"ecobiopsychosocial"** interventions
- Largely NOT been translated to real-world care and
  - Lack of scalable training programs for caregivers and pro
  - Time required
  - Lack of guidelines-what strategy to use and when?
  - So many interventions (e.g. acupuncture, music therapy, reminiscence)—what works?

- **Big problem #3: Lack of training among caregivers (or providers) on how to use proven non-pharmacological strategies to manage behavioral symptoms**

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Molinari et al, 2010;
Cohen-Mansfield et al, 2013

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How can we solve Big Problems #1, 2 and 3?

With innovation, "packaging" and technology

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The DICE Approach

- Program for Positive Aging organized and funded a 2011 meeting of national experts across disciplines
  - Consider possible etiologies
  - Include caregiver in process
  - Integrate pharmacologic and non-pharmacologic
  - Build in flexibility to use in various care settings
  - Goal to avoid knee-jerk prescribing without assessment of underlying causes

Kales, Gitlin, Lyketsos JAGS 2014

  - ***We need to better PACKAGE non-pharmacologic approaches**

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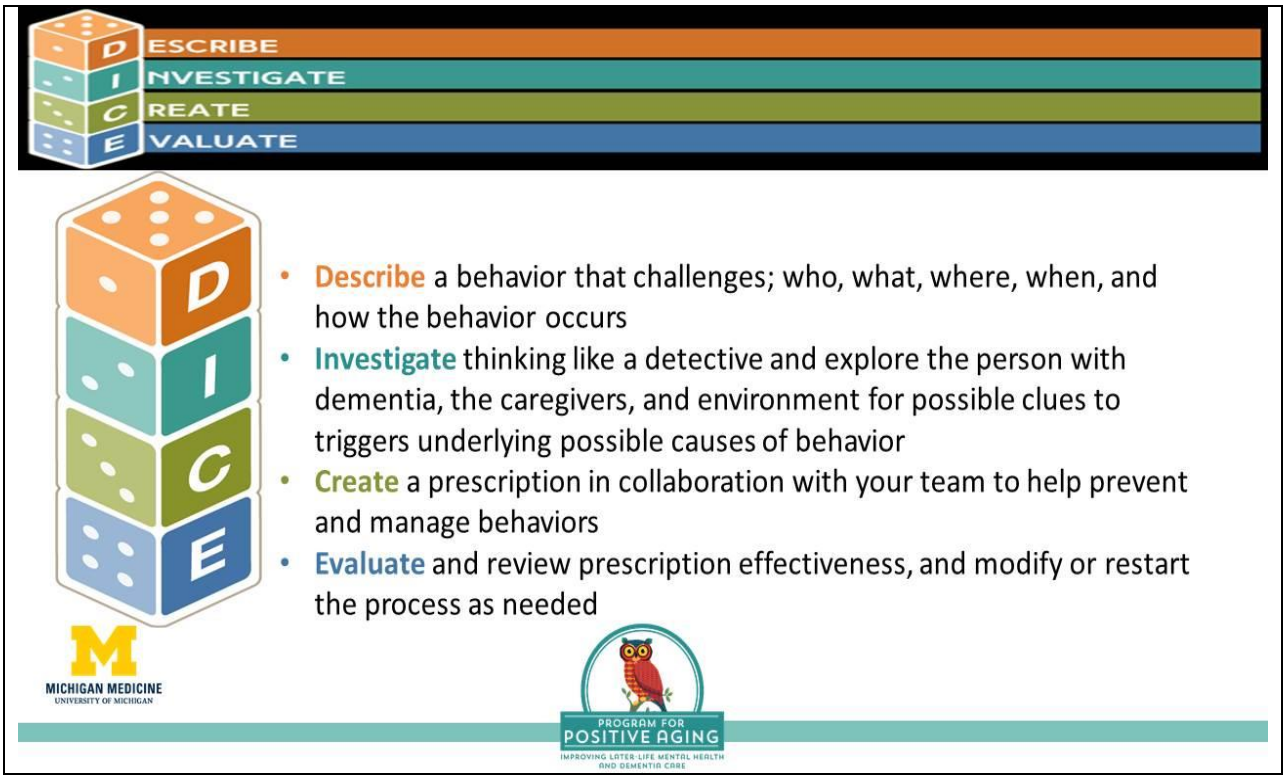
DESCRIBE
INVESTIGATE
CREATE
EVALUATE
D
I
C
E
Describe a behavior that challenges; who, what, where, when, and how the behavior occurs
Investigate thinking like a detective and explore the person with dementia, the caregivers, and environment for possible clues to triggers underlying possible causes of behavior
Create a prescription in collaboration with your team to help prevent and manage behaviors
Evaluate and review prescription effectiveness, and modify or restart the process as needed
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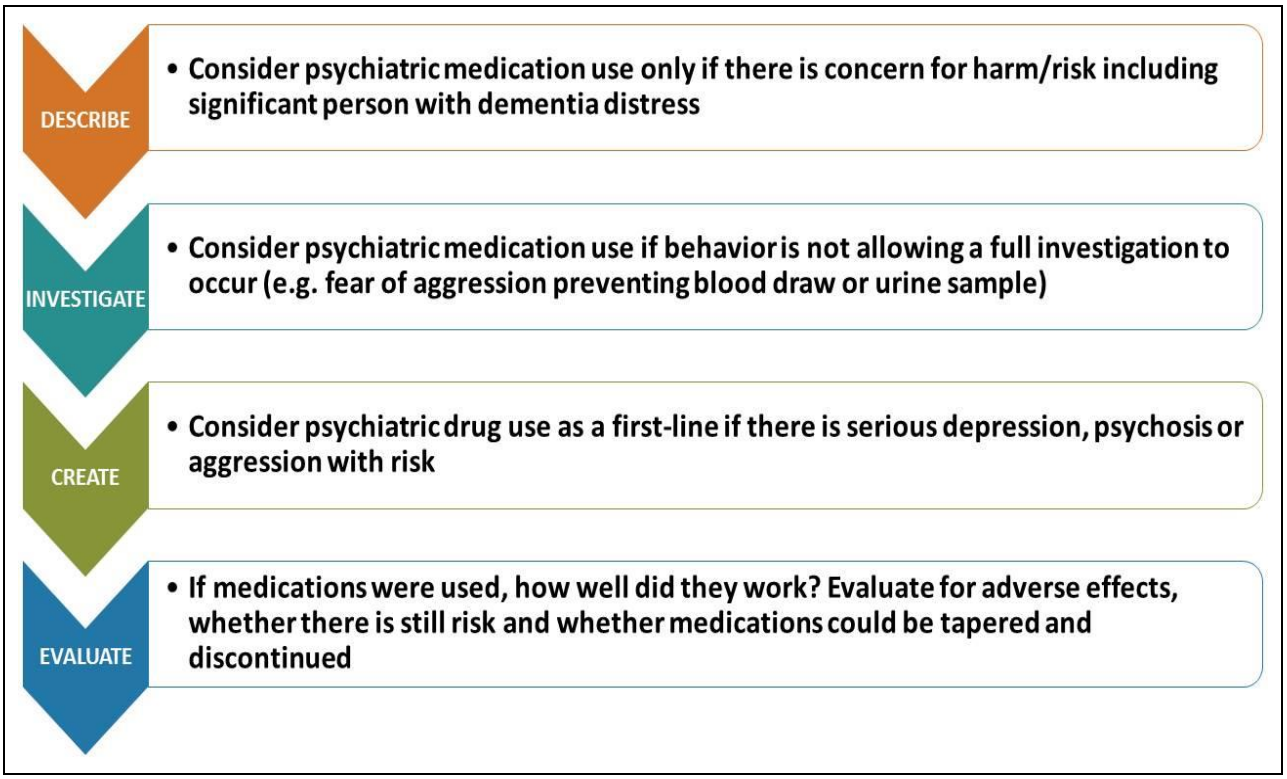
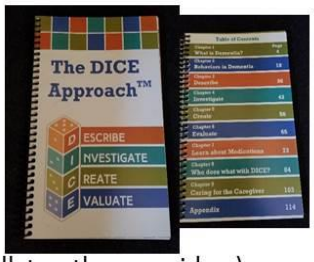

DESCRIBE
• Consider psychiatric medication use only if there is concern for harm/risk including significant person with dementia distress
INVESTIGATE
• Consider psychiatric medication use if behavior is not allowing a full investigation to occur (e.g. fear of aggression preventing blood draw or urine sample)
CREATE
• Consider psychiatric drug use as a first-line if there is serious depression, psychosis or aggression with risk
EVALUATE
• If medications were used, how well did they work? Evaluate for adverse effects, whether there is still risk and whether medications could be tapered and discontinued

We've "Packaged" the Approaches Via DICE, How do we Deliver Them?

- Pilot of DICE Training: 1 day; 8 modules with 1.5 hour brainstorming session
  - Wisconsin-1 statewide training n=125, results pending
  - Michigan-3 trainings (Grand Rapids, Ann Arbor, East Lansing)
    - Mix of family and professional (RN, LPN, CNA, PT, RT, SW) caregivers
    - N=182
    - Both groups with significant improvement from pre to post



- Most helpful aspects:
  - Use of workshop materials (case studies, role playing, time to talk to other providers)
  - Combining paid professionals and home/family care givers for interaction and learning
  - Use of simple framework (DICE) that is understandable to all
  - Covering medication issues (effect on older adult, family, paid caregivers)
  - Handouts to take home

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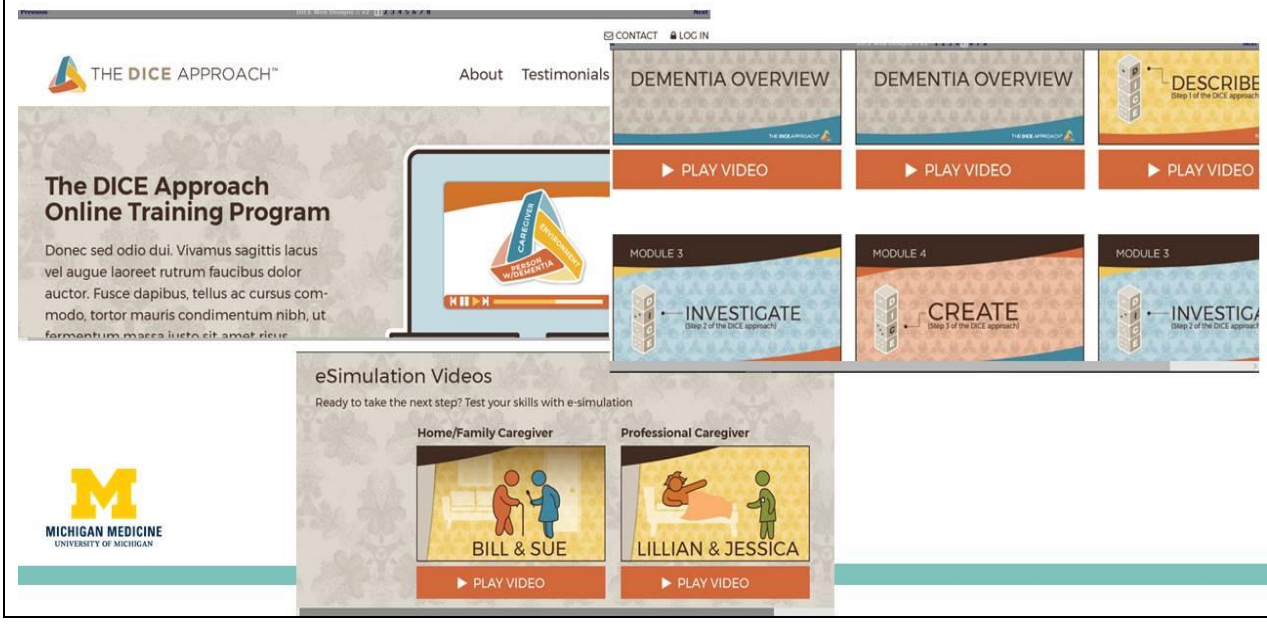
DICE Website—Coming Soon (Dec 1, 2018)



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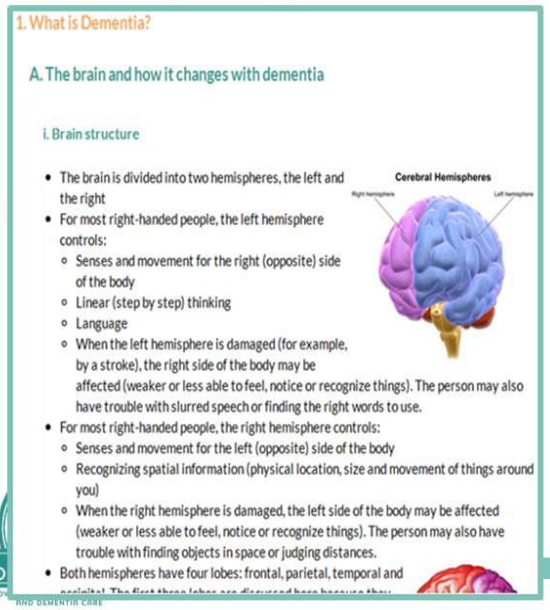
The WeCareAdvisor

Big Problem #1=Inability to access relevant resources precisely when needed

- The WeCareAdvisor contains a comprehensive "Caregiver Survival Guide" that includes vetted medical, legal, financial, functional and social information. It also includes linkage to additional outside resources
- Daily supportive/motivational messaging for caregivers



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Big Problem #2=Current dementia care is neither personalized nor precise

- Personalized peer navigator to lead caregivers through the tool
- Use of the **DICE Approach** within the tool to figure out the individual reasons for behavioral and functional changes (personalized care)

Here's what it's like to use the DICE process...

1. Describe - First choose a behavior that's challenging for you or Jacob. Then answer a few questions to describe the behavior. These questions help WeCareAdvisor choose the best tips for your situation.
2. Investigate - Next, you get to "play detective" and think about what might be contributing to Jacob's behavior. You'll answer questions to identify and rule out possible triggers for the behavior.
3. Create - Then, WeCareAdvisor will give you a behavior prescription with tips to help prevent and manage the behavior. The tips are based on your answers and are specific to your situation.
4. Evaluate - After a week, WeCareAdvisor will ask you how things are going and whether the tips were helpful. If things haven't improved, you can get new tips to try.

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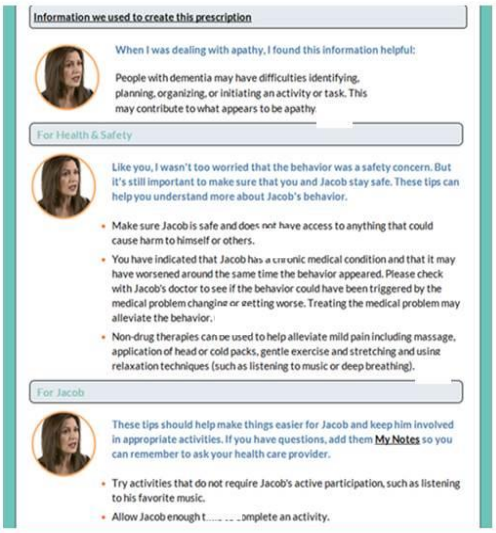
Big Problem #3=Lack of training for caregivers on how to use non-pharmacologic strategies to manage dementia behaviors

- After using the DICE approach within the WeCareAdvisor (to figure out the underlying causes of behaviors), an individualized "prescription" is created for the caregiver and person with dementia (precision medicine)
- Using a proprietary algorithm, (based on caregiver input during DICE) treatment strategies are selected from over 1000 contained in the tool



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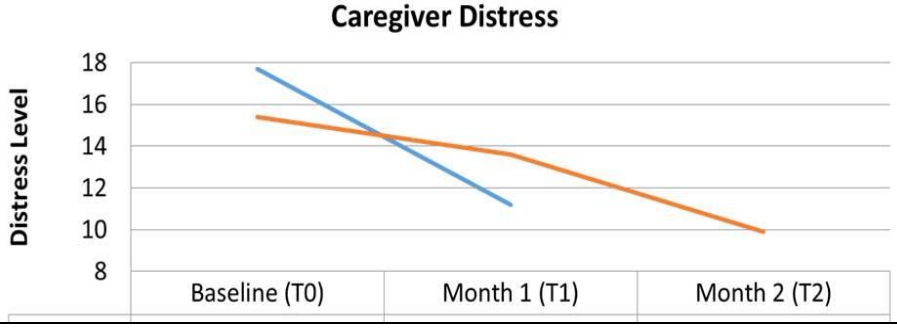
Nice. But does it work?

- Randomized controlled trial of the WeCareAdvisor in comparison to wait-list control (BMC Geriatrics, 2017)
- During brief (one-month) use of the tool:
  - Family caregivers had significant reductions on the primary outcome of DISTRESS
  - Distress is associated with most of the negative outcomes of dementia caregiving (hospitalizations, NH placement)
  - Trends to decreased dementia behaviors



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Caregiver Feedback

- "Wonderful new tool in my caregiving arsenal"
- "DICE structures my thinking"
- "Survival guide is comprehensive"
- "I shared the tool with my support group and everyone was impressed by the content and ease of use"
- "Love the feeling of support"
- "Ease of use if very nice"
- "Daily tips are awesome"
- "I wish I would have had this a long time ago"
- "I learned a great deal more about dementia and the skills to use in dealing with related behaviors"
- "This week my spouse had a UTI and the WeCareAdvisor helped to trigger in my mind that something was wrong and he should see the doctor"
- "We can go to the doctor, go to support groups, but I see the value of having this daily. This is advice every day"

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Summary

- The number of people with dementia and their family caregivers is large and growing every day with the aging of the population
- Living well with dementia is the goal
- Current care systems are inadequate and lead to multiple poor outcomes
- Innovative solutions like the DICE Approach with delivery methods including a manual, training and website as well as the WeCareAdvisor can put the key components of good dementia care at the fingertips of the people who need it most

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Center for Long-Term Care Quality & Innovation

Music & Memory: A Pragmatic Trial for Nursing Home Residents with Alzheimer's Disease (METRIcAL)

Study Principal Investigator: Vince Mor, PhD
Study Director (Presenter): Ellen McCreedy, PhD

Advisory Council on Alzheimer's Research, Care, and Services
October 19, 2018

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Acknowledgements & Disclaimers

- METRIcAL: Music & MEmory: A Pragmatic TRIal for Nursing Home Residents with ALzheimer's Disease
  - NIA R21AG057451 (PI: Vincent Mor, PhD)
  - NIA R33AG057451 (PI: Vincent Mor, PhD)
- 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.
- Pilot results do not imply causality. Brown will be conducting a pragmatic, cluster-randomized controlled trial (P-RCT) of the Music & Memory program in 81 nursing homes. This trial is set to begin in January, 2019.

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What is Music & Memory?

- Music & Memory is a personalized music program
- **Description**: Staff identify music a nursing home resident with dementia preferred when s/he was a young adult and load music on a personal music device (MP3 player)
- **Popularity**: Thousands of nursing homes in the US have become certified in the program, several state initiatives, subject of a powerful documentary "Alive Inside"
- **Potential benefits**: *non-pharmaceutical alternative to managing agitated behaviors*; improve sleep / alertness; decrease resistance to staff assistance with dressing or bathing; appetite stimulation; improve quality of life
- **Limitation**: Rigorous evaluation is necessary to establish efficacy and to characterize factors associated with effective implementation

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How does Music & Memory work?

- The mechanism for action is not totally understood
- Groundbreaking neuroscience suggests musical memories are encoded in regions of the brain that are "relatively spared in Alzheimer's disease." (Jacobsen, et al., Brain, 2015)*
- Based on Cohen-Mansfield's unmet needs model for behaviors in dementia, we hypothesize that personalized music (or familiar musical memories) may reduce agitated behaviors by addressing boredom, sensory deprivation, and/or loneliness. (Cohen-Mansfield et al., Psychiatry Research, 2015)*

*Full references available upon request: ellen_mccreedy@brown.edu

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Preliminary Evidence

- Using available administrative data, identified 98 nursing homes who became certified in the Music & Memory program during 2013 (Thomas et al., American Journal of Geriatric Psychiatry, 2017)*
- Matched to nursing homes which "looked like" the Music & Memory certified nursing homes in 2012 (pre-intervention)
- Found greater increases in antipsychotic discontinuation among residents with dementia living in nursing homes with Music & Memory certification
  - 2.6% increase in discontinuation in Music & Memory homes versus a .7% decrease in discontinuation in matched homes that did not become certified
- Found residents with dementia in nursing homes which became certified in Music & Memory were more likely to have reductions in agitated behaviors
  - 5.6% increase in behavior reductions in Music & Memory homes versus a .1% increase in behavior reductions in matched homes that did not become certified**

*Full references available upon request: ellen_mccreedy@brown.edu
**Among residents with behaviors at baseline

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Preliminary Evidence (Limitations)

- Music & Memory certification (4 hour online training) used as indicator of program implementation
  - large variation in intervention protocol and implementation intensity
  - unclear what is in the syringe
- Music & Memory certification subject to selection
  - Nursing homes becoming certified in Music & Memory are likely high performing, interested in quality improvement, and/or participating in other programs to reduce antipsychotic use
  - We are unable to observe these factors in the available administrative data
- Effect on behaviors was statistically significant but relatively small
  - Potential underreporting of behaviors in standardized residents assessments
  - Need better measures to capture change in agitated behaviors in response to Music & Memory

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Pragmatic Trial of Music & Memory

- Music & Memory: A Pragmatic Trial for Nursing Home Residents with Alzheimer's Disease (METRIcAL)
- 6-month pilot in 4 nursing homes to standardize protocol and test measurement strategy (R21) followed by a four year pragmatic, cluster-randomized trial in 81 nursing homes (R33)
- Addresses limitations of previous research by:
  - standardizing protocol and measuring variation in implementation,
  - randomizing nursing homes to timing of intervention (includes lower quality homes), and
  - supplementing administrative measures of agitated and aggressive behaviors with direct observation of residents when they are using and not using the music and staff reporting of resident behaviors

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Pragmatic Trial of Music & Memory

Characteristics of Participating Corporations

	Corporations			
	A	B	C	D
Eligible Nursing Homes (#)	69	12	25	76
Geographic Region	Mid-West	Mid-West	Mid-Atlantic	South
African American Residents (%)	1%	<1%	53%	42%
CMS Overall Quality Star Rating (Mean)	3.4	4.5	2.0	3.1
Ownership Type	Non-Profit	Non-Profit	For-Profit	For-Profit
Any Antipsychotic Use in Last 7 days (% of residents*)	23%	18%	25%	26%
Any Agitated Behaviors in Last 7 days (% of residents*)	27%	14%	15%	17%

*Long-stay nursing home residents with moderate to severe dementia

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Pragmatic Trial of Music & Memory

Measuring Agitated and Aggressive Behaviors (Tradeoffs)

Direct Observation

Courtesy of Michael Rossato-Bennett (musicandmemory.org)

Staff Interview

Administrative Data

Closest to intervention
Most likely to capture response to music
Least pragmatic
Most subject to confirmation / desirability bias

Furthest from intervention
Least likely to capture change response to music
Most pragmatic
Least subject to confirmation / desirability bias

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Pragmatic Trial of Music & Memory

Study Data Sources

Study Data Sources	Agitation / Aggression	Antipsychotics	Anxiolytics	Antidepressants	Sedatives	Depression	Quality of Life	Intervention Characteristics	Implementation Adherence
Evaluating Study Outcomes									
Standardized Assessments (MDS)	X	X	X	X		X			
Resident Observation	X							X	X
Staff Interview	X					X	X		
Medication Order Records		X	X	X	X				
Evaluating Implementation									
User Defined Assessment (EHR)								X	X
iPod Metadata								X	X
Key Informant Interviews								X	
Environmental Scan									X

Red = secondary data
Blue = primary data
MDS = Minimum Data Set
EHR = Electronic Health Record

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Music & Memory Pilot (R21)

- 4 nursing homes, 1 per partnering corporation
- 47 residents with moderate or severe dementia received the Music & Memory program during the 6-month pilot (January, 2018 – June, 2018)
- 34 of the 47 residents had data available pre-music and post-music
- Measured agitated behaviors by:
  - Directly observing residents when using and not using music (Agitated Behaviors Mapping Instrument),
  - Interviewing staff members about resident behaviors (Cohen-Mansfield Agitation Inventory), and
  - Using available administrative data (MDS 3.0, Section E)

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Music & Memory Pilot (R21)

- The staff interview tool was the Cohen-Mansfield Agitation Inventory (CMAI)
- 29-item scale to assess agitated behaviors in nursing home residents with dementia
- For each behavior, staff indicate average frequency during last two weeks
- Seven response choices for each item, ranging from never (1) to several times per hour (7)
- Validated overall score and sub-scores (domains): physically aggressive behaviors, physically nonaggressive behaviors, verbally agitated behaviors, and hiding and hording behaviors

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Music & Memory Pilot (R21)

Unpublished Pilot Data (do not distribute without permission): *Within-Person* Changes in Agitated Behaviors Before and After Using Music & Memory, Based on Staff Interviews using the Cohen-Mansfield Agitation Inventory*

	Before Music & Memory	After Music & Memory	Within Person Change	Wilcoxon signed rank test
	Mean (SD)	Mean (SD)	Mean (SD)	p-value
Total Score	61.24(16.32)	51.24(16.05)	-10.00(18.94)	0.002
Physically aggressive behaviors	18.03(7.16)	15.03(5.78)	-3.00(5.98)	0.013
Physically nonaggressive behaviors	15.85(6.51)	13.38(6.84)	-2.47(5.07)	0.002
Verbally agitated behaviors	13.74(6.20)	11.03(6.02)	-2.71(7.47)	0.033
Hiding and hording behaviors	2.65(1.23)	2.44(1.69)	-0.21(1.93)	0.303

*Includes 34 of the 47 residents with moderate to severe dementia who received Music & Memory during the pilot and had staff interviews before and after receiving the Music & Memory program. **Higher scores = more frequent behaviors**

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Music & Memory Pilot (R21)

- The direct observation tools were the Agitation Behavior Mapping Instrument (ABMI) and the Lawton's Modified Behavior Stream (LMBS)
- The Agitation Behavior Mapping Instrument (ABMI) records count of the number of times 13 specific verbally and physically agitated behaviors occurred during short, 3-minute observation windows
- After 3-minute observation, Lawton's Modified Behavior Stream (LMBS) used to record perceived affect / mood states
- Duration was of perceived mood states was recorded as: Never (1), Less than 16 seconds (2), Less than half (3), More than half (4), All or nearly all (5)

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Music & Memory Pilot (R21)

Unpublished Pilot Data (do not distribute without permission): *Within-Person* Changes in Agitated Behaviors and Mood while Using and not Using Music & Memory, Based on Direct Observation using the Agitation Behavior Mapping Instrument and Lawton's Modified Behavior Stream*

	Not During Music & Memory	During Music & Memory	Within Person Change	Wilcoxon signed rank test
	Mean (SD)	Mean (SD)	Mean (SD)	p-value
Total Agitated Behaviors	4.40(2.26)	1.56(1.49)	-2.83(2.25)	<0.001
Pleasure	1.41(0.46)	2.47(1.02)	1.06(1.07)	<0.001
Sadness	1.37(0.71)	1.06(0.28)	-0.30(0.80)	0.050
Interest	1.77(0.80)	3.11(0.83)	1.34(1.23)	<0.001
Anxiety	2.53(0.88)	1.79(0.90)	-0.74(1.20)	0.003

*Includes 31 of the 47 residents with moderate to severe dementia who received Music & Memory during the pilot and had observations when using and not using the music. **Higher scores = more frequent behaviors or more time spent in mood state**

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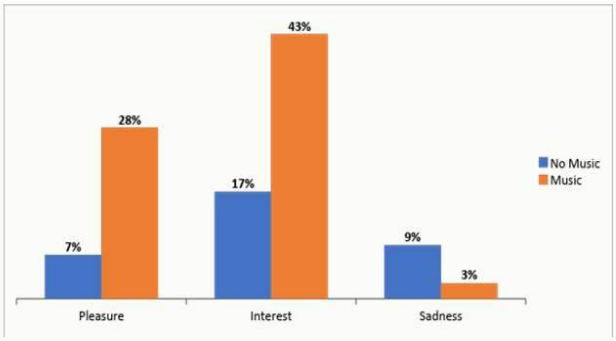
Music & Memory Pilot (R21)

Unpublished Pilot Data (do not distribute without permission): Percent of residents perceived as experiencing pleasure, interest, and sadness for more than half of a 3-minute observation, while using and not Music & Memory, Using the Lawton's Modified Behavior Stream*



*Includes 31 of the 47 residents with moderate to severe dementia who received Music & Memory during the pilot and had observations when using and not using the music.

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Music & Memory Pilot (R21)

"[Resident] fell in love with it and didn't want to take it off. She sat and hummed, an emotional peace for her, so she doesn't have flashbacks and calling out for people. [The music] keeps her happy."

"[Resident] has anxiety and tearful…loves his music, says "you got good music here." Wife visits, use splitter and listen together…sat a long while, holding hands."

"[Resident] was hard to wake up, slept through meals. When they put on music 15 minutes before meals, he listened. After about 10 minutes, he'd wake up, take off head phones, eat whole meal."

"[Resident] constantly moving at meals, shoveling food and grabbing others' food…now she sits at table. When done eating, she took her plate and put it aside and sat down calmly for 20 minutes."

"[Resident] likes gospel…She is agitated when washing up. [We] put [music] on her and calmed her down. Now do it any time there is a sign she is refusing care. She didn't want to take it off."

"Put it on [Resident] when she was upset and crying, three minutes of listening and then she calmed down and went to sleep."

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Music & Memory Pilot (R21)

Pilot results show a 16% decrease in nursing staff reported agitated behaviors among long-stay nursing home residents with moderate to severe dementia after exposure to Music & Memory program (No causality implied – stay tuned for RCT results)

Several barriers identified which likely apply to other pragmatic trials of non-pharmaceutical interventions:

1. Measurement challenges around capturing effects of non-pharmaceutical alternatives with varying "half lives"
2. Providing opportunities for nursing staff to "own" and witness the value of non-pharmaceutical interventions for managing agitated and aggressive behaviors. This is a necessary step, if these interventions are to be used as alternatives to PRN medications.
3. Technology! Lower quality nursing homes without consistent high-speed Wi-Fi will have difficulty downloading preferred music. All interventions must have low-tech adaptations or the most vulnerable will be left out.

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Pragmatic Trial of Music & Memory

- **Population**: Long-stay nursing home residents with moderate to severe dementia
- **Intervention**: Resident preferred music delivered by individual music players
- **Comparator**: Usual care (no personalized music)
- **Primary Outcome**: Staff reported frequency of resident agitated and/or aggressive behaviors
- **Secondary Outcomes**: Directly observed frequency of resident agitated and/or aggressive behaviors, frequency of resident agitated and/or aggressive behaviors from administrative data, antipsychotic use, anxiolytic use, antidepressant use, hypnotic use, quality of life, depression
- **Follow-up**: 8-months

*Please refer to clinicaltrials.gov for trial registration information

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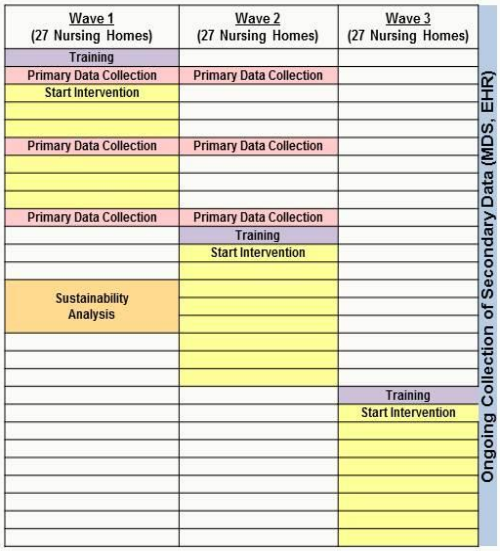
Pragmatic Trial of Music & Memory

Trial Design

- Primary outcome assessed using parallel design (Waves 1 and 2)
- Secondary outcomes assessed using stepped wedge design (All Waves)
- By combining primary and secondary measures of agitated behaviors, we are able to capture the "true effect" of the music and look for signal in widely available administrative data



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Discussion