

Georgetown University Medical Center

Memory Disorders Program Newsletter

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INSIDE THIS ISSUE:

The Director's Column Cont...	2
Patient Appreciation Day Announcement	2
Partnering with Support Services	2
Research Studies Status Table	3
Partnering with Support Services Continued	3
Aphasia Research Study	3
Everything you wanted to know about Research, Part 2	4

A Warm Welcome to Dr. John Little

The Memory Disorders Program is pleased to welcome Dr. John Little to our clinical team. He is a psychiatrist with a specialty in geriatrics. Dr. Little received his MD from Baylor College of Medicine in 1986. He completed his internship at Tufts University and his residency at the Boston University Medical Center. He is board certified in Psychiatry and has an added Board Certification in Geriatric Psychiatry.

Prior to joining the Memory Disorders Program at Georgetown University, Dr. Little held positions at the National Institute of Mental Health, University of Pittsburgh Medical School and Johns Hopkins University School of Medicine.

Dr. Little's clinical interest is geriatric psychopharmacology, which is a branch of pharmacology dealing with the psychological and medical effects of drugs on the geriatric population. His research interests include geriatric depression, memory disorders, and functional neuroimaging. For example, Dr. Little has recently completed a treatment study at Johns Hopkins Hospital examining the functional neuroanatomy of major depression in the elderly

using Positron Emission Tomography (PET scanning) and functional magnetic resonance imaging (fMRI). Currently, Dr. Little is the Medical Director of the Psychiatric Partial Hospitalization Program and a faculty psychiatrist in the outpatient clinic of the Department of Psychiatry at Georgetown University Hospital. He is a co-investigator in the Memory Disorders Program and also a geriatric psychiatry consultant at the Washington Home.

Dr. Little has been an invaluable resource to our program. With the growing elderly population and their very complicated medication regimens, Dr. Little's expertise in geriatric psychiatric care is extremely valuable. Dr. Little will

be seeing both cognitively normal and cognitively impaired geriatric patients who have psychiatric problems.

We are very much looking forward to our ongoing collaboration with him and learning from his wealth of knowledge in geriatric psychiatry. We hope you will have an opportunity to meet him along the way.

Written By Patrycja Zielinska, RN, MSN, NP



The Directors Column:

The Story of Immunotherapy for Alzheimer's Disease

Regular readers of this newsletter know that the Georgetown University Memory Disorders Program has been participating in the Phase II trial of Passive Immunotherapy sponsored by Elan. As excitement about the immunotherapy approach continues to build, more trials have been initiated. We are now participating in another Phase II immunotherapy trial, this one sponsored by Lilly. And we expect to begin enrollment in a Phase I active immunotherapy trial sponsored by Merck in early 2007. So this is a good time to review the field of immunotherapy for Alzheimer's disease.

First, some basic background information on the immune system. Our immune system is designed to fight off invading organisms, such as bacteria and viruses. When the immune surveillance system (which includes immune cells and proteins called antibodies) detects a foreign substance, it mounts a defensive response that includes the generation of many antibodies and cells that can attack and eliminate the invader. An active vaccine typically consists of a fragment of a virus or bacterium, combined with a substance that stimulates the immune response, and administered by injection. The body then mounts a cellular immune response against the fragment; this response is able to fight off actual infection by the virus or bacterium.

Story continues on page 2

The Directors Column Continued... The Story of Immunotherapy for Alzheimer's

When it was determined that a single molecule, called the amyloid peptide, is responsible for initiating and propagating the damage in Alzheimer's disease, investigators at Elan had the idea that active vaccination against this peptide would induce an immune response capable of attacking and clearing the peptide from the brain. This approach worked remarkably well in animal models of the disease. Unfortunately, the human trial of the active amyloid vaccine failed, because some individuals developed harmful brain inflammation in response to the vaccination. This brain inflammation, or encephalitis, is thought to be caused by the cellular component of the immune response. Though the trial of the vaccine was halted early, evidence suggests that the vaccine did have a beneficial effect in many study participants.

As a result, many efforts to develop safe and effective immunotherapy have been launched. New versions of the active vaccine are designed to produce antibodies against amyloid without stimulating immune cells; thus, such vaccines may provide benefits without the serious risk of the first amyloid vaccine. One such active vaccine, manufactured by Merck, will enter the earliest stage of clinical testing at Georgetown in January or February.

An alternate approach to safe anti-amyloid immunotherapy is called passive immunotherapy. With this approach, antibodies against the amyloid peptide are actually manufactured, and then infused intravenously at weekly, monthly or longer intervals. In comparison to active immunotherapy, passive immunotherapy allows greater control over the immune response; there is no cellular immune activity, and the antibody infusions can be halted if adverse effects occur.

Written by Paul S. Aisen, MD

WE APPRECIATE OUR PATIENTS AND RESEARCH VOLUNTEERS!!

All patients and research participants with the Memory Disorders Program, and their families, are invited to attend the first annual Patient Appreciation and Educational Luncheon. Come meet all the MDP staff, hear Dr. Aisen speak about the latest news on Alzheimer's disease, and enjoy a great lunch!

The event will be held at 12:00pm, at Georgetown University's Leavy Conference Center on Saturday, March 31st, 2007. (Free parking will be available.) Please RSVP by March 2nd to Dana at 202.687.3355 or via email at dab62@georgetown.edu



Partnering with Support Services

For a person with an unreliable memory, a comfortable and safe environment is essential. Socializing with peers and finding enjoyable things to do are important too. It can be challenging to let a loved one with a memory impairment maintain their independence, yet also provide supervision. As AD progresses, what works one year may not work the next. It is often hard for patients and families to know when to implement more support or make a change, and it can be a difficult subject to talk about with a loved one.

Searching for support services and new living environments can seem like a daunting task. A good place to start is to have a frank discussion with the doctor or nurse practitioner to gain a clear understanding of the person's disease stage, mild, moderate, or severe. Confirm if there are any restrictions on working, taking their own medications, driving, living independently, or leaving the house alone. Socialization and activity are important for everyone and often hard for a single person (such as a spouse or caregiver) to provide, especially if the person with AD is no longer working or participating in the activities they had in the past. Be open minded about exploring all options and talk with others who are experiencing the same situation.

The Alzheimer's Association, National Capital Area provides a range of support services, including information on where to find companion services, licensed nursing personnel, elderlaw professionals, local senior centers, adult day care, senior housing, assisted living, nursing homes, respite care, and support groups. Their Helpline (1-800-272-3900 or 703-359-4440, 24 hours a day, seven days a week) volunteers can provide information about chapter programs and can answer many caregiving questions. The website (<http://www.alz-nca.org>) has a lot of helpful information including CareFinder, an interactive tool which provides education about disease stages, care options, and finding good care. This tool allows individuals to input personalized information such as special needs, abilities, and preferences to generate care recommendations. The Alzheimer's Association website's online message board allows you to share your thoughts, experiences, and questions with others in similar situations. Joining a support group is helpful in finding resources to build a supportive team, which may enhance the life of both the patient and the caregiver.

For someone who is newly diagnosed with AD, it may be enjoyable to share interests and make friends with others who are newly diagnosed. IONA's Early Alzheimer's Club (202-895-9448) and The Friends Club (men only 301-469-0070) are two clubs that provide this opportunity. Senior centers also have activities that are suitable for many people and provide regular opportunities for socialization. The Eldercare Locator Service (www.eldercare.gov or 1-800-677-1116) is a nationwide toll free service offered by the U.S. Administration on Aging which connects seniors to information about state and local services and provides links to community based organizations that serve older adults and their caregivers.

Story continues on page 3

Studies Currently Recruiting Subjects at Georgetown:

Study Name	Required Diagnosis	Key Inclusion/Exclusion	Study Duration/ Number of Visits	Who to contact
*DHA (Fish Oil) (drug study)	Mild Alzheimer's Disease	Patient must be able to have an MRI or CT Scan	8 visits over 18 months	Dana at 202/687-3355
Mem-1003 (drug study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI or CT and Currently not taking Namenda	8 visits over 3 months	Kelly at 202/687-0413
Huperzine (drug study)	Mild to Moderate Alzheimer's Disease	Patient cannot currently be taking Aricept, Exelon, or Reminyl/Razadyne	9 visits over 24 weeks	Dana at 202/687-3355
Merck (Vaccine study)	Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI and Lumbar Puncture	17 visits over 36 months	Kelly at 202/687-0413
Nicotine (drug study)	Mild Cognitive Impairment	Patient needs to be a non-smoker	11 visits over 12 months	Kelly 202/687-0413
ADNI (imaging study)	Normal Elderly/MCI/ Mild to Moderate Alzheimer's Disease	Patient must be able to have an MRI	8 visits over 18 months	Kelly 202/687-0413
Lilly (antibody study)	Mild to Moderate Alzheimer's Disease/ Normal Controls	Patient must be able to have an MRI and a Lumbar Puncture	12 visits over 12 weeks	Dana at 202/687-3355
Caregiver Communications Study	Mild Alzheimer's Disease /Normal Controls	Caregiver must see patient at least twice a week.	2 visits over 12 months	Kris at 202/687-9078

Partnering with Support Services Continued...

The American Association of Homes and Services for the Aging (www.aahsa.org) provides listing of continuing care retirement communities, senior housing facilities, community service organizations, nursing homes, and information on types of accredited continuing care facilities.

For families that want support in making decisions and implementing changes, it may be helpful to hire a geriatric care manager. A geriatric care manager is a health and human services professional, such as a gerontologist, nurse, social worker, or psychologist, with a specialized focus on issues related to aging and elder care. A good geriatric care manager is knowledgeable about community resources and will assist families and individuals with issues such as assessing appropriate care options, long-distance caregiving, daily money management, planning for financing long term care, evaluating and locating appropriate long term care living options, and coordinating appropriate home care. A listing of Professional Geriatric Care Managers can be found at www.caremanager.org or 520-881-8008. Care managers should be interviewed as to their training, education, and background in care management and geriatrics. Ask them about their scope of practice. Ask for letters of reference and names of previous clients you may contact. Understand the care manager's billing policy, and get a written service agreement that outlines fee structure and practices.

Written by Kathleen Johnson, RN, MSN, NP

Aphasia Research Study is Recruiting Non Alzheimer's Participants

Have you experienced reading or naming difficulties following a stroke or brain injury? The Cognitive Neuropsychology Lab at Georgetown University Medical Center is seeking participants for studies that test the effectiveness of various cognitive therapies for reading disorders (alexias) and a naming disorder (anomia). A person with alexia may

have difficulty reading particular kinds of words. For example, nouns may be easier than verbs, or regularly spelled words may be easier than irregularly spelled words. Some people with alexia may have particular difficulty reading grammatical words such as "if," "then," "in," or "but." Others may be able to write but not read. People with anomia

may have difficulty retrieving words from their own vocabularies. If you experience any of these problems as a result of a stroke or brain injury and are interested in participating in one our studies, contact Leah Orchinik at (202) 687-2721 or email AphasiaResearch@georgetown.edu.

Many Things You Always Wanted to Know About Research But Were Afraid to Ask, Part Two:

All our treatment research protocols are approved by the US FDA and then go through rigorous review by Georgetown's own Institutional Review Board (IRB) before we can begin to enroll individuals in any study. The IRB examines materials provided to us by the study sponsor, such as the protocol (outlines the scientific justification for the research, how study findings will be measured, what preliminary safety studies have been done), the Investigator's Brochure (details the composition of the study drug), the Informed Consent Form (ICF), and any other flyers, brochures, etc., we may use for study recruitment.

Important new information about a study, including changes made to the ICF, must be reported to our IRB during the course of the study. Each year, the IRB reviews our protocols and receipt of a current stamp of IRB approval is required to continue a study. Sites that conduct research are also monitored by independent Data Safety Monitoring Boards (DSMBs) that oversee the safety of the studies. They review any data on severe adverse events that take place in studies. They can recommend the termination of a study if they find an unanticipated relationship between adverse events and a study medication. While we investigate medications we hope will aid in the fight against memory problems, we do not know for a fact that these medications will prove to work effectively. It is not a given that a subject will benefit from study participation. However, there are several advantages to enrollment in a research study. Individuals in our research programs are closely monitored by our clinicians and staff. All evaluations related to the study (lab tests, electrocardiograms, MRIs and CT scans) are paid for by the study sponsor. If any abnormalities surface during these tests, the subject and his or her family are informed. This information can also be provided to the subject's primary care physician.

Studies track a subject's cognitive status during their participation. While our site may not be able to provide specific analyses of each visit, if problems are noted, staff can address issues related to possible additional interventions, even if that means a person may need to leave a study. Our focus has to be what is best for the subject, independent of the needs of the trial.

Additional perks for research participants include reimbursement for parking and, depending on the length of the study visit, a meal. Some studies include a small stipend, but many do not have funds budgeted for that purpose. Perhaps the most significant aspect of research involvement is the contribution made to the advancement of treatment for Alzheimer's disease.

Written by Carolyn Ward, MSPH

For all clinic information please call Kelly:

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We're on the web
<http://memory.georgetown.edu>

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