



# THE PARKINSON ALLIANCE®

Post Office Box 308 • Kingston, New Jersey 08528-0308

July 16, 2009

Deep Brain Stimulation (DBS) therapy is one of the state of the art treatments in the present day for individuals with Parkinson's Disease (PD). Although many individuals have reported significant improvements in some motor symptoms and improved quality of life following DBS therapy, it is a necessity to critically review all of the related components of this intervention, its effectiveness, benefits, and risks.

A "Consensus Meeting" recently took place where many world leaders in DBS therapy gathered together to discuss the comprehensive approach to DBS and its effects on patients with PD. In fact, this meeting was designed to create "consensus statements" related to the use of DBS therapy with a "patient focus", which is our primary responsibility.

The topics of the Consensus Meeting were many and included patient selection, gait and speech DBS outcomes, non-motor DBS outcomes (mood and cognition) and long-term DBS outcomes, to name a few. At the conclusion of the Consensus Meeting, a group of PD patients with and without DBS was invited to an open forum where several clinicians shared their experiences and answered the participants' questions. We have attached a copy of the summary describing the important dialogue between patients and clinicians about many of the commonly asked questions that exist in the PD community.

We also want to take this opportunity to express our sincere and utmost appreciation to those who participate in our research endeavors. Your personal contributions in this capacity are indeed a true value and asset to the PD community as a whole, as it is your "voice" that helps us spread the word about the "patient's perspective" regarding the experience with PD for those with and without DBS. Your participation in our surveys and your sharing of your experiences provides feedback to the PD community, and to the treating clinicians whose entire goal is to help you improve your well-being, manage your symptoms, and ultimately improve your quality of life. It is because of your efforts that such a "consensus meeting" came to fruition and that further education can be spread to the community.

We hope you enjoy this summary. If you would like to discuss the write-up with any of our staff, you can contact us at 1-800-579-8440.

Sincerely,

Margaret Tuchman  
Founder & President  
The Parkinson Alliance

Carol J. Walton  
Chief Executive Officer  
The Parkinson Alliance

Jeff Wertheimer, PhD  
Research Consultant  
The Parkinson Alliance

## A Consensus Meeting to Discuss Deep Brain Stimulation for Parkinson's Disease

New York City: 4/01/09 through 4/03/09

Hosted by The Parkinson Alliance®

Deep Brain Stimulation (DBS) has proven to be effective in treating some of the cardinal signs of Parkinson's disease (PD) and motor complications of levodopa therapy. However, DBS has also been found to have limited impact, no impact, or at times worsening effects on other important symptoms that impair the quality of life of individuals with PD (e.g., poor balance, speech disturbance and psychiatric conditions). Therefore, 10 years after the "DBS revolution", there is a necessity to critically review all of the related components of DBS therapy, its effectiveness, benefits, and risks.

There is a widespread perception in the PD community that better education is needed about DBS. It is important not only to educate the healthcare professionals who are performing DBS, in order to enhance individual outcomes, but also to educate the PD patients, families, and general PD community about the relevant matters that define DBS therapy. In this context, a "Consensus Meeting" was established to discuss the comprehensive approach to DBS and the "state of the art" therapy for patients with PD. In fact, this meeting was designed to create "consensus statements" related to the use of DBS therapy with a "**patient focus**", which is our primary responsibility.

On April 1<sup>st</sup>-3<sup>rd</sup> The Parkinson Alliance (with shared sponsorship provided by the Davis Phinney Foundation, the LSVT Foundation, and the National Parkinson Foundation) convened a panel of the world's experts on DBS for PD. The task assigned to these experts was not to craft a typical consensus statement for themselves, but to come up with a document aimed squarely at their true customers—the patients. These world leaders discussed the current matters related to DBS therapy and where we need to go with this intervention. The ultimate focus was on improving the effectiveness of the intervention and the quality of life of those individuals who have undergone or those who will choose to undergo DBS.

The topics of the Consensus Meeting were many and included patient selection, gait and speech DBS outcomes, non-motor DBS outcomes (mood and cognition) and long-term DBS outcomes, to name a few. We will have a written report of this Consensus Meeting posted on our website (<http://www.dbs-stn.org/> and <http://www.parkinsonalliance.org/>) in the near future. At the conclusion of the Consensus Meeting, a group of PD patients with and without DBS was invited to an open forum where several clinicians shared their experiences and answered the participants' questions. The remainder of this document will include the list of questions that the patients asked and the responses from the physicians and clinicians in the room.

**The following treatment providers attended the Consensus Meeting and provided responses to the patients' questions during the open forum:**

Francois Alesch, M.D.	Neurosurgeon
Ron Alterman, M.D.	Neurosurgeon
Jeff Bronstein, M.D.	Neurologist
Mahlon DeLong, M.D.	Neurologist
Laura Marsh, M.D.	Psychiatrist
Bill McDonald, M.D.	Psychiatrist
Lorraine Ramig, Ph.D.	Speech Language Pathologist
Michele Tagliati, M.D.	Neurologist
Jeffrey Wertheimer, Ph.D.	Neuropsychologist

PATIENT QUESTIONS:

**1. *What was the purpose of this meeting, and what did you learn?***

**Physician Response:** “We spoke about the ‘whole person’. In addition to discussing motor symptoms related to PD, we also discussed cognition, speech, psychiatric symptoms, behavioral changes, and autonomic dysfunction.”

**Physician Response:** “The psychiatric and cognitive features are of great concerns to the neurosurgeons, neurologists, psychiatrists, and other clinicians who are providing the care for the patients. We want to treat all symptoms and make sure that the treatments do not have negative side effects.”

**2. *I hear individuals have to be programmed: How often and why?***

**Physician Response:** “It is difficult to give you a clear-cut answer, but in general, there is an initial programming day where the neurologist, nurse, or neurosurgeon will try to identify the best settings. After this initial programming day, it depends on how well the symptoms respond. We often check every two to three weeks and then on a monthly basis. After that, we like to have a routine follow-up every 2 to 3 months. Once we find the right settings, these settings are supposed to work for the long term, but they can be modified over time as needed.”

**Physician Response:** “Optimization of DBS parameters is usually achieved within 4-6 months over 4-5 programming sessions. But, it is an individual experience, and we assess how well the settings work on your symptoms.”

**3. *When in the disease process is the best time to do DBS?***

**Physician Response:** “The timing of surgery is individualized. We look at the disability that may occur despite medications being optimized. In the context of assessing the effectiveness of the medications, we believe that it is very important that treatment needs to

target the specific symptoms of the patient. The general guidelines relate to when individuals become disabled.”

**Physician Response:** “We want to focus on improving the quality of life. So we should keep in mind that DBS therapy should not be a last resort. This treatment can be quite therapeutic and appropriate to give ‘earlier’ in the disease process rather than later, but it is dependent on the individual’s well-being and needs.”

**Physician Response:** “There is no specific time in the disease course. It is an individual choice based on the level of disability and discussion with your doctor about the risk and benefit of the surgery.”

**Physician Response:** “It is important to address concerns with your doctor and explore the idea as a possibility to see if you are a good candidate.”

**Physician Response:** “If patients are properly selected for DBS, there is usually a very high success rate. If there is no benefit achieved after surgery and programming, patients should be advised to seek a second opinion at a specialized movement disorders center to ensure proper programming.”

#### ***4. What evidence is there for neuroprotection?***

**Physician Response:** “There is no evidence in individuals that DBS is neuroprotective. Also, there is no evidence that levodopa is toxic. In fact, the levodopa itself may even be protective; and it may be helpful in disease modification. It is important to keep in mind that the goal is to reduce the symptoms, not the medications.”

#### ***5. Can you talk about the impact of DBS on speech?***

**Patient Comment:** “Speech is one of the major issues for me, and it is very difficult to change.”

**Speech Language Pathologist Response:** “Ninety percent of patients with PD have a speech disorder (the classic symptoms are soft voice, hoarseness, monotone). Effective speech therapy (with Level 1 evidence) does exist for these patients, and it is called Lee Silverman Voice Treatment (LSVT). After DBS, the speech of patients with PD may not change or it may worsen. Speech improvement is not commonly reported following DBS. The speech characteristics after DBS are often different from the classic PD speech symptoms and may include the addition of mild to severe slurring, slowed speech or rushes of speech, strained voice and nasality; patients often report increased effort to produce speech. The most likely explanations for the worsening in speech after DBS include the location of the surgical leads and the stimulator settings. Patients should work with their DBS surgical team to have their stimulator settings optimized for speech. This is particularly important before they begin speech therapy.”

“ LSVT has been reported to be effective for many patients after DBS. However, it is important to note, that in some cases, the speech disturbance following DBS may require more LSVT (than the efficacious 16 hours in one month dosage) or more frequent follow-

ups. In addition, sometimes the speech disturbance following DBS may be difficult to treat with speech therapy.”

“There are a number of speech researchers studying ways to optimize speech outcomes following DBS and to improve speech treatment options. One idea is to pre-treat patients with LSVT before DBS. Researchers at Queen’s Square in London have seen positive outcomes with this approach. Other researchers at Rush Medical Center in Chicago are studying an auditory feedback device for the speech rate problems post DBS. A research team in Colorado is evaluating ways to tailor LSVT to the specific needs of the post-DBS patient. We have seen positive changes by increasing the standard dose of LSVT from four to six weeks and adding a treatment module that focuses on articulation.”

“We [Speech Language Pathologists] continue to encourage other treatment providers that speech therapy is an important component of the multi-disciplinary treatment team.”

**Patient Comment:** “I just wanted to add that DBS helped my speech.”

## ***6. Regarding DBS Adjustments...If you try to adjust for dyskinesia, do you get dystonia?***

**Physician Response:** “Dyskinesia is associated with levodopa, and the symptoms improve when you take the levodopa away. The dystonia or stiffness can be caused by levodopa or manifest independently as a symptom of the disease. It is important to look at the amount of medication and assess stimulation parameters to identify what is causing dystonia and then treat accordingly. In other words, dystonia can be indicative of either over- or under-treated disease – too much medication or too little medication, too much stimulation or too little stimulation. We have to explore the options and identify what the best parameters are.”

## ***7. How long does DBS last? Looking prospectively, how long will DBS be useful?***

**Physician Response:** “As one neurologist pointed out during this meeting, motor symptoms benefit from DBS for several years after the intervention. There is published data indicating that DBS is effective for the treatment of PD motor symptoms for at least 5 years. We saw individual cases that had benefited from DBS-STN for 10 years and up to 20 years of combined thalamic and subthalamic stimulation. It is important to note that these are individual cases.”

## ***8. What symptoms respond best to DBS?***

**Physician Response:** “DBS assists in the treatment of tremor, stiffness, and other difficulties with movement that responds to levodopa.”

**Physician Response:** “Surgery has been found to be extremely good for tremor. However, non-motor symptoms (depression, anxiety, cognition, sleep disturbance, etc.) can and usually continue to progress despite the best benefit of stimulation.”

“Medication and DBS programming need to be coordinated and managed by well-trained individuals, such as your neurologist or nurse practitioner [who works with your neurosurgeon or neurologist].”

### ***9. What are the effects of DBS on depression and anxiety in PD patients?***

**Physician Response:** The data on the effect of DBS surgery on depression and anxiety is still unclear and will require further research. The consensus of the experts is that patients undergoing DBS surgery should be evaluated and followed by a multidisciplinary team, including a neurosurgeon, neurologist, psychiatrist, neuropsychologist, internist, and other therapists such as speech therapist and physical therapist, to help treat the variety of systems that exist for the patient.”

### ***10. How do you address the shortage of programmers?***

**Physician Response:** “This is a huge problem, and we were cognizant of that in our discussions. It is a problem from big cities to rural areas. We had considerable discussions on this very issue, related to optimizing outreach networks.”

“We need increased training, but there are obstacles, such as financial restrictions (e.g., low insurance reimbursement).”

**Physician Response:** “It is important to have individuals properly trained. It is important to adjust the programming parameters along with the medications to have optimal outcome.”

“Some neurologists try to establish the programming plan from the beginning.”

**Physician Response:** “We do not find it acceptable that surgeons implant DBS electrodes and then let less than appropriately trained individuals perform the programming. That often leads to a suboptimal outcome. Furthermore, insurance will continue to be a barrier, and we need to find ways to work around that.”

**Patient Response:** “Parameter settings are extremely important. Without the right parameters, DBS effects may be limited, if not deleterious, on the patient.”

**Physician Response:** “Parameters are dictated by how the electrodes are implanted. There are ongoing and persistent attempts to train doctors and other clinicians to program DBS.”

“We discussed a systematic approach and highlighted the importance of sequentially testing the various parameters, all the while taking detailed notes to use in future appointments.”

**Physician Response:** “A patient who has DBS, who does not have benefit, and who does not seem to improve over a reasonable period of time, should seek a second opinion at a major center. We often find that the electrode is not in the right place, the programming is

not optimal, or that the patient was not a suitable candidate (these are the three big ones). Thus, having a second opinion from a reputable, major DBS center is recommended.”

### ***11. Can the DBS lead shift over time? Should I redo the surgery?***

**Physician Response:** “This is called ‘Lead Migration.’ I have never seen a lead move when implanted in a proper place and with the proper device.”

### ***12. What about erosion of the skin over the hardware?***

**Physician Response:** “There is a possibility for the hardware eroding. As the devices become smaller, that will be less of an issue. If there is continued erosion, then we will surgically replace the device.”

### ***13. What is the best target? GPi or STN?***

**Physician Response:** “We debated over this question at great length. There is a large Veterans Administration Cooperative study that was recently completed and is going to provide scientific evidence to answer this question. Right now, we each have our own opinions, but we are waiting for the objective data to provide more answers to the question.”

**Physician Response:** “As reported in the first part of the VA Cooperative study, DBS in general was better than best medical management (medication). The relative GPi and STN stimulation results will be coming out in the near future. But further study may be required. There is evidence that both sites help in treating some of the motor symptoms. It may be that one helps some symptoms more than the other. This is an important study, and we reserve comment until the results from the VA Cooperative study are published.”

**Physician Response:** “We are trying to have randomized-controlled studies to best identify what site is better. It is not only important to determine which one is better, though, but also which one has the side effect profile that may be more or less favorable. We want to have more data before coming out with opinions on the matter.”

### ***14. Would there be any interest or possibility for a neurologist to assume the role of a Primary Care Provider for PD patients with DBS?***

**Physician Response:** “There is a difference between the neurologist’s role as a primary care provider versus a principal care provider. Most neurologists feel comfortable treating the medical complications of PD and may provide referrals to other specialists. The neurologist should be able to synthesize the information from these consults to provide a comprehensive plan for the PD patient. However, this does not mean that the neurologist should be the physician who is in charge of other non-PD related complications, such as primary hypertension, cardiac issues, or diabetes mellitus. Patients need to have a primary care physician or internist to prevent, manage, and/or treat other medical diseases. There is a preventative role of the primary care provider, which is an important part of medical care for PD patients.”

**Physician Response:** “We should work along with an internist or primary care physician. A team of physicians should work together to make sure medications do not interact in a negative way, and the treatment team can address all the symptoms that emerge and also monitor the overall health of the patient to prevent or manage other non-Parkinson’s related illnesses.”

**Physician Response:** “Even though the neurologist will refer to a specialist, the neurologist is often the ‘gate keeper’ or the coordinator of services and other referrals to the variety of team players.”

“Most internists and primary care physicians do not understand PD nor do they understand the medication interactions. Thus, working closely together with the various treatment providers is crucial. We tend to provide ‘principal care’ not necessarily ‘primary care’.... helping to establish appropriate referrals and education to those referrals.”

**Physician Response:** “The principal care provider is the doctor you see most often. The neurologist may be able to address many of the corollary problems. The Primary Care Physician is the one who ‘actually takes care of the other problems’, like heart disease, lung problems, diabetes, prostate cancer, etc.”

***15. I had Activa Surgery. Should I move from two Soletra’s to one Kinetra? Could you talk about the length of the battery life ... Does one have a longer battery life?***

**Physician Response:** “Battery life is not different, and there would not be a reason to change. Medtronic’s new devices that are coming out in the near future may help with lengthening battery life.”

***16. Post MRI after Lead placement. Is there anything else coming out to look at lead placement besides MRI?***

**Physician Response:** “It was not a primary focus of the clinicians at this meeting. Many look at the MRI, and we recommended a systematic approach to assessing the settings/parameters to help patients.”

**Physician Response:** “We are looking at computer modeling to help develop programs to help guide less experienced programmers... to find better settings and parameters. Since there are so many variables involved, trial and error will continue to be a technique that is utilized.”

***17. Can you read the electrical activity from or around the electrodes to help with programming?***

**Physician Response:** “We record the brain activity during surgery using microelectrodes to assist precise implantation, but we cannot do it once the leads are implanted. Working through parameter settings with the patient and assessing the response (positive and adverse) is currently the optimal way to look at what is best for that patient. It is important to



assess all the contacts. Therefore, a map can then be created that will help with the individual's treatment/care and settings over time."

**Physician Response:** "Everyone's brain is different, from disease related factors to anatomical differences. There are so many variables; trial and error continues to be the best for identifying the best programming parameters."

### ***18. Can they use stem cells in addition to DBS in the future?***

**Physician Response:** "The answer is most likely yes. We are not creating a destructive lesion with DBS (there may be some tissue damage during the surgery itself, but not nearly like the previous permanent lesions); DBS is generally reversible in that the effects of DBS are stimulation dependent. However, it is important to note that the use of Stem Cells is highly unlikely to be available in the near future."

**Physician Response:** "Stem Cells are not ready for prime time. We should emphasize that stem cell research is currently in the works, and it is not expected to be approved for use in the near future (within 5 to 10 years). Patients should not hold out on available therapy today for the hope of receiving stem cell transplants in the future. In fact, we would caution against trying to receive stem cell therapy that may be available in other countries. There are still many unknowns and dangers, including reports of brain tumors."

**Physician Response:** "Having DBS would exclude a patient from participating in a stem cell transplant research trial because they often require 'virgin' brains where there have not been prior surgical interventions. However, if stem cell transplants were to be found effective and were to be approved as a treatment, having prior DBS surgery would not prevent the patient from receiving the therapy."

### ***19. What is the recommendation for having Physical Therapy following DBS?***

**Physician Response:** "Physical therapy and speech therapy are beneficial and important after surgery; it is very common to refer to these two services. DBS patients may be required to 'relearn' old functions that have been unused for a period of time. In some places, patients who received DBS can be directly admitted into an inpatient rehabilitation unit where they receive intensive physical therapy and speech therapy, if warranted, along with initial programming. This is an old idea that appears to be very effective, but due to the current reimbursement issues, it is not feasible everywhere. As an alternative, these therapies can be pursued aggressively as an outpatient, once again, if warranted."

### ***20. Is anyone aware of DBS causing dystonia and other pain?***

**Physician Response:** "Dystonia, as mentioned previously, is a very complicated symptom. It can be a manifestation of under treatment and progression of disease, a side effect of medical treatment, or a result of a poorly programmed DBS usually involving increased voltage."

"As an example of this complicated symptom, one physician described a case when a

patient with Essential Tremor with DBS complained of excruciating leg and back pain. This patient was diagnosed with sciatica by an outside physician [sciatica is inflammation of the sciatic nerve, usually marked by pain and tenderness along the course of the nerve on through to the thigh and leg]. She eventually underwent lumbar surgery with minimal improvement of symptoms. It was later found that the pain may have been due to abnormal stimulation from her DBS that was not readily identifiable at first presentation.”

“Pain is complicated, and the specific pain needs to be assessed thoroughly and methodically to help determine its cause.”

## **21. Can DBS ever cause patients to “over do it?”**

**Physician Response:** “Yes. DBS may cause behavioral changes. Even before DBS, many patients may experience behavioral changes, such as increased eating, impulsivity, gambling, hypersexuality, obsessive and driven behaviors, resulting from their medication regimen. After DBS these symptoms may reemerge. It is unclear whether the increased incidence after DBS may be due to under reporting pre-DBS symptoms. However, while the stimulation is on, PD patients may show increased impulsivity in their responsiveness and general behavior. There are also reports of patients who develop hypomania\*. Behavioral changes and hypomania may also be seen in previously depressed patients with the starting of antidepressants that push them over the edge.”

- Hypomania = symptoms including elevated mood, increased activity, decreased need for sleep, grandiosity, racing thoughts, and the like. Hypomanic episodes, unlike manic episodes, do not cause significant distress or impair one’s work, family, or social life in an obvious way while manic episodes do.