

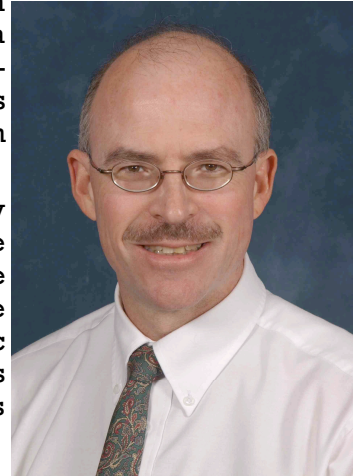
GEORGETOWN UNIVERSITY MEDICAL CENTER MEMORY DISORDERS PROGRAM NEWSLETTER



Georgetown University Medical Center Names R. Scott Turner, MD, PhD, New Director of the Memory Disorders Program

R. Scott Turner, M.D., Ph.D., an expert in the diagnosis and treatment of people with memory disorders, Alzheimer's disease, and other neurodegenerative dementias, and a highly regarded neuroscience researcher, has been named director of Georgetown University Medical Center's Memory Disorders Program, effective August 1, 2008. Turner's appointment by Georgetown University signifies a steadfast dedication to excellence in research, clinical trials, and patient care in the field of neurosciences.

Established in 1999 as the first program of its kind in the Washington area, the Memory Disorders Program provides the latest and most advanced clinical trials and patient care by combining state-of-the-art technologies and the newest treatments with the expertise of a team of clinicians and researchers. As a part of the department of neurology, the Memory Disorders Program conducts clinical trials including studies of new diagnostic methods and new treatments including vaccines. Patient care in the Memory Disorders Program is provided through Georgetown University's partnership with MedStar Health.



Turner's strengths in laboratory research and clinical care translate to exceptional leadership and vision at a critical time in biomedical research

"I look forward to the continued growth of GUMC's Memory Disorders Program under Dr. Turner," said Howard J. Federoff, MD, PhD, Executive Vice President for Health Sciences at Georgetown University and Executive Dean of the School of Medicine at Georgetown University Medical Center. "He is the right person at the right time to employ new technologies with rapid scientific advances that will ultimately improve how we treat people with neurological disorders."

Turner points to the need for intense collaboration to continue making advances in the field. "Scientific information about the underpinnings of Alzheimer's disease and other neurodegenerative disorders is being revealed at a rapid pace. It's critical that we rapidly translate that knowledge in meaningful ways to develop better treatments and discover ways to help prevent or dramatically slow the onset of disease. These enormous tasks demand the expertise of dedicated clinicians and keen laboratory researchers working together—this is a unique strength of the Georgetown program."

Prior to joining Georgetown, Turner served as chief of the neurology service at the VA Ann Arbor Healthcare System. He was also an associate professor and associate chairman for the University of Michigan Healthcare System's neurology department.

Turner graduated with honors from Clemson University with a B.S. in microbiology and molecular biology. He received his M.D. and Ph.D. in pharmacology from Emory University. Turner completed his internship, residency, and fellowship at the University of Pennsylvania and then joined the faculties of the University of Michigan and the VA Ann Arbor Healthcare System. Turner is board-certified in psychiatry and neurology.

Turner has directed a number of federal and foundation-funded research projects to study cognitive disorders, Alzheimer's disease and its basic mechanisms, and clinical studies of neurodegenerative dementias. He has received numerous awards, including a Paul Beeson Scholarship and a fellowship from the Howard Hughes Medical Institute. He lectures widely at scientific conferences, serves as a reviewer for numerous biomedical journals, and is widely published in his field. He is a member of the American Neurological Association, the Society for Neuroscience, and the American Academy of Neurology.

Turner succeeds Paul Aisen, M.D., the newly appointed director of the Alzheimer's Disease Cooperative Study and a professor in the department of neuroscience at the University of California, San Diego. Aisen founded Georgetown's Memory Disorders Program and continues to serve the program in an advisory capacity.

Excerpt from Georgetown University Medical Center Press Release August 1, 2008

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Communication and Caregiver Study: Report of Finding to Date

Communication problems are among the most difficult issues faced by people with Alzheimer's Disease (AD) and their caregivers. They contribute to increased stress, mortality, and decreased quality of life. Communication behaviors (e.g., telling jokes, making excuses) are often perceived as symptomatic of the disease rather than as an attempt by the person with AD to cope or maintain selfhood in the face of disease progression. This article presents preliminary data on the communicative coping strategies of people with AD using a new measurement tool, called the Communicative Coping Behavior Checklist (CCBC). Preliminary data were collected from a sample of persons with AD as well as a smaller sample of persons evaluated to be cognitively intact.

We found some interesting results in this preliminary data. The caregivers of persons with dementia noticed their loved ones used all of the 23 strategies on our Checklist including humor, word searching, and expression of gratitude. These caregivers most frequently noticed repetition and denial as coping strategies. We also saw strategies used by the cognitively intact dyads (two individuals who maintain a significant relationship). We studied the cognitively intact dyads who were studied as a comparison group. In these dyads, the person acting as the caregiver noticed that humor was the most frequently used coping strategy. The normal dyads did not use 6 out of the 23 behaviors on our CCB Checklist. We plan to conduct more research in this area to refine our checklist so that it can be used by caregivers and doctors.

Written by Pamela Saunders, PhD

Immunotherapy Trials

Written by Brigid Reynolds, RN, MSN, NP

Scientists have long been intrigued by the idea that Immunotherapy may prove effective in treating Alzheimer's disease (AD). This approach is based on what we currently know about the immune system's ability to fight off invading organisms, such as bacteria and viruses. When foreign substances enter the body, it is the immune system that mounts a defense by producing antibodies and cells that can attack and eliminate the invader. Immunotherapy research in AD was a major focus at July's International Conference on Alzheimer's Disease (ICAD), a large annual scientific meeting of physicians and scientists from around the world.

In 2001 Elan Pharmaceuticals launched the first vaccine trial for treatment of AD. The idea was that since a single molecule, the amyloid peptide, is linked to AD, vaccination against the peptide would induce an immune response to attack and clear the peptide from the brain. Subjects received vaccinations designed to target abnormal clumps of protein that form outside of brain cells (referred to as beta-amyloid plaques). This trial was halted after several subjects developed harmful brain inflammation. Initial analysis of the results, though far from conclusive, revealed that the AD vaccination held potential for clearing amyloid plaques from the brain. Additional data from this study were presented at ICAD. Cognitive test results and autopsy examination of brain tissue from subjects who had received the vaccine demonstrated that although the AD vaccine may effectively remove amyloid plaque from the brain, reduction in plaque did not correlate with slowing the pace of cognitive decline. Because only a small number of subjects were followed and the study was never completed, many questions remained unanswered.

Encouraging results coupled by significant safety concerns have led to the development of altered forms of the initial AD vaccine that are now being tested in humans. Several such trials are currently underway worldwide. Because these studies are in early stage human testing, referred to as phase II, they have been designed primarily to answer questions of safety and tolerability. Phase II studies, if positive, will lead to larger phase III trials designed to test treatment effect or efficacy. Another form of immunotherapy, involving antibody infusions and referred to as passive immunity, has entered phase III testing.

Passive immunity in AD involves infusion of antibodies designed to target beta-amyloid plaques. It differs from active immunity in which vaccinations stimulate the immune system to make antibodies. It is believed that the immune responses triggered by vaccination caused the brain inflammation that halted the initial vaccine trial. Providing antibodies directly bypasses this immune response and may prove to be a safe alternative to immunization. Several phase II studies of passive immunity with anti-amyloid antibodies have been completed. Results from these studies were presented at ICAD.

Bapineuzumab, an anti-amyloid antibody designed by Elan Pharmaceuticals, has undergone initial phase II safety testing. These findings have paved the way for phase III testing of this antibody which began in the spring of 2008. Because the phase II trial of Bapineuzumab did not meet efficacy targets, the study was reported to be negative. Researchers are optimistic that the much larger phase III trial of Bapineuzumab may prove positive treatment effect. A second anti-amyloid antibody designed by Lilly Pharmaceuticals has completed phase II testing and is expected to enter phase III testing in 2009. Evidence suggests that another type of antibody derived from human blood and FDA approved for a variety of non AD conditions could possibly be effective in treating AD. A phase III trial of this human antibody referred to as IGIV is expected to begin in the Fall of 2008.

For more information on AD related immunotherapy trials visit the Alzheimer's Disease Education and Referral Center's website at: www.alzheimers.org. Details about these studies can also be found at: clinicaltrials.gov. Links to Immunotherapy trials open to enrollment through the Memory Disorders Program can be found at our website: <http://memory.georgetown.edu>.



Mood Disorders Respond to Therapy

Persistent feelings of sadness, discouragement, irritability and low energy are hallmark symptoms of a common and often insidious medical illness among the elderly: depression. The good news is that depression is very treatable.

The incidence of depression is higher in people who have Alzheimer's disease (AD), possibly as high as 50%. Research shows that depression is not caused by knowledge that one has AD or knowledge of associated disabilities, but rather from the changes in the brain that occur as a result of having Alzheimer's disease. Seeking evaluation and treatment is imperative, as untreated depression decreases one's quality of life and can contribute to poorer general health and functioning.

Risk factors for developing depression in Alzheimer's disease include a family history of a mood disorder in a first degree relative, a prior personal history of depression, female gender, and younger age of Alzheimer's disease onset.

Depression may go unnoticed if symptoms are attributable to other medical conditions or if a patient is not willing or unable to talk about symptoms. Untreated medical issues (such as pain or infections) as well as the patient's environment (life stresses or isolation) may be contributing factors. Diagnosis is based on an examination by a clinician and includes a discussion of mood and behavior and may include lab tests. In persons with AD, symptoms of depression may include apathy, agitation, loss of appetite, fatigue, trouble sleeping, and abnormal thoughts about death.

Nonpharmacologic therapies such as developing a daily routine and instituting pleasant activities can be implemented for very mild depression. Antidepressant medication will often be considered early in the treatment course. In elderly patients, lower doses of antidepressants are used initially. Some improvement in mood is usually seen in a few weeks, however, dosages may need to be adjusted over a longer period of time to achieve the most symptomatic relief. Never discontinue medications without checking with your clinician.

Written by John T. Little, MD and Kathleen Johnson, RN, MSN, NP

The Memory Disorders Program staff members will be walking in the upcoming Alzheimer's Association Memory Walk on Oct. 18, 2008. We welcome anyone who wants to join us in the walk. Please contact Anne at 202-687-8800.

CURRENT RESEARCH TRIALS AT GEORGETOWN

Study Name	Required Diagnosis	Key Inclusion/Exclusion	Study Duration/ Number of Visits	Contact
Wyeth Vaccine (Vaccine Study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI and Lumbar Puncture	24 visits over 2 years	Kelly at 202-687-0413
Merck (Vaccine study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI and Lumbar Puncture.	17 visits over 18 months	Kelly at 202-687-0413
RI (Drug Study)	Mild to Moderate Alzheimer's Disease	Patient must be able to take oral medication.	13 visits over 18 months	Mary at 202-687-3355
Home Based Assessment (Detection and Prevention Study)	Cognitively Normal or Mild Cognitive Impairment	Willing to learn computer skills and have access to telephone and mail.	Various at-home visits over 4 years	Mary at 202-687-3355
Elan 301/302 (Infusion Study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI.	15 visits over 18 months	Mary at 202-687-3355
Elan D005 (Drug Study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI.	15 visits over 18 months	Kelly at 202-687-0413
Lilly Gamma Secretase (Drug Study)	Mild to Moderate Alzheimer's Disease	Patient must be able to take oral medication.	20 visits over 18 months	Kelly at 202-687-0413

INTRODUCING THE HOME-BASED ASSESMENT STUDY: AN ALZHEIMER'S DISEASE PREVENTION TRAIL

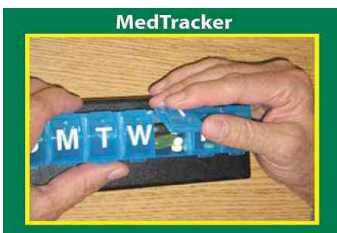
Most of the studies we conduct at the Memory Disorders Program are targeted to the treatment of Alzheimer's disease. The Home-Based Assessment (HBA) Study, on the other hand, focuses on Alzheimer's disease prevention and early detection. Currently, disease prevention trials are costly, require large numbers of subjects, and are time consuming. The HBA Study was created to address this unmet need for effective, efficient and economical methods for conducting AD prevention trials. This research is being sponsored by the Alzheimer's Disease Cooperative Study, through a grant from the National Institute on Aging, and is expected to enroll about 600 subjects at 30 sites nationwide.

This study aims to evaluate the feasibility of three at-home assessment methods for elderly people, 75 years of age or older, at risk for memory problems. These sensitive at-home testing methods can detect a change in both participants' daily living activities and their functional capabilities over a four year period.

The three methods of information collection in this study are the 1) mail-in questionnaires 2) automated phone technology with key pad entry and interactive voice recognition and 3) standard personal computer. The testing sessions range in duration from 20 to 45 minutes. The frequency of testing is dependent upon which method a participant is randomized into: either monthly, quarterly, or annually. Each participant is randomly assigned to a frequency of testing as well as one method of information collection. All equipment is provided by the study sponsor; assembly and training are performed by the research team in the participant's home.

No previous computer experience is required!

In addition to the memory testing, participants are required to take a multivitamin pill, twice daily, in order to assess their pill-taking behavior. (Taking two study vitamins pills per day is equivalent to a standard daily multivitamin dose.) The study will examine how well the various methods of information collection report participant medication compliance.



An HBA participant using a study-provided computer

Each participant has an initial in-person screening assessment in the clinic or at home. A small sample of blood is taken at this visit to examine chemicals in the blood that may be associated with memory loss. (Neither the study team nor the participants receive the results of the blood study.) In the course of the four years, if a participant exhibits memory change, as detected by the testing sessions, the study team will contact the participant to schedule an in person evaluation visit. Finally, at the end of the four year study, all participants undergo such an in-person evaluation.

So why participate in the HBA Study? Participants' health, memory, and thinking skills are closely monitored by the study personnel. They also have the opportunity to test new technologies before they are available to the general population. And finally, participants help to advance science without leaving the comfort of their own home.

So far at Georgetown University, we have enrolled 18 participants in the HBA Study. We have been lucky enough to work with engaging and excited participants from various demographic backgrounds across the Washington, D.C. Metropolitan area. We look forward to following the HBA Study participants in the coming years! For more information or questions about the HBA Study, please contact Mary Stevenson at (202) 687-3355.

Written by Patrycja Zielinska, RN, MSN, NP and Mary Stevenson

Please visit our new and improved website at:

[Http://memory.georgetown.edu](http://memory.georgetown.edu)

For all clinic information, please contact Kelly Behan at:

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Phone: (202) 687-0413