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Mental Health, Implantables, and Side Effects

When I was 8 years of age my older sister who was 8 years my senior was diagnosed with paranoid schizophrenia. As a result, my family spent quite a few years visiting hospitals and mental health facilities on a daily basis. It is painful to reflect on that period, as our whole world was rocked by this illness. My once vibrant, skilful, dynamic, energetic, extremely kind, and top-of-her-class sister was plagued by a disease process of schizophrenia that would have her attempting to take her own life on several occasions, battle with hearing voices, go into a state of catatonia for long periods of time, and suffer severe bouts of anxiety and depression.

The onset of my sister's schizophrenia was spontaneous, during what should have been the most carefree years of her life. We will never know what triggered her illness but for whatever reason that this "thing" landed in our household, we learned to come to terms with its impact. I grew up with an understanding that, in life, there are some things we can fix, and some things we cannot. There are some things we can explain, and some things we cannot. Sometimes medical science has the answers, and sometimes it does not. It does not mean I give up on the potential for a cure or therapy for various forms of mental illness, but I am more wary than most about silver bullet solutions.

In the 30 years my sister has lived with schizophrenia there have been numerous incremental innovations that have been beneficial to some sufferers. First, there have been advancements in pharmacology and in the composition of antidepressants so that they are more effective. But pharmaceutical treatments have not helped everyone, especially those sufferers who do not take their medication on a regular basis. Many persons living with depression who come on and off antidepressants without seeking medical advice are at an increased risk of suicide.

Cognitive behavior therapy (CBT), an empirically-based psychotherapy, has also aided increasing numbers of patients to better cope with their condition. Yet CBT is not given the same media attention as the new range of dynamic neural stimulators, commonly dubbed "brain implants," now on the market [1].

For sufferers who are diagnosed with major depressive disorder (MDD), and for whom antidepressants and CBT simply do not work, doctors have turned to the prospect of somatic therapies. These include: electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), vagus nerve stimulation (VNS), and deep brain stimulation (DBS). If an individual does not respond to ECT (and only fifty per cent do), they are said to have treatment-resistant depression (TRD) [2].

In plain language, ECT is when electricity is applied to the scalp generally over a treatment period of between 2-4 weeks, several sessions per week. rMTS treatment goes for 4-6 weeks, of 5 sessions per week and uses a fluctuating magnetic field from electromagnetic coil placed outside the skull sending an electrical current to the brain.

VNS and DBS are more intrusive procedures targeting specific parts of the brain [3]. In VNS, an electrode is wrapped around the left vagus nerve in the neck and stimulation occurs about every 5 minutes for about 30 seconds. The battery packs sit under the skin of

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the chest in both VNS and DBS, but in the DBS procedure, one or more leads are implanted in the brain, targeted through burr holes in the skull, and locked into place [2].

VNS and DBS were unavailable techniques when my sister first became ill, but I do recollect vividly the results of ECT upon her. Post the treatments, we lost her well and truly into a dark space one cannot reach – she was placed on higher dosages of antidepressants for the weeks to follow, and it was apparent to us she was not only in mental anguish but clearly in physical difficulties as well. Doctors claimed clinically that she "did not respond to the treatment," but never acknowledged that the ECT *process* might have caused her any short-term distress whatsoever. In fact, we were told: "There is no change in her condition. She continues to be as she was before the treatment." That was debatable in my eyes. Even though I was just a kid, I observed it took a good three months to get my sister back to where she was before the ECT treatment. But she was only one participant among many in clinical trials, and in no way do I generalize her outcomes to be the outcomes of all ECT patients.

VNS and DBS are again very different techniques, and while VNS is used as an adjunct therapy for major depression, DBS is mainly reserved for treating Parkinson's disease and has had only limited approval for combatting intractable obsessive compulsive disorder (OCD). However, what I gained from those childhood experiences is that human life is precious and experimentation can have some very adverse side effects without any direct benefits to the individual sufferer. Doctors need to be held accountable, caregivers and patients with MDD must be told clearly about the risks, and VNS patients must be monitored closely into the longer-term. I am alarmed at the lack of qualitative research being conducted across the spectrum of implantable devices in the health sector. And that is an area I intend to personally address in my own research in years to come.

To this day, I believe my sister was in no condition to consent to the treatment she received. At the time she intermittently thought I was Brooke Shields and that my siblings were other television personalities. She was delusional and completely unaware of herself. Prior to the trial my sister participated in, my parents had no real idea what ECT was, save for what they had heard anecdotally. As my sister's "guardians," my parents did not understand how ECT would be administered and were not given the option to accompany her during the actual treatment. They were simply told that my sister would wear something on her head and have an electrical current travel all around it to hopefully "zap" her back to normal. They were not informed of what the risks might be to their beloved daughter, although they were clear it was all "experimental." It was also emphasized, that this "electroshock treatment" was the only other alternate route of exploration to help my sister get better. I remember their expectations being raised so high, only to be dashed after each treatment [4]. My parents had to rely on an interpreter as my father did not speak English and my mother only broken English. When one was not available my brother and sisters and I would do the translation.

In the end, when all other routes failed, my family turned to God for help. Alongside an excellent medical and health team (psychiatrist, social worker, general practitioner), and a loving home environment, it was faith that gave my family the will to go on facing everyday issues, as my sister slowly regained parts of herself to become functional again, such as her mobility and speech. As the saying goes "prayer works," and while it might not make rational sense to believe in *miracles*, I remember witnessing these on at least a few occasions.

A few months ago, the cover of the February 2015 issue of *IEEE Spectrum* was graced with the title: "Hot-wiring the nervous system: implanted in the brain, smart-systems are defeating neurological disorders" (pp. 28) [5]. As someone who has spent the greater part of their academic career studying surveillance, risk, privacy and security, trust, and control, I have long reckoned that if we can "defeat" neurological disorders using implantable devices, then we can also "construct" and "trigger" them willingly, as well. But the point of my editorial is not to discuss the future of dynamic neural stimulators; we can debate that in another issue of *T&S Magazine*. Rather my point is to try to generate discussion about some of the fundamental issues surrounding the socio-ethical implications of penetrating the brain with new technologies, especially those that are remotely triggerable [6].

While the early studies for VNS with respect to MDD look promising, we need to acknowledge we are still at the very beginning of our investigations. I am personally more circumspect about published figures that simply categorize subjects post implantation using minimal labels like "non-responders," "responders" and "achieved remission" [7]. Longitudinal data will give us a clearer picture of what is really happening. DBS, on the other hand, has been used to treat well over 75 000 persons, mostly suffering from movement disorders [2], but it is increasingly being piloted to treat OCD [8]. This is a call to the research community, to publish more widely about some of the complications,

side effects, and resultant social life changes that implantees (of all kinds) are faced with post-surgery.

I am not referring here to issues related to surgical implantation (e.g., symptomatic haemorrhage after electrode placement), or even device failure or hardware-related complications (of which I have great concerns that there will be severe hacking problems in the future). Rather, I am referring to the resultant effect of "artificially constructed" dynamic stimulation on the human brain and its impact on an individual. In short, these are the unintended consequences, that range in scope from psychotic symptoms post stimulation (e.g., for epilepsy, or for patients presenting with auditory hallucinations for the first time), to modifications in sleep patterns, uncontrolled and accidental stimulation of other parts of body function [9], hypersexuality, hypomania [10], changes to heart and pulse rates, and much more.

Many implantees resort to social media to share their pre- and post-operative experiences. And while this is "off the record" self-reporting, clearly some of these discussions warrant further probing and inquiry. My hope is that the copious note-taking that occurs during pilots and clinical trials, specifically with respect to side effects, will be more accessible in the form of peer reviewed publication for doctors, engineers, government officials, standards organizations, regulatory approval bodies, and of course, the general public, so that we can learn more about the short-term and long-term effects of neural stimulation devices.

One patient, as a result of a particular procedure in a DBS pilot study described a sensation of feeling hot, flushed, fearful, and "panicky." "He could feel palpitations in his chest, and when asked indicated he had an impending sense of doom. The feelings were coincident and continuous with the stimulator 'on' setting and they rapidly dissipated when switched 'off'" [11]. Surely, this kind of evidence can be used to inform stakeholders towards what works and what does not, and the kinds of risks a patient may be exposed to if they opt-in, even if we know the same state will not be experienced by every patient given the complexity of the brain and body. In the more mature heart pacemaker industry, it is device manufacturers who tend to wish to hoard the actual physiological data being recorded by their devices [12], [13]; the brain implant industry will likely follow suit.

To conclude this editorial, at the very least, I would like to echo the sentiments of Fins *et al.*, that deep brain stimulation is a "novel surgical procedure" that is "emerging," and should presently be considered a last resort for people with neuropsychiatric disorders [14]. There needs to be some tempering of the hype surrounding the industry and we need to ensure that rigor is reintroduced back into trials to minimize patient risk. Exemptions like that granted by the U.S. Food and Drug Administration (FDA) on the grounds of a "humanitarian device" allow implant device manufacturers to run trials that are not meaningful because the size of the trial is inappropriate, lacking commensurate statistical power [14]. The outcomes from such trials cannot and should not be generalized.

I would go one step further, calling not only for adherence to more careful research requirements during clinical trials, but also urging the medical community in general to really think about the direction we are moving. If medical policies like these [15] exist, clearly stating that "there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with (vagus nerve stimulation) … for depression" then we must introduce major reforms to the way that consent for the procedure is gained.

Between 1935 and 1960, thanks to a rush of media (and even academic coverage), lobotomies were praised for the possibilities they gave patients and their relatives [16]. Although I am not putting lobotomies on the same level as VNS and DBS, I am concerned about placing embedded devices at the site of the most delicate organ in the human body. If we can "switch on" certain functions through the brain, we can also "switch them off."

It is clear to anyone studying emerging technologies, that the future trajectory is composed of brain implants for medical and non-medical purposes. Soon, it won't be just people fighting MDD, or OCD, epilepsy [17], [18], Parkinson's disease [19] or Tourette's Syndrome who will be asking for brain implants, but everyday people who might wish to rid themselves of memory disorders, aggression, obesity, or even headaches. There is also the potential for a whole range of amplified brain technologies that make you feel better – diagnostic devices that pick up abnormalities in physiological patterns "just-in-time," and under-the-skin secure identification [20]. And while the current costs for brain implants to fight mental illness are not cheap, at some $25 000 USD each (including the end-to-end surgical procedure), the prices will ultimately fall [1]. Companies like Medtronics are talking about implanting everyone with a tiny cardiac monitor [21]; it won't take long for the same to be said about a 24x7 brain monitor, and other types of daily "swallowable" implants [22].

Fears related to embedded surveillance devices of any type may

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often than I would like to admit, I am forced to ask for assistance from a sighted person, call a company if there is a phone number listed, or forget about doing whatever I had planned to accomplish online.

Another significant obstacle facing the blind is the prohibitive cost of assistive technology. Unfortunately, the vast majority of people who are considered legally blind, which encompasses a fairly wide range of visual acuity, are economically disadvantaged due to extremely high levels of unemployment and underemployment. An even greater financial burden falls upon those who rely on Braille displays. The Braille displays cost far more than a simple screen reader with synthesized speech that can run on virtually any computer and which can now, in some cases, be obtained free of charge. Imagine paying an extra $1500–$2000 for a computer screen because you don't want to listen to an automated voice but would rather read because it improves your efficiency. Consider how much this discourages Braille literacy and the negative impact on our entire society as our children are learning to rely on tools like spellcheck rather than learning to spell.

I believe the fact that the population of blind people is a minority is one of the major reasons our technology needs are not always met. Some people are not aware of what we need when they are creating websites and programs. When it comes to purchasing assistive technology, we face the law of supply and demand. Though I am grateful for the technology I use every day, only time will tell whether the situation will improve.

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be informed by cultural, ethical, social, political, religious concerns that must be considered during the patient care process [23]. Fully-fledge uberveillance, whether it is "surveillance for care" or "surveillance for control" might well be big business in the future [24], but for now academicians and funding bodies should be less interested in hype and more interested in hope.

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