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Implementation of a Deep Brain Stimulation Perioperative Pathway for Patients with Medically Refractory Neurological Movement Disorders

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Abstract

Title: Implementation of a Deep Brain Stimulation Perioperative Pathway for Patients with Medically Refractory Neurological Movement Disorders

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Purpose: This project aims to evaluate the outcomes of patients with medically refractory movement disorders treated with deep brain stimulation (DBS) following implementation of a standardized care pathway. Aims included decreasing length of stay (LOS), improving cost efficiency, reducing unintended 30-day readmission rates, and optimizing overall patient care.

Methods: A quality improvement project was conducted at a single, large academic medical center located in the southeastern United States and focused on adult patients (>18yrs) with Parkinson’s disease, essential tremor, or dystonia undergoing initial DBS implantation. A multidisciplinary team was developed and a value stream mapping (VSM) analysis of the DBS process was performed to identify areas of unnecessary cost, inefficiency, and potential improvement. An evidence-based DBS clinical pathway was developed and implemented into practice including updating patient education materials, perioperative order sets, anesthesia protocols and a patient satisfaction survey. Pre-implementation (N=150) and post-implementation (N=29) cohorts were statistically compared for differences in LOS, readmission rates and cost, during stage 2 (electrode implantation) of the DBS process.

Results: A significant predictor of increased LOS was living in a rural county (p=0.010). Increased cost was associated with age >65 (p<0.0001), primary diagnosis essential tremor (p=0.050), and ethnicity (p=0.004). Readmission rates are higher in patients with >2 baseline medical comorbidities (p<0.001) and males have a significantly shorter interval to readmission than women (p=0.013).
**Discussion:** Clinical pathways are used for quality improvement in many areas of healthcare as it provides evidence-based interventions such as protocols and guidelines for standardized care and optimization of patient outcomes. Despite high interest and value in clinical pathways, there is low utilization, particularly in functional neurosurgery. Implementing a clinical pathway can benefit DBS patients by ensuring they receive interventions in a timely and efficient manner, reducing practice differences, and improving patient satisfaction.

**Conclusions:** Implementation of this DBS perioperative pathway yielded improvements in patient education, provider-patient communication, optimization of perioperative order sets, supply costs, and medications. Further study with a longer post-pathway implementation period and larger patient sample size is warranted.

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Implementation of a Deep Brain Stimulation Perioperative Pathway for Patients with Medically Refractory Neurological Movement Disorders

In the United States, around 40 million people have some type of movement disorder (International Neuromodulation Society [INS], 2018). Patients with movement disorders may have involuntary movements such as tremors, abnormal posture, bradykinesia, difficulty walking, rigidity and/or stiffness (INS, 2018). Most neurological movement disorders are progressive, incurable and can significantly impact a person's ability to function independently resulting in decreased quality of life. Deep brain stimulation (DBS) is an established treatment option for neurological disorders such as Parkinson’s disease, essential tremor, and dystonia. Other disorders treated by DBS that are approved by the Food and Drug Administration (FDA) include obsessive-compulsive disorder and epilepsy. DBS is a neurosurgical procedure that encompasses implantation of electrodes into specific brain regions in combination with continuous electrical stimulation generated by an implanted battery to correct abnormal signals and improve clinical motor symptoms (Lozano et al., 2019).

As of 2019, more than 160,000 patients worldwide have undergone DBS implantation for various neurological conditions (Lozano et al., 2019). Long-term outcomes of DBS are beneficial for symptom relief, independent activities of daily living, mental health, and improved quality of life (Hitti et al., 2020). In review of published literature, tools such as clinical pathways are used for quality improvement in many areas of healthcare. A clinical pathway provides evidence-based interventions such as protocols to standardize care and optimize patient outcomes. Regardless of the known value of clinical pathways, there is low utilization and a significant lag in the implementation of neurosurgical functional pathways. This paper describes
a quality improvement project to implement a novel DBS pathway at a large academic hospital with a high-volume DBS program with the goals of decreasing length of stay, optimizing cost efficiency, reducing unplanned 30-day readmission rates, and ultimately optimizing patient care.

**Background & Significance**

A large academic medical center located in the southeastern United States was one of the first principal investigators for DBS. This single institution is one of the highest volume DBS centers in the country. The hospitals’ first DBS operation occurred in 1995 as a part of a multi-center trial of Medtronic’s DBS system, which received approval from the FDA in 1997.

Providing DBS therapy to approximately 120 patients per year and thousands of cases in over 25 years, this high-volume institution is a national leader in DBS treatment, using a multidisciplinary team of neurologists, neurosurgeons, neuropsychologists, neurophysiologists, anesthesiologists and physical therapists to provide safe and effective treatment.

DBS employs electrodes typically placed bilaterally in a one or two staged procedure, that are implanted into a targeted area of the brain, most commonly the subthalamic nucleus (STN), globus pallidus internus (GPi), or ventral intermediate nucleus of the thalamus (VIM). The target area is collaboratively chosen by a multidisciplinary team of physicians based on the patient’s symptom profile, age, and cognitive status. DBS implementation at this medical center is performed in a series of three staged procedures. Stage one is an outpatient procedure in which bone markers (small screws) are placed in the skull under general anesthesia and thin cut MRI and CT scans are obtained. These scans are then used to make a surgical treatment plan which is submitted to a company (FHC Inc.) that 3D prints and returns a custom stereotactic frame to be used during stage two. In stage two, the surgical team consists of a neurosurgeon, a neurologist, and a neurophysiologist. A DBS electrode (approximately 1.3mm in diameter) is implanted in
the brain region target of interest either unilaterally in a staged procedure (2A & 2B) or bilaterally in one procedure, through small holes made in the skull while the patient is awake and off medications to monitor neurologic status and perform testing to measure symptom benefit and side effects of stimulation. A combination of microelectrode recording (MER) and macroelectrode stimulation is used to find the preferred target physiologically. Once the targeted area is located, the DBS lead is anchored to the skull with a burr hole cap. Afterwards, a CT is done to confirm there is no hemorrhage. The patient usually stays in the hospital overnight after stage two. Finally, in stage three, under general anesthesia an implantable pulse generator (IPG) or battery is placed subcutaneously in the subclavicular region and connected to the intracranial electrodes (Crosley, 2018). A month after stage three, the neurologist activates and programs the DBS to provide therapy. When the system is completed and turned on, the DBS system sends electrical pulses to regulate the abnormal signals in the brain responsible for body movements. The amplitude, frequency, and pulse width of stimulation can be changed to control symptoms and minimize side effects. The usual stimulation parameters are an amplitude of 1-3 V, a frequency of 135-185 Hz, and a pulse width of 60-120 msec (Slavin, 2020). Once the DBS is programmed, the patient has the ability to use a handheld device to make minor adjustments to the strength of the stimulation, select different stimulation programs, and turn the stimulator on and off. Patients can follow up with their neurologists as needed for further adjustments.

A review of published literature shows postoperative DBS complications are rare, but can be serious, the most common complication of which is infection. There is a 4-12% risk of infection per patient or 1.5-9.7% risk per lead, with most cases of infection occurring in the first three months postoperatively (Lange et al., 2019). Infections can be superficial and treated with oral antibiotics while deeper infections may require removal of some or all of the DBS system.
along with long-term antibiotic treatment (Lange et al., 2019). Delirium is another post-operative complication, with around 22% of patients experiencing delirium or confusion after DBS surgery (Tanaka et al., 2018). Postoperative delirium is associated with worse outcomes, longer hospital stays, and increased cost (Tanaka et al., 2018; Li et al., 2021; Abboud et al., 2019). A more recent study reports postoperative delirium rates as high as 42.6%. Studies have shown age (> 55 years) to be a major risk factor for postoperative delirium with the average onset of delirium starting approximately 1.57 days after surgery and lasting approximately 1-4 days (Li et al., 2021). Causes of readmission include surgery-related events (3.7%), altered mental status (1.8%), seizures (1.2%), infection (0.6%), and intracranial hemorrhage (0.6%). All causes of 30-day readmission rates for DBS is 6.6% with a significant correlation to number and severity of comorbidities (Ramayya et al., 2017). Quality improvement projects should aim to analyze and increase awareness of these common complications to instigate change in practice.

The management of DBS patients requires specialized care in a multidisciplinary center. A well-organized and efficient patient flow is necessary to ensure that eligible patients can receive DBS treatment quickly. An analysis of the current practice helps to identify areas for improvement. Upon evaluation of this medical center’s current DBS process, discrepancies were found in provider-patient communication between the clinic and inpatient teams, cost efficiency, and consistency throughout the deep brain stimulation procedure process due to treatment by multiple rotating providers. Other program concerns included decreasing the number of calls or pages to the hospital and clinic staff, optimizing preoperative, intraoperative, and postoperative supplies, focusing on the overuse of medications, restarting neurological medications as soon as possible to prevent exacerbation of symptoms, along with prevention of nausea/vomiting, pain,
and delirium. Identifying these areas needing improvement would ideally aid in decreasing hospital length of stay, complications, cost and unplanned readmissions.

**Problem Statement**

A large academic medical center with a high-volume DBS program that does not have a defined perioperative pathway. Although the surgery is the same, there are multiple rotating residents and providers caring for DBS patients. Initiating a standardized approach will help optimize patient care and reduce costs.

**Purpose of the Project**

The purpose of this project is to implement an adult DBS pathway to decrease the length of stay, improve cost effectiveness, and reduce unintended 30-day readmission rates. This initiative is a quality improvement project designed to evaluate the implementation of an adult perioperative care pathway for patients with medically refractory neurological movement disorders, such as Parkinson’s disease, essential tremor, or dystonia, undergoing DBS treatment. The plan aims to evaluate the factors surrounding the quality improvement of the DBS process, including direct variable costs, length of stay, and causes for readmission.

**Clinical Question:** Will implementation of a standardized clinical pathway for adult deep brain stimulation patients decrease the length of stay, costs, and readmissions?

**Project Aims:**

1) Implementation of a deep brain stimulation clinical pathway during Stage 2 will decrease the length of stay in patients with medically refractory neurological movement disorders.

2) Analysis and optimization of direct variable costs during Stage 2 for cost effectiveness.

3) Decrease unplanned 30-day readmission rates with the implementation of the clinical pathway after Stage 2.
4) Evaluate demographic factors that contribute to each of the above three aims (LOS, costs, and readmissions), and determine how implementation of a clinical care pathway affects them.

**Mechanism of Deep Brain Stimulation**

Details of the mechanism of action are not entirely known but several hypotheses exist. Overall, DBS is thought to normalize or modulate the pathologic neurophysiological signals within motor networks that result in movement disorders. The purpose of electrical stimulation therapy is to apply an electric current that influences the opening and closing of voltage-gated sodium channels on neurons bringing about action potentials that control the release of neurotransmitters in targeted pathways (McIntyre & Anderson, 2016). The pathways involved are the cerebellothalamic tract that aids in reducing tremor, the nigrostriatal tract that increases dopamine, and the zone of uncertainty involved in any motor symptom (Marin et al., 2022). In general, the mechanism of action of DBS is that it alters the underlying neural activity near the implanted electrode and replaces it with a less harmful activity pattern (McIntyre & Anderson, 2016).

Experimentalists from the 1960s and 1970s determined that the primary result of electrical stimulation in the central nervous system was the generation of action potentials (AP) in axons. Theoreticians later found the response of an individual neural process to the applied field was related to the extracellular voltage distribution along its trajectory. Newer methods make it possible for the use of a tractography obtained from diffusion-weighted imaging to show the trajectory of a stimulated axon and then apply the DBS voltage on that trajectory called the tractography-activation model. This model makes it possible to predict which axonal pathways may be activated by DBS electrical pulses within the patient-specific anatomy. Thus, the applied
DEEP BRAIN STIMULATION PATHWAY

electric field on the neuronal process is to cause a transmembrane voltage change that can open voltage-gated sodium channels on the axon. The cathodic phase of the electrical pulse causes a membrane depolarization in the nodes of Ranvier near the electrode contact. The magnitude of that depolarization is reliant on the shape of the axon trajectory and its closeness to the electrode contact. If the stimulus amplitude is adequate to generate depolarization that crosses the activation threshold for that axon, an AP will be generated and spread in both directions. Once APs are generated, they usually disperse to their axon terminals and cause neurotransmitter release. In each stimulated neuron, each AP can generate hundreds of synaptic events throughout the complex axonal arbor of that neuron (McIntyre & Anderson, 2016).

Other theories propose that DBS functions through local and network-wide electrical and neurochemical effects of stimulation, regulation of oscillatory activity, synaptic plasticity, neuroprotection, and neurogenesis. DBS may hinder the network of neurons in the target, known as the inhibition hypothesis (Slavin, 2020). On the other hand, DBS can excite local neuronal components, just as a single stimulation called the excitation hypothesis (Chiken & Nambu, 2016). DBS can stimulate the efferent axons to reduce the pathological rhythms and involvement of neuronal networks, leading to effective benefits. Using high frequency stimulation may create a global hyperpolarization of the cell membrane, that results in a loss of excitability. Alternatively, stimulation can prevent the flow of signals from dysfunctional structures. Depolarization can also affect neuronal activity at sites distant from the stimulation target. Finally, stimulation-induced disruption of pathological network activity may explain the effects of DBS on abnormal movement disorders. Another theory is that DBS creates an informational lesion in the circuit that controls neuronal network activity by neurochemistry modulation, such
as an increased response of dopamine and gamma-aminobutyric acid (GABA) neurotransmission (Slavin, 2020).

In the future, a greater understanding of pathophysiology will allow for the discovery of useful biomarkers or biomarker combinations to target in order to control stimulation. As technology evolves, the use of rechargeable systems and secure telemetry will give providers the ability to wirelessly upload data with little impact on device longevity. This allows for more continuous patient assessments to assist in more individualized treatment. Modern device technology has enhanced algorithms that sense brain signals and apply stimulation only when a physiologic biomarker that correlates with clinical symptoms reaches a certain threshold (responsive closed-loop stimulation) or to change with the level of that biomarker (adaptive closed-loop stimulation). The ability to update algorithms is beneficial in those with rechargeable devices, as responsive or adaptive stimulation decreases battery use, prolongs battery life, and increases the time needed between surgical battery replacements. In addition, there will be minimization of device design and surgical techniques in which the leads can be implanted through a less invasive procedure to decrease the risk of infection in the hospital setting thus further advancing the field of neuromodulation (Cagan et al., 2019).

**Review of Literature**

Prior to the advent of DBS, movement disorder treatment consisted of ablative methods using mostly radiofrequency to lesion the thalamus or the pallidum, structures involved in common motor pathways. To predict the effects of the lesioning, surgeons used high frequency stimulation, which gave a constant effect on tremor that was immediately reversible. This idea to manipulate the function of neuronal tissue with electricity rather than to destroy it led to the development of neuromodulation therapies. Neuromodulation was first described in 1987, when
Alim Louis Benabid and colleagues revealed that in patients with Parkinson disease (PD), DBS not only imitated the beneficial effects of ablative surgery, but also offered adjustability and reversibility (Ashkan et al., 2017; Chiken & Nambu, 2016). This discovery brought about the development of a fully implantable DBS system, which changes neural function through the application of electrical currents (Jakobs et al., 2019).

As described by the National Institute of Neurological Disorders and Stroke (NINDS), DBS is a surgical procedure used to treat many neurological diseases, especially movement disorders that are refractory to medical treatment. It consists of a neurostimulator or battery device (similar to a cardiac pacemaker), which sends electrical stimulation to a specific area in the brain, blocking abnormal nerve signals. The Federal Drug Administration first approved DBS in 1997 to treat essential tremor, in 2002 it was approved for Parkinson’s disease, and in 2003 for dystonia. For a select patient population, DBS is the gold standard interventional treatment for medically refractory Parkinson’s disease. DBS is also used to treat epilepsy along with mental disorders such as depression, obsessive-compulsive disorder, and Tourette syndrome. DBS has several advantages over other surgical procedures such as reversibility, adaptability, and titratability to tailor therapy based on the progression of the neurodegenerative disease. It also has disadvantages such as high cost and procedure-associated risks or complications (Marin et al., 2022). Currently, use of DBS primarily occurs in high-income countries and is on the rise in several developing countries. DBS incurs large capital costs and therefore must be performed at a large institution with an expert multidisciplinary team to provide programs for patients (Lozano et al., 2019).

Deep brain stimulation is seen as giving a new life to people with movement disorders. Ongoing research continues to look at the off-label use of DBS in other disorders such as
addiction, anxiety, and schizophrenia. The literature is abundant, with research studies showing benefits such as a decrease in morbidity and mortality rates, optimization of medication dosages, and reduction in preventable adverse drug events. Successful deep brain stimulation requires multidisciplinary collaboration, communication, and care. A multidisciplinary DBS team includes a neurosurgeon with expertise in functional neurosurgery, a movement disorder neurologist, neuropsychologist, neurophysiologist and a physical therapist. The inpatient and clinic nurses play an essential role in the patient's outcome to gain maximum benefit from surgical intervention. All healthcare workers who care for DBS patients must be engaged and in sync for the patient to achieve optimal results. Therefore, implementing a deep brain stimulation clinical pathway may prove to be beneficial in maximizing patient outcomes. After reviewing the literature, there is limited information on DBS pathways and few on anesthesia management, but none specifically on a complete perioperative pathway.

**Clinical Pathways in Quality Improvement**

The primary focus of quality improvement initiatives is the optimization of patient safety and quality healthcare. Tools such as clinical pathways are implemented in many areas of healthcare to support continuous quality improvement. Despite high interest and value in clinical pathways, there is low utilization of pathways, particularly in functional neurosurgery. Clinical pathways aim to organize and standardize care processes, improve organization efficiency, and maximize patient outcomes. In the United States, clinical pathways have been used since the 1980’s. Their objective is to improve morbidity and mortality rates while containing costs and maintaining quality of care (Lawal et al., 2016).

**Gaps in Literature**
A systematic review of neurosurgery care pathways returns twenty-four clinical pathways with only one functional neurosurgery pathway (Lee et al., 2021). This systematic review shows a lag in functional clinical pathways but may not be all inclusive of the literature given the inclusion criteria used. In reviewing the functional pathway, Thomas et al. (2017) developed a DBS pathway in patients with Parkinson’s disease to optimize the flow process for access to DBS treatment earlier. The new pathway reduced referral time and length of inpatient hospital stay, while increasing the number of consultations and implants per year. Overall, the pathway allowed more Parkinson’s patients to benefit from treatment while improving the quality of care. Clinical pathways have been successfully developed across many neurosurgical subspecialties, however, there is a lack of design standardization (Thomas et al., 2017).

**Advantages of Enhanced Recovery After Surgery (ERAS) Pathways**

ERAS pathways in neurosurgery addresses all aspects of care from preoperative, intraoperative, and postoperative periods. The focus is on management of acute postoperative pain, nausea and vomiting, and early mobilization. The objective of post-operative care is to prevent or minimize complications such as pneumocephalus, intracranial hemorrhage, cerebral edema, seizures, and stroke. Research shows early functional recovery reduces the number of hospital days after elective intracranial surgeries with the implementation of an evidence-based ERAS pathway (Wan A & Luoma, 2020). Advantages of an ERAS pathway versus general perioperative management is that ERAS pathways help to improve healthcare value. In the United States, research shows the implementation of ERAS pathways results in a decrease in hospital length of stay which has an immense impact on the cost of acute care for hospital stays after surgery. In a minimally invasive spinal surgery study, looking at conventional perioperative care versus ERAS, the average cost savings was $3,444 per patient or greater than 15% cost
savings per patient (Patil et al., 2019). ERAS pathways may also encourage a decrease in opioid use by instead using local anesthetics or nonopioids medications such as nonsteroidal anti-inflammatory drugs (Patil et al., 2019).

Pathways enhance continuity of care and patient satisfaction while also improving efficiency, teamwork, staff education, and reducing variation in practice (Lee et al., 2021). Many studies have evaluated neurosurgery ERAS pathways for elective surgeries, including craniotomies. A randomized clinical trial, comparing a conventional protocol to an ERAS pathway, enrolled a total of 140 patients between October 2016 to May 2017. Findings showed the ERAS protocol decreased length of stay by four days, patients had less pain and a quicker recovery with no difference in 30-day readmissions. Overall, ERAS had significant benefits over conventional perioperative management (Wang et al., 2018). In another ERAS pathway, that included evidence-based interventions, protocols, and guidelines, it helped to maintain safety in the operating room, improve efficiency, decrease costs, improve postoperative recovery and patient outcomes. Also, using early mobilization and minimizing opioid use reduced postoperative complications. ERAS is a multidisciplinary approach that improves patient outcomes by decreasing recovery time, reducing the length of stay, and shortening procedural time (Patil et al., 2019). At a tertiary neurosurgery center from 2008-2017 order sets, protocols, and pathways were developed after a retrospective review of 3.693 admissions. After implementing these new order sets, protocols, and pathways, there was a reduction in craniotomy complication rates, improved length of stay, reduction in costs, increased teamwork and satisfaction. Patients and families felt better informed. Protocols and pathways improved the consistency of care after discharge from the hospital with medications, instructions, wound care,
activity levels, and appointments (Akins et al., 2019). Research significantly favors a clinical pathway or ERAS to move patient care forward while decreasing costs (Patil et al., 2019).

**Disadvantages or Barriers of Enhanced Recovery After Surgery (ERAS) Pathways**

There are a number of challenges to the implementation of clinical pathways, the largest being lack of physician awareness, limited buy-in, or pushback. Cost is another major barrier to pathway development (Chawla et al., 2016). Pathways also consume a considerable amount of time and resources (Rotter et al., 2019). A systematic review identified barriers to the implementation of clinical pathways such as insufficient staffing, increased workload, little education, lack of financial compensation, low motivation, and not enough time (Seckler et al., 2020). There is a lack of formal published standards for clinical pathways resulting in variations in development, implementation, evaluation, and the monitoring process (Chawla et al., 2016). Clinical pathways are perceived to be too restrictive, inflexible, and focus on a narrow part of the care-continuum. Restrictive technology is also felt to be a limitation given its influence on the way pathways are conceptualized, designed, and implemented (Patkar et al., 2017). These challenges provide insight into the lack of utilization of clinical pathways or ERAS.

**Successful Implementation of Enhanced Recovery After Surgery (ERAS) Pathways**

Nurses play a key role in the successful implementation of clinical pathways by providing education, perioperative care, postoperative evaluation, and cost containment (Brady et al., 2015). Other strategies for a successful implementation of the clinical pathway include ensuring patient participation, physician acceptance, full participation of support staff in the plan of care, and executive leaders allowing for appropriate execution. It takes a multidisciplinary approach to apply current evidence-based practice for improvements in perioperative care and patient outcomes with a reduction in healthcare costs. Encouraging patient participation in
recovery is important for success. Preparing patients with expectations, roles, and responsibilities helps to ease their anxiety and empower them to be successful in their recovery (Patil et al., 2019). Seeking out patient feedback about the care they received, and making resultant changes also reinforces the importance that patient experiences can have in shaping clinical practice. Identifying barriers to change, clinician involvement, identification of evidence-based practice gaps, optimizing the evidence-based content, adoption of evidence, staff education sessions, and monitoring of compliance and outcomes are key success factors for the implementation of research into practice (Rotter et al., 2019).

**Summary of the Literature**

Clinical pathways are implemented for specific groups of patients with similar health conditions. Pathways assist to reduce changes in patient outcomes, costs, and to help patients and families stay informed about their treatment course (Lawal et al., 2016). An enhanced recovery after surgery (ERAS) or clinical pathway is an organized perioperative healthcare pathway that encompasses evidence-based interventions such as protocols and guidelines aiming to provide standardized care (Patil et al., 2019). Despite the benefits, there are challenges in implementing clinical pathways or ERAS including conceptualization, implementation, evaluation, and sustainability. There are also many different terms used for clinical pathways in the literature such as care maps, critical pathways, protocols, or algorithms with no clear standard definition making the concept confusing and difficult to research (Lawal et al., 2016).

Pathways are viewed as a roadmap for patient care, relying on multidisciplinary involvement and utilization of a variety of health care specialties often showing positive results (Lee et al., 2021). A Cochrane review defined five criteria for a clinical pathway to include an organized multidisciplinary plan of care, translation of guidelines to current practice, provides
specific steps in a course of care, gives a timeframe, and aims to standardize care for a specific population, problem, or procedure (Youngerman et al., 2019). Implementing a clinical pathway can benefit DBS patients by ensuring they receive interventions in a timely and efficient manner, reducing practice differences, decreasing readmissions, and improving the length of stay and patient satisfaction (Lee et al., 2021). These aforementioned studies show that clinical pathways or ERAS vary greatly across medical institutions.

**Theoretical Framework**

Kurt Lewin (1947) is considered the founding father of change management. His Three-Step Model for Change was used as a basis in implementing a deep brain stimulation (DBS) pathway. Lewin’s theory suggests that people are influenced by restraining forces intent on keeping the status quo and driving forces for change that push and cause change to happen. To change the status quo and stay relevant, healthcare systems must respond to an ever-changing environment which can be a complex and challenging process. Change requires perseverance against the current culture and norms of already established behavior. As a part of the change process, leadership buy-in is crucial in implementing an organizational change. For change to be effective, it requires unfreezing old habits, introducing new behaviors, and re-freezing or maintaining the new habits and behaviors (Wojciechowski et al., 2016). This calls for health organizations to implement planned changes using Lewin’s three-step model. Lewin’s Three-Step Model for Change includes first unfreezing, or problem recognition, making it possible for people to let go of old habits (e.g., challenging the status quo), then changing, or seeking alternatives, demonstrating the benefits of change, and reducing negativity (e.g., brainstorming, role modeling new ways, training) and finally refreezing, which is establishing a new standardized system, creating new habits and behaviors (e.g., success, re-training, and
monitoring) (Wojciechowski et al., 2016). By utilizing a multidisciplinary team approach using Lewin’s Model to address problems and implement or update practices, healthcare systems can improve and maintain the best outcomes for safe and high-quality patient care.

In addition to Lewin’s change theory, the Lean Systems Approach Model was also used to develop the DBS pathway. The Lean Model is a people-based system and focuses on improving processes, standardizing workflow, and empowering staff. This model creates value by breaking down problems and eliminating waste (e.g., time, inventory, product use). Value stream mapping (VSM) is a resource in the Lean Model toolkit. VSM is used to identify the flow of materials and information. The Lean Model creates a culture where a multidisciplinary team is empowered to make changes using the VSM that leads to creating value, improving workflow, increasing quality, reducing costs, and maximizing efficiency (Wojciechowski et al., 2016).

Some people have criticized Lewin’s model for being too simple, while the Lean model is seen as inflexible. Despite this criticism, concepts from both Lewin’s Three-Step Model for Change, and the Lean Systems Approach promote a multidisciplinary collaboration, and a problem-solving approach for change. Lewin’s theory is significant in change management and continues to influence change theory and practice to this day (Wojciechowski et al., 2016).

Utilizing Lewin’s Model, the hospital stakeholders were supportive of changing the status quo or unfreezing the current DBS process. A multidisciplinary team was developed which was comprised of stakeholders, including neurosurgeons, neurologists, residents, anesthesiologists, clinical staff, operating room (OR) staff, advanced practice providers and nurses, who encompassed each part of the DBS patient’s journey from their first clinic visit through all three surgeries (Stage 1, 2, & 3). The multidisciplinary team was asked to participate in VSM illustrating the current state for a patient undergoing DBS, identifying a future state (ideal state),
and listing solutions. The stakeholders were able to identify areas of improvement, breakdown the problems and find solutions to limit waste, standardize processes, and improve workflow. Next, an action plan was established based on the ideal state and solutions from the VSM. The future state of the VSM was used to initiate standardization of intraoperative anesthetic management guidelines, cost analysis, education for the functional healthcare team (nursing staff, residents, anesthesiologists, advanced practice providers, and pharmacists), preoperative and postoperative patient education and order sets (changing). Finally, post-implantation analysis of the DBS pathway was performed using a retrospective chart review with the aim of demonstrating optimization of patient care and establishing a new culture (refreezing) within the functional medical team. Applying the Lewin’s Model and Lean Model to the development and implementation of the DBS pathway helps to establish a standardization of processes and optimization of patient care which is the purpose of this project.

**Methods & Implementation**

**Design**

The current project study design used a pathway for DBS patients focusing on patients with Parkinson’s disease, essential tremor, or dystonia, undergoing initial implantation of their system. The pathway started from the time of referral to neurosurgery until the completion of all three DBS stages. A retrospective chart review was conducted pre- and post-implementation. The patient population included adults (>18 years) with Parkinson’s disease, essential tremor, or dystonia patients undergoing initial DBS placement of all three stages in succession. Current procedural terminology (CPT) codes (e.g., CPT Codes for stage I: 70553; CPT Codes for stage II: 61867, 61868, 61863; CPT Code for stage III: 61886) and International Classification of Diseases, Tenth Revision (ICD 10) codes of Parkinson's disease (G20), Essential Tremor (G25),
and Dystonia (G24.1, G24.8, & G24.9) were used to identify the number of surgeries, patient details, procedural details and associated costs. IPG replacements were excluded.

**Setting**

This project was conducted in the ORs, inpatient floors and clinics at one of the largest Southeastern academic medical centers that is a primary resource for specialty and primary care throughout Tennessee and the Mid-South. This medical center has over a thousand hospital beds and manages more than two million patient visits each year. The neurological department is ranked in the top fifty in the nation (US News & World Report, 2021). Approximately 120 DBS cases are performed here each year.

**Variables**

Analysis of variables for length of stay at each stage includes age, sex, race, city, state, county, payor, medical comorbidities, complications and time of day for surgery. Other variables include the top three to four direct variable cost line items, their breakdown and unintended 30-day readmission rates.

**Resources**

An multidisciplinary team was developed which included stakeholders representing each aspect of care from referral to completed DBS implementation (i.e., neurosurgeons, neurosurgery residents, neurologists, neuroanesthesiologists, certified registered nurse anesthetists, advanced practice providers, pharmacists, operating room staff, frame companies, clinic and hospital nurses, and nurse educators). Statisticians collected pre- and post- intervention de-identified data using CPT codes and ICD 10 codes. The information technology team (IT) assisted with placing the DBS pathway into the EPIC computer system.

**Instruments/Tools**
Value stream mapping (VSM), was used to analyze the current DBS process to identify areas of waste, inefficiency, and improvement. Adjustments were made in these areas to optimize an evidence-based clinical pathway for DBS patients. The Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) were used as resources for standards of care and best clinical practices (Youngerman et al., 2019).

**Data Collection/Implementation Plan**

At a single institution, a multidisciplinary team was developed, and a zoom meeting was held where stakeholders discussed the current process for the initial implementation of the deep brain stimulation (DBS) system. It was determined there was a need to standardize a DBS pathway given the high volume of DBS cases performed. A retrospective chart review of Parkinson’s disease, essential tremor, and dystonia patients undergoing initial implantation of DBS between January 1, 2018 through January 1, 2020 was conducted. Data was collected on patient demographic data (age, gender, race, payor, primary diagnosis, comorbidities, complications, length of stay, and readmissions) on 150 pre-pathway implementation DBS patients. To evaluate the time aspect of the current process, value stream maps (VSMs) were created detailing steps at each stage from presentation at multidisciplinary DBS conference to the first clinic visit to each of the three stages of implantation (bone markers and CT/MRI under anesthesia, lead implantation with intraoperative testing, and internal pulse generator implantation). These VSMs were reviewed and areas for improvement were agreed upon by stakeholders. To evaluate the cost aspect of the current process, meetings were held with members of the billing department, neurosurgeons and OR staff to analyze the data of materials used for patients from January 1, 2018 through January 1, 2020, including operating room
materials, medications, and care-related charges. This data was reviewed to identify extraneous materials and inconsistencies in material use with the goal of minimizing cost by eliminating the use of unnecessary materials. Pre- and post-operative order sets, as well as pre- and post-surgical instructions given to patients were reviewed and standardized as agreed upon by all stakeholders including inpatient/outpatient clinical staff. Meetings were held with the anesthesia providers to optimize the DBS evidence-based practice anesthesia protocol for all three surgical stages. To evaluate the patient experience, an anonymous 10-question survey was administered to patients after the completion of the implantation process. After all of these aspects of the DBS process were discussed and analyzed, a standardized DBS pathway was drafted, shared, agreed upon and implemented by all stakeholders in the Fall of 2022. This pathway includes:

1. Clinic protocols detailing the timeline of initial clinic appointment, patient education materials (See Appendix A), patient information pamphlets (detailing when to stop certain medications and what to do to prepare for each procedure).

2. Peri-procedural/inpatient protocols - standardizing pre- and post-operative care order sets (including labs, scans, medications and post-surgical care, See Appendix B, C, & D).

3. Optimizing an evidenced-based anesthesia protocol (See Appendix E).

4. Operating room protocols - standardizing materials used for each case, and access to/location of certain materials (e.g., frame).

5. An ideal timeline for each stage of the process and the entire process.

6. Identification of deviations from this pathway and reasons they occurred.
All caregivers involved in and affected by this pathway were informed and educated, by voice over PowerPoint, to ensure all are adhering to the protocols. The new DBS clinical pathway was implemented from October 1, 2022 through December 31, 2022. Length of stay, cost, and readmission data were again collected by retrospective chart review in February 2023 and analyzed to quantify resultant changes. The same patient survey given pre-implementation was also administered post-implementation to understand the impact on patient experience, given time constraints this part of the project was unable to be completed as there was not enough time to receive all the post implantation patient surveys (See Appendix F for survey). The DBS pathway was discussed with all caregivers about its feasibility and ease of use, and ideally implemented into standard practice of care at this institution (See Appendix G for Gantt chart timeline).

**Institutional Review Board**

This project was determined to not meet research criteria as described in 45 CFR 46.101(I). IRB approval was not required by either the medical center or Florida State University (See Appendix H & I).

**Results**

**Demographics**

Of the 150 DBS pre-implementation patients who underwent stage 2, 101 patients (67.3%) underwent bilateral electrode implantation in one surgery and 49 patients (32.7%) underwent bilateral electrode implantation during a two-staged surgery with one electrode implanted per surgery. The majority of patients were male (62%) and Caucasian (94%). The age range of the total cohort was 28-81 years, with the majority being greater or equal to 65 (52%). Most patients were from Tennessee (71.3%) and Kentucky (11.3%). Patients were from 121
(80.7%) rural and 29 (19.3%) urban counties. Diagnoses included Parkinson’s Disease (53.3%), Essential Tremor (43.3%), and Dystonia (3.3%). Most patients had more than two comorbidities 159 (88.8%) and the major insurance provider was Medicare 77 (51.3%). This is summarized in Table 1.

Of the 29 DBS post-implementation patients for stage 2, all 29 patients (100%) underwent bilateral electrode implantation in one surgery and 0 patients (0%) underwent bilateral electrode implantation during a two-staged procedure with one electrode implanted per surgery. Previously only patients 75 years of age or older qualified for the two staged, stage 2 procedure, but over the last several years this rigid age “cutoff” has been removed and thus there are fewer staged procedures then previously. Now, if patients are at higher risk of delirium or cognitive deficits, then surgery will still be performed in a staged procedure. The majority of patients were female (58.6%) and Caucasian (93.1%). The age range of the total cohort was 25-84 years, with 44% greater than or equal to 65. Most patients were from Tennessee (72.4%) and Kentucky (6.9%). Patients were from 21 rural counties (72.4%) and 8 urban counties (27.6%). Diagnoses included Parkinson’s Disease (55.2%), Essential Tremor (37.9%), and Dystonia (6.9%). Most patients had more than two comorbidities 27 (93.1%) and the major insurance was Medicare 11 (37.9%). This is summarized in Table 2.

Analysis

There was a total of 150 pre-implementation patients and 29 post-implementation patients. Descriptive statistics were reported to compare two groups: one comparing all pre-implementation patients regardless of staged stage 2 procedure versus all post-implantation patients and one comparing only those pre-implementation patients who underwent nonstaged, bilateral stage 2 versus all post-implementation patients. Mean and standard deviation were
reported for continuous variables and frequency for categorical variables. T-tests were used as a parametric test for continuous variables, Wilcoxon signed rank or Mann-Whitney test were used as non-parametric tests to compare continuous variables, One-way ANOVA test was used to compare continuous and ordinal baseline variables of variables with more than two categories, and chi-square or Fischer’s exact test were used for categorical variables. Multivariable linear regression was subsequently performed to predict the impact of post-implementation on readmission, LOS, and cost, controlling for the factors that showed a significant difference on bivariate analysis: age, ethnicity, having nonstaged versus staged stage 2 surgery, and primary diagnosis. Alpha-value <0.05 was considered significant. All analyses were performed using SPSS version 22 (IBM Inc., Chicago, Illinois).

**Aim 1.** The first aim sought to evaluate if there was a statistical difference in length of stay (LOS) in hours for overnight admission after stage 2 between patients in the pre-pathway implementation cohort and the post-pathway implementation cohort. Pre-implementation LOS for stage 2 was a mean of 33.6 ±22.8 hours. For those pre-implementation patients who had nonstaged bilateral stage 2, LOS mean was 35.4 ±25.4 hours. Reasons for longer length of stay pre-implementation included hemorrhage around a lead, edema around a lead, hypotension, hypertension, nausea/vomiting, confusion/delirium, sedation, seizure, and pain. For post-pathway implementation analysis, LOS during stage 2 had a mean of 31.0 ±11.0 hours. Notably, none of the post-implementation patients underwent a two staged, stage 2 procedure. In comparison there does appear to be a trend of decreased length of stay in hours, however, there is no significance. However, a significant predictor in length of stay was home county, where patients living in rural areas had a longer LOS.
Aim 2. The second aim examines whether making changes to post-operative orders, operating room materials, and medications, decreases stage 2 total costs based on 4 sub cost variables (operating room services, supply, pharmacy, and nursing- for breakdown see Table 3). Pre-implementation stage 2 costs a mean of $16,336.7 ±$3,654.9. For those patients who underwent a nonstaged stage 2, the cost of the second procedure was a mean of $17,727.3 ±$3,336.1. For post-pathway implementation analysis, the cost of stage 2 in one surgery was a mean of $20,573.4 ±$2,989.4. There were no patients who had the two staged procedure post-implementation. The increased cost post-implementation was likely due to inflation over the 2-year interval between pre-and post-implementation, as well as the advent of new DBS devices that have increased cost. Relaxing the age criteria for a staged surgery and combining the two stages of the stage 2 surgeries into one resulted in decreased cost. There were three variables that affected cost - patients who were older, ethnicity, and primary diagnosis.

Aim 3. The third aim examines the statistical difference in 30-day readmission rates (in days) after completion of stage 2 in a pre- and post- pathway implementation groups. The pre-implementation cohort had a 30-day readmission rate of 11/150 (7.3%). Reasons for readmission included infection, seizures, headache, nausea/vomiting, cerebrospinal fluid leak, hemorrhage, subdural hematoma, and edema around a lead. For post-pathway implementation analysis there were no readmissions. This is a major finding that is not statistically significant, that may be seen trending in the direction toward improved readmission rates, thus a longer post-implementation period is required to truly study this outcome.

Aim 4. For each of the above three aims (LOS, costs, and readmissions), factors such as age, race, ethnicity, diagnosis, co-morbidities, or location (urban versus rural) were examined to
determine if they had any statistical effect on the pre-implementation versus post-implementation outcomes.

**Significance and/or Implications of Results**

**Factors affecting LOS/LOS hours:** LOS was not affected by age, staged procedure, gender, race, ethnicity, state, primary diagnosis, or comorbidities. When comparing all pre- versus post-implementation patients, home county was a significant predictor with rural county LOS 31.23 ±12.166 hours versus urban county LOS 26.68 ±2.418 hours with a significance of p 0.010. This data suggest patients are more likely to stay longer if they live further from the hospital in rural areas, perhaps due to hesitation or uncertainty of going home and providing self-care. However, this difference is no longer significant when comparing only non-staged stage 2 pre-implementation patients to post-implementation patients.

<table>
<thead>
<tr>
<th>Rural</th>
<th>Urban</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS hours</td>
<td>31.23±12.166</td>
<td>26.68±2.418</td>
</tr>
</tbody>
</table>

**Factors affecting cost:** Total cost of the procedure is affected by age, when looking at all pre-versus post-implementation patients regardless of staged stage 2, such that patients >65 years old exhibited higher cost, likely because they were more likely to undergo a staged stage 2 procedure. Also, both analyses demonstrated that when dichotomizing ethnicity by “non-Hispanic” and “others”, the “others” group exhibited higher cost, yet the explanation for this cost discrepancy remains unclear and requires further study.

<table>
<thead>
<tr>
<th>Age &lt;65</th>
<th>Age ≥65</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cost</td>
<td>18778.5±4644.2</td>
<td>28819.8±11083.6</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>Others</td>
<td>P-value</td>
</tr>
<tr>
<td>Total cost</td>
<td>16822.4±3694.7</td>
<td>20415.8±5390.4</td>
</tr>
</tbody>
</table>
Cost is also affected by primary diagnosis with essential tremor exhibiting increased cost over Parkinson’s disease and dystonia. This may be because these patients are more likely to be older and undergo a staged procedure, or because their devices cost more. Upon discussion with the billing group, group rate prices for devices and negotiations to decrease cost with vendors are constantly being discussed and pricing is currently as cost effective as possible.

<table>
<thead>
<tr>
<th></th>
<th>Parkinson</th>
<th>Essential tremor</th>
<th>Dystonia</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cost</td>
<td>23210.1±9222.4</td>
<td>25400.5±100759.1</td>
<td>16644.7±4005.5</td>
<td>0.050</td>
</tr>
</tbody>
</table>

**Factors affecting Readmissions:** The re-admission rate was affected by a number of medical comorbidities but was not affected by other patient factors including age, staged stage 2 procedure, gender, race, ethnicity, state, county, age, or primary diagnosis.

<table>
<thead>
<tr>
<th></th>
<th>0 comorbidity</th>
<th>1 comorbidity</th>
<th>2+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmission</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The number of days to readmission was significantly affected by gender, with males having shorter interval time to readmission than females, perhaps hinting at a gender bias in willingness to seek medical attention or a higher complication rate in men.

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to readmission</td>
<td>11.0±6.0</td>
<td>32.6±6.3</td>
<td>0.013</td>
</tr>
</tbody>
</table>

**Patient-provider Communications:** Patient satisfaction survey post-implementation suggest improvements in patient expectations, communication and experience. These results are indirect savings cost when looking at the Press Ganey Survey where the score may result in higher reimbursement for the hospital. Inpatient and clinic providers also anecdotally report fewer pages and calls, and ease of care expectations and orders with a standardized protocol. Ultimately, more objective measures and a longer follow up period are needed to better assess this outcome.
Discussion

During the time frame this study took place, the institution was experiencing an influx of patients with COVID-19. This pandemic resulted in elective surgical cases being placed on hold temporarily. In an effort to try to minimize the effects of COVID-19 on the study analysis, cases were included from January 2018 through January 2020 in the pre-implementation cohort. The post-implementation cohort was from October 1, 2022 through December 31, 2022 including looking at unplanned 30-day readmission rates into January 31, 2023, as operations have mostly returned to pre-COVID levels.

This quality improvement study demonstrates the utilization of a novel clinical pathway in a high-volume, commonly performed, functional neurosurgery procedure (DBS). The implementation of a DBS clinical pathway provides evidence-based interventions and proves to standardize care and optimize patient outcomes at this single medical center. As a result of this pathway implementation, there was success in improving patient education, provider-patient communication, optimization of preoperative, intraoperative, and postoperative order sets, supplies, and medications. Identification of factors affecting longer lengths of stay and readmissions was useful when looking at the evidenced-based literature for making adjustments to the current practice. Findings from review of the pre-implementation data suggested that the main patient factors increasing length of stay were nausea, vomiting, pain, confusion, delirium, and hemorrhage around the lead. These factors were also the most common reasons for readmissions, with the addition of infection. This correlates with the literature, which reports that the most common complication of DBS is infection with a 4-12% risk within the first three months (Lange et al., 2019) and with delirium affecting 22-42.6% of patients (Tanaka et al.,
Studies have shown age (> 55 years) to be a major risk factor for postoperative delirium and is associated with worse outcomes, longer hospital stays, and increased cost (Li et al., 2021). As for causes of readmissions, the literature reports surgery-related events, infection, intracranial hemorrhage, seizures, and altered mental status with a direct correlation of readmissions and co-morbidities (Ramayya et al., 2017). The primary focus of ERAS pathways is on the management of acute postoperative pain, postoperative nausea and vomiting, and early mobilization. The objective is to prevent or minimize complications such as pneumocephalus, intracranial hemorrhage, cerebral edema, seizures, and stroke. Research shows early functional recovery reduces the number of hospital days after elective intracranial surgeries (Wan A & Luoma, 2020). The implementation of an evidence-based ERAS pathway decreases the hospital length of stay which has an immense impact on the cost of acute care for hospital stays after surgery (Patil et al., 2019). ERAS pathways may also encourage a decrease in opioid use by using local anesthetics or nonopioids medications such as nonsteroidal anti-inflammatory drugs instead of opioids (Patil et al., 2019). There was also an anonymous 10-question patient satisfaction survey administered to patients after completion of the implantation process that was used to help identify the most important questions from patients that need to be addressed in the pathway implementation. Unfortunately, time did not permit for all the questionnaires to be returned by patients who underwent DBS with the new clinical pathway. Seeking out patient feedback about the care they received, and making resultant changes correlates with the literature in reinforcing the importance of patient experiences on shaping clinical practice.

To address these issues of postoperative infection, delirium, nausea/vomiting, pain and patient experiences, the following changes to the pathway were made:
### Preoperative Orders

<table>
<thead>
<tr>
<th>Preoperative Orders</th>
<th>Pre-Implantation</th>
<th>Post-Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic Prophylaxis</td>
<td>Clindamycin</td>
<td>Ancef, for severe cephalosporin allergy use Vancomycin and Aztreonam</td>
</tr>
<tr>
<td>Antiemetic Prophylaxis</td>
<td></td>
<td>Zofran 4mg PO once</td>
</tr>
<tr>
<td>Pain Prophylaxis</td>
<td></td>
<td>Tylenol 1,000mg PO once</td>
</tr>
</tbody>
</table>

### Aneurysm Prophylaxis

- Clindamycin for severe cephalosporin allergy
- Vancomycin and Aztreonam

### Postoperative Orders

<table>
<thead>
<tr>
<th>Postoperative Orders</th>
<th>Pre-Implementation</th>
<th>Post-Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foley catheter</td>
<td>Remove POD 1</td>
<td>Remove in PACU</td>
</tr>
<tr>
<td>Intravenous Fluids</td>
<td>Discontinue POD 1</td>
<td>Continue IVF until drinking &gt;300cc every 8 hours</td>
</tr>
<tr>
<td>Activity</td>
<td>Up out of bed with assistance</td>
<td>Ambulate the evening of surgery with assistance from the nursing staff</td>
</tr>
<tr>
<td>Antiemetics</td>
<td>Zofran 4mg IV at the end of the surgical case</td>
<td>Zofran 4mg every 6 hours PRN for nausea control with the first dose at the end of the surgical case</td>
</tr>
<tr>
<td>Pain Management</td>
<td>Toradol, Ibuprofen, Gabapentin, &amp; Dilaudid</td>
<td>Robaxin 500mg TID PRN for muscle spasms, Tylenol 1,000mg PO every 8 hours unless greater than 65 yrs or with liver disease then use 650mg, Oxycodone 5mg every 6 hours PRN pain, **Celecoxib for &lt;65yrs or &gt;50kg take 400mg PO once in the PACU then 200mg PO every 12hrs starting POD 1 or for &gt;65yrs or &lt;50kg take 200mg PO once in the PACU then 100mg PO every 12hrs starting POD 1</td>
</tr>
<tr>
<td>Bowel Regimen</td>
<td>Senna S 2 tabs PO BID &amp; Miralax 17g PO daily PRN</td>
<td>Senna S 2 tabs PO BID &amp; Miralax 17g PO daily</td>
</tr>
<tr>
<td>Shower</td>
<td>POD 3</td>
<td>POD 1</td>
</tr>
<tr>
<td>Wound Care</td>
<td>Bacitracin ointment topical to incision sites BID for 7-14 days</td>
<td>Apply a thin layer of bacitracin ointment topical to incision sites daily</td>
</tr>
<tr>
<td>Lifting</td>
<td>No more than 15lbs x4 weeks</td>
<td>No more than 10lbs x4 weeks</td>
</tr>
<tr>
<td>Labs</td>
<td>CBC &amp; BMP POD 1</td>
<td>No post-operative labs</td>
</tr>
</tbody>
</table>

*All patient orders were reviewed to ensure that the inpatient and outpatient patient education was cohesive*
Celecoxib, as the evidence suggests, has the same anti-inflammatory effect as the non-selective COX inhibitors (Ibuprofen, Ketorolac, etc.), but has no anti-platelet effect and a lower risk for gastrointestinal side effects (ulcers, dyspepsia). The risk of renal events was also significantly lower with Celecoxib than Ibuprofen, and there is new evidence suggesting there is no higher risk of cardiovascular events. Also, the dosing is more convenient than Ibuprofen (every 12 hours versus every 4-6 hours). Celecoxib is also preferred over Ketorolac because there is reasonable evidence that Ketorolac has a higher rate of hemorrhagic complications (Obeid et al., 2022). In patients with chronic kidney disease or who have a GFR <60, prescribing Celecoxib will be avoided, to minimize nephrotoxic effects or supratherapeutic levels.

In regard to changes in operating room materials, the neurosurgical attending surgeons changed from using bone cement to Stimloc caps to secure leads in place. This change decreased the use of the specialized electrocautery knife called Plasmablade to only be used for cases that already had hardware implanted, otherwise a regular surgical blade was used. Excess sutures and operating room materials were reduced. Thrombin-soaked gel foam was used in lieu of SurgiFlo/Floseal for hemostasis. Duraseal is no longer used for sealing dura to prevent cerebral spinal fluid leak (as these rarely occur with a supratentorial burr hole) and absorbable fast gut suture is used to close skin instead of staples, other types of sutures or Dermabond (all sutures streamlined and only opened if needed). The anesthesia protocol was updated looking at cost and waste of medications such as Remifentanil which is dispensed in a 100ml bag but only about 10ml is used and the rest wasted. Discussions are ongoing about using smaller volume syringes to reduce waste. Other cost saving orders include not applying a surgical dressing to cover the incision, just using bacitracin, not obtaining morning labs on post-operative day one and doing more bilateral procedures (one surgery) after liberalizing the criteria for staged procedures. The institutions billing department has negotiated with major vendors (Medtronic and Boston Scientific) for optimization of group pricing and decreasing the cost of the leads and IPGs. Lastly, after analyzing cost data, it was estimated that the institution could save approximately $5,000 dollars per patient by performing stage 3 (IPG implantation) surgeries at
an outpatient surgery center, but at this time this is not feasible with the available resources and surgeon schedules. There is a plan to gather more data from the anonymous 10-question patient satisfaction survey post-pathway implementation to evaluate improvements in the patient experience. The effect the DBS perioperative pathway had on the volume of calls the neurosurgical team received, both inpatient and outpatient, is difficult to quantify, but to measure this, one could distribute a questionnaire or call logs could be checked. Although it may not be statistically significant in this study, a pathway to reduce length of stay, cost, and readmission rates in this area should be further studied when given more time for implementation findings. Periodically, it is important for institutions and clinical teams to evaluate their protocols, cost effectiveness and patient satisfaction and to update them with the advent of new clinical or cost data. These endeavors are typically systems based and multidisciplinary and may take considerable time and effort to instigate change. However, all of this dedicated time and effort is worthwhile to provide patients with optimal care.

Limitations and Suggestions for Improvement

This study has some notable limitations. First, the post implementation sample size was limited by time constraints, COVID-19 pandemic, change in Neurosurgery attendings since obtaining the pre-implementation data; and post-implementation data was collected when fewer surgical operations occurred during the Thanksgiving and Christmas holidays. Second, this study collected data at only one hospital in the Southeast, therefore, the findings may not be generalizable to other medical centers who perform DBS surgeries that have different socioeconomical profiles or whose DBS procedure/process is different than this single medical center. Third, the study was limited to focusing on stage 2 (electrode implantation) and the three most common diagnoses. Future analyses should aim to gather data on all three DBS stages for
at least one-year post implementation and at more than one institution. Lastly, all the patients were awake during the stage 2 DBS surgery, so the findings may be different in patients that are under general anesthesia for this surgery.

Conclusion

An enhanced recovery after surgery (ERAS) or clinical pathway is an organized perioperative healthcare pathway that encompasses evidence-based interventions such as protocols and guidelines aiming to provide standardized care. Pathways assist to improve changes in patient outcomes, costs, and to help patients and families stay informed about their treatment course. The management of DBS patients is complex and requires specialized care in a multidisciplinary center. A well-organized and efficient patient flow is necessary to ensure that eligible patients can receive DBS treatment quickly and efficiently. It is reasonable to state that having a DBS clinical pathway in place enhances continuity of care and patient satisfaction while also improving efficiency, teamwork, staff/patient education, better communication and reducing variation in practice. Having evidence-based pathways, protocols, and guidelines, helps to maintain safety in the operating room, improve efficiency, decrease costs, improve postoperative recovery and patient outcomes. Also, using early mobilization and minimizing opioid use reduces postoperative complications. Pathways improve the consistency of care after discharge from the hospital with medications, instructions, wound care, activity levels, and appointments. Nurses play a key role in the successful implementation of clinical pathways by providing education, perioperative care, postoperative evaluation, and cost containment. Other strategies for a successful implementation of the clinical pathway include ensuring patient participation, physician acceptance, full participation and education of support staff in the plan of care, and executive leaders allowing for appropriate execution. It takes a multidisciplinary approach as
well as dedicated time, effort and commitment to update current evidence-based practice
protocols for improvements in perioperative care and patient outcomes while reducing healthcare
costs. This project should spark more interest in and lay the foundation for clinical pathways in
the neurosurgical patient population.
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### tables

<table>
<thead>
<tr>
<th>Preoperative Variables</th>
<th>Total (N=179)</th>
<th>Pre-implementation (N=150)</th>
<th>Post-implementation (N=29)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ±SD</td>
<td>64.3±9.8</td>
<td>64.3±9.6</td>
<td>64.0±11.4</td>
<td>0.858</td>
</tr>
<tr>
<td>Age, ≥65, n (%)</td>
<td>91 (50.8%)</td>
<td>78 (52.0%)</td>
<td>13 (44.8%)</td>
<td>0.549</td>
</tr>
<tr>
<td>Gender, male, n (%)</td>
<td>110 (61.5%)</td>
<td>93 (62.0%)</td>
<td>12 (41.4%)</td>
<td>0.677</td>
</tr>
<tr>
<td>Race, white, n (%)</td>
<td>168 (93.9%)</td>
<td>141 (94.0%)</td>
<td>27 (93.1%)</td>
<td>0.634</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>169 (94.4%)</td>
<td>146 (97.3%)</td>
<td>23 (79.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Others</td>
<td>10 (5.6%)</td>
<td>4 (2.7%)</td>
<td>6 (20.7%)</td>
<td></td>
</tr>
<tr>
<td>State, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tennessee</td>
<td>128 (71.5%)</td>
<td>107 (71.3%)</td>
<td>21 (72.4%)</td>
<td>0.624</td>
</tr>
<tr>
<td>Kentucky</td>
<td>19 (10.6%)</td>
<td>17 (11.3%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Missouri</td>
<td>11 (6.1%)</td>
<td>10 (6.7%)</td>
<td>1 (3.4%)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>21 (11.7%)</td>
<td>16 (10.7%)</td>
<td>5 (17.2%)</td>
<td></td>
</tr>
<tr>
<td>County, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>142 (79.3%)</td>
<td>121 (80.7%)</td>
<td>21 (72.4%)</td>
<td>0.322</td>
</tr>
<tr>
<td>Urban</td>
<td>37 (20.7%)</td>
<td>29 (19.3%)</td>
<td>8 (27.6%)</td>
<td></td>
</tr>
<tr>
<td>Primary diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parkinson</td>
<td>96 (53.6%)</td>
<td>80 (53.3%)</td>
<td>16 (55.2%)</td>
<td>0.615</td>
</tr>
<tr>
<td>essential tremor</td>
<td>76 (42.5%)</td>
<td>65 (43.3%)</td>
<td>11 (37.9%)</td>
<td></td>
</tr>
<tr>
<td>Dystonia</td>
<td>7 (3.9%)</td>
<td>5 (3.3%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>7 (3.9%)</td>
<td>7 (4.7%)</td>
<td>0</td>
<td>0.489</td>
</tr>
<tr>
<td>1</td>
<td>13 (7.3%)</td>
<td>11 (7.3%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>2+</td>
<td>159 (88.8%)</td>
<td>132 (88.0%)</td>
<td>27 (93.1%)</td>
<td></td>
</tr>
<tr>
<td>Insurance, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>88 (49.2%)</td>
<td>77 (51.3%)</td>
<td>11 (37.9%)</td>
<td>0.391</td>
</tr>
<tr>
<td>Medicare advantage</td>
<td>10 (5.6%)</td>
<td>8 (5.3%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Blue cross</td>
<td>22 (12.3%)</td>
<td>16 (10.7%)</td>
<td>6 (20.7%)</td>
<td></td>
</tr>
<tr>
<td>other</td>
<td>59 (33.0%)</td>
<td>49 (32.7%)</td>
<td>10 (34.5%)</td>
<td></td>
</tr>
<tr>
<td>2 stages 2b, n (%)</td>
<td>49 (27.4%)</td>
<td>49 (32.7%)</td>
<td>0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### outcome variables

<table>
<thead>
<tr>
<th>Readmission, n (%)</th>
<th>11 (6.1%)</th>
<th>11 (7.3%)</th>
<th>0</th>
<th>0.216</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmission days, mean ±SD</td>
<td>64.3±9.8</td>
<td>32.5±25.9</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LOS days, mean ±SD</td>
<td>1.1±0.9</td>
<td>1.2±1.0</td>
<td>1.1±0.4</td>
<td>0.502</td>
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<tr>
<td>LOS hours, mean ±SD</td>
<td>33.1±21.2</td>
<td>33.6±22.8</td>
<td>31.0±11.0</td>
<td>0.555</td>
</tr>
<tr>
<td>Cost 1, mean ±SD</td>
<td>9223.3±3877.8</td>
<td>16336.7±3654.9</td>
<td>20573.4±2989.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total Cost combined 1, mean ±SD</td>
<td>23883.4±9899.3</td>
<td>24523.3±10622.9</td>
<td>20573.4±2989.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Table 1.** Patient demographics for first analysis group comparing all pre-implementation patients regardless of staged or nonstaged Stage 2 to all post-implementation patients.
<table>
<thead>
<tr>
<th>Preoperative Variables</th>
<th>Total (N=130)</th>
<th>Pre-implementation (N=101)</th>
<th>Post-implementation (N=29)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ±SD</td>
<td>61.1±9.5</td>
<td>60.3±8.8</td>
<td>64.0±11.4</td>
<td>0.068</td>
</tr>
<tr>
<td>Age, ≥65, n (%)</td>
<td>45 (34.6%)</td>
<td>32 (31.7%)</td>
<td>13 (44.8%)</td>
<td>0.268</td>
</tr>
<tr>
<td>Gender, male, n (%)</td>
<td>80 (61.5%)</td>
<td>63 (62.4%)</td>
<td>12 (41.4%)</td>
<td>0.670</td>
</tr>
<tr>
<td>Race, white, n (%)</td>
<td>120 (92.3%)</td>
<td>93 (92.1%)</td>
<td>27 (93.1%)</td>
<td>0.855</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>121 (93.1%)</td>
<td>93 (97.0%)</td>
<td>23 (79.3%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Others</td>
<td>9 (6.9%)</td>
<td>3 (3.0%)</td>
<td>6 (20.7%)</td>
<td></td>
</tr>
<tr>
<td>State, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tennessee</td>
<td>93 (71.5%)</td>
<td>72 (71.3%)</td>
<td>21 (72.4%)</td>
<td>0.671</td>
</tr>
<tr>
<td>Kentucky</td>
<td>15 (11.5%)</td>
<td>13 (12.9%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Missouri</td>
<td>6 (4.6%)</td>
<td>5 (5.0%)</td>
<td>1 (3.4%)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>16 (12.3%)</td>
<td>11 (10.9%)</td>
<td>5 (17.2%)</td>
<td></td>
</tr>
<tr>
<td>County, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>107 (82.3%)</td>
<td>86 (85.1%)</td>
<td>21 (72.4%)</td>
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</tr>
<tr>
<td>Urban</td>
<td>23 (17.7%)</td>
<td>15 (14.9%)</td>
<td>8 (27.6%)</td>
<td></td>
</tr>
<tr>
<td>Primary diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parkinson</td>
<td>75 (57.7%)</td>
<td>59 (58.4%)</td>
<td>16 (55.2%)</td>
<td>0.900</td>
</tr>
<tr>
<td>essential tremor</td>
<td>48 (36.9%)</td>
<td>37 (36.6%)</td>
<td>11 (37.9%)</td>
<td></td>
</tr>
<tr>
<td>Dystonia</td>
<td>7 (5.4%)</td>
<td>5 (5.0%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>6 (4.6%)</td>
<td>6 (5.9%)</td>
<td>0 (0%)</td>
<td>0.310</td>
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<tr>
<td>1</td>
<td>13 (10.0%)</td>
<td>11 (10.9%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>2+</td>
<td>111 (85.4%)</td>
<td>84 (83.2%)</td>
<td>27 (93.1%)</td>
<td></td>
</tr>
<tr>
<td>Insurance, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>64 (49.2%)</td>
<td>53 (52.5%)</td>
<td>11 (37.9%)</td>
<td>0.279</td>
</tr>
<tr>
<td>Medicare advantage</td>
<td>7 (5.4%)</td>
<td>5 (5.0%)</td>
<td>2 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Blue cross</td>
<td>15 (11.5%)</td>
<td>9 (8.9%)</td>
<td>6 (20.7%)</td>
<td></td>
</tr>
<tr>
<td>other</td>
<td>44 (33.8%)</td>
<td>34 (33.7%)</td>
<td>10 (34.5%)</td>
<td></td>
</tr>
<tr>
<td>Outcome Variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmission, n (%)</td>
<td>6 (4.6%)</td>
<td>6 (6.0%)</td>
<td>0 (0%)</td>
<td>0.405</td>
</tr>
<tr>
<td>Readmission days, mean ±SD</td>
<td>21.8±13.1</td>
<td>21.8±13.1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LOS days, mean ±SD</td>
<td>1.2±1.0</td>
<td>1.2±1.1</td>
<td>1.1±0.4</td>
<td>0.396</td>
</tr>
<tr>
<td>LOS hours, mean ±SD</td>
<td>34.4±22.9</td>
<td>35.4±25.4</td>
<td>31.0±11.0</td>
<td>0.366</td>
</tr>
<tr>
<td>Total Cost, mean ±SD</td>
<td>18362.2±3461.4</td>
<td>17727.3±3336.1</td>
<td>20573.4±2989.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OR Services Cost</td>
<td>3818.0±1022.6</td>
<td>3405.0±694.7</td>
<td>5256.3±580.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Supply Cost</td>
<td>13204.7±2404.4</td>
<td>13013.6±2356.5</td>
<td>13870.1±2492.3</td>
<td>0.091</td>
</tr>
<tr>
<td>Pharmacy Cost</td>
<td>397.9±196.3</td>
<td>395.9±217.6</td>
<td>404.7±91.4</td>
<td>0.831</td>
</tr>
<tr>
<td>Nursing Cost</td>
<td>815.60±930.2</td>
<td>781.8±1046.8</td>
<td>933.1890±233.9</td>
<td>0.442</td>
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</table>

Table 2. Patient demographics for second analysis group comparing all pre-implementation patients who had nonstaged bilateral Stage 2 to all post-implementation patients.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Direct Cost (Pro)</th>
<th>Pre vs. post</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre implementation (1st)</td>
<td></td>
<td>150</td>
<td>5567.8</td>
<td>1888.9</td>
<td>154.2</td>
<td>0.083</td>
<td></td>
</tr>
<tr>
<td>post implementation</td>
<td></td>
<td>29</td>
<td>4755.2</td>
<td>2312.4</td>
<td>429.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR Services</td>
<td></td>
<td>pre-implementation (1st)</td>
<td>150</td>
<td>3118.7</td>
<td>741.0</td>
<td>60.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>post implementation</td>
<td></td>
<td>29</td>
<td>5256.3</td>
<td>580.2</td>
<td>107.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply</td>
<td></td>
<td>pre-implementation (1st)</td>
<td>150</td>
<td>11954.7</td>
<td>2742.5</td>
<td>223.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>post implementation</td>
<td></td>
<td>29</td>
<td>13870.1</td>
<td>2492.3</td>
<td>462.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy</td>
<td></td>
<td>pre-implementation (1st)</td>
<td>150</td>
<td>391.1</td>
<td>215.4</td>
<td>17.5</td>
<td>0.580</td>
</tr>
<tr>
<td>post implementation</td>
<td></td>
<td>29</td>
<td>404.7</td>
<td>91.4</td>
<td>16.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing</td>
<td></td>
<td>pre-implementation (1st)</td>
<td>150</td>
<td>752.6</td>
<td>927.2</td>
<td>75.7</td>
<td>0.300</td>
</tr>
<tr>
<td>post implementation</td>
<td></td>
<td>29</td>
<td>933.1</td>
<td>233.9</td>
<td>43.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3.** Patient demographics for pre- versus post- implementation comparing the breakdown of cost for operating room services, supply, pharmacy, and nursing.
Appendix A: Patient Education Booklet Stage 2

DBS surgery: Stage 2 Before surgery

- Wash your hair with baby shampoo the night before surgery.
- Do not eat after midnight the night before your surgery. You may drink clear liquids up to 2 hours before surgery (water, clear tea, fruit juice with no pulp, black coffee with NO creamer, carbonated drinks).

**Stop taking your Parkinson's or tremor medicines by 6 p.m. the night before surgery.**

On the day of surgery

- Bring your Parkinson's or tremor medicine bottles with you.
- Get to the hospital 2 hours before your scheduled surgery time.
- Go to the main entrance of VUH and check in at the admitting office.
- After check in, you'll wait in the waiting room until we call your name. We'll take you to the holding room. You may have 1 person with you.
  - We'll put in your IV for medicines.
  - You'll meet your anesthesiology team.
  - You'll sign a consent form.
  - We'll place a foley or condom catheter to drain urine from your bladder.
  - Then, we'll take you to the operating room for surgery.

The surgery

Stage 2 surgery usually takes 3 to 5 hours.

You'll be awake during the surgery. Your surgeon will tell you what they're doing as they operate. We'll do all we can to keep you comfortable.

**Steps of Stage 2 surgery**

- We'll attach the custom head frame to the bone markers (screws) while you're under local anesthesia. This means the surgical area will be numb.
- We'll make a small opening to place the lead into the target location of the brain.
- We'll do stimulation testing using electrical impulses. At the same time, we'll have you do certain tasks like holding a cup and putting your finger to your nose. This will help confirm the target area.
- We'll remove the bone markers.
- We'll coil up the DBS wires and put them under your skin until the Stage 3 surgery. During Stage 3, we'll connect the battery.
Appendix A cont.

After surgery

- We'll take you to the recovery room.
- We'll do a CT scan of your brain to record the correct placement of your electrodes and to check for bleeding or swelling in the brain.
- Your surgeon will talk to your family or caregivers about the results of your surgery and what to expect.
- After the CT scan, we'll take you to your hospital room.
- You'll restart your Parkinson's or tremor medicines. Your nurse will talk with you about your dosing schedule.
- We'll help you manage your pain while you're in the hospital.
- You'll get out of bed and walk in the hallway the day after surgery. You'll heal faster and manage your pain better if you move around.
- You'll be able to go home the day after your surgery as long as there are no problems. Our goal is for you to leave around 10 a.m.
- You'll leave the hospital with a plan to help you manage your pain.

You must have someone drive you home!

You can't leave on your own. If you don't have a ride, you may have to stay in the hospital overnight or reschedule your surgery.

DBS surgery: Stage 2

At home

Your medicines

Keep taking your Parkinson's or tremor medicines as usual.

If you need an opioid pain medicine, we'll give you a prescription. Follow the directions on the bottle. Take less as your pain gets better. We do not refill opioid pain medicines.

You'll also need to take a stool softener or a laxative as narcotics can cause constipation. Try not to strain when you go to the bathroom.

Remember, do not take any aspirin or aspirin products until you're done with all your DBS surgeries and your surgeon says it's OK to take them.

DBS surgery: Stage 2

Your incisions

- You may shower the 1st day after surgery. Gently wash your scalp and incisions with baby shampoo and pat dry.
- Use baby shampoo every day to wash your hair and incisions until we see you in the clinic again.
Appendix A cont.

- For 1 week after surgery, put bacitracin ointment on the incisions once a day. Do not use any other ointments or creams, unless your surgeon tells you to.
- Do not touch or pick at your incisions even if they begin to scab.
- Your incisions will be closed with stitches. They'll dissolve on their own in 4 to 6 weeks.
- It can take as long as 1 month for your incisions to heal all the way. If you have any questions, talk to your surgeon or nurse.
- Until your incisions heal all the way, do not:
  - soak in the bath or hot tub
  - swim
  - make any movements that could strain your incisions, like reaching over your head or twisting your upper body
  - do any strenuous activity, like house projects, baby sitting, helping someone move, working out, or yard work.
- For 1 month after surgery, do not lift anything more than 10 pounds (a gallon of milk).
- For 3 months after surgery, do not dye your hair.
- Change your pillowcase every day while your incisions heal.
- Do not wear anything that fits tightly on your head until you see the surgeon for your incision check. If you do wear a head scarf or skull cap, wash it every day.

Confusion

After surgery, you may feel tired, out of it, and confused. You should get a little better each day. If any of these symptoms get worse, call us.

Because you may have confusion and will have a greater risk of falling, have someone stay with you for 2 weeks after surgery to help you with daily living activities.

Swelling and pain

You may have swelling around your incisions and forehead for several days after surgery. This will move down your face and can even cause the eyelids to swell. This is normal and will go away on its own. Sitting up can help lower the swelling.

You may have pain on or around your incisions. This is normal and the pain should get a little better each day.

Driving

Do not drive until your surgeon tells you it's safe. We can talk about this at your first follow-up visit in the clinic.

Never drive when you take pain medicine.

Please note

After Stage 2 surgery, you may notice that your motor symptoms get better. This is called the honeymoon phase. It may last for days or weeks. The symptoms will likely come back. You'll see the real effect of your DBS therapy once the process is complete and we turn on the system.
Appendix A cont.

**DBS surgery: Stage 2 When to call us**

Call the Neurosurgery clinic or send a message through My Health if you have:

- redness, swelling, or drainage at or around your incision sites
- a fever of 101.5°F (38.6°C) or higher
- pain, sick stomach, or throwing up that gets worse and does not go away even with medicines
- any new weakness, numbness, or tingling in your face, arms, or legs
- a hard time with speech
- more sleepiness than usual
- confusion that lasts more than 1 week after surgery or gets worse
- any questions.
Appendix B: DBS Pre-operative Order Set

<table>
<thead>
<tr>
<th>Adult Neurosurgery DBS Pre-op Orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I and Stage III patients should be admitted using the same day procedure order. Stage II patients should be admitted using the inpatient admission order.</td>
</tr>
</tbody>
</table>

### Admission

- **Case Request**
  - Case request operating room
    - Scheduling/ADT

- **Admission**
  - (OPTIONAL) Patient class is currently Observation. ONLY use the orders below to update the patient class when clinically indicated.
  - Update patient class to inpatient - used when the procedure is inpatient only or the expected length of stay is 2 or more midnights
    - Pre-op (Holding/Floor/ICU)

### Nursing

#### Nursing Interventions

- **Place sequential compression device**
  - Instructions: Apply to BLE, on for 8 hours, off for 1 hour.
  - Routine, Once, today at 1025, For 1 occurrence
    - Pre-op (Holding/Floor/ICU), Sign and Hold

- **Forced air warming**
  - Care Instructions: Bair Hugger/ Bair Paw in holding room.
  - Routine, Once, today at 1025, For 1 occurrence
    - Pre-op (Holding/Floor/ICU), Sign and Hold

- **Stage 2 Orders**
  - If Male:
    - Apply condom catheter
      - Routine, Once, today at 1028, For 1 occurrence
        - Pre-op (Holding/Floor/ICU), Sign and Hold

- **Stage 2 Orders**
  - If Female:
    - Insert Foley catheter
      - Routine, Once, today at 1030, For 1 occurrence
        - Pre-op (Holding/Floor/ICU), Sign

### Diet

#### Diet / Nutrition

- **NPO Diet: Nothing by Mouth**
  - Diet effective now, Starting today at 1025, Until Specified
  - NPO: Nothing by Mouth
    - Pre-op (Holding/Floor/ICU), Sign and Hold
Appendix B cont.

**IV Fluids**

- **Insert Peripheral IV**
  - Routine, Once, today at 1025, For 1 occurrence
  - Pre-op (Holding/Floor/ICU), Sign and Hold

- **LR infusion (KVO)**
  - 10 mL/hr, intravenous, Continuous, Pre-op (Holding/Floor/ICU), KVO

- **electrolyte-R (NORMOSOL OR PLASMA-LYTE-A) bolus**
  - 10 mL/hr, intravenous, Continuous, Starting today at 1030, Pre-op (Holding/Floor/ICU), KVO
  - Sign and Hold

**Medications**

**Antibacterials**
- No beta lactam allergy
- Severe Cephalosporin Allergy or Steven's Johnson Syndrome or DRESS to penicillin

**Antiemetics**
-ondansetron (ZOFRAN) tablet 4 mg
  - 4 mg, oral, Once, today at 1030, For 1 dose, Pre-op (Holding/Floor/ICU)
  - In Holding Room
  - Sign and Hold

**Other Medications**

- acetaminophen: greater than or equal to 70 kg
  - acetaminophen (TYLENOL EXTRA STRENGTH) tablet 1,000 mg
    - 1,000 mg, oral, Once, today at 1030, For 1 dose, Pre-op (Holding/Floor/ICU)
    - In Holding Room
    - Sign and Hold

- acetaminophen (TYLENOL) tablet - if patient has no recorded weight
  - oral, Once, Pre-op (Holding/Floor/ICU), In Holding Room

**Stage I Medications**

- lidocaine-EPINEPHrine (XYLOCAINE W/EPI) injection
  - Pre-op (Holding/Floor/ICU)

- ketorolac (TORADOL) injection
  - 15 mg, Once, PACU (only)
Antibacterials
No beta lactam allergy

- ceFAZolin (ANCEF) 2,000 mg in SWFI 15 mL IV
  2,000 mg (rounded from 2 g), intravenous, Once, today at 1045, For 1 dose, Pre-op (Holding/Floor/ICU)
  Give to Anesthesia for Intra-Op Pre-Incision Administration
  Administer IV push over 3 - 5 minutes. Nurse to reconstitute each 1 g vial with 7.5 mL sterile water.
  Indications: Prophylaxis
  Pharmacist may adjust the dose according to the patient's renal function per the Pharmacist Antimicrobial Renal Dose Adjustment Protocol. Yes
  Sign and Hold

- Pt Weight > 119 kg: ceFAZolin (ANCEF) injection
  3,000 mg, intravenous, Once, Pre-op (Holding/Floor/ICU), Give to Anesthesia for Intra-Op Pre-Incision Administration

- Severe Cephalosporin Allergy or Steven's Johnson Syndrome or DRESS to penicillin

Antibacterials
No beta lactam allergy

- Severe Cephalosporin Allergy or Steven's Johnson Syndrome or DRESS to penicillin

- vancomycin IVPB 750 mg in 250 mL NS ADDvantage
  750 mg (rounded from 850.3 mg = 15 mg/kg x 56.7 kg), intravenous, Administer over 45 Minutes, Once, today at 1045, For 1 dose, Pre-op (Holding/Floor/ICU)
  NOTE ACTUAL TIME OF DOSE ACCURATELY
  Infiltration/Extravasation Risk = Yellow (Irritant)
  Indications: Prophylaxis
  Sign and Hold

- aztreonam (AZACTAM) 2,000 mg in NS 50 mL IVPB
  2,000 mg, intravenous, at 100 mL/hr, Administer over 30 Minutes, Once, today at 1045, For 1 dose, Pre-op (Holding/Floor/ICU)
  Indications: Prophylaxis
  Pharmacist may adjust the dose according to the patient's renal function per the Pharmacist Antimicrobial Renal Dose Adjustment Protocol. Yes
  Sign and Hold
## Appendix C: DBS Post-operative Order Set

### Admission

**Patient class is currently Inpatient. If Inpatient is not the medically appropriate patient class for this patient, please contact Utilization Management for assistance.**

VUMC Utilization Management: 615-836-8678

### Code Status

- **Full Code**
  - Post-op Admission
- **DNR (Do Not Resuscitate)**
  - Post-op Admission
- **DNR/DNI (Do Not Resuscitate/Do Not Intubate)**
  - Post-op Admission

### Precautions

- **Fall precautions**
  - Routine, Continuous, Starting today at 1510, Until Specified
  - High risk, Post-op Admission, Sign and Hold

### Vital Signs

- **Vital signs - High acuity**
  - Routine, Every 4 hours, First occurrence today at 1600, Until Specified
  - Post-op Admission, Sign and Hold
- **Vital signs - Medium Acuity**
  - Routine, Every 6 hours, Post-op Admission
- **Vital Signs - Low acuity - every 12 hours**
  - Routine, Every 12 hours, Post-op Admission
- **Vital Signs - Low acuity - every 24 hours**
  - Routine, Every 24 hours, Post-op Admission
## Activity

### Activity

- **Activity - Out of bed with assistance**:  
  
  Directions: Other (Specify)  
  Routine, 3 times daily, First occurrence today at 1800, Until Specified  
  Out of bed with assistance, Post-op Admission, Sign and Hold

- **Ambulate day of surgery**:  
  
  Routine, 3 times daily, First occurrence today at 1800, Until Specified  
  Post-op Admission, Sign and Hold

## Nursing

### Nursing Assessments

- **Assess fall risk score daily and PRN**:  
  Routine, Daily, First occurrence today at 1510, Until Specified  
  Post-op Admission, Sign and Hold

- **Identify fall risk patients with armband**:  
  Care Instructions: Discuss high fall risk status with patient and family.  
  Routine, Until discontinued, Starting today at 1510, Until Specified  
  Post-op Admission, Sign and Hold

### Nursing Interventions

- **Notify Covering Provider**:  
  Temperature greater than 101.4  
  Systolic blood pressure greater than 160  
  Systolic blood pressure less than 90  
  Diastolic blood pressure greater than 100  
  Diastolic blood pressure less than 50  
  Heart rate greater than 120  
  Heart rate less than 60  
  Respiratory rate greater than 29  
  Respiratory rate less than 8  
  Routine, Until discontinued, Starting today at 1510, Until Specified  
  Decreased LOC (Level Of Consciousness) Or saturated dressing, Post-op Admission, Sign and Hold

- **Intake and output**:  
  Routine, Every 8 hours, First occurrence today at 1600, Until Specified  
  Post-op Admission, Sign and Hold

- **Neuro checks – GCS**:  
  Routine, Every 4 hours, First occurrence today at 1600, Until Specified  
  Post-op Admission, Sign and Hold
## Appendix C cont.

### Incision line care - begin POD1
- Clean incision with baby shampoo beginning POD1, pat dry, leave open to air, then place a thin layer of bacitracin ointment to incision daily. Routine, Daily. First occurrence tomorrow at 0600, Until Specified
  - Post-op Admission, Sign and Hold

### Discontinue Foley for females

#### Foley Catheter Panel

- Per VUMC Policy, all VUMC patients with a urinary catheter will be placed on a nurse-directed discontinuation protocol unless specifically excluded by a provider order.
  - Indwelling Urinary Catheter Nursing-Directed Discontinuation Protocol
    - Foley catheter - Follow VUMC nursing-directed discontinuation protocol
    - Foley catheter - EXCLUDE from VUMC nursing-directed discontinuation protocol
    - Foley catheter - Designated discontinuation date
      - Foley catheter
      - Instruction: Maintain only (already in place)
      - Discontinuation instructions (designated discontinuation date)
      - Routine, Until discontinued, Starting today at 1510, Until Specified
      - Discontinue Foley catheter in PACU, PACU & Post-op, Sign and Hold

### Diet

#### Diet / Nutrition

##### Adult Diet Regular
- Diet effective now. Starting today at 1510, Until Specified
  - Diet Type: Regular
  - Post-op Admission, Sign and Hold

##### Adult Diet: Carbohydrate Controlled
- Post-op Admission

##### Adult Diet: Heart Healthy
- Post-op Admission

### IV Fluids

#### IV Fluids

- Insert peripheral IV
  - Routine, Once, Post-op Admission

- Electrolyte-R (NORMOSOL OR PLASMALyte-A) IV solution
  - 75 mL/hr, intravenous, Continuous. Starting today at 1510, For 1 day, Post-op Admission
  - Use until 0900 POD1, then can saline lock; avoid in patients with heart failure.
  - Sign and Hold

- Saline lock
  - Routine, Once, Post-op Admission

- NaCl 0.9% flush
  - 3 mL, intravenous, As needed, line care, Post-op Admission

### IV Carrier Fluids

#### IV Carrier Fluid Options

- NORMOSOL OR PLASMALyte-A carrier 500 mL
  - 500 mL, intravenous, As needed, other, for flush or carrier needs for administration of medication or blood products. Starting today at 1516, Post-op Admission
  - NOTICE: Certain IV medications may need a different flush or carrier due to compatibility issues.
  - Sign and Hold

- NS carrier 500 mL
  - 500 mL, intravenous, As needed, for flush or carrier needs for administration of medication or blood products. Starting 10/28/22, Post-op Admission, Notice: Certain IV medications may need a different flush or carrier due to compatibility issues.
## Appendix C cont.

### Medications

#### Pain Medications

- **Acetaminophen (Tylenol)**
  - Consider dose reduction in age greater than 65 years or those with liver dysfunction to 650 mg
  
  - Acetaminophen (Tylenol) tablet
    - Acetaminophen (Tylenol) tablet 1,000 mg, oral, every 8 hours scheduled, Post-op Admission
  
  - Acetaminophen (Tylenol) tablet 650 mg
    - 650 mg, oral, every 8 hours scheduled, First dose today at 1530, Post-op Admission
    - Sign and Hold

- Acetaminophen (Tylenol) suspension
- Acetaminophen (Tylenol) suppository

- Oxycodone (Oxycodone) immediate release tablet
  - 5 mg, oral, every 4 hours PRN, for pain unrelated by acetaminophen, hold for sedation, Post-op Admission

- Fentanyl
  - Do not give to patients with a history of GI bleeds, peptic ulcers, GFR less than 60, heart failure, and severe liver impairment or active hepatic disease.
  
  - For patients less than 65 years old or greater than 50 kg
  
  - For patients greater than 65 years old or less than 50 kg

- Inpatient Consult to Anesthesia or Pain Service

- Post-op Admission

#### Sleep

- Melatonin tablet
  - 3 mg, oral, Nightly PRN, sleep, Post-op Admission

- Melatonin tablet
  - 6 mg, oral, Nightly PRN, sleep, Post-op Admission
Appendix C cont.

- **Bowel Management**
  
  Avoid magnesium hydroxide (MILK OF MAGNESIA) in patients with end stage renal disease.

  - Sennosides-docusate sodium (PERI-COLACE) 8.6-50 mg tablet 2 tablet
    2 tablet, oral, 2 times daily. First dose today at 1800, Post-op Admission
    Sign and Hold

  - Polyethylene glycol (MIRALAX) packet 17 g
    17 g, oral, Daily, First dose today at 1530, Post-op Admission
    Mix before use as directed
    Sign and Hold

- **Bowel Management - PRN**
  
  Do NOT duplicate any scheduled medications ordered

  - Bisacodyl (DULCOLAX) EC tablet
    5 mg, oral, Daily PRN, If no bowel movement in 48 hours, Post-op Admission

- **Antiemetics - First-line agent**
  
  - Ondansetron (ZOFTRAN) injection 4 mg
    4 mg, intravenous, Every 6 hours PRN, nausea, Starting today at 1516, Post-op Admission
    (If unable to take PO) 1st-line agent
    Doses up to 4 mg may be administered undiluted. Inject over at least 30 seconds, but preferably over 2-5 minutes.
    Sign and Hold

  - Ondansetron (ZOFTRAN) tablet
    4 mg, oral, Every 6 hours PRN, nausea, Post-op Admission, 1st-line agent

  - Ondansetron ODT (ZOFTRAN-ODT) disintegrating tablet
    4 mg, oral, Every 6 hours PRN, nausea, Post-op Admission, 1st-line agent

- **Bacitracin**
  
  - Bacitracin topical ointment 1 application
    1 application, topical, Daily, First dose tomorrow at 1000, For 7 days, Post-op Admission
    Apply thin layer to incision; start POD1
    Sign and Hold

- **Methocarbamol Oral**
  
  - Methocarbamol (ROBAXIN) tablet 500 mg
    500 mg, oral, 3 times daily PRN, muscle spasms, Starting today at 1516, Post-op Admission
    Sign and Hold
Appendix C cont.

**Adult DVT/VTE Prophylaxis**

For the highest risk patients lacking contraindications to anticoagulation, low molecular weight heparin is the preferred agent.

**If patient is NOT receiving neuraxial (e.g. Epidural Infusion) anesthesia**

Preferred: Order enoxaparin 40 mg subcutaneously once daily (reduce dose to 30 mg if CrCl less than 30 mL/min) (higher dose will be suggested if BMI greater than 40)

High Risk: Ortho/Trauma/Turn

Order enoxaparin 30 mg subcutaneously every 12 hours AND order lower extremity sequential compression devices (reduce dose to 30 mg daily if CrCl less than 30 mL/min)

**If patient is receiving neuraxial (e.g. Epidural Infusion) anesthesia**

- Order unfractionated heparin 5000 units subcutaneously every 8 hours (higher dose will be suggested if BMI greater than 40)

Selected VTE risk factors:

- Increasing age: immobility, stroke or paralytic; previous thromboembolism; obesity; cancer; major surgical procedures; trauma; pregnancy and estrogen use; heart failure; lower extremity venous disease; critical illness; known hypercoagulable condition

Highest risk populations for development of VTE:

- Hip replacement or hip fracture; lines replacement: trauma; general surgery patients with multiple risk factors; ischemic stroke with hemiparesis

Anticoagulation Contraindications:

- Active serious bleeding or bleeding in a critical location (e.g. Intracranial)
- History of deficient or thrombocytopenia (HT): Use fondaparinux 2.5 mg subcutaneous daily if CrCl greater than or equal to 30 mL/min
- Severe thrombocytopenia (platelet count less than 60,000)
- Recent or scheduled procedure or opulation with high bleeding risk
- Presence of v. or plans to insert epidural catheter
- Patient received systemic thrombolysis (TPA) within the previous 24 hours

- Pharmacologic and/or Mechanical DVT/VTE Prophylaxis (Adult)
- Reason for Not Ordering VTE Prophylaxis (Adult, Patient already receiving VTE Prophylaxis / Contraindications)

**Imaging - CT**

- CT head without contrast
- STAT, once today at 1517, for 1 occurrence
- Additional Information (H107) St/P Deep Brain Stimulator Implant - DBS Protocol; CT must be done prior to patient being sent to floor
- Parkinson's
- Post-op Admission, Sign and Hold
Appendix D: DBS Discharge Order Set

Adult Neurosurgery Deep Brain Stimulation (DBS) Discharge Orders

Discharge

- Discharge to Home Self Care
  10/06/2022, Home or Self Care
  Discharge Attending Provider: ATKATER, KATELYN KENNEDY
  Discharge, Sign

- Discharge to SNF
  Skilled Nursing Facility, Discharge

- Discharge for
  Signature

Discharge Tobacco Treatment Orders

General Principles: For greater patient comfort and higher efficacy, consider combination nicotine replacement therapy; long acting patch + short acting gum or lozenge. Nicotine replacement is intended to treat nicotine withdrawal symptoms. Under treatment of nicotine withdrawal can lead to smoking relapse. The following recommendations are suggestions and can be modified (i.e., doses made higher or lower) to meet individual patient’s needs. Nicotine toxicity from medicinal nicotine products is very rare. These dosing guidelines are recommendations and do not substitute for clinical judgment.

Avoid nicotine in patients with Buerger’s disease (Thromboangiitis obliterans).

- Guidelines: Pharmacotherapy for Smoking Cessation

- Nicotine Patch
- 12-Week Taper Regimens
- Nicotine Replacement Lozenge (contains phenylethylamine)
- Nicotine Replacement: Gum
- Nicotine Replacement: Nasal Spray
- Nicotine Replacement: Inhalation cartridge
- Non-Nicotine Agents

Discharge - Activity

- Discharge activity - Lifting
  Care Instructions: Do not lift anything heavier than 10 pounds (for reference; about a gallon of milk) for 1 month after your procedure.
  Clinic Performed, Discharge, Sign

- Discharge activity - Light activity (2)

Discharge

- Discharge activity - Daily activity
  Care Instructions: Remember that walking and regular daily activity will help you get better faster.
  Clinic Performed, Discharge, Sign

- Discharge activity - Stromous movements/activity
  Care Instructions: Avoid doing any strenuous activities such as housework, yard work, or working out.
  Clinic Performed, Discharge, Sign

- Discharge activity - Driving
  Care Instructions: Do not drive until you have been cleared by your neurosurgeon to do so. This will be discussed at your first follow-up appointment in the clinic. Do not drive if you are taking narcotic pain medications.
  Clinic Performed, Discharge, Sign

- Discharge activity - No swimming/bathing
  Care Instructions: Do not take a tub bath, sit in a hot tub, or swim in a pool, lake or ocean for at least 4 weeks following surgery.
  Clinic Performed, Discharge, Sign

- Discharge activity - Shower
  Care Instructions: You may shower the first day after surgery. Gently wash your scalp & incisions with baby shampoo and pat dry. Apply bacitracin ointment to incisions once daily after showering for 1 week.
  Clinic Performed, Discharge, Sign

Discharge - Diet

- Adult Diet - Regular
  Diet Type: Regular
  Clinic Performed, Discharge, Sign
Appendix D cont.

- **Discharge - Instructions**
  - **Resume Neurology medications**
    - Routine, Clinic Performed, Resume your regular Neurology medicines, Discharge, Sign
  - **Pain medications**
    - Routine, Clinic Performed, Please do not call the Neurosurgery Clinic for refills for narcotic pain medications. They will not be able to be refilled, Discharge, Sign
  - **No aspirin**
    - Routine, Clinic Performed, No aspirin or aspirin products until all DBS surgeries have been completed and cleared by your physician to do so, Discharge, Sign
  - **Motor symptoms**
    - Routine, Clinic Performed, You may see your motor symptoms temporarily improve for days to weeks after lead implantation which is called the "honeymoon" phase. This is due to the effect of placing the lead in the brain but is not the true effect of your DBS therapy since the system is not complete or turned on yet. Your motor symptoms will likely return and the true effect of your DBS therapy will not be experienced until the system is complete and turned on, Discharge, Sign
  - **Healing**
    - Routine, Clinic Performed, It can take as long as 1 month for your incisions to completely heal. Avoid touching or picking at your incisions, even if they begin to scab, Discharge, Sign
  - **Incision Care**
    - Routine, Clinic Performed, Keep incision clean, dry and open to air. Do not try to remove your sutures. They will dissolve on their own in about 2 weeks. Do not pick at glue or stitches, Discharge, Sign
  - **Swelling**
    - Routine, Clinic Performed, You may have some swelling around your incisions and forehead for several days after surgery. This will move down your face and can even cause the eyelids to swell. Sitting up can help decrease the amount of swelling. This is normal and will go away on its own. You may have pain on or around your incisions. This is normal and the pain should get a little better each day, Discharge, Sign
  - **Headwear**
    - Routine, Clinic Performed, Change your pillowcase daily while your incisions are healing. Do not wear anything that fits tightly on your head, such as caps, wigs, or bandanas, until you are seen in the Neurosurgery clinic for your post-op appointment. If you do wear clothing items on your head, you must wash it every day, Discharge, Sign

- **Stage 2 Surgeries**

- **Stage 3 Surgeries**
# Appendix E: DBS Stage 2 Anesthesia Protocol

## Multidisciplinary Pathway

**DEEP BRAIN STIMULATOR**

### *STAGE II*

**Preop**
- **(By Surgeon)**
  - Ancef (2g if <120kg, 3g if >120kg)
  - Vancomycin/Aztreonam if allergic to PCN/Ancef
  - Foley (F); Condom Cath (M)

**Pre-Meds**
- **(By In-Room ANES)**
  - Acetaminophen 1g PO
  - Consider GI Prophy
  - **AVOID** Scopolamine Patch preop
  - Hold PD/ET Meds

**Induction**
- Remifentanil @ 0.03-0.07mcg/kg/min (for scalp block; then OFF)

**Airway**
- MAC with NC preferred
- ETT (if Epilepsy Pt)

**ASPIRE**
- Principles for intra-operative care per MPOG
- **ASPIRE** measures

**Access/Monitors**
- ASA Monitors
  - 2 PIV’s
  - O2 via NC for comfort

**Opioids**
- Remifentanil can be used for scalp block

**IV Infusions**
- Dexmedetomidine @ 0.2-0.7mcg/kg/hr (if not tolerating procedure)

**AFTER Leads/Testing**
- **On PRN Basis**
  - Fentanyl 25-100mcg IV
  - Versed 1-2mg IV
  - LMA + Propofol infusion

**Intraop**

**Access/Monitors**
- 2 PIV’s
- O2 via NC for comfort

**Opioids**
- Remifentanil can be used for scalp block

**Fluids**
- ≤ 75 ml/hr
- Normosol

**Postop**

**Multimodal Analgesics**
- **(By In-Room ANES)**
  - Celecoxib 400mg PO
  - Robaxin 250-500mg IV PRN

**Opioids**
- **(By In-Room ANES)**
  - AVOID Opioids
  - Oxycodeone 5mg PO Q4H
  - PRN **ONLY** if needed

**PONV**
- Zofran
- Scopolamine Patch

**CT Head to be done post-op while in PACU**
Appendix E cont.

Stage II: Preoperative Interventions

1) Preoperative Medication Orders/Interventions by {In-Room Anesthesia Team}
   
a) Pre-emptive Analgesia:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommended Dose</th>
<th>Exceptions/Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen³</td>
<td>1000 mg PO</td>
<td>• If age &gt;65y, reduce dose to 650 mg PO</td>
</tr>
<tr>
<td></td>
<td>1 hour before OR time</td>
<td>• If weight &lt;70 kg, reduce dose to 650 mg PO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• If history of any cirrhosis, reduce dose to 650 mg PO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Do not use if history of Child Pugh Class C liver disease</td>
</tr>
</tbody>
</table>

b) PONV Prevention:
   
i) No routine pre-operative scopolamine for PONV prevention, except for patients with 4 Apfel Risk Factors (female, non-smoker, h/o PONV/severe motion sickness, and likely postoperative IV or high dose parenteral opioids)
   
   **(1) Do NOT give Pre-op; ok to add to post-op regimen**
   
   ii) See Center for Evidenced Based Anesthesia: Post-Operative Nausea & Vomiting Guidelines

c) Parkinson’s Disease (PD) & Essential Tremor (ET) Medications
   
i) Patients are asked to HOLD their Parkinson’s or Essential Tremor medications for this Stage.
   
   ii) These patients have movement disorders - tremor, rigidity, or dystonia. Many patients have advanced Parkinson’s disease, Essential Tremor, or Paralysis Agitans. On the day of the procedure, they will NOT take their usual meds for the movement disorder. The surgeons and neurologists would like to see their tremor and or rigidity in full effect during the procedure to facilitate identification of the target for DBS electrode placement and stimulation settings.

d) GI Prophylaxis:
   
i) Patients with advanced PD are at increased risk for aspiration
   
   ii) Consider GI Prophylaxis for these patients
**Stage II: Intraoperative Considerations**

1) **Regional Considerations for the {Surgical Team}**
   a) 1% Lidocaine with 1:100,000 epinephrine, 8-10cc local injection
   b) Scalp block with Ropivacaine 0.5% + 100 mcg of clonidine
      i) In patients with severe hypertension or at risk for coronary events, avoid the use of epinephrine in the local anesthetic

2) **Intraoperative Considerations for the {In-Room Anesthesia Provider}**
   a) Stage II DBS is performed in the VOR suites.
   b) MAC with room air/nasal cannula is the preferred anesthetic for this Stage.
      i) LMA and/or ETT available in cases of emergency.
   c) The bed is commonly positioned 180° from the anesthesia machine, with the patient being positioned in the Beach Chair position.
      i) Significant measures are taken to pad the patient and ensure comfort
   d) **Anesthetic Considerations:**
      i) Remifentanil Infusion @ 0.03-0.07mcg/kg/min can be used initially for the application of the scalp block and drilling of burr holes. Dexmedetomidine @ 0.2-0.7mcg/kg/hr can be used to assist with anxiolysis; no bolus dose. These should be stopped once this part is completed.
      ii) It is preferred to avoid any further anesthetics/sedatives for the Intraoperative Testing/Lead Placements in order to facilitate the best outcome.
      iii) For patients who absolutely cannot tolerate this portion, Dexmedetomidine @ 0.2-0.7mcg/kg/hr can be used to assist with anxiolysis; no bolus dose. ALWAYS discuss with surgeon prior to initiation.
      iv) **AVOID** all other sedatives, to include: Fentanyl, Benzodiazepines, Propofol, or other narcotics.
   e) **Hemodynamic Considerations:**
      i) **Target SBP 140-160mmHg:** Hypertension during the procedure has been associated with increased risk of intracranial bleed. (Inform surgical team of ongoing hypertension and have a discussion about BP goals before surgery.)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommended Dose</th>
<th>Exceptions/Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicardipine</td>
<td>100-200mcg IV bolus; titrate to effect 0.5-15mg/hr IV drip; titrate to effect</td>
<td>• 1st line therapy</td>
</tr>
<tr>
<td>Diltiazem</td>
<td>10-20mg IV bolus -OR- 5-15mg/hr IV drip; titrate to effect</td>
<td>• Will cause a preferential decrease in heart rate • <strong>DO NOT GIVE</strong> if patient is bradycardic</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>10-20mg IV bolus Q4-6H</td>
<td>• Can cause indirect cardiac stimulation/tachycardia</td>
</tr>
<tr>
<td>Enalapril</td>
<td>1.25mg IV bolus Q6H</td>
<td>• <strong>AVOID</strong> in patients with history of angioedema or bilateral renal artery stenosis</td>
</tr>
</tbody>
</table>

**AVOID** beta blockers, as these may eliminate tremor or rigidity
Appendix E cont.

3) **Intraoperative Complications:**
   a) Incidence of complications (all-comers) is 12-16%
   b) Respiratory depression, hypertension, tachycardia, seizures, intracranial bleed, venous air embolism (VAE), nausea, vomiting and aspiration are the most commonly reported complications.
   c) **VAE** - In an awake patient, VAE can manifest as chest pain, coughing, tachypnea, hypotension, diaphoresis, and hypoxia. A drop in EtCO2 may be seen. Since these patients are in sitting position and breathing spontaneously, VAE is **not** a rare event, so remain vigilant.
   d) Other less common complications include: pneumocephalus; confusion; agitation; etc.
**Stage II: Postoperative Considerations**

1) **Postoperative Pain Management Ordered by {In-Room Anesthesia Provider}**:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommended Dose</th>
<th>Exceptions/Adjustments</th>
</tr>
</thead>
</table>
| Celecoxib              | 400mg PO X1 given immediately in PACU   | • **Reduce to** 200g PO immediately post-op if >65 years old or <50kg
|                        |                                        | • **Do not give** Celecoxib to patients with:                                            |
|                        |                                        |   o History of GI bleed                                                                   |
|                        |                                        |   o Peptic ulcers                                                                        |
|                        |                                        |   o GFR <60                                                                               |
|                        |                                        |   o Heart failure                                                                         |
|                        |                                        |   o Severe liver impairment or active hepatic disease.                                    |
| Methocarbamol (Robaxin)| 500mg IV X1 Q8H PRN                    | • Can increase initial dose to 1000mg if severe muscle spasms present                   |
|                        |                                        | • Repeat and future doses should be PO if possible                                       |
|                        |                                        | • Start with low dose and monitor for sedation, dizziness                                |
|                        |                                        | • Use with caution in the elderly                                                        |
|                        |                                        | • Avoid with hemodynamic instability                                                     |
| Acetaminophen\(^\text{a}\) | 1,000mg PO Q8H                          | * See Exceptions in Acetaminophen Box Above                                              |
| Oxycodone              | 5mg PO X1                               | **ONLY IF NEEDED,** after administration of Celecoxib and Robaxin                       |

2) **Postoperative Nausea and Vomiting Management ordered by {In-Room Anesthesia Provider}**:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommended Dose</th>
<th>Exceptions/Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zofran (Ondansetron)</td>
<td>4-8mg PO/IV Q6H PRN</td>
<td>• 1(^\text{st}) line for N/V</td>
</tr>
<tr>
<td>Scopolamine Patch</td>
<td>1 patch behind ear Q3D</td>
<td>• 2(^\text{nd}) line therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• DO NOT USE for patients:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o &gt;65 yo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Concern for oversedation (OSA, Dementia)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o With allergies or contraindications to anticholinergic use</td>
</tr>
</tbody>
</table>

**AVOID** Haloperidol (Haldol); Promethazine (Phenergen); Prochlorperazine (Compazine); and Metoclopramide (Reglan) – these can worsen Parkinson’s symptoms, and Haldol can induce severe extrapyramidal symptoms.

3) **PACU**:

a) Patients will recover in the PACU

b) CT Head scheduled while in the PACU, to be done prior to transfer to the floor.
Appendix F: DBS Patient Satisfaction Survey

DBS Patient Satisfaction Survey

The following is a list of questions about your satisfaction with the deep brain stimulation (DBS) implantation process. All information is strictly confidential and anonymous. Your answers will be used to help understand and improve what is important to patients doing this process so that we can continue to improve the quality of our care. Please select the answer choice that most closely represents your response to the question and include any comments or suggestions in the last question.

Thank you!

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) How satisfied are you with the results of your DBS surgery?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>2) In retrospect, would you have DBS surgery again?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>3) How likely would you be to recommend DBS surgery to someone else?</td>
<td>Very unlikely</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>4) How satisfied were you with your pain control?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>5) How satisfied were you with the care you received from the clinic and hospital staff?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>6) Did you feel well informed and properly educated before and after each surgical procedure?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>7) How satisfied were you with provider communication before, during and after each procedure?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>8) How satisfied were you with the amount of time it took from seeing the neurosurgeon in clinic the first time to the completion of the third surgery?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>9) How satisfied were you with your overall experience?</td>
<td>Not satisfied</td>
</tr>
<tr>
<td></td>
<td>(Place a mark on the scale above)</td>
</tr>
<tr>
<td>10) Is there anything you feel needs to be changed or improved upon?</td>
<td></td>
</tr>
</tbody>
</table>
Appendix G: Gantt Chart

Gantt Chart


- Literature Search/Review
- Frame Clinical Question
- Baseline Data Collection
- Stakeholder Meeting
- Identify Project Purpose/Aims
- IRB Approval
- Project Proposal to Committee
- Analyze Baseline Data
- Project Implementation
- Post Data Collection
- Complete Project Report
- Complete Project Presentation
Appendix H: IRB

Human Research Protections Program – HRPP
Supporting the work of the IRB and Providing HRPP Oversight

Medical Center

RE: IRB #211717 “Standardization of Deep Brain Stimulation Pathway”

Dear Debbie A Masemer:

A designee of the Institutional Review Board reviewed the research study identified above. The designee determined the project does not qualify as "research" per 45 CFR §46.102(f).

(l) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

This project’s purpose is to assess areas for improvement in cost efficacy, streamlining patient communications from the clinic and inpatient teams, standardizing order sets and patient medications in the peri-op period to improve quality and ease of care for DBS (deep brain stimulation) treatment at Vanderbilt.

As this does not meet the "criteria for research" as described in 45 CFR §46.102(f), IRB approval is not required.

Please note: Any changes to this proposal that may alter its “non-research” status should be presented to the IRB for approval prior to implementation of the changes. In accordance with IRB Policy III.J, amendments will be accepted up to one year from the date of approval. If such changes are requested beyond this time frame, submission of a new proposal is required.

Sincerely,

Emily Rice BFA
Institutional Review Board
Health Sciences Committee #2

Electronic Signature: Emily Rice (be609ac327c922889315e9e47dc0f37)
Signed On: 09/08/2021 3:29:18 PM CDT
Appendix I: IRB

FLORIDA STATE UNIVERSITY
OFFICE of the VICE PRESIDENT for RESEARCH

ACKNOWLEDGEMENT OF AN EXTERNAL IRB UPDATE

October 21, 2021

Debbie Masemer
850-644-5260
dam20eu@my.fsu.edu

Dear Debbie Masemer:

On 10/21/2021, the IRB staff reviewed the information for the following study that you request rely upon an external IRB (Vanderbilt University) as the IRB of record:

<table>
<thead>
<tr>
<th>Site Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Name:</td>
</tr>
<tr>
<td>Submission ID:</td>
</tr>
<tr>
<td>Site Investigator:</td>
</tr>
<tr>
<td>Additional Site Funding:</td>
</tr>
</tbody>
</table>
| Site Documents Reviewed: | • FSU IRB Clarification.pdf, Category: Other;  
                             • 2021-09-09 21-31.pdf, Category: External IRB Approval;  
                             • FSU IRB Determination Worksheet.pdf, Category: Other; |

<table>
<thead>
<tr>
<th>Study Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Title:</td>
</tr>
<tr>
<td>Study ID:</td>
</tr>
<tr>
<td>Study Funding:</td>
</tr>
<tr>
<td>IND, IDE or HDE:</td>
</tr>
</tbody>
</table>

This notification serves to acknowledge the information you provided for the above listed study. If not already submitted, you may be required to also submit these updates to __________

COVID-19 Information for Research Involving Human Subjects: Note that the U.S. is operating under the national emergency [Proclamation 9994](#) concerning the COVID-19 pandemic and that this national emergency remains in effect until rescinded or terminated by the President of the U.S. (go [here](#) for the Proclamation letter). Conditions are dynamic and related policies or

Page 1 of 2
Appendix I cont.

guidance evolve accordingly; as applicable, refer to the U.S. Centers for Disease Control and Prevention [web site], specific for universities or refer to our COVID-19 and Human Research Studies [web page] to learn more about how you should or may protect persons (whether vaccinated or unvaccinated) involved in any of your in-person research activities.

Other Information:

As a reminder and as applicable, please promptly notify the FSU Human Subjects Research Office upon:

1. Notification that [ ] has renewed its approval at continuing review
2. Closure of the study
3. Any new reportable information that affects this site

Sincerely,

Human Subjects Research Office
humansubjects@fsu.edu