



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

**National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and
AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)**



**BREAKING THE CYCLE:
HEALTH CARE SYSTEMS
INTERACTIONS
FOR IMPACTFUL RESULTS**

Housekeeping

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- Enter **all questions** in the Zoom **chat box** and send to All Panelists and Attendees
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- Visit impactcollaboratory.org
- Follow us on Twitter: **@IMPACTcollab1**



Breaking the Cycle: Health Care Systems Interactions for Impactful Results



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Senior Investigator and Senior Director of Neuroscience Research, HealthPartners Institute

IMPACT Collaboratory

Health Care Systems (HCS) Core Leaders

Breaking the Cycle: Health Care Systems Interactions for Impactful Results



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Archstone Professor of Medicine, Director, UCLA Multicampus Program in Geriatric Medicine and Gerontology, David Geffen School of Medicine at UCLA



Jeff Williamson, MD, MHS

Professor, Chief of Geriatric Medicine, and Director for Center for Healthcare Innovation, Wake Forest School of Medicine

IMPACT Collaboratory

HCS Core Executive Committee Members

Purpose & Agenda

- Communicate the need and promise for improvement of dementia care with embedded pragmatic trials within dynamic health care settings.
- Review what we have found to be key components of ePCT trial design and conduct for ensuring that study results are implementable.
- Provide learnings of two ePCT trialists from The Dementia Care Study: A Pragmatic Clinical Trial of Health System-Based Versus Community-Based Dementia Care (D-CARE)
- An invitation for your involvement (read: sales pitch)

What is the cycle that needs to be broken?

PERSONAL REFLECTION

of a long standing dementia researcher:

- **1978** - Just completed prestigious Chief Residency in Medicine:

“Knew it all!”

- **1978-80**: Geriatrics and Family Services Clinic founded:

Discovered existing knowledge and what I knew was wrong!

- Why? Example: "Dementia in the Elderly" seminal paper used wrong population.
- That stimulated a journey of discovery - community based studies of olde



What is the cycle that needs to be broken?

FAST FORWARD 2020

- Draft Minnesota EPC report released April 2020
- Immense progress in terms of "knowledge base" literally thousands of papers on caring for PLWD
- NAM Committee charged to find what might standards for widespread dissemination and implementation for PLWD and their care givers and **ONLY TWO QUALIFIED** and with only "low strength evidence."
- REACH 2 and "Collaborative Care" models - magnitude of benefit not large

What is the cycle that needs to be broken?

WHAT HAPPENED?

- Trials meeting modern evidence based standards are infrequent and challenging
- Trials are often not pragmatic
- Uptake has not occurred. Implementation is spotty.
- BUT - Testimony from experts indicate "we know" there are ways to improve care of PLWD and their caregivers.

Breaking The Cycle

TODAY: Pragmatic trials can lead the way to break that cycle!

- NIH Common Fund NIH Health Care Systems Research Collaboratory demonstrates feasibility and value of embedded PCT
- NIA with funding of IMPACT aims to transform field - build a bevy of robust ePCTs
- Unparalleled to advance evidence base and opportunity to implement care to improve lives of those PLWD and their caregivers
- Vast amount of information exists - need ways to demonstrate what is ready for dissemination and implementation through ePCT. No one questions the need and potential value of this work.

Health Care Systems (HCS) Core

Lead:

- Eric Larson, MD, MPH
KP Washington Health Research Institute

Associate Lead:

- Leah R. Hanson, PhD
HealthPartners Institute

Core Support:

- James Fraser and Leah Tuzzio, MPH
KP Washington Health Research Institute

Administrative Core Liaisons:

- Vincent Mor, PhD and Jill Harrison, PhD
Brown University

Focuses on engaging the varied health care settings providing care for persons living with dementia (PLWD) and their caregivers in the conduct of ePCTs

What the HCS Core does:

1. Establishes a **collaborative research resource** involving leaders from diverse health care settings to support and facilitate the conduct of ePCTs among PLWD and their caregivers.
2. Creates and disseminates **setting-specific approaches** to conducting ePCTs in PLWD and their caregivers within health care settings.
3. **Assists investigators** to partner with health care settings to conduct ePCTs of non-pharmacological interventions for PLWD and their caregivers.

Health Care Systems (HCS) Core

Executive Committee:

- Elizabeth Bayliss, MD, MSPH
KP Colorado Institute for Health Research
- Jerry Gurwitz, MD
Meyers Primary Care Institute
- David Reuben, MD
UCLA School of Medicine
- Jeff Williamson, MD, MHS
Wake Forest University School of Medicine
- Rosa Baier, MPH
Brown University

*Informs best research practices
for ePCTs and engaging health
organizations*

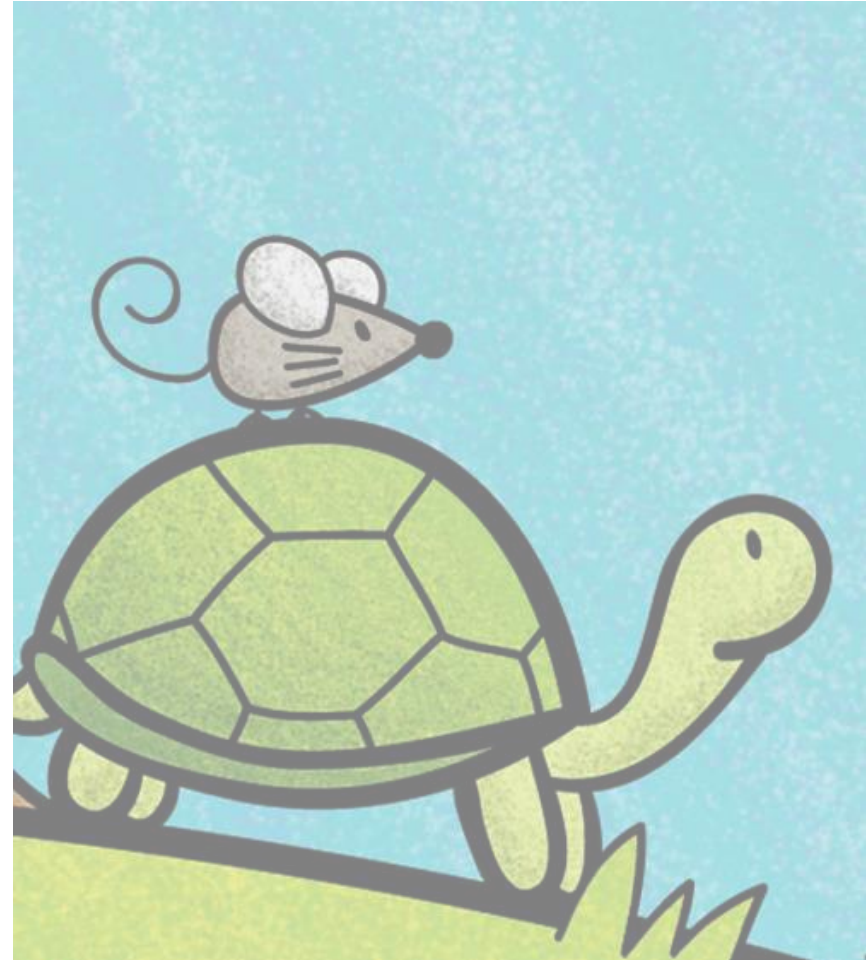
Health System Leaders Council:

- Chair - David Gifford, MD, MPH
American Health Care Association
- Sarah Greene, MPH
Health Care Systems Research Network
- Alan Stevens, PhD
Baylor Scott & White Health
- Stephen Waring, DVM, PhD
Essentia Institute of Rural Health
- Christopher Callahan, MD, MACP
Eskenazi Health

*Build connections with health care settings to
understand their priorities and environments
while raising awareness about IMPACT*

Partnering with Health Care Settings

- Build relationships early in the process
- Set expectations to work collaboratively
- Include multiple disciplines and areas of expertise
- Expect roadblocks and be flexible
- Maintain communication



Continuous Engagement

- Development of Proposal
 - Learn about health care setting's priorities, challenges, and where goals align
 - Co-design of implementation process and materials
- Planning Phase
 - Pilot test intervention and data collection in setting, evaluate buy-in
- Conducting ePCT
 - Iterative, continuous evaluation and adaptation with continuous communication
- Dissemination
 - Learn from stakeholders how best to communicate results within setting

IMPACT AD/ADRD Learning Health Network

- A consortium of individuals and organizations that deliver care to PLWD and their care partners - joined by the common goal of improving care quality, equity and accessibility.
- Development of 4 Communities within the Network
 1. Long-term Care (nursing homes, assisted living, and other settings that provide around-the-clock care for persons living with dementia)
 2. Healthcare Settings (Clinics, ACOs, MA Plans, Integrated Delivery Systems)
 3. Hospitals/Emergency Departments
 4. Community-based Organizations (Meals on Wheels, Hospice, Senior Centers, Adult Day Centers).



PCORI PCS-2017C1-6534 Comparative Effectiveness of Health System-based versus Community-based Dementia Care

NIA: 1 R01 AG061078-01 A Pragmatic Trial of the Effectiveness and Cost-effectiveness of Dementia Care

Organization of D-CARE Study

- Central Project Management (CPM)-UCLA
- Clinical Trial Sites (CTS)
 - Baylor, Scott, and White
 - Geisinger Health
 - University of Texas Medical Branch
 - Wake Forest University
- Data Coordinating Center (DCC)-Yale University
- Study Advisory Committee (SAC)
- Patients and Stakeholders
- Working Committees
- DSMB

Goal of D-CARE Study

- To compare the effectiveness and cost-effectiveness of community-based (CBDC) versus health system-based dementia care (HSDC) and to compare both interventions to Enhanced Usual Care in:
 - a pragmatic randomized clinical trial
 - at 4 clinical trial sites representing a range of
 - geographic regions
 - types of healthcare organizations
 - predominant payment systems

Study Design and Sample

- Pragmatic 18-month randomized (patient/caregiver dyad) 3-arm superiority trial
- Sample size: 2150, 1000 in each intervention arm and 150 in the Usual Care group
- Inclusion criteria:
 - community-living (not nursing home or hospice)
 - diagnosis of dementia
 - have family or friend caregiver(s) who speak English or Spanish
 - have a partnering physician

Recruitment

- Screening by generating lists of patients with dementia
 - Physicians review list and agree to serve as partnering physicians
 - Potential eligible participants are given option to opt out
- Physicians directly refer
- Sites may recruit directly in clinics
- Patients and caregivers may self-refer
- Telephone
 - eligibility determination
 - consent of caregiver +/- person with dementia
 - baseline and outcome measures collection

Interventions

- Health systems-based dementia care by a NP or PA Dementia Care Manager who works within the health system
- Community-based dementia care by a SW or nurse Care Consultant who works at a community-based organization
- Enhanced usual care with consistent referral to Alzheimer's Association Helpline to speak to master's level consultants

Analysis

- Primary outcomes – NPI-Q Severity and MCSI scores:
longitudinal repeated measures analysis (Baseline, 3, 6, 12, 18 months) based on maximum likelihood methods adjusted for the stratified randomization by site
- Heterogeneity of treatment effects, across sites and in 7 subgroups:
 - high vs. low patient function
 - high vs. low cognition
 - high vs low NPI-Q Severity
 - high vs low MCSI at baseline
 - those residing in urban vs rural areas
 - spouse caregiver versus other caregiver
 - white non-Latino versus nonwhite or Latino

Secondary Outcomes

- Timing: Baseline, 3, 6, 12, 18 months
- NPI-Q Distress (caregiver) (12 items)
- Caregiver self-efficacy (4 items)
- Caregiver depressive symptoms
 - PHQ-8 (8 items)

Tertiary Outcomes

- Quality of Life in Alzheimer's Disease (13 items)-12 months
- Dementia Burden Scale-Caregiver-all time points
- Composite measure of clinical benefit-all time points
- Dementia care quality (caregiver reported)-12 months
- Caregiver satisfaction with dementia care (9 items)-3, 12, 18 mo
- Physician satisfaction with dementia care (8 items)-18 months
- Mortality- 3, 6, 12, 18 months
- Goal attainment-3, 6, 12, 18 months

Tertiary Outcomes

- Functional status (10 item FAQ, ADL)-18 months
- Cognition (Dong shortened MoCA)-18 months
- Inpatient hospital, rehab, hospice use-18 months
- Post-acute SNF use-18 months
- All hospice use-end of study-18 months
- Patient long-term NH placement-18 months
- Spouse caregiver utilization-18 months
- Positive aspects of caregiving-Baseline and 6 month
- “Days spent at home”-18 months

Cost-effectiveness Analysis

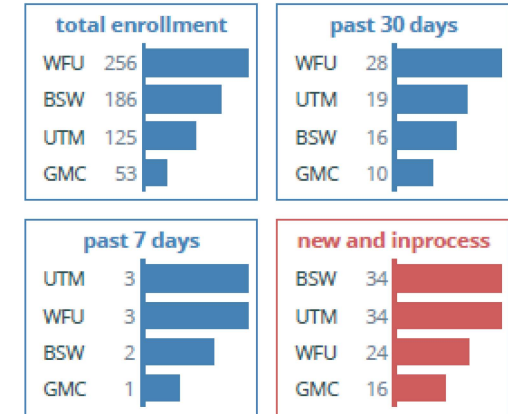
- Ratio of incremental net Medicare costs to incremental effects of the two primary outcomes
- Costs to Medicaid and consumers
- Changes in utilization by type of use

D-Care Study Progress as of July 13, 2020

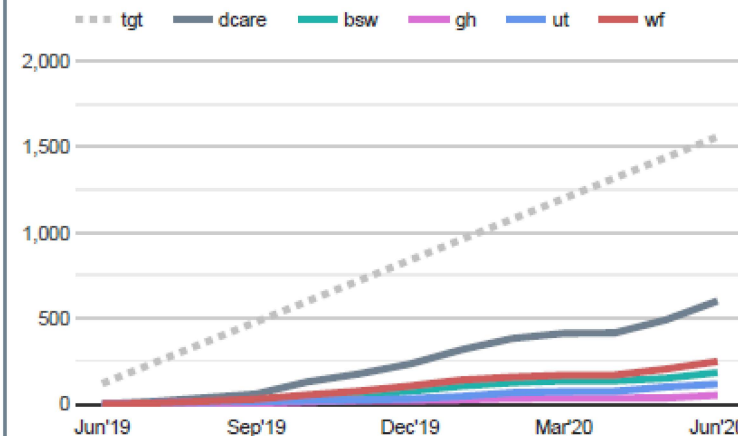
Screening, Enrollment and Study Participation

	DCARE
screens attempted	2150
screens completed	1918 (89.2% of attempted)
eligible for baseline	1603 (83.6% of screened)
verbally consented to baseline	835 (52.1% of eligible)
baselines newly scheduled (no calls)	42
baselines in-process (1+ call attempts)	66
baselines attempted	746
baselines completed	710 (95.2% of attempted)
eligible for study participation	688 (96.9% of completed)
consented to study participation	630 (91.6% of eligible)
screen / enrollment ratio	3.4
enrolled	620 (28.8% of study target)
active study participants	586
withdrawn from assessments	11
deceased	23

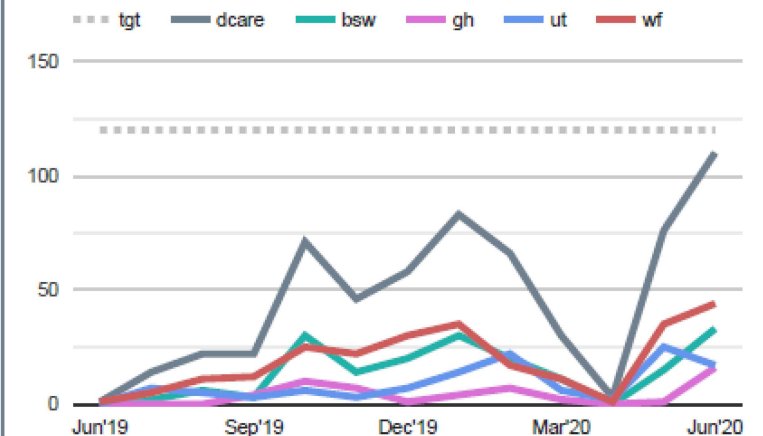
Site Enrollment Rankings



Cumulative DCARE Enrollment



Monthly DCARE Enrollment



Issues to Consider When Conducting Pragmatic Trials in Health Care Systems

- Entry into studies (research units versus clinical operations)
- Commitment to supporting clinical personnel
- Culture/mission
- Infrastructure supporting study
- Fidelity

Getting the Healthcare System & Its Providers to “Yes”

1. Your trial cannot add to their trials (& tribulations). The most important provider (and caregiver) currency is TIME.
2. Understand what the “win-win-win” is BEFORE you talk to health system leaders.
3. Understand what the “win-win-win” is BEFORE you talk to front line providers.

Getting the Healthcare System & Its Providers to “Yes”

4. Your PCT team MUST understand the WIN-WIN-WIN for each group.
5. As a PCT investigator, TRUST is your most important currency. It takes years to build trust and a few days (at most) to destroy it.
6. Start your pragmatic trial with pragmatic minded colleagues/practices, learn and take this to next layer of providers.

Call to Action

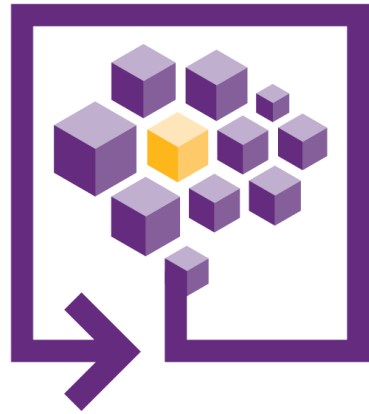
- Need to better understand the challenges unique to each care setting providing care for PLWD and their care partners
- IMPACT AD/ADRD Learning Health Network
 - Please join and encourage others to engage
 - <https://impactcollaboratory.org/>



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