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The VA Parkinson Report



*A Newsletter for the Parkinson's Disease Research, Education and Clinical Centers
and The National VA Parkinson's Disease Consortium*

Department of Veterans Affairs Volume 7, No. 1, Fall 2009

Comparing Best Medical Therapy to Bilateral Deep Brain Stimulation in Patients with Parkinson's Disease: Which Is Better?

Frances M. Weaver, PhD, Director, Center for Management of Complex Chronic Care, Hines VA Hospital

Deep brain stimulation (DBS) is an accepted treatment for advanced Parkinson's disease (PD). However, there have been few randomized trials comparing treatments, and most exclude older patients, those most likely to suffer from PD. We recently completed a study comparing DBS to best medical therapy (BMT) for PD at the 6 PADRECC centers and their affiliated university medical centers.

Patients were eligible if they had Hoehn and Yahr stage ≥ 2 when off medication, were responsive to levodopa, had persistent disabling motor symptoms, and experienced ≥ 3 hours/day when they were in an off state and/or had disabling dyskinesia. Exclusions included those with atypical syndromes, surgical contraindications, significant cognitive impairment or dementia. Patients completed a motor diary for two days, recording time spent in the on state, on with troubling dyskinesia, off, and asleep. Following informed consent patients were assessed using the Unified Parkinson's Disease Rating scale (UPDRS), and completed the Parkinson's Disease Questionnaire 39 (PDQ-39). A comprehensive neurocognitive battery was also completed to assess depression, dementia, attention, working memory, intelligence, verbal fluency and other standardized measures of cognitive function. 255 patients were randomized to receive DBS or BMT. Patients randomized to DBS were then randomized to surgical target: either subthalamic nucleus or globus pallidus interna. The DBS groups were combined for analysis and compared to BMT patients in Phase I of the study.

More than one-quarter (27%) of patients enrolled in the study were age 70 or older. The majority of patients were male (82%), 60% and most were white (96%). The primary outcome was patient self-reported motor function. DBS patients gained an average of 4.6 hours/day of 'on

time' (6.4 hours to 10.9 hours); while BMT patients had no change (7.0 hours to 7.1 hours; $p < 0.001$) based on diaries. On time with troubling dyskinesia and off time also decreased in the DBS group. Blinded assessments of UPDRS motor functioning showed DBS patients experiencing a 29% improvement, while BMT patients averaged a 4% improvement in motor function. Levodopa equivalents decreased by 296 mg. for patients with DBS, but increased 15 mg. in those with BMT ($p < 0.001$). Finally, quality of life using the PDQ-39 improved on 7 of 8 subscales for DBS compared to patients in the BMT group.

Both groups experienced a large number of moderate and severe adverse events, including falls, gait disturbance, dyskinesia, motor dysfunction, balance disorder, depression and dystonia. DBS patients experienced surgical site infections (9.9%) and surgical site pain (9%). 40% of the DBS and 11% of the BMT patients experienced serious adverse events (SAEs). Most SAEs in the DBS group (83%) were attributable to the surgical procedure, stimulation device, or stimulation therapy. There were two deaths, one was secondary to a cerebral hemorrhage 24 hours after lead implant, and the other was for lung cancer. The most frequent SAE was surgical site infection of the lead and/or battery pack ($n=16$), followed by nervous system (15) and psychiatric disorders (11). SAEs in the BMT group included nervous system (3), psychiatric, and cardiac disorders, falls, and infections (2 each).

This large randomized controlled trial demonstrated the superiority of DBS to BMT in improving motor function and quality of life for advanced PD patients. However, improvement was accompanied by a greater risk for adverse events. Patients and their providers should carefully weigh the potential benefits against the risks in making decisions about DBS to manage the symptoms of PD.

PADRECC Launches Audio Conference Series with EES

Lynn Klanchar, RN,MS, ADoE, Southeast (Richmond) PADRECC

In 2009, Parkinson's Disease Research, Education, and Clinical Centers (PADRECCs) began offering one hour audio educational conferences about Movement Disorders in conjunction with the Veterans Affairs Employee Education System (EES). Courses are listed by EES electronically on the VA education catalog and broadcasted nationally using a VANTS 800 line. The programs are archived on the PADRECC/National VA PD Consortium website www.parkinsons.va.gov where participants can download the Power Point slides, transcript, and an mp3 audio file. EES offers continuing education credit to physicians, nurses, social workers, and psychologists who complete registration and the course evaluation within 2 weeks.

The goal of the educational series is to disseminate the latest evidenced-based information so clinicians can incorporate new knowledge into their practice. The target audience is primary care providers, but any healthcare professional working in the Veterans Health Administration (VHA) who is interested in learning more about the treatment and management of veterans with movement disorders can participate. We encourage PADRECC staff and Consortium members to join in on the calls.

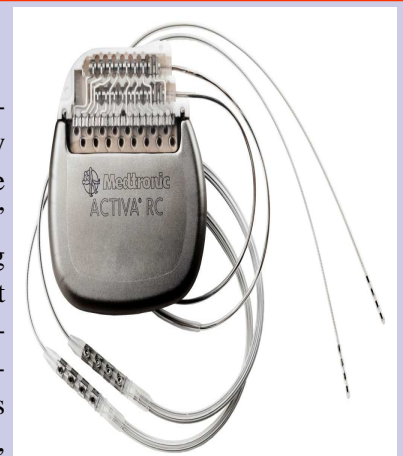
The programs run every two months, on the second Thursday, with broadcasts at 12 pm and 3 pm Eastern Time. The planning committee, comprised of the PADRECC Associate Directors of Education and an EES National Project Manager, Rivkah Lindenfeld, RN, PhD, selects topics based upon a needs assessment. The committee invites Consortium Center members to join as faculty or planning members.

The FY09 series opened on Nov 13, 2008, with Daniel Weintraub, MD (Philadelphia PADRECC) presenting "*Managing Neuropsychiatric Complications in PD*". The schedule included: Jeff Kraakevik, MD (Portland/NW PADRECC) on January 8th "*Impact of Falls and their Treatment*"; Fran Weaver, PhD (Hines VAMC) on March 12th "*Best Medical Therapy vs DBS for PD: 6 Month Results from a Multi-site Randomized Trial*"; Eugene Lai, MD (Houston PADRECC) on May 14th "*Atypical Parkinsonian Disorders*"; Jeff Bronstein, MD (WLA PADRECC) on July 9th "*Diagnosis and Treatment of PD*"; and Elaine Lanier, RN (SF PADRECC) on Sept 10th "*Caregiving and Psychosocial Issues in PD*".

The FY09 conferences have been well attended and informal feedback has been positive. Mark your calendar for the following FY10 dates: **Nov 12, 2009, Jan 14, 2010, March 11, 2010, May 13, 2010, July 8, 2010, and Sep 9, 2010.** Tune in at 12 pm ET or 3 pm ET on VANTS line 1-800-767-1750 code 53353#. Details about the topics and speakers will be forthcoming. Watch for advertisement on the PADRECC/National VA PD Consortium website at www.parkinsons.va.gov or contact the planning committee chairperson at lynn.klanchar@va.gov.

Rechargeable Battery Implanted in Parkinson's Disease Patient

Dr. Kathryn Holloway, Neurosurgical Director at Southeast (Richmond) PADRECC and Professor of Neurosurgery at Virginia Commonwealth University (VCU), was the first surgeon in the United States to implant the new rechargeable battery for Deep Brain Stimulation (DBS) on June 3, 2009. Benefits of "Activa RC" (pictured right) by Medtronic, Inc. include a smaller size, advanced programming options, and a 9 year battery life. The device is available to veterans receiving care at the PADRECC who are candidates for DBS. This longer lasting battery requires recharging compared to a traditional battery that must be changed every 3-5 years. Activa RC allows for fewer surgical procedures and overall reduced costs. Key factors for patient selection for the rechargeable model are patient interest, caregiver support, cognitive function, and expected battery consumption. See right diagram.



COLMR Study: Updated Results

Irene E. Cramer, PhD, MSSA, Boston University School of Public Health
Center for Organization, Leadership and Management Research

VA's Health Services Research & Development funded the Center for Organization, Leadership and Management Research (COLMR) to follow the PADRECC initiative to provide state-of-the-art care to VA's patients with Parkinson's disease (PD) and other movement disorders, disseminate knowledge, and enhance research. Study data include surveys of patients and informal caregivers, service utilization information, and interviews with VA employees. Early findings from our 2006 patient (n=2,375) and caregiver surveys (n=818) include:

- **Demographics:** 74% of the patients and 37% of the caregivers were over 70 years old. 82% of the patients reported that their spouse provided care.
- **General Health Status:** As could be expected, caregivers reported better self-rated health than did patients (57 vs. 35 on a 100-point scale with higher scores indicating better health). 40% of patients and 26% of caregivers reported experiencing depression and 45% of patients and 22% of caregivers did not regularly engage in exercise.
- **PD-Related Health Status:** Patients reported moderate levels of impairment during the time of day when medications were providing the maximum benefit. The mean score on the PDQ-8 was 39.9 on a scale of 0-100 and 16.9 on the UPDRS-ADL on a scale of 0-52 with higher scores indicating more disability. 22% experienced hallucinations.
- **Caregiver Burden:** About half reported having less personal freedom and time for themselves. Despite 55% reporting it was painful to watch the patient age, 67% also reported having positive feelings about the relationship with the patient.
- **Utilization:** 57% of the patients reported using both VA and non-VA care. Only 16% of the patients reported using education and/or support services from VA (26% from PADRECC sites; 8% from non-PADRECC sites). Reasons frequently cited for non-participation included not knowing about services, never being asked to participate, and distance/transportation challenges.
- **Satisfaction:** From VA's *Survey of Healthcare Experiences of Patients (SHEP)*, patients reported higher satisfaction with access to care, attention to personal preferences, and emotional support. Unmet needs identified with the *Patient Assessment of Chronic Illness Care (PACIC)* included the need for better follow-up/coordination, individualized goal-setting and treatment planning, problem solving, delivery system design, and patient activation.

Early findings from administrative utilization data analyses indicate that:

- In 2005, PADRECC patients used more neurology care in total, fewer days of long-term care, and one-half more days of outpatient care than other VA PD patients.
- The population using the PADRECC varied. For example, of 1,738 patients seen in PADRECCs in 2004, 871 were seen in PADRECCs in 2007.

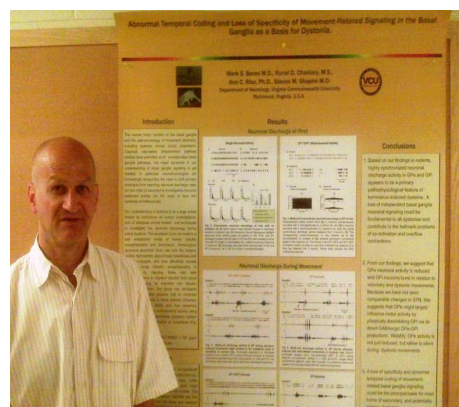
Analyses of survey, interview, and utilization data collected in 2009/2010 will allow us to describe the development efforts to improve patient care, enhance knowledge dissemination, and expand research efforts.

Study Team Members for the Evaluation of PADRECCs: Martin P. Charns, DBA, Principal Investigator; Irene E. Cramer, PhD, MSSA, Co-Principal Investigator; Ann Hendricks, PhD; Robert Holloway, MD, MPH; Konique Ballah, MPH; John Gardner, PhD; Mark Meterko, PhD; Terri Pogoda, PhD; Marjorie Nealon Seibert, MBA; Kelly Stoltzmann, MS; Center for Organization, Leadership and Management Research, VA Boston Healthcare System.



Pictured left: Sue Scott, MS, Active Living and Balance Specialist, demonstrates exercise for PD at a NW PADRECC educational event.

Pictured right: Dr. Mark Baron, Director SE PADRECC & Professor of Neurology at Virginia Commonwealth University, presents his research on dystonia at the Movement Disorder Society's 13 International Congress, 6/7-11/2009, Paris, France.

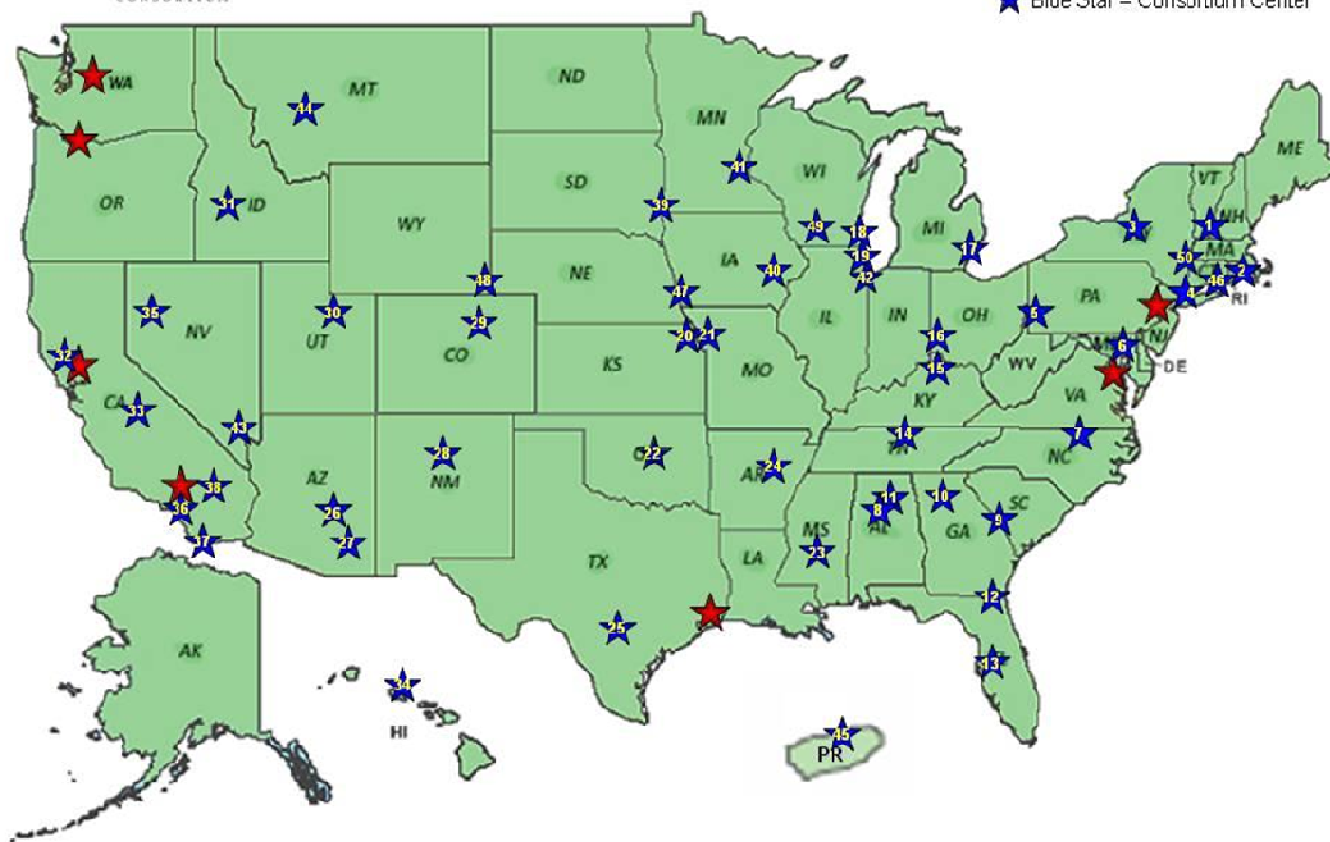


Rebecca Martine, MSN, RN, PMHCNS



National VA
Parkinson's Disease
CONSORTIUM

★ Red Star – PADRECC
★ Blue Star – Consortium Center



<http://www2.kenes.com/parkinson/pages/home.aspx>

The Role of Alternative Medicine in Parkinson's Disease Care

Nicholas Galifianakis, MD, MPH

For patients with chronic conditions such as Parkinson's disease (PD), alternative and complementary medicine is a rapidly growing form of health care. In the case of PD, this may be for many reasons. Medical science has not provided treatment that slows down the disease. Perhaps more importantly, the existing treatment of many PD motor and non-motor symptoms is inadequate or has intolerable side effects. Alternative medicine has grown to encompass a wide range of therapies (including acupuncture, massage, herbs, supplements, and yoga) with varying levels of efficacy and risk for the patient. It is estimated that 40-50% of Parkinson's disease patients in the U.S. have used alternative therapies for PD. The most commonly used are vitamins, herbs, massage and acupuncture. Younger patients, with higher income and education level are more likely to pursue alternative therapies, with the highest level of use on the Pacific Coast. A comprehensive review of the use of alternative medicine therapies in PD is beyond the scope of this article, however, we will briefly examine the role of alternative medicine in PD care.

Eastern medicine traditions have been practiced for centuries. It focuses upon attaining wellness rather than solely focusing upon disease. Ayurvedic (or ancient Indian) medicine addresses the interaction between the mind and body, using yoga and other cleansing therapies to achieve balance. Traditional Chinese medicine (TCM) uses herbal remedies, acupuncture, acupressure, and other exercise therapies to direct Qi (pronounced "chee") with the goal of balancing yin and yang. Most of these approaches have not been subjected to the scientific method, but occasionally some scientific rationale exists. For example, *mucuna pruriens*, a legume that has been used in India for centuries to treat parkinsonism, contains levodopa.

Eastern medicine has a strong tradition of physical techniques that may help patients with PD. There is growing evidence of the benefits of exercise in general. Many of the cardinal features of PD (such as rigidity and slowness) can be directly ameliorated by exercise. Massage therapy has long been recognized as helpful in reducing PD-related stress and stiffness. Tai chi is a Taoist practice from ancient China and yoga is a 5,000-year-old practice from ancient India. Both techniques use poses that coordinate the mind and body with breathing to address mental and physical well-being. Improvements in balance, posture, agility, tranquility, flexibility, and axial strength, all features that commonly affect PD patients, have been described with tai chi and yoga. They are both widely available in range of styles, frequently at beginner's levels. These forms of exercise are usually stationary, and seated versions have also been developed for patients

with balance problems. Acupuncture is low-risk and anecdotally helps some patients, although several studies in PD failed to show efficacy. Dance, music, and art therapy may also improve mood by reducing stress and keeping patients active.

The use of herbal remedies is more complicated. Some herbals may be relatively safe and beneficial for PD symptoms. A few examples include: ginger to counteract gastroparesis or nausea from dopaminergic drugs, passion flower to combat anxiety and insomnia, and triphala to combat indigestion and constipation. On the other hand, patients should be reminded that there are legitimate concerns in regard to the safety, cost, and scientific basis of many supplements and herbal therapies. Any ingested compound has the potential for drug interactions and dangerous side effects. A few examples include the interaction of St. John's wort with blood thinners and the agitation encountered with ginseng or ginkgo biloba. Since they are unregulated by the FDA, their contents may be inconsistent and may contain impurities. They are usually not covered by insurance and can be quite expensive. For treatment of PD, most supplements and herbal therapies have not been formerly evaluated in clinical trials. With this in mind, patients should be skeptical of anything that claims to be a "cure". If they still decide to use herbal therapies, they should find a reputable manufacturer (which put its address and detailed contents on the label) and seek out licensed herbalists, naturopaths, nutritionists and Doctors of Oriental medicine (D.O.M.s) to advise them.

While neurologists and other health care providers cannot be expected to become alternative medicine practitioners, it is important for the medical community to understand the potential risks and benefits of these therapies. Thankfully, as awareness of alternative medicine grows, so do the resources available to providers to learn more about them. There is now a Physician's Desk Reference (PDR) for Herbal medicines. The NIH has established the National Center for Complementary and Alternative Medicine and more universities are establishing programs for study of complementary medicine. These resources may help providers answer patients' questions about these therapies. Encouraging beneficial practices while discussing the legitimate concerns will lead to more optimal care of PD patients. In general, therapies that involve exercise (such as tai chi and yoga) are known to improve balance, strength, and flexibility. Furthermore, knowledge of many of the herbals and supplements that patients with PD take will not only keep them safe but will show that we take their interest in alternative therapies seriously.

Mark Your Calendar for FY2010!

PADRECC/EES Audio Education Conferences on Movement Disorders:

Nov 12, 2009; Jan 14, 2010; Mar/11/2010; May/13/2010; July/8/2010; Sept/9/2010

Philadelphia PADRECC Pioneers Chair Yoga and Pilates Class

Heidi Watson, RN, BSN, LVCYT, Philadelphia PADRECC

Exercise is an important therapy for people Parkinson's disease (PD). The Philadelphia VA PADRECC has developed an exercise program involving a hour-long Chair yoga and Pilates class for the veteran with Parkinson's disease. In the spirit of a comprehensive approach to treating PD, the exercise program was developed to fulfill the need to provide veterans with PD an opportunity to improve their mind, body, and spirit. The caregivers of the VA patients are invited to participate in the class. Encouraging joint participation is essential in: promoting long term exercise habits, providing a break from the often stressful patient-caregiver relationship, and fostering a mutually enjoyable activity.

Yoga started in India around 3000-5000 BC, targeting spiritual growth. The practice of yoga has gained popularity in the United States since the 1960's and is now an increasingly popular type of exercise for older adults. The goal of yoga is to balance body and mind through performing a series of postures while practicing controlled breathing and mental focus. Many practice yoga to relieve stress, anxiety and improve concentration. Other benefits include improved flexibility, endurance, and balance. Traditionally, yoga is performed on a mat on the floor; however people with physical challenges such as Parkinson's disease may not be able to do the series of postures on the floor. As a result, the exercises class is conducted with participants sitting on a chair, allowing for people with physical challenges to participate in the exercise class and reap the same benefits.

Pilates, developed by Joseph Pilates in Germany during World War I and brought to the US in 1920's, combines the idea of mind-and-body union, but puts more emphasis on core strengthening. Because Pilates teaches body awareness, good posture, and ease of movement, it particularly benefits patients with PD. The vulnerable motor-related hallmarks of PD like balance, mobility and movement can be targeted in yoga and Pilates. In addition, many non-motor symptoms of PD, such as sleep problems, constipation and depression can improve with regular exercise.

Heidi Watson and Eileen Hummel, nurses at the Philadelphia PADRECC, teach the weekly hour-long class. Both are Lakshmi Voelker Chair Yoga Teachers (LVCYT) and have completed certification in "Pain Free Yoga and Pilates for Seniors".

Movement Disorder Centers At a Glance

Atlanta, GA

Atlanta VAMC

Director: Marian L. Evatt, MD MS

404-235-3077 (referral number to VAMC Movement Disorders Clinic)

Established in 2003, The Movement Disorders Clinic at the Atlanta VAMC is staffed by Dr. Evatt, a nurse, and will soon include a nurse practitioner. The clinic provides subspecialty consultations, patient selection, and management services for DBS surgery, and botulinum toxin injections. Dr. Evatt is affiliated with Emory University and the Emory Parkinson's Disease Research Center, serving as the PI for clinical/translational studies. Veterans from the Atlanta VAMC Movement Disorders Clinic are recruited to participate in research.

Iowa City, Iowa

Iowa City, VAMC (Phone: 319-338-0581 x 5173)

Director: Ergun Uc, MD

(cont'd pg 7)

2008 National VA PD Consortium Conference

Rebecca Martine, MSN, RN, PMHCNS, Consortium Chairperson

The foundation of the National VA PD Consortium is built on education, collaboration, and advocacy, making it critical that our leaders have the opportunity to meet face to face for the purpose of alliance and professional development. On September 4-5, 2008, the Consortium held its third national conference in Pittsburgh, Pennsylvania. PADRECC staff and Directors from 32 Consortium Centers gathered for didactic lectures, case presentations, a poster session, and in-depth discussions on the future direction of the program. Friends from the Parkinson non-profit community also attended, with representatives from the American Parkinson's Disease Foundation, We Move, the Parkinson Alliance, the Parkinson Action Network, and the International Essential Tremor Foundation. The VA Employee Education System served as co-sponsor, providing conference management and continuing medical education credits.

Dr. Robert Jesse, VA Chief Consultant of Patient Care Services, honored the Consortium attendees with a welcome. Dr. Jesse urged the progression of the Consortium mission and acknowledged the growing role of this

innovative model of healthcare. Dr. Timothy Greenamyre, Director of the Pittsburgh Institute on Neurodegenerative Diseases, served as keynote speaker and shared a fascinating tutorial on the theories of pathogenesis in Parkinson's disease.

A significant outcome of the conference was the suggestion and subsequent submission of a proposal requesting financial support for the Consortium Center Network. The Consortium has endured the past six years on the unwavering dedication and charitable efforts of its members. Though the Network has been highly effective, the program has reached a juncture where additional support is required to guarantee its expansion. The grant request continues to be under review in the Office of Patient Care Services. PADRECC and Consortium Center staff is confident that the Consortium Center Network will soon be regarded as a fund worthy program that is changing the dynamics of veteran healthcare.

For additional information on the 2008 National VA PD Consortium Conference, including presentation slides, please visit www.parkinsons.va.gov.

Movement Disorder Centers (cont'd from pg 6)

The Movement disorders Clinic, operational since 2002, provides subspecialty services including consults, DBS case selection and programming, and botulinum toxin injections. Dr. Uc is an active member of the Parkinson Study Group and Huntington Study Group, and is the co-chair of the Cognition/Behavior Working Group of the PSG. His main focus of research is cognition and non-motor aspects of PD, and he is the PI on studies on prediction of driver safety in PD (NINDS, R01), driving rehabilitation in PD (Merit Review-Rehab R&D), and effect of aerobic exercise on cognition and function in PD (Merit Review-Rehab R&D).

Helena, MT

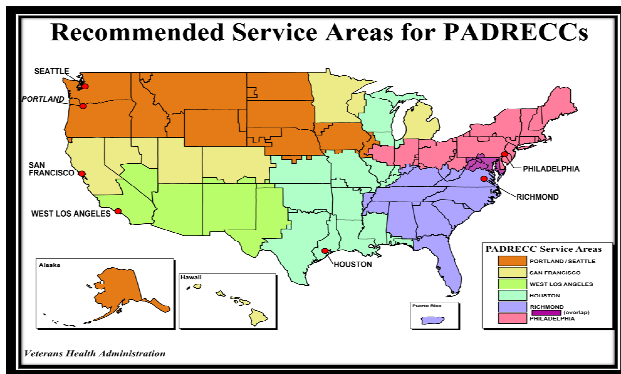
Fort Harrison VAMC (406-442-6410, extension 7708)

Director: Mark Dietz, M.D.

Fort Harrison VAMC has two neurologists who see movement disorder patients, Dr. Mark Dietz (since 2001), and Dr. Wynde Cheek (since 2008). Dr. Dietz, the Director, has been treating movement disorder patients for 23 years. Subspecialty consults are done for Parkinson's disease, pre-screening for deep brain stimulation, post surgery monitoring and programming for deep brain stimulation, evaluation of other movement disorders such as tremor, and providing botulinum toxin injections.

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Visit our Website
www.parkinsons.va.gov



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PADRECC Education Calendar

Philadelphia PADRECC

Sixth Annual PADRECC/MIRECC Symposium on Neurodegenerative Diseases: Early Detection and Management of Neuropsychiatric Disorders

10/2/2009

Patient Motivation Program: Todd Bischoff, MS, CCLS

11/6/2009

Southwest PADRECC (W. Los Angeles)

Speech, Voice, and Swallowing Issues in Persons with PD: Nancy Sedat, MS, CCC-SLP

9/22/2009

Community Resources for Veterans with PD: Linda O'Connor, LCSW, APDA Information and Referral Center

11/2009

Southeast PADRECC (Richmond)

US Military Veterans with Parkinson's Disease

PADRECC Support Group

10/29/2009

Annual PD Community Education DAY

SE PADRECC, American Parkinson Disease Association (APDA)

Richmond Metro Chapter, & APDA I&R Center of VA

11/7/2009

Northwest PADRECC (Portland/Seattle)

Essential Tremor

Dr. Amie Peterson, Movement Disorder Fellow

10/16/2009

Restless Leg Syndrome

Dr. Lissa Brod, Movement Disorder Fellow

1/15/2010

Houston PADRECC

DBS: Is It For You Or Your Loved One?

Patient and Family Conference

11/14/2009

PADRECC Support Group

Looking Ahead: Establishing Exercise Goals for 2010

1/5/2010

San Francisco PADRECC

3rd Annual Parkinson's Disease Teleconference

Topics: Agent Orange Exposure & PD; Neuroprotection Interventions; Alternate Therapies in PD; Gene Therapy in PD; Interventional MRI and DBS; SF VAMC—Results of COOP study

11/13/2009 (begins)