Title
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Permalink
https://escholarship.org/uc/item/1r51m17r

Journal
Annals of Neurology, 77(5)

ISSN
0364-5134

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Publication Date
2015

DOI
10.1002/ana.24411

Peer reviewed
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As humans, we can identify galaxies light years away, we can study particles smaller than an atom. But we still haven’t unlocked the mystery of the three pounds of matter that sits between our ears.”1 The time is ripe, remarked President Obama during his 2013 announcement of the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, to mount a focused effort to study the human brain’s 100 billion neurons and their connections. It is certain that neuroscience research funded through the BRAIN Initiative, and other sources, will advance our understanding of the brain and is also likely to lead to new treatments for incurable and costly health problems including Alzheimer disease, Parkinson disease, traumatic brain injury, blindness and other sensory disorders, schizophrenia, depression, post-traumatic stress disorder, and chronic pain, among many other disabling neurological and psychiatric conditions.

President Obama asked the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission), of which I am a member, to consider the ethical implications of neuroscience research in a broad context and also to focus specifically on its applications in conjunction with the BRAIN Initiative. The Bioethics Commission is an independent, deliberative panel of experts that advises the President and the Administration, and in so doing educates the nation on bioethical issues. The Bioethics Commission has released a series of reports, including reports on the ethical considerations of emerging science and technologies like synthetic biology, whole genome sequencing, and neuroscience. Other reports addressed human subject protections, including current and historical regulations and practices, ethical considerations of pediatric research, and research in the context of a public health emergency such as the western African Ebola epidemic.

This article provides a review of the ethical issues associated with the conduct and implications of neuroscience research. Every neuroscientist understands that to maximize the benefits of neuroscience research to individuals and society we must ensure that the science progresses ethically. However, to do this successfully will require a flexible, nuanced approach, guided by basic principles. We should develop, for example, a proactive strategy to deal with issues about which reasonable people will disagree, and to plan for the “known unknowns” that are certain to arise. Another key need is to avoid exaggeration and overstatement (“neurohype”) when communicating new findings. Even statements that are technically correct but presented in an overly optimistic or far-reaching manner in terms of health implications can easily be misinterpreted by the general public, leading to unfounded conclusions and ultimately an erosion of the public trust in science and medicine. The tendency to overestimate the significance of an advance is particularly germane to contemporary neuroscience, which often relies on and creates impressive new technologies.

The Bioethics Commission responded to the President’s charge in a 2-volume report, the first of which, Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society, was released in May 2014 and called for the active and iterative integration of ethics early and throughout scientific research. At the time of its release, I was pleased to author, in these pages and on behalf of the Bioethics Commission, a perspective on this first volume.2 In its second and final volume, Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society, the Bioethics Commission now addresses 3 topics that capture public and scholarly attention to explore ethical tensions and societal implications of advances in neuroscience. Through its report, the Bioethics Commission sought to clarify misperceptions and clear an ethical path forward for the field.

Cognitive Enhancement and Beyond

The Bioethics Commission expanded the cognitive enhancement conversation to include all neural modifiers, or any methods, behaviors, conditions, or interventions that alter the brain and nervous system. The Bioethics Commission believes that there is nothing inherently unethical about enhancement of human nervous system capabilities, including cognitive enhancement. Several neural modification techniques, such as good nutrition, exercise, and education, promote brain and nervous system function and are widely considered ethically permissible and desirable. Drugs such as methylphenidate, dextroamphetamine, modafinil, and cholinesterase inhibitors might have some possible, but quite modest, cognitive enhancement effects in healthy people. However, the use of some neural modification techniques might pose ethical concerns. Although most currently available neural modification approaches offer only incremental benefits, and some such as deep brain stimulation

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(DBS) carry risks, it is likely that future approaches will provide more significant benefits with acceptable levels of safety. Thus, the Bioethics Commission feels strongly that now is an ideal time for this conversation to advance in earnest.

Society must be prepared to examine the ethical considerations of neural modifiers on a case-by-case basis, and consider the intervention, its purpose, who is choosing it, who might benefit, and who could be harmed. For example, DBS to improve the symptoms of a psychiatric disorder such as depression might be ethical if proven safe and effective, and if freely chosen by a fully informed adult. However, DBS would be ethically problematic if the adult was coerced into receiving it. Guidelines developed by professional organizations such as the American Neurological Association could be of great value to help inform the public and assist health care professionals and other stakeholders to understand neural modifiers and their potential benefits and risks in various circumstances.

Neuroscientists should conduct, and funders should support, more research on neural modifiers. The opportunity to improve human health is too great to act otherwise. The Bioethics Commission recommended prioritizing research both on existing low-technology strategies to maintain and improve neural health and on interventions, including development of novel drugs, to prevent, treat, and repair neurological disorders. It is especially important that the worthy goals of the BRAIN Initiative do not inadvertently lead to reduced funding for neuroscience research that does not fall directly under the umbrella of the Initiative. Funders also should support research to better characterize the prevalence, benefits, and risks of novel neural modifiers to augment or enhance neural function beyond typical or normal ranges. Importantly, society must ensure equitable access to beneficial, safe, effective, and morally acceptable neural modification interventions so that existing social inequities are not exacerbated.

Capacity and the Consent Process
Contemporary neuroscience research promises to provide important insights into the very conditions that can impair one’s capacity to consent to enroll in research. To advance research that seeks to understand and ameliorate these conditions, researchers should responsibly include individuals with impaired consent capacity. Investigators conducting neuroscience research with human participants should be aware of the complexities of enrolling participants with impaired consent capacity. Neuroscientists who conduct research involving human participants are especially attuned to these complexities because they work with individuals whose consent capacity might be absent, impaired, fluctuating, or in question. Without specific regulations or uniform guidance about research with individuals with impaired consent capacity, however, investigators and review bodies are left to decide for themselves how to proceed ethically. This lack of certainty might stall important research. In many instances, legally authorized representatives (LARs) can give permission for an individual with impaired consent capacity to participate in research. Clear requirements for who can serve as an LAR to give permission to participate in research can alleviate ethical ambiguity.

The Bioethics Commission recommended that funders support research to address the gaps in knowledge about impaired consent capacity, including the development of assessment tools. It also recommended that neuroscience researchers engage with stakeholders, including members of affected communities, to build understanding of consent capacity and associated diagnoses. By engaging with stakeholders, neuroscientists can help dispel common assumptions about certain conditions; gain insight into the diversity of individual needs, abilities, and relationships with caregivers; and help alleviate stigma and discrimination. Stakeholder engagement will help neuroscientists uphold ethical standards and craft best practices for research with individuals experiencing impaired consent capacity.

Neuroscience and the Legal System
Neuroscience has the potential to add value to policy development and legal decision making by, for example, improving the accuracy of scientific evidence and detecting and removing bias. However, the intersection of neuroscience and the law raises concerns about scientific validity, the premature application of a developing science, and conceptions of free will and mental privacy. The Bioethics Commission recommended that neuroscientists engage with policy development and legal decision-making processes to ensure the accurate interpretation and communication of neuroscience findings. For example, neuroscientists can clarify that neuroscience research might provide information about a general population, but not necessarily about a specific individual. Avoiding overstatement will prevent unfounded expectations about technologies and research findings that are not yet ready for legal and policy applications. The Bioethics Commission recommended that groups such as the National Academy of Sciences, the US Department of Justice, the National Institute of Justice, and the Social Security Administration support and conduct research on the use of neuroscience in policy development and legal decision making, including its challenges and limitations.

Neuroscience has become part of the criminal justice system in the United States. Over the past decade, neurobiological evidence has been introduced in hundreds of criminal cases. Judges, lawyers, jurors, and the general public need guidance and education on how to apply and interpret neuroscience evidence in the legal system. The Bioethics Commission recommended that relevant organizations develop training resources to help
judges, lawyers, and jurors to understand neuroscience and its application to the legal system and to help neuroscientists understand the different ways that science and the courts approximate truth, and the challenging gaps between scientific and legal jargon. All stakeholders should be aware that although neuroscience might contribute to knowledge about the goals of punishment and rehabilitation, for example, it will not fundamentally alter normative questions like why we punish criminals (ie, is it because they deserve punishment, need rehabilitation, or require incarceration to protect society?).

Moving Forward

In the first volume of *Gray Matters*, the Bioethics Commission recognized that good science requires the early and explicit integration of ethics into research.3 In the second volume, it recommended that BRAIN Initiative partners establish multidisciplinary efforts to support neuroscience and ethics research and education. This requires adequate funding, resources, and efforts to bring together diverse expertise from neuroscience, ethics, law, policy, and other disciplines to address existing and new questions about neuroscience and ethics.

Neuroscientists are under enormous pressure to secure funding, conduct research, and publish findings, often in the face of stiff competition. Some might feel there is no time to communicate with the public, engage with caregivers of research participants, inform policy and legal decision makers, or participate in ethics research and integration efforts. However, society needs neuroscientists to contribute their expertise and clarify misunderstandings and misperceptions. The Bioethics Commission recognized that the enormous promise of modern neuroscience research will only be realized if neuroscientists are able to help direct and also fully participate in society’s critical conversations at the intersection of neuroscience and ethics.

Potential Conflicts of Interest

Dr. Hauser serves on the Scientific Advisory Boards for Symbiotix, Annexon, and Bionure.

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DOI: 10.1002/ana.24411