



## *Appendix X. Systematic Review Disposition of Comments Supplement*

### **Title: Care Interventions for People Living With Dementia and Their Caregivers**

Draft report available for public comment from March 24, 2020 to April 21, 2020.

**Citation:** Butler M, Gaugler JE, Talley KMC, Abdi HI, Desai PJ, Duval S, Fort ML, Nelson VA, NG W, Ouellette JM, Ratner E, Saha J, Shippee T, Wagner BL, Wilt TJ, Yeshi L. Care Interventions for People Living With Dementia and Their Caregivers. Comparative Effectiveness Review No. 231 (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2015-00008-I.) AHRQ Publication No. 20-EHC023. Rockville, MD: Agency for Healthcare Research and Quality; August 2020. <https://effectivehealthcare.ahrq.gov/products/care-interventions-pwd/report>.

### **Comments to Draft Report**

The Effective Health Care (EHC) Program encourages the public to participate in the development of its research projects. Each draft report is posted to the EHC Program Web site or AHRQ Web site for public comment for a 3-4-week period. Comments can be submitted via the Web site, mail or E-mail. At the conclusion of the public comment period, authors use the commentators' comments to revise the draft report.

This document includes full, verbatim comments on the draft report that did not fit on the Disposition of Comments Table. Comments are not edited for spelling, grammar, or other content errors.

April 21, 2020

Agency for Healthcare Research and Quality  
US Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

**RE: AHRQ Care Interventions for People with Dementia (PWD) and Their Caregivers**  
Submitted via AHRQ Effective Health Care Program Website

Dear Colleagues,

On behalf of The Gerontological Society of America (GSA), thank you for the opportunity to provide comments on the Draft Systematic Review for the Care Interventions for People With Dementia (PWD) and Their Caregivers.

GSA is the oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. GSA's principal mission — and that of our 5,300 expert members — is to promote the study of aging and disseminate information to scientists, decision makers, and the general public.

Our interest comes from our goal to translate our members' research into evidence-based practice and policy. Consistently, Alzheimer's Disease and Related Dementias and Family Caregiving rank in the top submissions for our Annual Scientific Meeting and in our five peer-reviewed journals.

Our responses are included below and also provided in the comment section on the website. If we can provide additional information or if you have any questions, please do not hesitate to contact Patricia D'Antonio, Vice President, Professional Affairs at [REDACTED]@geron.org or 202-[REDACTED]-[REDACTED]. We look forward to the final report.

Sincerely,



James C. Appleby, BSPHarm, MPH, ScD (Hon)  
Chief Executive Officer

### **Question 1. Comments on the Evidence Summary of the draft report.**

The evidence summary provides a brief, clear summary of the extensive review of non-drug interventions for people with dementia and their caregivers that was conducted by AHRQ's Minnesota Evidence-based Practice Center and is intended to support the work of the NASEM committee charged with providing recommendations about which care interventions are supported by sufficient evidence to be widely disseminated and implemented and to identify research gaps. GSA acknowledges and applauds the huge effort and careful analyses that went into conducting the review and preparing the draft report.

GSA has one suggestion for the Evidence Summary: the Summary indicates that only seven or eight of the almost 600 reviewed interventions met the evidence criteria that were used for the review. The Summary names only one of those programs, REACH II, and provides 3 references, including one for the original REACH II study (Belle et al., 2006), one for a German adaptation of REACH II (Berwig et al., 2017), and one for a comparative effectiveness analysis (Luchsinger et al., 2018) that compared two U.S. interventions, REACH-OUT (REACH Offering Useful Treatments) and NYUCI (the New York University Caregiver Intervention), both of which were provided for Hispanic family caregivers in New York. (It is not clear to GSA whether the report intends to identify both these interventions as meeting the evidence criteria for the review.) The comparison found no statistically significant differences between the two programs, and both programs resulted in positive outcomes for the caregivers. The other four interventions that met the evidence criteria for the review are not named in the Evidence Summary but are presented as "collaborative care models" and are identified by references for 1) ACCESS (Alzheimer's Disease Coordinated Care for San Diego Seniors (Vickery et al., 2006), 2) a telephone-based adaptation of ACCESS for family caregivers in a Latino community in Los Angeles (Chodosh et al., 2015), 3) Care Ecosystem (Possin et al., 2019), and 4) Dementia Care Management, a German intervention (Thyrian et al., 2017). GSA suggests that all of these interventions should be named in the Evidence Summary. Adding the intervention names, rather than referring to them more generally as "REACH II" and "collaborative care models" would add clarity and accuracy to the Evidence Summary. It would allow readers to understand that the review found that only these specific interventions, not all adaptations of REACH II and not all interventions often said to be "collaborative care," met the evidence criteria. Adding the intervention names to the Evidence Summary would add complexity and make the Summary longer, but GSA thinks it would increase the value of the Summary for all readers. GSA also suggests that consistently naming the interventions or, preferably, using a clearer and more accurate phrase than "REACH II and collaborative care models" would increase the value of other sections of the report.

### **Question 2. Comments on the Introduction of the draft report.**

The introduction provides useful information about the origin and goals of the review; the complexity of interventions for persons with dementia, their families, and formal/paid care providers; and the key questions selected for the review. This information helps the reader understand the rationale for the review and the organization of the report.

### **Question 3. Comments on the Methods section of the draft report.**

The review is based on AHRQ's Systematic Review Methodology and generally follows processes used in other systematic reviews. As required by the review funders, the review applies narrow inclusion criteria and excludes interventions that are in stages 0-2 of NIH Stage Model for Behavioral Interventions, thus limiting the number and types of interventions in the final analytic set (96 interventions). These inclusion criteria and processes are clearly explained in the Methods section, and that clear explanation helps the report reader understand the discussion in the following chapters. As noted in our response to question 14 below, GSA believes that it would have been better to use broader inclusion criteria. This is not a criticism of the report since the criteria were dictated by the report funders. In addition, the review will benefit from engaging individuals with dementia and caregivers in the review development. Stakeholders involvement in review studies is gaining popularity. Patient

and public involvement (PPI) is mandatory in countries such as the United Kingdom for funded research activities, including systematic reviews. They play a vital role in informing what is known about a topic, and what is not known, to support better programs, services, health care and policy. It has the goal to gain further knowledge about the patient/user barriers and challenges as well as to enhance the actual and perceived usefulness of synthesized research evidence.

**Question 4. Comments on the Search Results section of the draft report.**

The Search Results section provides a useful graph that helps the report reader understand how the 595 unique interventions that met the inclusion criteria were further reduced to 96 interventions that are in the analytic set. The table in this section of the draft report is a valuable resource for the whole report because it provides a concise picture of the number and types of studies that were reviewed and addressed in more detail in chapters 4-8.

It is not clear why the grey literature was not included since there is potential to gain further knowledge by including evidence that might be not available in the standard literature databases.

**Question 5-9. Comments on the Care Intervention Sections of the draft report (sections 4-8).**

The Care Intervention sections (chapters 4-8) provide details about the results of the review for particular types of interventions, using the same, highly structured format in each section. Use of the same format in all these sections helps the reader make sense of and draw conclusions from the many detailed results.

**Question 10. Comments on the Implementation of Care Interventions section of the draft report.**

No comments.

**11. Comments on the Discussion section of the draft report.**

GSA appreciates the many important ideas presented in this section, most of which match strong interests and concerns of GSA's diverse membership. Many of the limitations and gaps in the research literature mentioned by the authors may also present opportunities for future research. Some related to populations, outcomes, interventions, implementation, broader research context, and additional questions may be addressed as follows:

1. Additional areas of exploration related to functional and health status limitations, access to care and intervention services as well as accessibility, transportation, culture, race and related factors should be explored and discussed. (This speaks to the authors' note that due to the selection criteria and framework employed in the review process, some community-based interventions may not have been included in the review.)
2. The report states, "Unfortunately, quality of life was often not measured, and rarely as the outcome of primary interest. " We recommend that this be linked with a recommendation for future development of better measures for psycho-social outcomes in persons living with dementia and better methods of measurement.
3. As a next step / action item, GSA recommends that the authors consider presenting the gaps noted in the research literature as opportunities to researchers, including GSA members, who work in dementia care research and practice, especially regarding underrepresented populations mentioned in the report draft (e.g. PWD with Down syndrome, frontotemporal dementia, racial or ethnic differences, LGBTQ populations, and those in low-resource areas including rural and/or tribal communities). In addition, presenting the gaps as opportunities to members of specific GSA interest groups (such as the Alzheimer's Disease and Related Dementias, Family Caregiving, Rainbow Research Group, Lifelong Disabilities, and Rural Aging interest groups) could provide opportunities to reach large numbers of

members with similar interests and encourage them to consider collaborating on research, practice and interventions that may help reduce these gaps.

4. A current topic relevant to this discussion is the ability to deploy rapid response research on various aging topics, notably employed during the COVID-19 pandemic. New technologies allow researchers to rapidly develop and quickly implement surveys via methods such as websites, email, and social media. The ability to collect data in real time, while participants are experiencing challenges, difficulties, and positive outcomes, may provide robust data that can inform future research and interventions.
5. GSA agrees that those involved in dementia care research should work to make it more efficient and effective, as PWD living with this debilitating disease and their caregivers need help and support sooner rather than later. We appreciate the citing of the Benjamin Rose Institute's Best Practice Caregiving website as an example of a "way to close feedback loops and gain knowledge from real-world applications".
6. GSA is in strong agreement with the authors that, "Without clear answers, PWD, caregivers, programs that support PWD and caregivers, funders, and policymakers will continue to depend on subjective observations, low-quality evidence, economics, and local and institutional policies." Time is of the essence to provide evidence-based interventions and support to persons with dementia, their caregivers, and the organizations who serve them.

#### **12. Comments on the Abbreviations and Acronyms section of the draft report.**

No comments

#### **13. Comments on the References section of the draft report.**

No comments

#### **14. General comments on the draft report.**

The report provides an extensive review of those studies reviewed. It offers an opportunity to guide recommendations for grant proposal development to address the gaps noted. Though the report is informative, the GSA suggests caution in how the findings are interpreted and applied due to the narrow scope of the research reviewed. The report provides an excellent starting point to establish an agenda for future work and areas of focus for funding and research. However, due to its narrow scope to care intervention and care delivery, there is a potential for the recommendations to limit creativity, innovation, and relational delivery from a family-centered context. It is suggested to consider more exploratory and inclusive designs for developing the recommendations to fill the research gaps. There are three major areas for consideration the GSA is identifying regarding this report:

The narrow scope of the research reviewed fails to include the context within which the experience of the health condition and the caregivers occurs, therefore the complexity of the dynamic of health management is underrepresented. This becomes significant when identifying broad, "real-world" interventions. Gaps in intervention/program effectiveness will occur because the complexities have not been adequately identified and addressed to guide the research in a systematic manner.

The recruitment of this population not only encounters the traditional challenges of conducting research, e.g. lack of diversity, low-economic status, and special interest groups, e.g. LGBTQ, dementia-related diagnoses are riddled with additional challenges. These include the societal stigma for those experiencing the symptoms and not wanting to report them to a health care professional, an inability for people to differentiate between normal cognition decline and early symptoms of dementia, and cultural implications within the family. This may be the reason for smaller sample sizes and limited generalization of findings.

Progressive nature of trajectory of the dementia-related diseases is a challenge to demonstrate outcome improvement. Due to this dynamic of the disease trajectory, improvement outcomes need to be thought of differently and further defined, for clarity of research findings and its applications, not only for the person with dementia but for the caregiving related aspects. More longitudinal studies are needed to capture this changing dynamic over time.

Based on the above factors, GSA proposes the following for consideration regarding this report:

- Use of the report's gaps and limitations as a guide to delineate an agenda to address the concerns with a call of proposals including a variety of populations, interventions, and research methods that captures the qualitative context, translational, quantitative & traditionally rigorous designs,
- Increase funding amounts for proposals to encourage small and large-longitudinal studies with partnerships across the community connected to the home, qualitative studies to discover experiences and care needs from the PWD and their caregivers and understand the relational dynamics that influence outcomes,
- Identify the specific outcomes of interest related to the person with dementia and the caregiver, e.g. quality of life, etc., for measurement to address the gap in the ability to conduct systematic reviews across differing research methods and studies, and
- Encourage research studies that build upon researchers' previous findings to encourage development from preliminary research or first round findings to move toward innovative interventions and program testing, e.g. encourages use of established research.
- Ensure the inclusion of key stakeholders and organizations that are developing initiatives to address some of the unmet areas and noted limitations. For example, family caregiving of aging adults with Down Syndrome have unique needs and challenges as compared to a caregiver for a person with dementia. The caregiving needs of lifelong caregiver, such as a person who has been taking care of a person aging with a pediatric-onset disability and dementia is unknown and it has been neglected by the medical and scientific community. A person who has been a caregiver for an entire life and now is aging and taking care of someone who is also aging with a disability and dementia is overlooked. This is such an urgent and non-recognized issue.

The findings from this review are not surprising given the design of the study and the challenging, chronic condition trajectory of dementia. This report is an excellent opportunity to generate discussions across the gerontological interest groups for next steps. GSA offers our support to the NASEM, AHRQ and the NIA in developing the next steps to continue the opportunities to improve available care interventions that have impact from an individual-family framework to address what the report noted as the lack of, "granular details necessary for deeper understanding of applicability of the intervention."

Thank you for this opportunity to review and respond to this important health concern.

**15. Does this report describe both the problem and the evidence in a way that you could understand?**

Yes. The report is long and detailed, but it is clearly written and well organized, and therefore, understandable. However, many key areas were not emphasized and valued as previously noted.

**16. Did you find this report unnecessarily difficult to read?**

No. The report is readable in general. It is excellent for understanding and use of the information in diverse manners.

**17. Could you find and understand the results and conclusions?**

Yes. We were able to find and understand the results and conclusion.



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April 21, 2020

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Task Order Officer  
Center for Evidence and Practice Improvement  
Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

Dear Ms. Wittenberg,

We are writing in response to the Agency for Healthcare Research and Quality (AHRQ) call for comments concerning the Draft Comparative Effectiveness Review, “[Care Interventions for People With Dementia \(PWD\) and Their Caregivers](#).” The [Alliance for Aging Research](#) is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term. For more than 30 years, the Alliance has guided efforts to substantially increase funding and focus for aging at the National Institutes of Health (NIH) and Food and Drug Administration (FDA); built influential coalitions to guide groundbreaking regulatory improvements for age-related diseases; and created award-winning, high-impact educational materials to improve the health and well-being of older adults and their family caregivers. Additionally, the Alliance chairs the [Accelerate Cures/Treatments for All Dementias \(ACT-AD\) Coalition](#), a group of more than 50 national nonprofit organizations, founded in 2005, urgently working to speed up the development of potential cures and more effective treatments for all dementias.

### **Overall comments on review structure**

According to the Evidence-based Practice Center Systematic Review Protocol for this review, the National Institute on Aging (NIA) of the NIH, in collaboration with the National Academies of Science, Engineering, and Medicine (NASEM), commissioned “a summary of the available evidence for care interventions for people with dementia (PWD) and their formal and informal caregivers.” The goal of the review “is to understand the evidence base for effective care interventions, and to assess the potential for broad dissemination and implementation of that evidence.” The protocol acknowledges that “Unfortunately, no consensus has been reached on classification systems for types of interventions, leaving categorization up to empirical rather than theoretical approaches.”

Our first request is that the systematic review clearly define the evidentiary standard needed for “broad dissemination and implementation.” While reading the review we were often left wondering what standard is needed for broad dissemination of these interventions. To help the research community, patients,

providers, payers, advocacy community, and other stakeholders better understand an evidentiary standard to meet the goal of “broad dissemination and implementation,” we ask the review to answer the below three questions.

- ✓ What should the basic components of any evidence-based care intervention for PWD include?
- ✓ What are the evidence gaps that need to be filled for a care intervention for PWD to meet the evidence criteria for broad dissemination and implementation?
- ✓ What are the evidence gaps that need to be filled for a care intervention for PWD to qualify for coverage and reimbursement by private and public, including Medicare?

Our second recommendation would be for AHRQ to develop a standard for the type of intervention that should be involved in a systematic review. The objective of the review was to understand the evidence base of care interventions that have the “potential for broad dissemination and implementation.” However, there were interventions included in the systematic review that would very likely not scale nationwide and would almost certainly not be reimbursed by a payer.

### **Medicare and Alzheimer’s disease**

It would be helpful for the review to include a specific section on whether/how certain interventions—if evidence gaps were filled—could be considered for eventual coverage and reimbursement in the Medicare program.

In 2019, the Alliance for Aging Research commissioned a study with the actuarial firm Milliman to examine the real-world costs of Alzheimer’s disease on the Medicare program.<sup>1</sup> We undertook this work because actual Medicare spending on the disease is rarely discussed. Instead, “associated costs of care”—that combines Medicare and Medicaid spending, often with out-of-pocket spending by families, is generally used to effectively advocate for increased federal investment in research. The preference for using associated costs is understandable, however, direct costs better demonstrate what the Medicare program is doing, and not doing, for people with Alzheimer’s disease.

Published in the July 2019 issue of the *Journal of Managed Care and Specialty Pharmacy* the study found that Medicare spending on Alzheimer’s disease is low. The study examined almost 340,000 Medicare beneficiaries for up to 10 years and found that risk-adjusted annual costs were \$2,101 (2015 U.S. dollars) higher for Alzheimer’s disease and \$1,870 higher for general dementia than beneficiaries without a diagnosis. In the last year of life, Medicare spent \$1,300 less on patients with Alzheimer’s disease than other beneficiaries. The lower costs were often due to avoiding complex care, such as chemotherapy for cancer, for loved ones with advanced dementia.

The relatively low Medicare spending on Alzheimer’s disease makes sense. Medicare pays for medical care and only some short-term supportive care.

Additionally, turning to nonpharmacologic interventions is not standard practice in the nursing home setting. While evidence-based psychosocial (i.e. non-pharmacologic) interventions have shown some promise in managing these symptoms, they are rarely used in everyday clinical practice. CMS developed a training program and care plans to promote “person-centered high-quality care” and the use of non-pharmacologic treatment alternatives to antipsychotics.<sup>2</sup> Section 6121 of the Affordable Care Act of 2010 requires Centers for Medicare & Medicaid Services (CMS) to ensure that nurse aides receive regular training on caring for residents with dementia and on abuse prevention. CMS, supported by a team of

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<sup>1</sup> The Real-World Medicare Costs of Alzheimer Disease: Considerations for Policy and Care, Bruce Pyenson, Tia Goss Sawhney, *Journal of Managed Care & Specialty Pharmacy* 2019 25:7, 800-809. Open-access available at: <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.7.800>.

<sup>2</sup> <https://qsep.cms.gov/pubs/HandinHand.aspx>

training developers and subject matters experts, created this training to address the need for nurse aides' annual in-service training on these important topics. Unfortunately, less than 2% of facilities consistently implement the person-centered care approaches for NPS<sup>3</sup> and most staff lack the knowledge, skills, or experience to effectively implement nonpharmacologic approaches.<sup>4 5</sup> Such person-centered care requires resources, including reimbursement for implementation, and commitment to these goals.

On the other hand, there has been a lot of resources devoted to addressing the use of antipsychotics in residents with dementia. In 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes to "improve the quality of care" for nursing home residents with dementia, primarily by achieving reductions in the use of antipsychotics.<sup>6</sup> Also in 2012, the American Board of Internal Medicine initiated "Choosing Wisely,"<sup>7</sup> targeting "low-value care," including the first-line use of antipsychotics for NPS. Since the establishment of these efforts, antipsychotic use has reportedly been significantly reduced by 40% among long-term care residents from 2011 to 2019.<sup>8</sup>

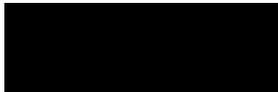
While CMS currently promotes the use of non-pharmacologic interventions over medication for NPS, there is not sufficient evidence for any such care interventions to be widely disseminated or implemented. We are concerned about the impact this could have on dementia patients experiencing NPS, and the professional caregivers tasked with managing them. We recommend that this systematic review 1) identify those interventions that demonstrate the most promise to help with NPS; and 2) highlight evidence gaps so that NIA/NIH can conduct or fund the research necessary for such interventions to be broadly disseminated and implemented as soon as possible, as well as eventually covered by payers.

## Conclusion

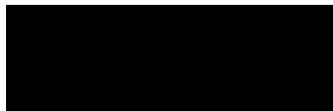
The Alliance appreciates the opportunity to provide feedback on this important evidence review. If you have questions for our organization, please do not hesitate to contact the Alliance's Public Policy Manager, Ryne Carney at (██████████) or ██████████@agingresearch.org.

Thank you for your consideration and please consider our organization a resource.

Sincerely,



Susan Peschin, MHS  
President and CEO



Ryne Carney  
Public Policy Manager

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<sup>3</sup> Grabowski DC, O'malley AJ, Afendulis CC, et al. Culture Change and Nursing Home Quality of Care. *Gerontologist* 2014;54:S35-S45.

<sup>4</sup> Kolanowski A, Van Haitsma K, Penrod J, et al. "Wish we would have known that!" Communication breakdown impedes person-centered care. *Gerontologist* 2015;55:S50-S60.

<sup>5</sup> Marx KA, Stanley IH, Van Haitsma K, et al. Knowing Versus Doing: Education and training needs of staff in a chronic care hospital unit for individuals with dementia. *J Gerontol Nurs* 2014;40:26-34.

<sup>6</sup> CMS announces partnership to improve dementia care. 2012. Available at: <https://www.cms.gov/newsroom/press-releases/cms-announces-partnership-improve-dementia-care-nursing-homes>.

<sup>7</sup> Choosing Wisely: A Special Report on the First Five Years. Available at: [www.choosingwisely.org/choosing-wisely-a-special-report-on-the-first-five-years/?ve-things-physicians-and-patients-should-question-press-release-april-4-2012/](http://www.choosingwisely.org/choosing-wisely-a-special-report-on-the-first-five-years/?ve-things-physicians-and-patients-should-question-press-release-april-4-2012/)

<sup>8</sup> Available at: <https://www.cms.gov/files/document/antipsychotic-medication-use-data-report-updated-01242020.pdf>

April 22, 2020

Agency for Healthcare Research and Quality  
Evidenced-based Practice Center Program  
5600 Fishers Lane, Rockville, MD 20857

Submitted via email to [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

Re: AHRQ **Systematic Evidence Review on “Care Interventions for People With Dementia (PWD) and Their Caregivers”**

Alzheimer's Los Angeles appreciates the opportunity to comment on the Agency for Healthcare Research and Quality (AHRQ) report entitled, “Care Interventions for People With Dementia (PWD) and Their Caregivers.” We fully support the AHRQ's goal of understanding the evidence base for care interventions for people with dementia (PWD) and their caregivers as well as assessing the potential for broad dissemination and implementation of that evidence. We also understand the report's conclusion that the level of current evidence at this time is insufficient and agree that this conclusion demonstrates the need for larger, longer-term and more rigorous studies of these interventions.

However, we are concerned that these results will be used to decrease or eliminate funding and/or reduce support for adoption of evidence-supported programs to assist people living with dementia and their family caregivers. By contrast, we believe additional supports are needed now to sustain this growing population, which experiences high levels of distress. While the level of evidence is still weak, there are intervention trials that demonstrate impact on a cross-section of meaningful outcomes, from caregiver depression to tolerance for behavioral and psychological symptoms of dementia. As the number of people living with dementia increases, we cannot wait for the results of more rigorous studies before we bring available evidence-supported interventions to scale. To that end, we propose a number of actions the federal government can take now to move the field in a positive direction. Some of these recommendations echo those that are included in recent National Alzheimer's Project Act (NAPA) Advisory Council's 2019 recommendations:

- I. Continue to support care intervention programs

While it is important to ensure the quality and efficacy of programs intended to improve quality of life, interventions that show promise for even modest improvement are worth supporting. We cannot leave individuals with dementia and their caregivers without access to care interventions because we are trying to craft the perfect program.

In addition, continued innovation in the design and implementation of care interventions must be encouraged alongside efforts to expand uptake of promising programs. Given the heterogeneity of dementia populations and the complexity of the

disease state, a wide variety of interventions are needed to fully reveal the promising strategies that will advance the development of effective interventions.

II. Expand care intervention program research

Alzheimer's Los Angeles agrees with the AHRQ report that additional research into these interventions is needed. Of particular concern, are the report's conclusions that insufficient evidence exists to draw conclusions regarding the effectiveness of the majority of the intervention programs included in the study, thus precluding a determination as to whether the interventions were appropriate for or had been successfully adapted to diverse communities and rural communities.

In response, the federal government should create Centers of Excellence to:

- disseminate promising evidence-supported interventions,
- identify barriers to uptake,
- provide technical assistance and guidance to address those barriers, such as guidance on how to scale up interventions that have shown promise in smaller pilot projects, and
- highlight successes.

Such information is critical to expanding adoption of the most promising care interventions in a wider variety of care settings, diverse communities and regions throughout the country.

III. Support the development of care interventions that meet the needs of diverse communities

Los Angeles is one of the most diverse communities in the country and Alzheimer's Los Angeles has been a leader in working with these communities to develop and deliver interventions that are linguistically and culturally appropriate, relevant, and accessible. A culturally competent approach must be central to the federal government's effort to expand access of evidence-based dementia interventions to diverse, underserved and high-risk populations. To this end, Alzheimer's LA recommends the federal government:

- Establish a repository of validated tools and instruments in a variety of languages
- Include in the repository Electronic Health Record-compatible tools and tools available in the public domain
- Fund efforts to "translate" evidence-based dementia interventions for diverse, under-served and high-risk populations, including the creation of low literacy materials
- Educate professionals and caregivers about evidence-based interventions that have been adapted for diverse populations
- Develop a repository of evaluation outcome measures that work for diverse groups
- Provide funding for adaptation of these programs to make them culturally competent

IV. Provide funding to support widespread adoption of evidence-based intervention programs

Finally, widespread adoption of care interventions for people living with dementia and their family caregivers will not occur without care and payment models that support implementation of effective evidence-based, non-pharmacological interventions. As the largest payer for health care services, CMS should develop payment models to support the design and implementation of care interventions – particularly those seeking to meet the needs of culturally diverse and underserved communities.

Sincerely,



Debra L. Cherry, Ph.D.  
Executive Vice President  
Alzheimer's Los Angeles



Barbra McLendon  
Public Policy Director  
Alzheimer's Los Angeles



April 20, 2020

Gopal Khanna, M.B.A.  
Director, Agency for Healthcare Research and Quality  
5600 Fishers Lane  
Rockville, MD 20857

Dear Mr. Khanna:

Thank you for the opportunity to comment on the Evidence-based Practice Center Draft Report “Care Interventions for People With Dementia (PWD) and Their Caregivers.” Because of the timing of the draft release relative to the COVID health crisis, we are offering only brief remarks.

We recognize the extensive amount of work that is involved in conducting a systematic review and constructing a report on the available evidence. We also recognize the difficulty in drawing conclusions about a highly heterogeneous body of evidence and a wide variety of interventions. As noted in the Draft Report, the increasing number of adults living with dementia makes it imperative to identify gaps in the available evidence and to implement effective interventions to assist these individuals and their formal and informal caregivers. For these reasons, we are highlighting major areas of concern and noting general ways in which the usability of the report could be enhanced.

Our primary concern relates to the way in which evidence was selected for inclusion in the analytic portion of the review. The description of the methods section notes that pilot studies and small sample size studies were excluded, each of which seems reasonable and appropriate. However, the text also notes that studies at stages 0 to 2 of the NIH development model were excluded. Within the NIH description of the behavioral intervention stages, stage 2 is described as consisting of traditional efficacy testing (Stage II) in which there is experimental testing of promising behavioral interventions in research settings with research-based providers. As shown in the evidence maps, some of these studies do seem to be reasonable in size and many of

these studies are conducted in outpatient or nursing home settings that would be generalizable to many PWD or caregivers. In addition, studies of this type are often included in systematic reviews, particularly if they have low to moderate risk of bias. We recognize that the review was requested by the National Academies of Sciences, Engineering, and Medicine (NASEM) to identify interventions that are ready for widespread dissemination and implementation. Nevertheless, given the paucity of studies at higher levels of the NIH development model, we are concerned that excluding typical efficacy-based research studies will deprive other readers of important information that could aid in decision making.

Our other comments are related to the current layout of the document and tables, which make it difficult to synthesize the substantial amount of information in the report. Part of the difficulty with the document organization is related to the way in which the key questions were defined. However, even if the document text must remain separated by key questions to fit AHRQ requirements, the layout could still be adjusted to enhance the clarity of the information that is provided.

Typically, when a clinician or guideline developer is deciding on a specific treatment, all beneficial and harmful effects of the treatment are considered in relation to a particular diagnosis. In this draft document, the key questions split up interventions depending on whether they are aimed at behavioral and psychological symptoms of dementia (BPSD) or at non-BPSD symptoms, quality of life, and functioning. The document also splits up effects of interventions on persons with dementia (PWD), caregivers (both formal and informal), and delivery models, even though there may be common threads across categories.

Accordingly, we strongly recommend that overview tables be constructed that are organized by intervention. This could easily be done by combining Table 3.1 with the information in the additional characteristics tables that are currently spread throughout the document. An additional overview table should be constructed to summarize the characteristics and conclusions of the analytic studies. As examples, overview tables could be formatted as shown in Tables 1 and 2 below.

If such tables were available in Excel files (as supplementary materials), they could easily be sorted and filtered by guideline developers and policy makers whose interests might be limited to specific intervention subgroups or specific outcomes.

If the summary of findings tables are left in each section of the document in addition to being displayed in an overview table, it would be essential to note which specific outcomes show benefits (or harms) rather than lumping all related outcomes together. For example, under

engagement for robotic-assisted therapies, the current table notes “2 found benefit, 2 found no difference”; however, this is difficult to interpret without knowing that visual and verbal engagement improved, whereas behavioral and social engagement did not. It is also crucial to provide readers with information on the magnitude of any benefits or harms. Within the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework, a large magnitude of effect can increase the confidence that some treatment effect is present. Also, in developing guideline recommendations, it is not possible to weigh the relative balance of benefits and harms without knowing their magnitude as well as their strength of evidence. Such considerations are also important in using the results of the systematic review to inform policy or to discuss treatment options with patients, family members, or other involved persons of support.

Again, we appreciate the opportunity to provide input on this draft report. We hope that these suggestions will be useful to the EPC and to AHRQ in making this document useful to stakeholders.

Sincerely,

A black rectangular redaction box covering the signature of the sender.

Laura J. Fochtmann, MD, MBI

Medical Editor, Practice Guidelines, American Psychiatric Association

SUNY Distinguished Service Professor, Departments of Psychiatry, Pharmacological Sciences and Biomedical Informatics, Stony Brook University

Table 1: Example table using fabricated data to show suggested revision of the layout of Table 3.1.

	Delivered to:	Dementia type/severity in patient	Outcome assessed in:	Total studies	Non U.S. studies	Evidence map	Analytic	Risk of bias analytic set
Assisted Therapy	PWD	All types and severities	PWD	12	11	11 total 5 pilot 4 small N 2 high RoB	1 total 1 cluster RCT	Moderate
Bright Light Therapy	PWD	Alz, Mod	PWD	3	3	1 total 1 high RoB	2 total 1 cluster RCT 1 RCT	Low
Exercise	PWD	Alz, Mod	PWD					
Multicomponent interventions	PWD	Alz, Mod	PWD					
Multicomponent interventions	FCG	Alz, Mod	PWD					
Multicomponent interventions	ICG	N/A	ICG					
Multicomponent interventions	Org	Alz, Mod to Severe	PWD					
Multisensory Stimulation	PWD	All types and severities	PWD					
Music	PWD	All types and severities	PWD					
Psychosocial therapies	PWD	Alz, Mod	PWD					
Psychosocial therapies	FCG	Alz, Mod	FCG					
Psychosocial therapies	ICG	Alz, Mod	ICG					
Etc.								

PWD=person with dementia; FCG=formal caregiver; ICG=informal caregiver; Org=delivery system, clinical unit, or institution

Table 2: Example table using fabricated data to show suggested layout for an overview table of analytic evidence.

Intervention	Comparators	Delivered to:	Dementia type/severity	Outcome assessed in:	Outcome	Analytic	Risk of Bias	N	Effect	Strength of Evidence
Assisted Therapy	PARO vs. deactivated PARO	PWD	All types and severities	PWD	Visual engagement	1 cluster RCT	Mod	312	Small benefit	Insufficient
Assisted Therapy	PARO vs. deactivated PARO	PWD	All types and severities	PWD	Auditory engagement	1 cluster RCT	Mod	312	Small benefit	Insufficient
Assisted Therapy	PARO vs. deactivated PARO	PWD	All types and severities	PWD	Social engagement	1 cluster RCT	Mod	312	No benefit	Insufficient
Assisted Therapy	PARO vs. no PARO	PWD	All types and severities	PWD	Agitation	1 cluster RCT	Mod	312	No benefit	Insufficient
Bright Light Therapy	Morning bright light vs. evening bright light	PWD	Alz, Mod	PWD	Agitation	1 cluster RCT 1 RCT	Low	442	No benefit	Low
Exercise	30 min stretching 3x weekly vs. no added exercise	PWD	Alz, Mod	PWD	Agitation	2 RCT	Mod	214	No benefit	Insufficient
Exercise	20 min walking vs. no walking as	PWD	Alz, Mod	PWD	Fall risk	1 cluster RCT 3 RCT	Low	341	Small benefit	Low
Interventions	TAU vs. TAU	PWD	Alz, Mod	PWD	Agitation	1 cluster RCT	Mod	188	No benefit	Insufficient
Multicomponent interventions	Multicomponent vs. TAU	ICG	Alz, Mod	ICG	Depression	5 RCTs	Low	524	Moderate benefit	Moderate
Multicomponent interventions	Multicomponent vs. TAU	FCG	Alz, Mod	FCG	Caregiver burden	3 RCTs	Mod	388	Moderate benefit	Low
Etc.										

Note: Table could also include information such as country or funding source if desired. Column on effect could include information such as standard mean difference (SMD), number needed to treat (NNT), or other measures of effect magnitude.



AMERICAN  
PSYCHOLOGICAL  
ASSOCIATION

Comment on AHRQ's Draft Comparative Effectiveness Review  
*Care Interventions for People With Dementia (PWD) and Their Caregivers*

April 21, 2020

*These comments were developed by members and staff of the American Psychological Association (APA) who have expertise on the topic, but they are not an official statement of the APA.*

Thank you for the opportunity to comment on AHRQ's draft comparative effectiveness review *Care Interventions for People With Dementia (PWD) and Their Caregivers*. We appreciate your inclusion of diverse populations in your search and review of the literature and agree that there needs to be more research in this domain within diverse populations. We also appreciate the call for developing a taxonomy of care interventions so that inconsistent reporting of interventions used in studies, such as "cognitive training" versus "cognitive rehabilitation," can be eliminated. We were wondering if you would be able to provide further explanation of how "informal caregiver" was operationalized in the studies reviewed, noting whether spouses, children of PWD, siblings of PWD, or grandchildren of PWD were considered "informal caregivers" as well.

We were surprised to see "reminiscence therapy" categorized separately from psychosocial or psychological interventions as this therapeutic intervention is considered a psychological intervention (see for example the group life-review/reminiscence therapy as a recommended intervention for the treatment of depression in older adults in American Psychological Association, 2019a, 2019b).

We are concerned that the following underlined sentence in the background section unintentionally gives a negative connotation to nondrug interventions:

"However, despite the availability of pharmacological options (e.g., antipsychotics), nondrug interventions are recommended as first-line treatments for behavioral and psychological symptoms of dementia (BPSD). And although nondrug interventions are generally presumed safe, few trials have reported information on their harms or other unintended consequences."

There are a variety of reasons that nondrug interventions might be recommended by some as first line, such as concern about the risk of negative side effects of pharmacological interventions like antipsychotics or concern about drug to drug interaction for older adults who might already be taking other medications. We agree it is important to obtain information on any potential harms or unintended consequences of nondrug interventions. However, we suggest modifying the underlined sentence above to a more neutrally toned statement such as the following:

"Nondrug interventions have been recommended as first-line treatments for behavioral and psychological symptoms of dementia (BPSD) although pharmacological treatment options such as antipsychotics are also available."

Overall, the report provided an excellent account of the current state of the science in caring for PWD and their caregivers and nicely addresses the need for more rigorous research in this domain, especially in diverse populations.

## References

American Psychological Association. (2019a). *Clinical practice guideline for the treatment of depression across three age cohorts*. <https://www.apa.org/depression-guideline/guideline.pdf>

American Psychological Association. (2019b). *Depression treatments for older adults*. <https://www.apa.org/depression-guideline/older-adults>



Dementia Action Alliance

**Powered by People with Purpose**

April 21, 2020

Eric B. Larson, MD, MPH, Chair, and  
Other Committee Members  
NASEM Care Interventions for Individuals with  
Dementia and Their Caregivers

Dear Committee Members,

The Board of Directors of the Dementia Action Alliance (DAA) appreciates the opportunity to provide comments on the "Care Interventions for People with Dementia and Their Caregivers" draft report. The DAA, founded in 1996, is a national advocacy and education non-profit organization creating a better society in which to live with dementia.

We applaud that the draft report recognized that dementia is complex and individual specific. The DAA supports the committee's sensitivity to "the primary need to provide research that is relevant to all of the populations that matter" (page 124).

We appreciate the extensiveness of the research and the acknowledgement that the parameters of the research limited the outcomes to the interventions that met a high biomedical bar. The biomedical evidence parameters, however, were too restrictive and excluded many effective interventions that people living with dementia, care partners and other supporters value and on which they rely. Care intervention considerations must be holistic and incorporate approaches that often require different research approaches that fall outside of the biomedical evidence bar.

Aspects of the draft report research and recommendations help to validate that regarding dementia as a clinical syndrome is insufficient. When psycho-social-spiritual elements are equally included along with biological elements, that frames the holistic experience of living with dementia as a combination of pathological factors, lifestyle

choices, social, emotional, and support components, as well as society's reaction to dementia.

The DAA's Advisory Board, comprised of individuals living with varying forms of dementia, have submitted their comments to the draft report separately. Their comments included a recommendation we strongly support. They recommend that the final report include an addendum that contains a second pragmatic evidence level (evidence-informed) of interventions, so that many of the psycho-social-spiritual interventions that were excluded from the initial evidence bar could be recognized. The omitted interventions would be a valuable resource for diverse stakeholders and provide a constructive element to the study outcome.

Thank you for the opportunity to provide comments.

Sincerely,

DAA Board of Directors

Jan Bays, PT  
Sandy Douglass  
Paul Gordon  
Josh Hansen  
Jessica Luh Kim, MA  
Karen Love  
Chris Perna

Jackie Pinkowitz, MEd  
Lon Pinkowitz, MA  
G. Allen Power, MD  
Laurie Scherrer  
Regina E. Sofer, DM, MPA  
Teepa Snow, MS, OTR/L, FAOTA  
Susan Wehry, MD



**Powered by People with Purpose**

TO: Eric B. Larson, MD, MPH and Committee Members - Care Interventions  
for Individuals with Dementia and Their Caregivers

FROM: Advisory Board Members

DATE: April 21, 2020

RE: Comments on the Draft Report

We are writing as the Advisory Board members of the Dementia Action Alliance (DAA), a national non-profit 501(c)(3) advocacy and education organization founded in 1996. The DAA is working to make a better society in which to live with dementia. The DAA uniquely focuses on helping individuals and families living with dementia and their care partners learn how to continue to live full and meaningful lives with the chronic condition of dementia. Respecting the culture of "nothing about us without us," the nine-member Advisory Board of people living with dementia informs and shapes all of our organization's efforts and activities.

About three weeks ago, we became aware of the NASEM's project, "Care Interventions for People with Dementia (PWD) and their Caregivers" and of the virtual meeting that was scheduled for April 15<sup>th</sup>. In reviewing the agenda for the meeting, we noticed that no one living with dementia was scheduled to speak and this both saddened and concerned us.

Karen Love, the CEO of DAA, reached out to the NASEM study director, Clare Stroud, on behalf of our organization to request a meeting to discuss the study. The zoom meeting, held on April 2<sup>nd</sup> with Clare Stroud, included the six individuals that form the Advisory Panel for NASEM's Decadal Study (four individuals living with dementia and two care partners) and Karen Love. Since the Advisory Panelists had already been vetted by NASEM, they offered to also serve as Advisory Panelists for the Care Interventions study since the important voices of people living with dementia had been omitted and only one care partner included. Following the meeting, Ms. Stroud passed along our offer to

serve in an advisory role, and we have been invited to speak with Dr. Eric Larson and Committee members on May 29<sup>th</sup>.

A number of us on the DAA Advisory Board attended the April 15<sup>th</sup> virtual meeting. In order to provide collective comments for the draft report, we held virtual meetings to review and discuss the virtual meeting and form our comments about the draft report. The following are our observations and comments.

### **Participation of People Living with Dementia**

To individuals living with dementia it is obvious that our voices and experiences were not involved in the study. In fact, the draft report feels tone deaf in many regards to our needs as well as containing some stigmatizing elements.

### **Biases**

- 1) The report had a bias toward “caregivers.” We noted that the report is filtered primarily through the lens of caregivers and the effect that dementia has on them. This is disconcerting and sends a not so subtle message that persons living with dementia are not valuable themselves and are unable to manage our lives without a caregiver (see Chapter 1, Background). The word caregiver has patriarchal overtones and not all people living with dementia have care partners.
- 2) There is a bias in the draft report towards a biomedical orientation rather than from a living with a chronic condition orientation. Where are the considerations of needing to learn how to live with dementia? Of learning how to manage our symptoms? Where are the considerations of building self-reliance or of the importance of a proactive orientation? A “living orientation” would provide approaches and strategies that would be helpful to many stakeholders including persons with dementia and care partners. A living orientation is standard practice for other chronic conditions such as heart disease, diabetes, and Parkinson’s. The biomedical orientation is stigmatizing and suppresses progress.
- 3) Another bias that was evident to us in the draft report was the focus on older adults with an Alzheimer’s diagnosis in the mid to later stages. The report seems to examine dementia primarily through a homogeneous lens rather than a heterogeneous lens. The reality is that we will experience different symptoms depending on our diagnosis, that in turn will necessitate different care interventions. There is little attention in the draft report to non-Alzheimer’s dementias; they are however mentioned in passing. Additionally, we were hoping that this report might cite studies that examine diversity beyond our medical diagnosis to take into account the heterogeneity of the lived experience with considerations of race, language, education, culture, socio-economic considerations and more.

- 4) There is a serious disconnect that is hindering advances and what contributes to our well-being/quality of life using biomedical standards and metrics to measure non-biomedical elements. The methods that often best capture constructive information about well-being/quality of life are qualitative or mixed methodologies that don't meet the biomedical research evaluation standards. Many psycho-social-spiritual studies cannot be duplicated because of limitations that include setting, participant diagnoses, and other factors. This conundrum affects our daily lives and must be addressed and sorted out.

Any of us living with dementia can describe many interventions that are highly effective in helping us live well, such as doing things that provide us with purpose and meaning, having a proactive mindset, and peer support to name a few. Sadly, these studies are excluded because they don't meet the biomedical evidence standard threshold. It is crushing to have yet another study conclude – *"...there is very little evidence to support interventions and programs for active, widespread dissemination because evidence was insufficient to draw conclusions about the effects of the vast majority of interventions studied."*

### **Language Is Important**

The draft report contains some words we find problematic. We prefer the term **care partners** to **caregivers** because partner implies a relationship where both are working toward a common goal. We certainly understand that more care will be needed as our dementia progresses. We want people to understand that we are not just recipients of care and services; we are able to offer something of ourselves to the relationship and want to weigh in on our care and services. As in every relationship, the balance may shift with one person being the one who is doing more of the support.

We prefer the term **people living with dementia** instead of **people with dementia** because it underscores the fact that we are living with a chronic condition which is generally overlooked. We recommend the report incorporate these terms throughout and change the title to, "Care Interventions for People Living with Dementia and their Care Partners".

In general, we prefer the word **support** to **care**. The word care carries patriarchal overtones while support denotes assisting and partnering together.

The use of the term behavioral and psychological symptoms of dementia or its acronym **BPSD** are deeply offensive and not acceptable to the community of people living with dementia because it underscores a biomedical orientation and the absence of understanding actual symptoms and triggers. We experience people using the term as a

pejorative label and as if it were a sufficient explanation for a reaction or behavior. The draft report goes even further and uses the term **non-BPSD**. We take exception to the use of either label to describe us or our actions.

We find the use of the word **burden** is offensive. Burden implies fault and has a negative connotation. Synonyms include hardship, hindrance and albatross. Other health conditions have elements that cause strain, such as autism and ALS, yet don't have a burden mentality. This is another example of the stigmatization we experience living with dementia.

### **Conclusions**

We ask Committee members to create an addendum to the report containing a second pragmatic evidence level of interventions, perhaps titled "evidence-informed" interventions. This action would allow the many bio-psycho-social-spiritual interventions that have been found to be effective but were eliminated from the "evidence-based" rigor to gain lower level recognition. The interventions contained in these "evidence-informed" studies could be an important resource for many stakeholders including those living with dementia, care partners, care systems, payers and advocacy organizations.

Thank you for your consideration of our observations and comments.

### **Dementia Action Alliance Advisory Board Members**

Michael Belleville

Diana Blackwelder

Barbara Cole

Paulan Gordon

Cynthia Huling Hummel

Chuck McClatchey

John Richard Pagan

Laurie Scherrer

Brian Van Buren

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University of Texas at Arlington

April 21, 2020

Arlene Bierman, MD, MS, Director  
Center for Evidence and Practice Improvement  
Agency for Healthcare Research and Quality  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Bierman:

The Society for Women's Health Research (SWHR) is pleased to comment on the draft report *Care Interventions of People with Dementia (PWD) and for their Caregivers*, prepared by the Effective Healthcare Program (EPC) of the Agency for Healthcare Research and Quality (AHRQ) at the request of the National Institute on Aging (NIA). Importantly, NIA asked AHRQ to conduct a rigorous systematic review to understand the evidence base for effective nondrug care and caregiving interventions that considers the complexities and multifaceted nature of dementia across diverse populations.

The draft report's executive summary states that "ultimately, we uncovered very little evidence to support interventions and programs for active, widespread dissemination because evidence was insufficient to draw conclusions about the effects of the vast majority of interventions studied."<sup>1</sup> SWHR is not surprised by this finding and strongly agrees that "in order for federal funders and stakeholders to expedite the transitional pipeline of idea development to implementation, as they aim to do, critical improvements are needed in dementia care research."<sup>2</sup>

SWHR is a 30-year-old national nonprofit dedicated to promoting research on biological sex differences in disease and improving women's health through science, policy, and education. To help overcome evidence insufficiencies, we are writing to recommend:

- AHRQ's systematic review include the evidence base on sex and gender differences in dementia and caregiving burden.
- AHRQ's final report prioritize sex and gender differences in caregiving research to address knowledge gaps.
- AHRQ's expert committee seek representative input from relevant stakeholders to inform its assessment.

In 2016, SWHR launched an interdisciplinary network<sup>3</sup> of eight top Alzheimer's disease (AD) researchers and clinicians to examine sex- and gender-based differences in AD. For the past four years, SWHR's AD network has surveyed the current state of AD research in women, examined research gaps, and published on their findings in peer-reviewed scientific journals<sup>4</sup> as well as media outlets such as STAT<sup>5</sup> and Scientific American.<sup>6</sup> SWHR appreciates this opportunity to share evidence-based information and recommendations for the AHRQ EPC's consideration as it finalizes its systematic review and report.

*SWHR Recommendation 1a: Include evidence on sex and gender differences in dementia and caregiving*

Unfortunately, in reviewing relevant research, most AD and caregiving studies combine data for women and men. Even though much is known about caregiving burden and its consequences on both caregivers and care recipients, there is a paucity of information on the sex and gender differences that may be present between male and female caregivers.<sup>7</sup>

A 2018 paper published in the journal *BMJ Open* discusses the importance of studying sex and gender differences in family caregiving, the state of the science in this area, and how these differences impact the mental and physical health of caregivers.<sup>8</sup> The paper outlines a protocol for a systematic review and synthesis of the literature that could inform AHRQ's work.

SWHR urges AHRQ to include existing evidence on sex and gender differences in dementia and caregiving, as well as in the separate drug intervention evidence review referenced on page 2: Diagnosis and Treatment of Clinical Alzheimer's-type Dementia (CATD).<sup>9</sup>

*SWHR Recommendation 1b: Prioritize sex and gender differences in caregiving research to address knowledge gaps*

In a 2018 paper published by SWHR's AD network in the peer-reviewed *Alzheimer's & Dementia* journal,<sup>10</sup> SWHR highlighted the state of the science on sex and gender differences in AD and addressed the knowledge gaps in assessing sex and gender differences. The paper also identified 12 priority areas that merit future AD sex and gender research, one of which was the role of sex and gender differences in caregiving and caregiving burden. We ask the AHRQ EPC to consider the following in its preparation of its final report:

Nearly 70% of caregivers are women,<sup>11</sup> and rates are even higher for Hispanics and African Americans. The responsibilities of caring for someone with dementia frequently fall to women, with daughters comprising over one-third of dementia caregivers.<sup>12</sup>

Women assume multiple roles while caregiving: hands-on caregiver, case manager, companion, decision-maker, and advocate. Women who are caregivers report a twofold higher level of caregiver burden compared to those who are men. While men also provide assistance, women tend to spend more time providing care than men (21.9 vs. 17.4 hours per week). Further, women are likely to assist with more difficult caregiving tasks, such as toileting and bathing, while men are more likely to assist with finances or arrange for other care.<sup>13</sup>

Caregiving is associated with elevated levels of cortisol and impaired attention and executive function. Dementia caregivers are broadly at risk for a variety of health difficulties, including increased rates of chronic conditions, more frequent interactions with the health care system, decreased engagement in healthy preventative behaviors, and increased behavioral health concerns, such as smoking. Caregivers also demonstrate poorer immune responses to vaccines, slowed healing time, and reduced overall immunity to diseases.<sup>14</sup>

Further, it has been hypothesized that spousal caregivers may be at higher risk of cognitive impairment or dementia than noncaregiver spouses in response to several psychosocial (e.g., depression, social isolation, and sleep problems), behavioral (e.g., exercise and diet), and physiological (e.g., metabolic syndrome and inflammation) variables.<sup>15</sup> These findings suggest that caregiving itself may have sex-dependent effects on disease risk and outcomes for caregivers. Developing and targeting sex-dependent interventions for these risks and disease outcomes early, prior to manifestation, could attenuate future disability or possibly prevent onset.

Caregiving has a broader economic impact as well. When faced with the need to forego employment to attend to a family member that requires full-time assistance, caregivers face hardships including loss of earnings and employee benefits, loss of social service benefits, and inability to contribute to a retirement fund or participate in a pension plan. Individuals facing financial restraints may be significantly less likely to attend to preventative health care behaviors or regular appointments, or may face challenging out-of-pocket costs for their own health care or for their family's care. This in turn creates increased financial burden to our national health care system. Given that women make up the majority of caregivers, they are disproportionately impacted by these concerns.

Thus, assessing sex and gender differences in dementia and caregiving represents an opportunity to improve early diagnosis, treatment plan, and the long-term care of individuals of any gender as well as their caregivers.

***SWHR Recommendation 2:** Seek representative input from stakeholders who have direct experience and expertise with dementia, people with dementia, and their caregivers*

We understand that a second phase of this project will involve an assessment of the AHRQ-EPC findings on this topic by an expert committee filled by the National Academies of Sciences, Engineering and Medicine (NASEM). The draft report states that because the project is following a unique model, there is no separate, independent technical expert panel.

To develop a report that conveys the current state of knowledge and describes relevant research gaps in the field, the NASEM expert committee should ensure representation from core stakeholders, including:

- Researchers and health care professionals with caregiving expertise especially those with knowledge of sex- and gender-based disparities.
- Mental health professionals who specialize in working with caregivers.
- Caregivers themselves, particularly those who assist people with dementia in their daily lives.

- Health care professionals (e.g., physicians, nurses, therapists) who specialize in clinical care for individuals living with dementia.
- Individuals with dementia diagnoses, as well as those individuals who have a diagnosed genetic predisposition to dementia.

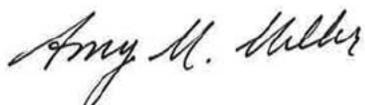
Since nearly 70% of caregivers identify as women,<sup>16</sup> we would strongly urge proportional sex and gender representation across stakeholder groups.

We applaud the NASEM committee for convening a public workshop on April 15, 2020, during the public comment period, to provide an overview of the AHRQ systematic review purpose, scope, methods, findings and implications. SWHR was pleased to join the virtual event. We agree with comments raised by several participants that obtaining input from individuals with dementia is needed and important, despite the possible challenges presented.

\*\*\*

Thank you for the opportunity to comment, and we look forward to serving as a resource on this topic and seeing the final report. If you have any questions, please feel free to contact our Director of Science Policy and head of the SWHR Interdisciplinary Network on Alzheimer's disease, Melissa Laitner, PhD, MPH, at [REDACTED]@swhr.org or 202-[REDACTED]-[REDACTED] or Sarah Wells Kocsis, our Vice President of Public Policy and SWHR AHRQ lead, at [REDACTED]@swhr.org or [REDACTED]-[REDACTED]-[REDACTED].

Sincerely,



Amy M. Miller, PhD  
President and Chief Executive Officer  
Society for Women's Health Research

Cc:

Mary Butler, PhD, MBA, Co-Director  
Minnesota Evidence-based Practice Center, University of Minnesota School of Public Health

Timothy J. Wilt, MD, MPH, Co-Director  
Minnesota Evidence-based Practice Center, Minneapolis VA Center for Chronic Diseases  
Outcomes Research

<sup>1</sup> Agency for Healthcare Research and Quality Effective Healthcare Program. Care Interventions for people with dementia and for their caregivers. Retrieved from: <https://effectivehealthcare.ahrq.gov/products/care-interventions-pwd/draft-report>

<sup>2</sup> Ibid.

<sup>3</sup> Society for Women's Health Research. Retrieved from: <https://swhr.org/society-for-womens-health-research-launches-new-interdisciplinary-network-to-focus-on-sex-differences-in-alzheimers-disease/>

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<sup>5</sup> Miller, A. & Nebel, R. 2018. Studying sex differences will improve health for women and men. *Stat*. Retrieved from: <https://www.statnews.com/2018/06/13/studying-sex-differences-women-men/>

<sup>6</sup> Nebel, R. 2018. Alzheimer's hits men and women differently, and we need to understand why. *Scientific American*. 2018 Retrieved from: <https://www.scientificamerican.com/article/alzheimers-hits-men-and-women-differently-and-we-need-to-understand-why/>

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<sup>8</sup> Family Caregiving Alliance. Family Caregiving and Transitional Care: A Critical Review. 2012. Retrieved from: <https://www.caregiver.org/family-caregiving-and-transitional-care-critical-review-2012>

<sup>9</sup> Agency for Healthcare Research and Quality Effective Healthcare Program. Diagnosis and Treatment of Clinical Alzheimer's-type Dementia (CATD) research protocol. Retrieved from: <https://effectivehealthcare.ahrq.gov/products/alzheimers-type-dementia/protocol>

<sup>10</sup> Nebel, RA., et al. Understanding the impact of sex and gender in Alzheimer's disease: A call to action. *Alzheimer's & Dementia*. 2018 1-13.

<sup>11</sup> Family Caregiver Alliance. Who Are Family Caregivers? Retrieved from: <https://www.apa.org/pi/about/publications/caregivers/faq/statistics>.

<sup>12</sup> Alzheimer's Association. 2018 Alzheimer's disease Facts and Figures. *Alzheimer's Dement* 2018;14(3):367-429.

<sup>13</sup> Family Caregiving Alliance. Family Caregiving and Transitional Care: A Critical Review. 2012. Retrieved from: <https://www.caregiver.org/family-caregiving-and-transitional-care-critical-review-2012>.

<sup>14</sup> Brodaty, H. and Donkin, M. Family caregivers of people with dementia. *Dialogues of Clinical Neuroscience*, 2009 Jun; 11(2), 217-28.

<sup>15</sup> Ibid.

<sup>16</sup> Family Caregiver Alliance. Who Are Family Caregivers? Retrieved from: <https://www.apa.org/pi/about/publications/caregivers/faq/statistics>.