



The VA Parkinson Report

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and The National VA Parkinson's Disease Consortium



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Stem Cell Therapies for Parkinson's Disease

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Stem cell therapies are one of the true revolutions in medicine over the last few decades. The potential that they hold for treating and preventing illness is enormous. However, as with most new therapies, it is a long, complicated process to complete the testing required to prove efficacy, and that the side effects justify the benefits. In Parkinson's disease, we have been attempting to replace nigrostriatal dopaminergic neurons ever since the early 1980s, and there have been several open and double blind trials since then. These trials proved that we have come a long way in our quest to recapitulate dopaminergic innervation of the striatum with surviving neurons that produced dopamine and integrated with host neurons. Unfortunately, regulation of these cells was not possible and there were some patients who developed significant side effects with graft-induced dyskinesias being the most problematic.

While researchers have continued studying stem cell therapies in animal models and have begun to understand why some patients developed the dyskinesias, some commercial entities decided not to wait for these scientific advances that would make the next round of well designed, double blind trials more likely to succeed. Some of these commercially available treatments are lacking in rigorous scientific validation and offer dubious claims of benefit that medical professionals should be aware of so as to adequately counsel patients. To be clear, there are no currently available FDA-approved stem cell therapies for Parkinson's disease. The testing required by the FDA to assure that a new therapy is safe and effective, while expensive and time-consuming, do protect consumers from wasting their money on ineffective treatments or worse, being harmed by unsafe treatments. However, in their haste to bring these therapies to a market that is desperate to realize the promise that these therapies hold, some companies have exploited loopholes in FDA regulations, and are already offering these therapies to patients with Parkinson's disease, outside of clinical trials.

The newest clinical trial to use stem cells to treat Parkinson's disease is a Phase I/IIa trial from the International Stem Cell Corporation using pluripotent stem cells in moderate to severe PD. While this was an exciting advancement in the field, some thought leaders have raised concerns about our readiness for proceeding to such a trial (Barker et al. J of Parkinson's disease (2016);6:57-63). Concerns raised by these authors included whether the type of pathenogenetic cells used in the study would really give rise to dopaminergic midbrain neurons; lack of publicly available preclinical data for safety; and inadequate trial design to detect clinical benefit, among others.

Stem Cell Therapies for Parkinson's Disease (continued)

Regarding the companies currently offering commercial stem cell therapies for Parkinson's disease, there are also several concerns that physicians should be aware of in order to adequately counsel their patients. In the past few decades hundreds of US and international clinics have begun offering stem cell therapies. These companies are offering primarily autologous stem cell therapies where in a patient's own cells are removed, the stem cell purified and then given back to the patient. These types of treatments are being advertised to treat numerous neurological conditions including Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease, multiple sclerosis, cerebral palsy, autism, spinal cord injury and stroke.

While the discussion with patients regarding whether to try these therapies would be similar regardless of what condition they are seeking treatment for, I have outlined a few questions that should be raised for any patient seeking treatment for Parkinson's disease.

Question 1: Are they safe and effective?

Answer: While there are many excellent researchers developing these therapies and numerous scientifically rigorous trials have been concluded, there are no stem cell therapies for Parkinson's disease that have been shown to be safe and effective enough to receive FDA approval.

Question 2: Do I have anything to lose, other than my money, if I try these therapies?

Answer: Yes, because these therapies are poorly regulated and tested, it is difficult to determine exactly what the short and long term consequences will be after getting these treatments. Some patients who have gotten stem cell treatments have developed tumors from the uncontrolled growth of the stem cells. Even cells taken from your own body and returned to you, are not automatically safe. In addition, having these therapies might make a patient with Parkinson's disease ineligible for enrollment in other clinical trials of stem cells or other novel therapies.

Question 3: But what about all the patients who have had great results?

Answer: Many of the companies offering stem cell therapy offer convincing patient testimonials about how well the treatment has improved their health or even cured their disease. Unfortunately, in Parkinson's disease, because of poorly understood mechanisms in the brain, placebo effects are particularly strong. There are too-numerous-to-count treatments that have been shown to be effective in open-label, unblinded trials (when both the patient and doctor know what the patient is getting and expect it to work), that have failed when tried in double-blinded placebo-controlled trials (when a placebo treatment is compared to the real treatment, and neither the patient and physician know which therapy is given). Typically, these placebo effects will disappear after a few months and there are no published studies demonstrating long-term benefit from stem cell therapies.

Question 4: Who pays for this therapy?

Answer: These therapies can be exceedingly expensive (\$5,000-\$50,000) and they are almost never covered by insurance. Therefore, the costs of these therapies, almost always are paid out of pocket by patients.

There are indeed many other factors to consider, and becoming an educated consumer is the best preparation when deciding whether or not to accept any medical therapy.

Fortunately, there is a highly reputable source to help educate clinicians and patients. This is the public education website from the International Society for Stem Cell Research at the address: www.closerlookatstemcells.org/

It is certainly hoped that one day stem cell therapies will become a viable component of our management of Parkinson's disease as a safe and effective option. Until that day comes, clinicians and patients must be aware of the concerns and risks involved in non-FDA approved therapies.

Targeting α -synuclein in Parkinson's disease: towards neuroprotective gene therapy?

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Mitochondria are cellular organelles that generate ATP (an essential energy source for a host of biochemical reactions) by mediating a series of chemical reactions between oxygen and substrates derived from sugars and fats. This process is called cellular respiration. It has been known for many years that mitochondrial respiratory function is decreased in PD patients' brains (Schapira et al., 1989). Surprisingly, mitochondrial respiratory function is also abnormal in PD patients' peripheral tissues, such as platelets and muscle, suggesting that there is a systemic deficit in mitochondrial function in PD (Krieger et al., 1992). Studies in animal models suggest this systemic mitochondrial defect might be an important mechanism underlying the neuropathology of PD. Rotenone is a naturally occurring insecticide, which works by inhibiting the same component of the mitochondrial respiratory machinery ('complex I') that is defective in PD patients. Rats exposed to rotenone show inhibition of mitochondrial function throughout their bodies. However, although mitochondrial impairment is systemic, there is selective loss of dopaminergic nerve cells in the substantia nigra of the brain (Betarbet et al., 2000). This model is remarkable for several reasons: it reproduces many features of PD, including selective loss of dopamine-producing nerve cells, movement abnormalities and Lewy body pathology (see below). Furthermore the development of specific neuro pathology in the presence of systemically decreased mitochondrial function suggests that dopamine-producing neurons are especially vulnerable to impaired mitochondrial function. Subsequent studies showed that repeated occupational exposure to rotenone substantially elevates the risk of developing PD (Tanner et al., 2011).

Shortly after defects in mitochondrial function were discovered in PD patients, a separate line of enquiry led researchers to look at rare cases of familial parkinsonism. The clinical and pathological features look very similar to PD, but – unlike the vast majority of PD cases – these cases are caused by single gene mutations. This is important, because in these hereditary phenocopies the cause of the disease can be established unequivocally by identification of the genetic mutation. One of these genes, SNCA, encodes a protein called α -synuclein. In some patients the mutated gene gave rise to an abnormal form of α -synuclein (Polymeropoulos et al., 1997), in other patients the protein was normal but it was made in 2-fold excess (Singleton et al., 2003). Although SNCA gene mutations are very uncommon, it was soon realized that the pathological hallmarks of PD, round eosinophilic inclusion bodies called Lewy bodies, contain large aggregates of abnormal, insoluble α -synuclein (Spillantini et al., 1997). This is true even in the common sporadic form of PD, in the absence of any SNCA gene mutation. These observations

suggest that abnormal accumulation of α -synuclein is a central mechanism in the pathogenesis of PD. Subsequent studies showed that common genetic variants around the SNCA gene (that may modestly change the amount of α -synuclein made in brain cells) alter the risk of developing PD, but are not alone sufficient to cause PD (Simon-Sanchez et al., 2009).

It was unclear how these two separate stories related to one another. It was known that mitochondrial inhibitors could increase the amount of α -synuclein in cells, and even cause formation of Lewy body-like inclusions (Betarbet et al., 2000). It was also known that increased levels of α -synuclein could compromise mitochondrial function (Hsu et al., 2000). These observations suggest that there may be a bidirectional interaction between α -synuclein and mitochondria in PD.

To test the role of α -synuclein in the PD-like pathology that occurs when rats are exposed to rotenone, we developed a genetically-engineered virus that turns down synthesis of α -synuclein (Zharikov et al., 2015). The virus (derived from a harmless virus called AAV that has been used previously in human clinical trials) was injected into the rat brain and caused approximately 30 – 40% reduction in α -synuclein levels in substantia nigra cells. This did not cause any adverse effects, such as cellular damage, motor or behavioral changes. However, substantia nigra dopamine nerve cells with decreased α -synuclein levels were strikingly resistant to the effects of rotenone (Zharikov et al., 2015). In one experiment, we knocked down α -synuclein on one side of the brain, and used an almost-identical virus that does not alter α -synuclein levels as a control on the other side of the brain (see figure). When these rats were exposed to rotenone, motor function was preserved only on the side of the body controlled by neurons that had received the α -synuclein knock-down virus, whereas the other side developed severe Parkinsonism-like motor abnormalities. The pathology in these animals' brains was also asymmetric: following rotenone exposure, the number of substantia nigra dopaminergic neurons, their dendritic processes and their axonal terminals in the striatum (the part of the brain to which substantia nigra neurons project) were all preserved on the α -synuclein knockdown side of the brain, but not on the control side. Together, these data show that endogenous α -synuclein expression is necessary for substantia nigra dopamine neurons to be selectively damaged by systemic mitochondrial impairment. These findings link the two most prominent biochemical abnormalities identified in PD and suggest that α -synuclein could be a valid target for therapies aiming to prevent the progression of PD.

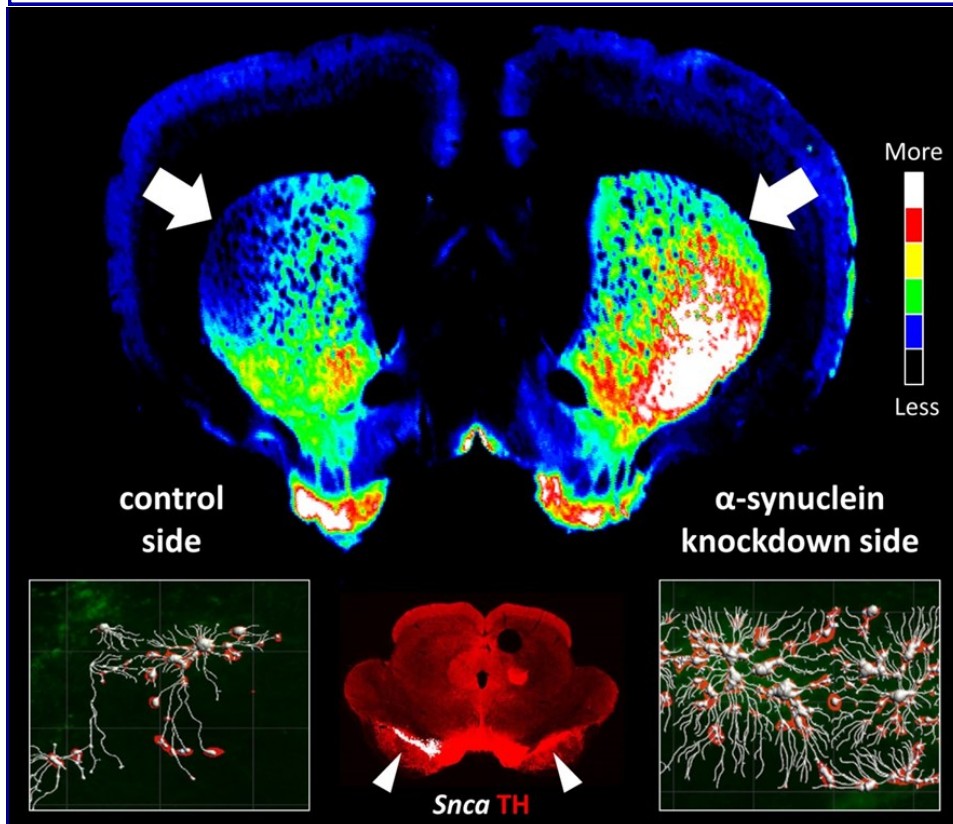
Targeting α -synuclein in Parkinson's disease: towards neuroprotective gene therapy? (continued)

We are currently engaged in several follow up studies. First, an obvious question is whether α -synuclein knockdown gene therapy could be useful in PD patients. Before this can be contemplated, it will be essential to determine whether long-term knockdown of α -synuclein is safe and whether targeting α -synuclein will be effective after disease pathogenesis starts; these experiments are ongoing. Second, if we understood how α -synuclein and mitochondria interact, it might be possible to design drugs that interfere with the relevant mechanism, so that gene therapy would be unnecessary. This is a more challenging

task that will involve understanding whether α -synuclein interacts directly with mitochondria or alters some aspect of cellular susceptibility to impaired mitochondrial function, in addition to delineating whether specific forms of α -synuclein are toxic to dopaminergic neurons.

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α -Synuclein knockdown is neuroprotective in the rat rotenone model of PD

The figure summarizes the findings from our recent study (Zharikov et al., 2015).

The images are arranged so that the side of the brain that received the α -synuclein knockdown virus is shown on the right side of the figure and the side that received control virus is shown on the left.

The lower central panel shows a midbrain section from a rat that did not receive rotenone. *Snca* mRNA (white) is knocked down on the side that received the targeting vector, but not on the control side. Dopaminergic neurons (red) are present in the substantia nigra (white arrowheads) on both sides. Following rotenone exposure, dopaminergic neurons and their striatal terminals were preserved on the side that received the α -synuclein knockdown virus.

The upper panel shows the forebrain labeled using a color scale to show the density of dopaminergic nerve terminals. The striatum is indicated with large white arrows.

The inset boxes in the lower part of the figure show magnified images of substantia nigra dopaminergic neurons and their dendrites on each side of the brain.

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Identification and Management of Communication & Swallowing Disorders in Parkinson's Disease (PD): The Role of the Speech-Language Pathologist

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Communication is a basic human need, and is vital to our ability to express our wants and needs, gain and maintain employment, engage socially, and maintain relationships. In other words, functional communication significantly contributes to our sense of quality of life. In fact, aspiration pneumonia as a consequence of dysphagia is the leading cause of death in the PD population (14). Evidence of swallowing abnormalities can be seen through videofluoroscopic studies in over 50% of patients with PD, this number increasing over the progression of the disease course (15).

PD is a progressive neurodegenerative disorder that leads to a wide range of deficits, and affects approximately 1-2% of the world's population (1). Researchers estimate that 89% of individuals with PD have speech and voice disorders of laryngeal, respiratory, and articulatory function, though only 3-4% of these individuals receive intervention for these impairments (3). Changes in communication can be subtle, and symptoms of speech and voice disorders can be missed or attributed to other processes such as aging, especially in the earlier stages of the diagnosis (2). When these subtle early signs are missed, the opportunity for early intervention is lost, consequently making management/improvement of speech and voice impairments more challenging as the disease progresses. Alternatively, when effective behavioral speech-language therapy is prescribed early, upon diagnosis, evidence suggests it may help slow or halt symptom progression (8).

The speech disorders in PD are collectively known as hypokinetic dysarthria, which is characterized by a gradual deterioration in speech intelligibility (speech clarity) along with decreased voice loudness, prosodic variation/monotone voice, breathy and hoarse vocal quality, short rushes of speech that can lead to reduced speech fluency, lessened facial expression, and reduced breath support for voicing (4). Dysarthria can be one of the main components of the disease that leads to feelings of social isolation in PD (5), and researchers believe there is a link between the decline of speech intelligibility and cognitive functioning(6).

Hypokinetic dysarthria in PD can result from reduced feedback and motor output from the basal ganglia, an important center for the control and regulation of speech movements, resulting in inadequate muscle activation (9). Additionally, reduced/altered internal cueing and sensory processing are common in PD, as is reduced amplitude of output (hypokinesia), which can collectively lead to communication impairment (10). It is easy to see how this ability can be taken for granted, however, for the individual diagnosed with PD, a gradual change in speech clarity, voice, cognition and facial expressiveness can occur, making communication more challenging. Progression of the disease can also lead to problems with swallowing (also known as dys-

phagia), and a decline in nutrition/hydration status, airway protection, and saliva management

While neurosurgical interventions (such as Deep Brain Stimulation) and pharmacological treatments for PD such as dopaminergic therapy have shown beneficial effects on the motor manifestations of PD, its effect on speech and voice impairments remains inconclusive with mixed and contradictory findings (7). However, a combination of medical therapy (optimal medication) with behavioral speech therapy provided by a qualified Speech-Language Pathologist (SLP) appears to offer the greatest improvement for speech dysfunction (3). According to the American Speech-Language Hearing Association (ASHA) 2016 Scope of Practice Guidelines, a SLP is defined as the "professional who engages in professional practice in the areas of communication and swallowing across the life span. Communication includes speech production and fluency, language, cognition, voice, resonance, and hearing" (11).

There are several therapeutic methods and techniques used by SLPs in the clinical setting with patients with PD, including the widely utilized Lee Silverman Voice Treatment (LSVT-LOUD), augmentative/alternative communication (AAC), traditional motor speech therapy, voice amplification, or a combination of these approaches. LSVT-LOUD is often a preferred treatment with level I efficacy which has been found to be highly effective for improving dysarthria in PD, and more effective than traditional motor speech therapy in this population (12). An SLP must have specialized training and certification in LSVT-LOUD in order to provide this treatment. The program is organized around a simple therapeutic principle: increasing vocal loudness to retrain the sensory motor processes involved in disordered speech communication (13). It is an intensive, repetitive, and cognitively non-demanding one-month behavioral speech treatment based on the principles of motor learning, and can result in improvements in facial expressiveness, voice intensity, voice quality, speech intelligibility, prosody, and respiratory-phonatory coordination (10). Interestingly, LSVT's system-wide spread of effects has been known to help alleviate dysphagia in PD, as the program may help activate better neuromuscular control over the aerodigestive tract, improving both oral and pharyngeal stages of swallowing which can lessen aspiration risk (12).

Swallowing disorders in PD typically result from the same mechanisms that impair speech and voice, including rigidity, tremor and hypokinesia (16), and can lead to devastating health consequences. Despite the high incidence of dysphagia in PD, many patients only report swallowing problems to their physicians after function is already significantly impaired due to decreased awareness and under recognition of the presence of symptoms (17). In a 2015 study conducted by Akbar et al (18),

Identification and Management of Communication & Swallowing Disorders in Parkinson's Disease (PD): The Role of the Speech-Language Pathologist (continued)

it was found that mortality from aspiration pneumonia may be decreased with early detection, diagnosis and timely treatment. The SLP will play a vital role in helping to minimize and remediate negative effects from dysphagia by providing early and regular subjective and objective swallow studies and targeted swallow therapy along with patient education and family counseling on safe swallow precautions.

This information further highlights the importance of early intervention and timely referrals to Speech-Language Pathology, solid-

ifying the notion that ongoing and earlier management of speech, voice, and swallow disorders in PD can help prevent complications of the disease and can improve quality of life and survival. Furthermore, caregivers and medical providers must be diligent in the recognition and identification of these impairments, especially given the fact that individuals with PD often have reduced awareness, internal cueing, sensory processing, and cognitive functioning leading to a delay or absence in patient reporting.

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Yoga in Parkinson Disease

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Yoga is very popular and is cited as a favorite non-medical therapy by many people living with Parkinson disease. People are often fearful of getting started in a yoga class since there is false portrayal of yoga in the media as being only for flexible, skinny ballet dancers. Yoga, on the contrary, is a very adaptable practice, with both functional and psychosocial benefits, that can be suited to a wide variety of abilities.

Yoga has become synonymous with holding and moving between a series of static postures (called asanas); however, this physical practice (called hatha yoga) is only one part of the larger lifestyle of yoga framework that includes branches such as philosophy, chanting and selfless service. Hatha yoga combines physical postures to address strength, flexibility, balance and mind-body-breath connection. Breathing practices (pranayama) and meditation are included to develop greater self-awareness and can have tremendous benefit on the mental state.

What do we know about yoga in Parkinson disease?

In looking through the scientific literature, there are a few studies that support hatha yoga for people with PD. This is an area of research that is just starting to build evidence. What studies do exist suggest modest benefits for:

1. **Mobility:** The issue of mobility has important implications for fall prevention in PD. Yoga participation can improve functional mobility and influences how a person with PD walks. Standing yoga poses target the hip extensor, knee extensor and ankle plantar flexor, which support center-of-gravity during walking and may improve overall stability.
2. **Balance:** Balance training is an important component of PD therapy, as 40 percent of nursing home admissions are preceded by a fall. Research shows yoga-related improvements in balance (tandem, one-leg) and an associated decrease in a person's fear of falling; this can also help keep people with PD active in their community.
3. **Strength:** Gains in lower-body strength occur for PD patients following yoga practice and are associated with improved postural stability. Yoga requires isometric contraction (i.e., the joint angle and muscle length do not change) of specific muscle groups to stabilize the body as one performs the postures, and may mimic isokinetic contractions (i.e., variable resistance to a movement performed at constant speed) when performing controlled systematic movements from one pose to the next. These mechanisms may be the reason why yoga improves muscular strength.
4. **Flexibility:** Improvements in flexibility and range of motion (ROM) are important since rigidity is a common clinical manifestation in PD. Research shows improvements in flexibility/ROM of the shoulder, hip and spine. Stooped posture is common in PD and can be related to short spinal flexors and weak spinal extensors; improved shoulder and spinal flexibility from yoga supports a more upright posture. Greater hip mobility from yoga may translate into improvements in shuffling gait which can be commonly seen in PD.

5. **Mood & Sleep:** The psychosocial benefits associated with yoga are important for disease management, as they are not often addressed with classic medications used to replace dopamine in PD. Many classic medications used to treat anxiety are not safe in PD patients. The calming effect of yoga (by enhancing parasympathetic output) may lessen perceived stress, enhance relaxation, and benefit sleep in PD. Many patients with PD have apathy and fatigue which anecdotally are helped with yoga. Since the mind and the body are very connected in PD, any mental state benefits are tangibly translated into motor benefits. A yoga class can offer a support group, improved confidence and self-efficacy. Caregivers can also participate and reap the rewards in the psychological realm as well.

Not everyone is lucky enough to live near a yoga instructor who has a deep understanding of PD – this makes it important to educate yourself, both about your specific PD-needs and how yoga postures can help, so you can feel comfortable and confident with utilizing the yoga resources that are available in your own community.

Yoga can benefit people with Parkinson's both physically and cognitively!

Yoga is both physically and cognitively engaging by focusing on body-awareness during complex body positions. Yoga postures improve physical strength, flexibility, and balance. Yoga postures are also considered *skill-acquisition* exercises and can benefit our brains thinking patterns and processes to make our movements more efficient and effective.

Yoga helps to increase muscle mass that is useable in everyday life by focusing on *functional movements*. For example, one-leg balance poses (i.e. *tree pose*) are helpful for climbing stairs; *chair pose* builds core and leg strength to help you get up out of bed and/or out of a seated position.

Yoga is actually a form of cueing/attentional training.

The ability to move in Parkinson disease is not lost; rather the brain mechanisms that initiate movement are defective. Attentional training/cueing may provide a non-automatic drive for movement, which may compensate for this faulty brain circuitry and improve performance. Yoga breaks up complex sequences and/or postures into component parts, enabling a person to focus their attention on individual aspects of the posture and improve performance. Specific external cues given during a yoga class can also benefit performance in persons with Parkinson disease.

- Utilize visual cues (i.e., watch the yoga instructor or use a mirror) to help you coordinate your movement.
- Utilize props (i.e., blocks, straps, chairs) to get *the experience of the full movement safely*, and then take supports away as you progress.
- Talk to your yoga instructor about giving you hands-on adjustments while performing the poses. Subtle adjustments

Yoga in Parkinson Disease (continued)

can help you with proper alignment and ensure you are not putting your body in a position that could be painful or result in injury.

- Focus on one aspect of the pose at a time to maintain your attention on your body in the present moment.

Know that yoga can both improve and aggravate your Parkinson's symptoms!

To avoid aggravating your symptoms, let your yoga instructor know that long holds may increase stiffness or muscle cramping. Instead of holding postures in stillness, try to move into the posture on an inhale breath, and relax out of the posture on an exhale breath

Yoga postures can be beneficial and improve rigidity, stiffness and slowness, especially in the chest muscles and spine. Focusing on yoga poses that safely extend the spine and/or deep diaphragmatic breathing exercises can create space in the chest and improve posture.

Many of the floor poses in yoga allow you to practice getting up safely off the floor. This practice can increase confidence, reduce the fear of falling and increase the likelihood that you can get back up on your own if you do fall. Practice in the company of a caregiver first at least twice per day. You can use two stable supports one on either side at first if needed.

Use yoga as an opportunity to focus on posture

Stooped posture in Parkinson disease is common. It is attributed to shortened contracted spine flexors and weak extensors of the spine. Asymmetry of stiffness can lead to misalignment and can

lead to misuse and disuse of muscles that can further worsen posture.

What can yoga do?

- Strengthens your core, especially your transverse abdominal muscles
- Lengthens your psoas muscle... a thick muscle that runs from under your armpits to your hips and connects your legs to your torso.
- Encourages gentle backbends to open upper spine
- Creates self-awareness, and good habits, around how you hold your body in standing posture.

Kaitlyn P. Roland completed her PhD research at the University of British Columbia (2012), which measured Parkinson's disease (PD)-related changes to daily muscle activity and consequences for physical function and frailty. She is currently a postdoctoral fellow at the University of Victoria's Centre on Aging and her most recent work examines care needs and well-being in PD dementia caregivers. Kaitlyn offers yoga workshops to persons with PD called "Yogadopa" and is on the board for the ParkinGo Wellness Society in Victoria BC (<http://parkingo.org>). She blogs about Parkinson's, aging and yoga-related information at <http://yogadopa.com>. Overall, she aims to support independent living, and reduce distress and healthcare utilization in persons with PD, dementia and their caregivers.

Parkinson's Disease News

Compiled by Suzanne Moore, MS, Health Science Specialist

Houston PADRECC, Michael E. DeBakey VAMC

Veterans and Agent Orange: Update 2014

On Thursday, March 10, 2016, the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine), released the report **Veterans and Agent Orange: Update 2014**. For the report, the committee reviewed any new peer-reviewed scientific publications from October 1, 2012, and September 30, 2014, comparing them with past information to come up with recommendations for the Department of Veterans Affairs. With regard to Parkinson's Disease, the committee recommended that those Vietnam Veterans without a formal diagnosis of Parkinson's disease, but who have "Parkinson-like symptoms" should be included as eligible for the presumption of service connection. The VA will take an opportunity to review the new report and will publish a response in a future issue of the Federal Register.

National Academies of Sciences, Engineering, and Medicine. 2016. *Veterans and Agent Orange: Update 2014*. Washington, DC: The National Academies Press.

<http://nationalacademies.org/hmd/reports/2016/veterans-and-agent-orange-update-2014.aspx>

Parkinson's Disease News (continued)

Gulf War and Health: Volume 10: Update of Health Effects of Serving in the Gulf War, 2016

This report is the tenth in a series and for this final report, the committee was asked to pay special attention to neurological disorders, such as Parkinson's disease. After weighing the evidence, the committee concluded that there was not adequate information to say whether or not an association exists between increased mortality from any neurologic disease (including multiple sclerosis, Alzheimer's disease, Parkinson's disease, and ALS). The committee recommended that the VA continue to conduct follow-up assessments in Gulf War Veterans for those diseases like Parkinson's disease that have a long latency. A previous report, Volume 7, had found that there was sufficient evidence to conclude there is a positive association between moderate or severe traumatic brain injury (TBI) and parkinsonism. The same report found evidence to suggest there is an association between mild TBI with loss of consciousness and parkinsonism, but the evidence was "limited because chance, bias and confounding could not be ruled out with reasonable confidence".

National Academies of Sciences, Engineering, and Medicine. 2016. *Gulf War and health: Volume 10: Update of serving in the Gulf War, 2016*. Washington, DC: The National Academies Press

<http://nationalacademies.org/hmd/reports/2016/gulf-war-and-health-volume-10.aspx>

Institute of Medicine. *Gulf War and Health: Volume 7: Long-Term Consequences of Traumatic Brain Injury*. Washington, DC: The National Academies Press, 2009. doi:10.17226/12436.

<http://www.nap.edu/catalog/12436/gulf-war-and-health-volume-7-long-term-consequences-of>

Considerations for Designing an Epidemiologic Study for Multiple Sclerosis and other Neurologic Disorders in Pre and Post 9/11 Gulf War Veterans

This report, released December 11, 2015, was commissioned by the VA in response to a law enacted in 2008 (PL 110-389) to determine the incidence and prevalence of neurologic diseases (for example, multiple sclerosis, Parkinson's disease, migraine) in those with service in 1990-1991 Persian Gulf and post 9/11 Global Operations. For several reasons, including that the post 9/11 service personnel cannot be compared for deployed vs non-deployed because they are almost all deployed, and that VA data would only be a subset of the population of service personnel with that military service, the committee decided not to proceed with the study. If additional data become available, a future study could be conducted. There is legislation pending in Congress that would create a national registry for MS and PD housed at the Centers for Disease Control and Prevention, CDC.* If created, the registry would be used to for research in these conditions and to find out more about the incidence and prevalence.

National Academies of Sciences, Engineering, and Medicine. *Considerations for Designing an Epidemiologic Study for Multiple Sclerosis and Other Neurologic Disorders in Pre and Post 9/11 Gulf War Veterans*. Washington, DC: The National Academies Press, 2015.

doi:10.17226/21870.

<http://nationalacademies.org/hmd/reports/2015/considerations-for-designing-epidemiologic-study-for-multiple-sclerosis-and-other-neurological-disorders-veterans.aspx>

*HR.6 House Report 114-190 - Part 1 - 21ST CENTURY CURES ACT

SEC. 399V-6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

S.849: Advancing Research for Neurological Diseases Act of 2016

Review of VA clinical guidance for the health conditions identified by the Camp Lejeune legislation

For this review, the VA asked the committee for clinical guidance for the 15 conditions listed in Public Law 112-154. For Parkinson's disease the committee made the following recommendation: "Despite the limitations of these studies, such as lack of statistical significance, the potential for recall bias, and the lack of incidence data pertaining to Parkinson's disease, the committee recommends including Parkinson's disease as an outcome associated with exposure to TCE and PCE."

IOM (Institute of Medicine). 2015. *Review of VA clinical guidance for the health conditions identified by the Camp Lejeune legislation*. Washington, DC: The National Academies Press.

<http://nationalacademies.org/hmd/reports/2015/va-clinical-guidance.aspx>

Parkinson's Disease News (continued)

VA Plans to Propose Expanded Disability Benefits Eligibility for Veterans Exposed to Contaminated Water at Camp Lejeune

Based on the findings from the clinical guidance, in a December 17, 2015, press release, the VA proposed adding several conditions to those with a presumption of service connection. Parkinson's disease is one of those conditions that will be included once the ruling is final. Links to additional information are below:

<http://www.va.gov/opa/pressrel/includes/viewPDF.cfm?id=2743>

<http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2743>

http://benefits.va.gov/compensation/claims-postservice-exposures-camp_lejeune_water.asp

<http://www.publichealth.va.gov/PUBLICHEALTH/exposures/camp-lejeune/index.asp>

Post-Vietnam Dioxin Exposure in Agent Orange–Contaminated C-123 Aircraft

Based on a report released January 9, 2015 by Health and Medicine Division (HMD) (formally known as the Institute of Medicine) of the National Academy of Sciences, Engineering, and Medicine, the VA decided that individuals in the Air Force or Air Force Reserve who had regular contact with aircraft that had been used to spray herbicide in Vietnam may qualify for benefits for Agent Orange exposure. Included are those who regularly operated, maintained or served aboard C-123 aircraft including those who trained and worked on the aircraft after its return to the United States from use in Vietnam. More information is available at:

<http://www.publichealth.va.gov/exposures/agentorange/locations/residue-c123-aircraft/index.asp>

IOM (Institute of Medicine). 2015. *Post-Vietnam dioxin exposure in Agent Orange-contaminated C-123 aircraft*.

Washington, DC: The National Academies Press.

<http://www.nationalacademies.org/hmd/Reports/2015/Post-Vietnam-Dioxin-Exposure-in-Agent-Orange-Contaminated-C-123-Aircraft.aspx>

PADRECC Consortium Member Update

Updates from the James J. Peters VAMC (Bronx)

Telemedicine

The Movement Disorders telemedicine clinic based at the James J. Peters VAMC in the Bronx continues to expand. Dr. Walker sees 10 patients/month in this clinic, from 10 sites - 4 CBOCs from Long Island, 3 from the Hudson Valley, one from Staten Island, and from the Brooklyn and Manhattan VAs. The clinic is booked up for the next 2 months. The vast majority of patients carry a diagnosis of Parkinson's disease or Essential tremor. Additional diagnoses include myoclonus and multiple system atrophy. Most patients have been seen initially in person by Dr. Walker, but if travel to the Bronx or Castle Point sites is not possible, she will consider evaluating the patient only via telemedicine.

DaTscan

Our nuclear medicine facility is now up and running, and is able to perform DaT scans, so we no longer have to refer patients out of the VA for this study

Deep brain stimulation

A number of patients with PD or essential tremor are referred for DBS under the Choice program from both the Bronx and Castle Point sites.

Hudson Valley

Dr. Walker continues to see patients at the Castle Point site 1.5 days/week. She sees many patients with PD, some of whom have decided that they no longer need to see their community physician. Two patients from Castle Point have undergone DBS, with excellent results. Dr. Walker also manages many patients with essential tremor, PSP, MSA, dystonia, myoclonus, Huntington's disease, and other movement disorders, who otherwise would have to travel 60 miles to the Bronx to be seen.

Philadelphia PADRECC Update

Clinical News

Dopamine transporter SPECT use patterns at the Philadelphia PADRECC

Dopamine transporter SPECT (DAT-SPECT) using 123I-Ioflupane was approved by the US FDA in 2011 for the evaluation of Parkinsonian syndromes via visualization of striatal presynaptic dopamine terminals. The studies used to support the initial approval evaluated the ability of DAT-SPECT to distinguish patients with Essential tremor and Parkinson's disease, but this technique may be useful in a variety of clinical settings. DAT-SPECT has been available at the Crescenz VAMC since October 2012. From that time until April 2016, PADRECC clinicians have ordered 50 DAT-SPECT studies for clinical purposes (just over 1 per month). While scans ordered to differentiate PD from ET accounted for 34% of studies (47% of these were abnormal), the most common indication (44%) was for the evaluation of suspected drug-induced Parkinsonism (DIP, 23% abnormal). Other indications were for the evaluation of suspected psychogenic Parkinsonism (10% of scans, 40% abnormal), dementia (8% of scans, 50% abnormal) or other secondary etiologies, such as, vascular pseudoparkinsonism (4%, 0% abnormal). The observation that nearly 1 in 4 patients with presumed drug-induced parkinsonism may have underlying neurodegeneration has led to several VA-funded research projects on the relationship of DIP to PD at the Philadelphia PADRECC (see below in Research News).

Brain Wellness Clinic

This new and innovative clinic was developed by Dr. John Duda and Heidi Watson, BSN, RN and provides patients the opportunity to focus in-depth on brain wellness. Current brain wellness risks are assessed and explored by looking at different lifestyle factors including sleep, nutrition, exercise, mindfulness/spiritual, cognitive and social interaction. During the visit, a thorough interview, several short written or web-based assessment of patients health status, and lab work (if appropriate) are completed. Clinicians discuss wellness goals important to the patient and together develop an individualized plan with realistic and achievable goals, and provide support to implement them. Patients' progress is followed either in person or through telehealth.

Research News

Telehealth and Parkinson's Disease

Dr. Jayne Wilkinson is publishing a PADRECC study in an upcoming issue of *Neurology: Clinical Practice* evaluating the use of telehealth in Parkinson's disease. Telehealth allows a patient to be seen by a provider using a video connection either to their home, or to a closer VAMC facility. Dr. Wilkinson found that telehealth visits were associated with a high level of overall patient satisfaction and improved satisfaction regarding convenience and accessibility, when compared with in-person visits. The study also demonstrated that telehealth resulted in financial savings related to travel and potentially impacts patient utilization of the healthcare system. Clinical outcomes for telehealth were similar to in-person visits, demonstrating that telehealth is a viable way to deliver effective care. Dr. Wilkinson continues to oversee the active clinical telehealth program at the Philadelphia PADRECC and future studies may focus directly on potential benefits to resource utilization and outcomes using telehealth in PD.

Drug-induced Parkinsonism (DIP): A canary in the coal mine?

DIP associated with dopamine receptor blocking drugs (most often antipsychotics) is the second most common cause of Parkinsonism and can be clinically indistinguishable from PD. In some cases, when symptoms persist after drug withdrawal, DIP may represent "unmasking" of prodromal PD-with the offending drugs acting as a "stress test" for dopaminergic pathways.

We previously reported that olfactory impairment (a non-motor feature that often precedes motor symptoms of PD) was more common in patients with persistent DIP (Morley *et al. Park Rel Dis*, 2015). Dr. Morley received a 2014 VISN 4 Pilot Award to study the relationship of DIP to PD using DAT-SPECT, olfactory testing and other biomarkers of PD. We have reviewed DAT-SPECT studies for 33 subjects performed clinically for suspected DIP or, more recently, under Dr. Morley's research protocol. DAT-SPECT was abnormal in 7/33 (21%) of suspected DIP cases. Olfactory testing was available for 30 subjects and was concordant with the DAT-SPECT result in 27/30 (Odds Ratio=63, 95% CI 4.8-820). Subjects with abnormal scans also had higher scores on the validated PD Non-Motor Symptom Questionnaire. This study is ongoing but already suggests that many patients with suspected DIP have abnormal DAT-SPECT suggestive of PD and that abnormal olfaction is predictive of underlying dopaminergic deficit.

Identifying early or prodromal PD that has been "unmasked" by DIP offers opportunities for intervention at the earliest stages of disease. Dr. Morley has recently been funded for a VA Rehabilitation R&D service Career Development Award entitled "**Effect of exercise on recovery in drug-induced Parkinsonism and Parkinson disease.**" Subjects with suspected DIP who also have abnormal DAT-SPECT will be randomized to exercise (aerobic walking) or no intervention. We will examine short term effects of exercise using the UP-

Philadelphia PADRECC Update (continued)

DRS and quantitative gait testing after 8 weeks. We will also examine a potential disease modifying effect of exercise using serial DAT-SPECT and biochemical markers after 52 weeks. These results of these studies may immediately influence identification of subjects with prodromal PD, clinical management of DIP and strategies for disease-modification in PD using exercise.

Traumatic Brain Injury

Dr. John Duda, PADRECC Director, and his colleagues, Drs. Kacy Cullen and John Wolf, from the Department of Neurosurgery at the University of Pennsylvania, continue studies funded by the Rehabilitation Research and Development Service of the Department of Veterans Affairs to develop animal models of Chronic Traumatic Encephalopathy (CTE) that sometimes develops years later in people such as football players and war fighters who have had traumatic brain injuries. The goal of these studies is to develop models of these changes in the brains of animals so that novel treatments and preventive strategies can be tested. It is hoped that these studies will lead to treatments to prevent the development of these neurodegenerative diseases in Veterans and others who have suffered head injuries.

Neurorestoration in Parkinson's disease and other causes of Brain Injury

Drs. Cullen, Duda and Wolf were awarded a two-year grant from the Michael J. Fox Foundation for Parkinson's Research to investigate experimental reconstitution of the nigrostriatal pathway (the pathway that degenerates in PD and causes the motor symptoms) in animal models of PD in a grant entitled, '**Restoring the nigrostriatal pathway with living micro-tissue engineered axonal tracts**'. This project involves growing cellular constructs in culture, comprised of dopaminergic neurons and the long axonal projections necessary to recapitulate the nigrostriatal pathway. These constructs with then be transplanted into animals that have had lesions of the nigrostriatal pathway to see if these cells can functionally replace the damaged cells. In addition, Dr. Isaac Chen, who is also from the department of Neurosurgery at the University of Pennsylvania and is mentored by Dr. Duda, was recently awarded a Career Development Award from the Rehabilitation R&D Service to try to grow complete cortical structures in culture and transplant them into animal models. It is hoped the lessons learned from all of these studies will one day lead to breakthroughs in our ability to restore function in Veterans suffering from many disorders that cause brain injury.

Education News

Monthly Case Conference

Monthly case conference calls continue to be held with service area Consortium Centers to share case studies and discuss diagnosis and treatment of difficult cases.

PADRECC/EES Movement Disorders Series

The Philadelphia PADRECC continues to participate in this professional education audioconference held bi-monthly. Dr. John Duda recently presented "**Nutrition and Parkinson's Disease-What your patients need to know.**" This presentation provided clinicians treating people with PD a basic understanding of how nutritional modifications can help manage symptoms, interact with standard medical therapies and potentially modify disease progression. This presentation also provided clinicians with an update on our understanding of how certain nutrients and dietary strategies can impact care for PD and introduce basic guidelines that can be used in clinic to give Veterans an introduction to the value of these strategies.

Patient & Caregiver Education/Support Group Program

This program runs from April-December and meets once a month for one hour to provide support and education on topics related to PD. To increase accessibility, the group continues to be broadcasted to two local CBOCs using tele-health technology.

PD 101 Information Session

This bi-annual program was offered on April 11, 2016 to patients who were newly diagnosed and/or new to the PADRECC clinic in the last two years. Dr. Michelle Fullard, PADRECC Fellow, provided an overview of PD symptoms and treatment as well as an introduction to the PADRECC Team and education programs available. This program was broadcasted to local CBOCs using tele-health technology.

Nutrition and PD

This patient education program was held on April 20, 2016 to educate attendees about the benefits of a healthy lifestyle in Parkinson's disease. In a 3 hour presentation, Dr. John Duda presented information on Nutrition and PD, and led a fun and interactive cooking demonstration. Attendees had an opportunity to try the food that was prepared and ask questions regarding nutrition and other lifestyle modifications.

Community Outreach

Clinical Staff continue to present at local support groups providing information and education on the PADRECC program and services available as well as information on topics related to PD. The Philadelphia PADRECC had an information table at the Partners in Parkinson's New Jersey Symposium held on December 2015 and the Jane Wright Symposium held in Philadelphia on April 2016.

Southeast/Richmond PADRECC Update

Clinical News

Psychiatric Collaboration

This is the third year of collaboration between the Richmond PADRECC and psychiatry psychosomatic fellowship program through the Virginia Commonwealth University/McGuire VA Medical Center. The psychiatry fellows are integrated into the clinic two days per week and assist with complex psychiatric issues and concerns while balancing the movement disorder pathology and medication effects. This collaborative effort allows us to provide expedited access to mental health care for our patients with psychiatrists who have an additional interest in neurodegenerative disorders as well.

Deep Brain Stimulation (DBS) programming via Telehealth

Eligible veterans have access to DBS surgery as part of their treatment for symptoms of medically refractory Parkinson's disease and essential tremor. For many of these veterans, they return to their local VA facilities for ongoing management and care. Due to the specialty nature of DBS, not all VA facilities have personnel trained in the art and science of programming the DBS devices. One workable option that is used in Richmond involves Telehealth. The PADRECC DBS team schedules a Telehealth visit with the Veterans at their nearest CBOC or home VAMC. An arrangement is made for a Medtronic representative to be present at the remote site with the patient. The Medtronic representative is knowledgeable about the DBS device and can assist with programming and maintenance. This saves veterans the unnecessary burden and cost of travel to and from Richmond.



Using Telehealth technology capability, Miriam Hirsch, RN and DBS Coordinator does programming with a veteran at Rome Outreach Clinic in Rome, GA with assistance from a Medtronic representative.

Research News

MJFF Grant for Eye Movement Study

Dr. Mark Baron and his colleagues have been awarded a \$1 million grant from the Michael J. Fox Foundation, in order to continue their research on eye movements in movement disorders. This will be a multicenter study, including the Richmond PADRECC, Virginia Commonwealth University, Emory University, and University of Iowa. The double blinded study will record eye movements of control subjects, PD patients, and patients with other movement disorders that may be mistaken for PD. The team aims to demonstrate that eye movement recordings can be effectively used to aid in differential diagnosis of movement disorders. Additionally, based on preliminary data from the Richmond PADRECC, the study will recruit subjects with REM behavior disorder, who do not exhibit any outward signs of PD. Preliminary data suggest the ability to use eye movements to pre-clinically detect subjects who will later convert to idiopathic PD. The study has just been initiated, and is currently procuring hardware for the other sites, and hopes to begin enrollment soon. For further information, contact George Gitchel Ph.D., at george.gitchel@va.gov.

Education News

Telephone Education Support for DBS patients

Twenty-one veterans from 10 Southeastern states who had undergone Deep Brain Stimulation (DBS) surgery at the Richmond PADRECC participated in an hour and a half telephone session on March 4, 2016. Monitoring of the DBS system, review of follow up care, and self-management strategies were agenda items along with time for Q&A. Telephone support groups are one of several strategies used to enhance communication, provide education, and ongoing support for veterans that have DBS.

Essential Tremor Education

PADRECC hosted the 7th Annual "Reasons for Hope Essential Tremor (ET) Seminar" community event on March 12, 2016 in collaboration with the Richmond ET support group, and Virginia Commonwealth University Movement Disorders Program. PADRECC Director, Jessica Lehosit, DO was the keynote speaker. A multidisciplinary panel of experts presented various therapies and coping strategies for living well with ET including medication, surgery, and assistive devices.

4th World Parkinson Congress

DBS Coordinator, Miriam Hirsch, MS, RN, BSN, CCRC and Associate Director of Education, Lynn Klanchar, RN, MS have submitted a poster abstract titled "Staying Connected to Veterans with Deep Brain Stimulation" to the World Parkinson Congress, being held September 2016 in Portland, OR. The poster will demonstrate a systematic approach to case management that facilitates follow up care, with the goal of maximizing the potential of DBS therapy, and minimizing adverse events.

PD Self Efficacy Learning Forum (SELF)

The Parkinson's Disease Foundation (PDF) selected PADRECC staff member Lynn Klanchar to participate in the PD SELF Leader Training May 11-14, 2016 in Denver, CO. PDF picked 10 teams from around the country. Each team consists of a movement disorder professional and a lay person with Parkinson's disease. Teams will be trained to deliver self-efficacy programs in their region to help newly diagnosed patient better manage their PD and improve their quality of life.

Southeast/Richmond PADRECC Update (continued)

500TH DBS by Dr. Holloway

Neurosurgeon Kathryn L. Holloway, MD performed her 500th Deep Brain Stimulation (DBS) lead implant surgical procedure on May 17, 2016 at the McGuire Veterans Affairs Medical Center in Richmond, VA.

Achieving this large number of DBS surgeries is a major milestone among functional neurosurgeons. Dr. Holloway ranks 8th nationally among 334 others who perform new DBS implants. As an early pioneer in this treatment, she has been performing DBS surgery at Virginia Commonwealth University medical center and the McGuire VAMC since 1997 when it was first approved by the Food and Drug Administration for the treatment of tremor. She has performed close to 1,000 DBS procedures including lead implants, extension and generator placements, and battery replacements.

Deep brain stimulation (DBS) is a surgical procedure that involves placing a neurostimulator in the brain which sends out electrical impulses to specific regions of the brain. DBS is commonly used to treat essential tremor, Parkinson's disease, and dystonia, a movement disorder in which the muscles contract and spasm. Electrical impulses are sent out to block abnormal signals that can cause a number of different neurological disorders.

In addition to hitting the 500th DBS case in her career, Dr. Holloway's achievements as a neurosurgeon are numerous:

She was instrumental in the design of the Nexframe Stereotactic Image Guided System. The Nexframe stereotactic image guided system allows patients to enjoy greater comfort and freedom of movement during implant procedures, in addition to providing operating room efficiency and reduced procedure time.

Dr. Holloway has had several "firsts" to her name. She was the first neurosurgeon in the US to:

Implant a DBS Kinetra device. The Kinetra is a dual-channel neurostimulator that uses electrical stimulation to manage some of the most disabling motor symptoms of advanced Parkinson's disease.

Implant an Activa RC. The Activa® RC neurostimulator is the first rechargeable deep brain stimulation device with 9-year longevity.

Incorporate the O-arm® Intra-operative 2D/3D Imaging System in the DBS procedure for registration and verification. The O-Arm allows the fiducials or frame to be registered in the operating room and allows visualization of the implants before leaving the operating room.

Dr. Holloway is the Chief of Neurosurgery at McGuire VAMC and the Director of Neurosurgical Services at PADRECC Richmond/Southeast. In addition, she is a Professor of Neurosurgery at Virginia Commonwealth University (VCU) and the neurosurgeon for Virginia Commonwealth University (VCU) Parkinson's and Movement Disorders Center.



Southwest PADRECC Update



Dr. Indu Subramanian was appointed the Director, Southwest Parkinson's Disease Research, Education, and Clinical Center in October 2015. Upon completing her two year movement disorder fellowship training at UCLA, she was appointed Associate Clinical Professor in Neurology at UCLA and established the movement disorder clinic at the West Los Angeles VA Medical Center. Her interests include complementary and alternative medicine with a special interest in yoga and mindfulness. She underwent a 200 hour yoga teacher training in 2015 and is currently studying to be a mindfulness instructor to teach Mindfulness Based Stress Reduction (MBSR) for the VA Health Promotion and Disease Prevention program. Other programs she is developing include a yoga teacher training program for yoga instructors who are interested in working with Veterans with Parkinson's disease (PD), a manual for yoga teaching in PD, and yoga videos for Veterans. Another area of interest is in palliative care and hospice care in PD and she mentors a palliative care neurology fellow at the West Los Angeles VA. Dr. Subramanian serves on the advisory board of the Brian Grant Foundation Power through Project, a wellness and exercise organization. Its founder, Brian Grant, a retired NBA player, was diagnosed with Young Onset Parkinson's disease at the age of 36. The mission of the program is to empower people with PD to live active and fulfilling lives.

Greater Los Angeles Healthcare System

Sunita Dergalust, Pharm.D., BCPS achieved a three year accreditation in March 2016 from the American Society of Health-System Pharmacists of the Post Graduate Year 2 Neurology Pharmacy Residency program for June 2014 to June 2019. This is the only neurology pharmacy program in the country and the first one to receive accreditation. She is the Director of the Postgraduate Year Two Neurology Pharmacy Residency Program.

Southwest PADRECC Update (continued)

Virginia Janovsky, MN, MS, RN, Lindsey Unger, MS, CCC-SLP, and Eric M. Cheng, MD, MS have been awarded a grant by National Parkinson's Foundation for a proposed retrospective chart review to investigate how effective early management of speech and swallow functions is in preventing complications and improving survival and quality of life in Parkinson's disease.

Karen Connor, PhD, MBA and Eric M. Cheng, MD, MS Principal Co-Investigators and research team have designed a model of care delivery to provide preventive/proactive care coordination across the care continuum for Veterans with Parkinson's disease (PD). The multi-center VISN 22 (Greater Los Angeles or GLA, Las Vegas, Long Beach, Loma Linda, San Diego) study, "Improving Quality of Care in Parkinson's Disease: A Randomized Controlled Trial," is a telephone-based, nurse-led PD care management intervention called, "Coordinating Care and Activities for Health Promotion in PD" (CHAPS). The aim of the study is to determine if the nurse-led intervention improves PD quality indicator adherence and if Veterans' health outcomes will improve in those subjects enrolled in the intervention arm. A secondary aim is to gather cost data for VA decision makers for potential dissemination to other PADRECCs if the intervention is found to be efficacious. The study was funded by VA HSR&D, Nursing Research Initiative.

In addition, **Virginia Janovsky, RN** at the GLA site leads a low cost and effective telephone-based education and support group for people with PD and their families or caregivers in response to barriers faced by Veterans and their families—lack of transportation, traffic congestion, parking shortages, difficult mobility, distance, assistive aid needs, and self-consciousness of their Parkinson's symptoms. Meetings are on the second Tuesday of every month through the VA toll-free telephone conference line and available across the nation. Two-way conversation and discussion is possible. Topics this year by VA and community professionals nationwide include side effects of PD medications, effects of exercise on cognition, non-motor aspects of PD, anticipatory grief, memory tips, palliative care, and nutrition and wellness in PD. For more information, call (310) 478-3711, x48041.

Albuquerque, New Mexico VA Health Care System

Sarah Pirio Richardson, MD, a movement disorders specialist, and **JoAnn Harnar, RN** run the PADRECC clinic in Albuquerque, New Mexico. Clinical activities include specialty care for patients with tremor, ataxia, Parkinson's disease and dystonia. Botulinum toxin injections and deep brain stimulation programming is done for patients in VISN 18 from eastern Arizona, southern Colorado, New Mexico and western Texas. Teleneurology and nurse education sessions are important parts of these services. Research efforts are focused on utilizing transcranial magnetic stimulation to improve dystonia symptoms.

Las Vegas, Southern Nevada Healthcare System

Dr. Selina Parveen provides movement disorder, deep brain stimulation and botulinum toxin management to a large catchment area in Nevada, Arizona and Utah in VISN 22. She often is a guest speaker at the community support group, Friends of Parkinson's in which many Veterans attend. She is also the site Principal Investigator for the study led by **Dr. Karen Connor**, Improving Quality of Care in Parkinson's Disease: A Randomized Controlled Trial.

Long Beach Healthcare System

Dr. Steven Schreiber is Chief of Neurology at the VA Long Beach Healthcare System where he oversees the local PADRECC and was instrumental in developing the first Teleneurology programs in the VA system that has evolved to include non-VA facilities to provide care for Veterans in areas where access to care is a challenge. In a recent study **Dr. Schreiber** showed that healthcare delivery through Teleneurology can be as efficacious and rewarding in the urban setting as it is in more rural and medically-underserved areas. He also serves as local Principal Investigator for PADRECC-related studies, including most recently, **Dr. Karen Connor's** study on "Improving Quality of Care in Parkinson's Disease: A Randomized Controlled Trial."

Megan Gomez, PhD, a licensed clinical psychologist in the Primary Care Mental Health Integration Clinic, who specializes in neuropsychology and neurodegenerative diseases, facilitates a new monthly Parkinson's Support Group at the Long Beach VA. Started in February 2016, in an effort to improve the quality of life for Veterans with Parkinson's, the support group has a focus on non-motor symptoms of Parkinson's disease. Thus far, the group has been warmly received and well attended by Veterans living with PD and their care partners. Guest speakers include Psychologists presenting on mindfulness/meditation for PD and cognitive changes in PD, Kinesiotherapists presenting on PWR! For PD, Speech-Language Pathologists presenting on Lee Silverman Voice Therapy (LSVT) for PD, and other relevant speakers/topics. For more information, contact Dr. Gomez at (562) 706-0740.

Loma Linda Healthcare System

Dr. Dorothee Cole manages the movement disorder clinic at the VA in Loma Linda, CA, which provides specialty care for patients with Parkinson's disease including deep brain stimulation programming. She also administers botulinum toxin injections for various kinds of dystonia and treats other movement disorders such as ataxia and tremor. She also is the Loma Linda site Principal Investigator for the multi-center VISN 22 study, "Improving Quality of Care in Parkinson's Disease: A Randomized Controlled Trial," headed by **Dr. Karen Connor** at the West Los Angeles VA.

Maribel Padua, PhD, a geropsychologist in the Primary Care Mental Health Integration Clinic, Loma Linda VA also offers a unique Parkinson's disease support group for both caregivers and Veterans. The four week program meets every Friday and includes a Lee Silverman Voice Treatment session with the speech pathologist, both Veteran and caregiver breakaway sessions with the psychologist and social worker, and singing

Southwest PADRECC Update (continued)

as a speech exercise strategy at the end. **Dr. Cole** and other neurologists provide guest talks. For more information, contact Dr. Padua at (800) 741-8387, x4890.

San Diego Healthcare System

Dr. Stephanie Lessig is the Principal Investigator (PI) for an investigator-initiated study sponsored by Parkinson’s Disease Foundation, “Self-Reported Benefits from Tremble Clef Participation in Parkinson’s Disease”. The Tremble Clefs are a group of Parkinson’s patients in San Diego who meet once a month to practice singing (vocal exercises) and who perform at local events a few times per year. The aim of the study is to test through standardized questionnaires whether regular singing can improve speech and swallowing. In addition, **Dr. Lessig** is the site PI for the multi-site, randomized study to assess quality of care of Veterans with Parkinson’s disease by comparing a nurse-led telephonic care management program to usual care. Other additional services include telehealth and a VA support group through the San Diego neuropsychology service.

Tucson, Southern Arizona Healthcare System

Scott Sherman, MD, PhD and his research laboratory focus on developing novel therapies for Parkinson’s disease (PD) and have several translational projects that could impact the management of PD. His research led to the discovery that neurotrophic factors, Vascular Endothelial Growth Factor-B and a factor derived from the retina are neuro-protective. Another study explores the use of a compound for the treatment of PD dyskinesia for which he has applied for a patent and plans to initiate clinical trials in the upcoming months. In addition, his pluripotent stem cell study can hold great promise in the field of regenerative medicine because they can propagate and be used to replace PD damaged cells. His research laboratory will be part of a new Regenerative Medicine Initiative at the University of Arizona.

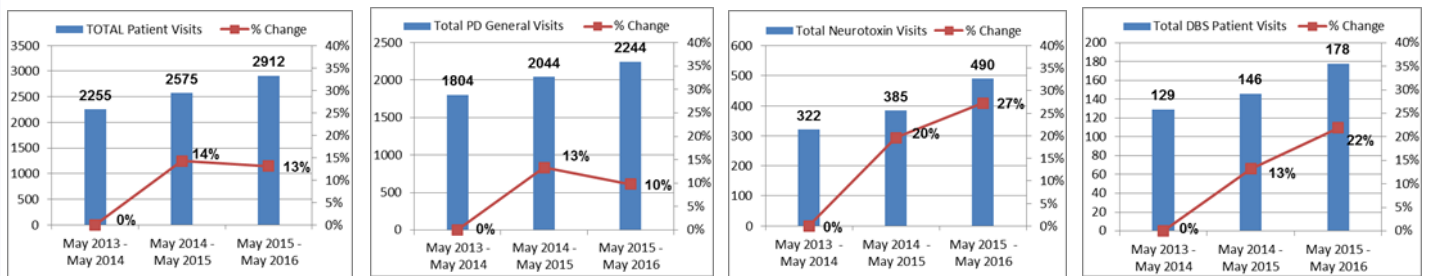
Houston PADRECC Update

Clinical News

Houston’s Parkinson’s Disease Research, Education and Clinical Center (PADRECC) housed in the Michael E DeBakey VA Medical Center continues to provide state of the art medical and surgical services to Veterans with Parkinson’s disease and related movement disorders who reside in the Southcentral and Midwestern United States.

Growth in Clinical Encounters

Since fiscal year (FY) 2013, year by year, our center has experienced an annual growth rate of approximately 14%. Within the overall increase in clinical care, there has been an average increase of 12% in the general patient encounters, 24% in neurotoxin injection procedures, and 18% in Deep Brain Stimulation (DBS) clinic visits.

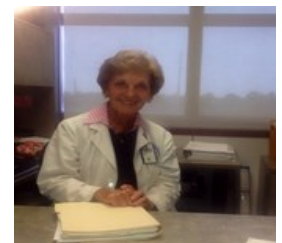


Deep Brain Stimulator Implantations

We have performed 14 DBS implantations from July 1, 2015 - June 30, 2016 using both conventional and frameless techniques as compared to 16 in the same period during the previous fiscal cycle (12.5% decrease). Our efforts on an initiative with the Departments of Neurosurgery to make the DBS surgery under sedation available to our patients are ongoing.

Retirement of Assistant Clinical Director

Linda Fincher, RN, Houston PADRECC’s Nursing Supervisor and Assistant Clinical Director since 2002, retired on April 01, 2016 after 14 years of service to Houston PADRECC and 39 years to the VA Hospital system. Her farewell reception celebrated her exemplary service to PADRECC and MEDVAMC and was attended by dozens of her recent and prior co-workers. We are currently recruiting to fill her position.



Houston PADRECC Update (continued)

Education News

New Associate Director of Education

Glennys Asselin-Cavey, MSN, RN, assumed the position of Associate Director of Education for Houston PADRECC on May 1, 2016. She, along with Linda Fincher, RN, served as the co-interim Associate Director of Education since August 2015. She has initiated a nurse based educational lecture series for the PD patients on a monthly basis that has been very well received by the patient and their care providers. Her future initiatives will include Tele-Education, Patient and Care provider based Satisfaction Survey and other educational research and outreach projects.



Collaboration with Psychiatric Pharmacy Residency Training Program

In FY16, Houston PADRECC has begun its first year of collaboration with Psychiatric Pharmacy Residency Training Program. One trainee would rotate through PADRECC each year. The goals of this collaboration would include:

1. Provision of education and training to the pharmacy residents in the psychiatric manifestations seen in movement disorders patients, and to include these trainees as part of the inter-disciplinary team that would serve as an authoritative resource on the optimal use of medications used to treat these patients
2. Optimizing the outcomes of diverse populations of movement disorders patients with a variety of psychiatric and neuropsychiatric manifestations exhibiting a range of complexity; by fostering evidence-based, patient-centered medication therapy.
3. Development of leadership and practice management skills in the trainees
4. Evaluating and improving the medication-use process in movement disorders clinics
5. Conducting movement disorders based pharmacy practice and outcomes based research

Collaboration with the Department of Veterans Benefits' Vocational Rehabilitation Program

In a continued collaborative agreement with the Department of Veterans Benefits' Vocational Rehabilitation Program, from September 2015 to May 2016, Houston PADRECC provided clinical training support to Ms. Demetrius Moore, a Certified Nurse Assistant, who acted as a valuable resource to boost our clinical nursing support during busy clinical operations. Mrs. Sheila Cruz, a Certified Medical Assistant was part of the same training program from September 2015 through April 2016 and was recently hired as a CNA on the Neurology inpatient Unit of MEDVAMC.

Patient Directed Clinic Based Education

Education is an essential component of the clinic visits at Houston PADRECC and is available to all patients and their care providers five days a week. It consists of 1:1 education by verbal instruction, videos, and printed educational material.

Monthly Patient and Caregiver Educational Support Group

The Houston PADRECC has a monthly Support Group for PD patients and their care providers. The group meets on the first Thursday of each month for 90-120 mins and provides education and support to the attendees. The group is led by the Education Director. Guest speakers are also invited to present and discuss educational topics that pertain to these patients. Relevant health care providers at the VA also routinely attend and participate. Feedback is invited from the attendees and incorporated for continued quality improvement.

Recent topics:

- “Sit and Exercise Program” by Dr. Krystal Vento, MEDVAMC Physical Therapist - Oct. 1, 2015
- “National Caregiver’s Month” educational presentation and discussion and “Outwit Stress with Laughter Yoga” by Lainie Diamond, certified instructor - Nov. 5, 2015
- “Nutrition and PD” by Aleyamma Baby, RN; Holiday party and Carols - Dec. 3, 2015
- “Immunizations for Patients with Parkinson’s Disease,” by Andrew Hunter, Pharm D - Jan. 7, 2016
- “Impulsive Behaviors and Parkinson’s Disease” from My Parkinson’s Story DVD- followed by Discussion on distraction strategies and short and long term pros and cons of a behavior by Glennys Asselin-Cavey, RN - Feb. 4, 2016
- “A Closer Look at Anxiety and Depression in Parkinson’s Disease” from Expert Briefings Educational Series DVD, by Laura Marsh, MD - March 3, 2016
- “Agent Orange” and “Memory” DVD presentation, followed by “Sleep Disorders” discussion led by Aliya Sarwar, MD - April 7, 2016
- “Speech and Swallowing in Parkinson’s Disease”, Power Point presentation and discussion: by Glennys Asselin-Cavey, RN - May 5, 2016

Houston PADRECC Update (continued)

Nurse Education Initiative

A new formal nurse education initiative has been launched. The first lecture of this series was presented on “Parkinson’s disease: Diagnostic Criteria,” by Glennys Asselin-Cavey, MSN, RN, CRRN on Dec. 29, 2015.

Medical Professionals based educational initiatives

Our ongoing educational programs include: monthly journal club, monthly live lecture series, and guest/audio lecture series.

Medical Trainees Program

The Houston PADRECC continues as the site for mandatory clinical elective for senior neurology residents from Baylor College of Medicine. The PADRECC director, Dr. Aliya Sarwar, M.D. is the rotation mentor and director of the clinical course. In the last fiscal year the center trained 12 Neurology residents in the phenomenology, diagnosis, medical and surgical management of Parkinson’s disease and other movement disorders. The residents are offered an opportunity to observe a DBS surgery and learn the basics of DBS programming. Movement disorders research opportunities would be made available to them in FY17.

Update on Consortium based Education and Clinical Support

Houston PADRECC has launched an initiative to expand consortium outreach by identifying and incorporating additional members to its educational and clinical support services. Two consortium physicians used Houston PADRECC’s tele-DBS programming services for DBS programming of patients at their local VA clinics.

Educational Newsletters

The topics of the latest issues of the Houston PADRECC’s patient/family based newsletter “PADRECC Pathways” were “Cognitive Behavior Therapy and Parkinson’s Disease”, Winter 2015 issue and “Vision Changes in Parkinson’s Disease”, Summer 2016 issue.

Research News

A PROSPECTIVE, RANDOMIZED PLACEBO CONTROLLED PILOT STUDY TO CHARACTERIZE THE INTESTINAL MICROBIOME AND TO EVALUATE THE SAFETY AND FECAL MICROBIOME CHANGES FOLLOWING WEEKLY ADMINISTRATION OF LYOPHILIZED PRIM-DJ2727 GIVEN ORALLY IN SUBJECTS WITH PARKINSON’S DISEASE

Limited studies have found fecal flora disturbances in PD. Dr. Sarwar will be collaborating with University of Texas School of Public Health and Kelsey Research Foundation in this pilot study that will completely characterize the microbiome in this group of subjects and evaluate microbiota replacement treatment as a means of flora restoration.

PREVALENCE OF HIGH RESOLUTION MANOMETRIC ABNORMALITIES OF THE ESOPHAGUS AND OF GASTROESOPHAGEAL REFLUX IN PATIENTS WITH PARKINSON’S DISEASE

Dr. Sarwar is collaborating with investigators in the Dept. of Medicine/Division of Gastroenterology to launch this pilot project that aims to assess UES, esophageal body and LES function in PD patients using high resolution esophageal manometry and the presence and severity of acid and non-acid reflux using 24 hour pH/impedance monitoring. It will compare the physiological findings among patients with different stages of PD, between patients with and without dysphagia or GERD and age matched control subjects without PD undergoing manometry and 24 hour pH during the same time period.

CIRCADIAN RHYTHM AND SLEEP IN PD – This is an ongoing study lead by Dr. Sarwar focusing on circadian rhythm and characterization of sleep patterns in Veterans with PD. 209 subjects have been recruited so far. To augment previously collected scale and questionnaire data, a funded pilot study collected objective data on a subset of subjects, utilizing a wristwatch-like device to record movement/activity (actigraphy) and laboratory based melatonin measures from saliva (Dim Light Melatonin Onset). Future work will involve development of methodology for home-based saliva collection in PD study participants to expand the data collection to those patients who cannot travel to the facility sleep lab for overnight collection. A poster, “Chronotypes, Nocturnal Melatonin Level and Excessive Daytime Sleepiness in Parkinson’s Disease”, was presented at the 2016 annual meeting of the American Academy of Neurology, held in Vancouver, British Columbia.

ANALYSIS OF HUMAN BASAL GANGLIA ELECTROPHYSIOLOGICAL RECORDINGS AND TARGETED STIMULATION FOR OPTIMIZATION OF DEEP BRAIN STIMULATION – This ongoing collaborative project between the Houston PADRECC, Baylor College of Medicine and University of Houston is designed to analyze human electrophysiological data collected during deep brain stimulator or pulse generator (IPG, battery) implantation on PD or ET patients while simultaneously stimulating with various stimulation parameters such as contacts

Houston PADRECC Update (continued)

pairs, voltage and frequency, and then observing the effects of the stimulation in the target structures and correlating with changes in the symptoms of the patient. The goal is to allow one to understand the real-time effects of stimulation on the target structure, and drive the stimulation module adaptively, setting the framework for individualized therapy.

LONGITUDINAL STUDY OF CHRONIC TBI IN OEF/OIF/OND VETERANS/SERVICE MEMBERS – Houston PADRECC continues to participate in this VA funded multi-center collaborative project designed to characterize the long-term effects of TBI on cognition, neuroimaging, and functional outcome in Veterans and service members who have been deployed to Iraq or Afghanistan. Additionally, the role of specific genes (catechol-O-methyltransferase (COMT), apolipoprotein E (APOE), and brain derived neurotrophic factor (BDNF) on cognition and functional outcomes will be explored.

FEASIBILITY OF HOME EXERCISE AND WALKING PROGRAM TO PROMOTE PHYSICAL ACTIVITY IN VETERANS WITH PARKINSON'S DISEASE – The primary goal of this collaborative project is to obtain feasibility data evaluating the efficacy of a home exercise and walking program (HEWP) with phone or clinical video telehealth into the home (CVTHM) coaching to increase physical activity in sedentary Veterans with PD. The secondary goal is to study the effects of physical activity on mobility and functional ability in Veterans with PD. 6 subjects have been recruited so far.

EFFECT OF RESISTANCE EXERCISE ON TREMOR AND HAND DEXTERITY OF PARKINSON'S DISEASE – The study looks at the effect of progressive resistance exercise on manual dexterity and tremor in persons with Parkinson's disease. The subjects receive training at the research site but perform the required 6 weeks of progressive resistance exercise of hand and arm at home. As of 06/09/2016, 10 subjects have been enrolled.

VITAMIN D DEFICIENCY AND PD – This study used medical record review to characterize vitamin D deficiency in those PD patients who have been screened for vitamin D deficiency and to describe the use and frequency of vitamin D testing in this patient population. An abstract has been accepted and will be presented at the upcoming World Parkinson's Congress in Portland, Oregon in September 2016.

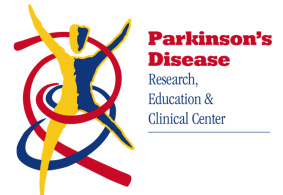


SAVE THE DATE!

SEPTEMBER 19, 2016

NATIONAL VA PD CONSORTIUM CONFERENCE

PORTLAND, OREGON



Consortium Center Directors are invited to a one day VA PD Consortium Conference to be held just prior to the World Parkinson Congress. Please email Dawn McHale (Dawn.McHale@va.gov) for more information.

Date of Program:	Monday, September 19, 2016
Program Title:	National VA Parkinson's Disease Consortium Conference
Program Location:	Ambridge Event Center 1333 Northeast Martin Luther King Junior Blvd. Portland, OR 97232 (503) 239-4246
Registration:	8:00am
Program begins:	8:20am
Program Ends:	6:30pm



Save the Date!
September 20-23, 2016
WPC2016.org

<p>Consortium Coordinating Center John Duda, MD, Chairperson 215-823-5934 Dawn McHale, Coordinator 215-823-5800 x 2238</p>	<p>Consortium Center Referral Line Tonya Belton 1-800-949-1001x5769</p>	<p>Newsletter Editor-in-Chief Aliya I. Sarwar, MD Newsletter Editors Suzanne Moore, MS Glennys Asselin-Cavey, MSN, RN</p>
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PADRECC National Directory

Center	Medical Center	City, State	Director	Telephone
Houston	Michael E. DeBakey VAMC	Houston, TX	Aliya I. Sarwar, MD	713-794-7841
Southwest	West Los Angeles VAMC	Los Angeles, CA	Indu Subramanian, MD	310-478-3711 ext. 48001
Northwest	Portland VAMC VA Puget Sound Health Care System	Portland, OR Seattle, WA	Joe Quinn, MD	Portland: 503-721-1091 Seattle: 206-277-4560
Philadelphia	Corporal Michael J. Crescenz VAMC	Philadelphia, PA	John Duda, MD	215-823-5934 or toll free 888-959-2323
Southeast	Hunter Holmes McGuire VAMC	Richmond, VA	Jessica B. Lehosit, DO	804-675-5931 or toll free 800-784-8381 ext 5931
San Francisco	San Francisco VAMC	San Francisco, CA	Caroline Tanner, MD	415-379-5530

