



# **State of the Science for Pragmatic Trials of Non-Pharmacological Interventions to Improve Outcomes Among Persons with Dementia and Their Caregivers**

## **Post-Summit Report**

**January 2018**

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Additional information can be found at the Summit website (<https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>) or the National Alzheimer's Project Act website (<https://aspe.hhs.gov/national-alzheimers-project-act>). The opinions and views expressed in this report are those of the authors. They do not necessarily reflect the views of HHS, the contractor or any other funding organization.

# State of the Science for Pragmatic Trials of Non-Pharmacological Interventions to Improve Outcomes Among Persons with Dementia and Their Caregivers

***A Workshop Hosted by the Brown University School of Public Health and the Hebrew SeniorLife Institute for Aging Research***

December 1, 2017

National Institute on Aging  
Bethesda, Maryland

*Revised January 12, 2018*

This meeting was organized by Brown University in partnership with the Hebrew SeniorLife Institute for Aging Research and supported through an administrative supplement to an NIA-funded award (#P01-AG-027296). This meeting was a post-summit activity of the 2017 Research Summit on Care and Services for Persons Living with Dementia and Caregivers sponsored by the Advisory Council on Alzheimer's Research, Care, and Services of the U.S. Department of Health and Human Services (DHHS). This summary was prepared by Chandra Keller-Allen, Rose Li and Associates, Inc., under contract to Brown University (PUR-0050669). The views expressed in this document reflect both individual and collective opinions of the meeting participants and not necessarily those of Brown University, the Hebrew SeniorLife Institute for Aging Research, the National Institute on Aging, or the National Institutes of Health. Review of earlier versions of this meeting summary by the following individuals is gratefully acknowledged: Rosa Baier, David Bass, David Dore, Richard Fortinsky, Laura Gitlin, Corita R. Grudzen, Eric Jutkowitz, Rose Maria Li, Julie Lima, Susan Mitchell, and Vincent Mor.



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## **Executive Summary**

### **Introduction**

On December 1, 2017, researchers from the Brown University School of Public Health and the Hebrew SeniorLife Institute for Aging Research convened a workshop at the National Institute on Aging (NIA) to review the state of the science for pragmatic clinical trials of non-pharmacological interventions for persons with dementia and their caregivers. The goals of the workshop were to (1) review the state of the evidence regarding the effect of interventions to improve care and outcomes for persons with dementia; (2) establish criteria for determining which interventions are ready for launch as pragmatic trials; and (3) consider the infrastructure necessary to conduct, translate, and disseminate such a program of research.

### **State of the Science**

There is a growing body of promising evidence from traditional randomized controlled trials (RCTs) of multi-component, non-pharmacological interventions to address one or more outcomes for persons with dementia. Trial evidence suggests that interventions can be successful at improving clinical outcomes and quality of life for persons with dementia and their caregivers in a variety of settings. Some interventions may be ready for pragmatic trials or other evaluation, involving testing within existing health care delivery systems and payment models. At the same time, the evidence base has numerous limitations, including inconsistent findings, lack of replication, insufficient understanding of the mechanisms of action or active components of interventions, lack of cost data and outcomes relevant to various stakeholders, and piecemeal interventions that do not address the comprehensive care needs of persons with dementia. Meeting attendees also noted a lack of coordinated infrastructure among investigators to enable the rigorous evaluation of non-pharmacological interventions in dementia care.

### **The Case for Pragmatic Clinical Trials in Dementia Care**

Providers, policymakers, and other stakeholders need evidence to inform decisions that lead to improved, efficient, and affordable care in real-world settings. However, there is a historical disconnect between research and clinical care. Traditional RCTs have goals, designs, and attributes that make application to real-world practice challenging and may slow or impede the translation of results into practice. To promote more rapid, continuous learning at a lower cost, dementia intervention research needs to be embedded in learning health care systems, and leverage big data, connectivity, team-based care, and systems engineering. Pragmatic clinical trial designs allow for rapid feedback of evidence into clinical care, while clinical care informs the refinement of the intervention and evolution of evidence.

Several factors make dementia research ideal for testing interventions under the rubric of a pragmatic trial. These factors include the following: programs are typically delivered at the level of a health care system and thus very amenable to cluster randomization; many care settings are part of or owned by health care systems or corporations; interventions are often low risk;

and key care settings (e.g., nursing homes) have well-established administrative data and electronic health records to facilitate subject characterization and outcome measurement.

In addition, pragmatic clinical trials face challenges that are unique to dementia intervention research, including identification of interventions with sufficient demonstrated efficacy in traditional RCTs or quasi-experimental designs; the complexity of multicomponent interventions; ethical and regulatory issues; the dyadic focus of interventions adding to their complexity; poor definition of clinical stages of dementia in many databases; variation in care needs at different disease stages; design considerations among community, nursing home, acute care settings; and the limitations of electronic health record (EHR) data in some settings (e.g., assisted living).

### **Criteria to Identify Interventions Ready for Pragmatic Clinical Trials**

Participant discussion yielded numerous considerations regarding whether a particular dementia care intervention is ready to be tested in a pragmatic clinical trial:

- Evidence of significant clinical efficacy (It is noted, however, that determining *how much* or *what strength of evidence* should be required, necessitates greater consideration and may depend on the complexity, or level of risk of the intervention.);
- Sufficient Stage I (NIH Stage Model) work to determine the active components of the intervention;
- Well-articulated intervention protocols;
- Feasibility of implementation in a pragmatic environment;
- Acceptability to study participants, including health care providers, systems, and corporations;
- Determination that the intervention is of low risk to participants with thoughtful consideration of potential adverse events and unintended consequences;
- Alignment of priorities between researchers and partner health care organization(s); and
- Cost-neutral, or cost-effective, program implementation for the partner health care organization and/or incentivization of the intervention services by one or more payers.

### **Research Priority: ADRD-Specific Pragmatic Clinical Trial Infrastructure**

It is clear, in part from the October 2017 National Research Summit on Care, Services, and Supports for Persons with Dementia and their Caregivers<sup>1</sup> and from this workshop, that the research and advocacy communities recognize that:

1. Dementia intervention research involves unique facilitators and challenges for pragmatic clinical trials;
2. Substantial evidence from efficacy trials of non-pharmacological interventions in dementia warrant further evaluation under the rubric of a pragmatic trial;

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<sup>1</sup> See <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>.

3. There is a need for greater infrastructure for dementia intervention researchers to share knowledge, data, methods, and measures on the conduct of pragmatic trial; and
4. The NIA is poised to leverage lessons learned from other NIH-funded pragmatic trial efforts and to translate them to dementia-specific research. An infrastructure that capitalizes on economies of scale for clinical, methodological, and regulatory expertise, data, relationships, and other common needs that pragmatic trial researchers have in testing interventions in the real-world of learning health systems is needed. Such an infrastructure would significantly strengthen the ability of the research community to develop, test, implement, and translate effective interventions and to improve the lives of persons with dementia and their caregivers.

To meet research infrastructure needs, participants envisioned an Alzheimer’s disease and related dementias (ADRD) Research Collaboratory following the model of the collaboratory for pragmatic clinical trials sponsored by the NIH Common Fund Program.<sup>2</sup> Participants recommended that the ADRD Research Collaboratory have the following cores to build investigator capacity, support pragmatic trial design, and maintain the resource and knowledge base:

1. Stakeholder Engagement
2. Interagency Interaction
3. Health Care Systems Collaborations
4. Training and Education
5. Biostatistics and Study Design
6. Participant Recruitment
7. Measurement
8. Pilot Study Design
9. Data (including EHR)
10. Ethical and Regulatory Issues
11. Evidence Synthesis and Systematic Review
12. Dissemination and Implementation

The cross-cutting themes of disease stage and care setting were identified as being critical to infuse across all the cores.

## Conclusion

Participants were enthusiastic about the large evidence base and state of the science for non-pharmacologic interventions for persons with dementia and their caregivers and stressed the importance of pragmatic research to ensure that such interventions can be implemented effectively in the real world. The current national focus on ADRD research, momentum provided by the National Research Summit on Care and Services and related activities such as this workshop, and the availability of powerful resources such as administrative data and

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<sup>2</sup> See <https://commonfund.nih.gov/hcscollaboratory>.

growing knowledge of pragmatic clinical trials techniques are evidence that the timing is opportune to build an infrastructure to support ADRD-specific pragmatic clinical trials to improve the lives of persons with dementia and their caregivers.

## Meeting Summary

### Introduction

On December 1, 2017, researchers from the Brown University School of Public Health and the Hebrew SeniorLife Institute for Aging Research, convened a workshop at the National Institute on Aging (NIA) to review the state of the science for pragmatic clinical trials of non-pharmacological interventions for persons with dementia and their caregivers. The goals of the workshop were to (1) review the state of the evidence regarding the effect of interventions to improve care and outcomes for persons with dementia; (2) establish criteria for determining which interventions are ready for launch as pragmatic trials; and (3) consider the infrastructure necessary to prepare to conduct, translate, and disseminate such a program of research.

Meeting co-chair Vincent Mor and the Director of the Division of Behavioral and Social Research, John G. Haaga, gave introductory remarks. Invited speakers presented research on pragmatic trial design considerations and evidence for interventions for persons with dementia. Meeting participants, including the invited speakers, a wide range of additional experts, and NIA staff, engaged in facilitated discussions about criteria to identify interventions ready for pragmatic trials, barriers to broad-scale implementation of evidence-based interventions, and the infrastructure needs for large-scale pragmatic clinical trials.

This meeting summary provides an overview of the presentations, a thematic summary of primary discussion points, and suggested future research priorities. The meeting agenda and participant list are provided in the appendices.

### Invited Presentations

#### **State of the Science for Pragmatic Trials of Non-Pharmacological Interventions in Dementia: Trial Design Considerations**

*Susan L. Mitchell, MD, MPH, Hebrew SeniorLife Institute for Aging Research*

There is a historical disconnect between research and clinical care, yet evidence is needed to inform decisions that lead to improved, efficient, and affordable care. Traditional randomized, controlled trials (RCTs) have goals, designs, and attributes that make application to real-world practice challenging. RCTs use stand-alone settings to ensure internal validity, use non-diverse populations, are underpowered (particularly for subgroup analyses), expensive, and not representative of the real world (e.g., real-world patients have comorbidities, but RCT populations typically do not). To promote continuous learning at a lower cost, clinical trials need to be embedded into learning health care systems using big data, connectivity, team-based care, and systems engineering. These designs allow for rapid feedback of evidence into clinical care, while clinical care informs the evolution of evidence.



The primary purpose of a pragmatic clinical trial is to inform decision-makers regarding the comparative balance of benefits, burdens, and risks of an intervention at the individual or population level.<sup>3</sup> Traditional RCTs and pragmatic clinical trials differ on key attributes. The goal of an explanatory RCT is to understand how and why an intervention works, and, if designed well, it can reveal a biological or social mechanism of the intervention. The goal of a pragmatic trial is to provide evidence to inform clinical and/or policy decisions and is designed to elucidate risks, benefits, and costs of an intervention under real-world conditions. Key attributes of a trial can be more or less explanatory versus pragmatic along a continuum.

Table 1: Key Attributes of Explanatory RCTs and Pragmatic Clinical Trials<sup>4</sup>

	<b>Explanatory</b>	<b>Pragmatic</b>
<b>Question</b>	Efficacy—can the intervention work?	Effectiveness—does the intervention work in practice?
<b>Setting</b>	Well resourced, “ideal” setting	Normal practice
<b>Randomization</b>	Usually individual level	Usually clustered at practice unit
<b>Participants</b>	Highly selected; individual consent	Little selection; may waive consent
<b>Intervention</b>	Strict enforcement and adherence monitoring	Applied flexibly as in normal practice
<b>Comparator</b>	Placebo/Non-treatment	Real-world alternatives
<b>Outcomes</b>	Short-term surrogate measures	Directly relevant to stakeholders
<b>Data Collection</b>	By researchers outside of clinical care	By clinicians/administrators at point of care
<b>Stakeholder engagement</b>	Not much, “top-down” driven by investigators/sponsors	Input from varied stakeholders at all stages

Mitchell discussed how these key attributes fit with the NIH Stage Model and the PreciS-2 model. She provided an example of an explanatory dementia trial (Educational Video to Improve Nursing Home Care [EVINCE]) and a pragmatic dementia trial (Pragmatic Trial of Video Education in Nursing Homes [PROVEN]) of similar interventions.

Several factors make dementia research ideal for testing interventions under the rubric of a pragmatic trial. These factors include the following: programs are typically delivered at level of health care system and thus very amenable to cluster randomization; many care settings are part or owned by health care systems or corporations; interventions are often low risk; and key

<sup>3</sup> Califf, R. M., & Sugarman, J. (2015). Exploring the ethical and regulatory issues in pragmatic clinical trials. *Clinical Trials*, 12, 436-441.

<sup>4</sup> Zwarenstein, M., et al. (2008). Improving the reporting of pragmatic trials: An extension of the CONSORT statement. *BMJ*, 337, a2390.

care settings (i.e., nursing homes) have well-established electronic health records to facilitate subject characterization and outcome measurement.

Pragmatic trials face challenges that are unique to dementia intervention research, including the following: difficulty in identifying adequately tested interventions, the use of multicomponent interventions, implementation error, dyadic nature of the participants, multiple possible intervention targets, lack of data on key outcome variables of interest to decision-makers, variation in complexity between community and nursing home settings, and the limitations of electronic health record (EHR) data.

Participants were asked throughout the workshop to consider priority next steps for enabling pragmatic clinical trials in dementia research by answering five key questions:

1. How do we identify interventions ready for pragmatic testing?
2. What key elements need to be in place?
3. How do we partner with health care systems?
4. How do we engage stakeholders?
5. What infrastructure is needed to meet priorities and coordinate effort?

### **Status of the Field: Community and Home-based Interventions for Persons Living with Dementia and Family Caregivers**

*Laura N. Gitlin, PhD, Johns Hopkins University School of Nursing*

There is substantial evidence from efficacy trials demonstrating the benefits of non-pharmacological interventions to improve outcomes for persons with dementia and their caregivers. Gitlin provided an overview of conceptual frameworks for understanding dementia interventions, described interventions to improve outcomes for persons living with dementia as well as for family caregivers, and recommended priorities for future intervention studies.

There are multiple direct and indirect pathways for supporting persons with dementia and their caregivers in the home setting. The intervention target could be the caregiver, the person with dementia, the environment itself, or some combination. In studies to date, caregiver outcomes have included mood, quality of life, efficacy, skills, burden of care, and physical health. Outcomes in persons with dementia have included mood, behaviors, quality of life, function, engagement, physical health, and aging in place. Treatment effect can occur through multiple pathways. Persons with dementia may derive positive outcomes from an intervention that directly targets them; alternately, an intervention that enhances a caregiver's wellbeing may indirectly positively impact the person with dementia. Furthermore, caregivers may be the indirect beneficiary of an intervention that enhances the quality of life of the person with dementia. Persons with dementia and caregivers are both heterogeneous groups. Persons with dementia may vary, for example, by etiology, disease stage, physical health, cognitive function, race/ethnic and cultural backgrounds, previous roles, and habits and preferences. Caregivers may vary by relationship to person with dementia, closeness, gender, race/ethnicity/culture, employment status, where they are in their life course, and level of readiness to provide care or

adapt their communication style and other behaviors to the changing needs of a person with dementia.<sup>5</sup>

A limitation of the body of existing dementia intervention research is that the targets, outcomes, participant characteristics, and process by which an intervention was developed are not always clearly specified, which makes translation to real-world settings challenging. The majority of existing dementia intervention research has been conducted as NIH Stage Model Stage II efficacy trials, and it can be argued that not enough Stage I work has been done to carefully identify active components and mechanisms, link components to theory, and determine dose-response relationships.<sup>6</sup> The clinical trajectory of disease also complicates translation because interventions tested in populations with mild or moderate cognitive impairment might not work at all or in the same way for persons with severe cognitive impairment. Interventions are needed that address changing needs as the disease progresses. Gitlin proposed design principles for dementia interventions including the need for interventions to address the evolving needs of individuals and family members and the need to tailor nondrug strategies to patient capabilities, environments, caregiver availability, readiness, capability, and resources.

Gitlin presented an overview of results from a systematic review of home-based intervention trials reporting outcomes for persons with dementia, which yielded 57 unique trials.<sup>7</sup> Gitlin and colleagues examined the targets of intervention, characteristics of persons with dementia, treatment components, sample sizes and design, risk of bias (most trials used single blinding), and key outcomes across the trials in the review. Greater than 80 percent of the trials in the review reported statistically significant differences between treatment and control groups for at least one outcome measure. One exemplar intervention is the Tailored Activity Program (also referred to as New Ways for Better Days: Tailoring Activities to Persons with Dementia and their Families [TAP]) which was the subject of five RCTs, all of which have reported reductions in behavioral symptoms, improvements in daily function, and caregiver benefits. TAP is currently being evaluated in nine countries, and it is being delivered by occupational therapists in the home, adult day care centers, hospitals, and residential settings.

Gitlin also presented an overview of results of a review of home-based intervention trials reporting outcomes for family caregivers, which included 7 meta-analyses and 17 systematic reviews and represented 200 caregiver support programs reaching 8,095 families. Types of interventions tested included professional support, psycho-education, behavior management skills training, counseling/psychotherapy, self-care/relaxation training, and multi-component

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<sup>5</sup> Gitlin, L. N., & Hodgson, N. (2015). Caregivers as therapeutic agents in dementia care: The context of caregiving and the evidence base for interventions. In J. Gaugler & R. Kane (Eds.). *Family Caregiving in the New Normal*, pp. 305-353. Elsevier Science.

<sup>6</sup> Onken, L., Carroll, K., Shoham, V., Cuthbert, B., & Riddle, M. (2014). Reenvisioning clinical science: Unifying the discipline to improve the public health. *Clinical Psychological Science*, 2, 22-34.

<sup>7</sup> Gitlin, L. N., et al. (2016). Home-based interventions targeting persons with dementia: What is the evidence and where do we go from here? In M. Boltz & J. Galvin (Eds.). *Dementia care: An evidence-based approach*, pp. 167-188. Switzerland: Springer International Publishing.

interventions. Average pooled effect sizes indicate small to moderate effects of the interventions across studies aimed at reducing caregiver burden, improving caregiver knowledge, reducing caregiver anxiety, reducing caregiver depression, and delaying time to institutionalization. Two exemplar interventions tested in RCTs include the New York University Caregiver Counseling and Support program, the Resources for Enhancing Alzheimer's Caregiver Health (REACH) I and II interventions, Savvy Caregiver, Project COPE, Project ACT, and Skills<sub>2</sub>Care®. The evidence suggests common principles underlie successful interventions that support caregivers; these include tailoring the intervention to caregiver unmet needs, repeating exposure to knowledge and skills, learning new ways of communicating, setting up tasks through doing, incorporating multiple components (problem solving, stress reduction, psychoeducation), being caregiver-centric, and ensuring exposure to treatment over an extended time period.

Although the body of evidence for interventions targeting persons with dementia and family caregivers is expansive and promising, there are limitations that contribute to a significant research-to-practice gap. Of the body of evidence reviewed, only 16 published studies of translational effects of six programs were found. As of 2015, translational activities and use of proven interventions has reached a small percentage of caregivers (about 0.003 percent of family caregivers have benefitted from a program, i.e., 37,783 of the estimated 15 million caregivers in the United States). Limitations of the evidence include the following:

- Most interventions were tested external to delivery systems.
- There is some evidence that approaches are cost-effective, but limited outcomes on health care utilization, health care savings, and physical disease burden were reported.
- There is limited to no evidence for certain subgroups (e.g., men, many minority populations, rural, long-distance caregivers, multiple caregivers).
- Samples are poorly characterized.
- Interventions are not linked to disease stage (or etiology, although this would be more challenging).
- The scope of outcomes examined is limited.
- Many needs of families are not addressed (e.g., physical burdens, financial strain, coordinating care and care transitions, early stage, late stage, bereavement).
- Mechanisms as to why interventions work are unclear.
- Theoretical frameworks are limited.

Collaborative and care coordination models show promise, such as the Partners in Dementia Care, Primary Care Collaborative Model, and the UCLA Alzheimer's and Dementia Care programs. Gitlin presented NIA-funded research on Adult Day Service (ADS) Plus, which embeds caregiver support in adult day service programs. ADS Plus is a 12-month multi-component intervention delivered on site by indigenous staff members. The trial was designed as a hybrid randomized trial combining effectiveness with implementation process research aims. Although it takes the form of a pragmatic trial, data capture occurs independently of adult service clinical records.

There is a growing body of promising evidence from RCTs testing multi-component interventions to address one or more treatment goals for dementia care. Trial evidence suggests a strong signal that many interventions can be successful at improving quality of life for the person with dementia and the caregiver, although more rigorous research addressing the needs of person-caregiver dyads is needed. Several interventions are ready for adaptation and widespread implementation, and such programs could be integrated into existing delivery systems and payment models. However, inconsistent findings, lack of replication, reliance on caregiver reports, lack of cost data and outcomes relevant to various stakeholders, and piecemeal interventions that do not address comprehensive care are limitations of the evidence base. Gitlin’s recommended research priorities to address these limitations and move the field forward include improving clinical relevance of trials, more adequately characterizing samples and interventions to enhance reproducibility and adaptation, improving outcome measures, and enhancing study designs by implementing pragmatic trials and hybrid designs. Table 2 provides further details for each recommended area of focus.

*Table 2: Recommendations to Improve the Evidence Base*

*Source: L. Gitlin presentation, December 1, 2017*

Domain	Specifics
<b>Improve clinical relevance of trials</b>	<ul style="list-style-type: none"> <li>• Examine mechanisms or why intervention has positive effect</li> <li>• Evaluate dose–response relationships</li> <li>• Evaluate cost</li> <li>• Determine and report clinical significance</li> </ul>
<b>Adequately describe interventions to enhance reproducibility and adaptation</b>	<ul style="list-style-type: none"> <li>• Identify theory base guiding intervention</li> <li>• Describe intervention characteristics</li> <li>• Detail number of sessions, duration, and length of intervention</li> <li>• Describe role of family caregiver in delivering intervention or supporting strategies for person with dementia</li> <li>• Describe treatment fidelity plan and adherence rates and impact on outcomes</li> <li>• Describe type of blinding applied to trial</li> </ul>
<b>Improve outcome measures</b>	<ul style="list-style-type: none"> <li>• Derive consensus in field as to set of common outcome measures for cross-study comparisons</li> <li>• Identify outcomes of relevance to stakeholders and sensitive to change</li> <li>• Consider use of objective, performance-based measures and subjective appraisals</li> </ul>
<b>Enhance study designs</b>	<ul style="list-style-type: none"> <li>• Use pragmatic trial designs, hybrid designs, and/or mixed methods</li> <li>• Report adverse events</li> <li>• Use attention control groups to address attention, attrition</li> <li>• Examine long-term treatment effects</li> </ul>

## **Service System Considerations in Evaluating Community-based Dementia Care Interventions within Pragmatic Trials**

*Richard H. Fortinsky, PhD, University of Connecticut*

There are many potential service system options for testing community-based dementia care interventions in pragmatic trials including care management organizations, home health agencies, Accountable Care Organizations (ACOs), patient-centered medical homes, Programs for All-inclusive Care for Elders (PACE), adult day care programs, continuing care retirement communities, and Medicare Advantage plans. Building relationships between researchers and pragmatic trial partners requires time, effort, patience, and considerations of several factors—common definition of dementia; data sources and measures; diversity of target population; methods for monitoring intervention fidelity; cost analyses; definition of health- and cost-related measures of success; and sustainability, which should be discussed from the beginning of the relationship.

An effectiveness-implementation hybrid pragmatic trial design can include key stakeholders and can use a patient-centered approach to involve persons with dementia and caregivers as partners in the research. This hybrid design incorporates an evaluation of individual-level outcomes as well as degree of success in implementing the intervention in a real-world setting, including consideration of feasibility, acceptability, sustainability, and cost-benefit.

As an example, Fortinsky presented an overview of an ongoing effectiveness-implementation hybrid design trial of the Care for Persons with Dementia in their Environments (COPE) intervention, funded in 2014 by the NIA as a “translational” study before common use of the term “pragmatic trial.”<sup>8</sup> Prior to the hybrid design study, known as the COPE Connecticut (CT) study, the COPE program was found to be efficacious as a non-pharmacological intervention in a traditional RCT with community-based subjects.<sup>9</sup> In the COPE CT study, the COPE intervention is embedded within Connecticut’s Medicaid and state-funded home and community-based waiver program for older adults. The Connecticut Medicaid Program was motivated to work with the research team to implement COPE because it was already pursuing long-term supports and services rebalancing initiatives, the COPE program aligned with the needs of its population with dementia, the program provided services to caregivers not already provided and fit well within its existing structure of home- and community-based care, and there was buy-in from the state’s largest care management organization known as Connecticut Community Care, Inc., the primary trial partner. The COPE CT hybrid design includes effectiveness, economic, and implementation evaluation components.

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<sup>8</sup> Fortinsky, R. H., Gitlin, L. N., Pizzi, L. T., Piersol, C. V., Grady, J., Robison, J. T., & Molony, S. (2016). Translation of the Care for Persons with Dementia in their Environments (COPE) intervention for publicly-funded home care clients and their families: Rationale and research design. *Contemporary Clinical Trials*, *49*, 155-165.

<sup>9</sup> The COPE intervention components are discussed in Gitlin, L. N., et al. (2010). A biobehavioral home-based intervention and the well-being of patients with dementia and their caregivers: The COPE randomized trial. *JAMA*, *304*, 983-991.

Although the COPE CT study is not yet completed, it has already provided many lessons for future pragmatic research. The researcher-stakeholder relationship has been successful, in part, because the researchers were (1) offering a program that met current needs in the target population and aligned with partner priorities; (2) able to provide evidence from published research showing that the target patients were high-cost users; and (3) willing to use (and validate) methods used by the stakeholders to identify the client population with dementia. The hybrid design study is also yielding information about the costs of COPE and willingness of caregivers to pay for the services in a way that is useful to the system partner for informing decisions (e.g., ~\$300 per month for 4 months). Ongoing challenges include maintaining systematic communication between the COPE interventionists and care managers, limiting care manager turnover, sustaining COPE intervention fidelity after the study, and translating the COPE intervention into Spanish. The features of and preliminary findings from this hybrid design study have garnered interest from other state Medicaid programs and legislative officials.

### **Evidence of Nondrug Interventions for Persons with Dementia in Facilities**

*Eric Jutkowitz, PhD, Brown University School of Public Health*

Similar to dementia home-based interventions, dementia interventions in nursing homes and assisted living facilities are complicated by multiple possible targets (e.g., person with dementia, professional care staff, family caregiver, dyad), outcomes (e.g., behaviors, function, and quality of life), and pathways for impacting the intended intervention target (e.g., impacting the person with dementia through the professional care staff or impacting the person with dementia through the care delivery system). As an example, an intervention that targets an outcome in the person with dementia could aim to improve quality of life, behaviors, function, and/or physical activity and intervenes directly with the person with dementia (e.g., physical exercise) through the care staff (e.g., Dementia Care Mapping), a family member (e.g., decision aids), the environment (e.g., functional modifications), or the care delivery system (e.g., de-prescribing interventions).

An overall challenge is to identify the criteria to determine whether an intervention is ready for testing in a pragmatic trial. The calculus to determine which interventions are ready for a pragmatic trial might vary depending on the potential outcomes weighed against cost, potential harms, and implementation challenges.

The literature on nondrug dementia interventions in facilities is broad, and there are challenges with assessing the state of the evidence. The evidence base is complicated by poorly described settings, the use of inconsistent terminology, one-off studies, and variations in interventions addressing general (e.g., improve quality of life) versus specific (e.g., agitation during meal time) aspects of care. Furthermore, traditional evidence-synthesis methods (i.e., systematic reviews and meta-analyses) have key limitations when synthesizing heterogeneous interventions. The body of evidence also suffers from measurement challenges (e.g., multiple methods for evaluating behavioral symptoms). For a given outcome (e.g., agitation) in an intervention study (or across studies), there could be multiple measures that yield conflicting results. In such cases, it is unclear how to weigh the importance of the conflicting results. In

addition, studies may measure multiple outcomes (e.g., agitation, quality of life, and depression). Results could conflict across the multiple outcomes, and how to weigh the different outcomes relative to importance is not clear.

Jutkowitz presented an overview of a review of 42 systematic reviews of the literature of non-pharmacological intervention RCTs with one or more outcomes in persons with dementia residing in nursing homes and assisted living facilities. Implementation challenges identified across the systematic reviews include complexity, scalability, long-term intervention fidelity and maintenance, and cost. The intervention Dementia Care Mapping (DCM) was included in the review and provides good insight into implementation challenges across settings. Namely, the DCM literature highlights the implementation challenge when trained researchers become less involved in the delivery of the intervention (i.e., mimicking real-world implementation).

Jutkowitz presented examples of interventions ready for testing in pragmatic trials, but noted that consensus is needed on the most meaningful outcomes to determine programs that are truly ready for testing in pragmatic programs. Beyond systematic reviews, other methods should be employed or developed to identify interventions ready for pragmatic trials and to predict success of implementation and diffusion. Implementation challenges should be anticipated and addressed from the outset.

### **Testing Acute Care Pathways for Older Adults with Serious Illness**

*Corita Grudzen, MD, MSHS, New York University School of Medicine*

The hospital emergency department (ED) is a possible setting for pragmatic trials of patients with dementia. The ED is a chaotic environment in which patient volumes are rising, providing a window to population health. The ED is a good setting in which to examine the needs of vulnerable populations because it is the only health care setting mandated to treat all patients. The portion of ED patients who are older adults is increasing. The default ED approach is to make quick decisions focused on the assumed benefit, and give less consideration to potential harms. Grudzen's work is trying to change this default approach, particularly with respect to palliative care services in the ED.

Grudzen is conducting comparative effectiveness research of telephonic nurse-delivered palliative care and outpatient specialty care in a recently awarded \$12.4 million pragmatic trial at nine sites—Emergency Medicine Palliative Care Access (EMPallA)—funded by the Patient-Centered Outcomes Research Institute (PCORI). She discussed a second proposed pragmatic study (not yet funded) to use a cluster randomized stepped wedge trial design in 35 ED sites across 18 health systems.

Principal Investigator Joshua Chodosh, MD, New York University, is currently conducting an NIA-funded ED-based pragmatic trial to test whether a novel care management intervention for family caregivers of ED users with cognitive impairment will reduce ED use at 3 and 6 months. In POISED (Program of Intensive Support in EDs for Care: Partners of Cognitively Impaired Patients), older patients presenting at the ED are given a cognitive screening assessment as part of the intake process. Those that score lower than 3 on the MiniCog (or higher than 3.4 if by



caregiver assessment) are asked for consent to be randomized for the trial. Potential participants must have a family or friend caregiver present and the capacity to consent or a proxy. Seeking consent prior to cognitive impairment screening can impact willingness to participate in the intervention, which is one reason investigators made the screening part of the intake process.

### **Infrastructure Needs for Large-scale Pragmatic Trials: Using CMS Data**

*Julie Lima, MPH, PhD, Brown University School of Public Health*

Centers for Medicare & Medicaid Services (CMS) data are a valuable resource for studying persons with dementia. Nearly all persons with dementia are covered by Medicare, and many reside in nursing homes or assisted living facilities or receive covered home health care services. Both nursing home and home health care settings have mandatory assessments including detailed clinical data that are readily merged with standard Medicare claims. Under the terms of an appropriate data use agreement (DUA), CMS allows the use of research identifiable files, which include these assessment data, enrollment data, Medicare Part A, B, and D claims data, as well as Medicaid claims and other data for research purposes.<sup>10</sup>

CMS data can provide information on persons with dementia to inform each stage of research including recruitment, implementation, and outcomes measurement. As mentioned, mandatory assessment data are available on nursing homes (Long Term Care Minimum Data Set [MDS]) and home health agencies (Outcome and Assessment Information Set [OASIS]), and while no such assessments are required of assisted living residents, researchers have recently developed an algorithm to more readily define Medicare beneficiaries residing in assisted living facilities, paving the way for studies targeting this group. CMS data linked to other identifiable person- and provider-level data collected directly within a pragmatic trial or through facility-specific EHRs can capture eligibility and censoring. CMS data can provide information relevant to utilization and mortality outcomes, or in-house, all-payer early MDS pulls for functional outcomes. Linkages between primary data and claims, enrollment, and assessment data allow for the creation of a residential history file that makes it possible to follow a person beyond the recruited facilities/providers for a longer term.

Although the use of CMS data is invaluable, the DUA processes to gain approval to use the data pose their own challenges. They are project- and institution-specific and must be renewed each year. For an experienced requester, it takes at minimum 4 to 5 months to obtain initial DUA approval for each project, which must be regularly amended through additional months-long processes to add more recent data as they become available. Data can be requested as annual files, typically available 14-18 months after the calendar year closes, or in quarterly batches, available 6 months' post-quarter. Researchers pay a premium for the earlier access to quarterly files; however, the cost for 1 year of quarterly files is 2.5 times that for annual data. A benefit to the current DUA structure is that data obtained in-house can be reused at the same institution for a new project under a new DUA for a minimal re-use fee.

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<sup>10</sup> See [www.resdac.org](http://www.resdac.org).

Although still requiring the same DUA process, CMS offers another venue for accessing some of the above data through its Virtual Research Data Center (VRDC). This allows researchers to work in a secure environment without having to locally store and secure the data themselves. In addition to annual and quarterly access to files as described above, there is an added opportunity for researchers to work with data in near real time (within 2 weeks to 1 month post claim-date) through the Workbench tool on the VRDC. Although the cost for DUAs written for in-house use are data-dependent, the cost for DUAs using the VRDC are user-dependent. Each user is required to have a seat. A VRDC seat costs \$25,000 per year and cannot be shared by multiple users. Data used in the VRDC cannot be re-used in other projects.

The challenges to obtaining and using CMS data can be mitigated by capitalizing on shared knowledge and experience. The process for obtaining these data is highly bureaucratic, lengthy, costly, and tedious. Working with these data requires analytic and policy expertise, and understanding of the tradeoffs between in-house and VRDC use comes mainly through experience.

The timing is right for innovative pragmatic clinical trial research that leverages the availability of timely national administrative data. Given the expertise and cost required to obtain and work with CMS administrative data, a common infrastructure that serves the pragmatic clinical trial research community focused on interventions to improve the lives of persons with dementia would be an important investment. Formal collaboration across institutions to maximize expertise could be facilitated by an entity serving as the hub of such an infrastructure.

### **Infrastructure for Pragmatic Trials of Dementia Care**

*David D. Dore, PharmD, PhD, Optum Analytics and Brown University School of Public Health*

Dore provided an industry perspective of innovations in the private sector to link existing data and create unique commercial data resources that physically integrate multiple sources. Optum, the health services business of UnitedHealth Group, maintains an EHR platform used in medical practice groups and hospitals that includes demographics, diagnoses, hospitalizations, lab results, medications, observations, provider notes, outpatient visits, procedures, and vital signs. UnitedHealth Group employs approximately 260,000 individuals globally, more than 100,000 of which work for Optum. Optum and other large-scale commercial entities are powerful potential partners in providing data infrastructure at scale for research purposes.

Dore discussed ongoing efforts at Optum to build and maintain a comprehensive longitudinal dataset created from Optum EHR data sources to facilitate pragmatic trial research, which currently has data of varying completeness on 70 million individuals in more than 60 health systems across the United States. Working with provider organizations, Optum compiles data from all relevant electronic medical records systems through customized extract, transform, and load procedures, giving rise to validated, normalized, standardized, and mapped EHR data that reside centrally in a common ontology. All decisions, metadata, and coding related to data processing are documented. There is substantial variability in the data that is largely attributable to variation in the data collected at the health systems, and Optum is working to characterize this variability.

Optum also has access to claims data for 120 million UnitedHealthcare beneficiaries from 1993 to the present. The claims data and EHR data have been linked for the overlapping populations of approximately 10 million individuals. Optum is working with a marketing research data company to link additional pharmacy benefit claims, front store data, loyalty card data, and media viewing data.

Dore acknowledged challenges with the overall project including determining the governance of data linkages and site management, data volume, extent of overlap of linked data, and methods used for missing data and how to implement collaborations that embed trials in routine care. Mor noted that these types of privately held health data will only continue to grow and, despite their limitations, represent great potential for future research applications and partnerships.

## Summary of Discussion Themes

### Barriers to Broad-scale Implementation

David Bass discussed barriers that health care systems face when contemplating implementation of dementia care intervention programs, specifically under the rubric of a pragmatic trial. Organizations are often unable to make informed decisions about what intervention fits with their system because the intervention is not sufficiently transparent. In addition, organizations' characteristics make implementation or change in general difficult. The success of a particular intervention in a pragmatic setting depends as much on the clinical efficacy of the intervention itself as it does on the health care organization's ability to adapt its practices to implement it.

The Dementia Caregiving Network, of which Bass was a member, developed and tested a carefully defined methodology for conducting comprehensive reviews of evidence-based programs for persons with dementia and their family caregivers and completed its work in 2016.<sup>11</sup> A new project currently in the data collection phase, Online Resource for Comparing Evidenced-Based Dementia Caregiving Programs, began in May 2017 and will be completed by the end of 2019. This 30-month project will create, launch, and evaluate a comprehensive web-based information source that will profile and compare 50 evidence-based, dementia caregiving programs that are ready for community implementation. This work is intended to help three primary target audiences (health care and community service organizations, health care and social service providers, and government and private-sector funders) understand the available evidence-based programs and care practices and make decisions about which ones to use.

Participants identified multiple barriers that intervention researchers face when implementing studies on a broad-scale, including within pragmatic clinical trials:

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<sup>11</sup> See <https://changeagents365.org/initiative-activities.html#dementia-caregiving-network>.

- Challenges with data access, data collection, and data linkages
- Investigators' needs for training in pragmatic trials, which require different skill sets and often different methodologies than classic RCTs
- Unique ethics and regulatory considerations
- Building and sustaining stakeholder relationships
  - Mismatch of timeframe needs of researchers versus health care settings
  - Mismatch of stakeholder and researcher priorities
  - Health care setting staff turnover and training needs
- Challenges with existing dementia intervention research
  - Multi-component interventions
  - Heterogeneity of settings and intervention targets
  - Lack of research base to identify mechanisms of action or active components of interventions (participants discussed the need for more Stage I work and the use of methods such as mediation analysis, simulation modeling, and tailored systematic review strategies<sup>12</sup> to address this issue)
  - Lack of consensus for determining which interventions are ready for a pragmatic trial
  - Poorly specified interventions in some existing research
  - Poorly characterized samples in some existing intervention research
  - Multiple care settings
  - Patient-caregiver relationship (dyadic target)
  - Ethical and regulatory issues (e.g., informed consent and human subject protections)
  - Measurement of patient-reported outcomes for persons with dementia
  - Clinical trajectory of disease
  - Multiple potential targets for intervention
  - Undiagnosed population
  - Health care systems may not see persons with dementia as a high priority population; unique stakeholder engagement issues
  - Lack of reimbursement and payment structures for many dementia care interventions

### **Criteria to Identify Interventions Ready for Pragmatic Trials**

Participant discussion yielded numerous considerations regarding whether a particular dementia care intervention is ready to be tested in a pragmatic clinical trial:

- Evidence of significant clinical efficacy (It is noted, however, that determining *how much* or what *strength of evidence* should be required, necessitates greater consideration and may depend on the complexity, or level of risk of the intervention.);
- Sufficient Stage I (NIH Stage Model) work to determine the active components of the intervention;

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<sup>12</sup> See, for example, the Behavior Change Technique Taxonomy (v1), developed by Susan Michie and colleagues: <http://www.ucl.ac.uk/health-psychology/bcttaxonomy> and <http://www.bct-taxonomy.com/>.

- Well-articulated intervention protocols;
- Feasibility of implementation in a pragmatic environment;
- Acceptability to study participants, including health care providers, systems, and corporations;
- Determination that the intervention is of low risk to participants with thoughtful consideration of potential adverse events and unintended consequences;
- Alignment of priorities between researchers and partner health care organization(s); and
- Cost-neutral, or cost-effective, program implementation for the partner health care organization and/or incentivization of the intervention services by one or more payers.

### **Research Priority: ADRD-Specific Pragmatic Clinical Trial Infrastructure**

It is clear, in part from the October 2017 National Research Summit on Care, Services, and Supports for Persons with Dementia and their Caregivers<sup>13</sup> and from this workshop, that the research and advocacy communities recognize that:

1. Dementia intervention research involves unique facilitators and challenges for pragmatic clinical trials;
2. Substantial evidence from efficacy trials of non-pharmacological interventions in dementia warrant further evaluation under the rubric of a pragmatic trial;
3. There is a need for greater infrastructure for dementia intervention researchers to share knowledge, data, methods, and measures on the conduct of pragmatic trial; and
4. The NIA is poised to leverage lessons learned from other NIH-funded pragmatic trial efforts and to translate them to dementia-specific research. An infrastructure that capitalizes on economies of scale for clinical, methodological, and regulatory expertise, data, relationships, and other common needs that pragmatic trial researchers have in testing interventions in the real-world of learning health systems is needed. Such an infrastructure would significantly strengthen the ability of the research community to develop, test, implement, and translate effective interventions and to improve the lives of persons with dementia and their caregivers.

To meet research infrastructure needs, participants envisioned an Alzheimer's disease and related dementias (ADRD) Research Collaboratory following the model of the collaboratory for pragmatic clinical trials sponsored by the NIH Common Fund Program.<sup>14</sup> Participants recommended that the ADRD Research Collaboratory have the following cores to build investigator capacity, support pragmatic trial design, and maintain the resource and knowledge base:

1. Stakeholder Engagement
2. Interagency Interaction

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<sup>13</sup> See <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>.

<sup>14</sup> See <https://commonfund.nih.gov/hcscollaboratory>.

3. Health Care Systems Collaborations
4. Training and Education
5. Biostatistics and Study Design
6. Participant Recruitment
7. Measurement
8. Pilot Study Design
9. Data (including EHR)
10. Ethical and Regulatory Issues
11. Evidence Synthesis and Systematic Review
12. Dissemination and Implementation

The cross-cutting themes of disease stage and care setting were identified as being critical to infuse across all the cores.

Participants were enthusiastic about the large evidence base and state of the science for non-pharmacologic interventions for persons with dementia and their caregivers and stressed the importance of pragmatic research to ensure that such interventions can be implemented effectively in the real world. The current national focus on ADRD research, momentum provided by the National Research Summit on Care and Services and related activities such as this workshop, and the availability of powerful resources such as administrative data and growing knowledge of pragmatic clinical trials techniques are evidence that the timing is opportune to build an infrastructure to support ADRD-specific pragmatic clinical trials to improve the lives of persons with dementia and their caregivers.

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## Appendix A: Agenda

### *State of the Science for Pragmatic Trials of Non-Pharmacological Interventions to Improve Outcomes Among Persons with Dementia and Their Caregivers*

#### AGENDA

*Revised November 28, 2017*

9:00 a.m.	<b>Welcome, Introductions &amp; Background</b>	<i>Vincent Mor</i> <i>Co-chairs: Susan Mitchell</i> <i>Rosa Baier</i>
9:20	<b>Methods &amp; Data for Pragmatic Trials: Design Considerations, from Explanatory to Pragmatic Trials</b>	<i>Susan Mitchell</i>
9:45	<b>Summary of Evidence for Interventions</b> <ol style="list-style-type: none"><li>1. Status of the Field: Community and Home-based Interventions for Persons Living with Dementia and Family Caregivers</li><li>2. Service System Considerations in Evaluating Community-Based Dementia Care Interventions within Pragmatic Trials</li><li>3. Discussion &amp; Clarification</li></ol>	<i>Laura Gitlin</i> <i>Richard Fortinsky</i> <i>Rosa Baier</i>
11:00	<b>BREAK</b>	
11:15	<b>Summary of Evidence for Interventions (Cont'd)</b> <ol style="list-style-type: none"><li>4. Assisted Living Communities &amp; Nursing Homes</li><li>5. Hospitals &amp; Emergency Departments</li><li>6. Discussion &amp; Clarification</li></ol>	<i>Eric Jutkowitz</i> <i>Corita Grudzen</i> <i>Rosa Baier</i>
12:30 p.m.	<b>LUNCH</b>	
1:00	<b>Criteria to Identify Interventions Ready for Pragmatic Trials</b> <i>What criteria should we use to determine which interventions are ready to be launched as pragmatic trials?</i>	<i>Facilitated Group Discussion</i> <i>(Rosa Baier)</i>
2:00	<b>Barriers to Broad-Scale Implementation</b> <i>What are the barriers to broad-scale implementation of evidence-based interventions? How can we mitigate them?</i>	<i>Facilitated Group Discussion</i> <i>(Rosa Baier)</i>
3:00	<b>BREAK</b>	

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3:15	<b>Infrastructure Needs for Large-Scale Pragmatic Trials</b> <i>What are the infrastructure needs to successfully prepare interventions for large-scale pragmatic trials, and to support trials once launched?</i>	<i>Facilitated Group Discussion (Rosa Baier)</i>
	<i>Examples of data infrastructure:</i> <ol style="list-style-type: none"><li>1. CMS Virtual Research Data Center</li><li>2. Optum Analytics</li></ol>	<i>Julie Lima David Dore</i>
4:30	<b>Summary of Research Priorities</b>	<i>Vincent Mor &amp; Susan Mitchell</i>
5:00	<b>ADJOURN</b>	



## Appendix B: Participant List

### *State of the Science for Pragmatic Trials of Non-Pharmacological Interventions to Improve Outcomes Among Persons with Dementia and Their Caregivers*

#### PARTICIPANT LIST

*Revised December 1, 2017*

#### Meeting Chairs

**Vincent Mor**, Brown University School of Public Health

**Susan Mitchell**, Hebrew SeniorLife

**Rosa Baier**, Brown University School of Public Health

#### Speakers

**David Dore**, Optum Analytics – Life Sciences and Brown University School of Public Health

**Richard Fortinsky**, University of Connecticut Health Center on Aging

**Laura Gitlin**, John Hopkins School of Nursing

**Corita Grudzen**, New York University School of Medicine

**Eric Jutkowitz**, Brown University School of Public Health

**Julie Lima**, Brown University School of Public Health

#### Participants (In Person)

**Abraham (Ab) Brody**, New York University Rory Meyers College of Nursing

**Gary Epstein-Lubow**, Hebrew SeniorLife and Brown University School of Public Health

**Nicole Fowler**, Indiana University School of Medicine

**Elizabeth Galik**, University of Maryland School of Nursing

**Joseph Gaugler**, University of Minnesota School of Nursing

**David Gifford**, American Health Care Association/National Center for Assisted Living

**Lisa Gwyther**, Duke Medical Center

**Susan Hickman**, Indiana University School of Nursing

**Lee Jennings**, University of Oklahoma Health Sciences Center

**Ann Kolanowski**, Pennsylvania State University

**Mark Kunik**, United States Department of Veterans Affairs

**Cheryl Phillips**, SNP Alliance

**Greg Sachs**, Indiana University School of Medicine

**Quincy Miles Samus**, John Hopkins Medicine

**David Schulke**, Health Quality Strategies, LLC

**Richard Schulz**, University of Pittsburgh

**Robyn Stone**, LeadingAge

**Joan Teno**, University of Washington

**Thomas Trivison**, Hebrew SeniorLife

**Kathleen Unroe**, Indiana University School of Medicine

**Ann Wyatt**, CaringKind

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## Participants (WebEx)

**David Bass**, Benjamin Rose Institute on Aging

**Laura Hanson**, University of North Carolina School of Medicine

**Helena Temkin-Greener**, University of Rochester Medical Center

**Kathleen Welsh-Bohmer**, Duke University School of Medicine

## National Institute on Aging

**Partha Bhattacharyya**, Division of Behavioral and Social Research (BSR)

**Elena Fazio**, BSR

**John Haaga**, BSR

**Lisa Onken**, BSR

**Marcel Salive**, Division of Geriatrics and Clinical Gerontology

## Contractors

**Chandra Keller-Allen**, Rose Li and Associates, Inc.

**Susan Kurdziolek**, Rose Li and Associates, Inc.