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CORRESPONDENCE

Letter: Ethical concerns and scientific communication on neuralink device

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Dear editor, on January 29, 2024, Neuralink, a company founded by Elon Musk, made a momentous announcement that significantly impacted the field of neuroscience. This announcement was the successful implantation of the world's first-ever "brain-reading device" into the human brain, representing a significant achievement in the realm of brain-computer interfaces (BCIs). The device, which was designed to record and decode brain activity, is intended to enable individuals with severe paralysis to control external devices, such as computers, robotic arms, and wheelchairs, simply by thinking about it. While the news was met with great interest and excitement, it also raised concerns among neurotechnology researchers. Some experts expressed cautious optimism about the device's potential, whereas others noted that more research is needed to fully assess its safety and biocompatibility.

However, the issue at hand is not about the potential risks, feasibility of the procedure, or assumption of science fiction scenarios. It is not uncommon for medical devices with recording capabilities to be implanted in the human brain, and deep brain stimulation (DBS) has been widely used since the 1980s for neurodegenerative diseases, such as Parkinson's disease. The main innovation with the neuralink device is the technological and material advancements used in its manufacturing. The Neuralink device features 96 small, flexible electrode threads, each with 32 independent arrays, amounting to 3,072 electrodes per array [1]. Prior research on DBS has demonstrated its ability to control computer cursors, robotic limbs, and speech synthesizers using only 256 electrodes. The use of individually implanted threads with numerous electrodes represents a significant improvement over older brain-machine interface technology [2]. The large number of electrodes in the device could lead to increased accuracy, classification, and interpretation of brain electrical activity as well as the ability to transfer a greater volume of data for interpretation or to send signals to the brain for the treatment of brain disorders. The Neuralink team has determined that a biocompatible polyimide coated with a gold thin film trace is the optimal choice for threads and its use instead of traditional rigid metals provides several advantages, such as reduced immune response, better biocompatibility, and the ability to conform to brain movement while avoiding brain vasculature [1].

However, the true focus about this announcement should be on how trials, studies, and outcomes are communicated. The announcement attracted considerable attention, effectively exploiting the marketing system while not fully complying with the principles of scientific ethics. First, there were no official announcements at the start of the study. The main source of public information about the trial was a concise study brochure that invited participation but did not provide details such as the locations of the implantations or the precise objectives of the trial.

Second, the study was not listed on ClinicalTrials.gov, a web-based repository maintained by the U.S. National Institutes of Health (NIH). Many researchers are disquieted that the trial is not registered on ClinicalTrials.gov and that any protocol has not been divulged, as transparency is also essential for the individuals who are intended to benefit from brain-computer interfaces (BCIs) [3].

The company's study brochure disclosed that volunteers will be monitored for five years and that the trial will assess the device's functionality by requiring participants to use

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it at least twice weekly to control a computer and provide feedback on their experience. All major university research centers mandate that researchers enroll participants in a clinical trial and protocol in a public repository before initiation and almost all medical journals require this registration as a prerequisite for publication in accordance with ethical principles aimed at safeguarding individuals who participate in clinical trials. Despite this, Neuralink has provided scant information about its trial objectives and has not responded to Nature's request for interviews. This trial was sanctioned by the US Food and Drug Administration (FDA), which previously rejected an application from Neuralink.

The development of the Neuralink device has sparked interest in its potential for use in clinical settings; however, to advance effective scientific progress, it is important to share findings and provide peer-reviewed technical notes, even if it means publishing replicable and reproducible data. Furthermore, conducting in-house experiments can compromise the validity of the results, as the procedure poses risks. To address the difficulty to implant a small-sized and flexible threads Neuralink developed a surgical robot that can precisely and safely insert each thread while avoiding surface vasculature and targeting specific brain regions. Although the device requires both a Neuralink robot and a live neurosurgeon, extensive training is necessary for the neurosurgeon to become comfortable and safe with the machine. The training required for the device is a key factor in the slow adoption of true robotic systems in neurosurgery and Neuralink device is not exempt from this trend. On the other hand, co-robots are increasingly being implemented in neurosurgical practice. Finally, despite the potential of this device, its efficacy could be limited by the specific types of pathologies that patients present with. If the damage to the motor cortex or spinal cord is too severe, restoring function with Neuralink or another BCI can be challenging [4]. Although there are many uncertainties about Neuralink, its implementation in future neurosurgical practice has the potential to improve patient outcomes so we trust and hope for better transparency and scientific rigor.

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