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**Background**

**What is Neuralink?**

- The Neuralink device is an invasive brain-implant that will function as a brain machine interface (BMI) and consists of an array of 96 flexible polymer probes possessing up to 3072 electrode channels, see Fig. 1a-c. Neuralink has developed a neurosurgical robot which inserts 6 polymer probes, 192 electrodes, per minute with micron precision in order to prevent damage to surface microvasculature and to target specific cortical areas of the brain. In rat models, the chronically implanted BMI achieved up to 70% spiking yield, which means that digitized broadband signals from the probes were effective at identifying action potentials in real time, see Fig.1c (10).

**Future Applications**

- Neuralink has submitted for Food and Drug Administration (FDA) approval with the intent to begin testing technology on human volunteers in 2020 (13)(16).
- Neuralink aims for the installment of its BMI to become as “safe and easy as LASIK eye surgery” (14).
- If successful in the anticipated clinical trials, Neuralink’s BMI has the potential to tackle brain lesions and disorders (10). However, Neuralink aims for eventual human cognitive enhancement and “symbiosis with artificial intelligence” via future iterations of its BMI technology (7)(6).
- It is speculated that the BMI electrodes will eventually permit recording of neural data and neural stimulation, which with the advancement of computer algorithms may in the future be used to decode existing or write new memories, among other possible cognitive enhancements (6). This may be possible once neuroscience advances to a point in which the complex circuitry of short and long term memory has been mapped.

**Concerns**

- A number of ethical, legal, and social implications (ELSI) arise regarding Neuralink’s BMI technology, particularly due to its anticipated human trials and access to user brain data. Should Neuralink’s technology be effective, these ELSI must be addressed to protect patient rights and safety. Although our focus is primarily centered around Neuralink’s BMI, the implications brought up extend to other BMI technologies. Regulations and safeguards to address the ELSI of BMI technology must be promulgated prior to large scale trials.

**Privacy and Cybersecurity**

**Hacking**

- Neuralink’s BMI design has digital USB-C and bluetooth capabilities, see Fig. 1b, which could theoretically allow for individuals’ installed Neuralink devices to be hacked knowingly or unknowingly, or “with or without the permission from the user” (6). As data has been referred to as the “currency of the future”, users may desire to sell brain data extracted via hacked Neuralink BMI devices, akin to selling organs in the black market (6). Furthermore, if Neuralink technology becomes capable of accessing brain data, policies must be established to prevent third parties from maliciously editing, manipulating, or placing false data in the brains of Neuralink users. While this may seem improbable, consider that in recent research experiments, false as well as artificial memories have been placed in the brains of mice (16)(19).

**Brain Data and Government / Third Party Spying**

- As a society we must ensure that emerging technology such as Neuralink can benefit individuals while protecting private brain data. We must decide whether Neuralink, the government, or an individual should have rights over personal brain data. For instance, several sections of the privacy policy of genomic and biotechnology company 23andMe permit the disclosure of personal data whether or not consent is obtained by the user (21). To this end, in 2018, 23andMe sold a \$300 million dollar stake of the company to pharmaceutical drug giant GlaxoSmithKline, permitting the company access to 23andMe’s genetic data gathered from users, with the goal of developing new drugs and to better prepare for clinical trials (2). Without oversight, conditions similar to this may present with a Neuralink technology that is capable of accessing users’ brain data. Indeed, our future brain data may become “commodified” (6). Moreover, given the 2013 disclosures regarding government surveillance programs by American whistleblower Edward Snowden as well as the Patriot Act, it is not difficult to imagine that there would be a desire and push in the future from governmental agencies and other organizations to acquire brain data via Neuralink or related neurotechnologies (19).
- This is the time to consider placing safeguards overseeing the development of this technology.

**Neuralink in the Legal System**

- The Frye standard permits the use of “scientific, technical or other specialized knowledge” in a legal court so long as there is a qualified expert to testify on the reliability of such evidence and that the evidence produced is from a modality generally accepted by the relevant scientific community (11). Federal Courts use the Merrill Dow standard for admissibility of evidence, which provides Judges wider latitude in accepting scientific evidence. It could be argued that application of brain data such as mental state may be held admissible in a court of law and could be used to either convict or prove innocence of defendants, enhance witness testimony or exonerate wrongfully convicted inmates, similar to how DNA evidence is used within the legal system and forensics (1)(15).
- The procurement of brain data may pose a legal or ethical dilemma, considering that U.S. citizens may or may not be protected from unreasonable searches and seizures or from incriminating themselves by the Fourth and Fifth Amendments of the U.S. constitution (1)(9). For these reasons there should be a committee that contains scientific experts which may be called upon to evaluate the reliability of brain data, as well as ethics and law experts, who would provide insight into the constitutionality of acquiring and utilizing brain data.
- Due to the concern that emerging “mind-reading” technology could threaten personal privacy, some have called for the establishment of a legal doctrine on the “right to mental-self determination” or “cognitive liberty” (3)(18).
- It is important to establish this doctrine prior to product debut, delineating whether Neuralink may be mandated to disclose private brain data. The company 23andme serves as an example of unintended consequences of there not being clear laws on similar technology. 23andme disclosed that they are required in “certain circumstances” to disclose individuals’ private genetic information to law enforcement (22).

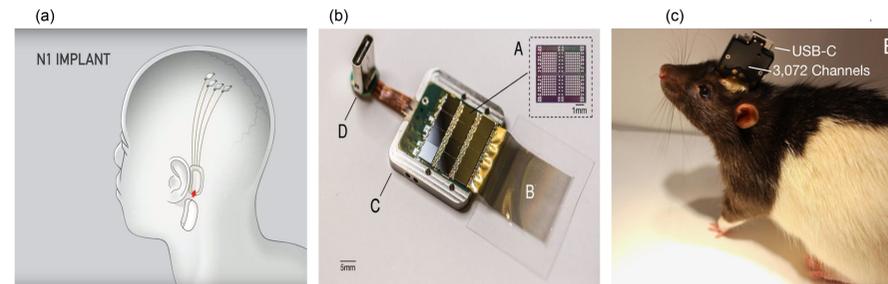


Figure 1a-c. 1a. Image representing the Neuralink device implanted in a human (12). 1b. Neuralink’s brain machine interface design, with a USB-C port. 1c. Image of Neuralink testing in rat models (10).

**Road Map for Future Concerns of Cognitive Enhancing Technology, Neuralink**

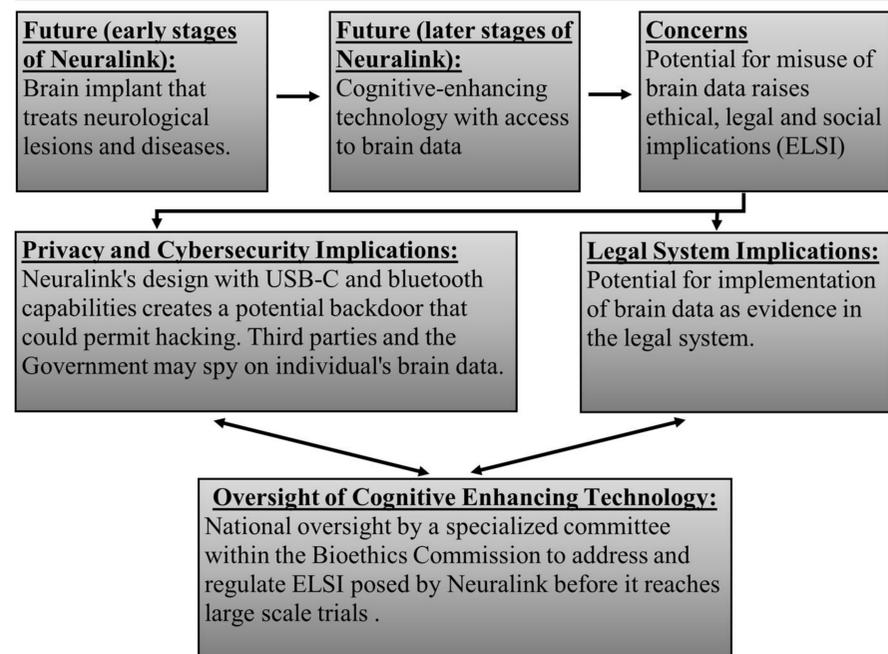


Figure 2. Flow chart outlining the concerns that may arise from Neuralink’s anticipated development of cognitive enhancing technology and the need to address such concerns with an oversight committee.

**Oversight Proposal**

- If the Neuralink BMI has the potential of transitioning into a medical and cognitive enhancing device (7), then the technology must be overseen with diligence and care by the society it may be impacting, see Fig. 2. It is therefore of utmost importance that policy is established in preparation for this.
- The aforementioned ethical scenarios are just a few of the many ways a Neuralink BMI with access to brain data can be exploited. Rather than suggesting an outright ban or sanction that would put a stranglehold on future advancement of neurotechnologies with the capacity to enhance the human condition, we suggest the development of a national committee that would oversee such technologies, akin to FDA’s oversight of pharmaceuticals. Thus, we call for a federal BMI technology oversight committee to be established. The task of such an oversight committee would be to anticipate, prepare for, and address through public policy ELSI and concerns that may arise as BMI technologies, such as Neuralink, advance.
- On April 2, 2013, the Obama administration announced the White House BRAIN Initiative (Brain research through Advancing Innovative Neurotechnologies) with the goal of supporting and developing novel neurotechnologies to create a map of brain functioning similar to that of the human genome project (9). Participants include DARPA, IARPA (Intelligence Advanced Research Projects Activity), and many other universities, private companies, and organizations. The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) was also established by Executive Order 13521 to explore the ethical, legal, and social implications raised by the BRAIN initiative and the field of neuroscience (8).
- The role of the FDA is to protect public health by ensuring that medical devices are safe and effective (5), but that is not enough considering that BMI technology has the potential to impact ethical, legal, and social dynamics. Since the ELSI of medical devices fall outside of the FDA’s oversight, we call for a BMI technology oversight committee to be added as an extension of the Bioethics Commission. A frequent public report should be made to describe the ethical analysis of advancing BMI technologies. The committee can coordinate with similar organizations such as the Australian Brain Alliance (ABA). The ABA’s mission is to develop “national guidelines for responsible neuroinnovation to assist neuroscientists, engineers, and developers to translate research into effective and ethical products” and to “mitigate potential ethical threats at the design stage, that meet the needs of the community, and that also enhance the capacity for implementing recommendations through public uptake and policy” (4).
- This proposed committee should also address and regulate other ELSI brought forth by BMI technology advances that cannot be anticipated. It is essential that we prepare for the anticipated societal and psychological implications of emerging BMI technology and its foreseeable impact on workplace/employment, family and community dynamics, as well as mental health, among many others.

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