

UNTIL THERE'S A CURE: HOW TO HELP ALZHEIMER'S PATIENTS AND FAMILIES NOW

FORUM

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

WASHINGTON, DC

DECEMBER 8, 2010

Serial No. 111-26

Printed for the use of the Special Committee on Aging



Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>

U.S. GOVERNMENT PRINTING OFFICE

64-225 PDF

WASHINGTON : 2011

For sale by the Superintendent of Documents, U.S. Government Printing Office
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WEDNESDAY, DECEMBER 8, 2010

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 1 p.m. in room G-50, Dirksen Senate office Building, Hon. Herb Kohl (Chairman of the Committee) presiding.

Present: Senators Kohl and Corker.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon, everybody. We welcome you here today. We especially would like to welcome our distinguished participants for being here with us. We are lucky to have Assistant Secretary Kathy Greenlee and Director Patricia Grady, as well as several other experts and advocates. We are happy to be hearing from them and we encourage all of you here today to participate in our activity.

Senator Corker and I are holding this forum so that we can exchange best ideas about how to provide the best care to the 5.3 million Americans suffering from Alzheimer's disease. This is a huge concern for the much larger number of family members, relatives, and friends whose lives are also affected. These caregivers do not have the luxury of waiting for a cure. They need support now.

I do feel strongly that we will find a cure and I congratulate the Senate HELP Committee for approving the National Alzheimer's Project Act last week, which will speed up the research process. But until there is a cure, we must focus on improving the services for people living with Alzheimer's disease.

Today's forum will highlight the best methods of care that can take place in a variety of settings, including nursing homes, assisted living facilities, and in the home. The right interventions can greatly improve the quality of life for people living with Alzheimer's disease as well as their families. We believe these best practices should be put to use by medical personnel, long-term care staff, and family caregivers.

In a few moments, we will hear from the Administration on Aging, the National Institute of Nursing Research, the Alzheimer's Association, and the Alzheimer's Foundation of America, about how they are spreading the word about models of new dementia care. They will talk to us about what type of training really works, who needs to be trained, and how this can be done in a cost effective manner.

The good news is that conversations about Alzheimer's care are happening all across the country. In my State, the Alzheimer's Association of Southeastern Wisconsin recently convened a multi-stakeholder task force to take a close look at how individuals with moderate and severe dementia who exhibit aggression and other challenging behaviors can be treated with greater skill and dignity by nursing homes, hospitals, and law enforcement.

The task force was founded following the tragic and untimely death of a longtime Milwaukee resident earlier this year, who was asked to leave his long-term care residential community after developing such challenging behaviors. Subsequently, he became even more confused and agitated and was arrested and restrained, a traumatic process that contributed to the deterioration of his health, and that ultimately hastened his death. We should not let these circumstances be repeated.

It is my hope that this forum will serve as a source of hope for the Alzheimer's community as we emphasize all the things we can do now to improve the quality of life for people with Alzheimer's disease and those who love them.

I will be turning now to Senator Corker for his opening comments. I regret I cannot be here with you throughout the forum as I have previous important engagement that I must attend. Thank you again for being here, and we look forward now to Senator Corker's remarks.

STATEMENT OF SENATOR BOB CORKER

Senator CORKER. I know, because of the many raucous things that are happening right now, we both have meetings that start at 1.

But I want to thank Senator Kohl and his staff and our staff for helping to organize this forum and certainly appreciate all of the many intelligent people who are here to talk and to hear from wonderful witnesses and others about how we deal with the protocols, how we deal with care, how we deal with this issue that affects our society in such a huge way.

I know that one of the things we talk about a great deal are the costs associated with Alzheimer's and what that does to our country as a whole. But on the other hand, we know that on an individual basis Alzheimer's affects millions of people. As a matter of fact, there is not a person in this room, it would be my guess, that in some personal way has not been affected. My dad passed away a month ago after being diagnosed with Alzheimer's 15 years ago, and I have watched the progression that takes place. I have watched the stress on the caregiver. I have watched all of that, and candidly our family was in a situation where financially we were able to ensure that he had the best of care. My biggest thought over the course of the last few years is how those families who do not have similar resources to us deal with this issue. It has to be absolutely devastating not just personally but in so many other ways.

So I thank Senator Kohl and all of you for focusing on this issue, and I hope that together as a country we deal with this issue that certainly affects us in many ways financially but also deal with it

in a way that over time in a more humane way our society with individuals can deal with it also.

Thank you very much.

The CHAIRMAN. Thank you.

Ms. WHITMAN. Welcome to you all. I am Debra Whitman. I am the Staff Director for the Senate Aging Committee. I would like to introduce our wonderful first panel.

We are pleased to welcome Kathy Greenlee, Assistant Secretary for the Administration on Aging. Prior to becoming Assistant Secretary, Ms. Greenlee served as a State long-term care ombudsman and Secretary of Aging for the State of Kansas. Ms. Greenlee will highlight the AoA's current efforts to implement evidence-based programs of services and training in Alzheimer's care.

Next we will hear from Patricia Grady, Director of the National Institute on Nursing Research. Dr. Grady joined NIH in 1988 where much of her scientific research has been in stroke and brain imaging. Dr. Grady will describe the role of research and training to improve the quality of care for people with Alzheimer's disease and to provide adequate support for their caregivers.

Thank you both.

**STATEMENT OF KATHY GREENLEE, ASSISTANT SECRETARY,
ADMINISTRATION ON AGING, WASHINGTON, DC**

Ms. GREENLEE. Good afternoon to you all. It is good to see you, and great to see such a good turnout. Thank you, Debra, for the introduction.

I would like to acknowledge Senator Corker and Senator Kohl for convening this forum. I had a chance to talk briefly with Senator Kohl before we started. I last saw him in Milwaukee in September. It was warm in Milwaukee then. I hear it is not now. Talking about Alzheimer's disease is just one of the many things that Senator Kohl focuses on with regard to seniors. As the chair of this committee, his knowledge is vast, his interest is deep, and we had a wonderful opportunity in Milwaukee to talk specifically about the reauthorization of the Older Americans Act. Many of the things that I am talking about today with regard to Administration on Aging programs are funded from that Act, and so I wanted to acknowledge that he sees the big picture as well as looking at specific topics that are this important such as Alzheimer's.

There are a few things I want to point out about Alzheimer's, and what I would like to focus on specifically are the things that we are doing at the Administration on Aging to help support home and community-based services for those people with dementia, as well as those who care for those.

Helping older Americans who have Alzheimer's disease and related dementias maintain their dignity is central to our mission at AoA. Access to appropriate supports is critical in understanding and managing these diseases, especially those services that allow families to plan in the early stages of the disease and those that support family caregivers.

The Administration on Aging supports embedding dementia practice into State long-term services and supports. This effort is designed to be responsive and improve the home and community-based services that currently exist so that they can better support

people with Alzheimer's disease and other related dementia. It is important to focus on the fact that we currently have a home and community-based service network in this country and that we need to embed the practice of paying attention to Alzheimer's and other dementias into those current systems, as well as to look at new things that we can be doing, to help people with Alzheimer's and their caregivers.

The challenges posed by Alzheimer's disease and related dementias for persons with the disease and their families are enormous. I know this personally as a granddaughter. I know this as the assistant secretary as I meet with members of various communities across this country, members and individuals who are providing support specifically to caregivers.

AoA works within HHS, with our partner agencies at the National Institutes on Aging (NIA) at the National Institutes of Health (NIH), with the Centers for Disease Control and Prevention (CDC), and with the Agency for Healthcare Research and Quality (AHRQ), to determine the universe of interventions that are suitable for translation in the community where three-quarters of the people with dementia live. The interventions that AoA funds are those that have been tested in randomized controlled trials and found to have positive effects on persons with dementia and their families. For example, we have worked closely with the NIA to understand and disseminate evidence-based interventions such as "Resources for Enhancing Alzheimer's Caregiver Health," or REACH. I believe you will talk about REACH, Patricia, as well in your testimony. This intervention is specifically aimed at enabling caregivers to cope with the daily, often intense stress they face in providing care to their loved ones. AoA and the National Institute on Aging have also collaborated in providing materials that we can disseminate to all the people in this country who are receiving home-delivered meals to provide basic education about Alzheimer's, other related dementias, and the services that we have available.

According to recent estimates, between 2.4 million and 5.1 million Americans have Alzheimer's disease. Unless the disease can be effectively treated or prevented, the number of people with Alzheimer's disease will increase significantly if the current population trend continues. That is because the risk of Alzheimer's disease increases with age and the U.S. population is aging. The number of people 65 and older is expected to grow from 39 million in 2008 to 72 million in 2030, and the number of people with Alzheimer's disease doubles for every 5-year interval in age beyond the age of 65. According to the Alzheimer's Association, at least 10 million baby boomers will develop Alzheimer's disease in their remaining lifetimes. That is twice as many people as the number estimated to have the disease right now. In addition, four million baby boomers will develop a related dementia, which poses similar challenges as Alzheimer's for people who have related dementias, as well as their families and the health and long-term care systems.

I want to stop and emphasize that point twice. We are talking today specifically about Alzheimer's, but the thing that we all know, those of us here and those of us who work in this area, is that the field of dementia is much broader than Alzheimer's. There are other related dementias that may have a slightly different dis-

ease progression but have the impacts on the individual and the community that are very similar to Alzheimer's disease. This is something that our partners at the Alzheimer's Association understand, as well as the community providers. Today we are talking about Alzheimer's and all of the other related dementias that impact individuals as they age.

States and the Federal Government are currently engaged in major efforts to transform health and long-term services. If those efforts are successful, they should also address dementia in order to transform the care that we are providing. While medical research pursues the cause and treatment of the disease, which is critically important for understanding why we must talk to clinicians and professionals in the field of health, we must also develop better, cost effective ways to support and sustain family caregivers and people who have the disease right now.

Leading policymakers are emphasizing prevention and chronic disease management as strategies for improving quality and controlling costs. AoA, through the administration of the "Alzheimer's Disease Supportive Services Program," is working with the States, communities, and researchers to translate proven caregiver support programs into practice at the community level. Through this work, we are developing tools to make available these programs so again we can embed them into the current long-term services system.

We began this specific emphasis on evidence-based research at AoA nearly a decade ago. We have had a focus on evidence-based research with a number of programs at AoA, and the one that I can point to and talk about the most is the work that we have done in the field of Alzheimer's. We began by developing research materials and evidence-based guidelines for physicians. As a result of that effort nearly a decade ago, we have physicians nationwide who have adopted our best practices.

This fall we announced funding to 16 States to field test nine evidence-based caregiver interventions with the goal of embedding successful translation in State programs and funding streams. We are looking at how those interventions can be effectively provided through the aging network, and if these interventions can be successfully translated to other community settings. If they are successful, they will have a significant impact on supporting caregivers and their families.

I would like to give you some examples of the types of interventions that we are looking at. One intervention currently being translated in six States, California, Florida, Georgia, Minnesota, Utah, and Wisconsin, is the "New York University Caregiver Intervention." Because this program has been tested in a randomized controlled trial, we know that the New York University Caregiver Intervention significantly delays institutionalization of persons with dementia by providing education, support, and counseling to spousal caregivers. The average institutional delay for persons with dementia who received support from this one program is 557 days. That has a significant impact on the health and life of the individual. It also has an impact on the cost. If you look at the national average nursing home rate of \$219 a day, if you can delay nursing home admission by 557 days, you have saved someone, whether it is private resources or a government program, \$121,000 for helping

one particular person. For each of these programs in these six States, we will work to implement and prove and test and find out what works.

We have other types of programs, the "Savvy Caregiver" program, which are operating in three States. The Savvy Caregiver is a different kind of training program that delivers 2-hour sessions over a 6-week period focusing on helping caregivers think about their situation objectively and provides them with the knowledge and skills that they need so they can manage stress and carry out their lives.

What we believe is that successful translation should be designed to be embedded in systems over time. The caregiver translations need to intervene at one point and be successful as the disease progresses to both help the individual with the disease, as well as the person providing care. We have numerous examples of evidence-based practices that we are working to embed with our partners.

I believe that there is a process for doing this work that involves partnership with NIA and our other partners where we look for promising practices. We find a way to test approaches like the examples that I have given so that we know nationally what are the best systems.

We have a good program working in New Mexico that is helping to specifically provide assistance to adult day providers on what they can do to better support and recognize people with Alzheimer's and provide respite services.

In Minnesota, we are working with the Aging and Disability Resource Center to identify opportunities so we can provide better education in the community.

There are a number of things it will take to tackle this overwhelming disease and to be able to move forward. As an administration, we are very committed to working with our partners, to working with those of you here to do something as basic as what works, how do we try it, and how do we make sure everybody in the Nation who needs the support gets it. This is a critically important issue and I would like to again thank the committee for talking about Alzheimer's and the related dementias today. Thank you very much.

[The prepared statement of Ms. Greenlee follows:]



Statement of
Kathy Greenlee
Assistant Secretary for Aging
U.S. Department of Health and Human Services

Senate Special Committee on Aging
Forum
Until There's A Cure: How to Help Alzheimer's Patients and Families NOW"

December 8, 2010

Good afternoon Chairman Kohl, Senator Corker and members of the Senate Special Committee on Aging.

I am Kathy Greenlee, Assistant Secretary for Aging in the Department of Health and Human Services. Thank you for the opportunity to share the current efforts of the Administration on Aging and our national aging network to improve the capability of home and community-based services to support those with dementia, and those who care for them.

Helping older Americans who have Alzheimer's disease and related dementias (ADRD) maintain their dignity and independence is central to our mission at the Administration on Aging (AoA). Access to the appropriate supports is critical in understanding and managing these diseases, especially those services that allow families to plan in the early stages of the disease and those that support family caregivers.

The Administration on Aging strongly supports embedding dementia practice into State long-term services and supports. This effort is designed to improve the responsiveness of home and community-based care systems to persons with dementia and increase availability of support services for persons with ADRD, their families, and their caregivers.

The challenges posed by Alzheimer's disease and related dementias for persons with the disease and their families are enormous. AoA works with HHS' research agencies (NIH, AHRQ, CDC) to determine the universe of interventions that are suitable for translation in community-based settings, where about three-quarters of persons with dementia live. The interventions AoA funds are those that have been tested in randomized-controlled trials and found to have positive effects on persons with dementia and their families. For example, AoA has worked closely with the National Institute on Aging (NIA) to understand and disseminate evidence-based interventions, such as Resources for Enhancing Alzheimer's Caregiver Health (REACH) II. This intervention is specifically aimed at enabling caregivers to cope with the daily, often intense, stresses they face providing care to their loved ones. AoA and NIA have also collaborated in the development and dissemination of other consumer education materials to the thousands of seniors who participate in the home-delivered meals program across the nation.

According to recent estimates, between 2.4 million and 5.1 million Americans have Alzheimer's disease (AD). Unless the disease can be effectively treated or prevented, the number of people with AD will increase significantly if current population trends continue. That's because the risk of AD increases with age, and the U.S. population is aging. The number of people age 65 and older is expected to grow from 39 million in 2008 to 72 million in 2030, and the number of people with AD doubles for every 5-year interval beyond age 65 (National Institute on Aging). According to the Alzheimer's Association, at least 10 million

baby boomers will develop Alzheimer's disease in their remaining lifetimes – twice as many people as the number estimated to have the disease today. An additional 4 million baby boomers will develop a related dementia, which will pose challenges similar to Alzheimer's for them, their families, and the health and long-term care system.

States and the federal government are currently engaged in major efforts to transform health and long-term services and supports and control the future growth of Medicare and Medicaid expenditures. Those efforts will succeed if they also address the challenge of dementia. While medical research pursues the causes and treatment of the disease, we must also develop better, cost-effective ways to support and sustain family caregivers to meet the social and on-going care needs of people who have the disease.

Leading policy makers are already emphasizing prevention and chronic disease management as strategies for improving quality and controlling costs. The Administration on Aging, through the administration of the Alzheimer's Disease Supportive Services Program is working with States, communities and researchers to translate proven caregiver support programs into practice at the community level. Through this work, we are developing the tools to make available these proven programs and learning how to embed them into the current Long-Term Service and Supports System.

Nearly a decade ago, AoA began exploring support of evidence-based research in community settings. This was through the development and dissemination of evidence-based guidelines for physicians on Alzheimer's disease management. These guidelines were published in a peer-reviewed medical journal and have been adopted nationwide.

Today we are working with 16 States to field test nine evidence-based caregiver interventions, with the goal of embedding successful translations in State programs and funding streams. We are looking at how these interventions can be effectively provided through aging network programs while attempting to ensure fidelity to the original intervention. If these research interventions can be successfully translated to community settings, they will have a significant impact on supporting and sustaining family caregivers.

One intervention currently being translated by six states (California, Florida, Georgia, Minnesota, Utah, and Wisconsin) is the **New York University Caregiver Intervention**, a support program that, in a randomized-controlled trial, significantly delayed institutionalization of persons with dementia by providing education, support, and counseling to spousal caregivers. The average institutional delay for persons with dementia who received this support program was 557 days.¹ According to a 2009 survey², the national average nursing home rate was \$219 per day; therefore, a 557 day delay in nursing home placement

would result in an average savings of \$121,983 in institutional costs per person. Although each of the six States is still in the implementation phase, early results indicate that projects are achieving some of the outcomes found in the original study.

Three States (California, Maine and Michigan) are translating **Savvy Caregiver**. This intervention trains families and others for the unfamiliar role they face as caregiver for a relative or friend with ADRD. *Savvy Caregiver* is a 12-hour training program that is usually delivered in two-hour sessions over a six week period; focuses on helping caregivers think about their situation objectively and provides them with the knowledge, skills, and attitudes they need to manage stress and carry out the caregiving role effectively. This intervention, also in the implementation phase, provides some caregiver training in a group setting and is also showing promise.

We have found that successful translation projects should be designed to be embedded in systems that can meet caregiver needs over time. The caregiver interventions that are being translated intervene at one point in a disease that goes on for a long time. If they are to have lasting impact, they must fit into a continuum of services that are available to families through the course of the disease.

The Administration on Aging is advancing State initiatives to create coordinated systems of home and community-based care to develop and deliver supportive services for individuals with ADRD and their family caregivers.

Some examples include:

- Providing information, counseling, skill-building and other activities specifically for individuals in the early stages of ADRD and their caregivers.
- Assisting individuals with ADRD and their family caregivers to develop consumer-directed plans for care.
- Transforming the capacity of existing models of caregiver support and home and community-based care services to provide services to individuals with ADRD and their caregivers.
- Empowering individuals to adopt brain-healthy lifestyle choices.
- Increasing coordination of care of individuals with ADRD and their caregivers across care settings through information, referral and case management services.

There are numerous other examples of success. New Mexico recently enhanced its options for consumer-directed support services by providing dementia-specific training and technical assistance to adult day care organizations and increasing awareness of available respite care services. Minnesota continues to develop the dementia-capability of its Aging and Disability Resource Centers by training

its workforce to identify people with memory problems and getting them the information and community services they need. California developed a community network of culturally-competent dementia care services for Latinos that has been sustained for over a decade; it has become a national model that is being replicated in other Latino communities and adapted for other cultural groups.

There are a number of factors that contributed to these successful projects. They have strong leadership at the State level and have created an influential focal point for Alzheimer's disease within State government. They develop strategies for sustainability and succeed in implementing them. They embed program successes in local community and State programs and funding streams. And they have sufficient funding over a period of years to achieve results.

While we have hope that a cure for Alzheimer's disease and related dementias is in our near future, I applaud the Senate Special Committee on Aging for its effort to focus on ways for our health and long-term care systems to help people with dementia and their family caregivers now.

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**STATEMENT OF PATRICIA A. GRADY, PH.D., R.N., F.A.A.N.,
DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH,
BETHESDA, MD**

Dr. GRADY. Good afternoon. I would also like to add my thanks to Senators Kohl and Corker and the committee for their interest in this important area.

I appreciate the opportunity to discuss the research and training activities of the National Institute of Nursing Research at the NIH for older adults with Alzheimer's disease, or AD, and their families.

I am the Director of NINR, one of the 27 institutes and centers at the National Institutes of Health and one of several that support research on AD.

Today I will describe some of the NINR's recent research findings and current efforts focused on older adults with AD and other dementias and also on improving the quality of life for caregivers. I will also stress the importance of supporting training opportunities to ensure that the next generation of scientists and caregivers have the knowledge and tools to serve the needs of our rapidly aging population.

We have heard that Alzheimer's disease affects up to 5 million Americans, and with the baby boomers' increased life expectancy, this number is expected to increase dramatically in the coming years. NIH is dedicated to supporting a broad interdisciplinary program of research to answer critical questions about what causes AD, how to better diagnosis it, how to best treat it, and ultimately how it can be prevented.

Over the past 20 years, we have significantly increased our understanding of the biological and the genetic underpinnings of this disease. However, there is currently no way to prevent the onset of AD and drug treatments are not very effective in delaying the progression of this disease.

Consequently, in addition to the efforts on prevention of AD, we must be equally mindful of improving the care and the quality of life for those suffering from this disease and from alleviating the burden faced by the informal caregivers who provide the majority of care for their friends and families with AD.

As an overview, these issues form the cornerstones of NINR's portfolio on AD research. We support clinical and basic research to build a scientific foundation for clinical practice, to prevent disease and disability, to eliminate symptoms caused by illness, and to enhance end-of-life and palliative care, as well as training the next generation of scientists.

As part of this mission, NINR focuses on quality of care and quality of life for older adults with AD and other dementias, as well as their informal caregivers. We study interventions for alleviating symptoms such as pain, discomfort, delirium, improving communication for clinicians, and memory support. For example, NINR is currently supporting a project to test the effectiveness of an activity-based intervention to increase quality of life by reducing agitation and passivity, and increasing engagement and positive mood in nursing home residents with dementia.

Another example is an intervention designed to improve early detection and management of delirium in those with dementia. This

has the potential to improve the quality of life and decrease costs of care.

A third project currently underway is one testing an evidence-based, nurse practitioner-guided intervention for patients with AD or other dementia and their family caregivers. This intervention is expected to improve overall quality of life by decreasing depressive symptoms, reducing burden, and improving self-efficacy.

NINR also emphasizes research on interventions aimed at improving quality of life and reducing burden for caregivers. There are nearly 11 million unpaid caregivers responsible for caring for loved ones with Alzheimer's disease. These caregivers often experience stress, burden, depression, and decline in their own physical health while taking care of their loved ones with chronic illnesses such as AD and other forms of dementia. We need better interventions to assist these caregivers, to help them manage their symptoms, and reduce stress, so they may continue to remain healthy while they provide care. Recognizing these challenges, nurse scientists conduct research to improve the skills caregivers need to provide in-home care, and to teach caregivers health promotion and behaviors that will help them to maintain and improve their own health and emotional well-being.

As an example, NINR currently supports a study that uses a telephone-based intervention for caregivers to enhance emotional support; locate needed resources; improve coping skills; and assist in attending to physical, social, and emotional needs.

Another current project involves the development and testing of an intervention to promote and improve shared decisionmaking and communication between the caregivers of persons with advanced dementia and clinicians in regards to tube feeding and treatment decisions.

A third example is studying the effects of a psycho-educational and physical exercise interventions in family caregivers of African American dementia patients, and the caregivers of heart failure patients, to promote health and reduce cardiovascular risk.

The studies that I have described just now provide merely a glimpse of the current efforts to improve the quality of life and care for those with AD and their caregivers, efforts that offer the promise of a better tomorrow for individuals affected by dementia.

But what have we learned so far? Scientists have made substantial progress in understanding the challenges of living with AD and developing interventions to support the caregivers. I would draw your attention to recent findings from some of these studies that are NINR-supported.

One of the challenges of providing quality care for older adults with AD is accurately detecting and treating symptoms such as pain and discomfort, which is critical to their quality of life. It is essential for health care providers as well as informal caregivers to have the tools to recognize pain in older adults with dementia who may not be able to express their need for pain relief. A recent study funded by NINR showed a discrepancy between the pain reported by the dementia patients and the pain behaviors that were observed. In this study, cognitively impaired older adults self-reported less intense pain after movement activities such as walking and other movements, than the cognitively intact older adults.

However, the behavioral observations of pain such as grimacing and verbal complaints showed no differences between the two groups. This suggests that commonly used self-report measures of pain may underestimate pain in older adults with dementia.

Another recent NINR funded study showed that a comprehensive exercise program increased positive mood and decreased negative mood in nursing home residents with AD. Preliminary findings regarding health promotion interventions for older adults with early stage dementia living in the community, as well as interventions to increase activity engagement in nursing home residents with dementia, demonstrate that such interventions have the potential for improving quality of life for this group.

Now, what about the caregivers? Recent findings from our supported investigators are also contributing to the development of an evidence base of interventions to support caregivers. One example is the “Resources for Enhancing Alzheimer’s Caregiver Health” program, which Kathy mentioned earlier, also known as REACH. Co-funded by NINR and the National Institute on Aging, REACH is a comprehensive, multi-site intervention to assist AD caregivers. This program teaches the caregivers about AD, along with giving strategies to help them manage the troublesome behaviors of the care recipients, something that Senator Kohl referred to earlier. It also emphasizes ways for caregivers to manage stress, maintain their social support groups, and enhance their own health with self-care activities.

In a recent study involving AD caregivers from diverse racial and ethnic groups, those who received the REACH intervention reported better physical, emotional, and overall health compared to those who received the usual care packet of basic AD educational information and two brief check-in telephone calls. In addition, the REACH caregivers had lower scores for depression, which contributed to reducing their sense of caregiving burden.

These findings indicate that the REACH program, by providing information about both AD and self-care, helped AD caregivers from diverse racial and ethnic groups maintain their own physical, emotional, and mental well-being. Multiple efforts across the Federal Government are currently underway to implement REACH in the community.

So with regard to teaching the next generation of scientists and caregivers, to ensure continued advancement in improving care for AD and other dementias, it is essential that we train the next generation of innovative, interdisciplinary scientists and clinicians with expertise in chronic illness and symptom management and with the knowledge necessary to translate successful research to clinical practice.

To this end, NINR supports extensive training activities across all of the areas of our scientific portfolios. Current efforts include training future nurse scientists and clinicians to conduct research on transitional and personalized care for chronically ill older adults, biobehavioral pain research, genetics, and basic neuroscience, all of which are relevant to the care of those with AD and other dementias.

In conclusion, I would like again to thank the committee for offering me the opportunity to present an overview of the research

and training activities at the National Institute of Nursing Research at NIH, those activities to improve the lives of older adults with AD and their caregivers. As we await the day when Alzheimer's disease can be prevented and successfully treated, we must never lose sight of the needs of the individuals suffering from these and other dementias and the people who care for them. Given this, the National Institute of Nursing Research and the NIH will continue our comprehensive efforts to provide the evidence base for providing and improving the quality of care and quality of life for individuals affected by these illnesses. We will also train the next cohort of researchers and clinicians to generate new discoveries and provide better care, and to translate this into everyday practice.

Thank you all very much.

[The prepared statement of Dr. Grady follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

The Role of NIH-supported Research in Improving Quality of Care and Quality of Life for
Individuals with Alzheimer's Disease and Their Caregivers

Witness appearing before the
Senate Special Committee on Aging

Dr. Patricia A. Grady, Director
National Institute of Nursing Research

December 8, 2010

Mr. Chairman and members of the committee, thank you for this opportunity to discuss the research and training activities of the National Institute of Nursing Research (NINR) that address the needs of older adults with Alzheimer's disease, or AD, and their families. I am the Director of NINR, one of the 27 Institutes and Centers at the National Institutes of Health, and one of several NIH Institutes and Centers that support research on AD. My statement today will describe some of NINR's recent research findings and current research efforts focused on older adults with AD and other dementias, and improving quality of life for caregivers. I also will briefly discuss the importance of investing in training opportunities to ensure that the next generation of scientists has the knowledge and tools to serve the needs of our rapidly aging population.

It is estimated that AD affects as many as 2.4 to 5.1 million Americans.¹ With the baby boomers' increased life expectancy, this number is expected to increase dramatically in the coming decades. NIH is dedicated to supporting a broad, interdisciplinary program of research to answer critical questions on what causes AD, how to better diagnose it, how best to treat it, and ultimately, how it can be prevented. Over the past 20 years or so, we have significantly increased our understanding of the biological and genetic underpinnings of this disease. In spite of this progress, however, there is currently no way to prevent the onset of AD, and drug treatments are not very effective in delaying the progression of the disease. Consequently, in addition to focusing on efforts to ultimately prevent AD, we must be equally mindful of improving the care and quality of life for those now suffering from AD, and alleviating the burden faced by the informal caregivers who provide the majority of care for their friends and family members with AD.

¹ Herbert LE et al. Alzheimer's Disease in the US Population: Prevalence Estimates Using the 2000 Census. Arch Neurol. 2003; 60:1119-22.

NINR RESEARCH ON ALZHEIMER'S DISEASE: AN OVERVIEW

It is around these issues that NINR has built its diverse portfolio in AD research. At NINR, we support clinical and basic research to: build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate the symptoms caused by illness, enhance end-of-life and palliative care, and train the next generation of scientists. As part of this mission, NINR focuses on issues related to quality of care and quality of life for older adults with AD and other dementias, as well as their informal caregivers. NINR research on interventions for the older adult with AD focuses on areas such as: alleviating symptoms such as pain, discomfort, and delirium; improving communication for clinicians; and memory support. For example, NINR is currently supporting a project to test the effectiveness of an activity-based intervention designed to increase quality of life by reducing agitation and passivity and increasing engagement and positive mood in nursing home residents with dementia. Another recently funded project is examining an intervention to improve early detection and management of delirium in persons with dementia, which has the potential to improve quality of life and decrease costs of care. A third NINR-funded study that is currently underway focuses on both the older adult and the family caregiver. This study involves an evidence-based, nurse practitioner-guided, intervention for patients with AD or other dementia and their family caregivers. The intervention is expected to improve overall quality of life by decreasing depressive symptoms, reducing burden, and improving self-efficacy for managing dementia in caregivers. A project such as this underscores the fundamental importance of nurse scientists who conduct research to improve the care of older adults with AD.

NINR also emphasizes research on interventions aimed at improving quality of life and reducing burden for caregivers. There are an estimated 10.9 million unpaid caregivers caring for

loved ones with AD.² These caregivers often experience stress, burden, depression, and decline in physical health while taking care of loved ones with chronic illness such as AD and dementia. Interventions are needed to assist caregivers in learning how to care for a loved one, help them manage symptoms and distress related to their illness, and reduce stress so that the caregiver may continue to remain healthy and provide care. Recognizing these challenges, nurse scientists conduct research on strategies to improve the skills caregivers need to provide in-home care, and to teach caregivers health promotion behaviors that will help them to maintain and improve their own health and emotional well-being. For example, NINR currently supports a study that uses a telephone-based intervention for caregivers to enhance emotional support, locate needed resources, improve coping skills, and assist in attending to physical, social and emotional needs. Another current project involves the development and testing of an intervention to promote and improve shared decision-making and communication between caregivers of persons with advanced dementia and clinicians in regards to tube feeding and treatment decisions. A third project is investigating the effects of a psycho-educational and physical exercise intervention in family caregivers of African American dementia patients, and caregivers of heart failure patients, to promote health and reduce cardiovascular risk.

The projects I have described provide just a glimpse of current NIH efforts to improve quality of life and care for those with AD and their caregivers, efforts that offer the promise of a better tomorrow for individuals affected by dementia.

IMPROVING QUALITY OF CARE FOR OLDER ADULTS

² Alzheimer's Association. 2010 Alzheimer's Disease Facts and Figures. 2010. Available at http://www.alz.org/documents_custom/report_alzfactsfigures2010.pdf.

Scientists have made great progress in understanding the challenges of living with AD for older adults and in developing interventions to support their caregivers. I would like to draw your attention to recent important findings in these areas from NINR-supported studies.

One of the challenges of providing quality care for older adults with AD is accurately detecting and treating symptoms such as pain and discomfort, which is critical to their quality of life. It is essential for health care providers, as well as informal caregivers, to have the tools to recognize pain in older adults with dementia who may not be able to express their need for pain relief. A recent NINR-funded study on pain showed a discrepancy between pain reported by dementia patients and pain behaviors that were observed. In this study, cognitively impaired older adults self-reported less intense pain after movement activities, such as walking and sitting, than cognitively intact older adults. However, behavioral observations of pain, such as grimacing and verbal complaints, showed no differences between the two groups.³ This suggests that commonly used self-report measures of pain may underestimate pain in older adults with dementia.

Some data suggest promising results of interventions for improving the quality of care and quality of life for older adults with AD and other types of dementia. For instance, a recent NINR-funded study showed that a comprehensive exercise program increased positive mood and decreased negative mood in nursing home residents with AD.⁴ Preliminary findings regarding health promotion interventions for older adults with early-stage dementia living in the

³ Horgas, AN et al. Pain Assessment in Persons with Dementia: Relationship Between Self-Report and Behavioral Observation. *JAGS*. 2009; 57:126-132.

⁴ Williams, CL, & Tappen, RM. Effect of Exercise on Mood in Nursing Home Residents with Alzheimer's Disease. *Am J Alzheimers Dis Other Demen*. 2007; 22:389-397.

community,⁵ as well as interventions to increase activity engagement in nursing home residents with dementia⁶ demonstrate that such interventions have the potential for improving quality of life.

IMPROVING QUALITY OF LIFE FOR CAREGIVERS

Recent findings from NINR-supported investigators are also contributing to the development of evidence-based interventions to support caregivers. One example is the Resources for Enhancing Alzheimer's Caregiver Health program, also known as REACH. Co-funded by NINR and the National Institute on Aging, REACH is a comprehensive, multi-site intervention, to assist AD caregivers. The REACH program teaches caregivers about AD, along with strategies to help them manage troublesome behaviors of the care recipients. It also emphasizes ways for caregivers to manage stress, maintain their social support groups, and enhance their own health and self-care activities. In a recent report of study findings involving almost 500 AD caregivers from diverse racial and ethnic groups, those who received the REACH intervention reported better physical, emotional, and overall health compared to those who received a packet of basic AD educational information and two brief "check-in" telephone calls.⁷ In addition, the REACH caregivers had lower scores for depression, which contributed to reducing their sense of caregiving burden. These findings indicate that the REACH program, by providing information about both AD and self-care, helped AD caregivers from diverse racial and ethnic groups maintain their own physical, emotional, and mental well-being. Multiple

⁵ Buettner, LL, & Fitzsimmons, S. Promoting Health in Early-Stage Dementia. *J Gerontological Nursing*. 2009; 35: 39-49.

⁶ Hill, NL et al. Agreeableness and Activity Engagement in Nursing Home Residents with Dementia. *J Gerontological Nursing*. 2010; 36: 45-52.

⁷ Elliott, AF et al. Enhancing Caregiver Health: Findings from the Resources for Enhancing Alzheimer's Caregiver Health II Intervention. *JAGS*. 2010; 58:30-37.

efforts across the federal government are currently underway to implement REACH in the community.

TRAINING THE NEXT GENERATION OF SCIENTISTS

To ensure continued advancement in improving care for AD and other dementias, it is essential that we also focus on training the next generation of innovative, interdisciplinary scientists with expertise in chronic illness and symptom management, and with the knowledge necessary to translate successful research to clinical practice. To this end, NINR supports extensive training activities across all areas of our scientific portfolio. Current efforts are training future nurse scientists to conduct research on transitional and individualized care for chronically ill older adults, biobehavioral pain research, genetics, and basic neuroscience, among many others.

CONCLUSION

In conclusion, I would like again to thank the Committee for offering me the opportunity to present an overview of efforts at the NINR to support research and training to improve the lives of older adults with AD and their caregivers. As we await the day when AD can be prevented and successfully treated, we must never lose sight of the needs of the individuals suffering from this and other dementias, and the people who care for them. Given this, NINR and NIH will continue our comprehensive efforts to support the science that will provide the evidence-base for improving the quality of care and quality of life for individuals affected by these illnesses, train the next cohort of researchers to generate new discoveries, and translate this evidence into everyday practice.

PATRICIA A. GRADY, PHD, RN, FAAN, DIRECTOR
NATIONAL INSTITUTE OF NURSING RESEARCH

Dr. Patricia A. Grady was appointed Director of National Institute of Nursing Research, on April 3, 1995. She earned her undergraduate degree in nursing from Georgetown University in Washington, DC. She pursued her graduate education at the University of Maryland, receiving a master's degree from the School of Nursing and a doctorate in physiology from the School of Medicine.

An internationally recognized researcher, Dr. Grady's scientific focus has primarily been in stroke, with emphasis on arterial stenosis and cerebral ischemia. She was elected to the Institute of Medicine in 1999 and is a member of several scientific organizations, including the Society for Neuroscience, the American Academy of Nursing, and the American Neurological Association. She is also a fellow of the American Heart Association Stroke Council. In 1988, Dr. Grady joined NIH as an extramural research program administrator in the National Institute of Neurological Disorders and Stroke (NINDS) in the areas of stroke and brain imaging. Two years later, she served on the NIH Task Force for Medical Rehabilitation Research, which established the first long-range research agenda for the field of medical rehabilitation research. In 1992, she assumed the responsibilities of NINDS Assistant Director. From 1993 to 1995, she was Deputy Director and Acting Director of NINDS. Dr. Grady served as a charter member of the NIH Warren Grant Magnuson Clinical Center Board of Governors.

Before coming to NIH, Dr. Grady held several academic positions and served concurrently on the faculties of the University of Maryland School of Medicine and School of Nursing.

Dr. Grady has authored or co-authored numerous articles and papers on hypertension, cerebrovascular permeability, vascular stress, and cerebral edema. She is an editorial board member of the major stroke journals. Dr. Grady lectures and speaks on a wide range of topics, including future directions in nursing research, developments in the neurological sciences, and Federal research opportunities.

Dr. Grady has been recognized with several prestigious honors and awards for her leadership and scientific accomplishments, including the first award of the Centennial Achievement Medal from Georgetown University School of Nursing and Health Sciences, being named the inaugural Rozella M. Schlotfeld distinguished lecturer at the Frances Payne Bolton School of Nursing at Case Western Reserve University, and receiving the honorary degree of Doctor of Public Service from the University of Maryland. Dr. Grady was named the Excellence in Nursing Lecturer by the Council on Cardiovascular Nurses of the American Heart Association. In 2005, Dr. Grady received Doctor of Science, Honoris Causa degrees from the Medical University of South Carolina and Thomas Jefferson University, and Columbia University School of Nursing honored her with its prestigious Second Century Award for Excellence in Health Care. In 2008, Dr. Grady received a Doctor of Science, Honoris Causa degree from the State University of New York Downstate Medical Center. Dr. Grady is a past recipient of the NIH Merit Award and received the Public Health Service Superior Service Award for her exceptional leadership.

Ms. MONTGOMERY. Well, thanks to both of you. I am Anne Montgomery. I am a senior policy advisor for the Aging Committee, and it is my pleasure to field a couple of questions for Assistant Secretary Greenlee who will not be able to stay for the second panel, as she has other commitments. We are going to be able to have Dr. Grady stay for the second panel.

So I would like to ask a couple of questions that both of you could answer, and since both of you discussed family caregivers quite a bit, I am wondering if you are a family caregiver out there in whatever State you live in, what are some of the very best ways and quickest ways you can access the most comprehensive information on how to support a loved one with dementia who is at home? Is there sort of a single best organized website or source, or is it really best to search widely?

Ms. GREENLEE. The best resource is the network of aging service providers around the country. They have different names sometimes in different places but a local aging and disability resource center, an area agency on aging; of course, if the caregiver is caring for someone with Alzheimer's or related dementia, the Alzheimer's Association locally. If someone looks at their local community and cannot figure out where to call, there are State resources with the State unit on aging and a State Alzheimer's chapter that would be helpful as well. We have information on our website at the Administration on Aging, aoa.gov. We support the National Alzheimer's Hotline where people can call and get information as well.

Dr. GRADY. Also, if I could add that we would recommend our website. But we do fund at least two web-based resources for education and training of both the caregivers at home and also the variety of health care workers in the care settings from the hospital to the nursing home and extended care. So I think there are a number of these. Also, as Kathy mentioned, the local Alzheimer's foundations and associations are really helpful with hands-on material.

Ms. MONTGOMERY. We are delighted to have them on the second panel.

Speaking of the second panel, one of our witnesses, Laura Gitlin, will be discussing interventions for family caregivers who support a relative or friend at home, and she includes a quote that I found very striking from the journal "Alzheimer's & Dementia." It says that, "failure to fund effective caregiver interventions may be fiscally unsound." So I am wondering if you agree with that, if you feel similarly, and if so, are there new strategies that we can embrace to make better family caregiver support a reality for more people, or do we need to just expand on what we already have and sort of keep going?

Ms. GREENLEE. Anne, as I am sure, you know and many people here and those watching now, 80 percent of the long-term care in this country is provided by families and family caregivers. It is a tremendous burden on everyone involved from the family, to the community, and to the individual. I think it is important that we work with local communities and other organizations to keep that care happening. There would be a tremendous loss of support for families if we could not do that. It also is something that if you quantified would be unaffordable for any system and is not what

people prefer. So it is a wise investment to help family caregivers because it is what they want, it is what families support, and it is a good investment and worth our time.

Dr. GRADY. I would echo that as well. In preparing for this forum, I was reviewing the figures of how much our country spends on health care in this particular population, and contrasting that with how much is invested in the front end, it is pretty dramatic. So I think that anything that we can do to help reduce the burden of suffering for this population is important to them as well, but also to our health care system.

We co-funded a study with the VA system that looks at what influences the decisions to have to place people in long-term care facilities and nursing homes. The first of these is related to the skills required to provide care at home for people, and that is something that we are trying to do something about and we can do something about much of that to help prepare people.

But the second of these, which is close to the third, was something happening with their own physical health, that people really cannot keep up with the demands of caregiving physically themselves. We are talking about typically middle-aged people who often are caring for young children as well as older adults. So again, it underscores the importance of the caregiver piece.

Then the third was related to the behaviors that people develop and some of the difficult characteristics of the disorder, and that also is something that we are funding studies to try to make a difference in and are showing some success—with engagement studies of patients even in the nursing homes show that there is a decrease in some of this very disruptive behavior if one can engage them.

Ms. MONTGOMERY. Finally, many more individuals will be screened in the coming years for detection of cognitive impairment as part of their Medicare wellness exam, and some percentage will, be diagnosed as having Alzheimer's or another type of dementia. For these individuals, there could well be feelings of anxiety or depression. So I am wondering what interventions would you point to that can give individuals who are living with Alzheimer's hope that they can maintain a high quality of life for as long as possible?

Dr. GRADY. There are a number of studies that are now giving us information to help out with this. Physical activity, and also a number of cognitive and memory system studies or approaches, as well as educational and developmental approaches, are able to show a decrease in the progression of the illness. Some of these decreases are modest, but they are promising. So I think that people now can look forward to being able to put off some of the progression of illness, not to mention that with each passing day, that there is a great deal of work which promises to be successful with time, and that may allow us to prevent and cure this disorder. For now, we do need to focus on maintaining these attributes. Much of the work that is going on in neuroscience gives us hope because it really points to the enormous plasticity of the brain and the ability to recruit other centers in the brain, other parts of the brain to help out in areas where those neurons and synapses are not working so well such as Alzheimer's.

Ms. GREENLEE. One of the benefits of preventative screening like we will have available in Medicare at no cost is the ability to detect

these diseases early. One of the things that we know in working with our clinical partners is when we can work with someone in a community setting at early diagnosis, that is the best opportunity to do person-centered planning. The early stages of any dementia disease, including Alzheimer's, is when you want to be involved with the person. They do not disappear when they receive this diagnosis. They need to be engaged and planning for their own future. Many of the good practices that we are now supporting in the field around the country is a way to continue to involve the person who has the disease in their planning so that they can be involved in making decisions so that when they are no longer able to be as involved, there is a plan of care that everyone can follow that has the input of the person who has the disease.

Dr. GRADY. If I could just underscore something that Kathy said, one of the marvelous things about having a forum such as this and having the Alzheimer's Foundation, the Alzheimer's Association, and people like yourselves in the audience is that attention is being brought to this problem. For many years, because Alzheimer's patients could not speak for themselves, they did just literally disappear. As we know, when people disappear and are not face forward in front of audiences, they are often forgotten. So we have lost some early ground, I think, in being able to address this issue. So the fact that all of you are here today and that we are paying attention to this and speaking openly, cannot be underscored in its importance.

Ms. MONTGOMERY. Well, thank you very much. Those are excellent presentations and remarks and very inspirational, if I may say so. So now we will say thank you again and have our second panel come up. [Applause.]

Ms. HENNIE. Hello. My name is Alicia Hennie and I work for Senator Corker's Aging Committee staff. It is my pleasure to call up our next panel and introduce them as they get situated.

First, we have Loren Shook. He is Chairman, President, and CEO of Silverado Senior Living, a nationally recognized leader in services to those with Alzheimer's disease and other memory impairing diseases. Silverado currently has 20 assisted living communities throughout California, Utah, Texas, and Arizona with plans for growth. In addition, Silverado has five care management home care offices and eight hospice offices.

Mr. Shook has served on various boards, including the Assisted Living Federation of America, the American Senior Housing Association, the National Investment Center, and is past chair and board member of the Alzheimer's Association of Orange County, CA. Before co-founding Silverado Senior Living, Mr. Shook was president of worldwide operations at Community Psychiatric Centers.

Next we will then hear from Dr. Laura Gitlin, Director of the Jefferson Center for Applied Research on Aging and Health at Thomas Jefferson University and a professor at the Jefferson School of Health Professions, Department of Occupational Therapy. As of January 15, 2011, she will be Director of a new center on innovation and aging and health at the Johns Hopkins University School of Nursing, with joint appointments in the School of Medicine, Departments of Psychiatry, and Behavioral Services and Medicine,

and the Division of Geriatrics. Dr. Gitlin's NIH-funded intervention, "Skills to Care for Families of Individuals with Dementia," has won numerous awards, including a SAMHSA service award and the Rosalynn Carter Institute caregiver program merit award.

Next is Dr. Christine Kovach, professor at the College of Nursing at the University of Wisconsin-Milwaukee. She researches innovative approaches to dementia care, including pain management in advanced dementia cases. Dr. Kovach opened and conducted research on some of the first hospice households designed to care for people with late-stage dementia. She has also researched the programmatic, environmental, and behavioral aspects of special care units for mid-stage dementia. Dr. Kovach is a fellow of the American Academy of Nursing and the Gerontological Society of America.

Our final panelist is Patricia McGinnis, Director of California Advocates for Nursing Home Reform. Ms. McGinnis has written and lectured extensively on elder abuse and long-term care issues, and has served as an adjunct professor in San Francisco State University's Gerontology program. She has received numerous awards for her advocacy on behalf of long-term care consumers in California.

For closing remarks and reflections on what we are about to hear from this panel, we are thankful to have the Alzheimer's Association and Alzheimer's Foundation of America to wrap up.

Robert Egge, the Alzheimer's Association's Vice President of Public Policy, will start our discussion. Chief among his priorities are increasing Federal support for Alzheimer's research, enhancing Alzheimer's care and support, and improving Alzheimer's planning, coordination, and education by Federal and State agencies. Previously Mr. Egge was executive director of the Alzheimer's Study Group, a blue ribbon task force of national leaders. Mr. Egge worked closely with the co-chairs, former Speaker Newt Gingrich and former Senator Bob Kerrey and other Alzheimer's Study Group members, such as former U.S. Supreme Court Justice Sandra Day O'Connor, to shape and develop the group's national assessment strategy and specific policy proposals.

Wrapping up will be Eric J. Hall, President and founding CEO of the Alzheimer's Foundation of America. Mr. Hall founded AFA to improve the quality of care for dementia patients and their families by allowing organizations nationwide to advocate for optimal care and enhanced services. AFA now includes approximately 800 member organizations and associate member organizations. As CEO, Mr. Hall started the AFA "Quilt to Remember," National Memory Screening Day, and the Nation's first magazine for dementia caregivers, among other major initiatives.

We welcome you all and look forward to an interesting and informative discussion, and with that, I turn it over to Mr. Shook.

**STATEMENT OF LOREN SHOOK, CHAIRMAN, PRESIDENT, AND
CEO, SILVERADO SENIOR LIVING, ON BEHALF OF THE
ASSISTED LIVING FEDERATION OF AMERICA, IRVINE, CA**

Mr. SHOOK. Thank you, Chairman Kohl and Ranking Member Corker, for having me here today to speak to you.

As mentioned, I am Loren Shook, President and CEO of Silverado Senior Living and Vice Chair of Assisted Living Federation of America. ALFA represents the assisted living industry, the owners and operators of assisted living communities, and the frail elderly residents they serve. The assisted living industry is resident-centered care in a community home-based setting.

My company, specifically Silverado Senior Living, operates 20 communities in four States entirely dedicated to serving those with memory-impairing diseases such as Alzheimer's disease and other dementias. I will be discussing how my company meets their needs.

The Silverado philosophy of care and the company vision is to give life. Our purpose is to give life to the residents we serve, their families, and the associates. We are additionally a purpose-driven company designed to change the way memory care services are provided, and it is in this process that we seek to touch the human spirit in all that we do. Silverado Senior Living cares for people with all types of memory-impairing diseases, including Alzheimer's, Parkinson's, and others. We provide a full continuum of memory impairment care, from the disease's early onset with geriatric care management and home care and residential care services, in addition to hospice care at the end of life.

We partner with many universities in the markets we work with, such as the University of Southern California, University of California at Los Angeles, University of California at San Diego, Baylor College of Medicine, Stanford University, and the University of Utah in Salt Lake City.

We founded the company in 1996, opening our first assisted living community in June 1997. Silverado now operates 20 memory care communities with 1,578 beds in four States. Silverado has five home care offices and eight hospice care offices. In addition, we offer skilled nursing services for rehabilitation purposes for those who have memory-impairing diseases in Salt Lake City, UT, and Dallas, TX.

We serve the population in the setting of their choice, be it at their own home, at residential settings such as Silverado or others, or even in a skilled nursing facility.

Providing care for our aging population, especially for those with memory-impairing diseases, is more than just meeting their medical needs. It is about providing for their psychosocial needs as well. It includes providing and supporting a quality of life that brings life-affirming meaning and fulfillment to them daily. In an assisted living setting, enhancing quality of life requires that the following elements be in place in order to create and maintain a supportive and life-enriching environment: a philosophy of care promoting independence, choice, dignity, and daily purpose for each resident; quality and compassionate staff who are trained to meet the unique needs of this population; and a strong supportive company culture which is clear to all staff. A culture where the operating philosophy of love is greater than fear prevails.

Our environments provide a social setting which is comfortable, home-like, and attractive. Age-appropriate, engaging activities which promote self-worth, involved, and purpose are offered. Coordination with care practitioners is encouraged and a comprehensive plan designed in conjunction with the primary care team is developed in order to create a holistic approach to meet individual needs.

The Silverado model of care is different than most traditional settings in that it focuses on creating an attractive social home-like residential environment in addition to adding a strong clinical support component, including physician medical directors, and licensed nurses 24 hours/7 days a week, and Masters-trained social workers who work with families and residents. In so doing, we meet the comprehensive needs of people from the beginning through the end of their life.

Silverado has developed extensive clinical outcome measures that provide the following benefits: documentable evidence-based results showing quality of care and quality of life benefits; provides a management tool to benchmark one Silverado community against another. It also demonstrates savings to payers that are real.

At the start of the company in 1997, Silverado collected data on use of psychotropic medications, ambulation, feeding, weight gain/loss, falls, and pressure wounds.

In the case of psychotropic medication use, we record each of our 1,250-plus residents' use of medications every month, separating medications by the following categories: anti-anxiety, antipsychotic, sedative hypnotic, and use of antidepressants. Every resident is assessed using the "Cornell Scale for Depression in Dementia," or a similar tool. We find that about 60 percent of the residents need treatment for depression.

Because of our excellent results in serving the most challenging behavioral cases and our expertise in serving complex diagnoses like frontotemporal dementia, which also is called Picks disease, Lewy-Body dementia, et cetera, we are the No. 1 referral choice for people with challenging behaviors from behavioral health hospitals, assisted livings, and even skilled nursing, as well as cognitive assessment centers. Taking the cases that no one else is willing or able to handle, we have experienced an overall reduction in the use of psychotropic medications in excess of 30 percent company-wide. We have served over 1,458 people who had major behavioral problems in a 3-year period between 2006 and 2009. We did not collect specific data before that.

Over the years, our clinical outcome scores were expanded to include the rate of transfers to acute care; the percent of residents on hospice care; and the percent of resident deaths on hospice care; and the number of prescription medications residents take. We have other clinical results that include reducing residents' medications from the 9 to 12 prescription medications they move in with to an average of 5.5 company-wide. This compares to skilled nursing at 12, and traditional assisted living at 7 to 8 medications per resident.

While it is estimated that 6 to 8 percent of people with dementia fall and experience fracture each year—including people within settings that restrain them—Silverado has a fall and fracture rate of

only one percent without restraining anyone company-wide. Compared to nursing homes where 10 to 20 percent of falls cause serious injury, at Silverado only 4.8 percent of falls cause serious injury.

The details of Silverado's award-winning fall prevention program and our award-winning grand rounds behavior intervention conference calls have been shared with the Committee on Aging and others who are interested in a document entitled "Enhancing the Quality of Life in a Dementia Care Assisted Living Environment." These programs are easily replicable by others. Silverado does teachings of these programs at industry conferences and just did a nationwide webinar on the fall prevention program.

Let me tell you a true life story that exemplifies how Silverado's vision to give life and the Silverado model of care affects people with all types of memory-impairing diseases. As chronicled in the book "Alive with Alzheimer's," Edith, a memory-impaired woman who was bedbound, unresponsive, terribly feeble, and frankly considered near the end of her life, was brought to the Silverado Senior Living-Escondido community in April 2001. We surrounded her with music and assigned a Silverado cat to Edith since we found she loved cats, spoke to her even though she could not speak to us, reduced the overly large number of medications she was being given in an effort to control her symptoms and behavior, and started the process of getting her out of bed and taking a few steps.

Within 4 weeks, Edith regained her ability to walk on her own. The book shows her sitting in the stands of the Del Mar Race Track in southern California, talking with her friends, and enjoying the company of her daughter, and cheering her horse on, we hope, to success. We are proud to say that Edith's story is replicated throughout Silverado 3,600-plus times. Edith has passed away in 2010, 9 years later.

We believe that people with Alzheimer's disease and other memory-impairing diseases want to lead purposeful lives.

Let me tell you my final story about Walter, a 99-year-old resident at Silverado, and Lisa, the 7-year-old daughter of a staff member who works in the laundry services. This is an adaptation from the book "Silverado's Story," which my partner, Steve Wynn, and I have written.

Whether Walter was in Silverado's country kitchen, the garden, his home, or elsewhere in the community, Lisa somehow knew where to find him. When she arrived after school, this was no mean feat, in a building of 38,000 square feet on a 5-acre campus, and Lisa having been blind at birth. But it was a kind of bond they had. Lisa always knew where to find Walter, and he was in places where she would like to be as well.

One afternoon, Lisa found Walter sitting in the gazebo. Walter spotted her crossing the lawn and broke into a wide grin. "Lisa, I am over here," he called out. He knew that Lisa's instincts would bring her to him anyway, but there was just too much pleasure in having to say her name. Lisa's face lit up and she hugged him right away. They sat and talked for a bit. Then Walter asked the question that Lisa was expecting, the one she hoped he would ask. "Lisa, can you count to 200 for me?" Lisa began counting. Walter leaned a little closer to hear her and listen attentively as she con-

tinued. He was committed to improving her math skills. Lisa, excellent in the subject already, in truth needed no additional practice. But every time she reached 200 without an error, Walter would congratulate her and the pride in his voice always made her happy.

Later that day, Lisa took Walter's hand and put it on her face. She asked Walter, "am I beautiful?" Walter replied, "you are the most beautiful little girl there ever was. Your hair has a soft sheen that reflects the sun. Your complexion would be the envy of little girls everywhere. Believe me. You are a gift from God." Lisa smiled and bowed her head and they both sat quietly for a while.

Walter was 99 years old. His advancing memory impairment had reduced the size of his brain by one-third, according to scientists, who say the actions of persons in his condition are not guided by intention or comprehension. But Walter knew exactly what to do for Lisa. Lisa was his purpose.

World-class health care is made up of four things: the physical, the science behind it; the psychological; the family; and the spiritual. Throughout Silverado's model of care all four of these essential elements are served resulting in measurable clinical results that are truly remarkable like the story about Walter and Lisa and Edith.

It has been an honor to present to you today, Chairman Kohl and Ranking Member Corker and members of the committee. Thank you for your time and attention.

[The prepared statement of Mr. Shook follows:]



***"UNTIL THERE'S A CURE: HOW TO HELP ALZHEIMER'S
PATIENTS AND FAMILIES NOW"***

SENATE SPECIAL COMMITTEE ON AGING FORUM

TESTIMONY OF LOREN SHOOK

CHAIRMAN, PRESIDENT, AND CEO

SILVERADO SENIOR LIVING

VICE CHAIR, ASSISTED LIVING FEDERATION OF AMERICA

DECEMBER 8 2010



LOREN B. SHOOK
President/Chief Executive Officer

December 8, 2010

Dear Chairman Kohl, Ranking Member Corker and distinguished members of the committee:

Thank you for inviting me to speak at the Senate Special Committee on Aging Forum "Until There's A Cure: How to Help Alzheimer's Patients and Families Now."

I am Loren Shook President, CEO of Silverado Senior Living and Vice Chair of Assisted Living Federation of America. ALFA represents the assisted living industry—the owners and operators of assisted living communities and the frail elderly residents they serve. The assisted living industry is resident-centered in a community home based setting and can be distinguished from institutional forms of care because we offer choice, independence, dignity and quality of life for frail elderly seniors who do not need 24/7 nursing care but need some assistance with activities of daily living. The average age of our industry's residents is 86.9. However, one third of the residents served by our industry have Alzheimer's Disease or other forms of dementia. They are well-served by our industry. My company specifically, Silverado Senior Living, operates 20 communities and we are entirely devoted to the care of residents with dementia. I will be discussing how my company meets their needs.

The Silverado philosophy of care and company vision is to "give life." Our purpose is to change the world in the way people with memory-impairing diseases are cared for. In the process, we seek to touch the human spirit in all that we do.

Silverado Senior Living cares for people with all types of memory-impairing diseases, including Alzheimer's, Parkinson's, and others. We provide the full continuum of memory impairment care, from the disease's early onset with geriatric care management and home care with hospice care through the end of life. Our services encompass assisted living for those with memory disorders, home care, geriatric care management, and hospice care. Silverado is consistently recognized as the leader and innovator in the \$110 billion assisted living industry's memory-care niche. This stature is borne out by our partnerships and programs with universities conducting dementia research, including University of California at San Diego, University of California at Los Angeles, University of Southern California, Baylor University, Stanford University, the University of Utah, and many others. Founded in 1996 and opening its first assisted living community in June 1997, Silverado now operates 20 memory-impairment communities with 1,578 beds in four states. Silverado has five home care offices and eight hospice offices. In addition, Silverado offers skilled rehabilitation services focused on the memory impaired in two of its communities, one in Dallas, Texas and the other in Salt Lake City, Utah. Our main customers are individuals with memory impairments and their families, and those in need of hospice care. We serve this population in the setting of their choice; be it their current personal home, a Silverado or other residential living environment or skilled nursing facility. We also serve the general medical community by providing services to their patients and clients.

Providing care for our aging population, especially for those with memory impairing diseases is more than just meeting their medical needs. It's about providing for their psychosocial needs as well. It includes providing and supporting a quality of life that brings life-affirming meaning and fulfillment to them daily. In an assisted living setting, enhancing quality of life requires the following elements be in place in order to create and maintain a supportive and life enriching environment:

1. A philosophy of care which promotes independence, choice, dignity and daily purpose for each resident.
2. Quality and compassionate staff who are trained to meet the unique needs of this population.
3. A strong supportive company culture which is clear to all staff. A culture where the operating philosophy of love is greater than fear prevails.
4. Environment. Providing and social setting which is comfortable, home-like and attractive.

5. Programming. Age appropriate engaging activities which promote self-worth, involvement and purpose.
6. Coordination with care practitioners. A comprehensive plan designed in conjunction with the primary care team in order to create a holistic approach to individuals needs.

In the case of Silverado a seventh element is also included: clinical services. Silverado is different than most traditional assisted living providers in that it has licensed nursing on-staff 24 hours per day seven days per week.

The Silverado model of care is different than most traditional settings in that it focuses on creating an attractive, social home-like residential setting in addition to an intensive clinical model of care "in the background." This model of care includes a physician medical director who is typically board certified in their medical specialty, a full time registered nurse as our Director of Healthcare services, licensed nurses around the clock seven days per week. In addition we have Masters prepared social workers to assist residents and families with support services, counseling and other assistance as needed.

Silverado has developed extensive clinical outcome measures that provide the following benefits:

- Documentable evidence based results showing quality of care and quality of life benefits
- Provides a management tool to benchmark Silverado communities against each other
- Demonstrates cost savings to the payer

At the start of the company in 1997, Silverado collected data on use of:

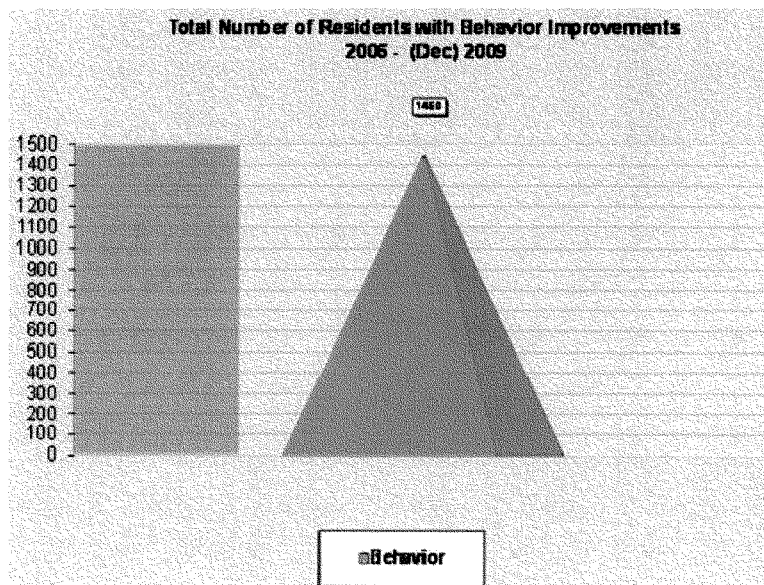
- Psychotropic medications
- Ambulation
- Feeding
- Weight gain/loss
- Falls
- Pressure wounds

In the case of psychotropic medication use, we record each of our 1250 plus residents' use of medications each month separating the medications by the following categories:

- Anti-anxiety medication rate
- Anti-psychotic medication rate
- Sedative hypnotic medication rate
- Use of anti-depressants

Every resident is assessed using the "Cornell Scale for Depression in Dementia" or similar tool. We find that about 60% of residents need treatment for depression.

Because of our excellent results in serving the most challenging behavioral cases and our expertise in serving complex diagnoses like frontotemporal dementia (Pick's Disease), Lewy-Body dementia, etc., we are the number one referral choice for people with challenging behaviors from behavioral health hospitals, other assisted livings, skilled nursing and cognitive assessment centers. Taking the cases that others cannot handle, we experience an overall reduction in the psychotropic medication use for controlling behaviors of over 30% across the company.



Over the years, our clinical outcome scores were expanded to include:

- Rate of transfer to acute care
- Percent of residents on hospice care
- Percent of resident deaths on hospice care
- Number of prescription medications residents take

Other clinical outcome results include:

- Reducing residents from the 9-12 prescription medications they move-in with to an average of 5.5, compared to skilled nursing at 12, and traditional assisted living of 7-8 prescription medications.
- While it is estimated that 6-8% of people with dementia fall and fracture each year including people within settings that restrain them, Silverado has a fall with fracture rate of only 1% without restraining people.
- Compared to nursing homes where 10-20% of falls cause serious injury, at Silverado only 4.8% of falls cause serious injury.

The details of Silverado's award winning Fall Prevention Program is shared with the Committee on Aging in the document entitled "Enhancing the Quality of Life in a Dementia Care Assisted Living Environment." This program is easily replicable by others to achieve similar results.

The details of Silverado's award winning "Grand Rounds Behavior Intervention Conference Calls" are shared with the Senate Committee on Aging in the document entitled "Enhancing the Quality of Life in a Dementia Care Assisted Living Environment."

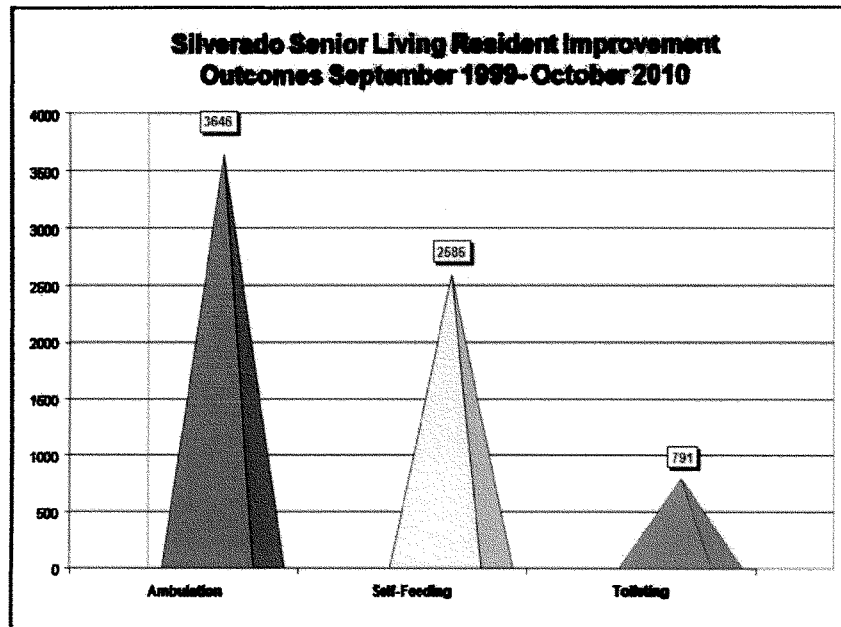


Let me tell you a true life story that exemplifies how the Silverado's Vision to Give Life and the Silverado model of care affects people with all types of memory impairing disease. As chronicled in the book *Alive with Alzheimer's*, Edith, a memory-impaired woman who was bedbound, unresponsive, terribly feeble, and frankly, considered near the end of her life when she was brought to the Silverado Senior Living - Escondido

community. We surrounded her with music and assigned a Silverado cat to Edith since she loved cats; spoke to her even though she could not speak back; reduced the overly-large number of medications she was being given in the effort to "control" her symptoms and behavior; and started the process of getting her out of bed to take a few steps.



Within four weeks, Edith regained the ability to walk on her own. The book shows her sitting in the stands of southern California's Del Mar Race Track, talking and laughing with a group of fellow Silverado residents on an outing there having walked on her own! We are proud to say that Edith's story has replicated throughout Silverado over 3,600 times so far. Edith passed away peacefully at Silverado in 2010.



We believe that people with Alzheimer's Disease and other memory impairing diseases want to lead a purposeful life.

Let me tell you about Walter, a 99 year old resident at Silverado and Lisa, the 7 year old daughter of a staff member who works in the laundry ...

World Class Healthcare is made up of:

- Physical
- Psychological
- Family
- Spiritual

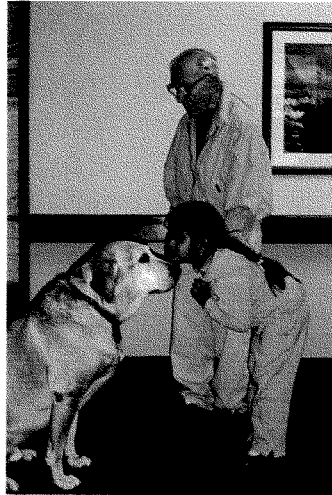
Through the Silverado model of care, all four of these essential elements are served resulting in measurable clinical results that are truly remarkable like the story about Edith and Walter.

It has been an honor to present to you today Chairman Kohl and Ranking Member Corker, and members of the committee. Thank you for your time and attention.

Sincerely,



Loren B. Shook
President, Chief Executive Officer
Silverado Senior Living



STATEMENT OF LAURA N. GITLIN, PH.D., DIRECTOR, JEFFERSON CENTER FOR APPLIED RESEARCH ON AGING AND HEALTH, THOMAS JEFFERSON UNIVERSITY, PHILADELPHIA, PA

Dr. GITLIN. Good afternoon. I would like to thank Senators Kohl and Corker and members of the committee for inviting me to present at this very critical and important forum.

I would like to start by telling you about Millie. Shortly after her husband passed away, Millie became increasingly forgetful and delusional. With time, however, Millie's condition worsened, and she was finally diagnosed with dementia. Millie moved in with her daughter Diane and her family. Diane had to stop working to care for her mother, and she quickly found that she had to manage many complications of the disease beyond that of memory loss. Millie constantly followed Diane around the house. She repeatedly asked questions such as what day and time it was and where Diane was going. She resisted bathing and appeared fearful of the tub, and she roamed the house in the middle of the night, sometimes trying to leave.

Diane thought that her mom also might be in pain due to arthritis, but she could not gauge her pain as Millie had difficulties communicating, a common factor in dementia.

Diane felt guilty that she was not doing enough for her mom. She became increasingly distressed due to her lack of sleep and having to juggle the care of her mother with that of her family. Her health in turn began to suffer and she missed her own doctor appointments.

Millie's story is not unusual. She is one of the over 5 million people in the United States who suffer from Alzheimer's disease or a related disorder, the majority of whom live at home with a family member or alone in the community. This is also the story of the over 11 million family members who, like Diane, are caring for their family members with dementia. Although each situation is unique, family caregivers share similar challenges and experiences. They are often exhausted, frustrated, saddened, and unsure how to manage functional dependence and troublesome behaviors such as wandering, agitation, or waking up at night such as in the case of Millie, which are common and can occur throughout the disease process. They also must make very difficult decisions with little to no help or formal support.

Although we know that a cure for dementia is not in sight now or in the near future, there are treatments available right now that could help Millie and Diane. Most families, however, do not hear about them. These therapies—called non-pharmacologic treatments—do not come in a pill. Instead, they may involve personal counseling, education, hands-on-skills training, home modification, exercise, or simplifying activities. These treatments, as you have heard from the morning panel, are based on over 2 decades of evidence from randomized controlled trials funded by the NIH and the Alzheimer's Association.

One example of an effective intervention is Project COPE. This was developed and tested recently by myself and my research team at Thomas Jefferson University. In a randomized trial with 237 families, we recently reported in the "Journal of the American Med-

ical Association” that our home-based intervention, provided by occupational therapists and nurses, minimized functional dependence, and minimized behaviors in persons with dementia such as Millie, while enhancing their quality of life. It also reduced caregiver burden and helped caregivers keep their family members at home. We also found an alarming number—close to 40 percent—of people with dementia in the intervention group, who had an undiagnosed but treatable medical condition, such as a urinary tract infection. This finding in particular raises significant concerns about the frequency with which this clinical population should be monitored medically.

When Millie became a recipient of Project COPE, an occupational therapist conducted a systematic assessment of her abilities and her deficit areas. She also observed Diane’s communication style, and the physical home environment for its safety and the way it supported Millie. The therapist helped Diane understand the disease and what Millie was still capable of doing, not just what she could not do. She introduced practical methods and new skills to help Diane cope, including stress reduction techniques to ease Diane’s stress level, assistive devices such as grab bars and tub benches to help Millie bathe safely and without fear, and simple activities to decrease Millie’s anxiety. As Millie had been a housewife, teaching Diane how to involve her mom in washing dishes and folding laundry enabled Millie to continue to participate in a meaningful way in the daily life of the family, and to feel an important sense of accomplishment.

The occupational therapist also helped to establish a night-time routine for Millie that included eliminating caffeinated drinks and before bedtime taking a bath, playing soothing music, and using a nightlight. The routine prepared her for bed in a relaxed manner and reduced her erratic behavior. This, in turn, benefited Diane, who was able to sleep through the night and have more time for herself during the day.

A nurse also helped Diane understand how to detect pain in her mother by paying attention to her facial gestures and physical movements, and also how to monitor her fluid intake and daily elimination patterns. The nurse also took blood and urine samples from Millie and discovered that she indeed had a urinary tract infection and hyperthyroidism—conditions which may have contributed to her agitated and sleepless states. These were subsequently treated by a doctor.

In the Philadelphia region, we are now able to offer COPE as an outpatient home care service for people with dementia who have Medicare and qualify for skilled care by an occupational therapist. However, most families do not have access to this and other proven non-pharmacologic dementia care services.

A recent study by researchers at Johns Hopkins University of 264 families surveyed at home found that of those individuals with dementia, 90 percent had home safety issues; 64 percent had medical care issues that were untreated; 48 percent had legal concerns; and 37 percent were not engaged in any meaningful activities. With respect to their caregivers, 88 percent needed a referral for a resource, 84 percent needed education about the disease, 45 percent had unaddressed mental health issues, and 24 percent had

unmanaged health problems. Yet, our research by me and that of numerous other scientists that Dr. Grady spoke about suggests that non-pharmacologic approaches can address all of these unmet critical needs.

As Dr. Covinsky stated in an editorial in the “Annals of Internal Medicine” in response to the positive caregiver outcomes of the NIH REACH initiative, if these interventions were drugs, it is hard to believe that they would not be on the fast track to approval. The magnitude of benefit and the quality of evidence supporting these interventions considerably exceed those of currently approved pharmacologic therapies for dementia.

There is also an economic argument to be made for better dementia and caregiver supportive programs. As we have heard, in 2009 nearly 11 million unpaid caregivers provided an estimated 12.5 billion hours of care to people with dementia, valued at nearly \$144 billion. Our country cannot afford the consequences of family caregivers becoming burnt out or too sick to carry on.

Non-pharmacologic therapies may save more than they cost. Peer-reviewed studies have shown, for example, that the “NYU Caregiver Intervention” of counseling and ongoing caregiver support delayed nursing home placement by an average of 557 days, as was spoken about in the earlier panel. This could mean a savings of \$100,000 per patient.

An occupational therapy activity program we developed and tested at Thomas Jefferson University not only radically reduced behavioral disturbances, but it cost an average of \$941 per family and was found to be cost effective. It saved caregivers up to 5 hours a day, at a cost of only \$2.37 per day. The cost of drug treatment is approximately \$5 per day, or \$1,825 per year.

Despite the promise of non-pharmacologic approaches, there are many challenges. Chiefly, we lack a national strategy for developing a new standard of care for individuals with dementia and their families that includes comprehensive and ongoing supportive, proven non-pharmacologic approaches. A national strategy might include funding large-scale demonstration projects that integrate the most promising non-pharmacologic approaches to date, and widespread training of health and human service professionals in these proven dementia care and caregiver supportive programs. It might include expanding our current reimbursement structures to allow for the provision of existing proven caregiver and dementia care programs at home. It might include expanding funding to support implementation of proven programs into a variety of practice settings, including home care, hospital discharge services, care management services, and rehabilitation services—all places where dementia patients are found.

I urge the Committee to move forward with the strategic vision for enabling non-pharmacologic strategies to become part of the standard of care that is available to all individuals with dementia and their family members in order to address one of the most devastating diseases of our time, and which soon will be an epidemic. Thank you.

[The prepared statement of Dr. Gitlin follows:]

Testimony of

Laura N. Gitlin, Ph.D.

Director,

Jefferson Center for Applied Research on Aging and Health

Thomas Jefferson University¹

Before the

Senate Special Committee on Aging Forum

Until There's A Cure: How to Help Alzheimer's Patients and Families NOW"

Wednesday, Dec. 8, 2010

¹ Dr. Gitlin, will become a faculty member in the Johns Hopkins University School of Nursing (JHUSON) Department of Health Systems and Outcomes with joint appointments in Psychiatry and Geriatrics, Johns Hopkins University School of Medicine on January 15, 2011

Mr. Chairman and members of the Committee, thank you for inviting me to present testimony before the Senate Special Committee on Aging regarding How to Help Alzheimer's Patients and Families Now.

I would like to tell you about Millie. Shortly after her husband passed away, Millie became increasingly forgetful and delusional. Her daughter, Diane, initially attributed her mother's memory loss to the stress of losing her husband. With time however, Millie's condition worsened and she was diagnosed with Alzheimer's disease. Millie moved in with her daughter Diane, and her family. Diane had to stop working to be her mother's primary caregiver and to manage the complications of the disease beyond the memory loss. Millie followed Diane around the house, she repeatedly asked Diane what day and time it was and where she was going, she resisted taking a bath and appeared fearful of the tub, and she roamed the house in the middle of the night sometimes trying to leave, and disturbing the rest of the family. Diane thought her mom's irregular sleep patterns might be due to pain from arthritis and possibly a kidney infection. However, Diane was unsure if she should take her to the doctor as she could not gauge her mother's level of pain as Millie had difficulties communicating—a common factor in dementia. Diane felt a lot of guilt that she was not doing enough for her mother. She was becoming increasingly distressed due to her lack of sleep and having to juggle caring for her mother and that of her family. Her health in turn began to suffer as she missed her own doctor appointments.

Millie's story is not unusual. She is one of the over 5 million people in the United States who suffer from Alzheimer's disease or a related disorder.¹ The majority of people with dementia live at home with a family member or in the community. This is also the story of the over 11 million family members who like Diane, are caring for their family members with dementia.¹ Although each situation is unique, family caregivers share similar challenges and experiences. They are often exhausted,

frustrated, saddened, and unsure how to manage functional dependence and troublesome behaviors such as wandering, agitation, or waking at night which often occur throughout the disease. They also must make difficult daily care decisions with little to no help or formal support.

Although a cure for dementia is not in sight now or for the near future, something can be done to change these stories. There are treatments available right now that most families coping with dementia never hear about, but which can significantly improve the quality of life of persons with dementia and their caregivers. We can help families stay together longer at home, and have happier and healthier lives.

Called non-pharmacologic therapies, these treatments do not come in a pill. Instead, treatments may involve personal counseling, education, hands-on skills-training of family members, home modifications to enhance safety; or simplifying activities to engage people with dementia. There are a growing number of such interventions that—based on over two decades of evidence from randomized controlled trials— demonstrate the benefits of non-pharmacologic therapies that are tailored to the strengths and needs of people with dementia and their family members. These approaches have been shown to support families and provide them the skills they need to protect their own health and cope with the intense demands of caregiving, while helping people with dementia stay independent and safe at home for as long as possible.²⁻⁶

One example of an effective intervention, Project COPE, was developed and tested by myself and my research team at Thomas Jefferson University. In a randomized trial with 237 families, we reported in the *Journal of the American Medical Association* (Sept. 1, 2010) that a home-based intervention provided by occupational therapists and nurses, minimized functional dependence in individuals with dementia and enhanced their quality of life; it also reduced caregiver burden, and helped caregivers keep their family member at home. We also found an alarming number—close to 40%—of people with dementia in the intervention group who had an undiagnosed but treatable medical condition such as a

urinary tract infection. This finding raises significant concerns about the medical care provided to this clinical population and how frequently individuals should be evaluated.⁷

When Millie became a recipient of Project COPE, an occupational therapist conducted a systematic assessment of her abilities and deficit areas, and observed Diane's communication style and the physical home environment for its safety and support for Millie. The therapist helped Diane understand the disease and what Millie was still capable of doing. She introduced practical methods to help Diane cope including stress reduction techniques to ease Diane's stress level, assistive devices such as a grab bar and tub bench to help Millie bath safely and without fear, and simple activities to decrease Millie's anxiety. As Millie had been a housewife, teaching Diane how to involve her in washing dishes and folding laundry enabled Millie to participate in a meaningful way in daily life and feel a sense of accomplishment. The occupational therapist also helped to establish a nighttime routine for Millie that included eliminating caffeinated drinks by early afternoon and before bedtime, taking a bath, playing soothing music and using a nightlight. The routine prepared her for bed in a relaxed manner and reduced her erratic behavior. This in turn benefited Diane, who was able to sleep through the night and have more time for herself. A nurse also helped Diane understand how to detect pain in her mother by paying attention to her facial gestures and physical movements, and also how to monitor her fluid intake and daily elimination patterns. The nurse also took blood and urine samples from Millie and discovered that she had a urinary tract infection and hyperthyroidism, conditions which may have contributed to her agitated and sleepless states, and were subsequently treated by her doctor.^{24,25}

A recent study by researchers at Johns Hopkins University of 264 families surveyed at home found that for individuals with dementia, 90% had home safety issues, 64% had medical care issues, 48% had legal concerns, and 37% were not engaged in any meaningful activities. With respect to their caregivers, 88% needed a referral for a resource, 84% needed education about the disease, 45% had

unaddressed mental health issues, and 24% had unmanaged health problems.¹⁰ Yet, the research by myself and my team and that of numerous other scientists suggest that non-pharmacologic approaches can address all of these unmet critical needs.

Collectively, research on nonpharmacologic interventions shows that for caregivers:

1. Providing specific skills training in stress reduction, communication and problem-solving techniques can reduce depression, and improve self-rated health, sleep quality, and overall well-being of caregivers;^{11, 15-17}
2. Addressing the specific concerns family caregivers themselves find problematic can enhance their sense of well-being and confidence, and improve their quality of life;^{12, 14, 16, 17}
3. Ongoing counseling and supportive services can reduce caregiver depression and delay nursing home placement.¹⁵⁻¹⁷

Collectively, research on nonpharmacologic interventions shows that for people with dementia:

1. Use of pleasant events and activities matched to the preserved capabilities of persons with dementia, minimizes or eliminates troublesome behaviors such as depression, agitation, and anxiety;¹¹⁻¹⁴
2. Simplifying everyday tasks can help people with dementia remain independent for as long as possible at home;^{7, 12, 13}
3. Simple, low-cost, common assistive devices and training in their use by an occupational therapist can enhance home safety and help family caregivers manage troublesome behaviors and functional decline;¹⁸
4. More frequent brief medical assessments by a nurse or other healthcare provider may be necessary to screen for underlying but treatable illnesses or pain that may contribute to troublesome behaviors;^{7, 12}

In the Philadelphia region, we are now able to offer COPE as an outpatient, home care service for people with dementia who have Medicare and qualify for skilled care. However, most families do not have access to proven nonpharmacologic dementia care services.

The NIH supported multi-site randomized caregiver trial (Resources for Enhancing Alzheimer's Caregiver Health (REACH II))¹⁴ has shown important benefits to Hispanic, White, and spousal African American caregivers including reductions in burden, depression, and upset with behaviors in addition to improved quality of life and health. In response to the outcomes of this trial, Dr. Kenneth E. Covinsky, stated in an editorial in the *Annals of Internal Medicine* (2006):

"If these interventions were drugs, it is hard to believe that they would not be on the fast track to approval. The magnitude of benefit and quality of evidence supporting these interventions considerably exceed those of currently approved pharmacologic therapies [for dementia]."

Improving quality of life for individuals with dementia and their families is a fundamental treatment goal endorsed by health professionals.⁸⁻⁹ It is also one of the new goals added to the 2020 version of Healthy People 2020, the nations 10 year framework for prioritizing public health activities (<http://www.healthypeople.gov/topics/objectives/2020/overview.aspx?topicid=7>).

However, improving quality of life consistently receives far less attention and funding than drug research. The Rosalynn Carter Institute for Caregiving states that there are proven programs which are actually "more effective" than any known drugs for Alzheimer's disease and adds, "to not make them widely available to caregivers is shortsighted and a violation of the best principles of public health." (http://www.rosalynncarter.org/how_effective). These programs meet the gold standard for both drug and non-drug treatments: they have been proven effective in randomized controlled trials. And, unlike drug therapy, there are no adverse side effects.

There is also an economic argument to be made for better dementia and caregiver supportive programs. In 2009, the nearly 11 million family and other unpaid caregivers provided an estimated 12.5 billion hours of care to people with dementia. This care is valued at nearly \$144 billion.^{1,19} The country can not afford the consequences of family caregivers becoming burned out or too sick to carry on. Moving a person with dementia to a nursing home, while sometimes unavoidable, is expensive, can increase confusion and agitation, and can sometimes even contribute to an earlier death.

Non-pharmacologic therapies may save more than they cost. Peer-reviewed studies have shown that the NYU Caregiver Intervention of counseling and on-going caregiver support delayed nursing home placement by an average of 557 days. Since nursing home care costs an average of \$65,000 per year, this could mean a savings of \$100,000 per patient.¹⁹

An occupational therapy program at Thomas Jefferson University which tailored meaningful activities to the capabilities of individuals with dementia (Tailored Activity Program) showed that the average cost of the intervention was \$941.63 per family. The intervention proved to be cost effective: caregivers saved one extra hour per day “doing things” at a cost of \$2.37 per day; and caregivers saved up to 5 hours a day in time otherwise spent in hands-on care.²⁰⁻²² The cost of drug treatment is approximately \$5 per day or \$1,825 per year.¹⁹

The NIH REACH II initiative similarly found that 12 contacts including a combination of in-home skills-training and group telephone support was highly cost effective providing caregivers 1 extra hour per day not spent in caregiving, at a cost of \$5 per day. The intervention as with the Tailored Activity Program, provided the most scarce of caregiver commodities - time.²³

Non-pharmacologic therapies can be so cost-effective that, according to a 2009 report in the journal *Alzheimer's & Dementia*. “...failure to fund effective caregiver interventions may be fiscally unsound.”¹⁹

Despite the promise of nonpharmacologic approaches, there are many challenges. Chiefly, we lack a national strategy for developing a new standard of care for individuals with dementia and their families that includes comprehensive and on-going supportive proven nonpharmacologic medical, social, psychological, and home environmental services. A national strategy might include:

- Funding large scale demonstration projects that integrate the most promising nonpharmacologic approaches to date.
- Wide-spread training of health and human service professionals in proven dementia care and caregiver supportive programs.
- Expanding our current reimbursement structures to allow for the provision of existing proven caregiver and dementia care programs at home.
- Expanding funding to support implementation of proven programs into different practice settings including home care, hospital discharge services, care management systems.

I would like to close with a quote by Sandra Day O'Connor and Ken Dychtwald from their recent op-ed in the *New York Times*, on Oct. 28 2010.

“Our government is ignoring what is likely to become the single greatest threat to the health of Americans: Alzheimer’s disease is an illness that is 100 percent incurable and 100 percent fatal. It attacks rich and poor, white-collar and blue, and women and men, without regard to party. A degenerative disease, it steadily robs its victims of memory, judgment and dignity, leaves them unable to care for themselves and destroys their brain and their identity-often depleting their caregivers and families both emotionally and financially.”

I urge the Committee to move forward with a strategic vision for enabling nonpharmacologic strategies to become part of standard care that is available to all individuals with dementia and their

family members in order to address one of the most devastating diseases of our time and which soon will be an epidemic.

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**STATEMENT OF CHRISTINE R. KOVACH, PH.D., R.N., F.A.A.N.,
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Dr. KOVACH. Good afternoon. In my time with you this afternoon, I will be talking about nursing home care, posing a few of the problems and some solutions. Because 50 to 75 percent of nursing home residents have dementia, the topic of nursing home quality of care is particularly relevant for this population.

The needs of nursing home residents with dementia are often left unmet because staff do not know how to interpret dementia behaviors, complete a comprehensive assessment, or intervene to meet needs. In a recent 6-month period, the Milwaukee Police Department was called 386 times to nursing homes. Many of these calls were for behavioral issues. Commonly the individual is restrained and handcuffed in order for law enforcement officials to transport him or her. A "Chapter 51" petition is initiated so the person can be involuntarily committed to a psychiatric facility. These transfers in and of themselves create trauma for the individual, and can worsen health and behavior. In too many cases, emergency detention is being used as a vehicle to involuntarily medicate people with dementia and to discharge or get them out of the nursing home, despite the fact that the FDA has issued a black box warning against such use. This should not be happening. We can do better.

We have tested an assessment and treatment protocol called the "Serial Trial Intervention" in two randomized controlled trials funded by NIH, and the intervention was found to be highly effective in decreasing agitated behaviors, discomfort, and comorbid problems. However, widespread diffusion of this intervention into practice, particularly in poor-performing homes, will not be far-reaching without Federal implementation programs. Our research and that of others shows that dementia behaviors often represent a physical or psychosocial unmet need. For example, if a person is being moved into the bathtub and is resistive, that often means that the person is having arthritic pain, and if you time their medications more appropriately, you will prevent this behavior from happening. If the etiology for the behavior is psychosocial, teaching staff to provide better anticipatory care can prevent the problem or at least prevent it from escalating to a crisis point.

Our research found that the most important factor in determining the speed with which a change in condition is identified in people with dementia is the quality of the nurse's assessment. I will share one example from our study.

A woman with dementia began exhibiting behavior that was deemed to be paranoid and she was medicated with an antipsychotic drug. Anytime any staff member went into her room or approached her, she would go, no, no, oo, oo, and get very anxious.

Well, looking back on her chart, I could see that there was something going on with her right hip. Finally, 27 days after this behavior changed, her hip was finally x-rayed and she was found to have a fractured hip. This was this woman's method of communicating that if you move me, I am going to hurt, but yet she was medicated

inappropriately. Imagine the month of pain that this woman endured before she was diagnosed with a fractured hip.

So in terms of solutions, competence of staff needs to be improved through training, through requiring that more registered nurses provide care in the nursing home, and through the widescale transfer of empirically validated interventions, such as the Serial Trial Intervention, into clinical care in nursing homes. The goal is to reduce out-of-facility placement into general acute or acute psychiatric hospitals, and to keep people comfortable in the nursing home. The Serial Trial Intervention is a clear and straightforward protocol that is initiated when the person has a behavior change and it is unclear what the cause or the problem is.

I will share one case. A gentleman was living at home and highly agitated on a daily basis. He was restless and obsessively complaining about burning in his legs and a deep itch. The family could no longer cope with this behavior and he was transferred into the nursing home. He continued to be very restless and agitated. He was entered into our study and he complained about his legs saying, "I could go down there and pull my skin off." Many of you may recognize that this symptom is a pretty typical complaint for people who are having neuropathic pain. However, because he was a person who had dementia, people viewed the behavior as psychiatric in origin, and none of the care providers thought that it might be pain until they got to step 4 of our protocol. The nurse administered a low-dose analgesic, saw a dramatic difference in the resident's responsiveness, called the physician, and he was placed on an appropriate med for neuropathic pain.

The staff described his behavior following treatment as a day-and-night difference. He was now 100 percent relaxed. We have to wonder if earlier detection and treatment of his pain could have prevented or delayed his transfer to the nursing home.

I want to emphasize that the majority of people we assess and treat with this intervention are treated with non-pharmacological interventions. It is common for us to find that the person has too many environmental stressors, is not receiving enough exercise, is bored, or is not receiving enough meaningful human interaction. These needs are easily met with inexpensive non-pharmacological interventions that have no side effects.

My recommendation is that this intervention be used to transform nursing home care across the United States. This intervention is not costly, it's replicable and effective, and has been associated with no serious side effects.

Next, I would like to talk a little bit about the fact that nursing homes are where a lot of people die. Twenty-two percent of people in the United States die in nursing homes, and that number would be considerably higher if not for the very common practice of transferring people out of the nursing home into the hospital just prior to death. Nursing home staff should be experts in the palliative model of care, which calls for comfort, for caring for the whole person, and caring for the family. Yet, research consistently shows that nursing home staff are very poor at symptom management and that hospice services are under-utilized. When hospice services are used, nursing home staff then think the responsibility for man-

agement of symptoms lies with the hospice staff, so they decrease their engagement.

In terms of solutions, the competence of nursing home and hospice staff needs to be improved. Hospice staff, while great at cancer management, often have limited understanding of how to care for people with end-stage dementia at the end of life. Nursing home staff need increased education, and they need to be held more responsible for symptom management and for family counseling.

Next, I would like to talk about nursing home culture and environmental design contributing to physical and psycho-social problems. There are many things I could touch on here, but I want to mention that many nursing homes were initially designed based on a medical model for care delivery, with long corridors, institutional scale, and very rigid schedules.

This creates a host of problems. For example, bodies are meant to move. When bodies don't move, when their movement is limited, all sorts of problems ensue. People end up in wheelchairs, they end up falling, they end up developing pressure sores and muscles atrophy.

In terms of psycho-social problems, a psycho-social problem of becoming institutionalized has been described in multiple reports regarding nursing home care. In this process, people give up having preferences and control over their daily activities. These changes are accompanied by increased depression and anxiety, and decreased perceptions of quality of life.

Nursing home staff can provide all of the skilled care needed to residents in environments that are much more home-like in scale, and with schedules that are much less rigid, that allow for residents to retain more control over their daily lives. So in terms of solutions, I think we need to begin the process of expecting that dining rooms in nursing homes will be smaller, and more home-like; for there to be living rooms, and for there to be space and opportunity for participation in quality of life activities, as well as opportunities for maximum mobility in the immediate environment. The preferences of residents, even if provided by family proxy, need to take more precedence. These are things that can be done right now to significantly improve the quality of care and the quality of life for those with dementia in nursing home.

Thank you for your attention and your interest in improving the care delivered to people with Alzheimer's disease.

[The prepared statement of Dr. Kovach follows:]

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Aging Forum: Until There's a Cure: How to Help Alzheimer's Patients and Families NOW"

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Nursing homes are often perceived of as either ineffective "junior hospitals" or as poorly executed residential options. Two critical themes dominate the research literature on the U.S. nursing home industry: 1) many patients receive poor quality care; and 2) hiring and retaining a workforce that is satisfied and high performing is a major problem. Because 50% to 75% of individuals in nursing homes have dementia, the quality of nursing home care is particularly relevant for those with Alzheimer's disease and related dementias.

Nursing homes provide important skilled care, and the need for this skilled care will not abate in the near future. In my time with you this afternoon, I will briefly outline three problems and some solutions.

1. Nursing Home Staff Do Not Adequately Understand or Treat People with Dementia Behaviors

- a. Problem. The needs of nursing home residents with dementia are often left unmet because staff don't know how to interpret dementia behaviors (DBs), complete a comprehensive assessment or intervene to meet needs (White, McConnell, Bales & Kuchibhatla, 2004; Kovach, Logan, Simpson, & Reynolds, 2010). In a recent six month period, the Milwaukee Police Department was called 386 times to nursing homes. The police department reports that many of those were calls to respond to resident behavior issues (Alzheimer's Association Task Force Report, 2010). Commonly, the individual is restrained and handcuffed in order for the law enforcement official to transport him or her. The Chapter 51 petition is initiated so the person can be involuntarily committed to a psychiatric facility. The transfers,

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in and of themselves, create trauma for the individual and can worsen health and behavior. In too many cases emergency detention is being used as a vehicle to involuntarily medicate and discharge nursing home residents, despite the fact that the FDA has issued "black box" warnings regarding such use (Alzheimer's Association Task Force Report, 2010).

We have tested an assessment and treatment protocol called the Serial Trial Intervention in two RCTs funded by NIH and the intervention is highly effective in decreasing dementia behaviors, discomfort and new comorbid problems (Kovach, Logan, Noonan, Schlidt, Smerz, Simpson, & Wells, 2006). However, the diffusion of this intervention into practice, particularly in poor-performing homes, will not be far-reaching without federal implementation programs. Our research and that of others shows that dementia behaviors often represent an acute delirium superimposed on dementia, which is caused by a physical problem such as pain, or a psychosocial unmet need (Kovach, Kelber, Simpson, & Wells, 2006; Beck, Baldwin, Modlin, & Lewis, 1990; Sloane et al., 1997). For example, if a person resists being moved for bathing, the problem is often arthritic pain and timing the person's arthritis medication for peak action during the scheduled bath time will prevent resistive behavior. When the behavior does have a psychosocial etiology, improved training of staff in providing anticipatory care for psychosocial and environmental needs could prevent escalation of the behavior to a crisis point.

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Our research shows an astounding lack of assessment following behavior change and that nursing staff do not have knowledge of or utilize a wide array of available therapeutic interventions. We found that the most important factor in determining the speed with which a change in condition is identified is the quality of the nurse's assessment (Kovach et al., 2010). I will share one example from our study. A woman with dementia began exhibiting behavior that was deemed to be paranoia and she was treated with a psychotropic drug. If someone came close to her she would exclaim, "No, no no!" Looking back over her records there was also some indication that there were changes in her movement of her lower right extremity. Finally, on the 27th day after this behavior change was first documented, the person's hip was x-rayed and found to be fractured. Her behavior, becoming anxious and exclaiming, "no" when people approached her, was her way of communicating that something was wrong, that she would hurt if she was moved. Imagine the month of pain she endured without treatment for a fractured hip.

- b. Solutions. Competence of staff needs to be improved through training, through requiring that more registered nurses provide care in nursing homes, and through the wide-scale transfer of empirically validated interventions such as the Serial Trial Intervention to clinical care provided in the nursing home. The goal is to reduce out-of-facility placement in acute general or psychiatric hospitals and to keep people comfortable in the nursing home. The costs of treating many acute illnesses of nursing home residents are directly related to illness severity (Kruse,

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Mehr, Van Der Steen, et al. 2005). The Serial Trial Intervention is a clear and straightforward protocol that is initiated when a person with dementia exhibits a change in behavior and the person's need or the reason for the behavior change is not clear cut. It involves assessing to identify the person's physical, psychosocial or environmental need and intervening to treat that need when appropriate or consistent with the goals of care for that resident. If an etiology for the behavior change is not found, we utilize nonpharmacological comfort measures to try to ease the person's troubled state. If that is not effective we administer a low dose analgesic, to determine if the person may be in pain. We know this population is tremendously undertreated for their musculoskeletal and neuropathic pain, so a trial of analgesics is used. I'll share one case: A gentleman was living at home and highly agitated on a daily basis. He was highly restless and obsessively complained about burning in his leg and deep itch. The family caregivers could no longer cope and transferred him to the nursing home. He continued to be very restless and agitated. He was entered into our clinical trial and he complained about his legs, saying "I could go down there and pull my skin off." Many of you may recognize that this symptom is pretty typical of neuropathic pain. But because he was a person with dementia who had agitation, none of the care providers thought of that until the nurse got to Step 4 of the Serial Trial Intervention. The nurse administered a dose of prescribed Tylenol, saw an improvement, realized the pain was probably neuropathic in origin, called the physician and got the person started on medication indicated for neuropathic pain.

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The staff described his behavior following treatment as "a day and night difference in which he was now 100% relaxed. We have to wonder if earlier detection and treatment of his pain could have prevented or delayed his transfer to the nursing home. I want to emphasize that the majority of people assessed and treated with the Serial Trial Intervention are treated with non-pharmacological interventions. It is common for us to find that the person has too many environmental stressors, is not receiving enough exercise, is bored or is not receiving enough meaningful human interaction. These needs are easily met with inexpensive nonpharmacological interventions that have no side effects. My recommendation is that the Serial Trial Intervention be used to transform nursing home dementia care across the United States. This intervention is not costly, is replicable and effective and has been associated with no serious side effects.

2. Palliative Care is Poorly Executed.

- a. **Problem:** Nursing homes are where a lot of people die. Approximately 22% of all deaths in the United States occur in nursing homes (Centers for Disease Control, 2006). And this number would be considerably higher if not for the common practice of transferring nursing home residents to the hospital immediately prior to death (Mezey et al, 2002). Professionals working in long-term care should be experts in the holistic model of palliative care, which calls for comfort care and treatment of the whole person and family rather than futile attempts at curative care. And yet, this model has not been embraced. Research findings from nursing

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homes reveals poor symptom management (Teno, Weitzen, Wetle, & Mor, 2001) and low use of hospice care (Happe et al., 2002). When hospice services are used, nursing home staff then think the responsibility for management of symptoms lies with the hospice staff. Hospice staff, while great at cancer symptom management, often have limited understanding of end-stage dementia care, come into the facility from outside agencies, and do not know the resident or family well.

- b. Solutions: The competence of nursing home and hospice staff needs to be improved. Nursing home staff need increased education and need to be held more responsible for symptom management and family counseling. Building a trusting relationship with family members over time through regular family counseling can prepare the family for shifting medical goals to symptom management and comfort rather than futile attempts at cure. There is a need for increased use of hospice services in nursing homes, but many hospice staff need increased skills regarding end-stage dementia care.

3. Nursing home culture and environmental design contribute to physical and psychosocial problems.

- a. Problem. It has been said regarding nursing homes, "There are few nurses and it is not a home." Many nursing homes were initially designed based on a medical model for care delivery with long corridors, an institutional scale, and rigid schedules for activities. This creates a host of problems. For example, bodies are meant to move. They break down in all sorts of ways when movement is limited. When there are decreased opportunities for remaining safely mobile, muscle

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atrophy, increased falls, use of wheelchairs, and resulting pressure sores and other problems associated with immobility occur.

A psychosocial process of becoming "institutionalized" has been described in multiple reports regarding nursing home care (Krause & Shaw, 2000). In this process people give up having preferences and control over their daily activities. These changes are accompanied by increased depression and anxiety as well as decreased perception of quality of life. Nursing home staff can provide all of the skilled care needed within more homelike settings and with less rigid schedules that allow for residents to retain more control over their daily lives.

- b. Solutions. We need to begin the process of expecting dining rooms in nursing homes to be small and homelike, for there to be living rooms, and for there to be space and opportunity for participating in quality-of-life activities and maximum mobility in the immediate environment. The preferences of residents, even if provided by family proxy, need to take more precedence.

There are things that can be done right now to significantly improve quality of care and quality of life for those with dementia in the nursing home. Thank you for your attention and your interest in improving the lives of those with Alzheimer's disease and related dementias.

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STATEMENT OF PATRICIA L. MCGINNIS, EXECUTIVE DIRECTOR, CALIFORNIA ADVOCATES FOR NURSING HOME REFORM, SAN FRANCISCO, CA

Ms. MCGINNIS. Good afternoon. I want to thank the committee and certainly the staff of the Senate Special Committee on Aging for inviting our organization to address this very important forum.

Our organization, California Advocates for Nursing Home Reform, is based in San Francisco and it has been active for over 28 years assisting people who need long-term care, and their caregivers and relatives. For more than 28 years, our organization has heard, firsthand, the confusion, distress, and loss that is associated with the misuse of anti-psychotic drugs, and other psychoactive medications, to chemically restrain nursing home residents who have dementia.

I want to start by reading a statement about nursing home drugging. "Excessive use of tranquilizers can quickly reduce an ambulatory patient to a zombie, confining the patient to a chair or bed, causing the patient's muscles to atrophy from inaction and causing general health to deteriorate quickly. It appears many doctors give blanket instructions to nursing home staff for the use of tranquilizer drugs on patients who do not need them."

This statement sounds as if it was made very recently, but in fact, it was made before Congress in 1970, and it was included in a 1975 report by the Senate Special Committee on Aging titled, "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks." Everything old is new again. Unbelievably, the problems have worsened considerably in the last 35 years.

Today, drugging has reached epidemic levels. Nationally more than 350,000 nursing home residents—one of every four residents—are given anti-psychotic drugs. The vast majority of these residents suffer from dementia, and are receiving drugs off-label, meaning that the drugs are provided to control behavior, and not to treat a diagnosed mental illness. The way anti-psychotic drugs are used in nursing homes is a form of elder abuse—let's not kid ourselves. Instead of providing individualized care, many nursing homes indiscriminately use these drugs to sedate and subdue residents.

Anti-psychotic drugs carry black-box warnings indicating that their use nearly doubles a person with dementia's risk of death. But nursing home residents and their representatives are rarely informed about these warnings. Anti-psychotics don't just hasten death, they often turn elders into people their own families don't even recognize by dulling their memories, sapping their personalities and crushing their spirits.

I'd like to make it clear for the Committee that, while some psychoactive drugs may have positive benefits for the treatment of depression, anxiety, or even dementias, the drugs we are focusing on today are anti-psychotics, such as Seroquel, Risperdal, Zyprexa, and Haldol, which was the drug of choice in the nineties. These drugs are designed for the treatment of schizophrenia. There are many reasons that anti-psychotic drugs have become the first alternative for intervention in nursing homes, particularly for residents who exhibit agitation or aggression. Drugs are cheaper than staff,

at least on a short-term basis, as most of these drugs are paid for by Medicare. I think the last year, it was about \$5 billion.

Additionally, many doctors who prescribe these drugs and the pharmacists who dispense them for dementia are ignorant of the risks and effects of the drugs prescribed, and in some cases, these doctors and pharmacists are intentionally misled by pharmaceutical companies. Just since 2009, over \$4 billion has been paid to the Federal Government by drug manufacturers to settle charges of fraudulent marketing, false claims, and kickback schemes.

Finally, reimbursement for alternative therapies—particularly for therapists, psychologists, and psychiatrists—are very limited under the Medicare and Medicaid programs. It's a shameful situation, but believe it or not, there are actually some positives in this situation, as well. If the biggest problem with drugging is that it is the first measure in behavioral control for people with dementia it, is also a gateway for the inevitable solution. If we shift this culture and deemphasize drugging, we can dramatically reduce the misuse of anti-psychotic drugs for people with dementia, and most importantly, improve their quality of life.

We already know what an effective campaign to shift this culture looks like. Over the last 25 years, there has been a pronounced effort by consumers, advocates, the government, providers, and others to stop the inappropriate use of physical restraints in nursing homes. The result has been startling. Physical restraint use has dropped from more than 25 percent of all residents, to less than 3 percent. The key to this has been concentrated and sustained education, awareness, effort, oversight and enforcement.

Our organization, CANHR, has initiated a campaign in California to stop drugging in California, and we are hoping that it will take root—throughout the Nation. Our campaign combines practical advice for residents and their families and caregivers on how to stop the misuse of drugs, along with a broad movement to raise awareness, strengthen laws and enforcement, and target offenders.

The Website includes a well-received video series and a free advocacy guide called "Toxic Medicine," that we've distributed to the committee.

We've also posted, very significantly for consumers, information on every California nursing home's use of anti-psychotic drugs, to help consumers avoid facilities that are using these drugs indiscriminately. The information shows that a resident's risk of being drugged varies tremendously by nursing home, with some facilities reporting no use of anti-psychotic drugs, while others drug all of their residents, or a majority of their residents.

The campaign also has a political component, including a petition to the Governor, and proposed legislation to strengthen informed consent requirements. I cannot emphasize enough the importance of informed consent in resolving this problem. It's not just about informing people about the risks and alternatives to these drugs, it's about treating people who suffer from Alzheimer's and dementia with dignity and respect, by recognizing their right to make decisions about their treatment. A culture of respect for victims of this disease will go a long way in curbing the drugging problem.

We also believe our campaign is a good model for a national campaign on this issue, and I urge the committee, and Congress, to

hold hearings on the misuse of anti-psychotics and to embrace the recent national recommendations made by the Consumer Voice to stop the chemical restraint of nursing home residents.

A couple of the key recommendations are as follows: First, Congress should adopt laws protecting the rights of nursing home residents to give informed consent before they are drugged. Both American common law and various State statutes protect the right of informed consent, but it does not appear in Federal nursing home laws. Codifying informed consent would give national priority to the concept that people with dementia—as any other healthcare recipients—deserve complete information about proposed treatments and have the right to ultimately decide what medications they can and cannot take.

Second, we propose an education campaign to elevate the issue of anti-psychotic drugs for people with dementia into the national consciousness. The Campaign for Families and Advocates for People with Dementia would offer information about anti-psychotic drugs, from the types of medications that are most often abused, to the side effects and black-box warnings, to the supremacy of alternative approaches, many of which we have heard about today.

As part of this education campaign, CMS should post each nursing home's drugging rate on its "Nursing Home Compare" Website, so that consumers can locate nursing homes that don't use anti-psychotic drugs as a substitute for basic dementia care.

For healthcare providers, the education campaign would offer best practices for doctors, pharmacists, and facilities, stressing that if anti-psychotic drugs are to be used at all, they should be used only as a last resort after all non-pharmacologic interventions have been attempted and failed. The essence of these practices should be the promotion of individualized care. Individualized care—as we all know, and we've known for years—fosters non-pharmacologic interventions by placing a premium on relationships with people who have dementia, and dignified care approaches, such as increased exercise, formal activities and pain management.

A recent study showed Vermont was able to dramatically reduce the use of anti-psychotics in nursing homes by focusing on relatively simple alternatives. One alternative was learning about a resident's past, so as to better understand the resident's needs and personality; understanding who the resident is.

Another alternative is providing consistent care in nursing homes, i.e., consistent schedules for nursing home staff so that they work with the same resident, and then they can understand the resident's personality and they can pick up on the early signs of any disturbances, or signs of personality changes.

What is especially helpful about these non-pharmacologic interventions is that they are less costly than drugging. Aside from the obvious high cost of the drugs themselves is the very expensive health care outcomes that they often precipitate—things like falls, infections, strokes, and hospitalizations that are often covered under the Medicare program, and which add to the escalating costs of Medicare and Medicaid.

Using pills to substitute for one-on-one care, or for adequate staffing, turns out to be not only bad medicine, but also a poor use of our resources. Reimbursement for alternative, non-pharmaco-

logic interventions—particularly psychotherapy services and many of the interventions and model projects we've heard about today—should definitely be expanded.

Congress should investigate, and the U.S. Government should continue to aggressively pursue, drug companies' marketing of off-label uses of anti-psychotics for nursing home residents.

I want to make a final conclusion. Twenty-five years ago the Senate Special Committee on Aging urged a coordinated attack on the dangerous drug misuse in nursing homes led by Federal and State officials. With your help, we can begin that attack again, and maybe this time actually be successful. We call upon our national leaders to not only join a campaign to end over drugging in nursing homes, but to lead this campaign. Thank you.

[The prepared statement of Ms. McGinnis follows:]

CANHR *Long Term Care Justice and Advocacy*

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Until There's a Cure: How to Help Alzheimer's Patients and Families NOW

**U.S. Senate Special Committee on Aging Forum
December 8, 2010**

**Testimony of Patricia L. McGinnis
California Advocates for Nursing Home Reform**

Mr. Chairman, members of the Committee, I thank you for this opportunity to participate in today's very important forum. I'd particularly like to thank the staff of the Senate Special Committee on Aging for organizing the forum. My name is Pat McGinnis and I am the Executive Director of California Advocates for Nursing Home Reform, a nonprofit organization in San Francisco that assists and advocates for people who need long-term care.

For more than 25 years, our organization has heard first-hand the confusion, distress, and loss that is associated with the misuse of antipsychotic drugs and other psychoactive medications to chemically restrain nursing home residents who have dementia. I want to start by reading a statement about nursing home drugging:

"Excessive use of tranquilizers can quickly reduce an ambulatory patient to a zombie, confining the patient to a chair or bed, causing the patient's muscles to atrophy from inaction and causing general health to deteriorate quickly . . . it appears many doctors give blanket instructions to nursing home staffs for the use of tranquilizer drugs on patients who do not need them."

This statement sounds as if it was made very recently but it was actually made before Congress in 1970 and included in a 1975 report prepared by the Senate Special Committee on Aging titled "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks." Unbelievably, the problems have worsened in the 35 years since the Senate detailed them.

Today, the drugging problem has reached epidemic levels. Nationally, more than 350,000 nursing home residents – one of every four residents – are given antipsychotic drugs. The vast majority of these residents suffer from dementia and are receiving the drugs off-label, meaning the drugs are provided to control behavior and not to treat a diagnosed mental illness.

The way antipsychotic drugs are used in nursing homes is a form of elder abuse. Instead of providing individualized care, many homes indiscriminately use these drugs to sedate and subdue residents. Antipsychotic drugs carry black box warnings indicating that their use nearly doubles a person with dementia's risk of death, but nursing home residents and their representatives are rarely informed about these warnings. Antipsychotics don't just hasten death, they often turn elders into people their own families barely recognize by dulling their memories, sapping their personalities and crushing their spirits.

We would like to make it clear to the Committee that, while some psychoactive drugs may have positive benefits for the treatment of depression, anxiety, or even dementias, the drugs we are focusing on today are antipsychotics, such as Seroquel, Risperdal, Zyprexa and Haldol, which are designed for the treatment of those with schizophrenia.

There are many reasons that antipsychotic drugs have become the first alternative for intervention in nursing homes, particularly for residents who exhibit agitation or aggression. Drugs are cheaper than staff – at least on a short-term basis – as most of these drugs are paid for by Medicare. Additionally, many doctors who prescribe these drugs and the pharmacists who dispense them for those with dementia are ignorant of the risks and effects of the drugs prescribed and, in some cases, are intentionally misled by pharmaceutical companies. Just since 2009, over four billion dollars has been paid to the federal government by drug manufacturers to settle charges of fraudulent marketing, false claims, and kickback schemes. Finally, reimbursement for alternative therapies, particularly for therapists, psychologists and psychiatrists are limited under both Medicare and Medicaid.

It is a shameful situation, but there are some positives in this situation as well. The biggest problem with drugging, the pervasive culture that treats drugs as the first measure in behavioral control for people with dementia, is also a gateway to the inevitable solution. If we are able to shift this culture and de-emphasize drugging, we can dramatically reduce the misuse of antipsychotic drugs for people with dementia and, most importantly, improve their quality of life.

We already know what an effective campaign to shift this culture looks like: over the last 25 years there has been a pronounced effort by consumers, advocates, the government, providers and others to stop the inappropriate use of physical restraints in nursing homes. The result has been startling. Physical restraint use has dropped from more than 25% of all residents to less than 3%. The key has been concentrated, sustained education, awareness, effort, oversight and enforcement.

CANHR has initiated a campaign to stop drugging in California and we are hoping that it will take root throughout the nation. Our campaign combines practical advice for residents and their families on how to stop misuse of the drugs, along with a broad movement to raise awareness, strengthen laws and enforcement, and target offenders. This past summer we launched a first-of-its-kind website on this campaign that includes a great deal of information to help consumers learn about their rights, the risks of the drugs, and most importantly, the effective alternatives such as those highlighted today. The site includes a well-received video series and a free advocacy guide, "Toxic Medicine", that we have distributed to the Committee.

We've also posted specific information on each California nursing home's use of antipsychotic drugs to help consumers avoid facilities that are using these drugs indiscriminately. The information shows that a resident's risk of being drugged varies tremendously by nursing home, with some facilities reporting no use of antipsychotic drugs while others drug all or nearly all of their residents.

The Campaign also has a political component, including a petition to the Governor and proposed legislation to strengthen informed consent requirements. I cannot emphasize enough the importance of

informed consent in resolving this problem. It's not just about informing people about the risks and alternatives to these drugs, it's about treating people who suffer from dementia with dignity and respect by recognizing their right to make decisions about their medical treatment. A culture of respect for victims of this disease will go a long way toward curbing the drugging problem.

We believe our campaign is a good model for a national campaign on this issue. I urge the Committee and Congress to hold hearings on this problem and to embrace the recent national recommendations made by Consumer Voice to stop the chemical restraint of nursing home residents. I will discuss a couple of the key recommendations.

First, Congress should adopt laws protecting the rights of nursing home residents to give informed consent before they are drugged. American common law and various state statutes protect the right of informed consent, but it does not appear in federal nursing home law. Codifying informed consent requirements would give national priority to the concept that people with dementia, as any other health care recipients, deserve complete information about proposed treatments and the right to ultimately decide what medications they take.

Second, we propose an education campaign to elevate the issue of antipsychotic drugs for people with dementia into the national consciousness. The campaign would focus on people with dementia, their families and advocates, as well as health care providers. For people with dementia and their families and advocates, the campaign would offer information about antipsychotic drugs - from the types of medications that are most often abused, to side effects and Black Box warnings, to the supremacy of alternative approaches that we've heard about today. As part of the education campaign, CMS should post each nursing home's drugging rate on Nursing Home Compare so that consumers can locate nursing homes that don't use antipsychotic drugs as a substitute for basic dementia care.

For health care providers, the education campaign would offer best practices for doctors, pharmacists and facilities, stressing that, if antipsychotic drugs are to be used at all, they should only be

used as a last resort after all non-pharmacological interventions have been attempted and failed. The essence of these practices should be the promotion of individualized care.

Individualized care fosters non-pharmacological interventions by placing a premium on relationships with people who have dementia and dignified care approaches such as increased exercise, formal activities, and pain management. A recent study in Vermont was able to dramatically reduce the use of antipsychotics in nursing homes by focusing on relatively simple alternatives. One alternative was learning more about a resident's past, so as to better understand the resident's needs and personality. Another alternative was giving nursing home staff more consistent schedules so they work with the same residents and learn to pick up on early signs of trouble and circumvent bad behaviors.

What is especially helpful about non-pharmacological interventions is that they are less costly than drugging. Aside from the obvious high costs of the drugs themselves is the very expensive health outcomes they often precipitate – falls, infections, strokes, and hospitalizations that add to the escalating costs of Medicare and Medicaid. Using pills to substitute for one-on-one care or for adequate staffing turns out to be, not only bad medicine, but also a poor use of resources. Reimbursement for alternative psychotherapeutic interventions, particularly psychotherapy services, should be expanded.

Congress should investigate and the U.S. Government should continue to aggressively pursue drug companies' marketing of off-label uses of antipsychotic drugs for nursing home residents.

Heightened awareness and increased information can make a major difference in the quality of lives of people with dementia. The massive reduction in physical restraint use in nursing homes is concrete evidence that federal leadership, coupled with an empowered consumer voice, can reach the far corners of the local nursing home, change the practices of health care providers and influence care in a way that dramatically improves the lives of our citizens with dementia.

Here is what we know:

- 1) The misuse and overuse of psychotropic drugs for people with dementia is at an all-time high;

- 2) There are many non-pharmacological alternatives to drugging that not only lead to better outcomes for people with dementia, but are also much less costly; and
- 3) A campaign to end over-drugging could improve the lives of perhaps millions of people with dementia.

Thirty-five years ago, the Senate Special Committee on Aging urged a “coordinated attack” on dangerous drug misuse in nursing homes, led by federal and state officials. With your help, we can finally begin that attack. Everyone here has demonstrated the sincerity of their concern for the plight of people with Alzheimer’s disease and other dementia-related illnesses. We call upon our national leaders to not only join a campaign to end over-drugging but to lead it.

**STATEMENT OF ROBERT EGGE, VICE PRESIDENT, PUBLIC
POLICY ALZHEIMER'S ASSOCIATION, WASHINGTON, DC**

Mr. EGGE. I want to thank, first of all, Chairman Kohl and Ranking Member Corker for this forum today. It's an outstanding presentation. I also want to thank the panelists for what I thought were very illuminating discussions with a common theme from a range of approaches—all were very helpful.

I have been given the unenviable task—along with Eric—of trying to summarize this in 5 minutes, from my perspective. I want to do so, though, by starting out, even with that time constraint, by acknowledging the leadership of this committee over recent years on Alzheimer's disease and related dementias. A year ago, in 2009, there was a hearing here where the results of the Alzheimer's Study Group's findings were presented along with key recommendations. One of those recommendations led to the bill that the chairman referenced earlier, the National Alzheimer's Project Act, which is right now poised, we believe, for passage in this Congress in the remaining weeks and signed into law. This legislation is extremely important for reasons that have been alluded to by panelists today. We need a comprehensive strategy for Alzheimer's and related dementias; a strategy that addresses the full range of issues, and it has to be a strategy that not only looks at issues like how do we encourage the dissemination of psychosocial interventions, but also one that approaches these issues with a bias for action. That bias for action, I think if you've listened today you've heard clearly, why we need that action emphasis in what we do. It is certainly true that, as you look at the dimensions of the Alzheimer's crisis and other dementias, you see repeatedly the cause for moving quickly.

You've heard today, that already, 5.3 million Americans have Alzheimers and 11 million serve as unpaid caregivers. You also have heard how, with the aging of our population, these numbers are going to increase dramatically to as many as 16 million Americans with Alzheimer's and other dementias. Of course, this means an increase in caregiver demands.

At the same time, you've heard reasons why this population is so costly to care for. Research that we have commissioned from Dartmouth University looking at Medicare claims data, has found that Medicare beneficiaries with Alzheimer's and other dementias, cost three times more than comparable beneficiaries without cognitive impairment. In the case of Medicaid, the ratio is nine times more. Again, you've heard reasons why this is true.

But also we've heard today that there is cause for hope that better care could lead to better outcomes. The other side of what we face today is the nature of this disease; it has to be said for the record what a cruel disease this is. It is a terminal disease, it is a progressive disease. We have no cure for this disease, we have no prevention strategy to stop its onset or even a way to slow the underlying progression of the disease. It's the sixth leading cause of death today, and of the leading causes of death, it's the only one for which we can cite those facts. So again, we need to act, and we need to act urgently.

In terms of what ought to be done, there's three major points I want to emphasize, here. The first I've already referenced, which

is a comprehensive strategy to approach this—to address things like psychosocial interventions that we’ve heard about today.

The second is in the area of research. I just want to make two quick points about that. The first is, often with research we think about what we ought to think about, which is biomedical research. We’ve also heard today from panelists about the important research that’s funded through the NIH and other agencies that deals in other ways—non-pharmacologic—with this, that are leading to outstanding results, and that too is an important cause for research investment.

Also, as we look at this from a systems perspective, we realize that the importance of having effective interventions is what makes, in part, more effective care possible. Some of you may have heard Dr. Zerhouni, former Director of the NIH, talk about as a physician at John’s Hopkins in the eighties, that looking at the HIV/AIDS crisis unfolding then they projected that soon all of their beds, or a large proportion, would be overwhelmed by the needs of caring for this population.

Fortunately, as means of prevention were disseminated, and interventions were developed, these changed that picture. That’s very much where we are right now from a care perspective as we look at an aging population, especially with Alzheimer’s and dementias. That is the course we’re on, if we don’t develop these kinds of approaches and disseminate them quickly.

Finally to go specifically to the thrust of this forum today, we must look at care practices. We’ve already heard today about what we think is an outstanding development this year in this foundational effort, which is a provision for cognitive impairment detection in the Medicare annual wellness visit. Much of what is discussed today is predicated on identifying these cases early and making sure we do what needs to be done.

On that latter point, in this past year, in the Senate and in the House, a bill was introduced called the “Health Outcomes Planning and Education for Alzheimer’s Act.” What this bill does is that it provides—once there is detection—for a package of services, notation in the medical record, and care planning.

We’ve heard reasons why this is very important. For instance, the reference earlier to self-reported of pain among those who are cognitively impaired. You need a notation of cognitive impairment to follow that person across different care settings to allow for care interventions to track those kinds of insights. In terms of care planning, we have also heard, amply today, about the many evidence-based programs that can be implemented when there’s a mechanism to encourage and provide for that kind of care planning. From the Alzheimer’s Association’s perspective, we have worked to advance each stage of these processes.

First of all, our chapters have often been partners with the national organization and partners with the development of the research evaluation, with the AoA, with the Veteran’s Administration, with NIH, and with others to develop this evidence base. As protocols have been verified by evidence to be effective—and we’ve heard about some of those, again, today, we have worked to disseminate those in a variety of ways.

In one set of interventions, we have spoken directly to families; those with the disease and caregivers. We reach them in whatever way is most appropriate, whether it's through our call center, as you've heard about earlier today, that's available every minute of the year. Whether it's online tools or whether it's in-person support—there are support groups and other training opportunities.

Also, in terms of the training for professionals who provide care, we provide training, based again on the evidence of which we've heard today, to these care professionals—both in-person training and also online through video-based training and other mechanisms—and try to disseminate these insights as quickly as we can. Also, on that front, we have worked with partners to develop practice recommendations across a variety of care settings so that, again, what we have heard about today and what we have learned is applied widely, and as quickly as possible. Our challenge is—everybody's challenge is, of course, to continue the development we've had along these fronts to understand what ought to be done as quickly as possible, and then to work together to make sure that these insights are applied as quickly and widely as we can.

So I thank the committee very much for this conversation today. I thank the panelists, and I look forward to a continued conversation with each of you about how to move forward. Thank you.

[The prepared statement of Mr. Egge follows:]

U.S. Senate Special Committee on Aging
 "Until There's A Cure: How to Help Alzheimer's Patients and Families NOW"

Testimony of Robert Egge, Vice President of Public Policy
 Alzheimer's Association

December 8, 2010

Good afternoon Chairman Kohl, Senator Corker and members of the Senate Special Committee on Aging.

I am Robert Egge, Vice President of Public Policy at the Alzheimer's Association. Thank you for the opportunity to share our current efforts, with particular reference to quality care for those suffering from Alzheimer's disease and other forms of dementia.

It is a privilege to participate in this Forum hosted by a Committee that has distinguished itself through its focus on the scale of and solutions to the Alzheimer's crisis. Both in 2008 and in 2009, the United States Senate Special Committee on Aging hosted important hearings featuring the findings of the Alzheimer's Study Group, an independent, bipartisan taskforce convened to assess the crisis and propose recommendations. I served as Executive Director of that effort, joining the Alzheimer's Association in my current role upon the completion of the Study Group's work.

About Alzheimer's Disease

Since its inception in 1980, the Alzheimer's Association has led the Alzheimer movement: promoting and funding innovative research; speaking out for greater public awareness and the need for increased research, prevention, and care; and actively engaging with the national and local communities to support and expand outreach that ensures greater knowledge, safety, and resources for Alzheimer's patients and their families.

The urgency of the Alzheimer's Association's work is driven by the millions now affected by Alzheimer's. Today, an estimated 5.3 million people suffer from Alzheimer's in the United States¹ and approximately 36 million are affected worldwide.² By 2050, there will be nearly 16 million Americans suffering from Alzheimer's, with a projected global total of more than 115 million.

Furthermore, today nearly 11 million Americans serve as unpaid caregivers for individuals suffering from this disease. According to Alzheimer's Association Facts and Figures, these Alzheimer and dementia caregivers dedicate as many as 12.5 billion hours of care valued at \$144 billion for care for their loved ones. Alzheimer's is a disease that lasts, on average, four to eight years from the time of diagnosis. Because there is no means to stop the progression of the disease, those with Alzheimer's who do not die first of other causes eventually lose the ability to converse with others and respond to their environment, requiring caretakers to provide constant supervision and attentive care.

¹ Alzheimer's Association, *2010 Alzheimer's Disease Facts and Figures*.

² Alzheimer's Disease International, *World Alzheimer Report 2010*

A combination of early detection and preventive or disease modifying medications will likely be needed to overcome this disease. In the meantime, however, much can be done to improve the care and support delivered to those with Alzheimer's and their caregivers.

The Alzheimer's Crisis Today, and How We Should Respond

In March 2009, the Alzheimer's Study Group's report, *A National Alzheimer's Strategic Plan*, was released in the hearing before this Committee. In their testimony co-chairs Speaker Newt Gingrich and Senator Bob Kerrey, ASG member Justice Sandra Day O'Connor, and California First Lady Maria Shriver focused on four elements:

- the scale of the Alzheimer's crisis,
- the need for a comprehensive federal strategy to address the crisis,
- the importance of increasing Alzheimer's research investment, and
- the improvements immediately possible in Alzheimer's care and support.

In my comments below, I would like to briefly revisit these four areas, emphasizing their relevance to today's important discussion.

The Scale of the Crisis

Today, the Alzheimer's Study Group concluded, Alzheimer's is already a grave national crisis. Tomorrow, because of America's rapidly aging population and the fact that age is the greatest risk factor for the disease, the Alzheimer's crisis will rapidly worsen. In fact, given current trends there is good reason to believe it may prove to be the leading U.S. public health crisis of the 21st Century. By 2050 as many as 16 million Americans will have the disease. The corresponding demands on caregivers will grow apace.

The numbers alone do not make Alzheimer's a crisis. What makes this a crisis are these numbers combined with the nature of the disease itself. Alzheimer's is a progressive, degenerative and ultimately fatal disease. It is cruel, and it is a killer. It kills by insidiously clogging and destroying the most vital of organs – the brain. In fact, it is one of the surest killers we know of. If you develop Alzheimer's we can say with absolute certainty that you will either die with it or from it.

Alzheimer's is already the sixth leading cause of death in this country. According to the Centers for Disease Control and Prevention, in 2007 – the most recent year for which data are available – Alzheimer's killed more Americans than diabetes, and more than breast cancer and prostate cancer combined. Further, of the top ten causes of death in America today, Alzheimer's is the only one among them without an identified means prevent, cure or even slow the disease.

The economic factors of Alzheimer's rival the human devastation of the disease. According to the Alzheimer's Association's report, *Changing the Trajectory of Alzheimer's Disease: A National Imperative*, we are spending \$172 billion annually on Alzheimer's and other dementia care in America. \$88 billion of that is for Medicare alone, which is 17 percent of the total Medicare budget. Medicare beneficiaries with Alzheimer's or another dementia cost the system three times more than someone else 65 or older in

Medicare who does not have a dementia.³ For Medicaid, the cost multiplier for someone with dementia is nine times more than a comparable individual.⁴

Alzheimer's also serves as a cost multiplier for other conditions. 95% of Americans with Alzheimer's or other dementia have one or more other serious medical conditions as well. Largely because Alzheimer's strips away an individual's ability to manage these other conditions, such as diabetes or cardiovascular disease successfully, the costs of care for people with these other conditions are far higher when they also have dementia. For instance, average per person Medicare payments for a person with diabetes are \$12,979, but for a person with both diabetes and Alzheimer's or another dementia average annual costs are \$20,655. The same is true for heart disease – those with only heart disease have average Medicare claims of \$14,640, while those that also have Alzheimer's or another dementia have annual costs of \$20,780.

Just as the numbers of those with Alzheimer's will grow sharply in the coming years, so will the costs. The *Trajectory* report also estimates that during the next 40 years, the cost of Alzheimer's and other dementias will exceed \$20 trillion.

The Imperative to Form a Federal Plan of Action

One of the most striking findings to the Alzheimer's Study Group was the mismatch between the dimensions of the crisis as just described, and the lack of a disciplined, strategy-driven federal plan to address it. And so one of their central, immediate recommendations presented before this committee was to embark on a process by 2010 to create a cross-governmental Alzheimer's plan characterized by clearly articulated objectives, accountabilities, and timelines. Updates and progress against this plan were to be reported annually to Congress and to the American people.

Fortunately, thanks to the leadership of members of this committee as well as other members in the Senate and the House, we are close to a major advance on this recommendation. The *National Alzheimer's Project Act* (NAPA), based directly on the Alzheimer's Study Group recommendations and drafted in close consultation with the Alzheimer's Association, is poised for passage into law this year.

This is highly important given the topic under discussion today in this Forum, for this strategic planning effort is not just to be focused on one agency or on one topic, such as biomedical research. Instead, this effort is intended to address all dimensions of the current crisis, and all opportunities to address them. For instance, many Alzheimer's experts make a compelling case that one of the most immediately promising and underfunded areas of Alzheimer's research is in the area of psychosocial interventions. The systematic planning process that will be set in motion by NAPA is designed to expose exactly such shortcomings and to ensure that they are adequately addressed.

Alzheimer's Research and its Critical Relationship to Care and Support

³ Alzheimer's Association, *Changing the Trajectory of Alzheimer's Disease: A National Imperative*; CBO's August 2010 Baseline: Medicare.

⁴ Alzheimer's Association, *2010 Alzheimer's Disease Facts and Figures*.

Alzheimer's impact is so immense in part because there are no treatments that delay onset or slow, let alone reverse or cure, the progression of the disease. This is not a matter that is independent of care. Too often we speak as if the emphases – cure and care – were completely unrelated.

In fact, it is the absence of good therapeutic interventions that makes the provision of care for those with Alzheimer's and other dementias so worrisome. As has been well documented by this committee and elsewhere, one of the looming constraints in caring for those with Alzheimer's compassionately and effectively is the declining geriatrics workforce, and the growing gap between the size of this workforce and the growing demands placed upon it as Alzheimer's cases steadily expand.

One way to close this gap is to increase the size of the geriatrics-capable healthcare workforce. There are excellent proposals today to do just that. Another way to address the gap, however, is on the demand side – that is, by reducing the number of Americans in need of Alzheimer's care through more effective therapeutic options.

To examine this, the Alzheimer's Association worked with the Lewin Group to create a dynamic model that examined the current baseline case where future therapeutic options remain much as they are today, and then contrasted this baseline with two scenarios. In the first, a hypothetical therapy was modeled that delayed the onset of Alzheimer's by five years, much like statins for cardiovascular diseases. In the second, a hypothetical therapy was modeled that slowed the progression of the disease, much as current therapies do in the case of HIV/AIDS.

In both cases, perhaps the most obvious impact was the reduction of healthcare and support costs. For instance, the five year delay in onset scenario reduced costs by almost 50%. But just as remarkable from a care and support perspective, in both cases the number of those with the disease in the moderate and severe stages were dramatically reduced. What this suggests is that with such treatment advances far fewer individuals would require full time attention in a long term care facility, hospital or hospice. Better treatments enable better care.

Improvements Underway in Alzheimer's through Dementia Care and Training

Finally, the Alzheimer's Study Group focused on care and support. And as they did so, they looked to the topic of this Forum, dementia care and training, as an essential key to progress.

For more than 28 years, the Alzheimer's Association has been committed to improving care for people with Alzheimer's and related dementias. The Association has consistently championed dementia care that is safe and respectful for each individual as well as to train providers and caregivers to provide the best possible dementia care.

The Alzheimer's Association Dementia Care Practice Recommendations for Assisted Living Residences and Nursing Homes were developed from the latest evidence in dementia care research and the experience of professional direct care experts. The dementia care practice recommendations and our trainings are based on a person-centered approach to dementia care. This means that care builds on a person's abilities and meets the changing needs of each person as the disease progresses.

The Alzheimer's Association understands the significant strain the aging population will pose on the country's long-term care infrastructure and we believe we can play an important role in building the quality workforce necessary to care for this emerging Alzheimer population. Ensuring appropriate training for all long-term care workers is consistent with the Alzheimer's Association's long standing policy that families must have access to quality care across the spectrum of home and community based care options including assisted living facilities, adult family homes, or state-licensed boarding homes. The recommendations and training reflect the importance of care providers having a good relationship with the person with dementia and his/her family as well as knowing the person's history, abilities, and choices about care. Care providers will be most successful if they have good dementia care training.

With more than 50 percent of residents in assisted living and nursing homes having some form of dementia or cognitive impairment and approximately 70 percent of people with dementia or cognitive impairment living at home, the Association launched several programs which explore different care training models and provide evidence based recommendations for both caregivers and health care providers.

In an effort to empower people with dementia, their caregivers and families to make informed decisions, we have developed the Alzheimer's Association CareFinder™. This interactive online guide is educating consumers on how to recognize quality care, choose the best care options, and advocate for quality within a residence.

Also for families, the Association has developed the *Savvy Caregiver*. This is an educational program for families and caregivers of those with memory loss, dementia, and Alzheimer's disease and has been developed and tested in research at the University of Minnesota.

To increase education among health care and direct care providers, the Association created several programs including:

- **The Foundations of Dementia Care.** A classroom training program that is offered by Alzheimer's Association chapters nationwide. The *Activity-based Alzheimer Care: Building a Therapeutic Program* helps professionals that implement activity programming.
- **The CARES training program.** An online dementia care training program for Certified Nursing Assistants (CNAs), supervisors, nurses, social workers, administrators, and other direct-care workers. The *Dementia Care Training for Team Leaders* program provides guidance for individuals who supervise others involved in the care of those with dementia.
- **The Alzheimer's Association Dementia Care Practice Recommendations.** Recommendations developed for assisted living residences, nursing homes, and in-home care which were based on the latest evidence in dementia care research and the experience of professional direct care experts.

All of these programs, taken together, have yielded a strong foundation for training and support. However, the Association continues to collaborate with experts such as those participants in today's Forum to constantly improve the programs we offer to care professionals as well as to families.

Looking Forward

This committee, through its recent hearings, has clearly documented the dimensions of the Alzheimer's crisis, and what our country can do to rise to this challenge, as we must. This Forum today follows in that same tradition of leadership. The Alzheimer's Association commends the committee for today's Forum and looks forward to continued work together to do all we can to improve the lives of those contending with dementia, as well as for those who care for them.

**STATEMENT OF ERIC J. HALL, PRESIDENT AND CEO,
ALZHEIMER'S FOUNDATION OF AMERICA, NEW YORK, NY**

Mr. HALL. Good afternoon, everyone. To Chairman Kohl, Ranking Member Corker, members of the committee, staff, and all of you, thank you so much for convening, for coming together for this forum, and for asking the Alzheimer's Foundation of America to provide comments.

I am Eric J. Hall, I am the AFA's Founding President and Chief Executive Officer, and I am truly honored to be here today representing our membership and families we are caring for across the country.

AFA was formed in February 2002, to provide optimal care and services to individuals confronting dementia, and to their caregivers and the families through member organizations dedicated to improving the quality of life. Today, our membership consists of more than 1400 organizations, including grassroots not-for-profit organizations, government agencies, public safety departments and long-term care communities. Our services include a hotline staffed by licensed social workers, educational materials, care advantage—a free, quarterly family caregiver magazine that reaches, right now, about a million readers—professional training programs, AFA Teens, which is an online web support and scholarship program, and National Memory Screening Day. We, as a Foundation, also provide grants to non-profit service organizations, as well as respite grants to families in need.

Advocacy is an important part of the AFA mission. AFA was the only national organization to support the Patient Protection and Affordable Care Act. We have also been active in efforts such as advising on the caregiver initiative for the White House Middle Class Task Force, doubling and making competitive the Federal appropriations available for the Missing Alzheimer's Disease Patient Alert Program. We played a leading role in the effort to include the detection of any cognitive impairment in the new annual Medicare wellness exam.

AFA also organized a letter, signed by more than 100 national and local organizations in support of the National Alzheimer's Project Act, and we are anxiously awaiting its final passage.

It is a pleasure to hear the important work being done by the Administration on Aging regarding its Alzheimer's disease supportive services program. As Assistant Secretary Greenlee noted, however, Alzheimer's is a long disease, and such programs cannot just be simply a blip on the radar of the screen of care. They must be sustained, and after a continuum of services that families cycle through at each stage of the illness. The committee is uniquely positioned to encourage policymakers to keep the momentum going next year when the Older Americans Act and the Lifespan Respite Care Act are up for reauthorization.

It is useful to spread the word about the success of caregiver initiatives, such as REACH, as described by Dr. Grady and Dr. Gitlin. Yet, it must be noted that Federal research funding for the National Institute of Aging, NIA, the lead NIH Institute on Alzheimer's, and co-founder of the REACH Program, is in dire straits. Out of each dollar appropriated to NIH, only 3.6 cents goes toward supporting the work of the NIA. AFA respectfully asks the com-

mittee to further explore the Federal investment in aging research, and to support increased resources for the NIA.

However, family caregivers do not need to be a part of a big research study to get help right now. AFA has several resources to help family caregivers, including “Your Time to Care,” an educational DVD series that addresses specific care issues in the home setting. We would be glad to provide copies of these materials to members of the committee and to any other interested parties.

On the topic of community-based models, Mr. Shook’s overview of Silverado Senior Living was inspiring. I know through AFA’s member organizations, that there are many effective models of care across the country; however, the cost of these types of care are not covered by Medicare, and many families simply cannot afford them.

AFA supported The Class Act, which will eventually help relieve some of the burden of long-term care. The Senate also included a “Sense of the Senate” on long-term care in its health reform bill that pledged to address long-term care services and provide in a comprehensive way that guarantees elderly and disabled individuals the care they need. We urge the committee to highlight the need for continued resources to address long-term services and support.

Dr. Kovach focused on staffing issues and dementia training in the nursing home setting, which AFA believes is particularly important, since CMS estimates that as many as 70 percent of all nursing home residents have some degree of cognitive impairment; nearly half have a diagnosis of Alzheimer’s disease or other dementia. AFA was proud to work in coalition to support enactment of provisions of the Nursing Home Transparency and Improvement Act as part of health reform.

Among its many positive reforms, the bill requires facilities to include dementia management and abuse prevention training as part of its pre-employment training. AFA believes that CMS should require that dementia training be integrated throughout nurse aide training and abuse prevention training.

AFA offers two national programs that are specifically designed to raise the bar on dementia care in the United States—Dementia Care Professionals of America, DCPA, and Excellence in Care, EIC. DCPA is a division of AFA that offers practical training to healthcare professionals. Presently, it has trained over 5,000 individuals.

EIC partners with care settings in the establishment of a nationwide standard of excellence in care for individuals with Alzheimer’s disease or related dementias.

The last issue of today’s forum addressed the overuse of chemical restraints in nursing home settings. AFA agrees with California Advocates for Nursing Home Reform that there is a lot of work still to be done on staffing levels and education of nursing home professionals. We do want to note that there is an appropriate time and place for anti-psychotics in the nursing home setting, but only under proper training conditions, as well as strict supervision of dosage, monitoring of symptoms, and length of treatment. At the Alzheimer’s Foundation of America, our strength over these years and our success has come from our collaboration. AFA looks forward to working with all of you here to address the issues raised

in today's forum, and in the long term, to end the devastation caused by Alzheimer's disease.

Thank you.

[The prepared statement of Mr. Hall follows:]



Our mission is "to provide optimal care and services to individuals confronting dementia, and to their caregivers and families—through member organizations dedicated to improving quality of life."

Statement by Eric J. Hall
President and Chief Executive Officer
Alzheimer's Foundation of America

Before the United States Senate Special Committee on Aging Forum
"Until There's a Cure: How to Help Alzheimer's Patients and Families Now"
December 8, 2010

Chairman Kohl, Ranking Member Corker, members of the Committee and staff, thank you for convening this forum and for asking the Alzheimer's Foundation of America (AFA) to provide comments. I am Eric J. Hall, AFA's founding President and Chief Executive Officer, and I am honored to be here today.

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Ms. MONTGOMERY. Well, thank you to all of our panelists. You can see that there's a wealth of information and expertise and research and practice here. I'm assuming that there is a wealth of expertise in the audience, as well. So, now is your turn.

You have the opportunity to come to the microphone, which is right there in the center aisle and ask some questions. So, if you would like to do so, I encourage you to do that. For those of you who would like to come to the microphone, please state your name and your affiliation, so that we have it for the record. So, who's going to be the first bold person?

While you're thinking, I'll start things off by addressing the anti-psychotic use issue. Pat McGinnis mentioned a proposal to include anti-psychotic use rates on "Nursing Home Compare," which is an interesting idea. One potential downside of this is that it could create an incentive to encourage discharging people because of difficult behavior, as Dr. Kovach mentioned. So, I'm wondering how could we create benchmarks that encourage people to improve the standard of care, rather than to pass on the problem?

Ms. MCGINNIS. We already include that information on our Web site in California. That information is already collected by CMS. It's on the Minimum Data Sheet (MDS) data; it is facility self-reported, so we don't even know if that's reliable—but when a facility reports that they've got 80 percent of their residents on psychotropics or anti-psychotics, you tend to believe, if that's what they're reporting.

We have all kinds of quality indicators, and we have all kinds of data that is collected by CMS, posted on "Nursing Home Compare"—it seems like that would be one of them. But are you suggesting that nursing homes may start discharging people?

Ms. MONTGOMERY. Yes. That might be a possibility, so if we could create better benchmarks to avoid that problem, that would be worth thinking about. We don't have to do that right here.

Ms. MCGINNIS. Yeah, OK. [Laughter.]

Ms. MONTGOMERY. All right.

Ms. MCGINNIS. Yeah.

Ms. MONTGOMERY. I'll ask one more question before we turn to the person at the microphone, and that is about the cost-effectiveness of the psychosocial interventions we've been talking about. They seem pretty overwhelmingly cost effective to those of us here today, and so I'm wondering, what ideas do you all have that would help us make the economic argument to those who fund programs, and in the medical community, that these interventions ought to be more widely considered for broad use?

Mr. SHOOK. One of the approaches that should be taken is the reduction and utilization of medical-surgical services, the reduction in trips to emergency rooms. We measured that, and found we have a significant reduction of hospitalization for behavioral health by implementing these different tools—some of which do use psychotropic medications, but as I said, we reduced the use of those by more than 30 percent. But these other measures that have been discussed by the panelists here are very effective in reducing people's behaviors, keeping them out of behavioral health.

But, you know, there are also tools that are available to keep people out of ERs. If an assisted living doesn't have a nurse avail-

able, having one on call or working with a hospice can help—71 percent of the people at Silverado, to 89 percent—depending on the year you want to evaluate, die on hospice care. In nursing homes, it's about 3 percent. In assisted living generally, it is nowhere near enough.

If you've got somebody with COPD and, late at night—any time of the day—you don't have medical support to assess that person, and they have a hard time breathing, what are you going to do as the operator? You're going to call 911 and send them to the ER. But they don't need to be there, they just need to have a cooperative arrangement with a good hospice company—even if they don't have their own—that gets a nurse out there and addresses that problem with the physicians. It is easily taken care of right on the site, and you don't have the pain and suffering and inconvenience of the resident going to the nursing home. ERs do not want to see them, I guarantee you. The hospital, however, has to admit them to protect themselves from a tort point of view. So there are many different tools to reduce costs.

We reduced the use of prescription medications from 10 to 12 per resident to five and a half. That's a cost savings right there. Medicare is usually picking up that cost. There are many others, I'll let others speak.

Dr. GRADY. We funded a series of clinical trials, working with the elderly—in particular with chronic heart failure, congestive heart failure. That is one of the most treatment-resistant groups that we have in our society, and it's also very common among the elderly—one of the most common disorders. That series of studies has a cost-effectiveness piece built into it, so that we can actually document how much money is saved. The components of that have been built into the health care reform bill, so there will be reimbursement for that by CMS all goes forward. This investigator is taking this into the community of Alzheimer's patients so that we will be able to show, for this group, how much the increase in quality of care is, as we've shown in this other group. So, hopefully that increase in quality of care will show in patients and also the cost effectiveness.

Dr. GITLIN. With regard to the psychosocial, non-pharmacologic approaches for people with dementia and family caregivers in the home, cost effectiveness measures have not traditionally been part of the randomized trial methodology and it's really rather recent that this has been understood as something that's very, very important. I think that what will be important, moving forward, is that there is funding at the NIH for these kinds of methodologies to be either supplemental to the randomized control trial, or that they be integrated within a randomized control trial. But, really, the history has been that we have, you know, two decades of caregiver support programs, and only very few have been evaluated from a cost perspective.

Mr. EGGE. I'd just like to underscore how important that is from a policy perspective, as you know full well, in driving that question, I'm sure, to do just what you've described, and Director Grady, what you've described. To build in these cost-effective measures is, in the current context, one of the most effective tools we can have,

then, to encourage the policy adoption that we need legislatively and by other means.

Ms. MONTGOMERY. All right, we'll go the microphone.

Ms. HORTON. I'm Kelly Horton, I'm a Health and Aging Policy Fellow working with Congresswoman Louise Slaughter. A speaker talked about training that then leads to reduced need for restricting the patient. It's of course very important to train people who work in nursing homes, and that has helped to reduce the need to physically restrict patients with Alzheimer's, but I'm also wondering was there a correlation, are they overmedicating them?

Ms. MCGINNIS. I think I was talking about the restraint—physical restraint reduction movement which, in fact, ended up reducing the use of physical restraints from 25 percent to less than 3 percent, and sometimes less than .1 percent in some of the States.

Clearly there's been a substitute; we used to have a very low use of anti-psychotic drugs, and then it went up. With the Nursing Home Reform Act the use went down, and then it started rising again. So, yes, you probably can find a real, direct correlation, the reduction in physical restraints, with the increase in the use of anti-psychotics. I don't think that there's any question about that. Certainly in California, and from what I've seen, in the rest of the country as well. I see some other advocates shaking their heads yes, too.

Anti-psychotics have become a substitute for adequate staffing in some instances. Anti-psychotics have also become a substitute for alternate interventions, as we've discussed today, no question about it.

Ms. MONTGOMERY. OK, next question?

Dr. DONG. Thank you very much, my name is Xinqi Dong, I'm a Health and Aging Policy Fellow, and also a geriatrician. I particularly appreciate the comments made by Ms. McGinnis linking Alzheimer's disease and elder abuse an area that I'm very passionate about.

My question is more toward the issue of culture in dealing with the Alzheimer's disease population. Amongst different cultures—and take Chinese culture, for example, the word dementia literally translates into the words “catatonic,” and “crazy.”

There's a lot of cultural misbeliefs regarding what is Alzheimer's disease, what is dementia, and it's many believe it's really a mark of shame on the ancestry of the family when doctors review these types of conditions.

So with screening, as a geriatrician, as someone working in the community, we face a lot of those barriers. So, I hope to seek your guidance as far as, where do you see this issue in the field dealing specifically with culture, linguistic barriers—not only the Asian population, but across other racial and ethnic populations as well?

Ms. MONTGOMERY. Anybody like to comment?

Mr. EGGE. I'll comment from one perspective, at least, which is that at the Alzheimer's Association, we've found it necessary to invest considerably in order to pursue our mission in translation services—to the linguistic point specifically—but also broadly in cultural terms.

So, you can see in our most recent edition of “Facts and Figures: A Special Report,” the differential impact that they have by different groups. So that has been a major emphasis of ours.

There are also some other encouraging things: for instance, a recent Nobel Prize winner, from China, has been very open about talking about Alzheimer’s disease, which is partly, I suspect, we need not only due to the outreach that we do proactively, but also due to those individuals courageous steps by individuals in terms of talking about this and making sure that others feel that it is a safe conversation to have and to really deal with the stigma.

Of course, stigma is still an issue overall for our culture far too much with these conditions. I think you’re right, that we have to work on that. It’s very important.

Mr. HALL. The Alzheimer’s Foundation of America this year just put out and did National Memory Screening Day in Spanish for Latinos. We actually started by going to the consulates from various countries and asking them to work with us on educating us, and allowing our materials to be succinct and culturally sensitive, but also by asking their communities to come together.

So, I think there are opportunities. There’s no doubt that there is a lift required—but it is quite necessary. Your translation into “crazy” is something that applies also to the Latino population, as well. So coupled with immigration issues there this population specifically has enormous difficulties, and so that is not something that one organization is going to be able to do; it’s probably something that we’re all going to have to stand shoulder-to-shoulder to accomplish.

Dr. GITLIN. Yes, I would like to say that your comment is very critical to “REACH.” The NIH-supported REACH initiative involved over 600 people with dementia who were white, African-American, and Latino. We have a lot more work to do in terms of a showing the effectiveness of REACH, as well as other non-pharmacologic approaches, in different groups, and I think that’s very important as part of what we might call the translational effort. If we have a randomized trial with a more homogeneous group of individuals, what does that mean for a much more diverse population?

Ms. MONTGOMERY. Please?

Ms. COMER. I’m Meryl Comer, I’m President of the Geoffrey Beene Foundation Alzheimer’s Initiative, and I’m a member of Us Against Alzheimer’s, I’m also on the Alzheimer’s Association Board, but my comments to you are as a caregiver of 17 years, for both my husband and my mother. I want to thank you for your efforts on our behalf.

But I want to pose a question to all of you. We’ve had this conversation for 25 years, with no action, with the same issues. I would like you to fast-forward and create a sense of urgency in how we manage a pending epidemic, with a baby boom generation beginning to turn 65 January 1 of next year. Now, apply the issues that you have just discussed—with great empathy and concern—and tell us how you would manage if it all overwhelmed you at the same time.

Dr. KOVACH. I think that on a national level, this is a call to action. It calls for a very bold move. It calls for us saying, “There are

problems, here, and we can do better.” We have interventions that have been tested, and how are we going to get these implemented, how are we going to be monitoring more carefully and raise our expectations.

Some of these are real caregiver issues and they come down to reimbursement and how much money is being put into the system right now to care for this population. We have a substantial amount of data that shows that if you increase the competence of the registered nurses who are in a nursing home, quality of care improves dramatically. It takes a national call to arms and an organized initiative.

Ms. MCGINNIS. I would like to speak to that, too. My mother went into the hospital 4 weeks ago—my mother is blind, she’s 89 years old, and she could probably beat anybody here in “Jeopardy” any day. [Laughter.]

Even though she doesn’t care for Alex too much. However, my mother went in for a broken hip. It’s not real serious, but serious enough that she’s going to be in rehab for awhile. Immediately, after she went into the hospital, they had given her Resperdol, which is an anti-psychotic. My mother did not need that, they never asked my sisters—I have 5 sisters and a brother—never asked any one of us, and of course, within 2 days we got her off of that.

But what it shows is, it’s just as a matter of course and that we need to take this seriously. It’s baby boomers in California who are rising up, too. Baby boomers in California who are saying, “You know, we’re tired of this, we’re not going to take it anymore. I want to know, I want nursing homes to be accountable. If they’re using a lot of anti-psychotic drugs, I want to know why.

If pharmacies and pharmaceutical companies are out there, using and issuing drugs and recommending their use—even though there are black-box warnings—they should be penalized, they should be sued. Those are some of the things—we have to look at all aspects. We have to look at advocacy, educating consumers, educating family members, we have to get our legislators to take this stuff seriously and say, “You know, 35 years, this is enough. Let’s start doing something about it.”

You’re absolutely correct—I think baby boomers are going to be the ones that start questioning and saying, “Nah, we’re not going to do this. We’re not going to take this.” I don’t think that we’re adequately prepared, by any stretch of the imagination, but I’m saying, we are at least able to just say no, as Nancy Reagan used to say. [Laughter.]

Ms. COMER. I will just validate that. I’ve been a caregiver for 17 years, because I knew that my husband would be overmedicated and restrained in a nursing home facility in 1990, based on the current conditions. Having slept on the floor of one facility that would take us, I knew there was no care.

So I applaud your efforts, Mr. Shook, around the quality of care, but you are dealing with the consequences—not the cause, often. It’s often a fact, that the staffing ratios of caregivers to patients has a great deal to do with quality care, and training. But again, unless we marry the issue of research with care, and had the call for more basic research around the cause and finding some disease-

modifying drug, we are in serious trouble. It is a national strategy that's needed. Thank you.

Mr. SHOOK. I would like to comment on that, and I want to agree with you that we've got a tremendous crisis coming that we're not prepared to handle. One of the things that hasn't been discussed is we need to open up our thinking and change the financing mechanism of how we pay for care.

Right now, if a family is able to supplement a Medicaid—or, in California, Medi-Cal—service delivery, it's against the law. That's ridiculous. People should be able to provide additional funding if their loved one qualifies for Medicaid or Medi-Cal, and the family members have additional money, enabling them to move up from a nursing home that receives Medicaid or Medi-Cal rates which are commonly not providing as much staffing as is found in Silverado. We have one full-time equivalent per resident care ratio. Medicare, Medi-Cal, in any State, will not pay for that.

If a family comes in with an additional \$10, \$20, \$30 a day—which families can do—then that would give choice to consumers to be able to elevate their care to the private sector which, you know, we would get our care from, if we had a choice, that would put competition into long-term care that does not exist today. That would drive a lot more resources.

Now, that doesn't take away the importance of education about the non-medication approaches to treatment, which are a huge opportunity. The book "Silverado Story," is about teaching families and explaining to families, "Don't let your loved ones sit in a wheelchair. Have them engaged, and don't accept what is commonly thought throughout the United States today as acceptable care for Alzheimer's." People don't know what they don't know. What we've heard about on this panel is news to much of the United States. When we went into Houston and took over four problem long-term care communities, I first did a satisfaction survey of the families. I thought they would say the care was terrible, and then after we took over, I thought they would say the care was great. From a business point of view, this is not a bad idea.

So I went in and I surveyed, and they said the care was great. It was terrible. But they didn't know, because there it wasn't anything to compare it to. This shows that the message of education is huge; it's so important. You had the knowledge to know that your loved one might be overmedicated in that setting, and kept them out. Most of the United States does not know that, and it's our job to get that word out. That's one of the reasons I'm here, and I suspect the reason these people at the forum are not only here, but in the profession they're in.

Ms. LOVE. My name is Karen Love and I'm the President for the Center for Excellence in Assisted Living. I am somebody who provided 20 years of care to people who have dementia. My dad had dementia and died of dementia, so it's near and dear to my heart.

But my question to the panel is, if we keep doing the same old, same old, isn't that what we're going to get? I hear inspiration from you, but specifically there are a lot of things that are out there that aren't getting tied together. For example, there is community-based participatory research, which is a type of research that integrates policy, practice, and the research field. The invested stakeholders

are all participating in the project from all of the stages. I think something like that would be a phenomenal project.

You could get providers, such as Silverado, that are renowned for their dementia care, some of the researchers on the panel with their body of evidence and research, and policymakers. It's a type of research where we translate it into practice. Because that's the problem.

We work a lot, for example, with the University of North Carolina at Chapel Hill. They have a wide and long history in dementia care research—yet it never gets translated into the field. There is this enormous disconnect—a disconnect between having information inform policy.

How do we pull all of these things together in a more effective role, so that we have better outcomes?

Mr. SHOOK. Excellent point. I want to add that the Assisted Living Federation of America, the National Investor Conference, and the American Senior Housing Association are now open to communicating with universities and doing research with them within the settings where people are actually being served. Silverado started doing that research in conjunction with those settings, and that has been expanded to many other companies—Brookdale's one of them, Emeritus—there's a variety of companies, and I know the CEOs are very active and interested in partnering with the universities to do research. That is how you get it in the field.

Dr. GITLIN. I would just like to add that I think our biggest challenge is taking the evidence that we do have—we certainly have to create more evidence—but taking the evidence that we do have and translating it. Some of the work that we have had funded from the Administration on Aging, as you heard from Assistant Secretary Greenlee, has been to translate some of the evidence-based programs funded by NIA, for example, and NINR, into the community. The lesson learned from that is that that you need money to translate, because the team is very different, just as you're suggesting. If you have evidence from the randomized trial and then you want to implant it in a treatment and a practice setting, the team is very, very different, and it takes time and effort and funding to support that, and you learn new lessons. But it's something that we have to do.

I also want to say that most other developed countries have made dementia a No. 1 health priority. That has meant that they have identified funding sources to support the widespread training of health and human service professionals, and have also supported translation of evidence-based programs developed all around the world, and have also supported an increase in funding for not only a cure, but also for more enhanced psychosocial and environmental interventions. So we could take the lead from our partners, because they have made dementia a priority, and they're making some progress with regard to some of the points that you raise.

Ms. LOVE. Well, in CBPR, it's not a separate step to translate the research, it's accommodated in that.

Dr. GRADY. Yes. We are actually funding a fair amount of CBPR, now. We're finding problems that are identified by the community and which are brought to us, and then we have vested partners in the community to implement it.

But it does take a partnership, as Dr. Gitlin said, and I think that part of the answer to your question is that's why we're here today, because we really do need more exposure about this, to get the word out, and it does need a national presence. It is starting to happen, basically we're facing a train wreck. We're facing the increasing age of the population—not all of whom have dementia, but a lot of whom do—and the problems that we're facing in this population are mirrored elsewhere. We have a new law out, and more people will be covered, and yet there are many people who do not receive care. We have a growing diversity in our populations; minority populations are quickly becoming majority populations, and we don't have a lot of research to address those needs. We're working on it, but we're not there yet.

All of these factors are converging in a way that demand attention. So, I really think the good news is that we have a lot of information that we could be implementing, but the urgency, and the tempo is really increasing. Those of us in this field have this sense of heading in a very fast train toward the end of a cliff and so I think that we are, by circumstances, forced to coordinate our efforts and so this is a very national approach.

Ms. MONTGOMERY. I think we have time for two more quick questions and then we'll wrap it up and thank you all.

Dr. LEVY-STORMS. Hello, my name is Lene Levy-Storms and I'm a professor, and a Health and Aging Policy Fellow from UCLA. My question is directed particularly at Mr. Eric Hall and Mr. Loren Shook. It seems like today we've spoken about caregivers of persons with dementia in the community. We haven't really mentioned or spoken about family members for persons with dementia who are institutionalized.

Mr. Hall, could you address any programs that your organization supports for those family caregivers? Also, Mr. Shook, could you address your knowledge of what issues family caregivers face once they do institutionalize their loved one?

Mr. HALL. There's no doubt that support is necessary even after institutionalization. The emotional burden to a family is still very real. I wanted to say something along these lines, as well. We're sitting here and we're talking about all of the things that need to get done—and there is no doubt that they do. I have had the honor of traveling most of the country and seeing organizations all over who are providing incredible care and support right now. There's an enormous footprint already present in our country. There are dedicated professionals, all over, who are giving their life's blood for this cause.

So, I simply just want to make sure that we posit that a lot more is needed. What we have right now is not enough, there's no doubt. But I wouldn't want anyone listening to us here thinking that we're not aware of all of the organizations all over the country who are providing care, and who are doing incredible jobs, and are seeing an increase in people coming to their door and less financial resources. They need a lot more support.

As far as support groups for these individuals, the family members, or sensitivity on behalf of nursing homes and assisted livings, across the country, I have found organizations who are stepping in and who are helping in those regards.

Another thing about the Alzheimer's Foundation of America, when we fund programs and services and we go through a very rigid review of grants, and then when we fund, we ask for a response of what the money has funded, and then the program that was funded, if successful, is made available so that other organizations can share. I have to tell you, the network that we have, of the 1400 organizations people don't care if you're a county away, or if you're the country away, on the East Coast. If an organization has a program that's really very effective, they're willing to share that with others. I think it's one of the things that we have found, is that a lot of it's about the research, but it's also about—this is how you do it. This is exactly how you fulfill this, this is exactly how you follow through, this is how you make this happen. I know that, organizations are hungry to provide those type of necessary services to their families.

Mr. SHOOK. As with all of the questions, this is an excellent question, and I'll be as brief as I can.

But, what we do at Silverado, is first of all, we relieve the burden from the family. We take the husband, the wife, the sister, the daughter, the son, and we take the burden of care giving away from them and let them return to be the loving wife, the loving daughter. We relieve them of their stress in terms of being able to count on us to do the right thing in caring for their loved one, so that they can return to more normalcy in their own life. We realize that the guilt is intense when we move people in. So, we will take pictures of their loved one the next day, when they're in an activity, seeing them smiling and engaged in an activity and email it to them, much as you might have experienced if you have children, what happens at kindergarten, when you know, they send you back a message that your child that you've given up to the school is, indeed, in good hands. Because sometimes family members—residents have a hard time transitioning when the family member is there, it's like, "Take me home, take me home," and then when they go away, they're laughing and having a great time.

So, when you have that kind of scenario, you try to give the family other proof that they're having a good time. But the transition happens fairly quickly.

We also put the family in touch with other families so they can have socially supportive time together with other people who have the same trouble in an enjoyable setting. We take them out for a lunch or dinner or something like that. We provide them with a constant education about what's going on.

We talk to them in the beginning about end-of-life concerns, and how do you want to handle end-of-life? This is a difficult problem that frequently is not covered in our culture, and end-of-life comes and people don't know what to do about it, and then they go off treating people who don't need treatment. We get the DNR do not resuscitate order you know, put together, so you're not sending someone off for resuscitation and incurring all of that trauma.

Children are also invited to come—the family's children. My father had dementia in the eighties, and the only thing I could find was a nursing home. My mother had Parkinson's, which I subsequently cared for at home—it was Silverado's Home Care, and she was the first patient, in fact. But the nursing home did not want

to see my children, that was really crystal clear. My dad loved them, and yet they did not want to see them in there. So, at Silverado we create an environment where children are welcome. We have playgrounds, we have pets, we have several hundreds pets, actually. We have things that engage children. The families eat for free. We want to re-engage families in a disease that disengages families, oftentimes, and that's one of our core values, so I don't want to charge you five bucks or eight bucks or whatever it is for dinner, and chase around a charge slip, and have my staff do all of that nonsense. Please come and eat for free and bring all of your family's members with you. Thanksgiving can get pretty large at Silverado—four and five hundred people is not uncommon. We have private dining rooms—you want to have a party, let's do it.

We connect families. There was an article written in the paper about Valentine's where a lady whose husband is 57 and had early stage Lewy body dementia, wound up in our community and, you know, she describes it as the best Valentine's Day they ever had, because the staff took into consideration that it was also a birthday, and got the husband set up with the birthday gift, and a party. The dinner in our private dining room was as though he presented it himself. I need that kind of help in my own home, by the way. [Laughter.]

But those are just some of the things we do. We have many parties, and families are always invited. A lot of our communities are considered rocking places—they are just happening. Nothing dull, nothing boring. That's part of what you need to get rid of in your minds about what's OK nationally, it is not "over-stimulating" for people with dementia to have a good time.

Ms. MCGINNIS. I just remind folks, too, that family councils in nursing homes are some of the most important groups that you can possibly have for family members to get the kind of support and validation, and all of that that they need. You can go on our Web site and get a free, "How to Organize a Family Council," and also, of course, from "Consumer Voice," right here in Washington. Every nursing home should have an independent family council.

Ms. MONTGOMERY. OK. Final question.

Dr. MUDANNAYAKE. Good afternoon. My name is Dr. Louis Mudannayake, I'm a geriatrician, internist, and hospice and palliative care specialist. I work out of Brooklyn in New York, and in the health care system that I work out of, which are nursing homes, we've reduced anti-psychotics by over 300 percent and gone down from average amount of drugs consumed per resident from 9 down to about 4.

The question I have was first raised by Lucette Lagnado on the front page of the "Wall Street Journal," in 2007, how can we change the culture when the Federal Government reimburses more readily for pills than people? It's a very difficult question, and I know Patricia McGinnis answered it in one respect by having consent forms, say, for the prescription of anti-psychotics, but that brings along its own set of problems—tort reform, and something I've been campaigning against, and certainly taught, one of the things that drives healthcare costs up.

So, is there any other way we could convince people that we really need, you know, to pay people more, rather than depend on medications that often just don't work and can do harm?

Ms. MCGINNIS. Yes, I absolutely agree. I'm not a doctor but as a non-professional health professional, I would say, if you demonstrate the high cost of poor care, we used to be able to do that, you know, before we had Medicare Part D, we could actually get the amount of money that the State of California spent on anti-psychotic and psychotropic and all of those kinds of drugs—if you show the high cost of poor care—there are more falls, more problems, more pneumonia, there are more admissions to acute care hospitals because of the use of anti-psychotic drugs; if you could track that, and show that it's going to cost more to drug people up than to provide them with decent care, then I think that we're going to get the Federal Government to follow. At least that's my opinion.

Dr. KOVACH. This issue is an example of how much cultural attitudes have consequences. We live in a society that fears death, does all sorts of things to avoid death, and we think there's a magic bullet that's going to cure everything and stave off death. Then when we have a family member that has the natural and the inevitable—a chronic illness that is going to eventually lead to their death, and we act in all sorts of ways that are inappropriate. We want care that is futile, we want you to do something. Prescribers just feel like, "I have to do something for you that's going to make you happy." Because we have been trained through television commercials, and other messages, that, "If you take this pill, you're going to get better." Physicians have a lot of pressure to write those prescriptions and do something.

In this country we need to get more comfortable with the notion of end-of-life and illness. I'm really happy when I see Michael J. Fox showing his tremors. When Christopher Reeve would get out there and show himself. You'll go to a restaurant and see somebody who has a disability and people are offended by that witnessing the symptoms while dining. We have to show that this is a normal part of life. That becoming ill and dying is a normal part, of the life cycle, so it's a major issue of education, cultural values.

Mr. SHOOK. We need to shift the focus from paying for treatment, and paying instead for results. Right now our whole system is set up for the number of incidents that we pay for that have been done to you. It doesn't mean that it's going to make you any better. At the end of life, there's nothing you're going to be able to do to prevent the end of life, and yet our culture is so blind to dealing with this. If there's one thing we know for sure, it's that we're all going to die, but we don't want to talk about it.

All of these interventions that are taken at the end of life, we avoid at Silverado by having those conversations, and 71 to 87 percent of the people pass away on hospice care. If every long-term care community had a standard of just doing something like that, there would be a tremendous reduction in cost. This is much bigger than the use of psychotropic medications.

But this is where the big money's at—are people going into surgery to fix that mitral valve? —My mother had a mitral valve failure at the end of her life. She also had Parkinson's, was blind in one eye, taking care of my dad and experiencing great stress there,

another lesion. Did we go in and fix it? No, we had a conversation. I sat with her surgeon and said, “What—what does this really mean? We can fix that, but then what’s the risk of significant dementia just from the anesthesia? Where’s your life going?”

At Silverado, we believe in a good death, and a good death brings the family together. It’s a magical moment, it’s a way to change people’s lives, and I can give you story after story after story of how it changes people’s lives who remain. It’s a growth in life for the person passing away and preparing to move on to the next stage for them. We, as a culture, have got to embrace that and understand that, and it’s not a bad thing.

Dr. MUDANNAYAKE. Thank you.

Dr. GRADY. I would be remiss if I didn’t mention that we are the lead at NIH for end-of-life issues. One of the major things that we deal with is, what do we call it? The resistance is such that we can’t use that term, and if we use “palliative care,” people are sensitive to that as well. So, we are now addressing it as with issues related to life-limiting and life-threatening illnesses.

But it is—but the biggest piece of that is about communication and changing the focus from focus on cure to focus on care.

Thank you.

Ms. MONTGOMERY. I think that’s a great way to end this forum; I think it’s been extraordinary. I want to thank everyone here today, the panelists, everyone in the audience, and especially my colleague Neil Thacker without whom this forum would never have been possible.

So, thank you again.

[Whereupon, at 3:22 p.m., the hearing was adjourned.]

A P P E N D I X

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH**

Enhancing the quality of LIFE in a dementia care
assisted living environment

Witness appearing before the
Senate Special Committee on Aging

Loren B. Shook, President,
Chief Executive Officer and Chairman of the Board
Silverado Senior Living

December 8, 2010

Enhancing the quality of LIFE in a dementia care assisted living environment

OVERVIEW

Today, over five million people in the United States have some form of memory impairment. That number is expected to reach 14 million by the year 2040. The rapid increase in Alzheimer's cases, the stress the disease places on individuals and families, and the intensity of care required as memory impairment progresses have healthcare and public policy experts agreeing that America faces an "Alzheimer's crisis." At Silverado, we are dedicated both to providing extraordinary services to those in our charge as well as to making a positive impact on how America and the world cares for the memory-impaired.



Silverado Senior Living cares for people with all types of memory-impairing diseases, including Alzheimer's, Parkinson's, and others. We provide the full continuum of memory impairment care, from the disease's early onset through the end of life. Our services encompass dementia care assisted living for those with memory disorders, home care, care management, and hospice care. Silverado is consistently recognized as the leader and innovator in the \$110 billion assisted living industry's memory-care niche. This stature

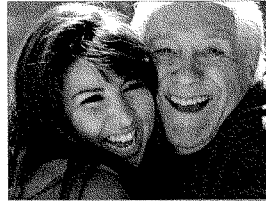
is borne out by our partnerships and programs with universities conducting dementia research, including University of California at San Diego, UCLA, University of Southern California, Baylor University, Stanford University, the University of Utah, and many others.

Founded in 1996 and opening its first dementia care assisted living community in June 1997, Silverado now operates 20 memory-impairment communities with 1,578 beds in four states. Silverado has five home care offices and eight hospice offices. In addition, Silverado offers skilled rehab services focused on the memory impaired in two of its communities, one in Dallas, Texas and the other in Salt Lake City, Utah.

Our main customers are individuals with memory impairments and their families, and those in need of hospice care. We serve this population in the setting of their choice; be it their current personal home, a Silverado or other residential living environment or skilled nursing facility. We also serve the general medical community by providing services to their patients and clients.

ENHANCING QUALITY OF LIFE

Providing care for our aging population, especially for those with memory impairing diseases is more than just meeting their medical needs. It's about providing for their psychosocial needs as well. It includes providing and supporting a quality of life that brings life-affirming meaning and fulfillment to them daily.



In an assisted living setting, enhancing quality of life requires the following elements be in place in order to create and maintain a supportive and life enriching environment:

1. A philosophy of care which promotes independence, choice, dignity and daily purpose for each resident.
2. Quality and compassionate staffing who are trained to meet the unique needs of this population.
3. A strong supportive company culture which is clear to all staff. A culture where the operating philosophy of love is greater than fear prevails.
4. Environment. Providing a social setting which is comfortable, home-like and attractive.
5. Programming. Age appropriate engaging activities which promote self-worth, involvement and purpose.
6. Coordination with care practitioners. A comprehensive plan designed in conjunction with primary care practitioners all working as a team in order to create a holistic approach to individuals needs.

In the case of Silverado, a seventh element is also included: clinical services. Silverado is different than most traditional assisted living providers in that it has licensed nursing on-staff 24 hours per day seven days per week. Our clinical programs are described in more detail below.



PHILOSOPHY OF CARE

The Silverado philosophy of care and company vision is to "give life." Our purpose is to change the world in the way people with memory-impairing diseases are cared for. In the process, we seek to touch the human spirit in all that we do. In addition we subscribe to a philosophy that there is "dignity in risk" which means allowing residents to continue to engage in those activities that they feel are rewarding and challenging to them.

QUALITY AND COMPASSIONATE STAFFING

Silverado has a strong clinical team in each of the communities. A registered nurse is on-site full time as the Director of Health Services, and licensed nurses are also on-site 24 hours a day, 7 days a week. We recognize that people with dementia are unable to articulate when they are in pain or becoming ill and they may also have other chronic medical conditions. Silverado's clinical team is available to do timely assessments, communicate with the primary care physicians and provide follow up to acute illnesses.



At Silverado, we truly wish to change how the world sees and cares for people with Alzheimer's Disease and other forms of memory impairment. We know that we can only achieve this goal by providing an extraordinary workplace that attracts and retains the passionate people who share Silverado's vision. We say this for two reasons. First, our employees are the ones who directly touch the lives of the memory-impaired, day and night, seven days a week. Our ability to offer life-affirming care depends entirely on hiring and keeping the best, most dedicated workforce.

Further, with the aging of baby-boomers, our nation is facing a work-force crisis. Unless employers innovate, there won't be enough qualified people to care for this coming generation of elders. Moreover, as the number of seniors grows, so will the number of those needing memory impairment care. Memory disorder affects one in 10 people over 65, 22.4% of those aged 75 or more, and nearly half over 85. And the truth is that providing meaningful care for those with Alzheimer's and other forms of memory impairment is not something everyone is suited to do. It takes dedication and the ability to look within each person to see the individual still there. If we can offer a workplace that is among the nation's best, a place where associates clearly love what they do and experience fulfilling careers, we believe we can inspire more people to perform this vital work.



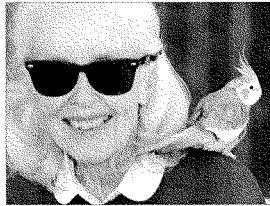
ENVIRONMENT/MODELS OF CARE

The Seniors Housing industry provides various options in living settings and models of care that an individual can choose. Options include Independent Living, which is a residential setting for active seniors. Assisted Living, a residential setting where assistance is provided for activities of daily living (ADLs) such as bathing, dressing, grooming needs, etc. Skilled nursing, generally a long term living setting where residents are also cared for who require more intensive skilled nursing interventions daily.

The Silverado model of care is different than most traditional settings in that it focuses on creating an attractive, social home-like residential setting in addition to an intensive clinical model of care “in the background.” This model of care includes a physician medical director who is typically board certified in their medical specialty, a full time registered nurse as our Director of Healthcare services, licensed nurses around the clock seven days per week. In addition we have Masters prepared social workers to assist residents and families with support services, counseling and other assistance as needed.



When Silverado was first opened, its founders said, “What can we do to make this more like a home, more like a place we could actually live in? We all are animal lovers and couldn’t imagine our homes without our pets. So naturally we brought pets into all our assisted living communities.” At a time when animals in assisted living communities were considered dangerous and unclean, Silverado broke ground and declared the benefits outweighed the risks. “We have seen time and time again how animals bring life to our residents. Pets are proven to reduce anxiety and depression in settings where they are used. They are truly a wonder.” And, in fact, pets are now included in all of our service lines.”

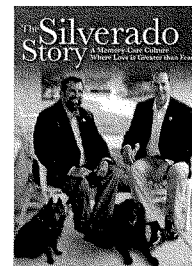


Associates can also bring their children to work, in the belief that an integrated, intergenerational program benefits our residents. Many residents will engage in activities with our children, bringing laughter and vigor throughout our communities. It is also good for the children to learn to appreciate the elderly and not be afraid of people with memory-impairing disease. It gives them an understanding of what 21st century care for the elderly looks like.

PROGRAMMING

Silverado's unique **Normalization Programming** is the foundation to the critical element of helping each individual find purpose and meaning in their daily lives. Normalization is core to the Silverado culture and beliefs. For additional information on Silverado's Normalization philosophy and program, please read more in the “The Silverado Story, A Memory-Care Culture Where Love is Greater than Fear.”

“Normalization” refers to responding to a person with Alzheimer's Disease no differently than one would respond to a person that society considers “normal” in behavior and mental capacity. This concept originated in the acclaimed work of Scandinavian academic Bengt Nirje





and was further developed by Dr. Wolf Wolfensberger with the developmentally disabled. For Dr. Wolfensberger, what he lived through as a child in World War II Germany led him in his adult life in America to explore how apparently good people could do bad things. How could the abuses uncovered in state facilities for the mentally handicapped in the 1970s possibly have happened, when each person on the staff seemed well-intentioned?

The explanation: these things occur when social structures allow certain groups of people to become devalued. Once a person is considered “not normal,” he or she loses worth in the eyes of those whom society thinks of as “normal,” or valued. From there, it’s an easy next step to begin treating that person in ways that would be unthinkable otherwise.

Silverado Chief of Culture and Co-founder, Steve Winner brought the concept of normalization to the company and refined it, and we are one of the few memory-care organizations to use it. Normalization – the resolute commitment to treat the memory-impaired as “normal and valued” and to forestall any thought or action suggesting they are “not normal and thus devalued” -- is fundamental to our mission of providing LIFE and life-affirming care.

Walk through a typical memory-care community and you’ll see the staff has given the residents blocks to play with and baby dolls to hold, as though memory impairment has cast these adults back into early childhood. Besides being un-fulfilling for the people involved, it causes those around them to treat them as something other than adults. After all, it isn’t “normal” to see a six-foot-tall man playing with toys. As was proven by the work of Bengt Nirje and Wolf Wolfensberger with the developmentally disabled, once one starts perceiving the memory-impaired this way, it’s easy to let the normalcy of their lives erode. As Mr. Winner puts it, “After a while, you start thinking it doesn’t matter if Mr. Smith is walking outside with no shoes on, because he’s not a regular person. You begin to believe that he is less valuable than so-called normal people. This is how attitudes evolve that can ultimately lead to elder abuse. Besides the issue of abuse, it’s the compelling question of maintaining human dignity.”

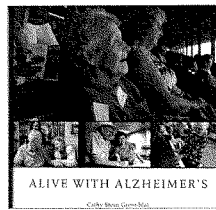


Walk around a Silverado community, and you will find residents taking part in normal adult activities that relate to their life-long interests. Woodworking, cooking, and gardening clubs are just a few of the things Silverado residents take part in every day. Rather than handing a resident a baby doll to hold, he or she is given a real baby to cradle (thanks to our policy encouraging our employees to bring their children to work with them).

Practices that are common in memory-care, but would be demeaning to any adult, are not permitted. There are no signs on the walls of residents' rooms about their personal hygiene habits or need for physical assistance. Residents' undergarments are stored neatly out of view in dressers, not heaped in plain sight next to their beds. All of these things are kept private, just as any "normal" adult would wish.

We also focus on keeping connected to the people our residents have been throughout their lives. Residents' rooms are decorated with things that express their achievements: their diplomas, personal photos, and other mementos are constant reminders of who these people were and still are, even if their communication and behavior are no longer what's thought of as "normal."

Recently, a second segment has been added to the normalization program. It's a **peer-evaluation review**, in which associates from one Silverado community visit another one, for a day long review, to rate whether there are any normalization gaps, and if so, discuss how to correct them.



Silverado's culture and practices are so distinctive that they are the subject of the profoundly moving book "Alive with Alzheimer's," the first-ever photographic book on the disease that was written by a sociologist with a B.A. from Vassar College and a Ph.D. from Columbia University, she is currently Professor Emerita of Sociology at Rutgers University, a Visiting Researcher at the International Observatory of End of Life Care (IOELC), University of Lancaster, UK, , and an Artist in Residence at the Hospital Network of Nice, France (CHU de Nice) and published by the University of Chicago

Press in 2004. The book has now been translated into German and Japanese; the photos have been displayed all over the world, including at the Alzheimer's Association's international conference in Kyoto, Japan.

Just one compelling example of how our unique approach touches the human spirit and transforms lives is that of Edith, a memory-impaired woman who was bedbound, unresponsive, terribly feeble, and, frankly, considered near the end of her life when she was brought to the Silverado Senior Living - Escondido community. We surrounded her with music and pets; in fact, our Social Worker discovered that she loved cats so a Silverado cat was assigned to Edith and placed in her lap upon move-in. Our staff spoke to her even though she could not speak back; reduced the overly-large number of medications she was being given in the effort to "control" her symptoms and behavior; and started the process of getting her out of bed to take a few steps.

Within four weeks, Edith regained the ability to walk on her



own. The book shows her sitting in the stands of southern California's Del Mar Race Track, talking and laughing with a group of fellow Silverado residents on an outing there having walked on her own! We are proud to say that Edith's story has replicated throughout Silverado over 3,600 times so far. Edith passed away peacefully at Silverado in 2010.

Silverado's Engagement Team also receives extensive training on how to provide age-appropriate engagement activities for residents. Engagement activities often take place in a "club-like" format, which is familiar to the generation that lives at Silverado. The activities of the clubs will be structured to match the abilities of the residents and each resident leaves the activity feeling successful. Silverado's dementia residents participate in active programs such as golf, swimming, bicycle riding, walking, and even service clubs. We also have the Wii as an activity for our residents, who enjoy the bowling, golf, tennis, and other programs on the Wii.

At Silverado, people with early or mild dementia have social and cognitive-stimulating activities designed specifically for their abilities. We have specific neighborhoods and programming for residents with mild cognitive deficits.



Read article at:
http://www.silveradosenior.com/newspaper_2009_wall_street

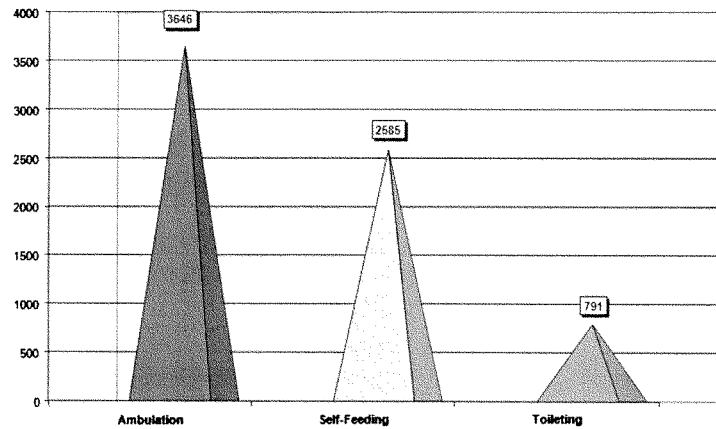
CLINICAL SERVICES - IMPROVING BEHAVIORS

Because of Silverado's specialty and high level of qualified staff, we often receive referrals to care for those that demonstrate the most challenging behaviors and require more intensive assistance.



Dementia residents often suffer difficult behaviors, due to confusion, pain, anxiety, hallucinations, adverse medication effects, or other causes. These types of behaviors are very distressing for both the residents and their families. At Silverado, the use of psychotropic medications is minimized and physical restraints are never used. Rather, Silverado's staff is trained to see resident behaviors as an expression of a "need" and our Behavior Intervention Program helps to uncover the cause of the agitation or other behavior. Since 2006, over 1000 residents have had interventions to help them feel peace of mind and decrease their agitated or aggressive behaviors. Silverado's intervention also substantially reduces behavioral health, strain on the family, primary care practitioners, hospitalizations, improving the residents quality of life, reducing and saving thousands of dollars of expense.

Silverado Senior Living Resident Improvement Outcomes September 1999- October 2010



Silverado has developed extensive clinical outcome measures that provide the following benefits:

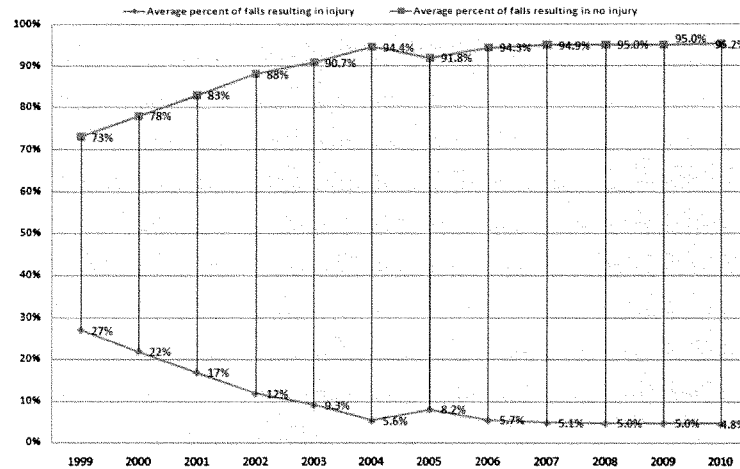
- Documentable evidence based results showing quality of care and quality of life benefits
- Provides a management tool to benchmark Silverado communities against each other
- Demonstrates cost savings to the payer

At the start of the company in 1997, Silverado collected data on use of:

- Psychotropic medications
- Ambulation
- Falls
- Feeding
- Weight gain/loss

In the case of psychotropic medication use, we record each of our 1250 plus residents' use of medications each month separating the medications by the following categories:

- Anti-anxiety medication rate
- Anti-psychotic medication rate
- Sedative hypnotic medication rate

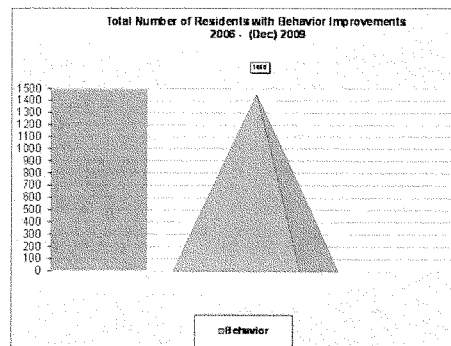
Percent of falls with/without Injury 1999-2010

Every resident is assessed using the "Cornell Scale for Depression in Dementia" or similar tool. We find that about 60% of residents need treatment for depression.

Because of our excellent results in serving the most challenging behavioral cases and our expertise in serving complex diagnoses like frontotemporal dementia (Pick's Disease), Lewy-Body dementia, etc., we are the number one referral choice for behavioral health hospitals, other assisted livings, skilled nursing and cognitive assessment centers. Taking the cases that others cannot handle, we experience an overall reduction in the psychotropic medication use for controlling behaviors of over 30% across the company.

Over the years, our clinical outcome scores were expanded to include:

- Pressure wounds
- Rate of transfer to acute care
- Per unit of residents on hospice
- Percent of resident deaths on hospice care
- Number of prescription medications residents take



Other clinical outcome results include:

- Reducing residents from the 9-12 prescription medications they move-in with to an average of 5.5, compared to skilled nursing at 12, and traditional assisted living of 7-8 prescription medications.
- While it is estimated that 6-8% of people with dementia fall and fracture each year including people within settings that restrain them, Silverado has a fall with fracture rate of only 1% without restraining people.
- Compared to nursing homes where 10-20% of falls cause serious injury, at Silverado only 4.8% of falls cause serious injury.

An example of our specialized model of care to provide the best quality of life to our residents, we established the **Grand Rounds Behavior Intervention Conference Calls** to further assist our associates in caring for these challenging residents.

Silverado's Grand Rounds allows for the presentation of clinically complex or interesting resident behavior cases for the purpose of a remote and multi-site audience to problem-solve together and raise clinical reasoning. The concept of Grand Rounds is consistent with Silverado's philosophy of providing opportunities for our associates to increase their knowledge of new developments in the field of dementia or geriatric health care, use all of the available Silverado resources to "brainstorm" together on complex cases, as well as minimize the use of psychotropic medications as a method to manage resident behaviors.

Leaders and experts from Silverado, as well as invited consultants such as psychiatrists and other therapists join the Grand Rounds Conference Call. During the Grand Rounds calls, Silverado associates from all of our 20 communities have the opportunity to present to the experts their challenging residents and receive consultation from the experts on the phone line. We have many examples of experts who are not on-site with the resident, sharing great ideas that have been very successful.

Silverado does not use physical restraints, even though many residents have very challenging behaviors. The Grand Rounds Conference Calls are an important part of Silverado's success in managing difficult resident behaviors, bringing in resources from across the company to brainstorm on how best to intervene and bring LIFE to our residents.

Silverado communities are often referred new residents considered to be difficult to handle skilled nursing or the assisted living dementia units from local Geropsychiatry Units. These residents come to Silverado with a history of difficult behaviors. At the time of move-in, Silverado's team begins to assess the new resident. Behavior mapping every 30 minutes is initiated, to establish any patterns or triggers for behaviors. The nursing team will assess the resident for any possible sources of physical pain or infection and current medications are reviewed with the medical director. The social worker will assess the resident for depression and anxiety.

The following is a copy of the Behavior Intervention Worksheet we use.



Behavior Intervention Work Sheet

Resident: _____ Behavior mapping started: _____

Brief description of the behavior: _____

- ☐ New behavior
☐ Escalation of existing behavior
Evaluate for the potential contributing medical causes:
☐ Any indication of pain - oral/foot/etc.? _____
☐ Constipation Date of last BM _____
☐ UTI
☐ Dehydration
☐ Gastric/digestive
☐ Skin issues
☐ Arthritic
☐ Depression
☐ Sleep problem
☐ Nail problem
☐ Other: _____
☐ Recent medication change/addition: _____
☐ Any medication side effects noted? _____
☐ Current psychotropic medications: _____

MED / DOSE / DATE STARTED

Evaluate for potential environment contributing causes.

- ☐ New roommate
☐ New caregiver
☐ Move to new room
☐ New disruptive resident
☐ Change in routine
☐ New stimulation
☐ Does resident appear bored?
☐ Does resident appear fearful? Consider possible abuse
☐ Caregivers/associates respond appropriately to behavior
☐ Other changes: _____

What redirection techniques work with resident?

What are the rewards for the resident?

Review this worksheet with interdisciplinary team and determine plan of care. Re-evaluate as needed.

Nursing Signature: _____ Date: _____

Silverado uses this Behavior Intervention form to look for triggers for changes in dementia residents' behaviors. Residents' behavior are seen as an attempt to communicate and the Silverado team looks for causes such as pain, anxiety, environmental causes, acute illnesses, and depression which may trigger this new behavior. If staff interventions are unsuccessful in mediating the behavior, anti-psychotic and anti-depression medications may be helpful. These medications are reviewed on a regular basis to see if they continue to be of benefit to the resident.

When the assessments are complete and the information is compiled, the Grand Rounds Conference call will be scheduled to present the resident's case to experts throughout Silverado. Participants on the call may include Silverado nurses, social workers, physicians, Administrators, care givers, Activity Directors as well as other team members and outside invited experts. An interdisciplinary approach is used to discuss the resident and suggest appropriate interventions. The Grand Rounds conference calls typically last approximately one hour and a follow-up call is scheduled to determine if the suggested interventions were effective.

The Grand Rounds calls have been very helpful in intervening with challenging resident behaviors. It is often the Silverado associate, who is not on location with the resident, but by hearing the description, can think "out of the box" and suggest creative interventions for the behaviors.

The Grand Rounds calls are also an excellent educational tool for our associates and they learn behavioral intervention techniques they can apply to their challenging situations at their own Silverado community.

In addition, by giving our associates an opportunity to present their cases on the Grand Rounds, they realize they have resources they can consult, beyond their own community walls, which are always available for them.

These Grand Rounds Conference calls are part of what makes Silverado a leader in dementia care. In addition to the monthly calls, we have occasionally convened a Grand Rounds call on "short-notice" if there is a community requesting an immediate consultation.

The Grand Rounds Conference Calls are innovative because they strengthen the concept of an interdisciplinary team, as well as a trans-geographic team, uniting team members from several different disciplines and geographic locations to brainstorm together on the optimal plan of care for challenging residents. It puts experts from across Silverado's company and across the country available at one designated time, to support the team who is faced with caring for challenging residents and assisting them to meet the dementia resident's needs.



The Grand Rounds Conference Calls are easily replicated, making optimal use of resources that each Assisted Living has available from all of their locations. The invitation to outside experts, such as geriatric professionals, also helps build relationship with possible referral sources. The process is low-cost, the only requirement is a conference line set up.

The details of Silverado's award winning "Grand Rounds Behavior Intervention Conference Calls" are shared with the Senate Committee on Aging in the document entitled "Enhancing the Quality of Life in a Dementia Care Assisted Living Environment." Silverado also received the 2009 Dementia Award from the Center of Excellence in Assisted Living (CEAL) for the Ground Rounds concept.

Silverado used the benefits of "The Effects of Natural Light on Persons with Dementia" in the published paper from a UCSD study at Silverado Senior Living - Escondido, which was led by Dr. Sonia Ancoli-Israel. This study found that residents exposed to two hours of outdoor light had significantly reduced behaviors in the evening.

Another example of Silverado's focus on innovative clinical services is its award winning fall and fracture prevention program.

Injuries from falls are the leading cause of accidental death in the elderly. Nationally, the annual incidence of falls is 30% in persons is greater than 65 years old and in nursing homes, 75% of patients will have a fall each year. Of those who fall, about 7% - 10% sustain a serious injury, such as fracture, joint dislocation, or severe head injury. Of all fall deaths, more than 60% involve people who are greater than 75 year old. 30% of hip fractures die within one year, most deaths within six months. Only 9% post hip fracture were able to walk again. At Silverado, we recognize the risk of fall and injuries and have put in place a very pro-active, award-winning injury prevention program and fractures are rare.

One of the initial concerns that needed to be addressed was the balance between our commitment to keep residents safe and their ability to maintain choice and independence. Often our favorite hobbies and past times can involve some risk and just because we have aged or have Alzheimer's disease shouldn't preclude us from continuing to pursue our interests, even if they involve some risk. The choices we make can often put us in a position that would be considered less than one hundred percent safe.

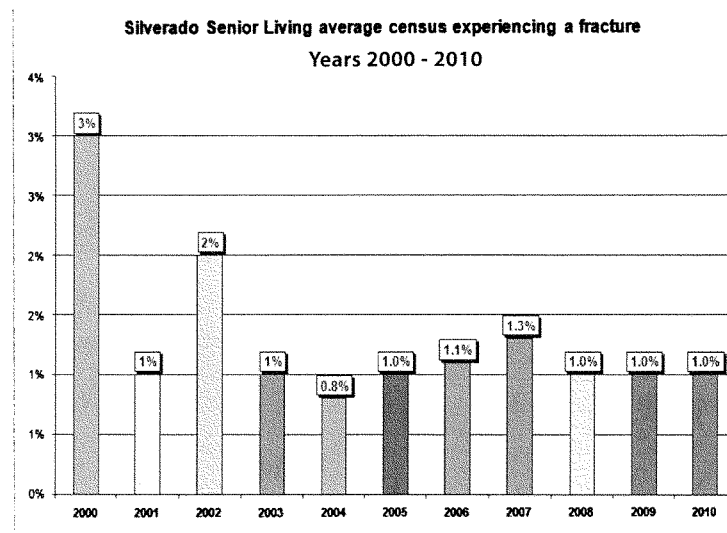
Silverado's fall and fracture prevention program, creates a balance between our philosophy of care of maximizing independence and choice while minimizing injuries that are related to falls and fractures.

When developing a program to ensure the least number of falls resulting in fractures the following elements were considered:

- History of previous falls
- Lower extremity weakness
- Gait disorders, range of motion
- Transferability – upper and lower extremity strength
- Balance
- Medications
- Age
- Chronic illness
- Environmental hazards
- Cognitive changes
- Vision changes
- Other Factors (time of day – fatigue)

The average resident at Silverado has at least 10 of the above risk factors. A multidisciplinary approach was undertaken to conduct an analysis of our falls and fractures. Our intent was to learn from our history of residents' falls in our communities. Some of the areas tracked and measured included:

- Witnessed/unwitnessed
- Location
- # of medications
- Recent medication changes
- Time of day/shift
- Acute illness



From this information we sought to identify which risk factors could we affect and which risk factors cannot be modified.

Not Modifiable:

- Age
- Dementia
- Sensory deficits

Modifiable:

- Lower Extremity Weakness
- Gait Disorders, Range of Motion (ROM)
- Transferability – Upper and Lower Extremity Strength
- Prevent deconditioning
- Balance
- Medications
- Acute Illness
- Chronic Illness – can we improve their health?
- Environmental Hazards
- Vision Changes
- Other Factors (time of day – fatigue)

With every resident having 10+ risk factors, we adopted a philosophy of “Universal Precautions” The precautions involved looking at each of the following opportunities:

- Reduction of Medications
- Maintaining Weights
- Environmental Assessment
- Interdisciplinary Team Meetings – Service Plans for Fall Risks
- Hip Savers garments
- Staff Awareness
- Alarm Systems

“Service plans” were then created for each resident that was considered “at risk” and the items identified above (previous falls, unsteady gait, weakness, recent illness or hospitalization, medications, etc.) were reviewed

The following elements were considered and as appropriate incorporated into each service plan:

- Restorative Care Program
- Physical Therapy
- Adaptive Activities
- Assist with Ambulation & Transfers
- Supportive Devices
- Lower Bed
- “Landing pad”
- Hip Savers
- Maintain Adequate Hydration/Nutrition

Silverado experts have presented at numerous state and national conferences about their fall prevention program. This year a national webinar presentation was made through Greenhouse.

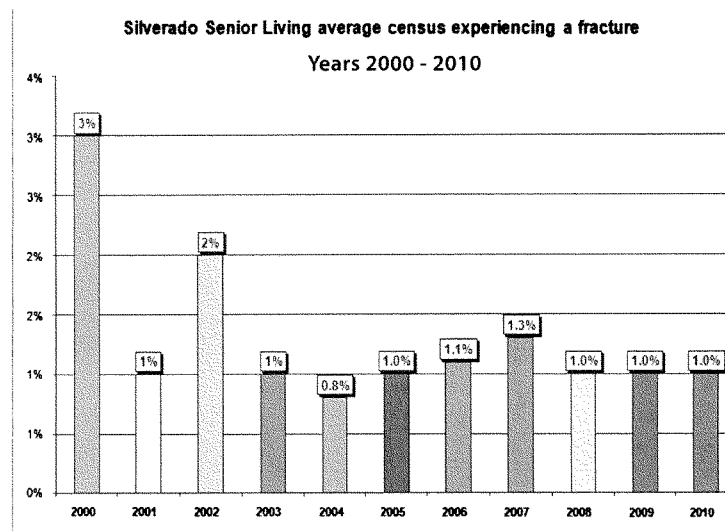
The details of Silverado’s award winning Fall Prevention Program is shared with the Committee on Aging in the document entitled “Enhancing the Quality of Life in a Dementia Care Assisted Living Environment.” This program is easily replicable by others to achieve similar results.

The success of Silverado’s Fall and Fracture Prevention program is reflected in the graphs below:

Compared to nursing homes where 10-20% of falls cause serious injuries at Silverado, only 4.8% of falls cause serious injury.

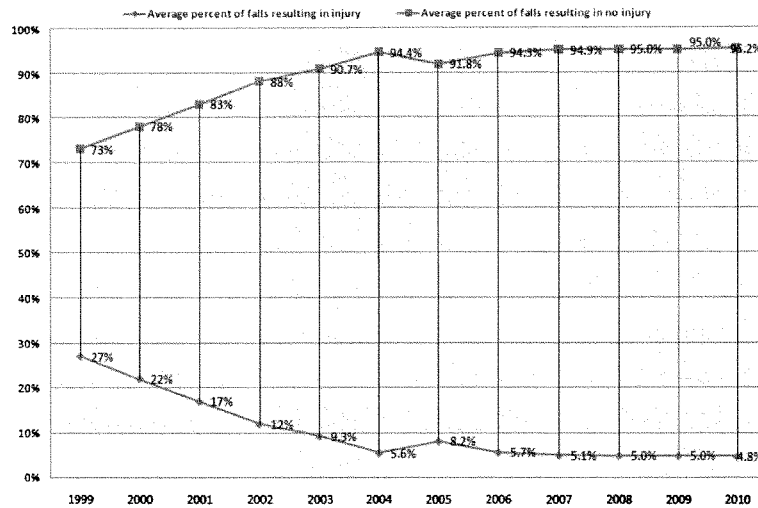
POLYPHARMACY**The Risks of Polypharmacy**

Many older adults face unknown risks from taking too many prescription and over-the-counter medications, a situation known as polypharmacy. The Journal of the American Medical Association (JAMA) had a recent article (Dec. 24, 2008) highlighting some of the dangers for seniors who are taking many medications. It is not uncommon for elders to have multiple chronic illnesses, as well as multiple physicians. This can lead to the gradual accumulation of medications



Some of the risk factors for medication-related problems include:

- 6 or more active chronic medical diagnoses
- 12 or more doses of medications per day
- 9 or more medications (including non-prescription medications)
- Low body weight
- Age 85 years or older
- Decreased kidney function (creatinine clearance)

Percent of falls with/without Injury 1999-2010

As we age, often we acquire not only multiple chronic diseases, but also multiple physicians that are treating the various illnesses. Generally, lower drug doses are required to achieve the same effect with advancing age.

The elderly population is especially vulnerable to drug reactions which often produce effects that simulate the conventional image of growing old. Adverse reactions to medications may include: unsteadiness, drowsiness, dizziness, falls, confusion, nervousness, incontinence and insomnia.

Silverado's residents suffer from dementia. If they are also taking multiple medications, the adverse effects of polypharmacy can greatly increase their confusion and disorientation.

Silverado has a proactive approach to decreasing inappropriate medications. All medications are reviewed by the RN, Director of Health Services and collaborating physicians to determine their risks and benefits. This regular review of resident medications facilitates the decrease or discontinuance of inappropriate or unnecessary medications. The average number of medications residents at Silverado take compared to the average number in Skilled Nursing Facilities (SNF) and other assisted livings.

- In a SNF, 12.7 is the average number of medications that residents take daily.
- In a traditional AL, 8.7 is average number of medications that residents take daily
2006 Overview of Assisted Living-AAHSA, ASHA, ALFA, NCAL, NIC
- Silverado Senior Living (SSL), 5.46 is average number of medications (2010)

In addition, all medications at all Silverado assisted dementia care living communities are administered only by licensed nurses. Silverado does not utilize medication aides to administer medications to our dementia residents. Silverado feels this is an especially important safety measure for our residents.

SILVERADO'S UNIQUE CLINICAL CARE PROGRAMS

Silverado Senior Living's communities hold a unique place in the assisted living industry. Only six percent of assisted livings are licensed as freestanding dementia care communities. Currently Silverado Senior Living has 20 dementia-specific assisted living communities while caring for over 1,200 residents.

Generally, Silverado cares for a very frail and elderly population. The average age of residents living at Silverado is 83 years old and less than four percent of Silverado residents are independent in their care needs. Providing care for those with dementia is a specialty, requiring a multidisciplinary team trained and focused together to offer the social stimulation and clinical assessment that supports our residents to be as independent as possible for as long as possible.

Silverado's model of care is to give LIFE to the residents as part of insuring that our residents receive quality care. As mentioned above Silverado has full complement of clinicians, including a physician as Medical Director, an R.N. as the Director of Health Services and licensed nurses on-site twenty-four hours a day, seven days a week. In addition, Silverado is affiliated with many outstanding universities and teaching programs, such as: University of California San Diego (UCSD) and the University of California at Los Angeles (UCLA), University of Southern California (USC), Baylor University College of Medicine in Texas, etc.

Silverado Senior Living	≤9% of move outs are due to health reasons
Traditional AL (2)	46.8% of move out's are due to health reasons

Silverado's clinical model allows dementia residents to age in place and avoids the trauma of having to relocate to a hospital or nursing home as they physically decline. In traditional assisted living, the most common reason that residents leave, is for health reasons. Because of Silverado's clinical model of care, it is rare that a resident would have to leave due to health conditions. Silverado's model also results in significantly reduced Emergency Room visits as well.

REGAINING INDEPENDENCE

Silverado's mission is to provide the maximum quality of life at every stage of the condition of dementia. Many residents move in to Silverado over-sedated, and debilitated. Residents' medications are reviewed by the clinical team and can often be reduced. Physical therapy and restorative care may assist residents to regain their abilities to enjoy greater independence. At Silverado, over 3000 residents have regained the ability to walk, over 2200 to regain the ability to feed themselves, and over 600 to regain independence in their self-toileting. (See attached chart). Through these improvements, residents regain independence and self esteem.

END OF LIFE CARE

Silverado cares for the residents throughout the progression of their condition and only 1.8% of Silverado residents are discharged to a nursing facility. In other assisted livings, 33.5% of residents will be discharged out to a nursing facility. Silverado is the last home for most of their residents, avoiding the trauma of having to transfer out to an acute-care hospital or nursing home as they decline. 92.4% of residents living at Silverado will pass away at Silverado, with over 70% supported by hospice care. Nursing homes show hospice use of less than 3% at end of life.



DECEMBER 2010

Silverado's assisting living communities combine a passion for giving LIFE to our residents, along with excellence in clinical outcomes, making our model of care unique in the assisted living industry.



Online article and related content
current as of September 1, 2010.

A Biobehavioral Home-Based Intervention and the Well-being of Patients With Dementia and Their Caregivers: The COPE Randomized Trial

Laura N. Gitlin; Laraine Winter; Marie P. Dennis; et al.

JAMA. 2010;304(9):983-991 (doi:10.1001/jama.2010.1253)

<http://jama.ama-assn.org/cgi/content/full/304/9/983>

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A Biobehavioral Home-Based Intervention and the Well-being of Patients With Dementia and Their Caregivers

The COPE Randomized Trial

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AMONG THE MORE THAN 5 MILLION dementia patients in the United States, most live at home, cared for by family members.¹ Functional decline, a core disease feature, represents a risk factor for poor quality of life, high health care costs, institutionalization, and mortality.²⁻⁴ With disease progression, families increasingly provide hands-on physical assistance with activities of daily living (ADLs) and instrumental ADLs (IADLs). This often results in heightened caregiver distress, a risk factor for patient nursing home placement.⁵

Few large randomized trials evaluate treatments for supporting physical function of patients with dementia. Trials of antidementia medications show few if any benefits for physical function or caregiver burden and have substantial adverse effects.⁶⁻⁸ In 1 study, twice-yearly comprehensive care planning in memory clinics showed no additional positive effects on functional decline.⁹ Previous nonpharmacologic intervention trials (exercise, use of pleasant activities, home environmental modifications) had promising findings, yet studies reported small effect sizes and outcomes other than func-

Context Optimal treatment to postpone functional decline in patients with dementia is not established.

Objective To test a nonpharmacologic intervention realigning environmental demands with patient capabilities.

Design, Setting, and Participants Prospective 2-group randomized trial (Care of Persons with Dementia in their Environments [COPE]) involving patients with dementia and family caregivers (community-living dyads) recruited from March 2006 through June 2008 in Pennsylvania.

Interventions Up to 12 home or telephone contacts over 4 months by health professionals who assessed patient capabilities and deficits; obtained blood and urine samples; and trained families in home safety, simplifying tasks, and stress reduction. Control group caregivers received 3 telephone calls and educational materials.

Main Outcome Measures Functional dependence, quality of life, frequency of agitated behaviors, and engagement for patients and well-being, confidence using activities, and perceived benefits for caregivers at 4 months.

Results Of 284 dyads screened, 270 (95%) were eligible and 237 (88%) randomized. Data were collected from 209 dyads (88%) at 4 months and 173 (73%) at 9 months. At 4 months, compared with controls, COPE patients had less functional dependence (adjusted mean difference, 0.24; 95% CI, 0.03-0.44; $P=.02$; Cohen $d=0.21$) and less dependence in instrumental activities of daily living (adjusted mean difference, 0.32; 95% CI, 0.09-0.55; $P=.007$; Cohen $d=0.43$), measured by a 15-item scale modeled after the Functional Independence Measure; COPE patients also had improved engagement (adjusted mean difference, 0.12; 95% CI, 0.07-0.22; $P=.03$; Cohen $d=0.26$), measured by a 5-item scale. COPE caregivers improved in their well-being (adjusted mean difference in Perceived Change Index, 0.22; 95% CI, 0.08-0.36; $P=.002$; Cohen $d=0.30$) and confidence using activities (adjusted mean difference, 0.81; 95% CI, 0.30-1.32; $P=.002$; Cohen $d=0.54$), measured by a 5-item scale. By 4 months, 64 COPE dyads (62.7%) vs 48 control group dyads (44.9%) eliminated 1 or more caregiver-identified problems ($\chi^2=6.72$, $P=.01$).

Conclusion Among community-living dyads, a nonpharmacologic biobehavioral environmental intervention compared with control resulted in better outcomes for COPE dyads at 4 months. Although no group differences were observed at 9 months for patients, COPE caregivers perceived greater benefits.

Trial Registration clinicaltrials.gov Identifier: NCT00259454

JAMA. 2010;304(9):983-991

www.jama.com

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tional dependence or required replication.^{10,11} Recent psychosocial caregiver interventions showed caregiver improvements, but benefits either did not extend to patients with dementia or did not address functional dependence.^{12,13}

Building on previous nonpharmacologic approaches and best clinical practices,¹⁴ we designed the Care of Persons with Dementia in their Environments (COPE) trial to test a nonpharmacologic, biobehavioral approach to support physical function and quality of life for patients with dementia and the well-being of their caregivers. The COPE program targeted modifiable environmental stressors to decrease sensorial, physical, and cognitive demands and align with patient capabilities and also ruled out underlying medical conditions that could lead to reduced patient functioning. The intervention sought to re-engage patients in daily activities and increase functionality, thereby alleviating caregiver burden.

We hypothesized that COPE patients, compared with those in a control group, would show reduced functional dependence, improved quality of life, and enhanced engagement in activities at 4 months (main study end point). We also hypothesized that COPE caregivers, compared with control caregivers, would report improved well-being and confidence using activities at 4 months. Also considered was whether COPE reduced occurrences of agitated behavior and eliminated problem areas identified by caregivers. Because the COPE study included a brief medical screen to rule out undiagnosed medical conditions, prevalence of these conditions are reported for intervention patients. Secondarily, we evaluated long-term effects (at 9 months).

METHODS

Study Population

Patients with dementia and family caregivers were recruited from March 2006 to June 2008 through media announcements and mailings by social agencies

targeting caregivers. Study procedures were explained to interested caregivers contacting the research team (telephone, return postcard), and a brief telephone eligibility screen was administered. Eligible patients had a physician diagnosis of probable dementia (using criteria from NINCDS/ADRDA [National Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Disorders Association]) or a Mini-Mental State Examination (MMSE)¹⁵ score less than 24; they also were 21 years or older and English speaking, needed help with daily activities or had behavioral symptoms, and lived with or within 5 miles of family caregivers. Eligible caregivers provided oversight or care for 8 or more hours weekly, planned to live in the area for 9 months, were not seeking nursing home placement, and reported difficulty managing patient functional decline or behaviors.

Exclusion criteria for dyads were terminal illnesses with life expectancy of less than 9 months, active treatments for cancer, more than 3 acute hospitalizations in the past year, or involvement in another caregiver trial. Patients were excluded if they had schizophrenia or bipolar disorder, had dementia secondary to probable head trauma, or had an MMSE score of 0 and were bed-bound.

Written informed consent was obtained from caregivers prior to baseline interviews using forms approved by the institutional review board. Caregivers provided proxy patient consent and patient assent was obtained for each patient-related assessment using scripts approved by the institutional review board. Families were compensated \$20 at each interview for their participation.

Following baseline interviews, dyads were randomized to the COPE or control group and reassessed by telephone at 4 and 9 months by interviewers masked to participant group. Consistent with other trials,^{13,16} caregivers of patients placed in nursing homes prior to 4 months ($n=7$) were reassessed at 4 months (but not 9 months) in areas amenable to reporting. Care-

givers of patients who died ($n=21$) were not reassessed at 4 months ($n=9$) or 9 months ($n=12$) nor included in analyses, as outcome measures were not relevant.

Randomization

Dyads were stratified by living arrangement (alone/together) and randomized within each stratum using random permuted blocks to control for possible changes in participant mix over time. The blocking number was developed by the project statistician and unknown to others. Randomization lists and 2 sets of randomization forms were prepared using opaque envelopes. The project director randomized each dyad within 48 hours of the baseline interview.

Treatment Conditions

The COPE program sought to support patient capabilities by reducing environmental stressors and enhancing caregiver skills. In this multicomponent intervention, all COPE dyads received exposure to each treatment element: assessments (patient deficits and capabilities, medical testing, home environment, caregiver communication, and caregiver-identified concerns); caregiver education (patient capabilities, potential effects of medications, pain, constipation, dehydration); and caregiver training to address caregiver-identified concerns and help them reduce stress. Training in problem-solving, communication, engaging patients in activities, and simplifying tasks was tailored to address caregiver-identified concerns and patient capabilities.

COPE dyads received up to 10 sessions over 4 months with occupational therapists and 1 face-to-face session and 1 telephone session with an advance practice nurse. Occupational therapists initially interviewed caregivers to identify patient routines, previous and current roles, habits and interests, and caregiver concerns. They also conducted cognitive and functional testing to identify patient strengths and deficits in attention, initiation and perse-

vation, construction, conceptualization, and memory.^{17,18} Occupational therapists then trained caregivers to modify home environments, daily activities, and communications to support patient capabilities; use problem-solving to identify solutions for caregiver-identified concerns; and reduce stress. For each targeted concern, a written action plan was provided^{11,13,16} describing treatment goals, patient strengths, and specific strategies. In a home visit, the nurse provided caregivers health-related information (pain detection, hydration), obtained patient blood and urine samples, and examined patients for signs of dehydration. Laboratory evaluations included complete blood cell count, blood chemistry, thyroid testing of serum samples, and culture and sensitivity testing of urine samples. Patient medications were reviewed for appropriateness, polypharmacy, and dosing using published guidelines.¹⁹ Caregivers were informed of results by telephone and mailed copies to share with the patients' physicians.

Dyads assigned to the control group received up to three 20-minute telephone calls from trained research staff members (not occupational therapists or nurses). Using scripts, staff asked caregivers about care challenges, mailed relevant informational brochures, and reviewed the materials in subsequent calls. Materials included tips from the Alzheimer's Association and government agencies on home safety and managing patient behaviors, functional decline, and caregiver stress. This controlled for professional attention and tailoring of information.

Treatment Implementation

Interventionists for both treatment groups were independently trained in protocols through readings, didactic sessions, and practices. For the COPE group, treatment fidelity was monitored through twice-monthly supervision and audiotapes submitted by interventionists, which were reviewed by investigators. For the control group, randomly selected telephone calls were

monitored for protocol adherence in real time. In both groups, interventionists completed documentation of duration and delivery content for each contact, which was reviewed for adherence. The COPE interventionists did not have contact with the control group interventionists.

Measures

Characteristics of dyads that were assessed included living arrangement (alone/together), sex, education, race, age, financial difficulty (1, not very difficult, to 3, very difficult paying for basics like food), and use of 10 formal services (eg, home health aide). To describe the racial background of participants, caregivers identified themselves and the patient with dementia as Caucasian/white, black/African American, or other.

Patient Outcomes

For functional dependence, we used a 15-item measure modeled after the Functional Independence Measure,²⁰ previously shown as psychometrically sound and corresponding to objective determinations of dependence and assistance required.^{21,22} Items included 8 IADLs (telephone, shopping, meal preparation, housework, laundry, travel, medicine, managing finances) and 7 self-care ADLs (bathing, dressing upper/lower body, toileting, grooming, eating, getting in/out of bed). For each item, caregivers chose a score to indicate the following: patients were completely independent (a score of 7); there was a safety concern, excessive time required, or assistive devices used (6); patients needed supervision, setup, or cueing but no physical help (5); or patients needed physical help (4 for a little help, 25% assistance; 3 for moderate, 50% assistance; 2 for a lot of help, 75% assistance; or 1 for complete help, >75% assistance). A total mean functional dependence score was derived by summing across items and dividing by number of items (actual range of means, 1.0-6.3). Lower scores represented greater dependence ($\alpha = .92$). Subscale scores for IADL dependence

($\alpha = .81$) and ADL dependence ($\alpha = .93$) were similarly derived.

We used the 12-item validated Quality of Life-Alzheimer Disease scale to assess caregiver perceptions of patient quality of life (1, poor, to 4, excellent).²³ Overall mean response was calculated by summing across items and dividing by number of items. Higher scores indicated better quality of life ($\alpha = .78$).

Activity engagement was measured using a validated 5-item scale²⁴ (eg, "showed signs of pleasure/enjoyment"), with items rated 1 for never to 3 for often. Scores were derived by summing across items and dividing by number of items, with 1 item reverse coded (actual range of means, 1.0-2.8). Higher scores indicated greater engagement ($\alpha = .62$).

We used the 16-item Agitated Behavior in Dementia scale to assess agitated behaviors in the past month.²⁵ At baseline, caregivers indicated whether agitated behaviors occurred (yes/no) and, if yes, the number of times. Total number of agitated behaviors was derived by summing yes items; a mean frequency score was derived by summing across items and dividing by number of items (actual range, 0.0-121.1). Higher scores indicated greater number of agitated behaviors and frequency.

Caregiver Outcomes

Caregiver well-being (improvement/worsening) was evaluated using the 13-item Perceived Change Index,²⁶ fashioned after pharmacologic trial measures and shown to have strong psychometric properties. Caregivers rated change in ability to manage dementia, emotional status (anger, distress), and somatic symptoms (energy, sleep quality) in the past month using 5-point scales (1, got much worse, to 5, improved a lot). Total mean score was derived by summing across items and dividing by number of items. Higher scores indicated greater improvement ($\alpha = .86$).

Caregiver confidence using activities over the past month was mea-

sured by 5 investigator-developed items (identify daily activities patient can do, involve patient in activities, use activities to distract patient, manage boredom, set up activities) with ratings from 0 for not confident to 10 for very confident.²⁷ Mean scores were derived across items (actual range of means, 0.60-10.00), with higher scores indicating greater confidence ($\alpha = .87$).

We used a targeted measurement approach employed in medical, pharmacologic, psychotherapeutic, and behavior management trials to capture the most challenging problems (eg, behav-

iors, dependence, respite) for caregivers.^{28,29} For each identified problem at baseline, caregivers indicated at 4 months whether that problem had been eliminated.

At 9 months, we evaluated caregiver appraisal of study benefits using an 11-item survey.^{13,16,29} Items concerned satisfaction (yes/no) with participation (study clearly explained, treated respectfully, effort required, recommend to others); and used ratings of not at all, some, and a great deal for perceived benefits (overall benefit, dementia understanding, confidence managing care, enhanced skills, life easier)

and perceived patient benefits (improved daily life, helped keep patient home).

Statistical Analysis

Based on previous research, we based sample size calculation on assumptions of 25.0% attrition by 4 months and study hypothesis tested at 90% power to detect moderate effect sizes ($d = 0.45$). We used $\alpha = .05$ level test. Given expected attrition, we planned to randomize 230 dyads.

χ^2 and Wilcoxon rank-sum tests were used to compare intervention and control participants on baseline character-

Table 1. Characteristics of Patients With Dementia and Their Caregivers Who Completed 4-Month Assessment

Characteristic	Control Group (n = 107)	Intervention Group (n = 102)	Total (N = 209)	χ^2	Z	P Value
Patients with dementia						
Age, mean (SD), y	81.8 (9.9)	83.1 (7.8)	82.4 (8.9)		-1.00	.33
Sex, No. (%)				3.42		.06
Male	40 (37.4)	26 (25.5)	66 (31.6)			
Female	67 (62.6)	76 (74.5)	143 (68.4)			
Race, No. (%)				2.18		.34
White	72 (67.3)	75 (73.5)	147 (70.3)			
African American	31 (29.0)	26 (25.5)	57 (27.3)			
Other	4 (3.7)	1 (1.0)	5 (2.4)			
Living arrangement, No. (%)				0.07		.79
Alone	5 (4.7)	4 (3.9)	9 (4.3)			
With caregiver	102 (95.3)	98 (96.1)	200 (95.7)			
No. of agitated behaviors, mean (SD)	6.0 (3.0)	6.8 (3.0)	6.4 (3.0)		-1.98	.048
MMSE score, mean (SD)	13.6 (7.9)	13.1 (8.2)	13.4 (8.1)		-0.51	.61
Caregivers						
Age, mean (SD), y	62.4 (11.7)	62.0 (12.4)	62.2 (12.0)		-0.31	.83
Sex, No. (%)				0.62		.43
Male	10 (9.3)	13 (12.7)	23 (11.0)			
Female	97 (90.7)	89 (87.3)	186 (89.0)			
Race, No. (%)				5.27		.07
White	71 (66.4)	75 (73.5)	146 (69.9)			
African American	31 (29.0)	27 (26.5)	58 (27.8)			
Other	5 (4.7)	0	5 (2.4)			
Relationship to patient, No. (%)				1.69		.19
Spouse	45 (42.1)	34 (33.3)	79 (37.8)			
Nonspouse	62 (57.9)	68 (66.7)	130 (62.2)			
Education, No. (%)				7.06		.03
<High school	26 (24.3)	38 (37.3)	64 (30.6)			
Some college	42 (39.3)	24 (23.5)	66 (31.6)			
≥College	39 (36.4)	40 (39.2)	79 (37.8)			
Time caregiving, mean (SD), y	3.9 (2.8)	4.0 (4.4)	4.0 (3.7)		-0.57	.58
Financial difficulty, mean (SD) ^a	2.2 (1.0)	2.2 (1.0)	2.2 (1.0)		-0.65	.52
No. of formal services used, mean (SD)	2.39 (1.3)	2.45 (1.27)	2.42 (1.28)		-0.38	.70

Abbreviation: MMSE, Mini-Mental State Examination.

^aValue represents median response category with 2 indicating "not very difficult paying for basics like food, housing, medical care" (range, 1-3).

istics and to compare those who stayed in vs those who dropped out by 4 months (main end point). These procedures were also used to examine potential differences at screening between eligible dyads willing to participate and those not willing. Means, standard deviations, and ranges for outcome measures were computed. The normality assumption for each dependent measure was tested by examining the distribution of residuals.

For main treatment effects, the outcome measure was 4-month score with design variable, living arrangement (alone/together), and baseline value of the outcome measure entered as covariates. For the 4-month sample, we found statistically significant differences between treatment groups at baseline for caregiver education and number of agitated behaviors (TABLE 1). We ran additional analyses of covariance with these variables as covariates. As results did not differ from the primary analyses, they are not reported. Cohen *d* was calculated to measure effect size.

Consistent with other trials, to evaluate clinical significance for outcomes reaching statistical significance at 4

months, we used the criterion of a 0.50-SD improvement from baseline to follow-up.¹³ This also represents the upper end of the distribution of effect sizes reported in the literature. We calculated number of dyads improving by 0.50 SD or more from baseline to 4 months and compared proportions between treatment groups using Mantel-Haenszel χ^2 analyses, controlling for living arrangement. We also compared proportion of COPE and control group caregivers eliminating 1 or more caregiver-identified problem by 4 months using χ^2 analysis, controlling for living arrangement.

To evaluate 9-month effects, intervention and control groups were compared on adjusted mean differences (baseline to 9 months) for each outcome using the same procedures as for 4-month effects. We also compared intervention and control group caregiver perceived benefit at 9 months using Mantel-Haenszel χ^2 analyses, controlling for living arrangement.

Statistical analysis was performed with SPSS version 17.0 (SPSS Inc, Chicago, Illinois) with the significance level set at $P < .05$. All analyses were 2-sided. Analyses included all caregivers ac-

tively caregiving (not bereaved) and providing 4-month data. Following intention-to-treat principles, we included participants regardless of exposure level to treatment.

We adjusted for 6 outcome measures (functional dependence, activity engagement, quality of life, frequency of agitated behaviors, and caregiver well-being and confidence) using a method controlling for false discovery rate (ie, proportion of rejected hypotheses expected to be erroneous).³⁰ Because .05 significance was used, we controlled the false discovery rate to be not more than 5%. Reported numerical *P* values were not corrected for multiple end points, but impact of adjustment is noted in TABLE 2.

RESULTS

Of 284 screened, 270 dyads (95.1%) were eligible, of whom 237 (87.8%) were willing to participate. No statistically significant demographic differences were found between the enrolled dyads and the 33 dyads eligible but unwilling to participate. Study attrition was low, with 28 dyads (11.8%) lost by 4 months. A higher percentage of male caregivers ($n = 12$, 34.3%)

Table 2. Comparison of Intervention ($n = 102$) and Control ($n = 107$) Group Patients and Caregivers at 4 Months*

	Mean (SD) Score				Adjusted Mean Difference Between Groups (95% CI)	P Value	Cohen's d
	Baseline		4-Month Follow-up				
	Control Group	Intervention Group	Control Group	Intervention Group			
Patient outcomes							
Overall functional dependence ^b	2.8 (1.3)	3.0 (1.2)	3.3 (1.3)	3.7 (1.3)	0.24 (0.03 to 0.44)	.02	0.21
IADL dependence	1.8 (1.0)	1.8 (1.0)	2.5 (1.1)	2.8 (1.2)	0.32 (0.09 to 0.55)	.007	0.43
ADL dependence	4.1 (1.8)	4.3 (1.7)	4.3 (1.7)	4.6 (1.6)	0.16 (−0.09 to 0.42)	.21	
Activity engagement	2.0 (0.4)	1.9 (0.4)	1.9 (0.5)	2.0 (0.4)	0.12 (0.07 to 0.22)	.03	0.26
QOL-AD score	2.1 (0.5)	2.1 (0.4)	2.1 (0.5)	2.2 (0.5)	0.10 (0.00 to 0.20)	.06	0.14
ABID score	9.8 (10.7)	11.0 (14.6)	5.5 (8.0)	6.7 (10.6)	−0.65 (−3.05 to 1.74)	.59	
Caregiver outcomes							
Perceived change in well-being	2.8 (0.5)	2.7 (0.5)	2.9 (0.5)	3.1 (0.6)	0.22 (0.08 to 0.36)	.002	0.30
Confidence using activities ^c	7.0 (2.2)	6.6 (2.1)	6.9 (2.5)	7.5 (1.9)	0.81 (0.30 to 1.32)	.002	0.54

Abbreviations: ABID, Agitated Behaviors in Dementia scale; ADL, activities of daily living; CI, confidence interval; IADL, instrumental activities of daily living; QOL-AD, Quality of Life-Alzheimer Disease scale.

^aRefer to the "Methods" section for descriptions of the scales used in all outcome measures. All analyses controlled for living arrangement (alone vs with caregiver) and baseline value of dependent variable. After adjustment for multiple comparisons by the method of Benjamini and Hochberg,³⁰ the *P* values for the 6 primary measures (not counting ADL and IADL subscales) were .006 for perceived change in well-being and confidence using activities, .04 for overall functional dependence and activity engagement, .07 for quality of life, and 0.59 for ABID score.

^bThis measure was assessed for 202 patients because 7 patients were placed in nursing homes and the caregivers were not asked functional dependence items at 4 months.

^cThis measure was assessed for 106 caregivers in the control group because 1 caregiver was unable to respond to items.

dropped out compared with female caregivers ($n=16$, 7.9%; $\chi^2=19.9$; $P<.001$) (FIGURE 1).

By 9 months, an additional 36 dyads (17.2% from 4 months) were lost to follow-up. Total study attrition by 9 months was 64 dyads (27.0%). This included 20 deaths (13 control group patients [65%], 7 intervention patients [35%]) and 10 nursing home placements (5 control patients [50%], 5 intervention patients [50%]); group differences were not statistically significant.

For the 4-month sample, patients had a mean (SD) age of 82.4 (8.9) years and a mean (SD) MMSE score of 13.4 (8.1). Most were female ($n=143$, 68.4%) and lived with caregivers ($n=200$, 95.7%). Caregivers reported managing many agitated behaviors (mean [SD], 6.4 [3.0]) and high functional dependence (mean [SD], 2.9 [1.3]). Most patients were taking medications: 95 were taking antidepressants (40.1%); 77, medications to manage behavioral symptoms (32.5%); 108, pain medications (45.6%); and 173, memory enhancers (73.3%).

Caregivers were a mean (SD) age of 62.2 (12.0) years. Most were female ($n=186$, 89.0%), white ($n=146$, 69.9%), and nonspouses ($n=130$, 62.2%; primarily adult sons and daughters [$n=115$, 88.5%]) (Table 1).

Treatment Implementation

Of 102 COPE dyads, 80 (78.4%) completed 8 to 12 sessions; 3 dyads (2.9%) had fewer than 3 sessions. Overall, dyads received a mean (SD) of 9.31 (1.54) face-to-face sessions (mean [SD] length, 68.24 [38.34] minutes) and 3.25 (0.79) telephone sessions (mean [SD] lengths, 20.15 [13.12] minutes for occupational therapists; 6.27 [16.50] minutes for nurses). Intervention cost was estimated as \$537.05 per dyad based on national hourly salary or fringe rates for occupational therapists (\$42.83) and nurses (\$74.41), patient laboratory costs (\$120), and the mean number and length of contacts.³¹ Control group dyads received a mean (SD) of 2.83 (0.42) telephone contacts lasting 15 (8.39) minutes as per protocol.

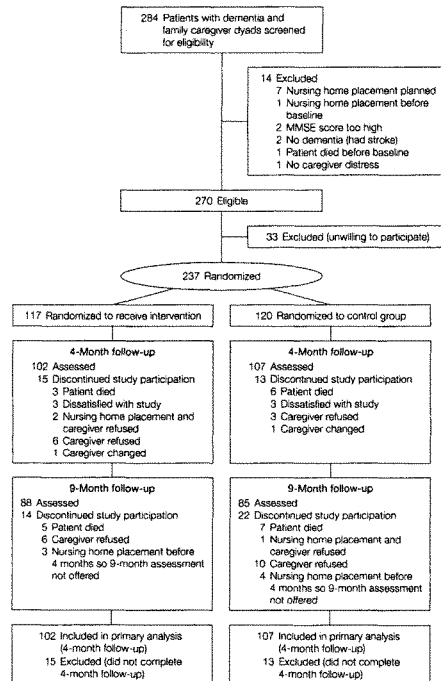
Undiagnosed Medical Conditions

Among 117 COPE patients, nurse assessments were obtained for 107 patients (91.4%) and blood or urine samples for 92 patients (85.9%); 3 refused and samples were unattainable from 12). Undiagnosed illnesses occurred in 40 patients (37.3%); 3 patients (2.8%) had 2 or more coexisting undiagnosed medical illnesses. Conditions included bacteriuria ($n=6$; 15%), anemia ($n=4$; 9%), and hyperglycemia ($n=2$; 5%). For the 40 patients with undiagnosed medical illnesses, 39 caregivers (97.5%) followed up with physicians; 1 refused. Among the 39 caregivers following up with physicians, 1 patient was admitted to a hospital and 29 patients were outpatients.

4-Month Outcomes

Statistically significant improvements were observed in functional dependence for COPE patients (baseline to 4 months) compared with control group patients (adjusted mean differ-

Figure 1. Flowchart of Study Design



Of the 102 dyads in the intervention group, 3 patients were placed in nursing homes and caregivers received a modified 4-month assessment. Of the 107 dyads in the control group, 4 patients were placed in nursing homes and caregivers received a modified 4-month assessment. MMSE indicates Mini-Mental State Examination.

Table 3. Clinical Significance of Main Outcomes at 4 Months

	Control Group, No. (%) ^a (n = 107)			Intervention Group, No. (%) ^a (n = 102)			Difference in Net Improvement (95% CI)	P Value
	Improved	Worsened	Net Improvement	Improved	Worsened	Net Improvement		
Overall functional dependence ^b	41 (39.8)	11 (10.7)	30 (29.3)	51 (51.5)	3 (3.0)	48 (48.5)	19.2 (2.7 to 36.0)	.02
IADL dependence ^b	52 (50.5)	7 (6.8)	45 (43.7)	64 (64.6)	3 (3.0)	61 (61.6)	17.9 (1.9 to 34.0)	.03
Activity engagement	40 (37.4)	42 (39.3)	-2 (-1.9)	44 (43.1)	31 (30.4)	13 (12.7)	14.6 (-8.8 to 38.0)	.22
Perceived change in well-being	42 (39.3)	21 (19.6)	21 (19.6)	58 (56.9)	11 (10.8)	47 (46.1)	26.5 (7.2 to 45.8)	.007
Confidence using activities ^c	29 (27.4)	24 (22.6)	5 (4.7)	41 (41.0)	10 (10.0)	31 (31.0)	26.3 (7.9 to 44.7)	.005

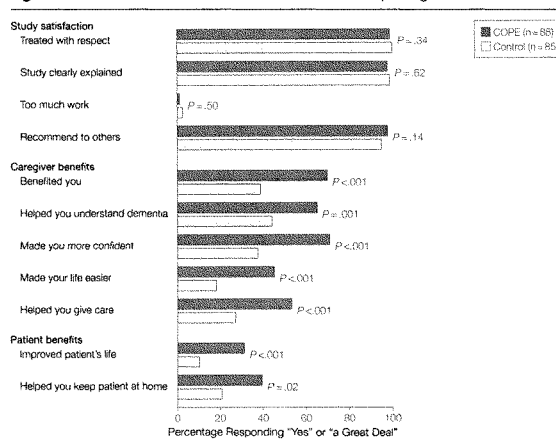
Abbreviations: CI, confidence interval; IADL, instrumental activities of daily living.

^aNot shown are the numbers (%) of those who stayed the same.^bThis measure was assessed for 99 of 102 patients in the intervention group and 103 of 107 patients in the control group because 7 patients were placed in nursing homes and the caregivers were unable to assess functional dependence.^cThis measure was assessed for 106 caregivers in the control group.

ence, 0.24; 95% confidence interval [CI], 0.03-0.44; $P = .02$; Cohen $d = 0.21$), representing a small effect. Improvement occurred mostly for IADLs (adjusted mean difference, 0.32; 95% CI, 0.09-0.55; $P = .007$; Cohen $d = 0.43$), a moderate effect. COPE patients improved slightly more in ADL functioning than controls, but this was not statistically significant (Table 2). Similarly, we observed small but statistically significant improvements in engagement for COPE compared with control patients (adjusted mean difference, 0.12; 95% CI, 0.07-0.22; $P = .03$; Cohen $d = 0.26$). We did not find statistically significant benefits for frequency of agitated behaviors or quality of life.

Compared with control group caregivers, COPE caregivers reported improvement in well-being (adjusted mean difference, 0.22; 95% CI, 0.08-0.36; $P = .002$; Cohen $d = 0.30$) and enhanced confidence using activities (adjusted mean difference, 0.81; 95% CI, 0.30-1.32; $P = .002$; Cohen $d = 0.54$), small to moderate effects (Table 2).

TABLE 3 shows proportions of participants with clinically meaningful changes (≥ 0.50 SD) for statistically significant 4-month outcomes. Net improvement across measures favored COPE participants over controls, with differences reaching statistical significance for all except activity engagement. Differences in net improvements ranged from 14.6% to 26.5%. Of 112 caregivers (53.8%) reporting 1 or

Figure 2. Perceived Benefits of Intervention and Control Group Caregivers at 9 Months

Percentages indicate those responding "yes" for Study Satisfaction items or "a great deal" for Caregiver or Patient Benefits items.

more caregiver-identified problems eliminated by 4 months, 64 (62.7%) were COPE and 48 (44.9%) were control group caregivers ($\chi^2 = 6.72$, $P = .01$).

9-Month Outcomes

We did not find statistically significant differences between COPE and control group participants from baseline to 9 months for any outcome measure. Both intervention and control

group caregivers considered study participation worthwhile and not time consuming, felt they were treated respectfully, and would recommend the study to others (all $P \geq .14$). However, COPE compared with control caregivers reported a "great deal" of improvement in their lives overall (70.9% vs 38.5%, $\chi^2 = 20.5$, $P < .001$), disease understanding (66.3% vs 43.6%, $\chi^2 = 15.0$, $P = .001$), confidence managing behaviors (72.1%

vs 37.2%, $\chi^2=25.4$, $P<.001$), made life easier (45.3% vs 17.9%, $\chi^2=34.2$, $P<.001$), ability to care for patients (54.7% vs 26.9%, $\chi^2=25.7$, $P<.001$), patients' quality of life (32.6% vs 10.3%, $\chi^2=17.0$, $P<.001$), and ability to keep patients home (39.5 vs 20.8%, $\chi^2=7.5$, $P=.02$) (FIGURE 2).

COMMENT

These findings add to an increasing evidentiary base for nonpharmacologic management of patients with dementia. We tested a multicomponent intervention that helped caregivers attend to patients' medical well-being and simplify everyday tasks to align with patient capabilities. COPE addresses core elements of dementia care: optimizing physical health and function, engaging in daily activities, maintaining quality of life, and supporting caregivers.³² At 4 months, COPE improved patient functioning, especially IADLs; patient engagement; and caregiver well-being and confidence using activities. COPE did not improve caregiver ratings of patient quality of life or frequency of agitated behaviors, although change was in the right direction.

Improvement in patient function, albeit small, compares favorably with pharmacologic trials, yet with no adverse events or known risks. Although different functional measures were used, trials of donepezil³³ and tarenflurbil⁶ showed no functional improvement, and benefits reported for donepezil were small (Cohen $d<0.10$)³⁴ compared with COPE (Cohen $d=0.21$ for overall function, Cohen $d=0.43$ for IADL). Other studies of cholinesterase inhibitors show statistically significant but small benefits for IADLs and a trend in ADL improvement, as in COPE.⁷ A multisite study found no differences in functioning from clinic-based treatments.⁹ In contrast, COPE decreased severity of overall dependence by 0.7 points and IADL dependence by 1 point. Control group caregivers also reported small functional gains of 0.5 points overall and 0.7 points for IADLs, although differences were statistically significant fa-

voring intervention. As points on the scale reflect increments of 25% in physical assistance required by caregivers, a 1-point reduction may be clinically meaningful. Poor patient functioning is a predictor of disease progression, heightening risk of caregiver burden and nursing home placement.¹² Also, dependencies are associated with increased health care costs.³ Thus, even small reductions in physical dependence may ease caregiver burden.

As to caregiver effects, pharmacologic interventions have shown only small benefits in caregiver burden (Cohen $d=0.18$),⁸ whereas in this study COPE participants showed higher effects compared with controls, from Cohen $d=0.29$ for well-being and $d=0.54$ for confidence using activities to engage patients. These improvements appear to be clinically meaningful. More intervention dyads improved 0.50 SD or more than controls on outcome measures. Also, more COPE caregivers than controls reported eliminating at least 1 problem initially identified as challenging.

Consistent with recent studies,^{16,35} a high prevalence (close to 40%) was found of undiagnosed, treatable medical conditions for intervention patients with all but 1 dyad (97.5%) following up with physicians for treatment. However, effects of their treatment are unclear. A comparison of COPE patients with identified and treated medical problems ($n=39$) with COPE patients without identified medical problems or treatment ($n=63$) showed similar 4-month gains. Nevertheless, managing physical health is an important aspect of dementia care. High rates of untreated conditions suggest the need for more frequent routine medical examinations because symptoms may present atypically and patients may not be able to report adequately.

At 9 months, there were no statistically significant differences in outcome measures. Nevertheless, perceived benefits favored intervention. Compared with controls, COPE caregivers reported a "great deal" of improvement in many areas, including

managing care better and keeping patients home. Lack of findings for standardized measures contrasts with perceived benefits, highlighting the complexity of measuring improvements in quality of life.³⁶

Of importance is that neither group reported finding the study burdensome, and both groups' participants were equally willing to recommend it to others. Training and telephone education were equally well received.

Study limitations include an inability to determine active treatment components. The trial was not designed to answer this question and COPE reflects the integration of multiple components. COPE may primarily affect caregiver appraisals. As outcome measures relied on proxy report, it is difficult to rule out this pathway.

Another limitation is study generalizability. Because caregivers volunteered for participation, they may have been more aware of their role and more motivated to learn skills than nonvolunteers.³⁷ Only 15% of study caregivers were male and a higher proportion of male caregivers than female caregivers dropped out, so it is unclear how best to address their needs.¹

A concern may be the placebo condition. Controls received information tailored to their needs,¹² but the amount of time staff spent providing information was not equivalent to that in COPE. Nevertheless, our approach is an advance over previous studies employing no-treatment comparison groups.

Because most patients live at home with functional decline, a nonpharmacologic, biopsychosocial-environmental intervention may positively contribute to disease management. Future research needs to examine effects of underlying medical conditions, ways to boost treatment effects, cost-effectiveness, COPE in combination with pharmacologic treatments, and translational potential.

Author Contributions: Dr Gitlin had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Gitlin, Hauck.

Acquisition of data: Gitlin, Winter.

Analysis and interpretation of data: Gitlin, Winter, Dennis, Hodgson, Hauck.

Drafting of the manuscript: Gitlin, Winter.

Critical revision of the manuscript for important intellectual content: Gitlin, Dennis, Hodgson, Hauck.

Statistical analysis: Gitlin, Winter, Dennis, Hodgson, Hauck.

Obtained funding: Gitlin.

Administrative, technical, or material support: Gitlin, Winter.

Study supervision: Gitlin.

Financial Disclosures: None reported.

Funding/Support: Research reported was supported in part by funds from the National Institute on Aging and the National Institute on Nursing Research (RO1 AG22254) and the Pennsylvania Department of Health, Tobacco Settlement (SAP100027298).

Role of the Sponsor: Funding agencies had no role in the design and conduct of the study; in the collection, analysis, and interpretation of the data; or in the preparation, review, or approval of the manuscript.

Additional Contributions: Barry Rovner, MD, Jefferson Hospital for Neuroscience, provided patient consultation, for which he did not receive additional compensation besides his salary. The interventionists who made important contributions were Michele Rifkin, MA, OTR/L, Health Through Action; Nicole Davis, MS, OTR/L; Lauren Lapin, OTR/L; Catherine Piersol, MA, OTR/L; Geri Shaw, OTR/L; and Tracey Vause-Earland, MA, OTR/L, and the nurse interventionist, Kathy Czekanski, RN, PhD. These individuals were employees or contractors for Thomas Jefferson University and were supported in part by funds from the listed granting agencies. We also acknowledge the contributions of our interviewing staff and thank the families for their study participation.

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Making Homes Safer:

Environmental Adaptations for People with Dementia

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Evaluating the safety of the home environment is an important component of clinical care for persons with dementia. This article discusses safety concerns for persons with dementia living at home alone or with family members, specific modifications to the physical environment to address these issues, and guiding principles for implementing environmental changes. A wide range of environmental strategies can be introduced to maximize home safety. Different adaptations may need to be implemented with progressive memory loss thus necessitating periodic reevaluation of the home.

Key words: Alzheimer's disease, best practices, environmental adjustments, family caregivers, home health care, home modification, safety

Many persons with dementia prefer to remain in their own homes or that of their family members for as long as possible. The home serves as an important source of comfort and security and enables people to maintain a sense of personal continuity and person-hood. As everyday competencies decline with memory loss; however, persons with dementia may have increasing difficulty navigating physical spaces and processing and interpreting environmental cues and stimuli. The home often becomes a hostile environment that poses barriers to the safe performance of self-care and other activities of daily living (ADLs). Common household items and longstanding environmental set-ups may jeopardize the safety of the person as the disease progresses from mild, to moderate, to severe.

Evaluating the home environment and modifying it to maximize safety is a critical component of clinical care for people with dementia.¹⁻⁴ The use of the environment as a treatment modality to increase safety is a relatively new intervention for persons with dementia, although it

has long been an integral component of occupational therapy and home health care practice. There are a wide range of adaptations that can be made to the material objects and permanent features of the home. Some adaptations are costly and require professional support, such as installing a ramp, handrail or widening a doorway. For the most part, however, adaptations are of minimal or no cost such as those involving the rearrangement or removal of furniture and/or objects, the installation of bells or deadbolt locks, or the use of visual cues. This article discusses safety considerations for persons with dementia living at home alone or with family members. Also, specific modifications to the environment are presented that can be implemented by families and health and human service professionals to manage unsafe conditions.

Alzheimer's Care Quarterly 2000; 1(1): 50-58
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WHY USE ENVIRONMENTAL MODIFICATION TO ENHANCE HOME SAFETY?

Environmental modification represents one set of techniques for managing unsafe environmental conditions at home that can be implemented independently or in combination with other treatment approaches. This approach is designed to create a supportive environment. It is in contrast to restrictive environments in which restraints are used or constant vigilance by family members are required.⁴ Applied environmental psychology and specifically a competence-environmental press framework⁵ provides the theoretical basis for using this approach to enable the home safety of persons with dementia. A competence-environmental press framework suggests that as competencies decline, the environment makes significant demands on an individual such that the outcome is dysfunctional behavior (eg, agitation, confusion, falls, and difficulty performing daily tasks safely). Adjusting or simplifying the environment to match the capabilities of the person to navigate and appropriately process cues from the environment serves as a preventive measure to minimize risk of injuries or accidents.^{2,4}

Research on dementia units and nursing homes has demonstrated the positive influence of environmental design on safety and well-being.⁶ However, the relationship between the environmental conditions of homes and the safety of people with dementia has not been studied systematically. There is limited research on the types of home conditions that are a hazard to people with dementia and the consequences of different home set-ups on risk of injury or unsafe behaviors. Research suggests that individuals with cognitive impairments tend to encounter a greater number of hazards in their homes than people with physical impairments.^{8,9} Much of what is known about home safety with this population is based on clinical practice and descriptive studies of what families themselves do in the home to manage the disease process.¹²⁻¹⁹ These studies suggest that families implement home modifications to cope with a wide range of dementia-related behaviors, and primarily to ensure safety in carrying out ADLs. For example, families report using modifications such as grab bars or other assistive devices, adjusting or rearranging furniture and appliances, removing furniture and/or potentially dangerous household items, and/or making adjustments to lighting to enhance home safety. More research is required to substantiate the consequences of home conditions on the well-being of persons with dementia. Nevertheless, reports of clinical practice and family expe-

riences offer important guidelines for safety practices at home. The recommendations offered here reflect a synthesis of the existing research literature, case reports, and ongoing research by the authors to test the benefits of environmental modification for family caregivers and persons with dementia.

PRIMARY SAFETY CONCERNS AT HOME

Six primary safety concerns for the person with dementia who lives at home alone or with a family member are listed in the box entitled "Home Safety Concerns". Individuals with dementia are at an increased risk of falling because of memory loss and poor coordination. They become more susceptible to common tripping hazards in the home. Conditions such as articles in pathways, frayed carpets or broken tile may place a person with dementia at increased risk of a fall. Excessive auditory noise or visual stimulation may be distracting to a person with dementia and also increase the risk of a fall. This is particularly the case when distractions occur during a transfer, ambulating around the house, or ascending and descending stairs. Another safety concern is the potential to ingest poisonous substances such as certain plants, cleaning fluids, or other common household chemicals. Confusion as to the appropriate use of these objects or the inability to read or comprehend labels places the person with dementia at increased risk. Although not all individuals with dementia manifest elopement attempts, leaving the home and getting lost and/or hurt is another safety concern that prompts many families to institutionalize their family member. Yet another safety concern is the presence of sharp objects such as knives, tools, scissors, or fireplace equipment. This may be the case especially for individuals who become agitated and are at risk of harming themselves or others. The potential for injury from a household fire or

Home Safety Concerns

- Injury from falls
- Injury from ingestion of dangerous substances
- Exiting home and getting lost
- Injury to self or others from sharp objects
- Fire or burns from inappropriate use of appliances
- Inability to respond rapidly to crisis

Table 1

Home Safety Environmental Checklist	
Environmental Feature	Potential Hazards
I. Specific Rooms and Areas	
1. Kitchens	<ul style="list-style-type: none"> • Inappropriate use of appliances (especially oven) • Access to medications • Access to sharp items (knives) • Improper storage of food • Poisonous plants • Access to alcohol, foods, condiments that may be harmful if eaten in large quantities
2. Stairs	<ul style="list-style-type: none"> • Objects in pathways • Lack of secure handrails (from top to bottom) • Stairs poorly lit at top or bottom • Steep, broken, uneven, or sloping steps • Safety gate at top of stairs
3. Bathrooms	<ul style="list-style-type: none"> • Floor surfaces and tub slippery • Water temperature too hot • Medications and cleaning fluids accessible • Lack of grab bars • Sharp objects available • Lock on door
II. Features throughout the Home	
1. Lighting	<ul style="list-style-type: none"> • Glare • Inadequate illumination • Pockets of shadows
2. Doors	<ul style="list-style-type: none"> • Access to dangerous locations (e.g., basement) • Ability to exit home • Height of threshold too high • Locks on bathroom doors • Location of locks
3. Electrical cords	<ul style="list-style-type: none"> • Cords in pathways • Cords too close to heat, water, or oven • Cords in disrepair
4. Common household objects	<ul style="list-style-type: none"> • Access to knives, scissors, razors, or other sharp and dangerous items • Access to breakables (glass tabletops, delicate items) • Access to medications • Access to firearms • Poisonous house plants (e.g., poinsettia)
5. Temperature control	<ul style="list-style-type: none"> • Too hot in summer, too cold in winter • Inability to open/close windows

continued

Table 1 continued

Home Safety Environmental Checklist	
Environmental Feature	Potential Hazards
6. Floor conditions	<ul style="list-style-type: none"> • Tripping hazards (throw rugs, objects in pathways, frayed carpets, broken tiles) • Slippery surfaces • Objects in pathways
7. Level of clutter	<ul style="list-style-type: none"> • Excessive number of objects in rooms • Excessive noise levels • Objects stored along baseboards or pathways • Excessive number of objects on countertops

burns from the inappropriate use of appliances is another pressing concern. Forgetting to turn off the oven, placing flammable objects on top of burners, or storing objects in the oven are common problems confronted by families. The final safety issue is the decreased ability of a person with dementia to respond rapidly to a crisis such as a fire or health emergency. This is a particular issue for persons who either live alone or are home alone for long periods of time. The concern for a person's safety in the home in these six areas increases with the progression of the disease as it impacts on memory, judgment, physical mobility and the ability to initiate and sequence ADLs.

EVALUATING HOME SAFETY RISK

In evaluating the relative safety risk of the person with dementia at home, three factors need to be considered: (1) the physical environment, (2) the cognitive capacity of the person, and (3) the behavioral manifestations secondary to the dementia. Each factor contributes to understanding whether an environment is safe or not, and the specific modifications that may minimize a person's risk. An environmental condition may not in itself be unsafe, but become a hazard as a consequence of the reduced capacities of the person with dementia. For example, keeping medications exposed on a kitchen counter may not be a hazard in the early stages of dementia but may become so with increased memory loss and the inability to remember the appropriate dosage and timing. Likewise, keeping kitchen knives exposed on the kitchen counter may not be a safety concern for many individuals with dementia. Yet for some individuals who experience extreme agitation and physical aggression, the situation may become unsafe. Given the vast variability in the

expression of dementia-related behaviors and the trajectory of decline as well as the natural variations in environmental set-ups, each household presents as a unique constellation of conditions and safety concerns. Thus, an environmental condition that presents as a hazard in one household may not present the same level of risk in another because of the person's cognitive status and behavioral repertoire.

*Wandering
outside often prompts nursing
home placement by family
members.*

able objects and hot water temperature and control. Finally, excessive auditory or visual clutter place persons with dementia at risk of agitation, elopement attempts, and increased confusion.

POTENTIAL ENVIRONMENTAL HAZARDS

Ten features of the home that have the potential to pose a hazard to persons with dementia are listed in Table 1. These items serve as a checklist for use in a home safety evaluation. The checklist informs the professional of the role these particular conditions play in placing an individual at risk for one or more of the six safety concerns.

The kitchen and bathroom are the most dangerous locations in the home. Among the potential hazards in these rooms are injury caused by the inappropriate use of appliances, access to sharp objects such as knives in kitchens or razors in bathrooms, and improper food storage and the possibility of eating spoiled food. Also, slippery floors and lack of grab bars to help with tub and/or toilet transfers place the individual at risk of falling. Storing medications and/or cleaning fluids in these rooms also pose the risk of poisonous ingestion.

Lighting is another environmental condition that can place a person at risk of a fall. The adequacy of lighting is often difficult to evaluate in the home and its effect on the person with dementia may vary depending on the time of day. Inadequate illumination of key areas such as long, dark hallways and stairs are common household problems. Glare presents a fall hazard and may be caused by light hitting high gloss floors, sunlight striking a cabinet of glassware, or exposed light bulbs. Glare may also increase a person's confusion in navigating the area and contribute to agitation. Doors and placement of locks are other features of the home that warrant evaluation. Doors leading to the basement or a steep staircase can be dangerous or those leading to the outside may trigger an elopement attempt. Locks on bathroom doors may inadvertently place the person in an unsafe situation. Also, door thresholds greater than an inch can be a tripping hazard.

Other aspects of home environments that require consideration include stairs, the placement of electrical cords in dangerous positions, accessibility of poisonous substances and medications, as well as sharp and/or break-

POTENTIAL UNSAFE BEHAVIORS

With regard to the individual, there are typically seven behaviors or activities that in particular, pose a hazard and are frequently reported by family members as safety concerns. As shown in Table 2, these include wandering outside or in the house in dangerous areas (eg, garage or basement); ascending and descending stairs; bathroom activities such as bathing, grooming, and toileting; the inability to appropriately and rapidly respond to a household crisis; and extreme agitation. Also shown in Table 2 are environmental techniques that can be implemented to minimize the hazards posed by these activities. It is important to note that the listed techniques are examples only and do not represent the universe of strategies that may be appropriate to implement. An environmental strategy must be designed to fit the particular environmental system of the household and set of manifest behaviors so that there are countless variations of strategies that are possible to implement for safety.

Wandering is a common behavioral symptom that often occurs in the moderate stage of the disease process. Of the different forms of wandering, getting lost outside the home is the most dangerous to the person with dementia and the most troublesome to family caregivers. Wandering outside often prompts nursing home placement by family members. There are many causes of wandering such as the emotional need to find home, boredom, agitation, medication side effects, or a catastrophic reaction, that may result in an elopement attempt. For some wanderers, there are particular environmental conditions that trigger an exit attempt. These triggers are highly individual or specific to a person and often represent life-long behavioral patterns and/or previous work or family life roles. For example, an alarm clock may initiate an attempt to leave the home to go to work, or a particular article of clothing such as a button-down bathrobe may appear to the person as a coat. Identifying antecedent conditions and the pattern of wandering is important to determine the most effective environmental intervention for that person. See the "Caregiving Challenges" column in this issue of Alzheimer's Care Quarterly for some responses to searching for home.

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Ascending and descending stairs is also a safety concern particularly for persons with impaired depth perception and/or balance difficulties caused by age-related functional decline or other underlying chronic conditions. Wearing poorly fitted shoes or slippers, poorly lit stairs, lack of securely fastened handrails, objects cluttering stairs all present as potential fall hazards to the person with dementia and impedes safety on stairs.

Ambulating around the home may become difficult for some persons with dementia. Individuals may tend to lean on furniture or other objects that may not be stable or able to support their weight as they ambulate through the home. A primary source of difficulty is extreme environmental clutter. It is not uncommon to find stacks of books or newspapers or bags of clothing, collectibles or other articles piled high along the walls or in pathways in homes. Clutter can distract a person as they ambulate, increase the risk of falling and serve as a source of confusion and agitation. Some individuals in the early stages of dementia may purposely place all objects on counters to make them visible and easier to locate. For some people this an adaptive strategy that is initially effective. However, as the disease progresses, the strategy tends to become ineffective as articles become highly disorganized.

Performing daily toileting, grooming, and bathing tasks also may present specific safety concerns. In the bathroom, the presence of objects that are used for different purposes (eg, toothpaste, shampoo, and deodorant) may become confusing to a person with dementia and may be used inappropriately. The ability to access medications and cleaning fluids may also become hazardous. Although family members may hide cleaning fluids out of sight of the person with dementia, their accessibility should be evaluated carefully. With respect to bathing, getting into and out of the tub may become difficult for persons with dementia, particularly for individuals with mobility impairments. Use of the towel rack or toilet roll holder to transfer, a common practice among older people, places individuals at increased risk of falling. Nighttime wandering and/or incontinence can pose a safety concern if the person is roaming in a dark house trying to find the bathroom.

Preparing meals and, particularly, using the oven are also potential hazards in the moderate stage of the disease. As discussed earlier, forgetting to turn appliances

off, especially the oven, or leaving or storing food in the oven are two important areas of concern. Consideration should be given to disabling the oven and using safety locks on cabinets to safely store medications, sharp objects and cleaning fluids. Also, if appropriate, setting up the environment to enable a person to engage in

simple meal preparations such as making a sandwich or salad can help maintain safe functioning in this area.

Difficulty responding rapidly to a crisis situation, such as a fire or medical emergency can pose a safety risk, particularly in households where the person is unattended for long periods of time. Placing bars on windows or locking the person inside the home, a common practice, only increases the risk that a person with dementia will not be able to escape from a house fire.

Persons experiencing extreme agitation or a catastrophic reaction may be particularly vulnerable to their environment and benefit from sitting in a quiet comfortable room with minimal distractions. Setting up a room that is clutter-free and has soft, pastel colors may be a soothing resting place for periodic breaks throughout the day that may help prevent the build-up of stress and reduce agitation and the potential to harm others or oneself.

PRINCIPLES FOR MODIFYING THE HOME

Although family members often initiate environmental adaptations, professional assistance is important to

Most people underreport home environmental problems and have difficulty discerning conditions that may place them or their family member at risk.

Guidelines for Modifying the Home Environment

- Observe each room of home
- Consider individual capabilities, family concerns, and environmental features
- Involve family members in evaluative process
- Introduce small, incremental changes to physical environment
- Readjust recommendations based on family feedback as to what worked best
- Provide family with information for future environmental strategies

ensure that modifications adequately address the range of safety issues presented here. Additionally, families may not have the necessary knowledge or physical materials to modify their environment to facilitate its safety or may modify their homes in ways that are unsafe. Although home safety information and modification strategies are important to share with families, they may benefit more by professional intervention. Previous research has shown that individuals are more likely to comply with home safety recommendations if they receive direct assistance in modifying their environment.¹¹ There are four principles in working with individuals with dementia and their family members to address home safety concerns.

Foremost is that a recommendation for a home environmental modification must be individualized to fit a unique person-environment system.¹⁴ The focus of a home safety evaluation and its modification is necessarily on the transactional piece, the interaction of the person, their cognitive status, and set of behaviors with the physical features of the home. Accordingly, environmental modification represents a highly individualized type of intervention that addresses specific person-environment transactional needs. A solution for one person may not work for another with a similar deficit because of differences in the objective conditions of the physical environment, the person's level of competency or the particular interaction of the person and the environment. Although this point may be obvious, it has critical implications for service delivery. It is not possible to develop a standardized delivery approach in which the same environmental modifications are recommended for all persons with dementia. Furthermore, for certain transactional situations such as carrying out daily self-care, highly skilled professionals such as an occupational therapist may be required to evaluate the best safety and functional fit between the person and his or her environment.

Second, as stated earlier, a home safety evaluation needs to be multidimensional, focusing on the person with dementia, and the concerns of the family within the environmental system. It is preferable to conduct a home safety evaluation by observing each room of the home. A home visit will yield many more significant safety issues than obtaining environmental information through an interview in a clinical setting.¹⁷ Most people underreport home environmental problems and have difficulty discerning conditions that may place them or their family member at risk.^{24,25} Consequently, self-report tends to yield unreliable information. For each room of the home it is important to identify the activities that are carried

Table 2

Environmental Modifications for Specific Behaviors and Activities	
Problem Area	Potential Modifications
Wandering outside	<ul style="list-style-type: none"> • Place "Stop" sign or "Authorized Personnel Only" on door leading to outside • Camouflage door/doorway with sheet, wall hanging, fabric, curtain, or screen • Install dead bolt lock, slide bars, or extra locks at top and bottom • Install simple bells or alarms • Store keys out of sight • Enroll in Alzheimer's Association Safe Return program • Place identification bracelet on person • Notify neighbors, local police • Keep copies of current photo available • Support the emotional need underlying the wandering attempt • Provide exercise and stimulation during day • Set up a safety proofed area for pacing and wandering in home or yard • Put away coat, boots, and other items that cue person to go out
Ascending or descending stairs	<ul style="list-style-type: none"> • Install secure handrails • Paint narrow strip or place bright color duct tape at edge of each step or other nonskid strips to stairs • Remove all objects from stairs • Secure broken steps or loose carpeting on stairs • Illuminate stairway at all times • Eliminate shadows from stairways • Have person wear fitted shoes
Ambulating around home	<ul style="list-style-type: none"> • Arrange stable furniture to use as support to move around home • Maintain clear passageways • Remove distracting objects • Eliminate clutter • Widen doorways to make rooms easier to enter • Remove or lower thresholds • Double tape area rugs or remove throw rugs • Remove low furniture and glass table tops • Pad sharp corners of furniture • Install grab bars in appropriate places • Limit access to unsafe areas (basement, garage, junk drawers)

continued on next page

Table 2 continued

Environmental Modifications for Specific Behaviors and Activities	
Problem Area	Potential Modifications
Toileting, bathing, and/or grooming	<ul style="list-style-type: none"> • Use grab bars for bathtub, toilet transfers • Use tub chair or hand held shower hose for bathing • Use nonskid bathroom mats • Remove lock, place tape on lock, or change its location on bathroom door • Set temperature on hot water heater 120° or less • Remove toxic substances (cleaning fluids, household detergents) and keep in locked cabinet • Group objects and label according to task • Remove unnecessary objects for tasks • Store medications, razors in locked cabinet • Remove sink stoppers to prevent flood • Add decals to sliding glass doors for visibility
Preparing meals	<ul style="list-style-type: none"> • Disable oven (remove knobs) and other appliances • Cover stove top with aluminum cover • Use safety locks to store dangerous items • Use signs (pictures or labels) to identify objects safe to use • Use small appliances with automatic shut off switches
Inability to respond to crisis	<ul style="list-style-type: none"> • Post emergency numbers by telephone • Use telephone with preprogrammed rapid dial numbers and train person to use • Place ID information in person's wallet • Notify neighbors • Install smoke detectors and regularly check batteries • Have copies of current photo available • Have person wear ID bracelet
Extreme agitation	<ul style="list-style-type: none"> • Remove sharp objects (scissors, knives, fireplace equipment) from common living spaces • Remove breakable objects • Set up a quiet room with comfortable furniture for rest breaks • Remove small ingestible objects

out in the area and if possible, to observe how they are actually performed. Observing the person ambulating or descending stairs provides a more accurate understand-

ing than relying on self or proxy (eg, caregiver) report. It is also important to ask persons themselves and their family members about any concerns or difficulties they are having in each room or for the activities they perform. An environmental solution must not only work for the person with dementia but also fit the needs of others in the household who themselves may have specific difficulties navigating the home environment.

A third related principle concerns the need to consider both the objective conditions of the environment as well as the perceived notions or subjective view of the individual and/or family caregiver. Professional intervention in the personal life space of people must be guided not only by an objective determination of its safety status, but also by life long psychosocial patterns and the personal preferences of individuals as to how they choose to set up their homes. The subjective experience of the home environment may have important implications for the type of environmental change that is accepted by families or individuals with dementia.^{22,23} There may be the lack of congruence between perceptions of family members and the normative assessments of the objective features of the home by health and human service professionals. For example, a home with many cherished delicate objects on display may be comfortable for and important to a family, although the professional may see the need to simplify the environment by removing these items. The person's personal goals and that of their family members may need to supersede objective determinations in developing appropriate home modification interventions. That is, the professional must focus on the goals of the individuals involved to derive solutions that will be effective.

This great potential for dissonance in perspectives when modifying the home has important implications for the approach used by professionals to introduce environmental solutions. A collaborative approach is recommended in which the professional forges a partnership with persons with dementia and their family members, elicits the particular areas of concern and the family's understanding of the situation.²⁴ This approach is in contrast to one that is prescriptive treatment in which the professional provides a list of observed safety difficulties and a standard set of recommendations. In a collaborative approach, the professional must listen carefully to the specific personal goals of individuals and/or their family members and apply environmental solutions that address those goals. For example, a home therapist may be very concerned with the stair safety of an individual with dementia who has mobility difficulties. On the basis of this concern,



safety recommendations might include installing a stair glide, moving a bed downstairs if there is a powder room, and/or providing meals upstairs. In contrast, the family may be more concerned with preserving daily routines, keeping the appearance of the home "normal," and continuing with life long patterns such that eating occurs downstairs and sleeping upstairs. A family with this perspective may reject the above safety recommendations of the therapist. Recommendations that may be more acceptable include teaching a family member to stay on one side of the individual with dementia and provide tactile guidance while descending stairs; placing bright (yellow, orange) duct tape on the edge of each step to heighten visibility; and minimizing need to ascend and descend stairs frequently by setting-up the downstairs living area (eg, use of a commode).

The fourth principle concerns the way in which environmental change is implemented in a household. It is preferable to introduce small, incremental changes in the environment so as not to upset the psychosocial tradeoffs inherent in using certain modifications. For example, grab bars are a visible reminder of disability and may be initially rejected by individuals as a strategy. Individuals must reconcile the need to address safety and functional concerns with sociocultural notions of dependence and disability. Furthermore, as the disease progresses, there may be a need to reduce the amount of stimulation in the environment by removing nonessential objects. An environmental strategy that is appropriate at one stage of dementia may need to be altered to fit needs and abilities at the next stage. Thus, the operative principle here is the need for progressive simplification of the environment with the advancement of the disease. This in turn requires periodic reevaluation of the home and continued adjustments to its physical features.

Finally, it is essential to maximize the number of choices offered to an individual and/or family caregiver. Offering multiple ways of accomplishing a safety goal empowers individuals to select and use the best strategy for their household values and lifestyle. Also, family members need information on how to manipulate the environment on their own to achieve desired safety goals. Involvement of the individual and family members enhances compliance to prescribed environmental strate-

gies. It also facilitates autonomous decision-making. Families that are provided with the necessary information feel empowered to continually simplify the environment as the disease progresses.

CONCLUSION

Safety is a fundamental requirement of living environments. Although the home provides an important source of security and comfort, it may also compromise the well-being of persons with dementia. Evaluating the safety of the home environment is thus paramount in the clinical care of persons with dementia. There are six concerns for the safety of individuals with dementia. An evaluation of the home for these safety concerns includes an examination of the physical features of the environment as well as the cognitive and physical and behavioral functioning of the person. Critical to the evaluative process is the involvement of family members to validate the material conditions and behaviors that may place the person with dementia at risk. Although a home safety checklist can alert individuals with dementia and families to potential home hazards, a professional evaluation that matches a person's characteristics to environmental conditions is important. There is a wide range of techniques that can be implemented in the home to maximize its safety. Different adaptations may need to be implemented with progressive memory loss thus necessitating periodic reevaluation of home safety.

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This work is based on research that was supported by funds from the National Institute on Aging (R01-AG10947 and U01 AG13265). The opinions contained in this publication are the authors and do not necessarily reflect those of the granting agency.

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Overwhelmed by the Challenges of Dementia Care? Jefferson Elder Care Can Help

We offer in-home services that teach new skills to both the person with dementia and the person who cares for them. We make living with dementia easier for everyone.

Families who receive our services are less upset by the behavior of their family member, need less assistance, and feel better about their situation. Our programs also help those with dementia better manage their daily activities, which may help them stay at home longer.

For more information, call
215-503-6791 or go to
www.jefferson.edu/elder_care

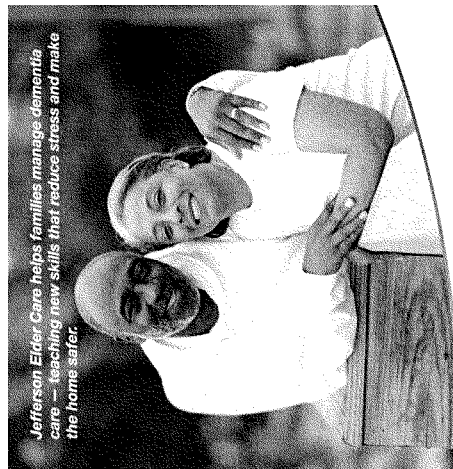
Improve Your Skills and Make Living With Dementia Easier

Jefferson Elder Care offers comprehensive services to help manage dementia. Our specially trained occupational therapists provide dementia services that were developed and tested by experts from Thomas Jefferson University.

Call 215-503-6791 for more information and to schedule a home visit.

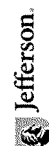
For details on the research supporting the program, or to learn more, go to www.jefferson.edu/elder_care

Services were developed and tested through funds from the National Institutes of Health, the Alzheimer's Association, the Pennsylvania Department of Health Tobacco Funds, the Rosalynn Carter Institute for Caregiving/Johnson & Johnson Caregivers Program, and the Administration on Aging.



Jefferson Elder Care helps families manage dementia care — teaching new skills that reduce stress and make the home safer.

Jefferson Elder Care Occupational Therapy Dementia Services



THOMAS JEFFERSON UNIVERSITY

Jefferson Elder Care Comprehensive Dementia Program

SkillsCare.

Caring for a family member with dementia can be difficult. SkillsCare can help. An occupational therapist will visit you at home and teach you how to:

- Manage challenging behaviors such as wandering or refusing help
- Make your home safer
- Reduce your stress
- Engage your family member in meaningful activities



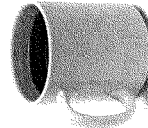
Jefferson Elder Care offers clinically proven options to help people with dementia and their caregivers.

Home Safety Assessment Service

People with dementia are at high risk for falls and other injuries. Ensuring home safety is an important part of dementia care.

An occupational therapist will assess the home and make safety recommendations such as:

- Appropriate bathroom equipment so the person with dementia can be as safe and independent as possible
- Placement of furniture and objects in order to promote a sense of security and easy access to areas that are safe
- Safe storage of medications and other potentially harmful items so they are not used inappropriately



I was doing more for my husband than he actually needed. The therapist worked with him to be more independent in the morning. She showed me how to set up his morning routine and now he is able to get dressed by himself. He says he feels better and I have a little time to sit and drink my coffee in the morning.

These statements are compiled from the reports of caregivers who have received services from Jefferson Elder Care. The individuals pictured did not make these statements.



Occupational Therapy Dementia Service

This is for patients with dementia who have Medicare Part B and qualify for occupational therapy.

An occupational therapist will make a home visit to evaluate the patient. If they qualify for continued therapy, the therapist will return to help them with the activities of daily living, and to make home safety recommendations.

This service includes SkillsCare and the Home Safety Assessment.

My wife followed me around the house and it was hard to get anything done. I learned strategies to manage day to day, and things are better now.

Until There Is a Cure: How to Help Alzheimer's Patients and Families NOW

Statement by Speaker Newt Gingrich

December 9, 2010

By devoting their time, money and energy, the caregiver frequently jeopardizes his or her own physical and mental health. This can often come at the cost of risking their livelihood. Here is where employers can make a difference.

Last week, the Center for Health Transformation launched ReACT, "Respect a Caregiver's Time," which is a corporate commitment dedicated to giving employers, including the state and federal government, the solutions to the common problems that plague their employee caregivers around well-being, empowerment and engagement. A key point here is that the private sector is taking the lead on helping caregivers live better lives as they assist their loved ones. ReACT can help employers help their employees without the intrusion of government bureaucracies.

Research has shown that employees who are caregivers of elderly parents, especially those suffering from dementia, can lose up to 20% productivity in the workplace. This number is high, but it is not as high as replacing a trained and qualified employee. And yet there is a disconnect, as the vast majority of companies do nothing to provide support.

Employers simply do not know the best approach to fully address a broad range of employee caregiving, particularly as it relates to an aging population. In the late 70s, more corporations began to understand the importance of child and dependent care. New programs for mothers, and more recently for new fathers, became common offerings to employees. The forms vary from better insurance options, child daycare and flex time. Generally speaking, few programs exist that expand these offerings to caregivers of the aging.

Employees rely on employer-provided healthcare and expect to see funds taken from their paycheck, with significant help from their employer. While this may take care of the basic healthcare needs of the employees and their families, it does nothing to support and empower an employee caregiver. America must challenge employers to also give employees assistance and flexibility around caregiving, above and beyond basic healthcare needs and on top of those provided only for healthcare.

Most employee caregivers cannot waltz into the boss's office on a moment's notice because their aging loved one slipped in the shower or wandered out of the house and was found blocks away. Employers are in many ways more empathetic when the caregiving is directed to a child rather than an aging loved one. It is expected that being taken away from work to address a child's need is a very rare occurrence and as children age, they will rely less on their parents. But with elderly patients, the opposite is true. And yet many employers continue to ignore this growing problem by not providing the proper tools and support for their employees.

When it comes to aging issues, caregiving becomes a daily, hourly, moment-to-moment and progressively worse issue. Specifically, when it comes to Alzheimer's, there is no cure, no escape, and no survivors. The caregiver is forced to see death, often slowly, dissolve their loved one away.

What role, therefore, can a company play? Can they provide support? Will they ultimately receive a return on investment from expanding or creating new programs to help employee caregivers? Will this help them retain valued employees? The answer is simply, "yes." In fact, I believe that companies can play a vital role as our country continues to face an aging population and the care needs that this creates.

We have begun exploring this with ReACT, which is designed to guide executives and HR departments on how to tackle this growing crisis. It is a multi-faceted approach incorporating HR, legal, technology and management divisions. Each area plays a role, and together, any company, big or small, private or public, like OPM, can develop this system of support. Given the tools, the knowledge of a true ROI, and the recognition of its importance, employers should be challenged to quite simply, care for their employee caregivers.

**U.S. Senate Special Committee on Aging Forum
Wednesday, December 8, 2010**

**Until There's a Cure:
How to Help Alzheimer's Patients and Families NOW**

**Dirksen Senate Office Building
Washington, DC**

**Testimony from:
Richard P. Grimes, CEO & President
Assisted Living Federation of America**



US Senate Special Committee on Aging Forum December 8, 2010
Until There's a Cure: How to Help Alzheimer's Patients and Families
NOW

Testimony submitted by the Assisted Living Federation of America (www.alfa.org)

My name is Richard Grimes, CEO & President of the Assisted Living Federation of America. I would like to thank Senator Kohl and Senator Corker for hosting this important forum.

Currently there are approximately 10 million adults in America who need long term care services and supports. Sixty percent of those adults are over the age of 65. The risk of needing long term care increases with age. By the year 2020 an estimated 15 million Americans will need long term care support and as many as 12.1 million will be over the age of 65.

Assisted living is a philosophy of care that embraces choice, independence and the opportunity for seniors to live enriching lives with dignity, respect and privacy. We are convinced that assisted living is popular because of the bedrock principle of choice.

Aging in America has changed. Thanks to advances in pharmacology and health care and the benefits of our affluent society, people are living longer than they ever imagined. The US Census bureau reports that the fastest growing demographic in our nation are those 85 and older. Study after study show that older Americans want to remain in their communities as they age and stay near friends, family and the familiar. Virtually no one wants to go into an institutionalized setting.

PROFILE OF AN ASSISTED LIVING RESIDENT

Assisted living is the resident-centered alternative to institutional care. More than one million seniors call assisted living communities' home. Our residents are frail seniors who need assistance with activities of daily living and can no longer (or choose not to) live in their family home. Our typical resident is an 85 year old widow. She takes eight to

10 different prescription drugs each day, and her medications enable her to manage chronic health conditions and live in her own room or apartment. She lives surrounded by caring staff and friends and maintains control over her own life, deciding when to go to bed, when to get up, when to bathe and when to eat. Institutional settings do not allow these choices.

HOME AND COMMUNITY BASED SETTINGS

ALFA supports the person's decision on how and where to live and receive services. Many of you are grappling with the challenge of caring for aging parents and grandparents. There are many home and community based options. Ideally everyone should have a choice regardless of age or income.

Home and community based settings such as assisted living are both a preferred choice for consumers and a cost effective choice as well. The cost of assisted living is about half as much as skilled nursing home care. Medicaid saves between 50 and 66 percent when a resident can live in an assisted living community instead of a nursing home.

WHY ALZHEIMER'S CARE IS AS IMPORTANT AS FINDING A CURE

The Assisted Living Federation of America applauds the Senate Special Committee on Aging for hosting this important Forum. Scientist's estimate more than 14 million Americans will suffer from Alzheimer's disease in the next 40 years and half of all people who reach the age of 85 will exhibit some symptoms of the disease. While drugs can slow the progression of the disease, there is no cure. Currently over 5 million Americans have Alzheimer's disease and up to 500,000 new cases are expected each year going forward. This devastating progressive brain disease robs individuals of personality, memory and the ability to communicate. Some exhibit behavior problems, even becoming violent, which make it impossible for them to live alone or with family members. Those with Alzheimer's live an average of eight to ten years after the diagnosis, some live as long as 20 years. The stress and strain on family caregivers can be overwhelmingly.

When and if it becomes unsafe to live at home, assisted living providers offer a safe and comfortable option for people with Alzheimer's disease. The Assisted Living Federation of America, is proud of the ground breaking work of its members and assisted living providers around the country in creating a dignified and secure living environment for the victims of this dreaded disease.

Assisted living is the fastest growing long term care option in the United States because industry providers are meeting the needs of an aging population that demands choice, independence dignity and quality of life. This is especially evident in the role that assisted living providers now play in caring for those who suffer with Alzheimer's disease or other forms of dementia. Knowing what services their families need and want has led to tremendous innovation in caring for individuals with Alzheimer's and other forms of dementia.

Assisted living providers offer a variety of care models for those who suffer with Alzheimer's disease and other forms of dementia. Some of our members, such as Forum panelist Loren Shook and his company, Silverado Senior Living of San Juan Capistrano, California, specialize in Alzheimer's and other forms of dementia. Many of our members offer neighborhoods, separate wings of assisted living communities, for their residents with Alzheimer's and related dementia. As residential and service providers on the front lines of care, our members have helped create and refine the modalities and standards of care for these residents in a non-institutional setting.

WHAT TO LOOK FOR IN ASSISTED LIVING

We would strongly recommend in light of the emphasis of today's forum in advising families who are considering a residential, non-institutional option such as assisted living to look for providers who can provide care environments that include:

- Care models and sensitivity to individual routines that significantly reduce behavior problems often seen among those suffering from various forms of dementia resulting in reduced use of anti-psychotic and anti-anxiety drugs

- Implementation of cutting edge best practices which encourage high degrees of independence and quality of life for seniors in residential care settings such as assisted living. Examples of this may include implementation of principles consistent with the Alzheimer's Association's Dementia Care Practice Recommendations for Assisted Living Residences.
- Use of new technology. Alzheimer's residents at many assisted living communities experience high levels of freedom of movement and life enhancement via new technologies which also promote safer living environments.
- Creation of secure and homelike living spaces with wall to wall carpeting, secure outdoor walkways and waist high gardening beds.
- Specialized training for staff to provide compassionate care for these residents.
- Specialized programming and activities for residents with Alzheimer's disease which increase resident participation and engagement. There has been a tremendous amount of innovation in this area which significantly increases the quality of life for residents with Alzheimer's disease and other forms of dementia.
- Consumer disclosure requirements for any provider, regardless of setting who advertise or promote that their setting provides specialized care for those who have Alzheimer's disease or dementia.
- Support groups for adult children and spouses of family members with Alzheimer's have been invaluable in helping families through this difficult process and most assisted living providers make available and encourage family support groups to their residents' families.

ALFA strongly supports the following Alzheimer's and dementia related public policy initiatives currently before the U.S. Senate:

- The National Silver Alert Act (S.557). Based on the Amber Alert system, this legislation would create a national notification system for identification and location of seniors who live with Alzheimer's disease and are prone to wandering away from their homes.
- National Office Dedicated to Alzheimer's Disease. Recently filed bi-partisan legislation by Senators Evan Bayh (D-IN) and Susan Collins (R-ME) would

create the country's first national office responsible for leading government efforts to treat and prevent Alzheimer's disease. Located within the Department of Health and Human Services, The National Alzheimer's Project Office would coordinate and oversee federal research on Alzheimer's disease to develop a plan to combat the disease and to eventually develop a cure.

RECOGNIZING EXCELLENCE IN ASSISTED LIVING CARE

Every year ALFA honors "Heroes" who are highly accomplished assisted living professionals who serve in a variety of roles e.g. administrator, caregiver, activities professional, volunteer etc. 5 out of 6 of the heroes selected in 2010 (out of thousands of applications) provided care or were involved with residents with Alzheimer's disease or other forms of dementia. We have enclosed a DVD which highlights our heroes' extraordinary service and accomplishments toward providing exemplary care for the residents who live in assisted living communities.

The Assisted Living Federation of American is the largest national association serving companies operating professionally managed assisted living communities for seniors. ALFA is the voice for senior living and advocates for informed choice, quality care and accessibility for all Americans needing assistance with long term care. For more information visit www.alfa.org.



Until There's a Cure: How to Help Alzheimer's Patients and Families NOW

Senate Special Committee on Aging Forum
December 8, 2010

Statement of the Center for Medicare Advocacy

The Center for Medicare Advocacy thanks the Senate Special Committee on Aging for seeking testimony from California Advocates for Nursing Home Reform (CANHR) on the issue of the inappropriate use of antipsychotic drugs with nursing home residents. When the Center and CANHR submitted a joint statement for the record for the Committee's March 24, 2010 hearing, "The War on Drugs Meets the War on Pain: Nursing Home Residents Caught in the Crossfire," we urged the Committee "to focus on the real medication that is literally killing nursing home residents each day – the inappropriate off-label use of antipsychotic medications with residents who do not have a diagnosis of psychosis." The Committee has now begun this work.

In April 2005, the Food and Drug Administration (FDA) issued "black box" warnings against the prescribing of atypical antipsychotic drugs for patients with dementia, cautioning that the drugs increased dementia patients' mortality.¹ In June 2008, extending its "black box" warning to conventional antipsychotic drugs, the FDA directly and unequivocally advised health care professionals, "Antipsychotics are not indicated for the treatment of dementia-related psychosis."²

Despite the seriousness of the FDA's warning, the use of antipsychotic drugs in nursing homes remains extraordinarily high. In the second quarter of 2010, the federal government reports that nursing facilities reported that 18.41% of their residents received antipsychotic drugs **in the absence of psychotic or related conditions**.³ With approximately 1,600,000 residents living in nursing facilities, the federal report means that nearly 300,000 residents are receiving antipsychotic drugs **in the absence of psychotic or related conditions**. "Residents who exhibit both cognitive impairment and behavior problems on the most recent assessment," but who have no psychotic or related conditions – a group that CMS calls "high-risk" – received antipsychotic

¹ FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>.

² FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>.

³ Centers for Medicare & Medicaid Services, *MDS Quality Measure/Indicator Report: Psychotropic Drug Use – April/June 2010*, http://www.cms.gov/MDSPubOIdandResRep/02_qmreport.asp?isSubmitted=qm3&group=10&qtr=22.

drugs at a staggering rate of 39.3% in the second quarter of 2010.⁴ In Connecticut, nearly half the high-risk residents, 48.9%, received antipsychotic drugs in the second quarter of 2010.⁵

Many residents are dying as a result of being given antipsychotic drugs that should not be prescribed for them. In February 2007, David Graham, M.D., MPH, Associate Director, Science and Medicine, FDA Office of Surveillance and Epidemiology, testified in the House of Representatives that, by his estimate, “15,000 elderly people in nursing homes [are] dying each year from the off-label use of antipsychotic medications for an indication that FDA knows the drug doesn’t work.”⁶

Nursing facilities’ gross misuse of antipsychotic drugs with nursing home residents is rarely sanctioned. Few facilities receive deficiencies for misusing antipsychotic drugs⁷ despite the fact that regulations implementing the federal Nursing Home Reform Law explicitly limit the use of antipsychotic drugs. 42 C.F.R. §483.25(l)(2).

The Center for Medicare Advocacy urges the Committee to continue and expand its work on the medically inappropriate and life-threatening use of antipsychotic drugs with nursing facility residents. The Committee and the Centers for Medicare & Medicaid Services should consider whether a computerized warning system should be implemented to help reduce the misappropriate prescribing of antipsychotic drugs with nursing facility residents,⁸ whether special Part D rules should be promulgated to limit the prescribing of drugs that carry a black box warning from the FDA, and other strategies.

We reproduce below the Center for Medicare Advocacy’s Weekly Alert of March 25, 2010 on this issue.

Toby S. Edelman
Senior Policy Attorney
Washington, DC
December 7, 2010

⁴ *Id.*

⁵ *Id.*

⁶ Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, “The Adequacy of FDA to Assure the Safety of the Nation’s Drug Supply,” 110th Cong., First Sess. (March 13, 2007), Serial No. 110-5, page 66, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_house_hearings&docid=f35502.pdf.

⁷ Nicholas G. Castle, John B. Engberg, “Nursing Home Deficiency Citations for Medication Use,” *Journal of Applied Gerontology*, Vol. 26, No. 2, 208-232 (April 2007).

⁸ Melissa L. P. Mattison, Kevin A. Afonso, Long H. Ngo, Kenneth J. Mukamal, “Less Is More: Preventing Potentially Inappropriate Medication Use in Hospitalized Older Patients With a Computerized Provider Order Entry Warning System,” *Arch Intern Med*/ Vol. 170 (No. 15), Aug 9/23, 2010.



March 25, 2010

OFF-LABEL DRUG USE IS COMMON AND HURTS NURSING HOME RESIDENTS

Introduction

The three-year old, and still ongoing, investigation and criminal prosecution of former staff members of a California skilled nursing facility for improper use of antipsychotic drugs on residents raises issues that go far beyond the gruesome facts of the case; issues that remain current today.

This Alert discusses that case, research and Federal Drug Administration (FDA) action related to the issues raised in the case, and advocacy steps available to people seeking to help nursing home residents who are victims of such abuses.

Background

In January 2007, a nursing home ombudsman reported to the California Department of Public Health that a resident at a Kern Valley skilled nursing facility had been held down and forcibly injected with a form of psychotropic medication from the group of drugs known as atypical antipsychotic drugs. According to the state Attorney General, the Department [s]ent an investigative team with a doctor, a nurse, and a doctor of pharmacology [who] determined that 22 patients, including some who were suffering from Alzheimer's at the skilled nursing facility, were being given high doses of psychotropic medication not for therapeutic reasons, but to simply control and quiet them for the convenience of the staff.[1] The health department cited the nursing facility with immediate jeopardy, the highest level of deficiency in the federal regulatory system, for administering psychotropic medications as chemical restraints to 22 residents. It referred the case to the State Attorney General.

Following a year-long investigation, the State charged the former Director of Nursing (DoN), pharmacist, and medical director in a 10-count felony complaint, with elder abuse resulting in death. The DoN and pharmacist were also charged with assault with a deadly weapon for allegedly forcibly injecting residents with drugs.[2] The State alleged that during her five-month tenure, the DoN ordered psychotropic medications for residents for "glaring, responding to her in a disrespectful manner, or refusing to eat dinner in the dining room." Three residents were alleged to have died and other residents were alleged to have "suffered weight loss, body tremors, slurred speech, sat in geri chairs all day with glazed eyes." The DoN had been fired from a different nursing facility in 1999 after the facility was cited with a deficiency for over-medicating residents with psychotropic drugs.

To date, the pharmacist has pleaded guilty to one felony count of conspiracy to commit an act injurious to public health; she is cooperating with the State. The facility administrator was added as a defendant.

Although this ongoing criminal prosecution represents an extreme example, the misuse of antipsychotic medications in the treatment (or control) of nursing home residents is pervasive. In the fourth quarter of 2009, the federal government reports that 26.1% of the nation's 1,359,787 nursing home residents – 354,904 people – received antipsychotic drugs.[3] Studies discussed below also report that 25-30% of nursing home residents nationwide are given these drugs, frequently for reasons not approved by the FDA. Many residents are dying. In February 2007, David Graham, M.D., MPH, Associate Director, Science and Medicine, FDA Office of Surveillance and Epidemiology, testified in the House of Representatives that, by his estimate, "15,000 elderly people in nursing homes [are] dying each year from the off-label [i.e., not FDA-approved] use of antipsychotic medications for an indication that FDA knows the drug doesn't work." [4]

The Use of Atypical Antipsychotic Drugs for Nursing Home Residents

Atypical antipsychotic drugs (including Seroquel, Risperdal, and Zyprexa) were developed in the 1990s and were believed to have fewer side effects than older, conventional, antipsychotic drugs such as Haldol. Although approved by the FDA for people with psychoses such as bipolar disorder and schizophrenia, atypical antipsychotic drugs have been used off-label for large numbers of nursing home residents who have dementia, but no psychoses. Under federal law, physicians are allowed to prescribe drugs for uses other than those specifically approved by the FDA, but drug companies may not market drugs for off-label uses.

In April 2005, the FDA issued "black box" warnings against prescribing atypical antipsychotic drugs for patients with dementia, cautioning that the drugs increased dementia patients' mortality.[5] In June 2008, the FDA extended its warning to all categories of antipsychotic drugs, conventional as well as atypical, and directly and unequivocally advised health care professionals, "Antipsychotics are not indicated for the treatment of dementia-related psychosis." [6]

Research Literature and the Popular Press Identify the Extensive Off-Label Use of Atypical Antipsychotic Medications for Nursing Home Residents

A retrospective analysis of the use of anti-psychotic drugs by Medicare beneficiaries in nursing homes in 2000-2001 found the highest rate of antipsychotic drug use in more than a decade. The analysis reported that 27.6% of residents received at least one prescription for antipsychotic drugs and that, of those, more than half (58.2%) "took doses exceeding maximum levels, received duplicative therapy, or had inappropriate indications according to guideline requirements." [7] The atypical antipsychotic drugs were inappropriately used for residents with depression, dementia, and nonaggressive behavior problems, such as restlessness, unsociability, uncooperativeness, and indifference to surroundings. Resident outcomes did not improve with use of the atypical antipsychotics. The most common atypical antipsychotic prescribed in 2000-2001 was risperidone (trade name, Risperdal).

Using data from the 2004 National Nursing Home Survey, a later study found that 23.5% of residents received at least one atypical antipsychotic drug, that 86.3% of the drug use was off-label, and that 43% of the use "was without strong scientific support."^[8]

Although the FDA's black box warning led to some decreases in the use of atypical antipsychotics for elderly patients with dementia,^[9] a recently-released study of nursing home residents who were admitted in 2006 – after the first black box warning was issued – found that more than 29% of newly-admitted residents received at least one antipsychotic medication in 2006 and that 32% of those residents "had no identified clinical indication for this therapy."^[10]

The popular press has also reported the overmedication of nursing home residents with antipsychotic drugs. Reviewing more than 40,000 federal and state inspection reports for Illinois' 742 nursing facilities, the Chicago Tribune, in an article in 2009, identified 1200 violations involving psychotropic medications and affecting 1900 residents, since 2001.^[11] The Chicago Tribune identified 12 resident deaths and dozens of incidents where residents broke bones after falling while they were medicated. The reasons for the medication: one resident "was 'yelling out' and 'easily annoyed,'" another resident "was teasing another resident and generally being 'nasty.'" Earlier this month, the Boston Globe reported that nearly 28% of all Massachusetts nursing home residents were given antipsychotic drugs in 2009 and that 22% of them (2483 residents) did not have a medical condition supporting use of the drug.^[12]

Litigation against Drug Companies

The extensive use of atypical antipsychotic drugs for nursing home residents may in part reflect drug companies' marketing of such off-label uses for residents, as reflected in recent litigation by the United States against a drug company and the nation's largest nursing home pharmacy.

In January 2009, Eli Lilly & Company pleaded guilty to the misdemeanor of introducing misbranded drugs into interstate commerce. Between September 1999 and November 2003, its long-term care sales force, as trained by the company, promoted Zyprexa for the treatment of dementia, depression, anxiety, and sleep problems in nursing home residents. Admitting its off-label marketing, the company agreed to pay the United States a criminal fine of \$615 million. At the same time, the company entered a separate civil settlement under the federal False Claims Act, admitting that it "caused invalid claims for payment for Zyprexa to be submitted to various government programs." Eli Lilly agreed to pay a civil fine of \$835 million to the United States and states.^[13] Between 2000 and 2008, Eli Lilly received \$36 billion in revenues for Zyprexa, "more than 25 times as much as the total penalties Lilly paid in January."^[14]

In November 2009, Omnicare, the nation's largest nursing home pharmacy, agreed to pay \$98 million and the drug manufacturer IVAX Pharmaceuticals agreed to pay \$14 million to the United States to resolve allegations involving kickbacks paid to Omnicare by Johnson & Johnson in exchange for Omnicare's consultant pharmacists' recommending the antipsychotic drug Risperdal for nursing home residents.^[15] The United States has also joined two separate False Claims Act lawsuits – one against two nursing home chains, Mariner Health Care and SavaSenior Care, and their principals, alleging that Omnicare paid the chains \$50 million "in

exchange for the right to continue providing pharmacy services to the nursing homes," and a second, against Johnson & Johnson and two of its subsidiaries, alleging that they paid kickbacks to Omnicare "to induce Omnicare and its pharmacists to recommend J&J drugs," including Risperdal.[16]

Advocacy Options

Various actions are available to advocates to address the inappropriate medication of residents with antipsychotic drugs.

Nursing Home Reform Law

Regulations implementing the federal Nursing Home Reform Law explicitly limit the use of antipsychotic drugs. 42 C.F.R. §483.25(l)(2) provides:

(2) Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

Guidance issued by the Centers for Medicare & Medicaid Services[17] encourages facilities to use non-pharmacological alternatives, identifies situations where antipsychotic medications are not indicated,[18] and provides an investigative protocol for unnecessary drugs, including antipsychotic drugs.

In 2005, the State of Minnesota responded to the FDA's black box warning and CMS's new guidance on unnecessary drugs by training its surveyors on antipsychotic drug use. The state's stepped-up enforcement of the federal regulations led to a decline in nursing facilities' use of antipsychotic drugs with residents who did not have a diagnosis of psychosis.[19]

State bills

State legislation may strengthen informed consent rules and practice. A bill pending in the state legislatures in Wisconsin[20] would require that a resident or, if the resident is incapacitated, a person acting on the resident's behalf, give informed written consent before any antipsychotic drug with a black box warning is given to the resident. Similar legislation introduced in Massachusetts[21] would require informed consent from "the resident, the resident's health care proxy, and a court appointed Rogers guardian" before any psychotropic medication is prescribed. Similar types of legislation addressing nursing home residents and antipsychotic drugs are under consideration in other states.

Advocacy brochure

California Advocates for Nursing Home Reform (CANHR), a statewide resident advocacy organization, has developed a consumer brochure to explain psychoactive drugs, including antipsychotic drugs taken by a quarter of California nursing home residents, and how families can advocate to stop their inappropriate use.[22]

Conclusion

Although the research articles discussed in this Alert generally reflect practices from several years ago, current data indicate that antipsychotic drugs are still commonly taken by nursing home residents. Medical evidence demonstrating the harm of antipsychotic drugs for residents with dementia and federal regulations requiring that residents be free from unnecessary drugs do not appear to have led to significant reductions in antipsychotic drug use in nursing homes.[23]

The Center is interested in hearing from advocates on this issue. Contact attorney Toby S. Edelman (tedelman @ medicareadvocacy.org) in the Center for Medicare Advocacy's Washington, DC office at (202) 293-5760.

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- [1] Office of the Attorney General, "Brown Announces Arrests of Nursing Home Employees Who Drugged Patients for Staff's Convenience" (News Release, Feb. 18, 2009), <http://ag.ca.gov/newsalerts/release.php?id=1682>.
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Until There's A Cure: How to Help Alzheimer's Patients and Families NOW
Abe's Garden statement for the record

Dear Concerned Committee Members

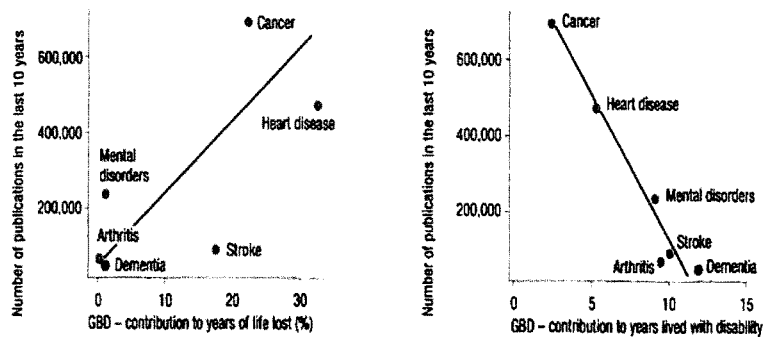
On behalf of the Abe's Garden board of directors, I would like to thank the Special Committee on Aging for its interest in the needs of Alzheimer's patients and families until a cure for this devastating and fatal disease is found.

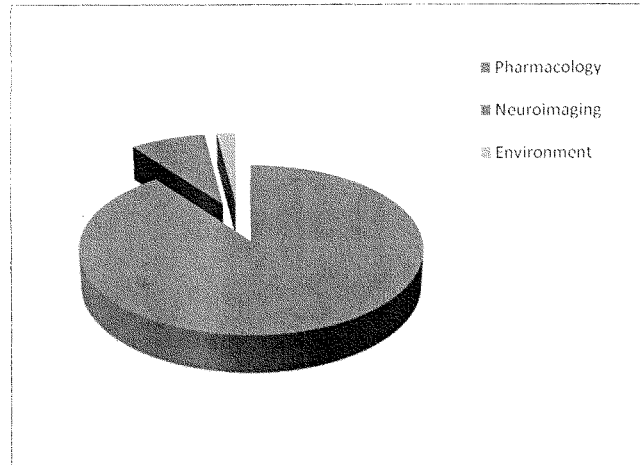
My father died from Alzheimer's disease in 1996. During the 11 years he suffered from the disease, he was forced to move six times. In addition to the irreparable damage he suffered as a result of each move, the overwhelming state of the care he received was grossly inadequate.

To address the inadequacy of services provided to affected men and women, many of whom are United States veterans like my father; our nation requires a much stronger commitment to behavioral research. Currently, the overwhelming proportion of federal funding is directed toward researching a cure. While the need for this type of research is critically important, a cure is potentially years away. It is imperative to address the needs of the millions of families currently affected by the disease by directing more funding toward enhancing Alzheimer's living environments and research-based programming.

Specifically, research is needed that addresses the inequities reflected in the following two charts:

Figure 3 Correlation of research effort (publications in last 10 years) with contributions to mortality (years of life lost) and disability (years lived with disability), for six major chronic diseases





In short, there is a vital need for additional funding to create more nurturing, research-based environments and programming that better meet the needs of this vulnerable and underserved population.

Abe's Garden is committed to improving every facet of daily life for individuals with Alzheimer's disease, their family members, and caregivers; while also positively affecting the larger communities in which they live. The most effective way to reach this lofty goal is by continuing efforts to enhance memory care living environments, to fund research-based programming and to collaborate with others. Abe's Garden is currently in different stages of collaboration with local and national non-profit organizations, major medical universities, including Vanderbilt University and various for-profit companies. And now we invite our federal government to join us in our quest to expand research efforts to make life better for all those affected by Alzheimer's today. Together, we can transform the full continuum of care for those affected by this fatal disease, and better care for our nation's rapidly expanding senior population.

Michael D. Shmerling

Chairman of the Board

Abe's Garden

Alzheimer's and Memory Care Center of Excellence

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Preliminary Research Shows Promise of Behavioral Interventions in Improving Cognitive Ability for Older Americans

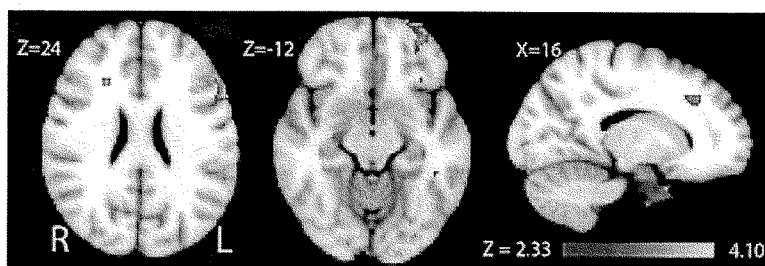
**United States Senate
Special Committee on Aging**
December 8, 2010

In a study published in the December 2009 issue of the *Journal of Gerontology: Medical Sciences*, volunteer activity in the Baltimore Experience Corps program—a program in which older Americans tutor young children in reading—was found to improve cognitive and brain functions in older women at risk for cognitive impairment. Researchers, led by Michelle C. Carlson, PhD., Associate Professor in the Johns Hopkins Bloomberg School of Public Health and Associate Director of the Johns Hopkins Center on Aging and Health, conducted this six-month case-control study in 17 older adults using brain functional magnetic resonance imaging (fMRI).

The research provides evidence that behavioral interventions, like Experience Corps, designed to promote health and function through volunteer activity may improve the brain's plasticity, or the ability to bounce back, in key regions that support executive function – cognitive abilities associated with planning and organizing one's daily life. These are the same areas critical to maintaining independent function in older age, and areas that are significantly affected by aging related diseases including Alzheimer's disease.

The Experience Corps fMRI pilot study enrolled 17 women aged 65 and older, half of whom were trained and integrated within existing Experience Corps programs in local Baltimore City schools from January-June, and half of whom were evaluated and wait-listed to enroll in the Experience Corps the following academic year. Participants underwent brain scans at baseline and six-months later. The fMRI analyses revealed that Experience Corps volunteers showed a 54% improvement in executive function beyond baseline compared to the control subjects. This is a huge effect by any intervention standard.

"The results of this study hold promise for enhancing and maintaining brain reserve and health in later life," said Dr. Carlson, who is now leading a much larger, multi-year study to confirm these preliminary findings.



Brain areas associated with improved executive function among Experience Corps volunteers.

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Evidence for Neurocognitive Plasticity in At-Risk Older Adults: The Experience Corps Program

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Objective. To determine whether Experience Corps (EC), a social service program, would improve age-vulnerable executive functions and increase activity in brain regions in a high-risk group through increased cognitive and physical activity.

Methods. Eight community-dwelling, older female volunteers and nine matched wait-list controls were recruited to serve in the ongoing EC; Baltimore program in three elementary schools. We employed functional magnetic resonance imaging (fMRI) preintervention and postintervention to examine whether EC volunteers improved executive function and showed increased activity in the prefrontal cortex relative to controls. fMRI volunteers were trained and placed with other volunteers 15 h/wk for 6 months during the academic year to assist teachers in kindergarten through third grade to promote children's literacy and academic achievement.

Results. Participants were African American and had low education, low income, and low Mini-Mental State Examination scores ($M = 24$), indicative of elevated risk for cognitive impairment. Volunteers exhibited intervention-specific increases in brain activity in the left prefrontal cortex and anterior cingulate cortex over the 6-month interval relative to matched controls. Neural gains were matched by behavioral improvements in executive inhibitory ability.

Conclusions. Using fMRI, we demonstrated intervention-specific short-term gains in executive function and in the activity of prefrontal cortical regions in older adults at elevated risk for cognitive impairment. These pilot results provide proof of concept for use-dependent brain plasticity in later life, and, that interventions designed to promote health and function through everyday activity may enhance plasticity in key regions that support executive function.

Key Words: Prefrontal cortex—Executive function—fMRI—Aging—Social engagement.

THE prevalence of one of the most costly and irreversible conditions, Alzheimer's disease (AD), is expected to rise fourfold, to 8.6 million, over the next 50 years (1). In order to be responsive to this potential health crisis, *Healthy People 2010* has emphasized efforts to increase the quality and years of healthy life and eliminate health disparities that magnify with age, particularly among those with low education and low income. Such efforts may include the design of activity programs that improve the health and well-being of our aging population and thus prevent or halt age-vulnerable cognitive and neurological declines.

Epidemiological observational studies have suggested that leisure-time cognitive, physical, and social activities help maintain cognitive and functional health (for reviews, see (2,3)). Executive planning and organizational skills appear to be important to maintaining functional independence (4–7) and appear to be particularly vulnerable to declines at later ages (8–10) along with the prefrontal cortical regions of the brain that support them (11–14). These findings suggest that executive functions may contribute to both

memory and functional difficulties and serve as an important target for preventive interventions.

To date, little is known about the efficacy of community-based cognitive and physical exercise programs to improve a range of cognitive abilities (3). Engaging in complex work and leisure environments has been associated with improved mental flexibility over the long term, particularly among older adults (15). Complex environments impose cognitive challenges through the diversity of stimuli and the number of decisions required. As a result, they exercise organizational, inhibitory, and working memory skills, all components of executive function.

We now describe a new model designed to enhance physical, social, and cognitive activity simultaneously, and how cognitive activity, broadly, and exercise of executive function, in particular, were intentionally embedded within the design of program roles. The Experience Corps (EC) program was designed (16) to train and place volunteers in participating elementary schools for an academic year during which time they assisted teachers in grades kindergarten-third

Table 1. Baseline Demographic and Cognitive Characteristics of Women Participating in the fMRI Pilot Study, Stratified by Intervention and Control Groups

Characteristic	EC, Mean	Control, Mean
N	8	9
Age, in y (SD)	68 (5.0)	67.78 (3.7)
African American, n (%)	8 (100)	9 (100)
Education, in y (SD)	12.4 (1.3)	11.6 (2.5)
Widowed, n (%)	5 (62)	1 (11.1)
MMSE (SD)	24.5 (3.6)	26.4 (1.7)

Note: EC, Experience Corps; fMRI, functional magnetic resonance imaging; MMSE, Mini-Mental State Examination.

grade with literacy and library functions (17). A pilot randomized trial of this program in Baltimore demonstrated program-specific benefits in children's academic achievement (18) and in the physical (17) and cognitive health (8) of senior volunteers. Specifically, we found that those at greatest risk for executive deficits showed substantial and clinically meaningful improvements in these and other functions because of participating in EC. Our promising short-term findings among individuals at risk for cognitive impairment suggest that they have sufficient neurocognitive reserves or plasticity to benefit immediately and substantially from this type of high-impact activity intervention.

We next sought to find preliminary evidence of brain plasticity in age-vulnerable executive functions among these cognitively at-risk older adults through a functional magnetic resonance imaging (fMRI) pilot study of EC in eight volunteers and nine matched controls (see Table 1). We describe results of this pilot study of EC, a program that provides an ideal environment in which to test the potential for a multimodal activity intervention to influence cognitive and brain health. Additionally, practical goals were to determine whether the use of fMRI would be feasible in participants who do not typically comprise volunteer samples for intervention.

METHODS

Participants

All prospective volunteers attended information sessions to describe the EC program and participation requirements, if interested. Eligibility criteria included (a) being 60 years of age or older; (b) English speaking; (c) agreeing to commit to at least 1 year; (d) agreeing to participate at least 15 h/wk for the full school year; (e) meeting minimum criteria for cognitive functioning necessary to function successfully in a school setting via an education-sensitive, two-step process using the Mini-Mental State Examination (MMSE) (19) score = 24 or higher or if scoring 20–23, with a high school education or less, and successful completion of the Trail Making Test (TMT) (20) within the time allotted (420 seconds). The TMT served as a measure of mental flexibility, a

skill presumed key to adaptability in the schools; (f) minimum fifth grade level reading literacy; (g) clearance on the Baltimore city public school's criminal background check; and (h) completing a 2-week training to participate in EC. In addition, to participate in this fMRI pilot study, participants also had to (a) be free of a pacemaker or other ferrous metal objects in the body, (b) have no history of brain cancer or brain aneurysm or stroke in the prior year, and (c) be right-hand dominant to avoid possible confounds due to laterality in left-handed individuals. They were then scheduled for a separate 1-hour fMRI visit at the FM Kirby Center at Johns Hopkins. This study was approved by the Johns Hopkins IRB, and each participant gave informed, written consent. All participants received a \$50 honorarium for each fMRI visit.

Participants were African American, 80% of whom had a high school education and marginally normal global cognitive scores on the MMSE (average = 24.5). Half were trained and integrated with existing teams of experienced EC volunteers in two elementary schools, and half were wait-listed for enrollment the following academic year.

Intervention

This multimodal EC activity program is described in detail elsewhere (21). It was designed to bolster memory and executive functions by exercising working memory skills via reading comprehension activities with children, in literacy and library support, cooperative problem-solving skills with team members, students, and teachers, and through program activities that operated along multiple dimensions of cognitive ability and by exercising mental flexibility through the need to shift across EC roles.

All volunteers were trained on the following modules and provided with a corresponding tool book covering the following:

General Literacy Support: provides a literacy support guide to train adults who are reading with and to children. It aids adults in assessing children's current reading levels to guide level-appropriate book selection, build vocabulary and comprehension, and ask questions about the book.

Library Support: supports library functions, including shelving or cataloguing books, reopening and helping staff school libraries, helping children pick books they will enjoy, and reading to/with children, all under the guidance of a librarian.

Conflict Resolution, entitled "Partners in Play" (18): teaches children conflict resolution through play in a supervised recess program. Volunteers are trained in how to lead, set goals, and play a variety of both quiet group activity games and board games.

Outcome Measure: Flanker Task

This selective attention task measures one's ability to rapidly determine the direction of a central target (arrow)

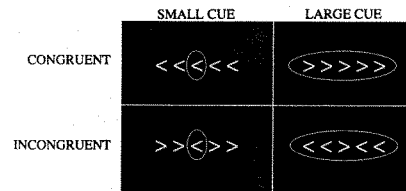


Figure 1. Flanker task conditions in which participants were instructed to respond to the direction of the center arrow. The magnitude of interference from flankers was manipulated by cue size (small and large).

while effectively inhibiting distracting information that flanks the target and may conflict with the target response (e.g., central target points left, whereas flanking arrows point right). Each trial consisted of visual presentation of a central target arrow flanked on either side by two arrows using a magnetic resonance imaging (MRI)-safe back projection system. If the center arrow pointed right, participants were instructed to press the button in their right hand; if the center arrow pointed left, participants were instructed to press the button in their left hand. Speed and accuracy were emphasized. Task difficulty was manipulated across trials by varying the direction of the flankers, which were either *incongruent* (<<<< and >>>>) or *congruent* (<<<< and >>>>) with the central arrow. In the congruent condition, flanking arrows reinforced the target response. In the incongruent condition, flankers conflicted with the target response. The magnitude of interference from flankers was manipulated by cue size on each trial (small and large), which was composed of a red circle that was either drawn only around the central target (small) or around both target and flankers (large; see Figure 1). The small cue helped focus attention on the target and minimize the impact of distracting flankers, whereas the large cue provided no information.

These task manipulations yielded four conditions (small circle incongruent, small circle congruent, large circle incongruent, and large circle congruent), which were each presented 40 times for a total of 160 trials in a rapid event-related paradigm. Each stimulus was displayed for 2 seconds on a black background in the middle of the screen. Baseline consisted of a 3-second presentation of a central fixation cross followed by a 40% interstimulus jitter optimized by optseq2 (<http://surfer.nmr.mgh.harvard.edu/optseq/>).

MRI Parameters and Preprocessing

All MRI data were collected on a 3.0T Phillips scanner (Best, the Netherlands). The functional MRI protocol employed a fast echo-planar imaging sequence with blood oxygenation level-dependent contrast acquiring 20 slices in sequence at a sampling rate of 1000 milliseconds. In addition, for each subject a high-resolution T1-weighted

anatomical image was also collected, stripped of all nonbrain tissue (22), and subsequently used for image registration.

The functional MRI data were preprocessed using FSL version 4.0 (23). Images were slice-time and motion corrected using a rigid-body algorithm (24), temporally filtered with a bandpass filter cutoff at 30 seconds and 1 second, and spatially smoothed with a 7-mm FWHM 3D Gaussian kernel.

Residual noise from excessive head motion was isolated and corrected using MELODIC, an independent components analysis used in FSL. Residual motion artifacts for each participant were signal filtered from her respective time course before the first-level analysis (25).

Data Analysis

A repeated measures analysis of variance (ANOVA) was run on all behavioral data (response times [RTs] and accuracy) with time (baseline, postintervention) and condition (congruent large cue, congruent small cue, incongruent large cue, and incongruent small cue) as within-subjects factors and group (control and treatment) as a between-subjects factor.

The neuroimaging data were convolved using a double-gamma function with temporal derivatives in an event-related analysis. Each condition was added separately to the general linear model. For each participant, a parameter estimate was calculated at each voxel across each of the four conditions. Contrasts of the flanker task conditions were calculated at this level and then forwarded to a higher-level, group-wise analysis in which a mixed-effects ANOVA was carried out. All registration matrices to a standard-space template (Montreal Neurological Institute) were calculated on the individual level and then subsequently applied to the parameter estimates and variance estimates before forwarding to group level analyses. These analyses were conducted separately at each time point. To minimize statistical constraints associated with conducting multiple comparisons, we defined regions of interest (ROIs) based on main effects of congruency (incongruent > congruent collapsed across cue size) at baseline: the anterior cingulate cortex (ACC) and left and right dorsal and ventral prefrontal cortex (dPFC and vPFC, respectively). These ROIs were similar to activated regions found in previous studies of the flanker task (26). The main aim of this study was to examine the effects of the EC intervention; therefore, we used these regions to analyze the follow-up session so that our exploration of the data was restricted to well-defined and theoretically important regions. Data were extracted from these regions and analyzed via a repeated measures analysis in SPSS version 14.0 for Mac (Chicago, IL) to assess effects and interactions of group, time, and condition. We first assessed whether the intervention group exhibited a greater change in activation than the controls over the 6-month interval (Time \times Group interaction). Second, we determined whether such intervention-specific change in activity would

be selective to the most difficult flanker condition (incongruent) compared with the easier congruent conditions (Time \times Group \times Condition interaction).

Analysis of the neuroimaging data was carried out using FEAT (fMRI Expert Analysis Tool) version 5.1 part of FSL. Group level analyses were carried out using FLAME. All Z -statistic images were thresholded using clusters determined by $Z > 3.1$ and a corrected cluster significance threshold of $p = .01$.

RESULTS

As shown in Table 1, both groups were matched on all sociodemographic variables. Participants were African American, with low income, low education levels, and an average MMSE score of 25, a score lower than typically observed in volunteer samples. Only one participant, in the intervention group, dropped out prior to follow-up due to personal health reasons. No adverse events were reported in the intervention or control arms, and the fMRI protocol was well tolerated at baseline and follow-up.

Response Data

The control group and intervention group did not reliably differ for any condition at the baseline assessment (all $p > .05$). Furthermore, at baseline, RTs were slower for the incongruent condition compared with the congruent condition ($F(1,15) = 21.27$; $p < .001$) and for large cues compared with small cues ($F(1,15) = 25.33$; $p < .001$), as expected. At baseline, both groups showed improved performance on the incongruent condition when a small cue was available but showed no similar benefit of cue size on the congruent condition ($F(1,15) = 19.52$; $p < .001$).

In pre-post comparisons, RTs were analyzed using repeated measures ANOVAs with intervention status as a between-subjects factor, time (baseline, postintervention) as a within-subjects factor, and cue size (small circle and large circle) as a within-subjects factor. Percent interference $((\text{incongruent RT} - \text{congruent RT}) / \text{congruent RT}) \times 100$ was calculated to adjust for general slowing effects related to aging (denominator) and served as the primary dependent variable. We observed a significant Time \times Group interaction ($F(1,13) = 5.28$; $p < .04$) in interference scores such that the intervention group showed a greater reduction in interference over the 6-month interval compared with matched controls (see Figure 2). The percent reduction in interference was equivalent across large and small cue sizes. Similarly, the Time \times Group \times Cue-size interaction was not significant ($F(1,13) = 1.80$; $p < .20$).

Accuracy rates did not reliably differ between the control and the intervention groups at baseline (all $p > .05$). At baseline, accuracy was worse for the incongruent condition compared with the congruent condition ($F(1,15) = 6.32$; $p < .02$) and marginally worse for large cues compared with small cues ($F(1,15) = 2.59$; $p < .06$). In addition, the small cue

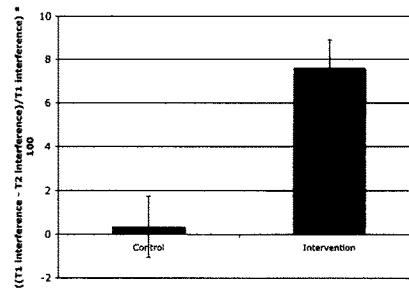


Figure 2. Change in percent interference from baseline to postintervention for both the intervention and the control groups collapsed across both small and large circle cues. *Group \times Time interaction significant at $p < .04$.

improved accuracy more for the incongruent condition than the congruent condition ($F(1,15) = 4.52$; $p < .05$). No other main effects or interactions were significant (all $p > .05$).

Repeated measures ANOVAs were also conducted to examine accuracy rates by intervention status and task difficulty (congruent vs incongruent). Time (baseline and postintervention) and cue size (small circle and large circle) were also within-subjects factors. Compared with RT measures, there was no significant Time \times Group interaction ($F(1,13) = 1.28$; $p < .28$). However, there was a significant Time \times Group \times Congruency interaction ($F(1,13) = 5.77$; $p < .03$). Post hoc comparisons revealed that this three-way interaction was due to a greater intervention-specific improvement in accuracy in the incongruent conditions ($p < .05$) that was independent of cue size ($F(1,13) = 2.160$; $p < .16$).

Neuroimaging

Results are first presented for baseline within- and between-group comparisons and then for intervention-related changes over time. Consistent with prior fMRI studies using the flanker task, we observed significant increases in activity in regions associated with the attentional network, including the left and right dorsal lateral prefrontal cortex, the ventral lateral prefrontal cortex, and the ACC (26). These regions showed elevated levels of activity for the incongruent condition compared with the congruent condition (collapsed across cue size) that met a voxel-wise threshold of $p < .01$ and a cluster-wise threshold of $p < .05$. Prior studies have extensively described these effects in relation to cognitive function, and age-related decline allowing this study to focus on how the EC intervention may impact on processing efficiency and plasticity in these regions. At baseline, both intervention and control groups showed comparable levels of activity across all three ROIs, the ACC, left ventral prefrontal cortex (vLPFC), and left dorsal prefrontal cortex (dLPFC). The effects of the intervention are highlighted subsequently.

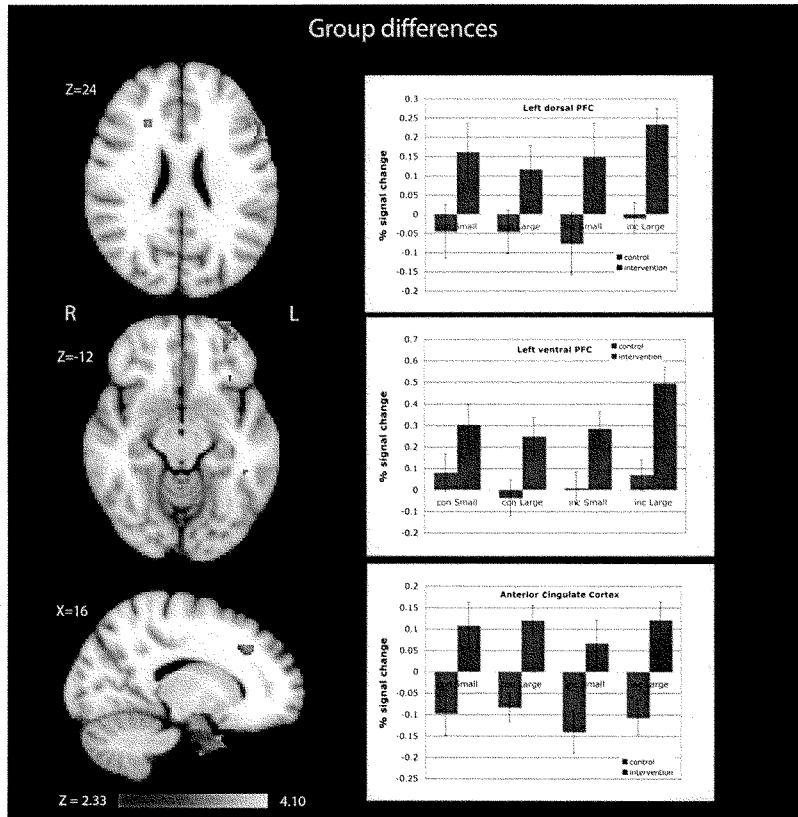


Figure 3. Images and plots showing differences in activity between the Experience Corps (EC) group and the control group for the left dorsolateral prefrontal cortex, the left ventrolateral prefrontal cortex, and the anterior cingulate cortex. These regions were not reliably different between the groups at baseline but showed significant increases in activity at postintervention for the EC group (Time \times Group, $p < .05$). PFC, prefrontal cortex.

In a repeated measures analysis of the ACC (cluster size = 1704 mm³), we observed a significant Time \times Group interaction ($F(1,13) = 13.22$; $p < .003$) that was due to a significant intervention-specific increase in activity over the 6-month follow-up (see Figure 3). There were no interactions with congruency or cue size, suggesting that intervention-specific gains in the ACC were independent of congruency condition or cue size or that there was insufficient power.

Similar analyses of the left dLPFC (cluster size = 2704 mm³) also revealed a significant Time \times Group interaction ($F(1,13) = 5.16$; $p < .04$) with the intervention group showing

a significant increase in activity over time (Figure 2). As with the ACC, there were no significant interactions with congruency or cue size. The left vLPFC (cluster size = 1576 cubic mm) showed a similar Time \times Group interaction ($F(1,13) = 8.99$; $p < .01$) with those in the intervention group showing a significant increase in activity at follow-up. Again, neither congruency nor cue size interacted with time or group, indicating that the intervention group showed increases in this region across all conditions (Figure 2).

No regions showed an intervention-related decrease in activity. The right prefrontal regions, although active at

baseline for both groups, did not show significant changes in activation that met threshold. However, there was a non-significant increase in the right dorsal prefrontal activity for the incongruent condition for both the intervention and the control groups ($p < .16$).

Pre-post comparisons of each group's ability to filter conflicting distracters (incongruent RT-congruent RT) for small and large cues are presented in Figure 3 and show EC-intervention-specific improvements in the ability to selectively attend during the most attention demanding task conditions (incongruent). Corresponding fMRI group comparisons similarly showed increased activity in attentional control regions of the PFC (middle and inferior frontal regions bilaterally) and the parietal regions, suggesting more efficient filtering or inhibiting of target information from distraction (Figure 3).

DISCUSSION

This pilot study provides proof of concept for the feasibility and utility of neuroimaging to begin to understand how a multimodal activity program in the community gets *under the skin* to improve executive functions and supporting brain regions. These at-risk individuals exhibited measurable brain plasticity in direct response to such environmental enrichment, providing initial evidence of this program's potential to reverse cognitive and corresponding neural declines with age. Individuals exhibited use-dependent neural plasticity by exercising and reactivating skills that may have been relatively unused for years or even decades. This finding is best captured by a personal observation from one of the volunteers, who stated that "it [Experience Corps] removed the cobwebs from my brain." Additionally, these previously sedentary at-risk participants were amenable to the fMRI environment on repeated exams, as demonstrated by 100% retention, and those enrolled in the program met the intensive service requirements, which led to unprecedented doses over a relatively short-exposure period.

The results replicate and build on the previous pilot trial of EC and cognition, and on an fMRI trial of physical activity in older adults. First, we replicated the impact of EC on executive functions using a sensitive measure that focuses on the age-vulnerable ability to inhibit distraction in one's environment. Indeed, the present finding suggests generalization of EC improvements over different measures of executive function. These improvements extended to corresponding increases in the activity of supporting prefrontal cortical substrates, further replicate seminal findings on the neurocognitive benefit of physical activity (26–28). The patterns of increased functional activity here differed slightly from the exercise findings in two ways. First, we observed EC-related increases in the ACC during the executive function task, whereas the exercise intervention led to decreased activation in this region. The ACC has been implicated in the efficient filtering or inhibiting of conflicting information

prior to generation of a motor response. Although both studies demonstrated improved inhibitory efficiency (speed), EC participants started with lower baseline inhibitory ability than those in the exercise intervention. Thus, as in a prior pilot trial of EC (21), these individuals were at elevated risk for executive dysfunction and likely exerted more effort to successfully develop inhibitory skills, which may be reflected by increased ACC activity. Second, we observed the lateralized increases in left prefrontal cortical activity in the EC sample while the exercise intervention observed the right prefrontal cortical increases. These laterality differences may be due to the nature of EC volunteer activities, which rely heavily on verbal communication and mediation strategies, and may thus elicit greater improvements in regions associated with communication, such as the left prefrontal and temporomedial cortices. These hypotheses require replication in a larger sample.

Although the functional significance of the laterality differences is unclear, greater unilateral activation of cortical regions following the EC intervention contributes to discussions in the functional neuroimaging literature (11,29) on the nature of brain plasticity, reserve, and compensatory function. We have yet to determine whether these changes were accompanied by structural changes and changes in supporting white matter tracts that facilitate rapid and efficient communication across regions.

The implications of these findings to the assessment of postretirement lifestyle activity are that a broader range of cognitive activities embedded within social settings may confer great cognitive and brain benefits for older adults. Recent epidemiological evidence in twin pairs suggests that socially engaging cognitive activities in midlife and early late-life may reduce risk for AD and dementia decades later (30) and may be indicative of an enriched environment, which enhances the proliferation of new brain cells and promotes brain repair in animal models (31–33). The implications of these findings to the assessment of postretirement lifestyle activity are that a broader range of cognitive activities may confer great cognitive benefits for older adults and may further confer neurocognitive protection.

Cognitive activity embedded within social settings may further increase task novelty, interactive problem-solving skills, and motivations to sustain these activities. In addition, these activities are generative in giving meaning and purpose to one's life (volunteering, civic organizations, assisting others), which may make them more rewarding and personally enriching than highly stimulating activities performed alone (34). As a result, individuals may place more value on these activities beyond their immediate personal benefit and may sustain interest longer (35). This important developmental need to be generative could provide an important vehicle for enhancing and sustaining behaviors important to successful aging, namely remaining active—socially, physically, and cognitively (34).

Limitations of this pilot study include the small sample size necessarily restricted to women (due to gender differences in brain morphology), which limits generalizability but provides proof of concept for the potential of well-validated parametric fMRI tasks, such as this, to sensitively detect program-related functional brain changes in a larger randomized study of men and women. Second, although the sample represented an important and often under-studied segment of the aging adult population, we have yet to determine whether this program enhances or maintains cognition among more ethnically and socioeconomically diverse individuals. Finally, this study design does not allow us to definitively discern whether the effects of this intervention on cognition function were mediated primarily by cognitive and physical pathways, respectively, or whether benefits represent the synergy of increased activity in all domains. Understanding the mediating source may not be as critical as the observation that a multiple pathway approach set in the community was associated with high doses, good retention, and short-term effects spanning many abilities in the most at risk.

These findings offer next-level questions about the ability of this program, and others like it, to reset one's trajectory of cognitive decline with age, particularly among those at elevated risk for dementia by virtue of impoverished environments over the life course, as marked by low or poor quality (36) education and low income. These individuals require further follow-up in order to determine the potential and boundaries of plasticity in a dose-dependent manner. Questions include whether a lower weekly exposure may confer equivalent benefits and whether continued exposure would lead to accruing benefits, perhaps in other brain regions interacting with these prefrontal circuits, such as parahippocampal and hippocampal regions that support some memory functions. Furthermore, it will be key to determine whether short-term benefits will be sustained after program exposure is discontinued. Overall, these pilot findings hold promise for enhancing functional reserve and neural plasticity among those at great risk.

FUNDING

This work was supported in part by the Research Career Development Core of the Older Americans Independence Center (P30-AG021334) and a gift from S. B. Bechtel.

ACKNOWLEDGMENT

We would like to thank Mr. Vijay Varma for editing an earlier draft of this article.

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Received February 2, 2009

Accepted July 16, 2009

Decision Editor: Luigi Ferrucci, MD, PhD



Early identification and treatment of Alzheimer's disease: Social and fiscal outcomes

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Abstract

Background: Alzheimer's disease (AD) is a progressive neurodegenerative disease that places substantial burdens on those who provide support for family members with declining cognitive and functional abilities. Many AD patients eventually require formal long-term care services because of the absence, exhaustion, or inability of family members to provide care. The costs of long-term care, and especially nursing home care, often deplete private financial resources, placing a substantial burden on state Medicaid programs. Current evidence suggests that pharmacological treatments and caregiver interventions can delay entry into nursing homes and potentially reduce Medicaid costs. However, these cost savings are not being realized because many patients with AD are either not diagnosed or diagnosed at late stages of the disease, and have no access to Medicare-funded caregiver support programs.

Methods and Results: A Monte Carlo cost-benefit analysis, based on estimates of parameters available in the medical literature, suggests that the early identification and treatment of AD have the potential to result in large, positive net social benefits as well as positive net savings for states and the federal government.

Conclusions: These findings indicate that the early diagnosis and treatment of AD are not only socially desirable in terms of increasing economic efficiency, but also fiscally attractive from both state and federal perspectives. These findings also suggest that failure to fund effective caregiver interventions may be fiscally unsound.

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Keywords:

Alzheimer's disease; Cost-benefit analysis

1. Introduction

With the aging of the United States population, the annual incidence of Alzheimer's disease (AD) is expected to increase from approximately 377,000 in 1995 to one million by 2050 [1]. The rapid increase in AD will have profound implications for the delivery and financing of long-term care (LTC) because the oldest old with AD are the largest consumers of LTC services (especially nursing home care). Although studies estimated a wide range of total annual costs to the United States economy of AD, the most likely estimates are on the order of tens of billions of dollars [2]. Alzheimer's disease has substantial fiscal impacts internationally

[3], and in the United States, influences federal and state government costs in both the Medicare and Medicaid programs. Patients with AD incur about 60% higher costs than non-AD patients in the Medicare program [4]. For states, AD patients impose a substantial cost on Medicaid programs through nursing home use. The LTC costs account for 34.6% of Medicaid spending nationally and for 42.9% in Wisconsin [5]. One approach to reducing the cost of LTC is to lower the demand for LTC services by delaying the onset or slowing the progression of AD.

Although the available therapies for AD are less than ideal, accumulating evidence indicates that they may slow the progression of the disease in some patients. In particular, therapies that slow the progression of AD, or support caregivers, have the potential to reduce the risk of nursing home placement [6,7]. A major barrier to implementing these therapies and reducing state and Medicaid LTC costs is the

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failure of the medical profession to diagnose and treat persons with AD. Studies suggest that between 40% to 80% of persons with dementia are undiagnosed in primary care [8–10] and, as a result, are untreated. The failure to diagnose and treat persons with AD was attributed to the lack of physicians' knowledge about dementing illnesses, the absence of cognitive screening, and the public perception that nothing can be done about the disease [11].

The early diagnosis and treatment of any dementing disorder requires that clinicians be alerted to the presence of potential cognitive problems. The United States Preventive Services Task Force recommends screening only for persons in whom cognitive impairment is already suspected, or for persons who meet certain triggers of suspicion for cognitive impairment [12]. The current recommendations against broader screening ignore the expressed wishes of older adults who, in some studies, overwhelmingly (80%) stated that they would want to know as early as possible that they had AD [13,14]. In general, current recommendations focus on the narrow clinical situation and ignore the growing need for early diagnoses that would allow for patient and caregiver interventions early in the course of the disease.

The present analysis evaluates the costs and benefits of the early identification and treatment of AD patients, using LTC cost data from Wisconsin and data about the potential benefits of pharmacologic and nonpharmacologic therapies. Are the early identification and treatment of AD patients socially desirable? Do the early diagnosis and treatment of AD offer fiscal benefits to states or the federal government? Our analysis answers these questions by predicting the net social benefits and changes in state and federal expenditures for early intervention programs, using Wisconsin as an example.

2. Methods

2.1. Modeling strategy

Our analyses proceed in two steps. First, the net social benefits and net fiscal savings to Wisconsin and the federal government are estimated, assuming early intervention with drug treatment, a program for caregivers, or both of these interventions. Net social benefits algebraically sum the monetized value of impacts of an intervention on all persons, e.g., patients, caregivers, and taxpayers. The fiscal effects are the changes in public expenditures borne by taxpayers. The large variation in AD progression and the uncertainty about a number of parameters call for a stochastic model. Because a large number of uncertainties must be considered and disease progression is irreversible, a Monte Carlo model is used.

A detailed summary of the modeling strategy for the Monte Carlo trials is shown in Appendix I, and is recapped here. For each set of assumed parameters and interventions, a hypothesized cohort of identical AD patients is followed over the course of their lives. Each patient suffers a random cognitive annual decline, drawn from an appropriate distribution. The cognitive level determines the probability that a patient will be institutionalized in a nursing home, taking into

account age, gender, and the presence of a spouse as caregiver. Throughout this process, patients have some probability of surviving until the next year. The experience of the cohort provides a distribution of the present values of net social benefits and fiscal savings from interventions occurring at different stages of the disease, as defined by the Mini-Mental State Examination (MMSE).

Second, the cost of identifying an AD patient is estimated by using the results of an early detection and diagnostic regime from Boustani et al [15]. This analysis incorporates the false-positive rate as well as empirical rates of voluntary participation at various stages of the diagnostic process. The predictions of the benefits of early intervention, and the predicted costs of the diagnostic program, permit an estimate of the overall net social benefits and fiscal savings that would result from the implementation of an early-stage diagnostic and treatment program.

2.2. Monte Carlo parameters

2.2.1. Overview

The Monte Carlo analyses use a number of assumptions related to the calculation of costs and benefits, and are summarized in Appendix II. Many of these assumptions are conditional on cognitive ability, as measured by the MMSE. Although many psychosocial and functional factors influence the risk of institutionalization, the model uses the MMSE because of the data available about the relationship between a given MMSE score and the outcomes on which estimates are based. The analyses classify MMSE scores of 28 to 21 as indicating mild AD, 20 to 11 as indicating moderate AD, and 10 to 1 as indicating severe AD.

Several categories of costs accrue to society during the years of survival of AD patients as a function of their MMSE score: expected nursing home institutionalization, direct costs to caregivers, reductions in the quality of life of patients, and reductions in the quality of life of caregivers. The analyses assume that the primary benefits of drug treatment accrue through reductions in costs resulting from a slower decline according to MMSE score. There may be additional benefits of drug treatment, such as improved patient behavior that reduces caregiver burden [16]. Because our analysis does not account for any effects not related to slowing disease progression, it may underestimate the benefits of drug treatment. As costs and benefits accrue over a number of years, it is necessary to discount them to present values. We do so using midyear discounting with a real discount rate of 3.5%.

2.3. Base-case assumptions

2.3.1. Survival probabilities

The analyses assume that the spouses of patients have sex-specific and age-specific annual survival probabilities, based on the most recent United States life tables [17]. Data from the Cardiovascular Health Study, which followed more than 5000 people over age 65 years for up to 10 years, estimate a hazard ratio for death of 2.1 for AD patients relative to persons with

normal cognition [18]. This hazard ratio is applied to the annual survival probabilities for patients, which shortens the expected lifespan. Whereas a 65-year-old with normal cognition would live to about age 81 years on average, a 65-year-old with AD would live on average only to about 76 years. This is a conservative approach, because it is likely that the increased death rate for AD patients is larger for those at more severe stages of the disease, so that uniformly applying the odds ratio results in too many deaths during the mild and moderate stages of the disease, when interventions are most likely to be of benefit. Although one study [19] reported a possible reduction in mortality from donepezil therapy, consistent with the findings of Lopez-Pousa et al [20], we assume that drug treatment does not affect longevity.

2.3.2. Drug costs

The cost of drug treatment is approximately \$5 per day or \$1,825 per year, and is eligible for Medicare Part D coverage. Mays et al [21] estimated that 15% of participants will be below the doughnut hole where they bear a 25% copayment rate and 24% of program participants will fall in the doughnut hole, where they bear a copayment rate of 100%. As a base-case estimate, we assume that the state will pay the 25% copayment for 15% of the population and 100% for the 24% falling into the doughnut hole or an average of 28% of drug costs. The federal share is 72%. Note that we assume that, to ensure high levels of participation, the state pays this share of drug costs for all AD patients rather than just for those who are Medicaid-eligible.

2.3.3. Institutionalization risk

The estimates of baseline risk of nursing home institutionalization derive from Hauber et al [22]. They estimated a piecewise Cox proportional hazard model of the risk of nursing home institutionalization as a function of MMSE score for the average AD patient, using data collected by the Consortium to Establish a Registry for Alzheimer's Disease. We used their estimated models to produce risks contingent on MMSE score, sex, marital status, and age (older or younger than 72 years). Applications of their models, which were performed piecewise in terms of mild, moderate, and severe AD, required adjustments at the boundaries to maintain a monotonic increase in risk of institutionalization with declining MMSE score. Using this approach, the annual risk of institutionalization is about 1% when the MMSE score falls to 24 points and increases to over 90% when the MMSE score falls to 2 points, averaging across all demographic categories. For single older males and females, the probabilities reach 100% at MMSE scores of around 11. At the beginning of each year in our analysis, surviving AD patients are moved from the community to nursing homes, using the probabilities of Hauber et al [22]. After AD patients are institutionalized in a nursing home, they are assumed to remain there until death.

2.3.4. Caregiver costs

Patients with AD receive some care from family caregivers. Estimates of the time that caregivers provide to AD patients are derived from a study conducted by Bell et al [23].

That study estimated the average time that caregivers spend providing personal-care assistance to patients at home (or in nursing homes) as 15.4 (0.6), 44.5 (1.6), and 70.2 (2.2) hours per week for mild, moderate, and severe AD patients, respectively. In the analyses, estimates of the actual hours spent were randomly selected from uniform distributions, ranging from 50% below to 50% above the estimates of Bell et al [23]. Following common convention, these hours were monetized using the median hourly wage in Wisconsin for 2006 of \$14.69.

2.3.5. Nursing home costs

The 2005 private-pay cost for a nursing home day in Wisconsin was \$189, or \$66,795 per year, and the Medicaid reimbursement amount was \$127 per diem, or \$46,355 per year [24]. In Wisconsin, on average, 23% of the Medicaid per diem is paid by patients; 40% of the remainder is paid from state funds, and 60% from federal funds. Consequently, on average, 31% of Medicaid nursing home costs are paid from state funds, or 22% of the private-pay cost. The private-pay rate is considered the social cost of nursing homes, with 22% of that amount paid by Wisconsin, and 33% by the federal government.

2.3.6. Quality of life

Changes in the quality of life of both patients and caregivers may also result from slowing the progression of the disease and changing the venue of care. The utility estimates in these analyses reflect how much a person might value the quality of a year of life in a demented versus nondemented state. Neumann et al [25] reported estimates of utilities for both patients and caregivers as a function of AD severity, and in terms of whether care is provided in the community or a nursing home: for patients in community (or nursing home) care, the utilities are 0.68 (0.71), 0.54 (0.48), and 0.37 (0.31) for mild, moderate, and severe AD, respectively. For caregivers of patients in the community (or nursing home), the utilities are 0.86 (0.86), 0.86 (0.88), and 0.86 (0.88) for mild, moderate, and severe AD, respectively. For caregivers, we used the utilities of Neumann et al [25] as base levels, adjusted for the risk of depression. Following Lave et al [26], we assigned a quality of life of 0.59 for caregivers suffering from major depression. The prevalence of depression among caregivers is about 32% [27]. Thus, caregiver utilities are assumed to be the same as the utilities of Neumann et al [25] when depression is absent (68% of the time), and 0.59 when depression is present (32% of the time).

These utilities can be applied to the statistical value of a life-year to obtain monetized, quality-adjusted life-years. The average statistical value of life for the United States population, suggested by a number of meta-analyses of empirical estimates, is about \$4 million [28]. At the assumed discount rate of 0.035, this corresponds to the statistical value of a life-year as \$187,000. We make the conservative assumption that the statistical value of a life-year is distributed uniformly over a range \$93,500 to \$187,000.

2.3.7. Rate of cognitive decline

The opportunity to initiate treatment early in AD is a primary benefit of early diagnosis. The analyses predict the

impacts of early intervention with AD treatment conditional on age, sex, marital status, and initial MMSE score. An untreated AD patient will typically decline, on average, about 3 to 4 MMSE points per year. Treatment with drugs appears to slow this decline by about 1 to 2 MMSE points per year [29].

Each Monte Carlo trial that assesses drug treatment compares the MMSE path for a person both with and without drug treatment immediately after diagnosis. For each year looking forward, declines in MMSE score are randomly selected from a treatment distribution and a nontreatment distribution. Because there are no lifelong, long-term, randomized controlled trials comparing disease progression in treated and untreated patients, we estimated the effect of treatment using the two models summarized in Appendix III.

The MMSE/Lopez (L) model is based on the results of a multiyear study of 135 matched pairs of patients with probable AD for whom the primary benefit of treatment was to increase the odds (2.5) of running a slow progressive course, defined as a decline of 2 or fewer MMSE points each year [6]. On average, slow progressors had near-zero MMSE point declines (0.1 for the treatment group, and -0.2 for those in the control group). On average, fast progressors in the treatment group lost 4.0 points per year, whereas fast progressors in the control group lost 4.9 points per year. We modeled the annual decline in MMSE score by assuming that slow progressors randomly receive declines from a uniform distribution between -1 and 2 (yielding a mean decline of 0.5), and fast progressors on drug treatment randomly receive declines from a uniform distribution between 3 and 5 (yielding a mean decline of 4). Fast progressors not on drug treatment randomly receive declines from a uniform distribution between 3 and 6.8 (yielding a mean decline of 4.9). Further, the analyses randomly assign 60% of patients on drug treatment to be slow progressors, and 40% of patients not on drug treatment to be slow progressors. Overall, this yields mean declines of 1.9 and 3.1 for treatment and nontreatment, respectively. The 1.2 -point difference in mean declines is conservative, in view of other studies involving drug treatment that typically found mean differences between 1.7 and 2.3 MMSE points per year [30–32].

Alternatively, the MMSE/Normal (N) model assumes that declines for those receiving drug treatment are drawn from a normal distribution with a mean of 1.5 and a standard deviation of 1.5 (with negative values set to zero), whereas declines for those not receiving drug treatment are drawn from a normal distribution with a mean of 3.5 and a standard deviation of 1.5 (with negative values set to zero). The truncation in this process yields a mean difference in decline between treated and untreated patients of approximately 1.9 MMSE points.

2.3.8. Caregiver intervention

The early detection of AD also creates the possibility of providing support services to caregivers, such that AD patients remain at home longer. Although a majority of caregivers appear to view delaying placement of loved ones in nursing homes as very important in absolute terms, as well

as in terms of reducing mortality risk [33], the strain of providing care, especially for severely affected patients, has the potential to exhaust caregivers and lead to institutionalization. Various support services can be provided to caregivers to help them cope with the burdens of providing care.

We used the results by Mittelman et al [7] of a randomized trial of enhanced counseling and support intervention for spouse caregivers, to estimate the net benefits of caregiver intervention. Over an almost 10-year period, Mittelman et al [7] randomly assigned over 400 spouses of AD patients to receive either the usual care or enhanced counseling and support intervention. The enhanced counseling included 2 individual sessions, 4 family sessions, weekly support group participation, and ad hoc telephone contacts initiated by caregivers. Each counseling session involved, on average, 4.0 hours of professional time, including 0.2 hours for arrangements, 2.0 hours in actual sessions, 1.15 hours in travel time to caregiver homes, and 0.65 hours in peer review of the session. Approximately 45% of caregivers sought telephone counseling per week, with an average counseling session lasting 0.4 hours. Thus, for each participating caregiver on average, there was an initial expenditure of 24 hours of counselor's time, and an additional 9.4 hours per year of participation. Although agreement to participate in support groups (usually in the caregiver's own neighborhood) was a condition for receiving enhanced counseling, after 1 year, only 58% had joined groups, compared with 42% for those in the usual-care group.

Using a Cox proportional hazard model, the impact of enhanced counseling and support services was estimated to be a reduction in the risk of nursing home placement of 0.72, with a 95% confidence interval range of 0.54 to 0.96, or an average delay of nursing home admission by about 1.5 years [7]. In addition, Mittelman et al [7] reported a statistically significant odds ratio of 0.91 for each later year of entry into their sample. For example, those entering in the fifth year of a 10-year program have an odds ratio of 0.61, relative to those entering in the first year.

Our analysis considers the possible replication of the program studied by Mittelman et al [7], using the above assumptions, as summarized in Appendix III. Taking medical and public health social workers (Standard Occupational Code [SOC] 211022, May 2005) in Wisconsin as the employment category, and assuming that benefits comprise 30% of the total compensation (the rate for all civilian employees in June 2006), we assumed that a counselor has an annual salary of \$42,290 and benefits of \$18,124, for a total of \$60,414 per year, or \$35.05 per hour. For each AD patient and each year, we applied a random selection from the confidence interval for the odds ratio of the effect of program participation on the risk of institutionalization, adjusted for entry into the program in the fifth year (out of a possible 10 years), to the schedule according to Hauber et al [22] of the risk of nursing home institutionalization as a function of MMSE score.

Mittelman et al [34] reported reductions in caregiver depression of approximately 15.3, 5.7, and 3.8 percentage

points for those receiving enhanced counseling at 1, 3, and 5 years, respectively. We applied the 3-year reduction, assuming that the risk of depression for those receiving enhanced counseling is 26.3%, rather than the 32% assumed for those not receiving enhanced counseling.

2.3.9. Induced service use

Those receiving the caregiver intervention possibly made greater use of generally available support services provided through public and private programs. Data on the utilization of these extra-treatment support services were not reported or analyzed by Mittelman et al [7]. Consequently, to predict the marginal utilization of services that likely result from implementation of a program like that of Mittelman et al [7], we used data from the Alzheimer's Disease Project, which involved the provision of case management and community-service reimbursement to a randomized treatment group [35]. In that study, treatment resulted in a 16% increase (from an average base of about 42%) in the fraction of caregivers using any homecare services, as well as a 45-hour per year increase in utilization (from a base of approximately 286 hours per year). Treatment also resulted in an 18-percentage-point increase (from an average base of about 15%) in the fraction of caregivers who used adult daycare services, as well as a 7-day-per-year increase in utilization (from an average base of approximately 166 days per year). Thus, on average, treatment resulted in an increase in homecare services utilization of about 72 hours per year [$0.16 (286 \text{ hours} + 45 \text{ hours}) + 0.42 (45 \text{ hours})$], and an increase in adult daycare utilization of about 32 days per year [$0.18 (166 \text{ days} + 7 \text{ days}) + 0.15 (7 \text{ days})$]. We monetized these service increments, using national averages of \$19 per hour of in-home care and \$50 per day of adult daycare, to estimate an incremental annual cost of \$2968. We also assume that Wisconsin pays for all marginal services. Because it is unclear how applicable the Alzheimer's Disease Project results are to an intervention like that of Mittelman et al [7], we treated the \$2968 as an upper bound. Specifically, in each Monte Carlo trial, a value was randomly drawn from a range of \$0 to \$2968. This approach may underestimate the social costs of the additional service use that the counseling program entails. However, the assumption that Wisconsin would pay the entire amount most likely overestimates the cost of caregiver intervention to the state.

2.3.10. Counterfactual: those not diagnosed at early stages of disease

The final set of assumptions concerns the counterfactual against which early detection and treatment is compared. Many patients who are not identified at early stages will eventually be diagnosed, and some will be treated with drugs. Based on a retrospective study of patients diagnosed with AD at a memory disorders clinic, average MMSE scores upon presentation were 20.8, 18.8, 16.8, and 15.3 for those referred from screening programs, physicians, family and friends, and other sources, respectively [36]. In a study based on over 12,000 beneficiaries in the 2002 Medicare Current

Beneficiary Survey, 24.7% of dementia patients in community settings and 26.3% of dementia patients in long-term care settings received dementia drugs [37]. Drawing on these studies, we assumed that AD patients not detected at early stages of the disease will present for diagnosis at an MMSE score of 19, and have a 25% chance of receiving drug treatment.

3. Results

3.1. Monte Carlo results

Each Monte Carlo analysis produced a similar distribution for net social benefits, net Wisconsin fiscal benefits, and net federal fiscal benefits. This distribution was the basis for predicting mean values, i.e., if a large number of people with a particular set of characteristics were treated, then on average, the reported mean values would result. The means contain some sampling error for any finite number of trials. In the present analyses, 10,000 trials produced 95% confidence intervals of approximately \$2000 for estimates of net social and net fiscal benefits.

Table 1 shows the impacts of various interventions for a 70-year-old married woman or man with an MMSE score of 28, 26, or 24 when diagnosed and treated. The first row within each MMSE level shows the net social and fiscal benefits, assuming drug treatment with MMSE/N decline, i.e., those receiving drug treatment experience declines drawn from a normal distribution centered around 1.5, with a standard deviation of 1.5. These impacts are substantially larger than those estimated assuming drug treatment with MMSE/L decline, as shown in the second row. The third row shows the effects of caregiver intervention, assuming MMSE/L decline for untreated patients. The final row for each MMSE level shows the combination of drug treatment and caregiver intervention, assuming MMSE/L decline.

As indicated in Table 1, all cells show positive net social and fiscal benefits. Caregiver intervention offers a much higher ratio of fiscal to social benefits than drug treatment alone. Keeping AD patients at any level of severity out of nursing homes saves the state and federal government money, but caregivers continue to bear time costs. There is a synergistic effect between drug treatment and caregiver intervention: drugs slow the decline in MMSE score, and caregiver intervention reduces the risk of institutionalization for any level of MMSE score.

The net social and fiscal benefits are consistently higher for a woman than for a man. This result is true for different ages and MMSE scores at diagnosis and treatment, and is attributable primarily to the higher expected years of additional life for women. The analysis in Table 1 is for AD patients with spouses at time of screening. Repeating the analysis for unmarried patients yields small reductions in net social benefits (less than \$2000 on average) for both men and women.

Fig. 1 shows the distribution of net social benefits for 10,000 trials for a particular Monte Carlo analysis, assuming a drug-treatment effect (MMSE/L) for a 70-year-old married

Table 1
Net benefits of diagnosis and treatment of a 70-year-old married woman (or man, in parentheses) with AD in \$1000s

	Present Value of Net Social Benefits	Present Value of Wisconsin Fiscal Benefits	Present Value of Federal Fiscal Benefits
MMSE = 28 at time of diagnosis			
Drug (MMSE/N)	172 (147)	15 (12)	28 (24)
Drug (MMSE/L)	98 (84)	6 (5)	13 (12)
Caregiver intervention (MMSE/L)	10 (7)	4 (2)	21 (17)
Drug (MMSE/L) and caregiver	125 (101)	16 (11)	34 (27)
MMSE = 26 at time of diagnosis			
Drug (MMSE/N)	149 (129)	13 (10)	22 (19)
Drug (MMSE/L)	94 (80)	5 (4)	10 (9)
Caregiver intervention (MMSE/L)	11 (9)	6 (4)	22 (19)
Drug (MMSE/L) and caregiver	116 (104)	15 (13)	31 (28)
MMSE = 24 at time of diagnosis			
Drug (MMSE/N)	122 (106)	10 (8)	15 (14)
Drug (MMSE/L)	69 (64)	4 (3)	6 (6)
Caregiver intervention (MMSE/L)	15 (11)	7 (6)	24 (20)
Drug (MMSE/L) and caregiver	93 (80)	15 (12)	29 (25)

woman with a starting MMSE score of 26. Averaging across trials, the mean net social benefits are \$94,000, the mean net Wisconsin fiscal savings are \$5000, and the mean net federal fiscal savings are \$10,000. As shown, 68.3% of the trials had positive net social benefits, i.e., whereas on average an early intervention is efficient, the net social benefits are negative in about one third of the trials. In many cases, death comes early, before the benefits of treatment-delayed decline can be fully realized. Averaging over trials, the mean age at death is 80.4 years, and the mean number of years spent in a nursing home is reduced by 1.2 years, from 7.6 years to 6.4.

Fig. 2A–C considers the relative benefits of pharmacologic and nonpharmacologic interventions when AD is detected at different disease stages, as defined by MMSE score. Fig. 2A shows the net social benefits, Fig. 2B shows the net Wisconsin fiscal benefits, and Fig. 2C shows the net federal fiscal benefits of interventions after a diagnosis at various levels of MMSE score for a 70-year-old married woman.

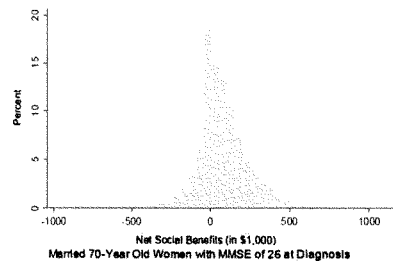


Fig. 1. Distribution of 10,000 trials of Monte Carlo analysis, showing net social benefits of diagnosis and treatment of 70-year-old married women with MMSE score of 26 at diagnosis.

Assuming either MMSE/N or MMSE/L decline, drug treatment yields declining, but positive, net social benefits as MMSE scores decline from 28 to 14. Adding caregiver intervention to drug treatment (MMSE/L) increases net social benefits at each MMSE score. Repeating the analysis, assuming more effective drug treatment (in terms of MMSE/N decline) combined with caregiver intervention, would dramatically increase the social and fiscal benefits of an intervention (results not shown). The net Wisconsin fiscal benefits become negative at an MMSE score of 18, unless drug and caregiver interventions are combined. This result occurs because the benefit of caregiver intervention goes up with decreasing MMSE score, whereas the benefit of drug therapy declines. As shown in Fig. 2C, the net federal fiscal benefits of combining drug treatment and caregiver intervention yield positive net benefits even when the MMSE score at diagnosis is as low as 14.

Fig. 3A shows the net social benefits of interventions as a function of age for a married woman with an MMSE score of 26 at diagnosis. As expected, the net social benefits decline with age, but remain positive. Fig. 3B,C shows similar patterns for net fiscal benefits: net Wisconsin and net federal fiscal benefits decline, but remain positive through age 80 years.

3.2. Early identification and diagnostic evaluation costs

An important question is whether the cost savings generated by early intervention are large enough to offset the costs associated with early identification and diagnostic evaluations. We estimated a cost per diagnosis of dementia of approximately \$4000, based on estimated costs and charges as well as negative results and refusals to proceed (48% of those screening positive declined further evaluation) according to Boustani et al [15]. Assuming that 70% of those diagnosed with dementia would be further diagnosed as having AD and would be candidates for intervention, the cost per AD diagnosis was approximately \$5700, which we take as an estimate of the social cost of case-finding and diagnostic costs.

Because the dementia population is primarily over 65 years old, it is Medicare-eligible. Assuming that Medicare covered all diagnostic costs, the cost to the federal government per identified AD patient would be \$3170. Assuming that Wisconsin covered all other associated costs, the cost to the state per identified AD patient would be \$2530.

The cost per diagnosis of this particular protocol is lower than the net fiscal Wisconsin benefits of the combination of drug treatment (MMSE/L) and caregiver intervention shown in Table 1, i.e., if Wisconsin paid all costs of implementing an early identification and caregiver intervention protocol not covered by the federal government, the combined intervention would yield overall savings to the state of approximately \$10,000 per diagnosed patient.

4. Discussion

We report the results of a Monte Carlo analysis of the potential benefits of early diagnosis and treatment, using best estimates of the effects of available therapies, both pharmacologic and nonpharmacologic. These analyses suggest that the early recognition and management of persons with AD will generate cost savings. The net benefits were highest when cases were identified at earlier stages, e.g., an MMSE score of 28, and when drug therapy was combined with a caregiver intervention program [7]. We also estimated the state and federal fiscal benefits of early diagnosis and treatment, and as expected, the federal benefits were consistently more substantial than the state benefits. These results indicate that a program implemented at the national level has the potential to generate substantial cost savings to society as a whole, as well as to state and federal governments. Efforts to promote the earlier identification and better management of AD patients seem to hold promise in terms of stemming the future rise in costs associated with an increasing prevalence of AD in an aging population. More effective treatments could be expected to generate even greater cost savings than those reported here.

Our estimates of the benefits of pharmacologic therapy were based on two models: 1) one that assumes a slowing of deterioration through reductions in mean annual decline; and 2) another that uses the findings of Lopez et al [6], in which the major benefit of therapy involved increasing the likelihood that a person would have a slow progressive course. Neither of these models is based on the results of long-term randomized controlled trials (RCTs) evaluating the effects of current drug therapy. There simply are no life-long, long-term RCTs on which to base assumptions. Because of this, these analyses report the social and fiscal savings that might be realized if available treatments had two different effects on disease course. Our analyses also assume that the use and therefore benefits of drug therapy continue to death. The model of drug benefit by Lopez et al [6] is more conservative, but if treatment is implemented early, it still generates substantial cost savings. If the benefits of future therapies were more robust and reduced the mean MMSE decline to 0.5 rather than 1.5 in the MMSE/N model,

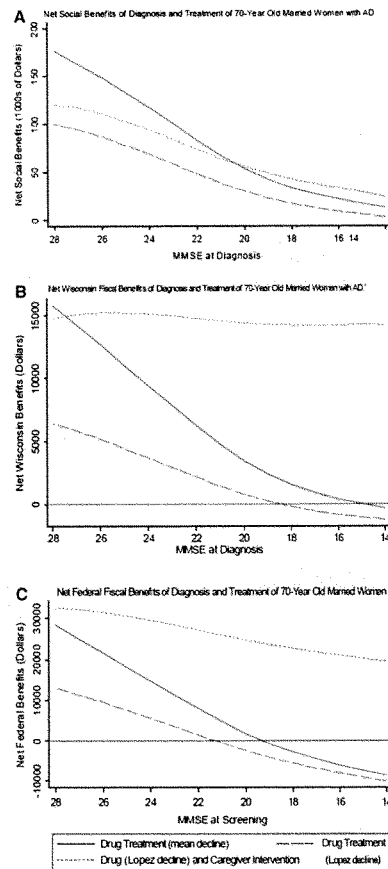


Fig. 2. Net social and fiscal benefits of diagnosis and treatment of 70-year old married women diagnosed at different stages of AD (A–C), as defined by MMSE score.

then the net social benefits would rise from \$149,000 to \$406,000 for a 70-year-old married woman diagnosed at an MMSE score of 26. These analyses illustrate the importance of research directed at developing more effective AD-modifying therapies.

We used a model developed by Mittelman et al [7] to estimate the potential costs and benefits of a caregiver intervention. We chose this model because its effectiveness was evaluated in

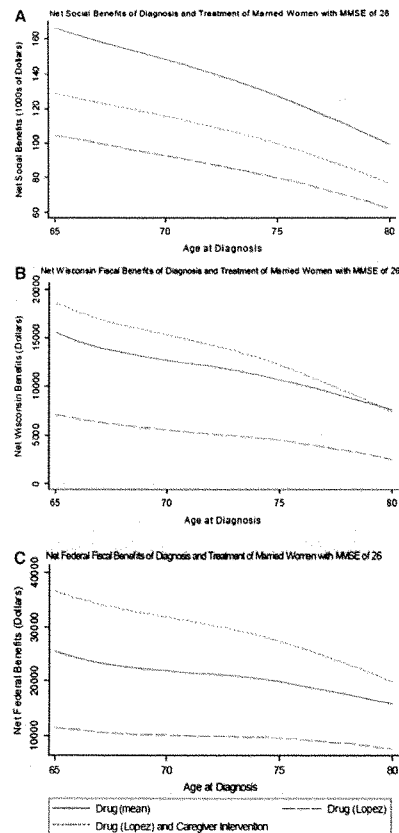


Fig. 3. Net social and fiscal benefits of diagnosis and treatment of married women with MMSE score of 26 (A–C), diagnosed at different ages.

RCTs lasting almost 10 years and the benefits were time-dependent, i.e., they increased with longer participation in the program. Other caregiver interventions were limited by small sample sizes [38] or by interventions lasting less than 1 year [39], and did not show reductions in nursing home use. Net social and fiscal savings were consistently larger when drug treatment was combined with caregiver intervention. These analyses confirm what is already known, i.e., that caregivers are important components of successful dementia-management

programs, and should not be ignored. Current Medicare reimbursement policies do not support the development of caregiver interventions similar to the model of Mittelman et al [7]. Our analyses suggest that this failure is fiscally unsound.

Our analyses suggest that the net social benefits of interventions are sufficiently large to justify even relatively expensive programs to promote early diagnosis and treatment. In view of the fiscal pressures facing states, the more relevant question is whether an early diagnosis and treatment program can be designed to yield a cost per AD diagnosis sufficiently small to make early diagnosis and treatment, including caregiver intervention, fiscally desirable from the state or federal perspective.

To answer this question, we estimated the results and costs of a dementia-diagnosis protocol, using the findings of Boustani et al [15]. We chose this protocol because we believe it represents a likely high estimate for screening costs and outcomes. The mean MMSE score in that study was 18 at time of diagnosis and 70% of the population was African-American, and as a result, findings from that study may not be generalizable to the larger population. In that study, only 52% of persons screening positive agreed to further evaluation, and of those, 47% were diagnosed with dementia. Our diagnostic cost estimates were also taken from that study, and assumed that neuroimaging and extensive neuropsychological tests were performed in all agreeing to further evaluation. Despite this conservative approach to estimating program costs for early diagnosis, the combined drug/caregiver intervention still generated cost savings. The net fiscal benefits of the combined intervention to Wisconsin were large enough to generate savings of approximately \$10,000 per diagnosed patient, even if Wisconsin paid all program costs. However, we also assumed that physicians would act on the results of the diagnostic process to provide drug or caregiver interventions. This may be an overestimate, especially for persons with early AD [40].

Does our analysis suggest that we should implement population-based cognitive screening programs to promote early detection and intervention? We do not think so. We think that scarce resources could be better spent developing more effective disease-altering therapies and financing caregiver interventions that were shown to reduce costs. At present, the benefits of current therapies are marginal, Medicare does not support caregiver interventions, and access to dementia diagnostic services is limited. Until these deficiencies in AD management are resolved, population-based cognitive screening will continue to be controversial.

There are numerous arguments against cognitive screening to promote the early diagnosis and treatment of AD [41]. There is concern that many people will experience fear and anxiety about being labeled with a cognitive disorder such as AD. Studies suggest that this assumption may not be valid [13,42]. The marginal benefits of available therapies are another reason often cited for not screening. However, as illustrated in these analyses, savings do not necessarily accrue simply because of pharmacologic treatment. Nonpharmacologic caregiver interventions, like the intervention of

Mittelman et al [7], if made available, can offer significant savings to state and federal governments, regardless of the effectiveness of current drugs.

The analyses presented here answer two important public policy questions. First, is the early detection of AD, followed by drug treatment and caregiver support, socially desirable? The estimation of positive net social benefits provides an affirmative answer to this question. Second, from a political economy perspective, do early detection, treatment, and caregiver support offer sufficient fiscal savings to either the federal or state governments, to make these interventions politically viable in a time of fiscal austerity? The analysis also provides an affirmative answer to this question. Potentially large fiscal savings for the federal government should encourage changes in Medicare reimbursement and the present approach to dementia management. Moreover, potential fiscal savings for a state like Wisconsin should encourage the development of state-level programs, even in the absence of a national program. As states devote increasing amounts of their Medicaid dollars to LTC for AD patients, state policymakers are likely to be receptive to the potential for early intervention to reduce these expenditures. These programs could include some form of cognitive screening combined with public and professional education and improved access to dementia diagnostic services, and proven programs of caregiver support.

Over the next 5 to 10 years, emerging therapies may become more effective in slowing the course of the disease and reducing the LTC costs and caregiver burden [43]. Our analyses suggest that improving access to even marginally effective therapies and effective caregiver interventions may be not only good medicine, but also sound fiscal policy. Nevertheless, public policy as well as professional attitudes about AD will need to change from that of neglect to proactive recognition and management, if these savings are to be realized.

Acknowledgments

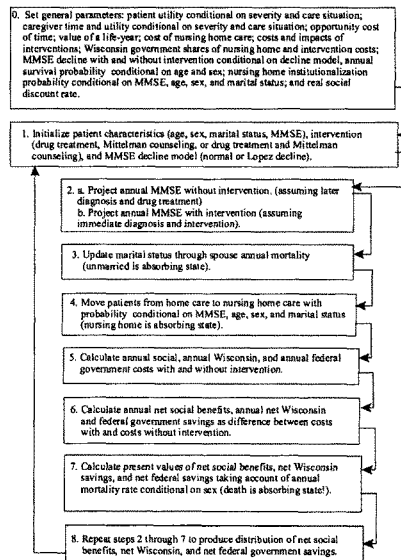
We thank Elizabeth Drilias and Marc Ratkovic for research assistance, and for financial support we thank the Institute for Clinical and Translational Research, the Community Academic Partnership Program, and the Robert M. La Follette School of Public Affairs (University of Wisconsin-Madison). We thank Dana Mukamel, Aidean Vining, and participants in the 2008 Workshop of the Society for Benefit-Cost Analysis for helpful comments.

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Appendix I. Summary of modeling strategy for Monte Carlo trials



Appendix II. Overview of general base-case parameters

Parameter	Assumed Value	Source
Annual nursing home cost	Private pay, \$66,795	Wisconsin Department of Health and Family Services [24]
	Medicaid, \$46,355	
Weekly hours of caregiver time at home	Mild AD, 15.4	Bell et al (2001); assumes variation of $\pm 50\%$ [23]
	Moderate AD, 44.5	
	Severe AD, 70.2	
Weekly hours of caregiver time for nursing home care	Mild AD, 0.6	
	Moderate AD, 1.6	
	Severe AD, 2.2	
Median Wisconsin hourly wage	\$14.69	Center on Wisconsin Strategy (2007)
Opportunity cost of caregiver time	Median wage	Opportunity cost of leisure
Patient utility at home	Mild AD, 0.68	Neumann et al [25]
	Moderate AD, 0.54	
	Severe AD, 0.37	
Patient utility in nursing home	Mild AD, 0.71	
	Moderate AD, 0.48	
	Severe AD, 0.31	
Caregiver utility at home	Mild AD, 0.86	
	Moderate AD, 0.86	
	Severe AD, 0.86	
Caregiver utility for patient in nursing home	Mild AD, 0.86	
	Moderate AD, 0.88	
	Severe AD, 0.88	
Annual survival probability	Varies by age and sex; applies 2.1 hazard rate for AD patients	Arias [17]; Fitzpatrick et al [18]
Annual nursing home institutionalization risk	By MMSE, sex, age, and marital status	Based on estimated models of Hauber et al [22]
Real social discount rate	0.035	Boardman et al [28]; upper bound value of life-year consistent with \$4 million statistical value of life
Value of a life-year	Uniform distribution over \$93,500 to \$187,000	
Annual cost of drug treatment	\$1825	Assuming \$5 per day

(Continued)

Appendix II Overview of general base-case parameters

Wisconsin share of drug costs	0.28	Assumes Wisconsin pays out-of-pocket costs under Medicare Part D; Mays et al [21]
Wisconsin share of nursing home costs	Medicaid, 0.31 Market, 0.22	Based on 23% average patient payment, and 40% of remainder paid by state
Counterfactual to screening	Assumed MMSE at presentation, 19 Probability of CEI upon diagnosis, 0.25	Barker et al [36] Gruber-Baldini et al [37]

Appendix III. Intervention assumptions

Drug Intervention		
Mean Decline Model (MMSE/N)	Assumption	
Source		
Annual MMSE decline without treatment	Normal distribution with a mean of 3.5 and a standard deviation of 1.5, with negative truncation	Consistent with findings by Sabbagh et al [30], Matthews et al [31], and Small et al [32] of mean decline differences across studies of between 1.7 and 2.3 MMSE points per year for untreated compared with treated
Annual MMSE decline with treatment	Normal distribution with a mean of 1.5 and a standard deviation of 1.5, with negative truncation	
Decline Model of Lopez et al [6] (MMSE/L)		
Probability of being slow progressor without treatment	0.39	Lopez et al [6]
Annual decline of slow progressors without treatment	Uniform distribution over range of –1 to 2: mean, 0.5	
Annual decline of fast progressors without treatment	Uniform distribution over range of 3 to 6.8: mean, 4.9	
Probability of being slow progressor with treatment	0.60	
Annual decline of slow progressors without treatment	Uniform distribution over range of –1 to 2: mean, 0.5	
Annual decline of fast progressors without treatment	Uniform distribution over range of 3 to 5: mean, 4.0	
Caregiver Intervention		
	Assumption	Source
Initial counselor time in hours	24	Mittelman et al [7]
Annual counselor time in hours	9.4	
Counselor wage and benefits	\$35.05	SOC Code 211022, May 2005, assuming 30% benefits rate
Odds ratio reduction in nursing home risk	Uniform draw from confidence interval of 0.54 to 0.96	Mittelman et al [7]
Base annual risk of caregiver depression	0.32	Mittelman et al [34]
Annual reduction in caregiver depression risk from counseling	0.057	
Caregiver utility with depression	0.59	Lave et al [26]
Annual incremental home service use by counseled caregivers	Uniform draw from range of \$0 to \$2968	Upper bound estimated from Newcomer et al (1999); assumes Wisconsin pays entire amount [35]

The Cost-Effectiveness of a Behavior Intervention with Caregivers of Patients with Alzheimer's Disease

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OBJECTIVES: To examine the cost-effectiveness of a randomized, clinical trial of a home-based intervention for caregivers of people with dementia.

DESIGN: This cost-effectiveness analysis examined Resources for Enhancing Alzheimer's Caregivers Health (REACH II), a multisite, randomized, clinical trial, from June 2002 through December 2004, funded by the National Institute on Aging and the National Institute of Nursing Research, of a behavioral intervention to decrease caregivers' stress and improve management of care recipient behavioral problems.

SETTING: Community-dwelling dementia caregiving dyads from the Memphis REACH II site.

PARTICIPANTS: Of Memphis' random sample of 55 intervention and 57 control black and white dyads, 46 in each arm completed without death or discontinuation. Family caregivers were aged 21 and older, lived with the care recipient, and had provided 4 or more hours of care per day for 6 months or longer. Care recipients were cognitively and functionally impaired.

INTERVENTION(S): Twelve individual sessions (9 home sessions and 3 telephone sessions) supplemented by five telephone support-group sessions. Control caregivers received two "check in" phone calls.

MEASUREMENTS: Incremental cost-effectiveness ratio (ICER), the additional cost to bring about one additional unit of benefit (hours per day of providing care).

RESULTS: At 6 months, there was a significant difference between intervention caregivers and control caregivers in hours providing care ($P = .01$). The ICER showed that in-

tervention caregivers had 1 extra hour per day not spent in caregiving, at a cost of \$5 per day.

CONCLUSION: The intervention provided that most scarce of caregiver commodities—time. The emotional and physical costs of dementia caregiving are enormous, and this intervention was able to alleviate some of that cost. *J Am Geriatr Soc* 56:413–420, 2008.

Key words: dementia; behavioral interventions; cost-effectiveness

The increasing prevalence of dementia and the associated increase in dementia-related healthcare costs have prompted a call for cost-effective interventions that increase caregivers' ability to provide home care for persons with dementia.¹ This article presents the first cost-effectiveness analysis of a randomized, clinical trial of a home-based intervention for caregivers of people with dementia.

In 2000, 4.5 million people in the United States had Alzheimer's disease (AD).² Researchers^{3–7} have forecasted an increase in this number to 13.2 million by 2050 and an associated rise in care costs.^{8–10} Ten years ago, the U.S. cost of dementia care was nearly \$100 billion, including medical and long-term care, home care, and lost caregiver productivity.¹ More-recent estimates are \$18,408 per patient per year for mild AD, \$30,096 for moderate AD, and \$36,132 for severe AD.¹¹ Based on these estimates, national costs will be more than \$350 billion per year by 2050, excluding inflation.

Currently, informal caregivers provide most of the care for those with dementia. Informal costs of care provided by the family and other caregivers are often higher than formal costs. For community-dwelling patients with dementia, in 1994, formal care costs were \$15,886 and informal costs \$20,812 per year,⁸ highlighting the amount of time that caregivers spend providing care. In 1997 dollars, the total annual caregiving cost per care recipient for black, Hispanic, and white caregivers¹² amounted to \$23,436 for

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DOI: 10.1111/j.1532-5415.2007.01569.x

informal services and \$8,064 for formal services. Additionally, dementia costs U.S. businesses \$61 billion per year, including \$36.5 billion in absenteeism and lost productivity.¹³ Interventions that enable caregivers of people with dementia to enhance their coping skills and management of care-recipient behaviors may decrease caregiver burden, improve caregiving skills and quality of life for care recipient and caregiver,^{14–17} and reduce the cost of care.

This study evaluated the cost-effectiveness of Resources for Enhancing Alzheimer's Caregivers Health (REACH II), a national, multicomponent, randomized, clinical trial, from June 2002 to December 2004, of an intervention for family caregivers of patients with AD or related disorders that was funded by the National Institute on Aging and the National Institute of Nursing Research. The data reported in this paper are from the Memphis site only, which had a health economist to assist in the capture of intervention costs.

METHODS

Resources for Enhancing Alzheimer's Caregivers Health II Five sites (Birmingham, Memphis, Miami, Palo Alto, and Philadelphia) and a Coordinating Center in Pittsburgh participated, with 642 black, Hispanic, and white caregiving dyads. Each site obtained local institutional review board approval. After written informed consent was obtained, caregivers were randomly assigned to the intervention (323 participants) or control (319 participants) arm within each of the three racial or ethnic groups. The intervention included five components that targeted five problem areas linked to caregiver risk and quality of life: caregiver burden, emotional well-being, self-care and healthy behaviors, social support, and care-recipient problem behaviors.

The 6-month intervention included modules focusing on information, safety, caregiver health and well-being, and behavior management for the care recipient. Twelve individual sessions were delivered in the caregivers' home (9 sessions) and through telephone (3 sessions), supplemented by five telephone-administered support-group sessions of five to six caregivers. Control caregivers received two brief "check in" phone calls. An assessment battery including measurements of depression, burden, self-care, health, and social support was administered at baseline and 6 months postrandomization.¹⁸ The primary outcome comprised standardized differences between baseline and 6-month follow-up for each of five measures central to caregiver quality of life: caregiver burden (Zarit Burden Interview),¹⁹ depression and emotional well-being (Center for Epidemiologic Studies Depression Scale (CES-D)),²⁰ self-care activities and healthy behaviors, social support (received support, satisfaction with support, and negative interactions and support), and care-recipient problem behaviors (Revised Memory and Behavior Problem Checklist (RMBPC)).²¹

Hispanic and white intervention caregivers experienced significantly greater improvement in quality of life than those in the control group ($P < .001$ and $P = .04$, respectively), as did black intervention spouse caregivers ($P = .003$). Prevalence of clinical depression was also lower for intervention caregivers at the 6-months endpoint ($P = .001$).¹⁸ An underlying assumption was that the inter-

vention would reduce caregiver stress and improve the caregiver's ability to manage behavior problems, leading to a decrease in the amount of time the caregiver spent in caregiving activities.

Sample Selection

Caregivers were aged 21 and older, lived with the care recipient, and had provided at least 4 hours of supervision or direct care per day for at least the previous 6 months. Caregivers were excluded if they were enrolled in another study or if they or their care recipients had an illness or disability that would prohibit them from study participation. Care recipients had a diagnosis of AD or related dementia (ADRD) or scored less than 24 on the Mini-Mental State Examination (MMSE)²² and had at least one limitation in activities of daily living (ADLs)²³ or two in instrumental activities of daily living (IADL2).²⁴

Caregiver Data

Caregiver demographics included age, sex, race, education, marital status, and income. Caregiving variables included duration of caregiving, relationship to care recipient, caregiver bother, and hours spent providing daily care. Bother was measured using the RMBPC bother score,²¹ with higher scores indicating more bother. Caregiver depression was measured using the CES-D,^{20,25} with higher scores indicating more depressive symptoms. Caregivers were also asked about the use of formal healthcare services in the month preceding data collection. Supportive services for the combined dyad included homemaker, aide, meals, transportation, home care nurse, senior center, and day care. Physician and other provider visits, emergency department visits, hospitalizations, and nursing home stays were captured for caregiver and care recipient.

Care Recipient Data

Care recipient demographics included age, sex, and race. Factors that could influence hours of care, including use of cognitive enhancing medications, were examined. Cognitive status was measured using the MMSE, with higher scores indicating better cognitive abilities. ADLs were assessed using a modified Katz ADL scale²³ and IADLs with the Lawton and Brody scale.²⁴ For both scales, higher scores indicate greater impairment. Dementia behaviors were assessed using the RMBPC dementia behaviors score,²¹ with higher scores indicating more behaviors.

Baseline characteristics were compared using chi-square for contingency tables or independent-samples *t*-tests, as appropriate. $P \leq .05$ was considered statistically significant, and those $> .05$ and $< .10$ were considered trends toward significance.

Incremental Cost-Effectiveness Ratio

Cost-effectiveness was examined using the incremental cost-effectiveness ratio (ICER).²⁶ The ICER, the additional cost incurred to bring about one additional unit of benefit per day per caregiver, is computed as follows.

$$ICER = \frac{\Sigma Cost_{Intervention\ CG} - \Sigma Cost_{Control\ CG}}{(\text{NCHS}_{Intervention\ CG} - \text{NCHS}_{Control\ CG}) \times 30 \text{ days} \times 6 \text{ months}}$$

where $\sum \text{Cost}_{\text{Intervention CG}}$ and $\sum \text{Cost}_{\text{Control CG}}$ represent the sum of costs per intervention caregiver and per control caregiver, respectively, up to the 180-day endpoint of the study, and $\text{NCHs}_{\text{Intervention CG}}$ and $\text{NCHs}_{\text{Control CG}}$ are the average noncaregiving hours per participating intervention and control caregiver respectively per day at the endpoint.

Cost-effectiveness analysis (CEA) requires the use of a single, composite outcome that represents multiple components of outcomes and at the same time produces a CEA outcome that can be meaningfully interpreted²⁷ (e.g., years of life gained, days of work gained).²⁸⁻³⁰ For this study, a noncaregiving hour represents an assortment of benefits from the intervention and produces a CEA outcome that can be meaningfully interpreted as cost per hour of noncaregiving time gained. The ICER represents the cost of an additional hour of noncaregiving time that can be "purchased" by the intervention. ICER calculation requires data on noncaregiving hours and dollar cost for intervention and control caregivers.

Noncaregiving Hours

Each caregiver was asked to report number of hours per day "actually doing things" for the care recipient. Daily noncaregiving hours were 24 hours minus the average number of hours of care. Beyond its face validity, the REACH caregiver question about time spent doing things for the care recipient has not formally been the subject of a reliability and validity study, although it is included as one of four component items in the Caregiver Vigilance Scale.³¹ In collecting the caregiving hours data, to assure reliability, the question was asked of all caregivers according to a protocol specifying that question wording and its place in the instrument battery remained identical across all interviews. The present study provides evidence of construct validity, in the finding of an interaction effect favoring the treatment group. Intervention and control group data were compared using repeated measures analyses of variance to examine between-group differences in change in average number of

noncaregiving hours per day from baseline to 6 months, controlling for any significant or trended baseline variables as covariates.

Intervention and Control Costs

Following the Panel on Cost-Effectiveness in Health and Medicine recommendations,^{27,32,33} intervention and control costs were calculated for staff training time for intervention and control protocols, staff time spent in preparation and wrap-up, staff time in intervention and control group protocols, caregiver time, supervisor and staff supervision time, travel time and mileage, and materials.

Intervention delivery time was documented on the delivery assessment form. For the other task categories, time and number of staff involved were recorded for each activity. Research activity time (e.g., data collection) was not included.

Personnel cost was per-hour salary cost, using annual salary and benefits and a work year of 2,087 hours, for time spent on study tasks, rounded up to the nearest 5 minutes. Costs for materials were actual costs. Travel costs were mileage reimbursement of \$.032 per mile for the distance and personnel cost during travel time to and from participants' homes, calculated using MapQuest software (America Online, Inc., Denver, CO). The Department of Labor rate for a home care aide during the study period (\$8.12) provided a standard estimate of costs for caregivers' time.

RESULTS

Sample

Of 55 intervention and 57 control group caregivers, 46 in each group completed the 6-month study without death or loss to follow-up. There was a trend toward fewer female caregivers in the intervention group ($P = .05$), as shown in Table 1. Also, intervention group caregivers had been providing care longer than control group caregivers ($P = .047$) and spent fewer hours in care recipient care ($P = .04$). Care

Table 1. Intervention and Control Caregiver Baseline Characteristics

Characteristic	Control (n = 46)	Intervention (n = 46)	P-Value*
Age, mean \pm SD	58.6 \pm 3.9	61.0 \pm 13.2	.40
Female, %	91.3	73.9	.05
Black, %	54.3	47.8	.68
Income > \$20,000, %	65.2	75.6	.36
Education > 12 years, %	89.1	87.0	1.00
Relationship to care recipient			.13
Spouse	34.8	43.5	
Child	47.8	52.2	
Other	17.4	2.2	
Caregiving years, mean \pm SD	2.7 \pm 2.2	4.1 \pm 4.3	.047
Revised Memory and Behavior Problem Checklist bother score (range 0-96), mean \pm SD	19.1 \pm 14.3	15.1 \pm 9.9	.13
Center for Epidemiological Studies Checklist (range 0-30), mean \pm SD	9.4 \pm 6.6	8.2 \pm 4.9	.34
Hours spent caregiving, mean \pm SD	8.4 \pm 4.5	7.1 \pm 4.5	.04
Physician visits per month, mean \pm SD	3.4 \pm 2.2	3.3 \pm 2.2	.90
Support group visits per month, mean \pm SD	1.4 \pm 1.1	1.0 \pm 0.5	.39

* Chi-square or t-test for independent samples, as appropriate.

SD = standard deviation.

Table 2. Intervention and Control Care Recipient Baseline Characteristics

Characteristic*	Control (n = 46)	Intervention (n = 46)	P-Value*
Female, %	45.7	69.6	.03
Cognitive enhancer, % yes	41.3	54.3	.30
Age, mean \pm SD	78.5 \pm 10.3	78.5 \pm 9.6	.98
Mini-Mental State Examination score (range 0–30), mean \pm SD	12.0 \pm 8.1	15.4 \pm 7.4	.04
Number of activities of daily living care recipient had trouble with (range 0–6), mean \pm SD	3.5 \pm 2.1	3.0 \pm 1.9	.24
Number of instrumental activities of daily living care recipient had trouble with (range 0–8), mean \pm SD	7.0 \pm 1.1	6.6 \pm 1.7	.20
Revised Memory and Behavior Problem Checklist behavior score (range 0–72), mean \pm SD	24.6 \pm 10.3	22.0 \pm 8.6	.19
Physician visits per month, mean \pm SD	2.7 \pm 2.0	2.7 \pm 2.4	.95
Emergency department visits per month, mean \pm SD	1.0 \pm 0.0	1.3 \pm 0.5	.44
Home care visits per month, mean \pm SD	3.6 \pm 4.0	2.9 \pm 2.3	.63
Day care days per month, mean \pm SD	11.4 \pm 8.2	10.9 \pm 2.3	.89

* Chi-squared or *t*-test for independent samples, as appropriate.
SD = standard deviation.

recipients in the intervention group were more likely to be women ($P = .03$) and had higher MMSE scores ($P = .04$), as shown in Table 2. There was no significant difference in formal healthcare use between control and intervention dyads, caregivers, or care recipients. Sample sizes were small. Only physician visits, support group visits, emergency department visits, home care nurse visits, and day care days had at least five people total that reported service use.

Time Spent Caregiving

Controlling for baseline differences, intervention caregivers decreased caregiving hours per day, whereas control group caregivers did not ($P = .01$), as shown in Table 3. The difference between intervention and control caregivers in baseline values for average caregiving hours per day was controlled for in this analysis. The difference between intervention and control group caregivers remained after controlling for caregiver and care recipient sex, care recipient MMSE score, and years of care.

Results of Costs for Intervention and Control Groups

Staff Salary Costs

Staff hourly costs were \$21.11 for interventionists, \$28.99 for first-line supervisor, and \$51.46 for second-line supervisor.

Staff Training Time and Costs

Initial training for individual-session intervention components, including readings, review of all intervention materials,

lectures, observations, role plays, written tests, and certification, was a one-time event. Additional training time was needed when interventionists delivered a module for the first time. Thirteen hours of this training were identical to control group training and were allocated between the two groups for cost calculation. Total nonprorated times are shown on Table 4 to highlight time involved in each study condition. Support group training also included initial and additional training time for the first support group. Total staff intervention training time was 104 hours (97.5 hours prorated for cost calculation). Supervision training time was calculated for staff and first- and second-line supervisors. Training cost per intervention caregiver was \$101 and per control caregiver was \$10, as shown in Table 5.

Staff Intervention Time and Costs

Preparation and wrap-up times for each module varied, from 2.5 hours for the introduction and behavioral management modules to 0.5 hours for the safety, stress management, mood management, and closure modules. Some modules were only presented once for each caregiver (e.g., introduction), others might be presented more than once (e.g., managing behavioral problems, stress management). On average, for each caregiver, 1.7 behavioral management modules and 6.7 stress modules were presented.

Each telephone social support group took 1 hour for initial setup (e.g., calling caregivers) and 2.0 hours preparation and wrap-up for each of the five sessions, for a total of 11 hours for five support group sessions and a staff cost of \$232 per support group.

Table 3. Change in Daily Hours of Care

Variable	N	Time of Measurement		Interaction Effect		
		Baseline	6 Month	Degrees of Freedom	F	P-Value*
Intervention	46	7.1 \pm 4.5	5.8 \pm 4.0	1	6.65	.01
Control	46	8.4 \pm 4.5	8.4 \pm 4.4			

* Analysis of covariance controlling for baseline values.

Table 4. Hours of Resources for Enhancing Alzheimer's Caregivers Health II Intervention and Control Components During 6 Months

Program Component	Control	Intervention	In Home	Telephone Support
Initial training per interventionist	15.5	98.2	86.2	12.0
Additional training time for new modules per interventionist	—	5.8	3.8	2.0
Training supervision per supervisor	1.0	6.3	5.0	1.3
Preparation and wrap-up per caregiver	0.3	13.8	11.6	2.2
Session activities per caregiver	0.5	20.5	15.5	5.0
Supervision and support per staff member per week	0.2	1.2	1.0	.3
Staff travel time per caregiver	—	5.1	5.1	—
Caregiver time per caregiver	0.5	20.5	15.5	5.0

Preparation and wrap-up for each control group call (e.g., notes, safety alerts that needed to be discussed) was approximately 10 minutes. Total intervention preparation and wrap-up cost per caregiver was \$291, as shown in Table 5. Control group preparation and wrap-up cost was \$7 per caregiver.

Staff cost for the intervention delivery for each caregiver was \$348, with staff cost of \$327 for 15.5 hours of individual-session delivery and \$21 for 5.0 hours of support group delivery (each hour shared with four other caregivers). Staff cost for delivery of two 15-minute calls to control caregivers was \$11 per person.

Supervision Cost

Over 26 weeks the two interventionists and one first- and one second-line supervisor spent 1.5 hours per week each in supervision activities, with control group supervision approximately 15 minutes per week for each staff member. Supervision cost per intervention caregiver was \$105, with time allocated to the two components based on their hours. Control supervision per caregiver was \$17.

Travel Expenses

For nine in-home visits, average round trip travel was 22.3 miles (range 0.8–61.0 miles) for a total of 201 miles per caregiver and 34 minutes (range of 1–72 minutes) for 5.1 hours total per caregiver. Travel expenses to and from the in-home sessions included staff time cost of \$108 and mileage reimbursement of \$64, for a total travel cost for each caregiver of \$172 per person.

Materials Costs

Materials were \$30 for each intervention participant and \$5 for each control participant.

Caregiver Time and Cost

With an estimated cost per hour for caregiver's time of \$8.12, the cost per intervention caregiver over 6 months was \$167 (individual session cost of \$126 and support cost of \$41). Cost per control group caregiver was \$4.

Table 5. Total Per-Person Cost of Resources for Enhancing Alzheimer's Caregivers Health II Intervention for All Caregivers During 6 Months

Intervention Component	Control	Intervention	Intervention Components	
			In Home	Telephone Support
			\$*	
Total training cost [†]	10	101	86	15
Staff costs	8	90	77	13
First-line supervisor costs	1	4	3	1
Second-line supervisor costs	1	7	6	1
Preparation and wrap-up	7	291	245	46
Session delivery	11	348	327	21
Supervision and support [†]	17	105	79	26
Travel (mileage)	—	64	64	—
Travel (staff time cost)	—	108	108	—
Materials	5	30	30	—
Caregiver time	4	167	126	41
Total per person	54	1,214	1,065	149

* Costs rounded to nearest dollar amount.

[†] Costs allocated between intervention and control groups, according to hours for each.

Incremental Cost-Effectiveness Analysis**Numerator—Total REACH II Time and Cost**

Total cost for the REACH II intervention was \$1,214 per intervention caregiver, with intervention costs per caregiver of \$1,065 for the individual sessions component and \$149 for the support group component. Costs per control caregiver were \$54.

Denominator—Noncaregiving Hours

To determine average noncaregiving hours at the 6-month endpoint, control group noncaregiving hours per day at 6 months (24.0–8.4) were subtracted from intervention group hours per day at 6 months (24.0–5.8), for a difference of 2.6 hours per caregiver per day. Because the intervention and control groups differed by 1.3 noncaregiving hours at baseline, this amount was subtracted from the 2.6-hour difference at 6 months, which left a net group-by-time interaction effect of 1.3 more noncaregiving hours per day for the intervention group.

Incremental Cost-Effectiveness Ratio

Using the total costs for the intervention and control groups and the outcome of noncaregiving hours, the incremental intervention cost-effectiveness ratio was computed as

$$\text{ICER} = \frac{\Sigma \text{Cost}_{\text{Intervention CG}} - \Sigma \text{Cost}_{\text{Control CG}}}{(\text{NCH}_{\text{Intervention CG}} - \text{NCH}_{\text{Control CG}}) \times 30 \text{ days} \times 6 \text{ months}}$$

$$\text{ICER} = \frac{\$1,214 - \$54}{(2.6 - 1.3) \times 30 \text{ days} \times 6 \text{ months}} = \$4.96$$

Thus, the results show that the 6-month intervention is cost-effective if one is willing to spend \$4.96 per day for 1 extra hour of noncaregiving time per day for each caregiver. In addition, when interpreted in the cost-benefit sense, the intervention can be thought of as being financially positive because it results in \$10.56 (\$8.12 of caregiver hourly wage \times 1.3 hours) of time gained versus \$4.96 of intervention cost per hour per day per caregiver.

DISCUSSION

This study examined the cost-effectiveness of a multicomponent psychosocial intervention to decrease the stress and burden of caregivers of people with dementia and improve their ability to manage behavioral problems of the care recipient. REACH II was one of the first studies to systematically assess the efficacy of a multicomponent intervention in a racially and ethnically diverse dementia caregiving sample. Moreover, the current study is the first cost-effectiveness analysis comparing an in-home-based family caregiving intervention with a control condition. At the end of 6 months, there was a significant difference between intervention caregivers and control caregivers in hours providing care, such that the caregivers in the intervention group had more time to allocate to noncaregiving activities. For the 6 months, total cost for each intervention caregiver was \$1,214, and total cost for each control caregiver was \$54.

The ICER showed that, for an additional hour of noncaregiving time per day, intervention costs were \$4.96 per day per caregiver (\$893 total over 6 months). The intervention would be even more cost-effective if the reduction in hours spent caring extends beyond the 6-month period without additional intervention. The unit cost (hour) in-

vestment decreases with increase in length of intervention effect.

A major limitation of the study was the lack of additional follow-up data after the intervention ended. These data would have allowed the sustainability of the intervention effect to be determined, although it is not unreasonable to assume that the intervention effects would last for at least 6 months. Other caregiving studies with similar interventions have shown that intervention effects can last 3 to 8 months,^{34–37} up to 1 year,^{38–41} or up to 18 months.⁴² In one cost-effectiveness study⁴³ of a multicomponent institution-based dementia intervention,¹⁷ in addition to significant psychological improvement, cost savings of \$5,975 (1990 U.S. dollars) were evident at 39 months. Further study to determine duration of intervention effect would be beneficial.

Another study limitation was the lack of objective healthcare utilization data. Although no significant differences were reported, data were according to caregiver report for use of services by the dyad, the caregiver, and the care recipient and covered only the month preceding baseline and 6-month follow-up data collection. Numbers were small, and examination of Medicare services use is an area for future study.

Because family caregiving accounts for a large proportion of the care of those with AD, providing relief to families is an important goal. At the beginning of the study, caregivers reported an average of approximately 8 hours per day providing care. At the end of the intervention, hours providing care had remained the same for control group caregivers and decreased for intervention caregivers. Although this cost-effectiveness analysis focused on the Memphis site, findings were similar across all REACH II sites, which included the three racial and ethnic groups: whites, blacks, and Hispanics. One intriguing area for future research is to investigate whether spending less time in caregiving activities is related to health outcomes.

Although 68% of the Memphis REACH II caregivers were not working, providing additional time may be even more critical for those who are still working to allow them to provide care without excessive loss of job productivity or having to quit their job. Twenty-five (27.5%) of the 92 caregivers had quit work to care for their care recipient, and 14.3% reported reducing their work hours to provide care. Less time spent in caregiving tasks might make it possible for caregivers to remain employed and reduce work interruptions, although time costs for participating in interventions may affect homemakers and retired or employed caregivers differently, competing not only with caregiving tasks, other familial obligations, and personal needs, but also real wage earnings and may influence who chooses to participate in an intervention.

In addition to the intervention, other factors had the potential to influence the outcome of noncaregiving hours. Recent research has shown that caregivers whose care recipients use cognitive enhancers may gain additional time per day not spent in providing care.^{44,45} For the REACH study, there was no significant difference between the intervention and control groups in use of cognitive enhancers at baseline. The percentage of control care recipients using cognitive enhancers was 43.2% at baseline and 47.7% at 6-month follow-up, and intervention care recipients' use was 56.8% at baseline and 52.3% at follow-up.

Other factors, including care recipient behaviors, caregiver bother, and depression, could have influenced the amount of time spent providing care, but there was no difference in these factors between the intervention and control groups at baseline. The 6-month change in the REACH II multicomponent outcome, which included caregiver burden, emotional well-being, self-care and healthy behaviors, social support, and care recipient problem behaviors, was significantly different between the intervention and control groups. Further study of the potential contribution of each of these five components to the time saved is warranted.

For the purposes of translating this study to an agency setting, the cost estimates may be biased upward for several reasons. For example, in an agency setting, the caseload typically is larger, suggesting that the costs of the intervention would be less. The two Memphis interventionists continued to work with all 103 caregivers during the course of the study, including those whose care recipient died or was placed in an assisted living or nursing home facility, but these additional caregivers were not included in the cost analysis breakdowns. For example, if all 56 intervention caregivers had been included in the intervention training cost analysis, because they benefited from the training, costs for that component would have been \$83 per caregiver, instead of \$101, indicating greater cost-effectiveness. At least one of the REACH II sites used interventionists with bachelors degrees (as opposed to masters degrees in Memphis), which would further decrease personnel costs, which were the major component of intervention costs. In addition, although caregiver time for participation is valuable and a cost to them and an important component of the cost-effectiveness analysis, these costs of \$167 per caregiver would not be part of an agency's costs. Because the intervention included two distinct components, each with separate costs, future work could investigate whether both are necessary to achieve this intervention effect.

As AD progresses, costs increase, from \$9,239 per year in early stages to \$19,925 in later stages.⁴⁶ Costs increase based on cognitive levels and comorbid conditions, although costs are 21% lower for patients who live at home than for those who are institutionalized.⁴⁷ The REACH II intervention was designed to assist caregivers of people with dementia who were providing care at home to enhance their coping skills and management of care recipient behaviors. The intervention significantly improved caregiver quality of life—caregiver burden, depression and emotional well-being, self-care and healthy behaviors, social support, and care recipient problem behaviors. It also provided that most scarce commodity for caregivers—time—in an additional hour per day not providing direct care. Although most caregivers of people with dementia express a desire to provide care in the home, the emotional and physical costs to caregivers are enormous. This intervention was able to alleviate some of that cost.

ACKNOWLEDGMENTS

Conflict of Interest: This research was supported through the REACH project, funded by the National Institute of Aging and the National Institute of Nursing Research (Grant U01-AG13313) and by the Office of Research and

Development, Department of Veterans Affairs, and the Memphis VA Medical Center.

Author Contributions: Dr. Nichols had full access to all the data in the study and takes responsibility for the integrity for the data and the accuracy of the data analysis. All contributors are included as authors. Study concept and design: Burns, Chang, Czaja, Nichols. Acquisition of data: Coon, Lummus, Martindale, Nichols. Analysis and interpretation of data: Burns, Chang, Czaja, Graney, Lummus, Nichols. Drafting of the manuscript: Chang, Lummus, Nichols. Critical Revision of the manuscript for important intellectual content: Burns, Chang, Coon, Czaja, Graney, Martindale, Nichols. Statistical analysis: Graney, Lummus. Obtaining funding: Burns, Coon, Martindale, Nichols. Administrative, technical, or material support: Burns, Coon, Czaja, Graney, Lummus, Martindale, Nichols. Supervision: Martindale, Nichols.

Sponsor's Role: No sponsors were involved in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation or review of the manuscript. The Department of Veterans Affairs approved the manuscript.

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“Nursing Homes Struggle to Kick Drug Habit”

With the demographic imperative of rising numbers of elderly, we need to focus on Dementia care.

As a Geriatrician and Certified Medical Director involved in Long Term Care medicine, I feel we need more clinical methodologies that improve quality of care and reduce burden on the elderly, **demented institutionalized patients**.

Examples of such programs include **Interdisciplinary** methodologies that reduce **antipsychotic use, polypharmacy** and **unnecessary hospitalizations**. This will improve quality of care and reduce cost in a fiscally conscious environment. Involving team members improve individual confidence and enable each Nursing Home discipline to provide positive input into improving the quality of life of institutionalized elderly afflicted with dementia. We need to increase awareness and training of health care professionals dedicated to Long Term Care setting.

Patients and their families need to be treated as one composite unit of care. These units need counsel on the natural history of Alzheimer’s disease and medical futility in advanced disease states. This must be considered within a culturally sensitive and patient centered context. Finally, we must try to educate these patients and their family on the importance of **achieving a peaceful death** at the end stage of Dementia.

* Lucette Lagnado-Wall Street Journal, December 20, 2007

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Geropsychiatric Nursing and Care of Persons with Dementia

Geropsychiatric nursing evolved in the 1970s as a blended sub-specialty of both psychiatric nursing, an illness-oriented specialty, and gerontological nursing, which focuses more broadly on health and illness. Today, advanced practice geropsychiatric nurses possess the broad and deep knowledge needed both to treat dementia in a variety of care settings and across diverse older populations.

The education of an advanced practice nurse in this field begins with a 4-year baccalaureate degree in nursing and state licensure as a Registered Nurse (RN). Nurses then engage in a rigorous program of graduate studies that cover biobehavioral and pharmacological sciences; recognition and diagnosis of common mental disorders; cognitive, behavioral, and interpersonal treatments; research; and other interests such as communication theory and practice, consultation, conflict resolution, and exposure to the ethical and legal issues unique to the treatment needs of older adults.

Efforts are underway to standardize educational requirements for nurses who will specialize in this field, and to spread key skills to nurses broadly. Reflecting awareness of needs in the population, nurse educators now are integrating geropsychiatric nursing content into related specialties, including psychiatric nursing as well as adult/gerontological, family, and women's health advanced practice nurse programs. Urgently needed are strategies for bringing needed information to already practicing nurses.

Masters-prepared geropsychiatric nurses practice in the varied settings in which older adults with dementia and mental disorders reside. Foremost among these are nursing homes, where residents with dementia present special clinical challenges such as confusion, resistance to care, communication difficulties, agitation, wandering, sleep disruptions and resident-to-resident aggression.

Reports have found high rates of dementia among elders in Assisted Living Facilities (ALFs), one of the fastest-growing settings for elder care and which are subject to minimal regulation for staff training and health care issues. ALFs are a natural context for geropsychiatric nurses, who possess the research-based therapeutic skills to make such settings more supportive to all residents, regardless of health status, so that they can better age in place.

The New England Journal of Medicine reported that medications commonly used to treat aggression and agitation in patients with Alzheimer's disease carry adverse effects that significantly offset the medications' benefits. This finding testified to the timeless value of geropsychiatric nursing's "person-environment" framework, which focuses on helping individuals and providers create and maintain nurturing and healthy living spaces. For example geropsychiatric nursing studies led to eliminating the once-common practice of tying down agitated elders, while devising interventions that support their well-being and dignity. Nursing research identified the shower/bath as an event likely to trigger agitation and aggression, and demonstrated the benefits of towel-bathing; other nursing-directed studies have found specific non-verbal communication and thermal discomfort as triggers for caregivers to avoid.

Geropsychiatric nurses also play a critical role in hospital emergency rooms and special care units. Adults aged 65 and older are the highest users of hospital-based emergency services in the U.S.; nearly one quarter of all older adults make at least one emergency department visit in a given year, with rates even higher for those aged 75 and older – and GPNs often are the first providers to greet them in emergency situations.

The adaptability of geropsychiatric nurses to diverse care settings enables them to play a critical role in caring for the nearly one-third of home-health care patients who need mental health care services. With the aging of the Nation's population, nurses also provide care in many non-traditional settings, including primary care offices, the criminal justice system and State- and community-run homeless health care services.

Today, 16% of psychiatric nurses have subspecialty preparation in geriatrics, and the field is poised to grow substantially to help meet the demands of our rapidly aging society. Ongoing innovations in education, credentialing, and practice models reflect the priority nursing attaches to the needs of older persons with mental disorders.

Many older adults with a dementia also have at least one chronic general medical disease. Geropsychiatric nurses, with their strong base of education in general health, are exceptionally well-qualified to assume the role of care coordinator for clients who will need special attention and guidance through both the medical and mental healthcare systems.

There are also exciting opportunities for geropsychiatric nurse researchers to collaborate with interdisciplinary colleagues in genetics, neurology, epidemiology and psychiatry. They can contribute to the understanding of the mechanisms by which environmental and experiential influences confer risk for developing Alzheimer's disease, how the symptoms of Alzheimer's disease represent the latter stages of a process that began years earlier, how developmental periods of transition and change may increase vulnerability for the emergence of disease risk, and how interventions can address the increased morbidity and mortality of caregivers.

Geropsychiatric nursing contributes significantly to caring for the mental health needs of our burgeoning population of older adults and their families and developing the science to inform this caring. Progress toward making full use of the profession will require partnering with advocates and organizations to target three main areas: further research and knowledge dissemination; training for evidence-based geropsychiatric nursing practice; and leadership to heighten the visibility and attractiveness of the field. Working together, nurses, legislators, and others can achieve the following goals:

- Raise awareness, within nursing and among the public broadly, of urgent, unmet mental health needs among older persons, and use this awareness to recruit nurses to the specialty;
- Collaborate with professional and consumer organizations interested in health care to leverage activities and resources;

- Garner funds to support nurse scholars' programs of research in mental health and aging;
- Support interdisciplinary centers of excellence in geriatric mental health to expand the science undergirding mental health care;
- Provide models for graduate programs in psychiatric nursing and adult/gerontological, family, and women's health advanced practice nurse programs to include core GPN content and clinical learning experiences;
- Obtain student support for graduate education to enable preparation of greater numbers in the field;
- Develop innovative programs to prepare practicing nurses for providing mental health services to culturally diverse older adults;
- Introduce evidence-based best geropsychiatric practices into all settings where older adults receive care;
- Encourage specialty organizations in nursing to incorporate geropsychiatric competencies in their scopes and standards of practice; and
- Challenge and eradicate health disparities in geropsychiatric research, training and provision of mental health services to older adults.

Submitted by the Geropsychiatric Nursing Collaborative (GPNC). The GPNC is a project of the American Academy of Nursing and supported by the John A. Hartford Foundation (www.aannet.org/GPNCgeropsych).

The GPNC has posted the following resources on the Portal of Online Geriatric Education (POGOe) website (www.pogoe.org/product/20660): exemplars of curricular materials, geropsychiatric nursing competency enhancements, key concepts, and a definition of geropsychiatric nursing.

Sustained Benefit of Supportive Intervention for Depressive Symptoms in Caregivers of Patients With Alzheimer's Disease

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Objective: The long-term effect of counseling and support on symptoms of depression was examined in spouse-caregivers of patients with Alzheimer's disease.

Method: The participants were 406 spouse-caregivers of Alzheimer's disease patients who lived at home at baseline. The caregivers were randomly assigned to either a group receiving enhanced counseling and support treatment or a group receiving usual care (control group). Caregivers in the enhanced treatment group were provided with six sessions of individual and family counseling, agreed to join support groups 4 months after enrollment, and received ongoing ad hoc counseling. The Geriatric Depression Scale was administered at baseline and at regular follow-up

intervals for as long as the caregiver participated in the study.

Results: After baseline differences were controlled for, caregivers in the enhanced treatment group had significantly fewer depressive symptoms after the intervention than did the control subjects. These effects were sustained for 3.1 years after baseline, similar across gender and patient severity level, and sustained after nursing home placement or death of the patient.

Conclusions: Counseling and support lead to sustained benefits in reducing depressive symptoms in spouse-caregivers of Alzheimer's disease patients and should be widely available to provide effective, evidence-based intervention for family caregivers.

(*Am J Psychiatry* 2004; 161:850-856)

Family members, often at great personal cost, provide much of the care for older adults with Alzheimer's disease and other dementias in the community (1). Family caregivers of relatives with Alzheimer's disease are at high risk for psychological distress, with rates of clinical depression and depressive symptoms far in excess of those for age-matched comparison subjects (2). This risk persists over the many years of caregiving (3) and even after caregiving ends with the death of the care recipient (4).

Carefully designed psychosocial interventions have been shown to be effective in reducing caregiver depressive symptoms (5, 6). Little is known about the long-term impact of caregiver interventions in reducing depressive symptoms. Caregiver intervention studies rarely follow participants for longer than a year or after potentially stressful transitions in caregiving, such as the nursing home placement or death of the care recipient. The New York University Spouse-Caregiver Intervention Study provided an ideal context in which to study the long-term impact of caregiver intervention on depressive symptoms. Over 9.5 years, 406 spouse-caregivers, enrolled in two successive cohorts, were randomly assigned to either enhanced counseling and support intervention or to usual care, which served as a control condition. The project is unique in that it has followed caregivers for a long period

of time, with little attrition. Results from the first 206 subjects enrolled in the project have been reported previously (6, 7) and indicate that the intervention had an increasingly stronger effect on depressive symptoms in the first year after enrollment (6). Analyses of the entire study group of 406 caregivers and of the long-term effects of the intervention on depressive symptoms beyond the first year have not heretofore been reported.

Because the intervention was designed to improve caregiving skills, mobilize the support of naturally existing family networks, and provide the opportunity for counseling as needed over the entire course of caregiving, we hypothesized that the intervention would yield sustained benefits in reducing depressive symptoms, regardless of gender or level of dementia severity, not only while the family member continued to provide care at home but also after potentially stressful events such as nursing home placement and death of the patient. A secondary hypothesis was that the demonstrated effectiveness of the caregiver intervention in comparison to usual care for symptoms of depression 1 year after enrollment for the first cohort would be replicated in the second cohort, even though educational material and community supports have become increasingly available for caregivers since the study began. Finally, we were interested in exploring

whether the intervention was of similar effectiveness for caregiving husbands and wives and for caregivers of patients at all levels of dementia severity.

Method

Subjects

Each study subject was the spouse of a patient with a clinical diagnosis of Alzheimer's disease and had the primary responsibility for the patient's care. All patients were living at home with their spouses at baseline. In each family, the patient or the caregiver had to have at least one other relative living in the New York City metropolitan area.

Subjects were recruited through the New York University Alzheimer's Disease Center, the local chapters of the Alzheimer's Association, media announcements, and referrals from physicians, social workers, lawyers, Alzheimer's disease day care centers, and social service agencies. The institutional review board of the New York University School of Medicine reviewed and approved this project. Written consent to participate in the project was obtained from each caregiver, as well as from any other participating family members.

The total study group consisted of 406 caregivers. The study had two enrollment phases, resulting in two cohorts of subjects. In the first phase, 206 subjects were recruited over a 3.5-year period beginning in August 1987. In the second phase, an additional 200 subjects were recruited over a 5.5-year period beginning in June 1991.

Study Design

After a comprehensive baseline assessment, study subjects were randomly assigned by lottery to one of two groups—a treatment group that received enhanced counseling and support or a control group that received the usual care offered family members of patients at the New York University Alzheimer's Disease Center. Participants were free to seek additional assistance and support elsewhere at any time throughout the study.

All caregivers were interviewed every 4 months during the first year and every 6 months thereafter, by telephone or in person, with the comprehensive battery of structured questionnaires first administered at baseline.

All caregivers were followed until 2 years after the death of the patient or until they refused or were no longer able to participate in the study. The analysis for this report is confined to the first 5 years after enrollment, the time period for which we have follow-up interviews for the most recently enrolled subjects. Thus, the analyses include the results of up to 12 interviews: intake, every 4 months for the first year, and every 6 months for years 2 to 5. Of the original 406 subjects, we assessed 380 (93.6%) at 1 year, 328 (80.8%) at 3 years, and 223 (54.9%) at 5 years of follow-up.

Treatment

The enhanced counseling and support treatment was delivered by counselors with advanced degrees in social work or allied professions and has been described in detail in a recent publication (8). The first component consisted of two individual and four family counseling sessions that included relatives suggested by the caregiver but never included the patient. The content of these sessions was determined by the needs of each caregiver (e.g., learning techniques for management of troublesome patient behavior, promoting communication among family members). Counselors also provided education about Alzheimer's disease and community resources.

The second component of the intervention was participation in a support group, beginning after the first follow-up interview. Caregivers in the group receiving enhanced treatment agreed at

baseline that they would join support groups that met weekly and provided a venue for continuous emotional support and education. The third component of the treatment was ad hoc counseling—the continuous availability of counselors to caregivers and families to help them deal with crises and with the changing nature and severity of their relatives' symptoms over the course of the disease. The emergence of new psychiatric and behavioral problems of patients, which are generally more stressful than the need for assistance with activities of daily living or physical limitations (2), often precipitated ad hoc calls from caregivers. Ad hoc counseling made it possible for caregivers and families to determine the amount of contact they had with the counselors beyond the scheduled structured sessions. Each caregiver in the enhanced treatment group was offered all of the treatment components. Caregivers in the usual care group received the services provided to all families of patients at the New York University Alzheimer's Disease Center, which included information about resources and advice upon request, but they did not have formal counseling sessions and their family members did not have contact with the counselors. They were free to participate in the same support groups and ad hoc counseling used by caregivers in the enhanced treatment group if they so chose. Because the same highly skilled and trained counselors at the New York University Alzheimer's Disease Center were available to participants in both the intervention and control groups, caregivers in the control group undoubtedly received more information and support than is generally available in typical medical and community settings.

One counselor was assigned to each caregiver because we felt that counseling and support would be most effective if each caregiver had an ongoing relationship with someone who was familiar with his or her situation. Anecdotal evidence suggests that the follow-up assessments, conducted by the same counselors, were viewed as helpful by the caregivers receiving usual care, as well as by those receiving enhanced treatment.

The study had a low dropout rate; in the first 5 years after enrolling, 28 (6.9%) of the caregivers dropped out, of whom 13 (3.2%) were caring for patients at home at the time of refusal. An additional 55 caregivers dropped out because they became too ill to participate ($N=20$, 4.9%), entered nursing homes ($N=4$, 1.0%), or died ($N=31$, 7.6%). These retention rates are a major strength of the study and suggest that caregivers in both groups valued the contacts and assistance they received through the project.

Measures Used in the Analysis

Caregiver depression was assessed at baseline and at every follow-up assessment with the Geriatric Depression Scale (9), a 30-item self-report questionnaire with a yes/no format that was specially developed for use with the elderly; possible scores range from 0 to 30 ($\alpha=0.94$). A cutoff score of 11 yields a sensitivity of 84% and a specificity of 95% (10). At baseline, 42.9% of the caregivers in this study (52.0% of the women and 29.0% of the men) had scores above the cutoff, indicative of possible clinical depression.

The severity of the patient's dementia was determined at baseline and at each follow-up interview by using the Global Deterioration Scale (11) ($\alpha=0.83$), a semistructured rating of patient functioning by the interviewer based on information provided by the caregiver. Patients with dementia have scores ranging from 4 to 7 on this scale, with 4 representing mild dementia and 7 representing severe dementia.

Statistical Methods

Changes in depression over the first year of the clinical trial were examined by using an intent-to-treat analysis, with the last value carried forward for the 26 participants (6.4%) who did not provide complete data through the 1-year follow-up assessment. In addition, mixed-model growth curve analyses were conducted by using SAS Proc Mixed (12) to examine the longitudinal trajec-

CAREGIVERS OF ALZHEIMER'S PATIENTS

TABLE 1. Baseline Characteristics of Patients With Alzheimer's Disease and Their Spouse-Caregivers in Two Cohorts of a Caregiver Intervention Study

Variable	Caregiver Cohort 1 (1987–1991) (N=206)		Caregiver Cohort 2 (1991–1996) (N=200)		Total Group (N=406)	
	Mean	SD	Mean	SD	Mean	SD
Age of caregiver (years)	70.9	8.9	71.8	9.1	71.3	9.0
Age of patient (years)	73.6	8.2	75.1	8.5	74.3	8.4
Caregiver's baseline score on Geriatric Depression Scale (9) (possible scores=0–30)	9.8	6.5	9.8	6.7	9.8	6.6
	N	%	N	%	N	%
Gender of caregiver						
Female	119	57.8	125	62.5	244	60.1
Male	87	42.2	75	37.5	162	39.9
Race/ethnicity of caregiver						
White	186	90.3	183	91.5	369	90.9
Black	15	7.3	11	5.5	26	6.4
Hispanic	4	1.9	6	3.0	10	2.5
Asian	1	0.5	0	0.0	1	0.2
Patient's baseline score on Global Deterioration Scale (11)						
4 (mild dementia)	65	31.6	71	35.5	136	33.5
5	83	40.3	85	42.5	168	41.4
6	58	28.2	43	21.5	101	24.9
7 (severe dementia)	0	0.0	1	0.5	1	0.2

tories of depression. These growth curve models offer important advantages over more traditional repeated-measures analyses, especially in handling missing data (13). Growth curves were fit for each individual subject on the basis of the number of data this person provided, allowing subjects who discontinued or completed the study before the 5-year assessment to be included in the longitudinal analyses without imputation of data for the missing observations. Imputing the last observed value and carrying it forward was considered acceptable for the relatively few missing data in the first year, but it would have led to considerable bias if applied for the increasing number of missing data through 5 years after randomization.

Variability in the actual time of the assessments was explicitly included in the growth curve models by analyzing time as a random effect. Individual growth curve parameters were modeled as a function of group (enhanced treatment versus usual care) and other predictors of interest. Restricted maximum likelihood estimation was used, and an unstructured covariance structure was specified. The depression scores obtained after treatment onset (i.e., 4-month follow-up, 8-month follow-up, etc.) were analyzed as repeated observations of the dependent variable, with "mean-centered" baseline depression scores serving as a covariate. These "mean-centered" scores consisted of deviation scores; the mean baseline depression score across all caregivers (9.64) was subtracted from each individual caregiver's baseline depression score. Other predictor variables included gender (female versus male), group (enhanced treatment versus usual care), the amount of time from baseline to when each follow-up depression score was obtained, the status of the patient at the time of the interview (living at home, in a nursing home, or dead), the interaction of group and time, and the interaction of baseline depression and time. The status of the patient was analyzed as a time-dependent covariate, whereas baseline caregiver depression, gender, and group were analyzed as time-invariant covariates.

Linear, quadratic, and logarithmic growth models were examined for two different time periods. First, we analyzed changes over the first year of the study only (4-month, 8-month, and 12-month follow-ups); the group main effect and group-by-time interaction effect from these analyses addressed hypotheses similar to those tested by the intent-to-treat analyses. Second, we analyzed effects from the end of year 1 to the end of year 5 (12-month, 18-month, 24-month,.... 60-month follow-ups).

Additional growth curve analyses were conducted to determine whether depression varied as a function of cohort (enrollment phase 1 versus enrollment phase 2, time-invariant) or patient Global Deterioration Scale score (time-dependent). For all growth curve models, the Akaike information criterion (14) was used to evaluate overall model fit and to select the best-fitting longitudinal change pattern (i.e., linear, quadratic, or logarithmic).

Results

The 203 caregivers assigned to enhanced counseling and support treatment had a mean age of 71.5 years (range=40–93) and consisted of 111 wives and 92 husbands. Caregivers in the usual care control group had a mean age of 71.1 years (range=47–95), and this group comprised 133 wives and 70 husbands. Table 1 shows demographic and clinical characteristics of the caregivers and patients at baseline. Even though the caregivers were randomly assigned to the intervention and control groups, the difference in the gender composition of the two groups was statistically significant ($\chi^2=4.65$, $df=1$, $p=0.03$). Baseline depression scores were also significantly lower for the caregivers receiving enhanced treatment (mean=8.9, $SD=5.7$) than for the caregivers in the control group (mean=10.6, $SD=7.2$) ($F=6.59$, $df=1$, 404 , $p=0.01$), mostly because wives (of whom there were more in the control group) had higher baseline depression scores (mean=11.1, $SD=6.7$) on average than husbands (mean=7.7, $SD=5.7$) ($F=28.93$, $df=1$, 404 , $p<0.0001$). These baseline differences indicated that baseline depressive symptoms and gender should be included as covariates in the longitudinal models.

Effects of Intervention Over First Year

In the first year after baseline, there was a gradual decrease in symptoms of depression among caregivers in the group receiving enhanced treatment and an increase among the group receiving usual care. At the 1-year follow-

TABLE 2. Logarithmic Model of Depression Changes From Baseline Through Year 1 Among 406 Spouse-Caregivers of Patients With Alzheimer's Disease Who Received Enhanced Caregiver Treatment or Usual Care^a

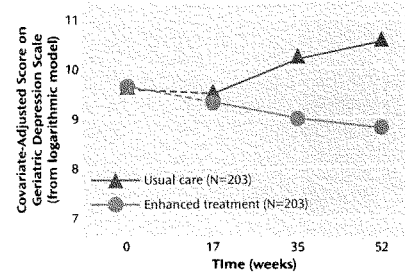
Predictor	Effect on Caregiver's Score on Geriatric Depression Scale From Baseline Through Year 1				
	Estimate	SE	t	df	p
Intercept	9.696	0.445	21.78	387	<0.0001
Baseline depression score (minus 9.64 [group mean])	0.737	0.324	22.75	331	<0.0001
Caregiver gender: female (1) versus male (0)	0.104	0.413	0.25	331	0.81
Caregiver group: enhanced treatment (1) versus usual care (0)	-1.141	0.409	-2.79	331	0.006
Time (log weeks since baseline minus 3.49 [mean])	0.925	0.314	2.95	359	0.004
Patient placement: nursing home (1) versus community (-1)	-0.468	0.281	-1.66	331	0.10
Patient death: death (1) versus nursing home or community (0)	-2.012	1.374	-1.46	331	0.15
Interaction of caregiver group and time	-1.378	0.438	-3.15	331	0.002
Interaction of caregiver's baseline depression score and time	0.153	0.034	-4.54	331	<0.0001

^a Enhanced treatment included individual and family counseling, a regular support group, and access to additional ad hoc counseling. Usual care consisted of information and access to support groups and counseling.

up, the difference in the change on the Geriatric Depression Scale score between the enhanced treatment group (mean=-1.1, SD=5.0) and the usual care group (mean=0.3, SD=6.0) was statistically significant ($F=6.40$, $df=1, 404$, $p=0.02$) according to the intent-to-treat approach. For the growth curve analyses examining changes over the first year after randomization, the logarithmic growth curve model was found to provide better fit than either the linear or quadratic model, as indicated by the lowest Akaike information criterion score (logarithmic=5985, linear=6002, quadratic=6016). This means that better fit was obtained when the rate of change in depression was allowed to gradually decrease over time (the logarithmic model) than when this rate of change was constrained to be constant over time (the linear model). Table 2 presents the results for the logarithmic growth model during the first year after baseline for participants in both intervention groups from both cohorts. The predictor labeled "time" was obtained by calculating the natural logarithm of the number of weeks from baseline to an assessment and "centering" this value by subtracting its mean of 3.49.

The significant predictors of depressive symptoms over the first year after randomization were the baseline depression score, intervention group, time since baseline, the group-by-time interaction effect, and the baseline-by-time interaction effect. The predicted effects for group,

FIGURE 1. Covariate-Adjusted Depression Scores From Baseline Through Year 1 Among Spouse-Caregivers of Patients With Alzheimer's Disease Who Received Enhanced Caregiver Treatment or Usual Care^a



^a Enhanced treatment included individual and family counseling, a regular support group, and access to additional ad hoc counseling. Usual care consisted of information and access to support groups and counseling. The dashed lines represent the baseline covariate adjustment, that is, the equating of groups at baseline, with the actual covariate-adjusted curves beginning at the 4-month assessment point.

time, and the group-by-time interaction are depicted in Figure 1. The model-predicted values indicate that depression scores decreased during the first year for caregivers in the enhanced treatment group but increased slightly during the first year for those in the control group. As in the intent-to-treat analyses, the treatment and control groups were significantly different on covariate-adjusted depression scores at 1 year ($p=0.0005$) but not at 4 months ($p=0.58$) after randomization. In contrast to the intent-to-treat analyses, the covariate-adjusted growth curve models also revealed significant group differences at 8 months ($p=0.004$). The analysis also revealed that 39.9% of the caregivers in the group receiving enhanced treatment were above the threshold for clinically significant depression at baseline, while only 29.8% of these caregivers exceeded the cutoff after 1 year of intervention. The corresponding percentages for the caregivers in the control group were 45.8% and 45.1% for baseline and 1 year, respectively.

We investigated whether the previously published findings on the first cohort 12 months after randomization (6) could be replicated by using mixed-model growth curve analyses. Traditional regression analyses of data from the first cohort had shown a steadily increasing difference between the enhanced treatment and usual care caregivers in the change from baseline in the number of depressive symptoms. In the present study, we investigated the replicability of this longitudinal pattern by fitting growth models for the first year for the two cohorts separately. Consistent effects were found across both cohorts, with the group-by-time interaction effect from the logarithmic model significant for both cohort 1 ($t=-2.38$, $df=167$, $p=0.02$) and cohort 2 ($t=-2.13$, $df=161$, $p=0.04$).

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TABLE 3. Linear Model of Depression Changes From Year 1 Through Year 5 Among 406 Spouse-Caregivers of Patients With Alzheimer's Disease Who Received Enhanced Caregiver Treatment or Usual Care^a

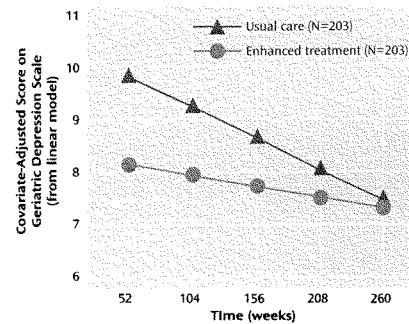
Predictor	Effect on Caregiver's Score on Geriatric Depression Scale From Year 1 Through Year 5				
	Estimate	SE	t	df	p
Intercept	9.070	0.469	19.22	388	<0.0001
Baseline depression score (minus 9.64 [group mean])	0.527	0.037	14.19	1725	<0.0001
Caregiver gender: female (1) versus male (0)	-0.065	0.499	-0.13	1725	0.90
Caregiver group: enhanced treatment (1) versus usual care (0)	-1.047	0.473	-2.22	1725	0.03
Time (log weeks since baseline minus 142.16 [mean])	-0.012	0.003	-4.29	368	<0.0001
Patient placement: nursing home (1) versus community (-1)	-0.696	0.141	-4.93	1725	<0.0001
Patient death: death (1) versus nursing home or community (0)	-2.472	0.361	-6.84	1725	<0.0001
Interaction of caregiver group and time	0.007	0.004	2.01	1725	0.05
Interaction of caregiver's baseline depression score and time	-0.001	0.000	-4.75	1725	<0.0001

^a Enhanced treatment included individual and family counseling, a regular support group, and access to additional ad hoc counseling. Usual care consisted of information and access to support groups and counseling.

Sustainability of Intervention Effects in Years 1-5

For the growth curve analyses examining long-term effects from the end of year 1 through year 5 after baseline, a linear growth model was found to provide better fit than either a quadratic or logarithmic model (Akaike information criterion: linear=13,848, quadratic=13,867, logarithmic=13,877). This suggests that the rate of change in depression was fairly constant across time for both groups. Table 3 presents the results for the linear growth model for the two cohorts combined. Significant effects were found for all predictors except gender. The baseline-by-time interaction effect reflects the finding that depression scores were less correlated with baseline depression scores as the time from baseline increased. Figure 2 shows the significant group main effect, time main effect, and group-by-time interaction effect from this linear model. The caregivers receiving enhanced treatment averaged 1.05 depression points lower than the caregivers receiving usual care over this time period. While the difference between groups decreased in magnitude as time went on, post hoc analysis of the least squares means indicated that, after baseline differences were controlled for, caregivers in the enhanced treatment group had significantly lower depression scores ($p<0.05$) than caregivers in the control group through 161 weeks (3.1 years) after enrollment.

FIGURE 2. Covariate-Adjusted Depression Scores From Year 1 Through Year 5 Among Spouse-Caregivers of Patients With Alzheimer's Disease Who Received Enhanced Caregiver Treatment or Usual Care^a



^a Enhanced treatment included individual and family counseling, a regular support group, and access to additional ad hoc counseling. Usual care consisted of information and access to support groups and counseling.

The proportion of subjects above the threshold for clinically significant depression remained higher in the control group throughout the 5 years of the analysis. Among caregivers in the enhanced treatment group, 29.8% exceeded this threshold after 1 year of intervention, 26.2% exceeded the threshold after 3 years, and 27.0% exceeded the threshold after 5 years. The corresponding rates for caregivers in the control group were 45.1%, 31.9%, and 30.0% for 1, 3, and 5 years after baseline, respectively.

Additional models were run to examine the effects of caregiver gender and of patient severity of dementia, nursing home placement, and death on depressive symptoms and treatment-related changes. The patient's Global Deterioration Scale score was added to the growth models as a time-dependent categorical covariate with four levels. Significant main effects were found for dementia severity both for the first year ($F=3.69$, $df=3$, 327 , $p=0.02$) and for years 1-5 ($F=3.94$, $df=3$, 1548 , $p=0.009$), indicating that caregiver depression was higher when the patient's dementia was more severe. However, neither severity of dementia nor caregiver gender had a significant interaction with treatment group in either the analysis for the first year or the analysis for years 1-5, indicating that the intervention was equally effective in reducing symptoms of depression across dementia severity level and gender. While the analyses showed that caregiver depressive symptoms decreased significantly after nursing home placement or death of the care recipient (Table 3), the interactions between treatment group and these patient outcomes were not significant, suggesting that the intervention continued to have an impact even after these highly stressful transitional events.

Discussion

The results indicate that the enhanced counseling and support intervention is an effective treatment for caregiver distress. Spouse-caregivers who received this intervention showed fewer depressive symptoms than participants receiving usual care at the 1-year follow-up, and sustained improvements were detectable more than 3 years after enrollment. The effects were replicated across cohort, caregiver gender, dementia severity level, and even nursing home placement or death of the patient.

These intervention effects were detected despite comparison with a control group that was likely to have received much more assistance than the typical care available in community and medical settings. In contrast to longitudinal studies following family caregivers of dementia patients without providing intervention, which have shown stable levels of depressive symptoms over time (3, 4), this study provided benefits to caregivers in the usual care control group. They, as well as caregivers in the enhanced treatment group, showed significant decreases in depression from years 1 through 5, suggesting benefit from study participation. Thus, our results may actually underestimate the full impact of the intervention.

Few caregiver intervention studies have demonstrated effects on symptoms of depression beyond 12 months of follow-up, and we are aware of none that has shown results beyond 18 months. In our study, while no group differences were evident at the first follow-up (4 months after baseline), there were increasing differences apparent at 8 and 12 months, suggesting that the benefit of treatment was fully realized only after the caregivers received all three components of the intervention. The sustained effects demonstrated by the intervention may be due to its flexibility and the opportunity to learn skills or develop psychosocial coping resources useful over the long course of providing care for a patient with Alzheimer's disease.

Although the present project has attained a large number of subjects, long follow-up, and low rate of attrition that we believe are unique in the caregiving intervention literature, several limitations should be noted. The counselors who provided the enhanced treatment or usual care, and therefore were not blinded to treatment condition, conducted the follow-up interviews. However, the Geriatric Depression Scale consists of yes/no self-report questions, which are less subject to interviewer bias than interviewer rating measures. Previous research has shown that even when interviewers are blinded, 86% can accurately guess which participants have received active psychotherapy in a randomized trial, but only interviewer rating measures (not used as outcomes in our project) are typically affected by interviewer knowledge of group assignment (15). In studies of psychosocial intervention, it is not possible for the subjects themselves to be blinded to treatment condition. However, the subjects in this study completed the Geriatric Depression Scale, a symptom in-

ventory, without reference to the treatment they received. Moreover, the subjects in the usual care group also received a considerable amount of support and counseling. Consequently, the lack of blinding in our study is unlikely to explain the observed differences in scores on the Geriatric Depression Scale. Another limitation is that we have studied the impact of this intervention only on spouses in an urban setting, and our subjects were predominantly Caucasian. Future studies should investigate whether similar interventions are as effective with more diverse groups of caregivers.

In summary, our results suggest that a short course of intensive counseling and readily available supportive maintenance can have long-lasting effects in reducing symptoms of depression among caregivers of dementia patients. Caregivers generally do not have access to such intense, individualized, multifaceted, and carefully planned interventions. In most clinical settings, caregivers may be referred to support groups and advised to use informative self-help materials, such as *The 36-Hour Day* (16). Our results, and those of previous studies (5), suggest that support and information alone are helpful but are not optimal interventions for caregivers.

The New York University Alzheimer's Disease Center counseling and support intervention, if widely available, could have a major impact on health care costs, on the emotional distress associated with caregiving, and perhaps on factors related to depressive symptoms, including health, disability, and related health care utilization and costs (17). Since family caregiving affects about 25 million American families (1), providing effective interventions for caregivers should become a high priority. With the increasing emphasis on providing patients with evidence-based treatment, caregivers should have access to interventions that have demonstrated effectiveness.

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Supported by grants from NIMH (R01 MH-42216) and the National Institute on Aging (R01 AG-14634). Additional resources were provided by the New York University Alzheimer's Disease Center (supported by grant P30 AG-08051 from the National Institute on Aging).

The authors thank the New York University Counseling Team, especially Emma Shulman, C.S.W., and Gertrude Steinberg, M.A., for inspiring the New York University Spouse-Caregiver Intervention Study and Olivia Clay, who assisted with the data analysis.

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Improving caregiver well-being delays nursing home placement of patients with Alzheimer disease

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Abstract—Objective: To determine the effectiveness of a counseling and support intervention for spouse caregivers in delaying time to nursing home placement of patients with Alzheimer disease (AD), and identify the mechanisms through which the intervention accomplished this goal. **Methods:** We conducted a randomized controlled trial of an enhanced counseling and support intervention compared to usual care. Participants were a referred volunteer sample of 406 spouse caregivers of community-dwelling patients who had enrolled in the study over a 9.5-year period. The intervention consisted of six sessions of individual and family counseling, support group participation, and continuous availability of ad hoc telephone counseling. Structured questionnaires were administered at baseline and at regular follow-up intervals, every 4 months for the first year and every 6 months thereafter. Cox proportional hazard models were used to test the effects of the intervention on the time to nursing home placement for the patients after controlling for multiple time-invariant and time-dependent predictors of placement. **Results:** Patients whose spouses received the intervention experienced a 28.3% reduction in the rate of nursing home placement compared with usual care controls (hazard ratio = 0.717 after covariate adjustment, $p = 0.025$). The difference in model-predicted median time to placement was 557 days. Improvements in caregivers' satisfaction with social support, response to patient behavior problems, and symptoms of depression collectively accounted for 61.2% of the intervention's beneficial impact on placement. **Conclusion:** Greater access to effective programs of counseling and support could yield considerable benefits for caregivers, patients with Alzheimer disease, and society.

NEUROLOGY 2006;67:1592–1599

Dementia increases the risk of nursing home placement (NHP) among the elderly more than fivefold.¹ Family caregivers help people with dementia remain at home, although they vary considerably in their ability to do so.^{2–4} NHP reduces direct care obligations, but does not necessarily reduce caregivers' distress,⁵ and is very costly to society.^{6,7}

A randomized controlled trial of a counseling and support intervention for spouse caregivers of patients with Alzheimer disease (AD) began in 1987 at New York University (NYU). The median time from baseline to NHP of patients was 329 days longer in the treatment group than in the control group among the 206 subjects who enrolled between 1987 and 1991.⁸

An additional 200 spouse caregivers enrolled between 1991 and 1997, resulting in a final sample of 406 subjects. Caregivers have been followed longitudinally for up to 17 years, with documentation of the dates of NHP, death, and study termination. The NYU study, with its large sample size and extended length of follow-up, provides a unique opportunity to

gauge the potential long-term impact of psychosocial intervention.

Over the past two decades, efforts at cost containment have led to substantial decreases in utilization of nursing homes in the United States.⁹ We hypothesized that despite this trend, the NYU counseling and support intervention would continue to demonstrate a significant effect on time to NHP over the entire time period examined (1987–2005), mediated by previously demonstrated improvements in spouse caregivers' social support, depressive symptoms, and tolerance of problem patient behaviors.^{10–12}

Methods. *Overview.* Caregivers were assigned a family counselor when they enrolled in the study. Participants completed a comprehensive baseline assessment, consisting of structured self-report questionnaires, and then were randomized by lottery to an enhanced counseling and support intervention ($n = 203$) or to usual care ($n = 203$). Allocation was concealed from participants and counselors until after the baseline assessment, and was then revealed by the counselors opening a sealed envelope in the caregivers' presence showing randomization to treatment or usual care conditions. The assessment was repeated 4, 8, and 12 months after baseline, and every 6 months thereafter. Participation con-

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Funded by the NIMH (R01 MH 42216) and the NIA (R01 AG14634). Additional funding was provided through the NYU Alzheimer's Disease Center (P30-AG08051). W.E.H. was supported by the Florida AD Research Center (P50-AG025711).

Disclosure: The authors report no conflicts of interest.

Received September 14, 2005. Accepted in final form August 1, 2006.

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tinued until the caregiver became too ill to participate, died, or refused to continue in the study, or until 2 years after the death of the patient with AD. No adverse events were reported during the study.

Participants. Approximately half the caregivers who were recruited were spouses of subjects of our AD Center ($n = 214$, 53%); these patients had received a diagnosis of AD according to National Institute of Neurologic and Communicative Diseases and Stroke-AD and Related Disorders Association (NINCDS-ADRDA) criteria.¹⁴ The rest of the sample of caregivers ($n = 192$, 47%) were spouses of patients who had received a diagnosis of AD and were recruited through referrals from the New York City chapter of the Alzheimer's Association, other community organizations, private physicians, or other study participants. To be eligible, caregivers were required to be living with the patient at baseline and they or the patient had to have at least one relative living in the metropolitan area. This study was approved by the Institutional Board of Review of the NYU School of Medicine. Informed consent was obtained from all participants.

Treatment. The intervention consisted of two individual and four family counseling sessions tailored to each caregiver's specific situation, encouragement of weekly support group participation, and availability of ad hoc telephone counseling. Individual and family counseling sessions occurred within 4 months of enrollment. The content of the counseling sessions depended on the needs of each spouse caregiver and family (e.g., learning techniques for managing troublesome behaviors, promoting better communication between concerned family members). The family counseling sessions included relatives suggested by the caregiver; the person with AD was not included. Caregivers in the intervention group agreed at baseline that they would join a support group that met weekly after the 4-month follow-up for ongoing emotional support and education. There are many support groups in the New York metropolitan area, and caregivers were encouraged to join groups in their own neighborhoods. Ad hoc telephone counseling was available to caregivers and their families, making it possible for them to determine the amount of contact they had with counselors beyond the scheduled individual and family counseling sessions and helping them deal with crises and with the changing nature of the patient's symptoms over the course of the disease. Counselors also provided resource information and referrals for auxiliary help, financial planning, and management of patient behavior problems. Each caregiver in the intervention group had access to all the interventions, and was provided with support for an unlimited time. A published counseling manual describes the intervention in detail.¹⁴

Caregivers assigned to the usual care group received services routinely provided to patients and their families in the NYU-ADRC, such as resource information and help upon request, but they did not participate in formal counseling sessions, and these caregivers' family members did not generally have any contact with the counselors. Although the nature of the study made it impossible for caregivers or counselors to remain blind to group assignment, caregivers in the usual care group were free to join support groups and could call the same counselors as those in the intervention group. Thus usual care participants undoubtedly received more information and support than is generally provided in typical medical or community treatment settings.

While agreement to participate in a support group was a criterion for inclusion, and no one refused at the outset to do so, not all participants in the treatment condition ultimately joined support groups, and many subjects in the usual care condition joined support groups on their own; 42% of the caregivers in the control condition joined support groups within 12 months of enrollment, compared to 58% of those in the treatment condition ($\chi^2 = 10.13$, $p = 0.0015$). All caregivers were permitted to continue in the study, and remained in the condition to which they were originally assigned regardless of whether they joined support groups.

Measures. Demographic information, including patient and caregiver age, caregiver gender, and caregiver reports of patient income, was obtained at the baseline assessment. A number of self-report instruments were completed by caregivers at baseline and at each follow-up assessment to determine the extent of patient impairment, the psychological status of the caregiver, and the physical health of the patient and caregiver. Dates of permanent nursing home placement and of death were monitored throughout the project during regular follow-up interviews and

telephone contacts with caregivers and family members. Dates of death were subsequently confirmed by use of the Social Security Death Index.¹⁵

Patient functioning was assessed by the counselor, using the Global Deterioration Scale (GDS; Cronbach's $\alpha = 0.83$),¹⁶ a semi-structured rating based on an interview with the caregiver. Patients with dementia have scores ranging from 4 to 7 on this scale. Caregivers also reported on the frequency of 30 memory and behavior problems using the Memory and Behavior Problems Checklist (MBPC, $\alpha = 0.80$).¹⁷

We included several self-report scales to assess the psychological status of the caregiver. The Geriatric Depression Scale ($\alpha = 0.94$)¹⁸ is a 30-item, yes/no depression scale specifically designed for older adults. Caregivers reported on the degree to which they found each of the memory and behavior problems in the MBPC upsetting; this has been used in previous research as an indicator of caregiver appraisal or burden.^{11,13,19} The Burden Scale ($\alpha = 0.88$)¹⁷ consists of 22 questions to measure the perceived burden experienced by caregivers of patients with dementia.

Caregiver satisfaction with social support was assessed by averaging three questions from the Stokes Social Network Questionnaire ($\alpha = 0.92$)²⁰ about the caregiver's satisfaction with general support, assistance, and emotional support from family and friends, each ranging from 1 (very dissatisfied) to 6 (very satisfied). Caregiver and patient physical health were estimated for these analyses with the subjective rating of overall health (excellent/good/fair/poor) from the OARS Physical Health Form (ICC = 0.83).²¹ Caregivers provided ratings for themselves and their spouses with AD.

Data analysis. The predictors of nursing home placement were primarily examined using Cox proportional hazards models.^{22,23} The time, measured in days, from date of enrollment and randomization into the project until date of nursing home placement, served as the primary outcome variable. Two patients entered Alzheimer's units in assisted living facilities and were included in the analyses as nursing home placements. For patients who died without ever being placed, date of death was used as a right-censoring event (except in supplemental cumulative incidence analyses described below, in which date of death was considered a competing risk event). For patients who dropped out of the study, the date of the last follow-up interview was used as the censoring date. Caregivers who were continually active in the study and were still caring for their family member in the community were censored at the date August 30, 2005, for these analyses.

Treatment group and gender were included as indicator variables (enhanced counseling = 1, usual care = 0 and female = 1, male = 0). Information on patient income, which was obtained in seven categories and coded at the midpoint of each category interval, was transformed by taking $\log_{10}(1 + \text{income})$, to reduce the effects of extreme values. The Global Deterioration Scale was recoded into a set of three dichotomous (0,1) variables representing moderate dementia (GDS 5), severe dementia (GDS 6), and very severe dementia (GDS 7), with the mild stage of dementia (GDS 4) serving as the reference group for the other GDS levels. Other variables were entered without transformation.

Predictors were categorized as either time-invariant (do not change over time) or time-dependent (variation assessed over time). The primary time-invariant predictor was treatment group, but we also examined other potentially important time-invariant predictors including caregiver and patient age, caregiver gender, patient income, and year of study entry. Time-dependent predictors were classified as to whether they were likely to be influenced by the enhanced support intervention. Time-dependent risk factors for placement that were likely to be affected by psychosocial intervention included caregiver burden,²⁴⁻²⁶ caregiver depression,^{27,28} caregiver social support,⁴ and appraisal of patient behaviors as stressful.^{11,29} While unlikely to respond to our intervention, we also considered other time-dependent risk factors, GDS stage, caregiver and patient physical health, and frequency of memory and behavior problems.

In the Cox proportional hazards models, we first examined the predictive effects of each variable individually. Next, in a multivariable model, we examined the effect of the intervention after taking into account the effects of time-invariant predictors and the baseline (pre-intervention) observations of the time-dependent predictors. Baseline covariates were included primarily to esti-

mate their own effects on time to placement, and also to account for these effects before estimating the incremental effect due to the intervention. Including baseline variables as covariates to adjust for small and random baseline imbalances is a common and well-accepted strategy that yields an estimate of the intervention effect that is both adjusted for and stratified by the covariate influences.³⁰⁻³²

Mediation analysis is increasingly being used in intervention research to identify the likely underlying mechanisms of successful psychosocial interventions and the factors that should be targeted to maximize intervention effectiveness.³³ Changes in the time-dependent covariates, including caregiver satisfaction with social support, reaction to patient memory and behavior problems, burden, and number of depressive symptoms, were subsequently added to the multivariable model to test our hypotheses that these changes would mediate or explain a significant portion of the intervention's effect on nursing home placement rates.

In order to demonstrate statistical mediation according to accepted guidelines,³³⁻³⁵ the intervention must lead to significant change in the potential mediator (e.g., caregiver depression), and this intervention-induced change must also explain a significant proportion of variance in the primary outcome, time to nursing home placement. The structure of our mediation analysis models is summarized below:

$$\log h(t) = a(t) + b_1X_1 + b_2X_2 + \dots + b_jX_j \text{ (time-invariant and baseline covariates)} \\ + b_{j+1}(M(t) - M(0)) \text{ [change from baseline in hypothesized mediator]} \\ + b_{j+2}(\text{group}) \text{ [direct (unmediated) intervention effect]}$$

In these models, t represents the time, in days, of each observation up to placement (or censoring), j indicates the number of individual time-invariant and baseline covariates, and M represents the hypothesized mediating variable. Consequently, $M(t) - M(0)$ is a time-dependent predictor that quantifies the change observed on the mediator over time from baseline.

By examining the predictive influence of time-dependent changes in each potential mediator separately, we were able to determine that mediator's total mediation effect. The proportion of the intervention effect that can be attributed to the mediator is the difference in magnitude between the intervention effect in the baseline covariate-adjusted model and the intervention effect in the mediation model that also includes the change score for that time-dependent predictor. We determined the percentage of the intervention effect that could be attributed to changes in the mediator as follows:

$$\% \text{ mediated} = 100 \times ((\ln(HR_B) - \ln(HR_M)) / \ln(HR_B))$$

where HR_B = the hazard ratio for the intervention effect from the baseline covariate-adjusted model and HR_M = the hazard ratio for the intervention effect from the mediation model.

The total mediation effect for each mediator includes the unique contribution of that mediator as well as the effect it might share with other mediators, since intervention-induced changes in these mediators are not necessarily independent from each other. Indeed, we have previously shown that intervention-induced changes in depression and reaction to patient behavior problems after 1 year of intervention were correlated both with each other and with changes in satisfaction with the social support network.³⁶ This suggests that these mediators would share explanatory power in the present analyses, accounting for a significant portion of the intervention's impact on nursing home placement. Therefore, additional multivariate mediation models were estimated in which multiple time-dependent changes were entered simultaneously. These models allowed us to quantify the proportion of the total intervention effect on nursing home placement rates that could be attributed to changes on the potential mediators collectively.

Because patient death was a common right-censoring event, we conducted a supplemental analysis to estimate the effect of treatment, using Kaplan-Meier cumulative incidence analysis methods,^{37,38} in which patient death was an informative competing risk event rather than a non-informative right-censoring event. The magnitude of the treatment effect was compared to similar findings from the right-censored proportional hazards models to examine whether simple treatment group differences might be an artifact of an informative censoring process. There is little information available on the use of cumulative incidence for competing

risks analyses in multivariate models, particularly those with time-dependent predictors, so these methods were not used for the multivariate and mediation model analyses that were central to our primary research questions.

Results. *Baseline characteristics of subjects, subject accrual, and follow-up.* Salient baseline characteristics of caregivers and patients are presented in table 1. We used t-tests to compare the treatment and control groups on continuous variables, and χ^2 tests for caregiver gender and GDS. In spite of randomization, imbalances ($p < 0.05$) were found between the treatment groups on four of the baseline variables—gender, GDS, MBPC, and depressive symptoms. These variables were included, along with the other baseline variables, in our analytic models as potential prognostic predictors of nursing home placement. Effects for intervention and for other variables are also adjusted for these imbalances between treatment groups by including the relevant baseline variables in the models as covariates.

At least one follow-up interview was obtained from 396 of the 406 caregivers, and information on the primary endpoint for this analysis was available for all 406 subjects. There were 210 nursing home placements and 196 censored cases as of August 30, 2005 (figure 1).

Univariate effects on nursing home placement. The results of the univariate proportional hazard models, including hazard ratios and 95% CIs, are presented in table 2. This analysis, unadjusted for covariates, showed that caregivers in the intervention group were able to keep their spouses at home longer than caregivers in the usual care control group (hazard ratio = 0.714, $\chi^2 = 5.88$, $p = 0.015$). The difference in the model-predicted median time from baseline to nursing home placement for the two groups in this univariate analysis was 585 days; the estimated median time for the usual care group was 1,181 days compared to 1,766 days for the enhanced counseling and support group.

Slightly stronger group differences were found in supplemental analyses using Kaplan-Meier cumulative incidence methods that treated patient death as a competing risk event. Cumulative incidence rates in analyses that account for competing events are generally lower than those that treat such events as censoring events.³⁷ In this context, a median (i.e., 0.50) cumulative incidence rate from the censored analysis corresponded to a cumulative incidence adjusted for competing risk (CICR) of 0.40 for the intervention group, and the two groups differed by 697 days at this CICR point (intervention = 1,766 days, usual care = 1,069 days). Thus, the right-censored proportional hazards estimate of the intervention effect was lower than the similar estimate from the CICR approach, suggesting that the censored approach was not leading to a spuriously inflated estimate of the intervention effect.

Among the demographic variables we considered, the proportional hazards models summarized in table 2 indicated that neither caregiver gender nor age were significant predictors of placement. An effect that approached conventional levels of statistical significance was found for patient age. Patient income was a significant predictor, with people of higher income being less likely to place. Year of study entry also had a significant impact, with those who entered more recently being less likely to place their relatives than those who entered in the earlier years.

Table 1 Key demographic and predictive characteristics at baseline by treatment

	Treatment, n = 203	Control, n = 203	Total, n = 406
Female caregiver, n (%)	111 (54.68)	133 (65.52)	244 (60.10)
Caregiver age, y, mean (SD)	71.52 (8.61)	71.15 (9.31)	71.33 (8.96)
Patient age, y, mean (SD)	73.80 (8.46)	74.81 (8.30)	74.31 (8.38)
Patient income,* mean (SD)	3.54 (1.45)	3.70 (1.26)	3.62 (1.36)
Global Deterioration Scale (GDS), n (%)†			
4	72 (35.47)	64 (31.53)	136 (33.50)
5	91 (44.83)	77 (37.93)	168 (41.38)
6 or 7	40 (19.70)	62 (30.54)	102 (25.12)
Caregiver physical health, mean (SD)	2.15 (0.64)	2.07 (0.63)	2.11 (0.64)
Patient physical health, mean (SD)	2.20 (0.72)	2.17 (0.73)	2.18 (0.72)
Satisfaction with social support, mean (SD)	4.52 (1.32)	4.41 (1.41)	4.47 (1.37)
Frequency of memory and behavioral problems, mean (SD)	41.15 (18.29)	46.55 (19.49)	43.85 (19.07)
Reaction to memory and behavioral problems, mean (SD)	22.31 (13.77)	24.77 (16.99)	23.54 (15.50)
Depressive symptoms, mean (SD)	8.92 (5.74)	10.58 (7.21)	9.75 (6.56)
Caregiver burden, mean (SD)	34.46 (14.01)	37.13 (16.25)	35.80 (15.21)

* Patient income was log transformed.

† Only one patient had a GDS of 7 at baseline, so this case was combined with those who had a GDS = 6 for the baseline covariate analyses only.

Among the time-dependent predictors, increased severity of dementia, poorer caregiver physical health, poorer patient physical health, lower satisfaction with social support, greater frequency of memory and behavior problems, greater reaction to memory and behavior problems, more symptoms of depression, and higher caregiver burden were all significant predictors of higher nursing home placement rates ($p < 0.020$, see table 2).

Effect of the intervention on time to nursing home placement after adjusting for the effects of baseline covariates.

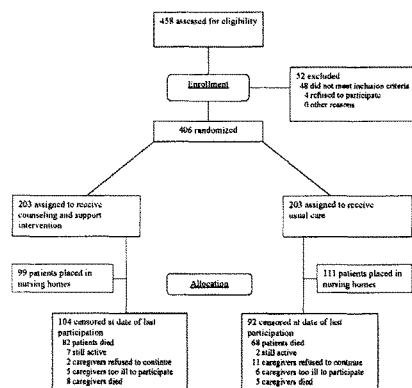


Figure 1. Trial profile. Information about the nursing home placement status (placed, deceased, still at home) and date of placement was known for all patients.

The time-invariant covariates and the baseline (pretreatment) values of the time-dependent predictors were entered simultaneously along with treatment group in our baseline covariate-adjusted model of the effect of the intervention condition. The hazard ratios and 95% CIs from this model are displayed in table 3. The primary effect of interest from this table is the one for treatment group (hazard ratio = 0.717, $\chi^2 = 5.05$, $p = 0.025$), indicating that, after considering the influence of all other covariates in table 3, including those with significant imbalances at baseline between the intervention and usual care groups, the patients who were cared for by spouses in the enhanced counseling and support group were placed at slightly less than 72% of the rate observed for those whose spouses were in the usual care group. The difference in the model-predicted median time from baseline to nursing home placement for the two groups from this model was 557 days (usual care = 1,209 days, enhanced counseling and support group = 1,766 days). The intervention effect, adjusted for baseline covariates, is displayed graphically in figure 2, where 11-year survival curves show the significant difference between the two groups. In addition, significant covariate effects were found for patient income, year of study entry, GDS, and depressive symptoms.

Mediators of the intervention effect on nursing home placement. The results of the mediation analyses are presented in table 4. The hazard ratio of 0.717 for treatment group from the baseline covariate-adjusted model (table 3) represents the intervention effect before considering the impact of any time-dependent changes in potential intervention mediators. Each row of table 4 reports the results when changes on that time-dependent predictor only are added to the model summarized in table 3. The hazard ratio for the intervention effect will move closer to the null value of 1.00 if the change in the mediator under consideration

Table 2 Univariate Cox proportional hazard ratios for the effect of each time-invariant and time-dependent variable on time to nursing home placement

	Hazard ratio (95% CI)	p Value*
Time-invariant predictors		
Group (intervention vs usual care)†	0.714 (0.544–0.937)	0.0153
Caregiver gender (female vs male)†	1.237 (0.939–1.629)	0.1310
Caregiver age	1.005 (0.990–1.020)	0.5163
Patient age	1.013 (0.996–1.030)	0.1285
Patient income‡	0.840 (0.769–0.918)	0.0001
Year of study entry§	0.908 (0.863–0.955)	0.0002
Time-dependent predictors		
Global Deterioration Scale at baseline		
5 vs 4	14.529 (1.994–105.838)	0.0083
6 vs 4	46.154 (6.434–331.098)	0.0001
7 vs 4	33.049 (4.420–247.081)	0.0007
Caregiver physical health	1.287 (1.059–1.565)	0.0113
Patient physical health	1.228 (1.042–1.447)	0.0141
Average satisfaction with support network	0.830 (0.757–0.910)	<0.0001
Frequency of memory and behavior problems	1.042 (1.033–1.052)	<0.0001
Reaction to memory and behavior problems	1.032 (1.026–1.039)	<0.0001
Depressive symptoms	1.049 (1.029–1.070)	<0.0001
Caregiver burden	1.038 (1.028–1.048)	<0.0001

* χ^2 test.

† Treatment group was coded as a dichotomous variable (intervention = 1; usual care = 0) as was caregiver gender (female caregivers = 1; male caregivers = 0).

‡ Patient income was log transformed.

§ Year of study entry was coded as 1987 = 0 to 1997 = 10.

ation is both predictive of placement rate and an effect of the intervention. The proportion of the intervention effect that could be attributed to each mediator was determined from the natural logarithms of the hazard ratios for the intervention condition from models with and without the mediator in question. For example, we determined that 22.6% of the baseline-adjusted intervention effect on nursing home placement rates could be attributed to treatment-induced changes in depression from the natural logarithms of the relevant hazard ratios [$\ln [0.717] - \ln [0.773] / \ln (0.717) = 0.226$, or 22.6%].

Neither change in caregiver nor patient physical health mediated the intervention effect on nursing home placement. This can be inferred from the fact that the change scores did not predict nursing home placement rates and the intervention effect was still significant with nearly the same hazard ratio after including changes on these time-dependent variables in the model. Although changes in dementia severity did predict nursing home placement rates, these changes did not mediate the intervention effect, as indicated by the fact that change in dementia severity did not alter the size of the hazard ratio associated with the intervention.

There was evidence for partial mediation effects for the remaining time-dependent variables listed in table 4. The largest effects were observed for changes in caregiver reaction to patient memory and behavior problems, satisfaction with social support, and caregiver burden. Each of these mediators was significantly affected by the intervention,

and these intervention-induced changes accounted for at least 30% of the intervention's effect on nursing home placement rates when examined individually. Most striking was the effect of the intervention through decreasing caregiver reaction to patient behavior, which accounted for 48.7% of the impact of the intervention on nursing home placement. Depressive symptoms and frequency of memory and behavior problems were significant, but weaker, individual mediators of the intervention effect.

The proportional hazards models that included all the time-invariant covariates and multiple time-dependent changes from baseline simultaneously indicated that the model with changes in caregiver reaction to patient memory and behavior problems, satisfaction with social support, and depression included together reduced the hazard ratio for the intervention condition to 0.879 ($\chi^2 = 0.689$, $p = 0.406$). The comparison of this hazard ratio and the reference value of 0.717 indicated that, collectively, these three mediators accounted for 61.2% of the intervention effect on nursing home placement rates [$\ln [0.717] - \ln [0.879] / \ln (0.717) = 0.612$].

Discussion. The current analyses of data collected over an 18-year period indicate that, both before and after comprehensive covariate adjustment, the enhanced caregiver support intervention developed for spouse caregivers at NYU led to significant delays in nursing home placement. The covariate-adjusted

Table 3 Covariate-adjusted Cox proportional hazard ratios of nursing home placement from a multivariable predictor model with time-invariant and baseline covariates

	Hazard ratio (95% CI)	p Value*
Time-invariant predictors		
Group (intervention vs usual care)	0.717 (0.537–0.958)	0.0247
Caregiver gender (female vs male)	1.249 (0.883–1.767)	0.2081
Caregiver age	1.004 (0.979–1.029)	0.7642
Patient age	1.015 (0.989–1.043)	0.2855
Patient income	0.839 (0.760–0.925)	0.0005
Year of study entry (0 = 1987 – 10 = 1997)	0.907 (0.859–0.957)	0.0004
Baseline values of time-dependent predictors		
Global Deterioration Scale		
5 vs 4	1.939 (1.332–2.824)	0.0006
6 vs 4	2.505 (1.578–3.977)	<0.0001
Caregiver physical health	1.079 (0.835–1.394)	0.5628
Patient physical health	0.982 (0.786–1.227)	0.8742
Satisfaction with support network	1.129 (0.997–1.279)	0.0552
Frequency of memory and behavior problems	0.987 (0.975–1.000)	0.0499
Reaction to memory and behavior problems	1.013 (0.999–1.027)	0.0743
Depressive symptoms	1.016 (0.988–1.044)	0.2791
Caregiver burden	1.009 (0.996–1.021)	0.1759

* χ^2 test.

model indicated a median delay in placement of 557 days, or approximately 1.5 years. This is substantially larger than the median delay of 329 days that was reported in 1996 over a more limited time period for the first 206 participants.⁹

Delaying placement was not accomplished at the expense of caregiver well-being. Caregivers in the treatment group were not only able to keep their spouses at home with them longer, but, as the results of our mediation analysis indicate, the effects of the intervention on nursing home placement were largely achieved through improvements in caregiver well-being that we have reported previously^{10,11,36}:

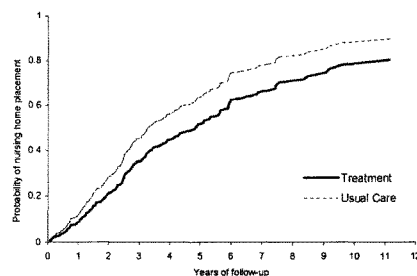


Figure 2. Probability of nursing home placement (1 – survival probability) as estimated from a Cox proportional hazards model. Curves are depicted for each intervention group at the mean value of the covariates.

greater tolerance for patient memory and behavior problems, improved satisfaction with the support provided by family and friends, and fewer symptoms of depression.

Our results suggest that with sufficient counseling and support, it is possible to achieve outcomes that are beneficial to most family caregivers, older patients, and society. While nursing home placement may be necessary when caregivers are unable or unwilling to manage the care of their relatives at home, it typically does not reduce caregiver distress.^{5,39} With placement, caregivers may encounter new stressors such as coping with guilt, feeling their relatives are not receiving adequate care, and conflicts with nursing home staff. Remaining at home longer is generally also to the advantage of patients with dementia, for whom nursing home placement can lead to increased confusion due to the strain of adapting to an unfamiliar environment⁴⁰ and increased risk of mortality.⁴¹ Nevertheless, we recognize that nursing home placement may be the best option for some individuals. Caregivers should be supported in decisions to seek placement, and clinicians should be alert to circumstances where placement should be recommended to protect the caregiver's health and well-being.

This study had several limitations that should be addressed in future research. Despite utilization of random assignment, we found imbalances at baseline between treatment and control participants on several key measures. We entered these variables, along with other covariates, in our analyses to ad-

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Table 4 Covariate-adjusted Cox proportional hazard ratios of nursing home placement for change in each time-dependent predictor and for the treatment group*

Time-dependent predictor added to the model†	Change from baseline (b_1, χ^2)			Treatment group (b_0)			% of Group effect mediated‡
	HR (95% CI)	χ^2	p	HR (95% CI)	χ^2	p	
Global Deterioration Scale				0.742 (0.56–0.99)	4.04	0.0443	10.31
5 vs 4	12.059 (1.63–89.18)	5.95	0.0147				
6 vs 4	35.705 (4.81–265.30)	12.21	0.0005				
7 vs 4	25.405 (3.20–201.73)	9.36	0.0022				
Caregiver physical health	1.053 (0.82–1.35)	0.16	0.6851	0.734 (0.55–0.98)	4.27	0.0388	7.06
Patient physical health	1.139 (0.93–1.40)	1.55	0.2134	0.726 (0.54–0.97)	4.66	0.0309	3.76
Average satisfaction with support	0.853 (0.75–0.97)	5.68	0.0171	0.803 (0.59–1.09)	1.98	0.1597	34.05
Frequency of memory and behavior problems	1.048 (1.04–1.06)	72.64	<0.0001	0.770 (0.58–1.03)	3.09	0.0788	21.43
Reaction to memory and behavior problems	1.030 (1.02–1.04)	44.21	<0.0001	0.843 (0.63–1.13)	1.29	0.2565	48.66
Depressive symptoms	1.036 (1.01–1.07)	5.87	0.0154	0.773 (0.58–1.04)	2.94	0.0864	22.60
Caregiver burden	1.038 (1.03–1.05)	42.66	<0.0001	0.800 (0.60–1.07)	2.21	0.1367	32.94

* Each row reports the results for a model that includes the change scores associated with one time-dependent predictor.

† The rightmost column in each row shows the reduction in the size of the intervention effect after accounting for the changes in the potential mediator in the model represented by that row.

‡ Added to the time-invariant and baseline covariates from table 3.

just our test of the intervention effect for baseline imbalances, but future studies might use stratified randomization techniques to ensure baseline equivalence on major covariates such as gender and disease severity. In addition, this project was conducted in a university hospital setting, and focused on spouse caregivers, few of whom were of minority ethnic backgrounds. More recent caregiver intervention projects have shown that culturally diverse family caregivers can respond well to appropriate psychosocial interventions offered in community settings.⁴²

Interventions that help reduce nursing home utilization without overburdening family members will be essential for our society, which is confronted with a projected tripling of cases of AD in the decades ahead.⁴³ Given the average annual cost of \$60,000 for nursing home care in the United States in 2004,⁶ a delay in placement of 1.5 years represents about a \$90,000 savings per patient. While our study did not collect sufficient information to conduct a careful cost-benefit analysis, the average nursing home cost savings for a single participant in the treatment group is far greater than the annual salary of a full-time counselor. Future research should include detailed cost-benefit analyses, but the results of this study suggest that wider dissemination of this intervention would be cost-effective health care policy.

The value of social support for family caregivers is not restricted to AD. For example, family support has been found to have positive effects on quality of life of caregivers for patients recovering from stroke.⁴⁴ Despite the fact that results from this project and others demonstrate the effectiveness of

evidence-based interventions for family caregivers, such specialized and individualized caregiver intervention programs are not widely available. Most caregivers in the United States do not receive individual or family counseling services from trained professionals. Typically, those who seek services are only provided referrals to support groups, even though recent research suggests that unstructured support groups may be far less effective at achieving desirable outcomes than individualized caregiver interventions.⁴⁵

In community settings, caregivers frequently have even greater need for resources and patients more commonly have multiple etiologies underlying their dementia. Studies to determine the feasibility and effectiveness of counseling and support interventions in typical community settings are necessary. One promising recent study showed that community service providers can be trained to deliver effective, evidence-based caregiver intervention in caregivers' homes, and intervention improved caregiver depression, burden, and stress appraisal, while also improving patient quality of life and behavioral problems.⁴⁶ Further efforts to extend evidence-based caregiver interventions beyond research settings should be a high priority, given their potential benefit to caregivers, patients with dementia, and society.

Acknowledgment

The authors thank the NYU Caregiver Counseling staff and Steven Ferris, PhD. They also thank the caregivers for their participation.

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