Introduction:

Over the course of roughly seventy years, subcortical neurostimulation has grown from a tool utilized predominantly for the neurological localization of brain structures for ablation to effective therapies for medically refractory disorders (1). Since the late 1980’s, deep brain stimulation (DBS) technology has become increasingly popular in the management of treatment-resistant movement, seizure and more recently psychiatric disorders (2,3). As a neurosurgical intervention, DBS entails the intracranial insertion of neurostimulatory probes into clinically defined or hypothesized subcortical neuropathways or nuclei, such as the subthalamic nucleus in the case of Parkinson’s Disease (PD). Following the late 1990’s, DBS has gradually expanded into the potential management of severe psychiatric conditions. These have included treatment-resistant variants of Obsessive-Compulsive Disorder (OCD), Treatment-Resistant Depression (TRD), and Anorexia Nervosa (AN) through the stimulation of neuroanatomical areas including the internal capsule, ventral capsule/striatum, and nucleus accumbens among others (2). In this research the majority of utilized DBS devices are open-loop DBS (oDBS) devices which utilizes manually programmed stimulation settings as opposed to its successor, closed-loop DBS (cDBS), which relies on real time intracranial neural recordings via an electrocorticogram to initiate stimulation (4). In the clinical setting, the only Food and Drug Administration (FDA) certified cDBS system, synonymously known as responsive neurostimulation (RNS), is utilized for the treatment of adults with treatment refractory epilepsy (5).
Ideally, medical treatments become established over time from a well-researched hypothesis. While there can be various scientific avenues to this verification, its ethical characterizations include having scientific or social value, fair subject selections, respect for all subjects, informed consent, unbiased review, and greater benefit than harm profiles (6). Given the typically vulnerable patient populations seen in the practice of neurosurgery, hopefully, a study’s treatment provides direct or indirect benefits to both those individuals enrolled and their respective communities in an equitable fashion for their participation (7–9). It’s been described that typically those patient populations with treatment-refractory disorders tend to enroll in novel interventions in the hope of some degree of therapeutic efficacy (7). As a clinical example, the RNS device, like other pediatric medical devices before it (10), is technically not yet approved by the Food & Drug Administration (FDA) for pediatric refractory seizures despite being approved for adults and informally accepted by the pediatric neurosurgical community as safe and effective in children (11,12). Why medical devices for kids are in such a regulatory predicament is a multifactorial topic that is beyond the scope of this essay, but it’s important to highlight that due to this pediatric patients obtaining the RNS over the past few years would of unwittingly be “enrolled” in an informal innovative trial (13). However, with no federal regulatory process for developing novel surgical procedures, there is an ongoing need to identify how to properly supervise these unique medical situations for vulnerable pediatric patients (14). Such a situation arguably shares similar characteristics to patients with severe psychiatric diagnoses given pediatric patient’s high levels of vulnerability on average (15–18) and society’s paternalistic role over them in the medical context (19).

Recent expansions of DBS from the neurological and into the psychiatric populations has not been without ethical concern. This is a historically tense area as some of the founding neurostimulatory devices utilized in the 1930s for epilepsy later became related to the socially unfavored psychosurgical neuro-destructive procedures of the mid-20th century (2,20,21). There were also other socially concerning perceptions of neuromodulation due to prior highly questionable neurostimulatory treatments of schizophrenic and homosexual patients (22,23). Given these historical stumbles, moral concerns have
continued to be voiced about the vulnerabilities of psychiatric patients as surgical candidates given their possibly compromised decision-making capacities and the chronicity of their mental disorders. Specifically, emerging questions about the potential impact these cDBS devices have on a patient’s mind are sometimes inferred from clinical data compiled from reports and studies of oDBS (24–27). It is unclear, however, how these prior oDBS studies translate to cDBS systems. In the broader schema this inherent lack of research data to approve said treatment may relate to how surgical interventions for the most severe and refractory mental disorders have understandably been given stringent guidelines globally (28–32). The echoes of medicine’s and neurosurgery’s controversial past create a sense of caution moving forward, especially since a bulk of these cDBS indications remain within the realms of innovative clinical trials, and thus inherently containing somewhat unknown risk and benefit ratios (33).

In order to better understand how to ethically evaluate these cDBS devices, it is important to examine the nuances of how research versus clinical innovations infer different meanings when being used for psychiatric versus pediatric populations, respectively.¹ The remainder of the examination will focus on clarifying how specifically the personalized neurostimulatory therapy of cDBS, as a quintessential example, fit within these currently overlapping paradigms of innovation. In order to do so, further clarification of what evidence-based medicine, clinical research, and standard of care (SoC) practices entail more broadly will be articulated after the ethical and regulatory settings are described. Completing this analysis will help ethically clarify treatments like cDBS as they become more ubiquitous as an intervention for both pediatric and psychiatric patient populations.

Neurosurgical stewardship:

Clarifying ambiguous terms in contemporary ethical discourse is important since medicine as a human-built institution in part reenforces the surrounding social system it’s founded in. For example,

¹ There are concerns of implicit biases towards the perceived superiority of “innovative” treatments, which has motivated the use of nomenclature of “non-validated”. The latter phrasing is more accurate to the unknown risk and benefit ratios seen with these essentially unique interventions, however, since the essay specifically examines the term “innovative” it’s continued to be utilized throughout the text (6).
pediatric patients have long been subjected to experimentation in the pursuit of medical knowledge. These historical abuses have included injecting the children of a poorhouse in Philadelphia in 1802 with an experimental smallpox vaccine, the refinement of the lumbar puncture procedure with hospitalized children in 1896, and a trial of the pertussis vaccine with infants being cared for at the Hebrew Asylum in New York in 1900 (13). Nowadays, neurological surgery, particularly psychiatric surgery, still resides within the shadow of the abuses of the prefrontal leucotomy era of the 1940’s and its associated Nobel Prize (34–36). Back then, enthusiastic media portrayals of the procedure in part contributed to the boost in positive attitudes toward “psychosurgery” (37). These characteristics of medicine coupled with the existing drive for therapeutic discoveries had put many in vulnerable situations. Now with recent enthusiastic media depictions of oDBS and cDBS (38,39), it should be asked whether similar outcomes may emerge, given a setting where negative outcomes are rarely reported (40,41). Namely, as neuromodulatory interventions, like vagus nerve stimulation (VNS) and DBS, continue to develop momentum in the treatment of psychiatric disorders while touting eerily similar rhetoric to past medical practices, it’s best to be hesitant before concluding that history won’t repeat itself (16,42,43). Thus, some have argued that even though researchers point to “modern” scientific knowledge from advanced imaging techniques to justify a “promising” or “emerging” neurosurgical intervention, there has been little to differentiate modern social standards from those of the prefrontal leucotomy era (16). Although it’s also important to note that in part the prefrontal leucotomy’s harm was a byproduct of the relatively laxed requirements of surgical research of the time, given they often lacked the ethical and methodological rigor seen with modern pharmaceutical therapies (7).

With the above-mentioned historical lessons in mind, striving for a realistic reflection of neurosurgery’s scientific justifications allows for a more critical examination of the field’s various innovative practices. This tempered position on contemporary neurostimulatory practices is not presented in preparation for their disapproval, but instead as an attempt to genuinely avoid undue influences from medical desperation or professional tradition when analyzing treatments of severe medically intractable
conditions (34,44,45). Thus, striving to act as a kind of neurosurgical steward, the tone of the argument will strive to hold a high standard of epistemological rigor towards innovative interventions to help elevate effective therapies when identified while also leaving behind medically intriguing experiments or practices that lack major evidence of efficacy (46).

The regulatory history:

Through the 20th and 21st centuries there were a flurry of legislative acts regarding medical device regulation, particularly after the initiation of the Federal Food, Drug and Cosmetic Act (FD&C) of 1938 and the Medical Device Amendments of 1976 (47). Since then, there has been the passing of the Safe Medical Devices Act of 1990, Medical Device User Fee and Modernization Act of 2002, Medical Devices Technical Corrections Act of 2004, and Pediatric Medical Device Safety and Improvement Act of 2007, with each prioritizing the development and access of pediatric medical devices (48). More recently, the FDA Safety and Innovation Act was signed in 2012 followed by the 21st Century Cures Act in 2016. However, it’s important to note that even within these recent bills, they did not explicitly define the term “innovation” (49,50). That said, gleaning from literature on the drug innovation domain, this may have been referring to the creation of first in-class therapies for rare or refractory disorders (51). This use of the term stands in contrast to surgically innovative treatments which are considered personalized and last-resort interventions outside the SoC, thus coincidentally also outside many institutional and federal regulations (10,14,52,53).

The shades of grey in neurosurgical research:

Understandably, neurosurgical research has been limited in its ability to perform large randomized-control trials (RCTs) like other fields of medicine given its need for elevated ethical justifications. Each neurosurgical procedure comes with varying degrees of associated risk but generally involves neurologic deficits, cerebral spinal fluid leak, infection, complications from anesthesia, and stroke, to name a few. These affiliated risks with an innovative procedure normally outweigh the
unknown therapeutic benefits it may provide, even if it’s done in affiliation with an established procedure. As one psychologist put it when describing the use of experimental treatments, “we're not going to know until we're doing it” (54). The elevated risk profiles of neurosurgical procedures have had a significant impact on the level of scientific justification that can reasonably be obtained. This can be seen in how less than 4% of the neurosurgical literature has met the highest level of evidence for clinical efficacy (i.e., Level I evidence out of the five possible levels (55)(16). For example, at the turn of the century there was no level I evidence clarifying the efficacy of radical resection for either low or high-grade gliomas (i.e., brain tumors) and instead the debate had relied on class II evidence (7,56). Notably as discussed previously, the statistics for level I evidence in pediatric neurosurgery was likely worse off than the field at large given the higher level of rigor required with this patient population’s involvement in research.

Importantly, other factors of conducting RCT such as their labor, time commitments, financial burdens, and possible focus on rare diagnoses contribute to the level of difficulty there can be with this modality of research (16). Similarly, these trials can come with strict inclusion/exclusion criteria for participants subsequently limiting the degree in which the findings may be applicable to the general patient population (16). However, these factors, while statistically impactful to RCT at large, are beyond the scope of this discussion. Instead, the focus is on the ethical tension inherent in these procedures that have mostly uncertain efficacy and risks associated with them. To help ease the tension present in surgical trials subjects considered “treatment refractory” are favored to be enrolled given they have “less to lose” than healthier patients (57). However, this priority to enroll patients possibly desperate for effective medical therapies inherently involves those with a serious vulnerability to being harmed or wronged in the research process (46). As previously mentioned, levels of patient vulnerability increase when considering pediatric patients or those with psychiatric disorders given their varying levels of decision making capacities (16). Thus, adult patient populations have frequently subsumed the place of more scientifically relevant but ethically delicate pediatric focused research (58).
Along with the presence of a placebo/control group, the quantity of enrolled research subjects alters the power of a study’s findings. Recent analyses identified the typical trial size of surgical placebo trials to be relatively small with >100 patients being randomized in 65% of studies while only a small chunk had >200 participants (46). Similarly, as the number of research enrollees weans closer to small cohort studies or case studies, the resulting data’s generalizability becomes increasing inaccurate (6,59). That is, as the quantity of patients enrolled decreases, the subsequent research findings are positively correlated with developing a bias that may misguide clinical practice directions (60). Thus, if larger scale analytic studies are not possible at a single location or if clinical trials are not typically performed for a particularly rare disease, the collection of data in dedicated registries has been argued as a vital way to obtain the necessary evidence to ascribe meaningful findings (34,54) (see UFHealth 2022 for an example of DBS registries).\(^2\) For example, outside VNS for TRD (63) or DBS for OCD (64), psychosurgical investigations are still experimental in nature and may benefit from such a registry-based approach due to inherent difficulties in local enrollment practices (16,63,65). Separately, these registries can also be used if a patient population’s particular vulnerability inhibits their ethical enrollment in RCT. This methodology can be seen with pediatric patients receiving cerebral spinal fluid diverting shunts (16), those needing neuromodulation therapies for neurodevelopmental disorders (58), or with disabled patients who are dependent on their brain-computer interface neuro-prosthesis (16).

Perspectives from evidence-based medicine:

Evidence-based medicine’s (EBM) methodology has been focused on integrating the best available research evidence with a patient’s clinical circumstances and values to provide them with an optimum level of care (16). EBM finds itself throughout modern medicine, including neurosurgery, with interventions supported from a spectrum of datasets, including RCT or other empirical studies. Given the

\(^2\) It should be noted that “although registries can provide useful ex post information about new medical interventions, they cannot resolve legal and ethical issues that arise when an innovation is first introduced, such as patient selection, informed consent obligations, and substantive assessment of benefits, risks, and uncertainties” (62).
variable methodological rigor and quality of these investigations, the findings often require hierarchical 
organization based on their power and generalizability, normally related to the number of enrolled 
participants and use of a placebo group, to answer a particular treatment related question (16). Since DBS 
technology has the unique ability to aid in setting up placebo conditions with “sham stimulation”, the size 
of enrolled participants plays a larger role in the quality of DBS research. In order to aid this process, 
guidelines have been published for assessing the quality of various evidence sources, such as with the 
Enhancing the Quality and Transparency of Health Research (EQUATOR) guidelines (16).

Given the broad range of evidence available, it appears that the skill of an evidence-based 
neurosurgeon rests in how they make the most of what data there is available for a particular procedure or 
pathology when treating individual patients. This can be challenging in a contemporary neurosurgical 
setting given the multitude of available approaches developed in recent decades to treat the similar 
pathologies. Such a situation can be seen in the surgical management of focal or generalized refractory 
epilepsy, where there exist the VNS, DBS (oDBS), RNS (cDBS), laser interstitial thermal therapy (LITT), 
and open resection treatments (66). However, in line with historical trends the rapid evolution in the 
neurosurgical field in general has come with few high evidentiary supports for one approach over another, 
outside of the clinical and possibility anecdotal experiences of surgeons (7). Theoretically then treatment 
likely becomes more challenging when the particular pathology under consideration is ill-defined, as is 
the case with some psychiatric conditions that are still largely based on phenomenological or subjective 
factors (16). These psychiatric presentations would normally be explored in RCT for DBS by the 
identification of a corollary biomarker in which to target (67). However, this is difficult if these 
subcortical targets are still under debate for a severe psychiatric presentation, such as with anorexia 
nervosa (68), in which proceeding with experimental trials comes with affiliated risks of an

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3 However, it should be noted this sham stimulation has limits given “all patients are operated on, so placebo effects 
and lesion effects have to be expected for all patients. Therefore, strictly speaking, no real sham-controlled DBS 
studies have yet been performed with psychiatric patients. For that, another control group would be necessary that 
receives a sham operation without electrode implantation. However, this must not be done for ethical reasons.”(59)

4 Details at www.equator-network.org/reporting-guidelines/stard.
undermanaged disorder, namely how this case could involve surgical complications due to subjects experiencing severe chronic malnutrition (45). It should be noted there are efforts being made to remedy this to allow a more informed placement of DBS leads to unique and objective neuronal targets (69). This process has consisted of “personalized stimulus-response mapping, pairing of resting-state signals with clinical symptom measures and identification of functionally and structurally connected subnetworks across the corticolimbic network” (67). However, until this research has grown to have clinical verification, the ethical examination of most psychiatric surgical procedures, in this case DBS, are limited to an ethical debate with incomplete or unreliable data. Thus, the major justifications for adult subject enrollment typically rests on the validity of the aforementioned research, a lack of any known effective treatments, and the treatment population having a substantial percentage of subjects who are treatment-resistant (46).

Prior to extending a particular treatment to the level of RCT, personalization of surgical treatments via innovative adjustments provides an alternative middle ground between RCT and formal case reports of clinical care (like N-of-1 trials). This trend towards precision medicine (PM) can be seen occurring in neuro-oncological investigations of treatments given the difficulty with conducting large scale trials on rare brain tumors (6). This PM approach relies on tumor classification and patient clustering/molecular stratification to deliver tailored oncologic therapies (70). The pros of this approach include maximizing clinical effects of a therapy while minimizing associated negative side effects. However, the cons include difficulty in determining the likely side effects given the lower statistical power of the study (6). Either way since these trials are intended to provide patient benefit, as opposed to purely the generation of knowledge, their status as “innovative” treatments still retain several biases as opposed to a RCT (71). As previously discussed, invasive neuromodulatory therapies are being investigated to remedy psychiatric disorders through the implementation of cDBS devices (72). The

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5 With these novel adjustments, it is important to note, “repeated use of an innovative procedure followed by retrospective review of clinical outcomes using that procedure, while not technically research under federal guidelines, encompasses many of the features of a formal clinical trial” (62).
previous oDBS style, while generally considered effective for OCD (65,73), has had to experience revisions since its investigation as an intervention for disorders such as TRD (74). Given the high variability with the implantation of these devices per patient via processes like personalized stimulus-response mapping (67,75), they can run into some of the same problems of treatment generalizability found with PM treatments. Thus, even if it was logistically feasible, their ability for investigation via large cohort placebo controls is debatable. However, given the obligation for investigational surgical interventions to hopefully provide a benefit to its enrollees, there isn’t a clear ethical distinction between trials based solely for the development of generalizable knowledge versus those for possible participant betterment.\footnote{There are, however, important distinctions in how a patient/participant stands in relation to the surgeon. In a clinically innovative treatment approach a typical doctor-patient relationship can be seen while in research a surgeon’s priority as an investigator is technically the study (76).}

The nuance of neurosurgical innovation:

The investigation of neurosurgical procedures as ethically relevant innovative practices is overall a relatively modern debate (6). However, in particular to the field of surgery, innovation is a long held tradition that intertwines clinical care with the fast pace development of new medical or technical approaches (16). Surgeons are actually recognized for their ability to innovate given the associated opportunities for publication, prospective patient attraction, and professional advancement (62,77,78). Now, using a broad definition of “innovation” some authors support it as those practices that are off-label since they are not SoC, nor strictly part of a clinical trial (16,34). Although not always the case, innovative practices are most commonly cited as attempts to hopefully elevate a patient’s level of care. A publicly available administrative document from Boston Children’s Hospital, highlights that no more than one or two of these procedures ought to be conducted, for it/them to still be considered innovative (79). Interestingly enough though these personalized adjustments, for example individual patients having similar or separate cDBS neuroanatomical targets, if collected and analyzed together may still assist in the
production of generalizable knowledge (16,78). Such a categorization fits well with the last few years of publications involving RNS device utilization in pediatric populations (11).

Other authors have instead described innovative practices as present in both the clinical and research domains when saying, “innovation in research is aimed at generating generalizable knowledge, while innovation in clinical care is aimed at improving the outcome of the individual patient” (6). This latter definition of innovative practices appears to subtly add “innovation in research” to what was previously described in the former definition by Honeybul 2020 as more in line with clinically innovative practices. Thus, the expansive grey area that is neurosurgical innovation, per the suggestion of Broekman 2019, may have separate research and clinical roles. However, the dichotomy of rigid protocols with clinical research on one end versus flexible clinical care on the other is challenging to grapple with given how smoothly an innovative personalized clinical practice can then become research as soon the medical team synthesizes the results of an innovative practice retrospectively for possible publication (see footnote 5)(60).

Psychiatric surgery with cDBS demonstrates this broad categorization of innovation well given how it provides personalized treatments to patients who are few in number, exhausted conservative alternatives (i.e., talk, pharmaceutical, and extracranial neuromodulation therapies), and are in a vulnerable patient category that appear to favor enrollment in a clinical over a single participant (N-of-1) trial via compassionate use/expanded access (80). This last characterization is notable as a difference between the broad use of innovation (clinical and research) in psychiatric cDBS compared to the narrower clinical use of the term in pediatric epilepsy patients (81–85). Some of this differentiation between these two populations may be due to a National Institutes of Health– and Dana Foundation–sponsored consensus conference titled “Deep Brain Stimulation for Disorders of Mood, Behavior and Thought: Scientific and Ethical Issues” which specifically recommended in 2009 that “patients should not undergo DBS for disorders of MBT [mood, behavior, & thought] without participating in an established, duly constituted, independently reviewed research protocol. Deep brain stimulation performed for
compassionate or humanitarian use in single or small groups of patients should not be exempted from independent ethical review and oversight” (86). More contemporary influences may include the lack of expanded access opportunities for medical devices, as listed on ClinicalTrial.gov (87).

In response to these two categories of cDBS innovation, it is tempting to classify either of them into one class or the other via its primary intention when implemented. That is, if a provider’s goal with the placement of cDBS leads in a different hypothesized subcortical region for TRD or the electrocorticogram relying on a different local field potential was to primarily benefit the patient instead of necessarily collecting publishable data, it maybe should be classified under the narrow definition. While this is a valid way to differentiate examples of innovation, it may be problematic in a couple of ways. Firstly, it could be impractical to base a classification system on an “intended” purpose as it would be difficult for audiences and regulators to identify the priorities of the original researchers. Secondly, it seems to rely heavily on there being a clear dichotomy between clinical care and research. Instead, appreciating the heterogeneity of innovative cDBS treatments as some ratio of both research and clinical care, better consolidates the definitions provided by Honeybul 2020 and Broekman 2019. These devices can therefore help better demonstrate the amalgam of research and clinical care goals present in innovative neurostimulatory practices. This conclusion should not be taken as implying it’s impossible to have clear examples of innovative neurosurgical practices or clinical trials. Instead, it humbly denotes that likely the majority of the times cDBS devices are being utilized in contemporary medicine are for tasks that are not well differentiated between traditionally understood research or clinical care methodologies. Due to this distinction, it is critical that notions from both clinical and research ethics are utilized when investigating the use of cDBS implementation (16).

7 There are surgical “variations” that do not appreciably change the risk/benefit ratio, and thus would not meet the threshold for being labeled a clinically innovative modification that would subsequently require disclosure to the patient (77).
Typically, speaking of innovative practices would incite the possible utilization of principles from clinical and/or research ethics. However, it should be that both domains are relied upon for the examination of cDBS interventions. Among research principles pertinent to these examinations, there will be the need for obtaining a thorough informed consent, a favorable risk-benefit ratio, and attempts made to maximize scientific validity (16). Some of these were demonstrated in a recent qualitative investigation that pointed to research subjects enrolling or declining in cDBS trials due to the associated novelty of the therapy. For those who enrolled, the hopes for symptom relief, contributing to the generation of knowledge, and obtaining access to an expert team of providers were noted as frequent rationales that swayed participants in favor of enrollment. However, what some interviewed subjects had been biased to was the technological enthusiasm with what was thought of as a “newer equals better” technology bias (88). Although technically most innovative practices should not have too substantial of a change to elevate its surgical risks, interviewed participants were also noted to not be acknowledging that there is the possibility there may still be additional risks of harm despite the provider’s best attempts (7,88). In line with this subtle shift from medical to research-like settings, other authors have described the transition from SoC treatments to innovative practices as “the crossing of an invisible border” (see footnote 6)(7).

Once the device has been implanted, an important component of neuromodulation’s clinical examination has been its ability to be turned off or significantly adjusted and act as a placebo-like phase (i.e., sham DBS), unless negative side effects are elicited (64)(a helpful protocol for understanding the “ON” and “OFF phases of investigational stimulation can be seen in (89)). Then during subsequent post-operative evaluations, it has been advised parties other than the original surgeon be utilized to collect the relevant data so as to avoid both unconscious and conscious biases (16). Ideally, participants would not

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8 The actual regulation of clinically innovative procedures is beyond the scope of this examination but importantly relies on the legal system (i.e., Tort law) given it calls outside the coverage of research studies that utilize Common Rule and the Federal Drug Administration. This regulatory territory “requires physicians to solely bear the liability costs of innovative treatment” (62).
hold financial responsibilities for the investigative cDBS treatments they are receiving, given the at least partly experimental nature of the care (16). However, assuming a clinical response to the intervention, how subjects may retain the device over the long run remains a topic of debate (90). To accommodate for the likely sparse numbers of enrolled patients at any individual institution, multi-institutional database registries may be gradually developed to account for these difficulties. Examples of this can be seen in the United Kingdom’s pilot study of DBS for AN and University of Florida’s examination of DBS for Tourette’s Syndrome (see footnote 5)(45,61,91). Having these inter-institutional treatment groups, although likely varying in methodology by some degree, can help circumvent the challenges with the RCT design that inherently utilize large participant groups to obtain meaningful statistical findings (6). That said, it’s important that innovative investigations not present their eventual findings as an adequate replacement of more classic RCT or to inattentively allow the “innovative” practices to be taken up in clinical practice too soon, as can be common in pediatric specialties. Plus if an opportunity to perform high-level research was obtained in the near future, investigators may have a hard time identifying patients willing to enter a RCT if those previously evaluated innovative practices were already in clinical use.

Conclusion:

As the practice of neurological surgery evolves through modern medicine, it’s reliance on developing novel practices does not show signs of slowing. If anything, these practices, commonly referred to as “innovations”, help establish the field’s knowledge before formal high-grade research has the chance to be conducted. However, given the elevated level of ethical standards required with these procedures, desperation ought not undermine scientific validity. Particularly as invasive brain technologies develop at a rapid pace, this integrity may become increasingly difficult. It is integral to the field that the methodological rigor of innovative procedures remains on par with more traditional forms of RCT, particularly as these treatments venture further into the psychiatric and pediatric populations. To
help in this pursuit, this argument examined the unique presentations of cDBS devices in both of these populations as holding goals of clinical care and the generation of generalizable knowledge. Despite their nuanced differences, the amalgam of these goals presented the technology as being at a middle ground between classical understandings of clinical care practices and RCT models. With these distinctions in mind, the inclusion of both clinical and research ethics principles was advocated for when evaluating the use of cDBS devices in vulnerable patient populations. This way the best balance between knowledge acquisition and patient care can be found.

Acknowledgements:

This essay is derived from a chapter of my master’s thesis completed at the University of Tasmania in 2022. As such, I would like to thank the University of Tasmania for the funding to have completed that research, Dr. Frederic Gilbert for his supervision through the course of my graduate work, and Dr. Lázaro-Muñoz (Harvard Medical School) for his insightful feedback regarding the thesis. This submission also includes knowledge obtained while a graduate student at Harvard Medical School’s Center for Bioethics. Thus, I would also like to extend my appreciation to the various professors who’ve fostered my continued exploration of this topic in numerous course assignments.

Work Cited:


