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Report to Congressional Committees

December 2024

TECHNOLOGY ASSESSMENT

Brain-Computer Interfaces

Applications, Challenges, and Policy Options

Accessible Version

GAO-25-106952

The cover image displays a stylized representation of experimental applications of brain-computer interfaces.

Cover source: GAO analysis of scientific literature (data and illustration); Macrovector/VRTX/stock.adobe.com (images). | GAO-25-106952

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Highlights of GAO-25-106952, a report to congressional committees

December 2024

Why GAO did this study

BCIs may offer quality-of-life improvements for people living with disabilities due to neurological disorders, stroke, or injuries. BCIs also have emerging nonmedical uses in the workplace, national defense, and entertainment.

With rapid progress in BCI development, policymakers may want to consider how best to support this technology while also ensuring quality medical care and protecting users—both of medical and nonmedical BCIs.

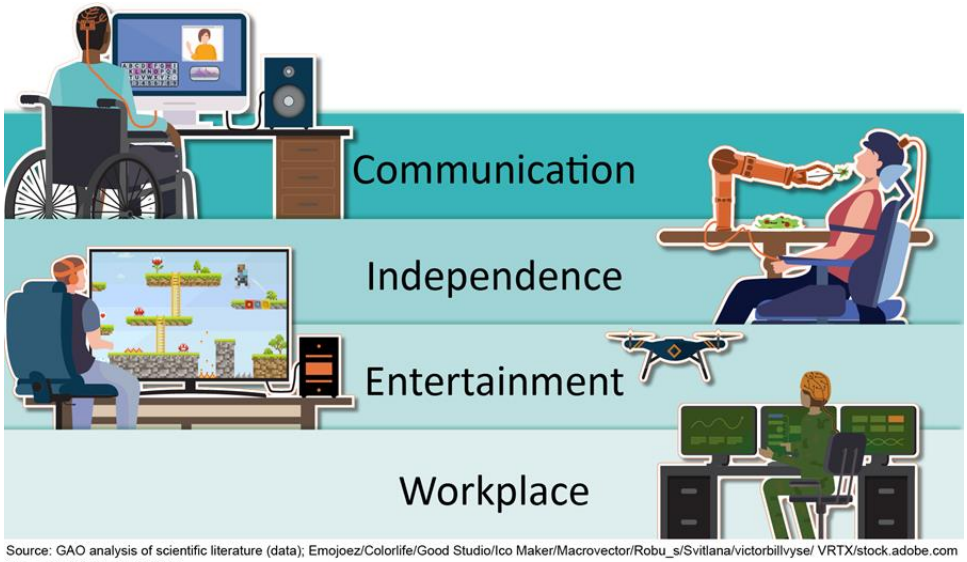
This technology assessment examines (1) BCI technologies available or in development, along with their potential benefits, (2) challenges to the development and use of BCIs, and (3) options policymakers could consider to help address the challenges.

To conduct this work, GAO reviewed scientific literature and federal agency guidance. GAO also interviewed federal agency officials and other experts from government, academia, industry, nonprofit organizations, and end user groups. GAO is identifying policy options in this report.

View GAO-25-106952. For more information, contact Karen L. Howard at (202) 512-6888 or HowardK@gao.gov.

What GAO found

Brain-computer interfaces (BCI) are electronic systems—either implanted in the brain or worn on the head—that let people control computers, robots, or other devices using brain signals. In clinical trials, BCIs have helped people with severe disabilities communicate and use robotic limbs, though these BCIs are not yet on the market. Researchers are also investigating—and companies are investing heavily in— BCIs for the workplace, national defense, and consumer uses.



Source: GAO analysis of scientific literature (data); Emojoez/Colorlife/Good Studio/Ico Maker/Macrovector/Robu_s/Svitlana/victorbillvyse/ VRTX/stock.adobe.com (images). | GAO-25-106952

Experts identified several challenges to BCI development and use, including:

Uncertainties in data ownership and control. Without a unified privacy framework for all BCIs, or standards on data ownership and control, companies that develop and sell BCIs may have access to sensitive brain signal data without users' understanding or consent. In addition, agreements between developers and users may be predatory or unclear.

Potential loss of access or support. Experts told us that users may lose access to the benefits of their implanted BCIs for various reasons. For example, some clinical trial participants have had a BCI removed because there were no funds or medical support provided after the trial. Experts said there is a need to prioritize support and maintenance for participants after a trial or if a developer ceases operation.

Medicare coverage decision process. The Centers for Medicare & Medicaid Services (CMS) makes coverage determinations for Medicare. Private insurers and other public programs may use CMS decisions as a guide for their own coverage. Experts told us that it can be challenging to interact with CMS about BCIs. Officials said CMS has provided a specific point of contact to facilitate early dialogue between developers and reviewers and has improved guidance for navigating CMS processes for determining coding, coverage, and payment.

GAO developed eight policy options that could help address the challenges described above. The options identify possible actions by policymakers, including legislative bodies, government entities, academia, industry, and other groups. In addition, policymakers could choose to maintain the status quo, whereby they would not take additional action beyond current efforts. Some of the policy options are included below. See tables 3–6 in this report for additional policy options and details.

Selected Policy Options to Mitigate Challenges Associated with Brain-Computer Interfaces (BCIs)

Selected policy option	Opportunities	Considerations
Provide consumers with more control over the use of their data, including brain signal data and other data associated with use of a BCI (report p. 19). *This policy option could help address uncertainties in data ownership and control.*	• Increased autonomy may bolster consumer confidence in BCIs. • May increase transparency, if companies disclose the types of personal information they are collecting and what they may do with that information. • May increase protection for other types of sensitive data.	• Providing consumers with certain data rights may require new regulations or new legislative authority. • Too many opt-in or opt-out choices could further confuse or overwhelm users. • Limiting developers' access to data may slow BCI development. Data access can help developers understand the brain better and improve algorithms that decode brain signals.
Consider options for protecting brain signal and other data associated with use of a BCI (report p. 19). *This policy option could help address uncertainties in data ownership and control.*	• Options that protect brain signal data could also protect other types of biometric data. • If a unified framework covering all BCIs were considered, policymakers might better understand whether it could reduce the regulatory burden of complying with a patchwork of data privacy laws that differ across states.	• May place additional burdens on stakeholders to coordinate. • May require additional resources to evaluate potential effects of a unified framework.
Prioritize device maintenance and support for users (report p. 24). *This policy option could help address the challenge faced by users who may lose access to, or support for their BCI.*	• Could reduce potential physical or psychological harms to participants following conclusion of a clinical trial. • Creating interoperability standards across BCIs may increase the availability of parts or maintenance options and could also lead to improvements in components used beyond BCIs.	• Developers may lack resources or willingness to fund post-trial support for participants. • Without a clear return on investment, interoperability standards could burden developers and limit their ability to innovate.
Consider strategies to increase coordination between BCI developers and the Centers for Medicare & Medicaid Services (CMS). (report p. 25). *This policy option could help address the challenge of CMS coverage decision processes being a potential key hindrance to adoption.*	• Could increase awareness of CMS Ombudsman and other points of entry into the agency, as well as awareness of the requirements for coverage, payment, and coding. Experts said one potential example to emulate is "breakthrough device designation" from the Food and Drug Administration (FDA). • Could encourage new products and may speed up the review process. • May provide more timely advice and avoid unnecessary delays or uncertainty when developers submit data that are not sufficient for CMS to make a coverage decision.	• May require additional resources to bolster the workforce of reviewers at CMS. • CMS officials said there may be benefit in engaging early with CMS, but also that the agency may be limited in its ability to give meaningful feedback before a device is tested in humans.

Source: GAO. | GAO-25-106952

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Abbreviations

AI	artificial intelligence
BCI	brain-computer interface
BRAIN	Brain Research Through Advancing Innovative Neurotechnologies®
CMS	Centers for Medicare & Medicaid Services
COPPA	Children's Online Privacy Protection Rule
DARPA	Defense Advanced Research Projects Agency
DOD	Department of Defense
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NSF	National Science Foundation
TCET	Transitional Coverage for Emerging Technologies

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

December 17, 2024

The Honorable Gary C. Peters
Chairman
The Honorable Rand Paul, M.D.
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable James Comer
Chairman
The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
House of Representatives

The Honorable Nancy Mace
Chairwoman
Subcommittee on Cybersecurity, Information Technology, and Government Innovation
Committee on Oversight and Accountability
House of Representatives

Brain-computer interfaces (BCI) enable people to direct their brain signals to control computers, robots, or other devices. BCIs may be worn in the form of a tight-fitting cap or headband or implanted in or near the brain.[1] BCIs may offer quality-of-life improvements for people living with disabilities due to neurological disorders, stroke, or injuries. For example, in clinical trials, BCIs have allowed people with paralysis to use robotic limbs to grasp objects. They have also allowed people who cannot speak to communicate through a computer. Researchers are also investigating—and companies are investing heavily in—the use of BCIs to control devices for nonmedical purposes, such as workplace tasks, national defense applications, entertainment, and other consumer uses. For example, video gamers have used BCIs to play hands-free.

Recent advances in artificial intelligence (AI), advanced materials, and technologies for data management and transfer have driven rapid progress in BCI development. The BCI market is

[1]This report does not discuss devices that collect data from other parts of the body, such as the peripheral nervous system. Thus, we use the term “brain signal data” instead of “neural data.”

expected to grow. Market analysts estimate the global market will increase by approximately 10 to 17 percent annually through 2030.[2]

This report builds on prior GAO work that described BCIs, related opportunities and challenges, and policy questions.[3] We prepared this report under the authority of the Comptroller General in light of congressional interest in the potential uses of BCIs.[4] It examines:

(1) BCI technologies available or in development, along with their potential benefits.

(2) Challenges to the development and use of BCIs.

(3) Options policymakers could consider to mitigate the challenges.

To address these objectives, we conducted a literature search; reviewed federal agency guidance on the development and deployment of relevant technologies; and interviewed federal agency officials and other experts from technology companies, universities, and research institutes, and national advocacy organizations. See appendix I for the full objectives, scope, and methodology used in this report and appendix II for the list of experts.

We conducted our work from June 2023 through December 2024 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for the findings and conclusions in this product.

[2]According to five private market studies GAO analyzed.

[3]GAO, *Science & Tech Spotlight: Brain-Computer Interfaces,* GAO-22-106118 (Washington, D.C.: Sept. 08, 2022)

[4]31 U.S.C. § 717(b)(1).

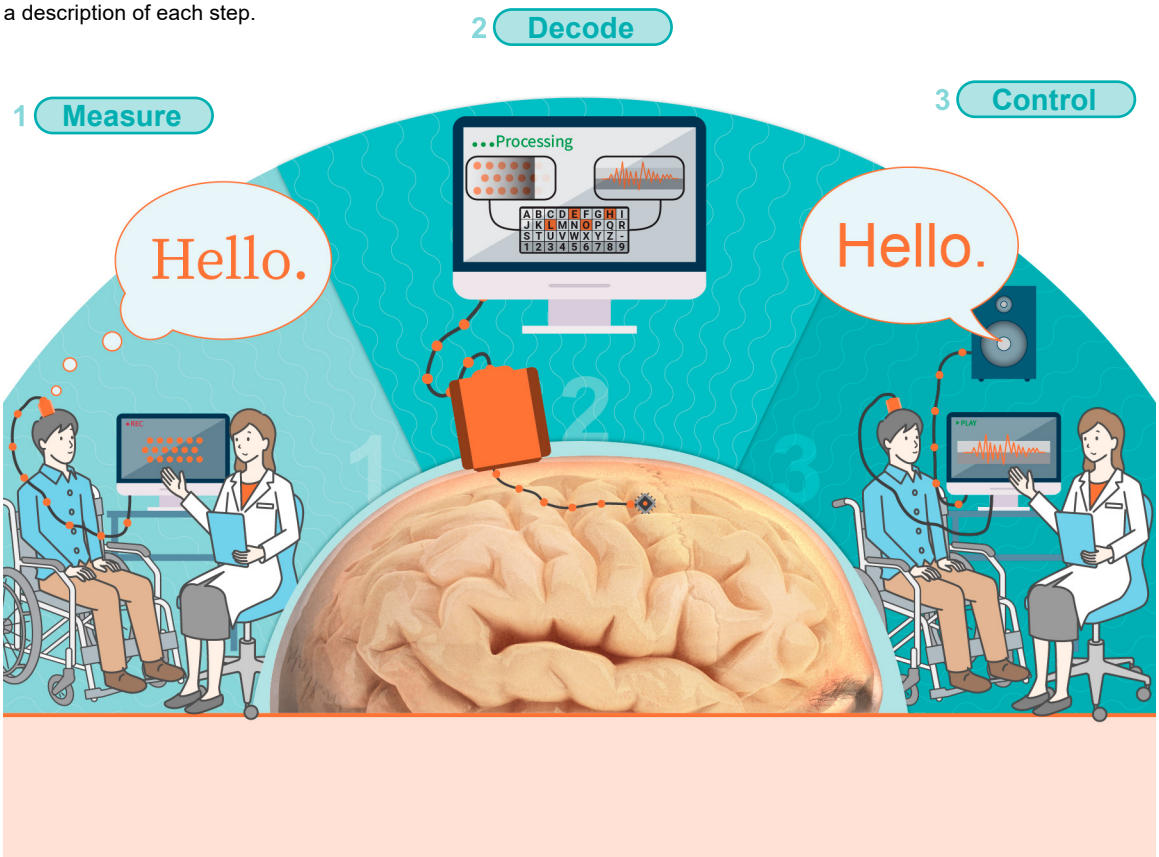
1 Background

1.1 Definition

While there is no consensus on the definition of a BCI, we previously reported that it can generally be defined as an electronic technology that enables a person to control an external device using brain signals.[5] BCIs measure the user's brain signals and decode the intent of those signals to control a device (see fig. 1). Some definitions of BCI also include technologies that stimulate or modulate brain activity, but we did not examine those technologies in this report.

Figure 1: Steps of a brain-computer interface (BCI)

Interactive: Press the buttons to read a description of each step.



Source: GAO analysis of scientific literature (data and illustration); hidamari/matis75/stock.adobe.com (images). | GAO-25-106952

[5]BCIs may also be called brain-machine interfaces.

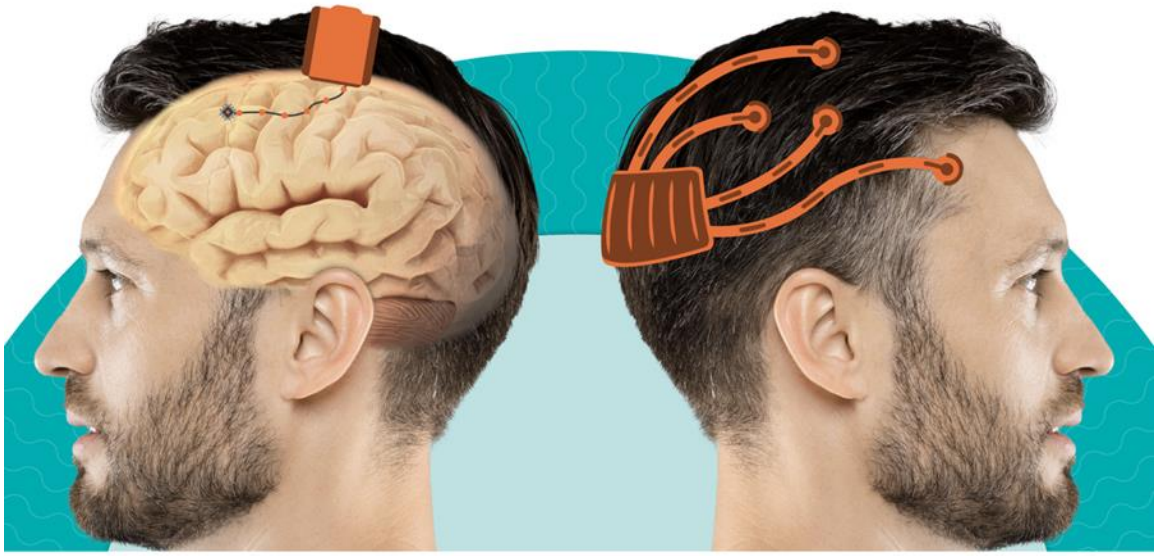
In 2024, the BCI Society attempted to develop a consensus definition for BCI. BCI Definition, https://bcisociety.org/bci-definition/, accessed Nov. 13, 2024.

1.2 Types of BCIs

BCIs may be implantable or wearable (see fig. 2).[6] Implantable BCIs are often surgically placed in, on, or near the surface of the brain, though one type of implantable BCI is inserted through a vein in the neck. Currently, the Food and Drug Administration (FDA) has not granted marketing authorization for any implantable devices for BCI use. Furthermore, the risks associated with brain surgery currently limit participation in implantable BCI clinical trials to people with severe disabilities. While these individuals primarily use implantable BCIs to restore or replace function, according to experts, some may also use them for nonmedical functions, like controlling a video game. Some people with disabilities may also use wearable BCIs in the form of a tight-fitting cap or headband. And researchers are investigating potential workplace, national defense, law enforcement, and entertainment uses for wearable BCIs.

BCIs measure the user's brain signals while the user imagines performing different actions. Such signals may include the electrical charges that brain cells use to communicate with each other or changes in blood flow and oxygen levels within the brain.

Figure 2: Implantable and wearable brain-computer interfaces (BCI)



Source: GAO analysis of scientific information (data and illustration); matis75/Prostock-studio/stock.adobe.com (images). | GAO-25-106952

[6]Implantable and wearable BCIs may also be called invasive and noninvasive BCIs, respectively.

1.3 Recent advances

Researchers have been developing BCIs since at least the early 1970s, when a computer science professor coined the term. As early as the 1980s, researchers began developing wearable BCIs that allowed users to complete simple computer-based tasks, such as selecting letters on a screen to spell words. In the late 1990s, a person with total paralysis became the first human to receive an implantable BCI. Implantable BCIs enable users to control devices faster and more precisely than wearable BCIs. We previously reported that this is because implantable BCIs measure signals directly from the brain, making the measured signals stronger and more precise.[7] Recent advances in three key technologies have accelerated the development of BCIs.

Artificial intelligence (AI). Recent advances in AI have played an important role in new BCI development. BCIs need to be individually calibrated to each user's unique brain signals, which is very time consuming. AI can reduce the time it takes to calibrate BCIs and make devices faster and more accurate. For example, BCIs are being developed that use AI language models and prior experience to predict what the user intends to say. This increases the speed with which the BCI user can communicate.

Advanced materials. Innovations in microfabrication, biocompatible materials, and innovative designs may allow implantable BCI components to become smaller, less invasive, and minimize tissue injury. New flexible electronics do less damage to brain tissues and may increase the clinical viability of implanted BCIs. Both wearable and implantable BCIs have benefited from improved semiconductor manufacturing that makes devices smaller and offer better performance.

Data management and transfer technologies. Advances in computing power, data storage, and data sharing technologies have helped researchers process large datasets to better understand the brain. For example, cloud-based systems facilitate data sharing and storage. Also, technology that allows wireless transmission of data—such as Bluetooth or ultra-wideband—has many advantages for BCI users. Wireless devices may improve the user friendliness and safety of BCIs. Bluetooth enabled BCIs can allow users to seamlessly interface with commercially available technology like tablets and run multiple applications.[8]

1.4 Federal agency activities that affect BCI development and use

Multiple federal agencies fund BCI research and development or help protect users from safety concerns, false or misleading claims, or disclosure of brain signal data and other personal data. Parts of the regulatory framework may vary based on whether the BCI is implantable or wearable and whether

[7]GAO, *Science & Tech Spotlight: Brain-Computer Interfaces,* GAO-22-106118 (Washington, D.C.: Sept. 08, 2022).

[8]Ultra-wideband is a short-range, wireless communication protocol that operates through radio waves. Ultra-wideband can be used to capture highly accurate spatial and directional data and has been shown to have potential to support certain BCI applications.

its intended uses are medical or nonmedical. Some examples include:

The Center for Devices and Radiological Health (CDRH) within FDA evaluates the safety and effectiveness of medical BCIs. FDA regulates the sale of medical devices including all BCIs that are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of a disease in the U.S. FDA also regulates devices that are intended to affect the structure or any function of the body. FDA monitors the safety and effectiveness of all regulated medical devices and oversees clinical trials. Currently, FDA monitors all BCIs that are placed inside the body for safety and effectiveness because they alter the structure and function of the body, according to FDA officials.[9] While implantable BCIs in development for medical purposes may also have nonmedical functions (e.g., a BCI developed to control a prosthetic arm may also enable the user to play a video game), these devices may fall under its regulatory purview.[10] Some wearable devices may also alter the structure or function of the body. For example, a wearable device may alter the function of the body if it helps the user create new pathways in the brain to control a limb.

FDA also regulates all wearable BCIs that are used to treat a medical condition. While the risks of physical harm associated with wearable BCIs are lower than those associated with implantable BCIs, they must still be safe and effective in treating a condition to obtain FDA marketing authorization.

The Centers for Medicare & Medicaid Services (CMS) makes coverage, coding, and payment decisions. Medicare is the federal health insurance program for people who are 65 and older, younger people with certain disabilities, and those with end-stage renal disease. CMS is the agency that implements the Medicare program and determines coverage and payment for medical items and services, as required by statute.[11] This coverage and payment apply only to Medicare; however, Medicare coverage is sometimes looked to by private insurers as an example, even though there are often differences in the Medicare population compared to the privately insured population.

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights enforces the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules. HIPAA required HHS to propose and adopt privacy and security standards, but the agency did not set those standards.[12] The HIPAA Privacy, Security, and Breach

[9]According to FDA documents, FDA classifies medical devices based on the risk posed by a device. Class I devices pose the least amount of risk to consumers while Class II devices pose more risks. Usually, Class III devices support or sustain life, are implanted in the body, or have the potential for unreasonable risk of illness or injury. See 21 U.S.C. §§ 321-399i, 21 U.S.C. § 360c.

[10]FDA stated that these implantable devices may fall under its regulatory purview because they affect the structure or function of the body or because of their intended use (e.g., diagnosis or treatment).

[11]Medicare may establish national coverage policies, local coverage policies or decisions of coverage on a claim-by-claim basis. For an item or service to be covered and paid for under Medicare, the item or service must fall within a statutory benefit category and be reasonable and necessary for the diagnosis, or treatment of illness or injury or to improve the functioning of a malformed body member. See 42 U.S.C. § 1395y(a)(1)(A), 42 U.S.C. § 1395y(l).

[12]See 45 C.F.R. § 160.103 (definitions of "business associate", "covered entity", "health care provider", "individually

Notification Rules protect individually identifiable health information that is maintained or transmitted by a HIPAA covered entity or business associate.[13] This information (called "protected health information") includes sensitive information, including brain signal and other data associated with use of a BCI, generated during treatment by a covered health care provider.

The Federal Trade Commission (FTC) may regulate marketing claims and data generated through use of nonmedical BCIs. Wearable BCIs developed for nonmedical uses are generally treated the same as other consumer electronics. FTC can challenge acts or practices as deceptive or unfair.[14] If a company is disseminating false or misleading claims, the FTC has the authority to investigate and bring enforcement actions against the company producing the BCI (so long as the company is within FTC's general jurisdiction). The FTC's regulatory authority also allows for enforcement against companies that fail to adequately protect or mishandle identifiable and sensitive consumer data or use misleading user agreements.

The Bureau of Industry and Security within the Department of Commerce regulates dual-use items (i.e., items that can be used for both civilian and military applications) through export controls. In 2021, it sought public comments on the potential uses of BCIs, including whether the U.S. or its adversaries could use BCIs to gain a military or intelligence advantage. Later, in 2023, it hosted a conference with industry experts to further consider national security implications of and export controls for BCIs.[15]

The National Institute of Standards and Technology (NIST) encourages the development of standards for BCI hardware and software. International standards, which reflect contributions from broad stakeholder groups and are developed through a consensus-based process, can promote interoperability. These standards may include guidance or recommendations on a wide array of topics like safety, cybersecurity, privacy, and data storage and transfer.

The Executive Office of the President has included BCIs in its Critical and Emerging Technologies list. In 2020, the National Science and Technology Council within EOP established a subcommittee to identify critical and emerging technologies to inform national security-related activities. The subcommittee listed human-machine interfaces in its inaugural list in 2020 and added BCIs as a subfield of this area in its 2022 update. In its

identifiable health information", "protected health information", and "treatment").

[13]Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021 (Aug. 21, 1996) (codified at 42 U.S.C. §§ 1320d–1320d-9) and the HIPAA Privacy, Security, and Breach Notification Rules, 45 C.F.R. pts. 160, 164. HIPAA requirements apply to covered entities (health plans, health care providers, and health care clearinghouses) and business associates (an entity that creates, receives, maintains, or transmits protected health information on behalf of a covered entity or another business associate). Only health care providers that conduct standard transactions adopted by HHS under HIPAA are covered entities.

[14]15 U.S.C. § 45(a)(1). An unfair practice occurs when the device is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition.

[15]Announcement of the Brain-Computer Interface (BCI) Two-Day Hybrid Conference, 88 Fed. Reg. 7655 (Feb. 6, 2023).

2024 update, it replaced BCIs with neurotechnologies.[16]

The National Science Foundation (NSF) funds many levels of BCI Research. NSF's mission to promote science across broad topic areas—such as, chemistry, biology, and engineering— allows it to support interdisciplinary BCI development at all levels of research, including basic science and clinical studies. NSF has funded BCI research and educational opportunities, including the foundational study that coined the term BCI. Through its Industry-University Cooperative Research Centers program, it also funds the Building Reliable Advances and Innovation in Neurotechnology Center in which government, university, and industry partners collaborate to develop and test neurotechnologies, including BCIs.

The Department of Defense (DOD) is researching whether BCIs could allow service members to control certain types of equipment, hands-free. This could help military service members simultaneously control multiple pieces of equipment. For example, fighter pilots could use their hands to fly planes while using BCIs to control radar systems that detect targets and obstacles. If this were feasible, the pilots would need to split their attention across controlling each piece of equipment. The Defense Advanced Research Projects Agency (DARPA) within DOD has historically funded much of the foundational research that has advanced BCIs for prosthetics and rehabilitation and continues to provide support for innovative BCI research.

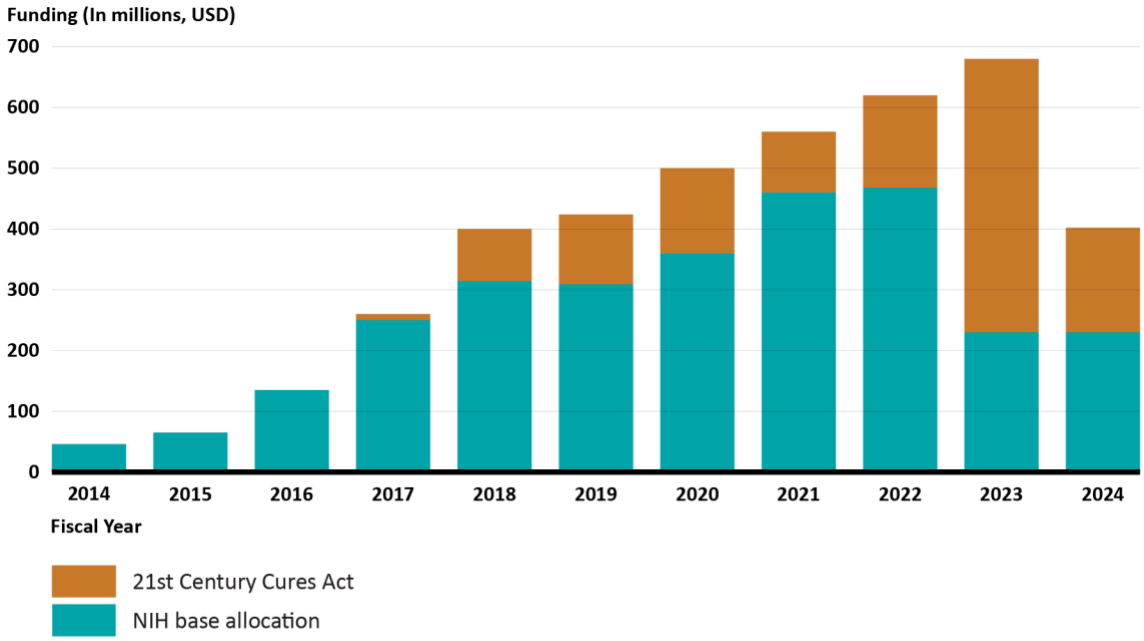
The National Institutes of Health (NIH) leads the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. The BRAIN Initiative, which includes federal and nonfederal partners, aims to accelerate the development of innovative neurotechnologies, including BCIs.[17] Ten Institutes and Centers at NIH participate alongside four other federal partners—FDA, NSF, DARPA, and the Intelligence Advanced Research Projects Activity (IARPA). It provided over $3.5 billion in funding for neuroscientific research from 2014 to 2024 (see fig. 3). For example, in 2021, it funded research on BCIs intended to enable communication for people with severe motor paralysis.[18]

[16]BCIs are a subset of a broader field of developing technologies that interact with the nervous system, collectively referred to as neurotechnologies. National Science and Technology Council, "2024 Critical and Emerging Technologies List Update" (Washington, D.C.: Feb. 2024), accessed Aug. 26, 2024.

[17]"BRAIN Initiative, Overview," the National Institutes of Health, https://braininitiative.nih.gov/about/overview, accessed Aug. 7, 2024.

[18]BRAIN Initiative Funding Received for BCI Development and Testing, https://mirm-pitt.net/brain-initiative-funding-received-for-bci-development-and-testing/, accessed Oct. 8, 2024.

Figure 3: Funding levels for the National Institutes of Health (NIH) Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative



Source: National Institutes of Health (NIH), "Understanding the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative Budget". | GAO-25-106952

2 Current and Potential BCI Applications

Researchers are investigating the potential for BCIs to enable users to control a variety of devices (see fig. 4) for both medical and nonmedical purposes.

Figure 4: Examples of experimental brain-computer interface (BCI) applications

Interactive: Click on the various rooms to learn about potential applications of the technology. Click the X to reset the view.

Source: GAO analysis of scientific literature (data and illustration); Anlomaja/Emojoez/Colorlife/Good Studio/Ico Maker/LanaSham/Macrovector/Robu_s/Svitlana/victorbillvyse/VRTX/stock.adobe.com (images). | GAO-25-106952

Note: This figure shows (from left to right and top to bottom): A military service member using a wearable BCI to control drones, a woman with an amputation using a wearable BCI to control a thermostat, a man using a wearable BCI to play a video game, a man with a paralysis using an implantable BCI to generate speech, and a woman with paralysis using an implantable BCI to eat using a robotic arm.

2.1 Medical applications

Implantable BCIs in development and some wearable BCIs are intended to allow people with disabilities to control assistive or rehabilitative devices. Such disabilities may result from conditions such as:

- Amputation
- Amyotrophic lateral sclerosis (ALS)
- Cerebral palsy
- Epilepsy
- Locked-in syndrome (complete or extensive paralysis of a conscious person)
- Multiple sclerosis
- Parkinson's disease
- Spinal cord injury
- Stroke

BCIs may assist with:

Communication. Researchers are developing implantable and wearable BCIs that decode the letters or words a person intends to communicate. People have used BCIs in clinical trials to communicate faster and potentially more accurately than they could with other available options, such as touch screens and eye tracking systems (see text box).

Control of a prosthetic, robotic, or own limb. BCIs may help people with disabilities regain movement abilities. For example, in clinical trials, people with paralysis or limb loss have used BCIs to control robotic limbs (see text box).

All implantable and many wearable medical BCIs are still in the process of clearing regulatory benchmarks before they can be prescribed or used widely. FDA has several device authorization pathways, based on the type of device and the risks involved. The FDA Breakthrough Devices program is a process to designate breakthrough devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The device also must meet one of the following conditions: (1) the device represents breakthrough technology; (2) no approved or cleared alternative exists; 3) the device offers significant advantages over existing approved or cleared alternatives; or (4) the device's availability is in the best interest of patients.

Several BCIs in development may qualify for Breakthrough Device status. This status qualifies devices for timely review, with the goal of expediting their time to marketing authorization. Marketing authorization is the last hurdle a device must clear before becoming commercially available. After

Real-world brain-computer interface (BCI) for communication

According to the developer, in 2023, the Food and Drug Administration (FDA) granted Breakthrough Device designation to a wearable BCI that integrates AI and augmented reality to help people with disabilities communicate. This speech generating BCI uses artificial intelligence (AI) to predict possible word choices. Users direct their brain signals to select a word out of the choices displayed on a visor.

Source: GAO. | GAO-25-106952

Real-world brain-computer interface (BCI) for limb control

In April 2021, a device that helps stroke survivors regain arm and hand control became the first wearable BCI for rehabilitation to receive premarket authorization from the Food and Drug Administration (FDA). It uses a wireless electroencephalography (EEG) headset and robotic glove to form a new pathway between the user's brain and limb. Once this pathway is formed, users may be able to decrease or discontinue their use of the BCI.

Source: GAO. | GAO-25-106952

achieving this status, devices may continue to be monitored for safety (known as postmarket device safety monitoring).[19]

2.2 Nonmedical applications

Agency officials said it is unknown whether wearable BCIs for nonmedical applications may someday allow people to control devices faster and more accurately. In the near term, technologies that allow individuals to control devices using voice, gesture, or pressure controls—or those that measure muscular stimulation or movement, rather than brain signals—are more likely to enhance human capabilities. Also, the hardware used in consumer-grade wearable devices generally lack the capabilities available in research-grade wearable devices. For example, many consumer-grade wearable devices use fewer sensors to measure the user's brain signals. While some manufacturers claim that consumers can use these devices to control virtual or real-world objects or determine the user's mental state to enhance concentration or meditation, some researchers have asserted that such claims are unsubstantiated.[20] They have said that these claims are based on a placebo effect, and it is unlikely that these devices accurately measure brain signals. The following describes three areas of potential nonmedical application.

Wellness. Consumers may currently purchase wearable products that claim to measure brain signals for personal development or general wellness.[21] For example, available products claim to detect the user's level of focus and use apps to graphically display fluctuations in attention and focus throughout the day. One available product plays music to purportedly cue a user to refocus. It is important to note, however, according to FDA, it does not focus its regulatory oversight on products that are low risk and claim to promote a healthy lifestyle but do not diagnose, cure, or treat a disease or condition.[22]

Entertainment. Consumers can purchase wearable products that claim to allow users to control personal electronics such as computers or gaming systems. Artists have used these to draw with brain-controlled cursors. They have also used wearable products that claim to measure the user's mental state. For example, a fashion designer

[19]The Breakthrough Devices Program is a voluntary program that offers manufacturers an opportunity to interact with FDA experts through several different options during the premarket review phase. This interaction can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. Breakthrough device designation is not a marketing authorization.

[20]Some of the nonmedical consumer devices described may fall outside the BCI definition used in this report.

Anna Wexler and Peter B. Reiner. "Oversight of direct-to-consumer neurotechnologies: Efficacy of products is far from clear." Science. 2019 January 18; 363(6424): 234–235. https://doi.org/10.1126/science.aav0223.

[21]FDA has described "general wellness products" as products that promote a healthy lifestyle and has issued guidance regarding low -risk general wellness products. 'General Wellness: Policy for Low-Risk Devices Guidance for Industry and Food and Drug Administration Staff' (September 2019). Some experts believe that FDA's hands- off approach to the regulation of low- risk general wellness products does not apply to BCIs that enable a person to control an external device using brain signals or to BCIs that stimulate or modulate brain activity. We include a description of wellness applications that promote a healthy lifestyle, though we do not focus on these types of technologies in this report.

[22]The Food and Drug Administration, "General Wellness: Policy for Low Risk Devices: Guidance for Industry and Food and Drug Administration Staff" (September 2019), accessed Aug 26, 2024.

collaborated with researchers to create a dress fitted with lights that display various colors and patterns based on the user's brain activity. The DIY community has come together to share tutorials and shopping lists for home users to build and program their own simple BCIs for educational and entertainment purposes. While some products are sold as "stand-alone" headbands or headsets, other developers are integrating BCI technologies into existing electronics like headphones. These products may have the potential to integrate with household devices, like smart thermostats, connected via the "Internet of Things."

Workplace. BCIs may have the potential to aid people in higher-risk occupations, such as truck drivers and pilots. For example, researchers are investigating whether it might be feasible for a driver to use a wearable BCI to control an emergency braking system, helping them stop the vehicle faster. Researchers are also investigating the potential for military service members to use BCIs. For example, DARPA has funded research on BCI use for hands-free control of drones.

3 Challenges and Policy Options for Brain-Computer Interfaces

Based on information from experts and a literature search, we identified and grouped challenges that may hinder BCI development and use into three categories: BCI data, access and adoption, and manufacturing. We also identified potential for unethical and inequitable outcomes. In each case, we developed options that policymakers could consider to help address these challenges.[23] The policy options are possible actions by policymakers—which may include legislative bodies, government entities, academia, industry, and other groups. In addition, policymakers could choose to maintain the status quo, whereby they would not take additional action beyond current efforts. See below for details of the policy options.

3.1 Challenges related to BCI data

Data associated with BCI use could provide access to intimate information and inferences about the user's emotions, attention, and thoughts. Some of these data enable BCI functioning, but their misuse could lead to harms like privacy breaches, discrimination, embarrassment, or reputational damage. Some U.S. regulations protect such data in health care settings, but they may not always apply to consumers outside health care, such as those using BCIs for entertainment purposes. Additionally, experts told us consumers may not have full control over or awareness about the collection or use of their data because of their uncertainties or lack of understanding about what protections apply and who owns the data. We identified two key challenges associated with the collection and storage of data associated with BCI use.

Cybersecurity vulnerabilities and gaps in data protections. In 2023, we reported that medical device vulnerabilities have not been commonly exploited but are nevertheless a source of cybersecurity concern warranting significant attention.[24] Experts we interviewed also expressed concern that data may be vulnerable to unauthorized access, especially when collected via use of BCIs that do not fall under FDA's purview. They noted that use of BCIs outside a controlled laboratory environment underscores the need for cybersecurity. In 2019, we reported that harm resulting from privacy and security violations can be difficult to measure and can occur years in the future, making it difficult to trace a particular harm to a specific breach.[25] However, efforts to develop cybersecurity standards for sectors outside of medicine and national defense are underway. For example, the NIST Cybersecurity Framework 2.0 provides guidance on understanding, communicating about, and reducing cybersecurity risks across industries and institutions, including BCI developers.[26] Experts also told us that some potential BCI uses—for example, in schools, the workplace, when completing legal documents, or other

[23]Our definition of "policymakers" includes Congress, federal agencies, state and local governments, academic and research institutions, and industry.

[24]GAO, *Medical Device Cybersecurity: Agencies Need to Update Agreement to Ensure Effective Coordination*. GAO-24-106683. (Washington, D.C.: Dec. 21, 2023).

[25]GAO, *CONSUMER PRIVACY: Changes to Legal Framework Needed to Address Gaps.* GAO-19-621t. (Washington, D.C.: June 11, 2019).

[26]NIST Cybersecurity Framework, https://www.nist.gov/cyberframework, accessed Aug. 1, 2024.

higher-risk contexts—may warrant higher cybersecurity standards than others, such as entertainment uses.

Some protections may apply to the collection and use of sensitive data, including FDA review and oversight, HIPAA Privacy, Security, and Breach Notification Rules, and FTC's general authority (see table 1).[27]

Table 1: Selected protections that may be applicable to brain-computer interface (BCI) data

Food and Drug Administration (FDA) review and oversight of the cybersecurity of medical devices. *(See section 524B(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360n-2(b))*	Requires developers of certain medical devices to demonstrate that their devices meet FDA's cybersecurity requirements.
Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules. *(42 U.S.C. §§ 1320d–1320d-9) and the HIPAA Privacy and Security Rules, 45 C.F.R. parts 160, 164)*	Protects individuals' medical records and other individually identifiable health information that is maintained or transmitted by covered entities, including health plans, health care clearinghouses, and most health care providers, and their business associates. The rules do not apply to identifiable health information held or disclosed by other entities that do not meet the definition of a covered entity or business associate.
The Federal Trade Commission's (FTC) general legal authority, Healthcare Breach Notification Rule, and Children's Online Privacy Protection Rule (COPPA). *(See section 5 of the Federal Trade Commission Act (15 U.S.C. § 45); 16 C.F.R. pt. 318; 16 C.F.R. pt. 312)*	Prohibits unfair or deceptive practices in the marketplace. FTC protects consumers' privacy and personal information by bringing enforcement actions to stop unlawful behavior and requiring companies to take affirmative steps to remediate it. The Health Breach Notification Rule requires vendors of personal health records and related entities that are not covered by the HIPAA to notify individuals, FTC, and, in some cases, the media of a breach of unsecured personally identifiable health data. However, the HIPAA Rules may overlap with the FTC Breach Notification Rule under some circumstances. COPPA imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age.

Source: GAO review of agency documentation and interviews with agency officials. | GAO-25-106952

[27]This is not an exhaustive list of all potential laws and regulations governing BCI data. These examples were chosen because they are commonly applied to a variety of medical and consumer devices.

While these protections may help protect data in certain circumstances, experts told us it may be difficult to understand whether and how they apply across different types of BCIs and uses. For example, when a BCI has both medical and nonmedical functions, it may be difficult to understand which protections apply in various scenarios (see table 2).[28] If data sharing causes harm, the appropriate regulatory framework will depend on both the type of BCI and its use when the harm was incurred.

Table 2: Potential use cases for data collected by brain-computer interfaces (BCI), and regulatory entities that are likely to have jurisdiction

Scenario	Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered data use[29]	Food and Drug Administration (FDA) regulated medical device[30]	Federal Trade Commission (FTC) jurisdiction[31]
Implantable BCI used exclusively in a clinical setting.			
A person with paralysis uses a BCI to operate a wheelchair. The BCI is furnished by a health care provider that is subject to the HIPAA. The provider accesses the person's data to adjust the BCI's settings and improve its performance.	☑	☑	☑
Nonmedical product used exclusively in a nonclinical setting.			
A person with attention deficit hyperactivity disorder (ADHD) uses a low-risk wearable product that is advertised to consumers as a BCI and claims to track mental load and fatigue for general wellness use. The product is not	☒	☒	☑

[28]For additional scenarios, see https://www.hhs.gov/sites/default/files/ocr-health-app-developer-scenarios-2-2016.pdf, accessed Aug. 2, 2024

[29]HIPAA privacy and security requirements safeguard protected health information (PHI), which includes most individually identifiable health information transmitted or maintained in any form by a covered entity or its business associates. Covered entities are health plans, health care providers, and health care clearinghouses. Only health care providers that conduct standard transactions adopted by HHS under HIPAA are covered entities. A business associate is an entity that creates, receives, maintains, or transmits protected health information on behalf of a covered entity or another business associate. Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021 (Aug. 21, 1996) (codified at 42 U.S.C. §§ 1320d–1320d-9) and the HIPAA Privacy and Security Rules, 45 C.F.R. pts. 160, 164.

[30]FDA is responsible for ensuring that medical devices, including BCI, marketed in the U.S. provide reasonable assurance of safety and effectiveness and do not pose a threat to public health. To assess whether medical devices provide such assurance, FDA conducts a premarket review of medical devices and relies on the sponsor of the device to provide data that support the device's safety and effectiveness.

[31]Depending on the facts of the scenarios and if the person is under 13 years old, FTC may have jurisdiction based on one or more of the following: FTC general authority, the Health Breach Notification Rule, or the Children's Online Privacy Protection Rule (COPPA).

Scenario	Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered data use[29]	Food and Drug Administration (FDA) regulated medical device[30]	Federal Trade Commission (FTC) jurisdiction[31]
furnished by a HIPAA-covered entity or business associate. The person uses it without a health care provider's guidance.			
Medical BCI used in clinical and nonclinical settings.			
A child with a speech impairment has a wearable BCI for communication. The BCI is not furnished by a HIPAA-covered entity or business associate. The child practices using it at the direction and supervision of a speech therapist who is a HIPAA-covered health care provider and records information communicated using the device.	☑	☑	☑
At home, the child uses it to play video games. The games have a user agreement that describes what data are collected.	☒	☑	☑
Nonmedical product used in clinical and nonclinical settings.			
A person uses a wearable product that is advertised to consumers as a BCI and claims to help with focus while meditating. The product is not furnished by a HIPAA-covered entity or business associate.	☒	☒	☑
The person shares the data collected with a HIPAA-covered health care provider in case it provides more information about symptoms that are causing concern.	☑	?	☑

Source: GAO review of agency documentation and interviews with agency officials. | GAO-25-106952

Legend:

✓ = The indicated regulatory entity has jurisdiction in this scenario.

X = The indicated regulatory entity does not have jurisdiction in this scenario.

? = FDA may have jurisdiction depending on whether and how the data are analyzed, and how the device is marketed.

Uncertainties in data ownership and control. Experts told us that the lack of a unified framework for data privacy and data protection that covers all BCIs, along with a lack of standards for BCI development could allow companies that develop and sell BCIs to access sensitive brain signal data without users' understanding and consent. Experts also told us that product developers need access to users' brain signal data, but it is

often unclear who has access to these data, for what purposes, and whether the data can be shared with third parties. Further, they told us that user agreements between developers and end users may be predatory and unclear. They expressed concern that agreements may protect companies from legal action and lack consumer-friendly language to clearly state how developers may collect, store, and use the data. They said that users should have the option to prohibit collection of certain types of data or request that developers later delete their data. They also said that users should have the option to own and store their data locally on a device to reduce the amount of data shared with developers.

Experts told us that there is no mandatory unified framework that covers both medical and nonmedical BCI applications that would provide uniform rules and protections for consumer BCI data across the U.S. For example, the U.S. does not have a comprehensive privacy law governing the collection, use, sale, or other disclosure of consumers' personal data. Further, existing federal consumer protection laws may not apply to some emerging uses of consumer data, including BCI data. Some state laws such as the California Consumer Privacy Act and Colorado Privacy Act may extend to data associated with BCI use in some jurisdictions.[32] However, experts told us these requirements might not apply to nonmedical BCI developers who may still collect and share data with third parties due to ambiguity as to whether the data are sensitive, identifiable, biometric, or biological.[33] Legal, sector, and technology neutral voluntary guidance exists to support enterprise privacy risk management. For example, the NIST Privacy Framework 1.0 provides guidelines on understanding, communicating about, and reducing privacy risks applicable across industries and institutions, including BCI developers.[34]

For this report, we developed three policy options to help address data-related challenges, shown in table 3.

[32]Several other states have enacted or proposed bills intended to have comprehensive approaches to governing the use of personal information. https://iapp.org/resources/article/us-state-privacy-legislation-tracker/ , accessed Aug. 28, 2024.

[33]The California Privacy Rights Act (CPRA) of 2020 amends and extends the California Consumer Privacy Act of 2018. It applies to any business that collects, uses, or shares the personal information of Californians. It gives Californians the right to know what personal information is being collected about them. They also have the right to know how that information is being used and shared, and they have the right to tell businesses not to sell their personal information. A September 2024 amendment to the California Consumer Privacy Act of 2018, effective on January 1, 2025, adds neural data to the definition of sensitive personal information. See https://cppa.ca.gov/regulations/, accessed Aug. 2, 2024.

The Colorado Privacy Act of 2021 provides additional protections to the "Colorado Consumer Protection Act". This act extends the consumer protection to include biological data, including data generated by a consumer's neural properties. These protections cover data used singly or in conjunction with other personal data. See https://leg.colorado.gov/bills/hb24-1058, accessed Aug. 3, 2024.

[34] NIST Privacy Framework. https://www.nist.gov/privacy-framework, accessed Nov. 4, 2024.

Table 3: Policy options that may help address challenges related to brain-computer interface (BCI) data

Policy options	Opportunities	Considerations
Provide consumers with more control over the use of their data, including brain signal data and other data associated with use of a BCI. *Potential implementation approaches:* *BCI developers could clarify their user agreements to include consumer-friendly language that clearly states how data are stored, collected, and used.* *BCI developers could allow users to limit the data that can be collected and shared by default.*	• Increased autonomy may bolster consumer confidence in BCIs. • May increase transparency, if companies disclose the types of personal information they are collecting and what they may do with that information. • May increase protection for other types of sensitive data.	• Providing consumers with certain data rights may require new regulations or new legislative authority. • Too many opt-in or opt-out choices could confuse or overwhelm users. • Limiting developers' access to data may slow BCI development. Data access can help developers understand the brain better improve algorithms that decode brain signals.
Consider options for protecting brain signal and other data associated with use of a BCI. *Potential implementation approaches:* *Key stakeholders—such as councils, associations of governments, federal or state agencies, industry representatives, or patient advocacy groups—could coordinate to evaluate options for protecting user brain signal data.* *Policymakers could consider the potential effects of a unified framework for brain signal data associated with both medical and nonmedical BCI applications.* *Experts also suggested that policymakers could consider whether comprehensive federal privacy legislation is needed to protect brain signal and other data associated with use of a BCI.*	• Options that protect brain signal data could also protect other types of biometric data. • If a unified framework covering all BCIs were considered, policymakers might better understand whether it could reduce the regulatory burden of complying with a patchwork of data privacy laws that differ across states.	• May place additional burdens on stakeholders to coordinate. • May require additional resources to evaluate potential effects of a unified framework.
Maintain the status quo.	• Could delay consideration of potential changes to the regulatory framework until the needs of future technologies are better understood. • Could save government or private sector resources for other priorities, including promising medical technologies other than BCIs.	• The privacy and security of users' brain signal and other data associated with use of a BCI could be at increased risk of compromise in the absence of protections offered in other options.

Source: GAO. | GAO-25-106952

3.2 Challenges related to BCI access and adoption.

We identified three challenges that could limit access to or adoption of BCI technologies.

Recruiting for BCI clinical trials. Before health care providers can prescribe medical BCIs to people with disabilities, researchers must test them in clinical trials to demonstrate their safety and effectiveness. But it is difficult to connect interested participants to ongoing BCI clinical trials for many reasons. For instance, in the case of trials for implantable BCIs, it may be difficult to find participants because, to be included, they must have profound disabilities yet be healthy enough to withstand surgery. A further difficulty is the fact that participants in past trials may be ineligible for future trials because of changes to the surface of the brain caused by the BCIs in past trials (see text box).

Another reason recruiting is challenging is that many health care providers and potential users are unaware of BCIs generally, or unaware of opportunities to participate in clinical trials. Providers may not track research or trials as part of their primary responsibilities. In addition, experts told us that ClinicalTrials.gov—an online database of clinical research studies—can be difficult to navigate, and prior GAO and HHS Office of Inspector General reports found that the information is not always up to date or accurate.[35] Without accurate information, health care providers and potential users cannot know the full extent of any harms or benefits from a treatment, nor can they share or recommend future trials for which potential users may be eligible. Conducting specific outreach and education efforts to diverse communities could increase awareness and could help more people with disabilities access BCIs that could benefit them. It could also increase the size and diversity of the user datasets, which may help developers improve the algorithms that BCIs use to decode the intent of the user's brain signals.

Challenges with measuring brain signals

The skull and tissues that protect the brain make it difficult to measure a person's brain signals. Even the best wearable brain-computer interfaces (BCIs) are limited in their ability to measure brain signals with high precision. Implantable BCIs measure brain signals more precisely, which makes them better suited to assist people with severe mobility or speech impairments. However, it is difficult to place them on the wrinkled, uneven surface of the brain in areas that may provide the most benefit. Some BCIs may perform better—operating limbs more smoothly or generating speech at a conversational pace—if they access large parts of the brain, but available space on the surface of the brain may limit BCI capabilities. Implants can also cause scarring and inflammation at the insertion site, and it not known if this scarring will prevent replacement of broken or worn-out devices, or if subsequent implants would be as effective as the original. This may decrease the functionality of the BCI over time.

Source: GAO. | GAO-25-106952

Access or support. Experts told us that users may lose access to their BCIs for various reasons—a challenge that may reduce the utility and appeal of BCIs. For example, some clinical trial participants have had a BCI implanted but then removed after the trial

[35]In 2023, GAO reported that in fiscal years 2019 through 2022, 16 to 18 percent of NIH funded clinical trials were registered late in the public database ClinicalTrials.gov. GAO-23-105656. The HHS Office of Inspector General reported in August 2022 that only about half of NIH-funded clinical trials submitted results on time to the database in calendar years 2019 and 2020 due to insufficient monitoring and enforcement by NIH. Department of Health and Human Services, Office of Inspector General, *The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance with Federal Requirements*, A-06-21-07000 (Washington, D.C.: August 2022).

because the funding entity or trial administrator did not provide financial or medical support beyond that point. In other trials, the implanted portion of the device has been left in place due to risks associated with removal, but the user was no longer able to use it outside of the lab setting. Some users may be able to keep their devices, but the devices may stop working without access to maintenance or regular programing updates. This can have lifelong effects because implants may preclude certain medical care, such as MRI. Experts explained that there is no mechanism or enforcement entity to ensure that participants are cared for if the clinical trial administrator stops supporting device maintenance.[36] These devices may be abandoned or "orphaned" at any stage of development, even after obtaining FDA marketing authorization. Users can also lose access if a device developer halts operations and does not continue to maintain existing devices. Experts said that users who lose access to their BCIs may experience physical or psychological harms. Interoperability standards across BCIs may allow a company to provide parts or maintenance if another company ceases operations, but this solution may not be sufficient to protect all users (see text box).

Different expectations between developers and CMS. CMS is the agency responsible for deciding what devices are eligible for insurance coverage by Medicare.[37] We heard from BCI developers and CMS officials that these two groups have different expectations and understandings for how to navigate the process in which developers apply to CMS for payment and code assignments.[38] We also heard about differences in expectations for how clinical studies can provide sufficient information to meet both FDA and CMS requirements.[39] Both groups agreed that early interactions with each other can help to mitigate differences in understanding and expectations.

Standards to increase interoperability between BCIs across manufacturers.

Efforts to assess standards for BCIs are underway. For example, the Institute of Electrical and Electronics Engineers (IEEE) Standards Association Industry Connections program published a roadmap that outlines the current state of BCI standards and makes recommendations. Increasing the interoperability of BCI components could allow users to have multiple developers service their BCIs and decrease the cost of device components. However, it could also hinder developers' ability to develop innovative components outside the interoperability standards and harm developers' business economics.

Source: GAO. | GAO-25-106952

[36]Clinical trials can be funded by government agencies, private companies, charitable organizations, universities, and other research institutions.

[37]CMS may influence private sector coverage and reimbursement decisions, as commercial payers may look to Medicare.

[38]Coverage, coding, and payment are the building blocks of health care reimbursement. Every payer including CMS aims to pay only for products and services which positively affect the health of the insured. Payers meet this aim by requiring detailed information about the item or service rendered to be described using a standard, specific identifier for the item or service, also known as a code.

[39]Separate and differing FDA and CMS requirements are the result of the discrete statutory authorities of the agencies and the differing purposes of those authorities. FDA evaluates whether a device provides reasonable assurance of safety and effectiveness. CMS determines whether an item (e.g., a drug or a medical device) or service is reasonable or necessary for the diagnosis or treatment of an illness or injury. According to CMS, in general, to determine whether an item or service is reasonable and necessary, CMS reviewers look for evidence of improved health outcomes in the Medicare beneficiary population that the disease is affecting, or the device is treating. See 21 U.S.C. §§ 321-399i, 42 U.S.C. § 1395y(a)(1)(A), 42 U.S.C. § 1395y(l).

One area of difference in expectations has to do with when developers should begin working with CMS to navigate the application process. Experts told us that developers were not aware of channels for early interaction with CMS reviewers or for submitting questions that receive timely responses. They said one potential example to emulate is FDA's breakthrough device designation, which, although challenging, offers a streamlined process with support channels while the CMS process does not offer the same. For example, FDA offers opportunities for early interaction through its recently launched Total Product Life Cycle Advisory Program Pilot.[40] CMS officials told us that, to mitigate these differences, agency officials have met with FDA regarding ways to develop synergies between the CMS and FDA processes, as well as to request the ability to interact with developers alongside FDA early in the process, if permitted.

Experts said that it could be helpful for CMS to continue to evaluate how to provide opportunities for increased interactions with BCI developers, especially early in the development process. For example, CMS could borrow from FDA's practices to improve its interactions with product developers and other stakeholders. These options could encourage new products and may speed up the review process. They may also provide more timely advice, such as advice on the inclusion of Medicare recipient populations in clinical trials to avoid delays later.

When asked about opportunity for early interaction with CMS, officials said that the agency is under tremendous resource constraints, but they emphasized that developers can engage early with CMS and that several BCI manufacturers have met with CMS coverage, coding, and payment officials. CMS officials also noted that the agency has a point of contact through the Medicare Pharmaceutical and Technology Ombudsman.[41] CMS officials also told us that they have guidance materials available for developers on the agency's website. Examples include CMS's Getting Started guidance and its Guide for Medical Technology Companies and Other Interested Parties.[42]

CMS officials acknowledged that it may be difficult for experts to figure out when in product development is the right time to engage. They noted there may be benefit in engaging early with CMS. For example, developers could get early input for their clinical trial design, such as input on which populations to include and what measures of trial outcomes to use.[43] However, officials said that issues arise if a developer engages with CMS too early in product development, such as before their device is tested in

[40]TAP is voluntary and is intended to help promote early, frequent, and strategic communications between the FDA and medical device developers. https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap, accessed Aug. 9, 2024.

[41] Medicare Pharmaceutical and Technology Ombudsman. https://www.cms.gov/center/special-topic/ombudsman/medicare-pharmaceutical-and-technology-ombudsman, accessed Nov. 13, 2024.

[42]Getting Started. https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/getting-started, accessed Nov. 13, 2024.

CMS Guide for Medical Technology Companies and Other Interested Parties. https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties, accessed Aug. 12, 2024.

[43]Medicare is the federal health insurance program for people who are 65 and older, younger people with certain disabilities, and people with end-stage renal disease.

humans, which prevents them from giving meaningful feedback without reviewing clinical trial data. Aware of the concerns raised by experts, CMS officials told us they are developing a series of guidance documents to improve predictability and transparency of their expectations for evidence from clinical trials.

Experts and CMS officials described differences in expectations for the types of health outcomes data that CMS uses when making coverage decisions. Experts expressed concern about differences between FDA and CMS standards. FDA's standard for approval of medical devices is whether the device provides a reasonable assurance of safety and effectiveness whereas the CMS standard is whether an item or service is "reasonable and necessary for the diagnosis or treatment of illness or injury is or to improve the functioning of a malformed body member".[44] CMS officials confirmed that health outcomes data that meet FDA's standards will not necessarily meet CMS's. For example, a developer may expect that a BCI will receive a favorable coverage decision if it safely and effectively allows patients to move their fingers. However, CMS officials said the agency expects the data to show outcomes that are functionally necessary to patients, such as the ability to feed themselves with BCI-enabled finger movements (see text box).

We developed five policy options to help address challenges related to BCI access and adoption, shown in table 4.

Opportunities for collaboration

CMS coverage and payment represent a major junction for enabling users covered by Medicare to access medical Brain-computer Interfaces (BCIs). While medical BCI devices authorized for marketing by the Food and Drug Administration (FDA) can be paid out of pocket by a user, the price of the device may be prohibitively expensive. At the same time, the Centers for Medicare & Medicaid Services (CMS) has a statutory obligation to ensure any item or service that is covered is reasonable and necessary.

Developers and CMS officials agree that the industry may benefit from collaborating to develop a common understanding of the important, beneficial, and appropriate patient-centered health outcomes for BCIs. CMS officials told us that the Transitional Coverage for Emerging Technologies (TCET) pathway may help resolve some of the disconnect. The program is intended to provide manufacturers with opportunities for increased pre-market engagement with CMS and create a new and unprecedented level of flexibility to address any evidence gaps for coverage. However, experts told us that the TCET pathway would exclude any devices that have already passed a certain point in the FDA process and there would therefore be no benefit to innovative devices already past that point. CMS noted that the TCET pathway would expedite market access through coordination among multiple parties in advance of FDA marketing authorization, for example, coordination within CMS for coding and payment and the identification of evidence gaps. If the developer contacts CMS within the 12-month period prior to the anticipated FDA decision on a marketing authorization submission as determined by the manufacturer, there likely would not be enough time to coordinate and issue a coverage determination under TCET. However, the traditional national coverage determination process would still be available.

Experts told us it may be helpful if CMS identified mechanisms to collaborate with stakeholders and establish beneficial and appropriate health outcomes. For example, CMS could solicit feedback from various stakeholder groups (including beneficiaries, patient groups, medical professionals and societies, medical device manufacturers, other federal partners, and others involved in developing BCIs) in the same manner it did for TCET to identify additional or improved mechanisms for collaboration. This may allow for additional health outcome considerations not currently included and may make it easier for device developers to understand and meet requirements. However, it may require additional resources from CMS and other relevant federal agencies, which are already constrained. CMS is developing a series of guidance documents on clinical endpoints that are appropriate for Medicare beneficiaries and has published proposed Evidence Review and Coverage with Evidence Development study guidance documents. Additional guidance on fit-for-purpose studies and study protocols using real world data are forthcoming. CMS also considers it possible for developers to convene appropriate parties, bringing together researchers, regulators, and patients for these discussions.

Source: GAO | GAO-25-106952

[44] See 21 U.S.C. §§ 321-399i; 42 U.S.C. § 1395y(a)(1)(A).

Table 4: Policy options that may help address challenges related to brain-computer interface (BCI) access and adoption

Policy options	Opportunities	Considerations
Improve the quality and accessibility of the information available to health care providers and people with disabilities to learn about BCIs generally and opportunities to participate in clinical trials. *Potential implementation approaches:* *The National Institutes of Health (NIH) could consider improving the navigability of clinicaltrials.gov. It could also consider ways to increase the accuracy of the information listed in the database.* *BCI researchers and health care systems could further develop and disseminate informational material through additional patient registries and patient groups about BCI clinical trials open for enrollment.* *Federal agencies could consider conducting a public awareness and education campaign to provide information regarding potential benefits, risks, and uses of BCIs.*	• Expanding the number and diversity of clinical trial participants could help more people benefit from BCIs. • Could generate larger and more diverse datasets to improve product development.	• Individuals ultimately decide what is best for their health based on their personal circumstances. Decisions on whether to undergo an intervention are complex and depend on the person's condition, consideration of medical risks, trust in research or medical institutions, and other factors. • May place additional burdens on federal agencies, researchers, and health care systems.
Prioritize device maintenance and support for users. *Potential implementation approaches:* *The Institute of Electrical and Electronics Engineers (IEEE) Standards Association Industry Connections program and other groups could continue to assess which, if any, interoperability standards could allow multiple developers to service a BCI.* *Stakeholders could explore the possibility of designating a portion of the funds or create escrow accounts to provide access to psychological and caregiving*	• Could reduce physical or psychological harms to participants following conclusion of a clinical trial. • Creating interoperability standards across BCIs may increase the availability of parts or maintenance options and could also lead to improvements in components used beyond BCIs.	• Developers may lack resources or willingness to fund post-trial support for participants. • Without a clear return on investment, interoperability standards could burden developers and limit their ability to innovate.

Policy options	Opportunities	Considerations
services for participants following conclusion of the trial.		
Consider strategies to increase coordination between BCI developers and the Centers for Medicare & Medicaid Services (CMS). *Potential implementation approaches:* *CMS could consider options for potentially providing additional opportunities for increased and earlier interactions with BCI developers.* *CMS, other public programs, and private insurers could consider identifying mechanisms to collaborate with stakeholders to establish appropriate measures of health outcomes.* *CMS could consider soliciting feedback from stakeholder groups (including beneficiaries, patient groups, medical professionals and societies, medical device manufacturers, other federal partners, and others involved in developing BCIs) in the same manner it did for the Transitional Coverage for Emerging Technologies pathway to identify additional or improved mechanisms for collaboration.* *Other public programs and private insurers could make independent coverage decisions.*	• Could increase awareness of CMS Ombudsman and other points of entry into the agency, as well as awareness of the requirements for coverage, payment, and coding. Experts said one potential example to emulate is "breakthrough device designation" from the Food and Drug Administration (FDA). • Could encourage new products and may speed up the review process. • May provide more timely advice and avoid unnecessary delays or uncertainty when developers submit data that are not sufficient for CMS to make a coverage decision. • May encourage developers to include Medicare recipient populations in clinical trials to avoid delays later. • May increase alignment between the functional outcomes required by CMS for coverage and payment with innovative outcomes that may improve quality of life for people with disabilities. • May make it easier for device developers to understand and meet requirements. • Improving coordination between BCI developers and CMS could also improve developers' coordination with other public programs and private insurers. • Could encourage BCI developers to involve CMS in conversations when FDA is consulted.	• May require additional resources to bolster the workforce of reviewers at CMS. • CMS officials said there may be benefit in engaging early with CMS, but also that the agency may be limited in its ability to give meaningful feedback before a device is tested in humans.
Maintain the status quo	• Could save government or private sector resources for other priorities, including medical technologies other than BCIs.	• People with disabilities and other potential BCI users may have difficulty accessing BCIs, or their access may be delayed

Source: GAO. | GAO-25-106952

3.3 Challenges related to BCI manufacturing

High manufacturing costs and a limited number of specialized facilities in the U.S. may limit production and availability of BCIs. Experts told us that few companies have the capability to manufacture implantable BCIs domestically. Experts said an increasing number of clinical trials to test medical BCIs and increasing demand for nonmedical BCIs may exacerbate this challenge. For example, machining electronics small and delicate enough to implant in the human body requires high precision micro-electromechanical systems. Limited semiconductor fabrication plants, or foundries, have these production capabilities. In July 2024, a foundry in the U.S. became the first of its kind to receive funding from the CHIPS and Science Act to increase its production of these systems. Experts expressed concern that the current small number of domestic precision electronics machining and manufacturing facilities would hinder progress in developing and producing BCIs. They said that start-up costs for building or purchasing facilities is high and that companies may face long delays before seeing profit due to regulatory processes. This may limit the number of BCIs that successfully make it to market.

Experts also said that manufacturing medical BCIs is particularly challenging for facilities with limited resources because such manufacturing must meet FDA's clean room and other requirements to help assure device safety and effectiveness.[45] These facilities also require a highly skilled workforce to operate, which may be difficult to recruit and retain (see text box).

Potential effects of public-private manufacturing facilities

Experts told us that public-private manufacturing facilities may foster development of BCIs. For example, the Interuniversity Microelectronics Centre (imec), located in Belgium, is a major supplier of BCI components to the U.S. market. It has received funding from the Flemish government, as well as the Defense Advanced Research Projects Agency (DARPA) and other international funding bodies, to develop a centralized and collaborative research and manufacturing infrastructure for highly specialized electronics.

Source: GAO. | GAO-25-106952

We developed two policy options to help address challenges related to manufacturing BCIs, shown in table 5.

[45]Clean rooms are highly controlled, isolated environments that strictly control airborne particles, including dust and microorganisms; temperature; humidity; air pressure, flow, and motion; and lighting. Facilities must carefully monitor room conditions and follow written procedures to prevent contamination by cleaning and sanitizing surfaces and equipment. These standards ensure that implants are free from biological or chemical contaminants that would impair their functionality or increase risks to patients receiving them.

Table 5: Policy options that may help address challenges with manufacturing brain-computer interfaces (BCI)

Policy options	Opportunities	Considerations
Establish shared manufacturing facilities. *Potential implementation approaches:* *Government agencies, industry, and other organizations could consider mechanisms such as public-private partnerships that can share costs for building U.S. manufacturing facilities that meet Food and Drug Administration (FDA) and other manufacturing requirements.* *Industry stakeholders could partner with academic researchers to increase manufacturing readiness of technologies and prepare them for commercialization.*	• Pooled resources may reduce the financial burden and risk for individual companies. • May allow companies to access new resources, technologies, and expertise that they lack. • May accelerate product development as components may be more readily available in shared facilities. • Existing public-private partnerships with the Interuniversity Microelectronics Centre, Howard Hughes Medical Institute, and the Allen Institute, have led to advancements in available neurotechnology. Increasing the number of such partnerships may further accelerate development.	• It may initially require a considerable amount of taxpayer resources to build shared manufacturing infrastructure. • Some companies might not be willing to share their technologies or methods to protect intellectual property. • It is unclear which entities should be responsible for funding and operating shared facilities. • Not all stakeholders may agree that there should be a government role and may, instead, prefer to maintain the current free-market model for manufacturing BCI products.
Maintain the status quo.	• Could save government or private sector resources for other priorities, including promising medical technologies other than BCIs. • Given anticipated growth in the global BCI industry, private investors may fill gaps in funding without government intervention.	• Expensive manufacturing and component scarcity may pose difficulties advancing new technologies to the market.

Source: GAO. | GAO-25-106952

3.4 Potential for unethical and inequitable outcomes

Experts noted several potential unethical and inequitable outcomes related to BCIs, including the following:

- **Deceptive marketing.** Some experts told us that companies could exaggerate the benefits or downplay the risks of BCIs, both for medical and nonmedical uses. People with profound disabilities may be especially vulnerable to such deceptive marketing. Similarly, children and people facing mental health difficulties may be among the target users of certain consumer BCI applications.

- **Unequal access for users with disabilities.** Participating in clinical trials requires significant time, travel, and access to full-time caregivers. Trial requirements may exclude individuals who do not have steady financial resources and a good support network. There are also historical racial and geographic disparities in clinical trial participation and access to new technology. The expense of devices and specialized skill needed to administer and maintain BCIs may increase disparities in related health outcomes.

- **Loss of access to benefits.** BCI users may lose access to their BCIs either as part of planned endpoints during a clinical trial, or the loss of device maintenance and support when a company ceases operations. For those with profound disabilities, this loss of communication abilities or mobility can be devastating. BCI users, researchers, and other advocates expressed a strong desire to enact protections that ensure individuals can keep their devices and access to their benefits.

- **Unethical human augmentation.** BCIs could be used to augment human capabilities in a way that some would consider unfair. It may be challenging to make ethical judgments in this area, since BCIs can be assistive for some users and augmentative for others. For example, a BCI that uses predictive AI language models to enable hands-free typing could help a user with a disability. However, that device could enable a user to complete exams more quickly than those who do not have access to AI enabled typing.

- **Erroneous consent.** We previously reported that translation of brain signals to speech by a BCI could cause harm if inaccurate. For example, inaccurate translation might indicate consent—for example, to make a legally binding decision or undergo a medical procedure—that the person did not intend to give.

- **Required use.** Schools, militaries, and workplaces could require people to use BCIs. For example, an employer might require employees to use a BCI to ensure that they are working or that they are paying attention during training. This would be a novel requirement that could become coercive if, for example, a warfighter or employee is required to share their brain data as a condition of employment or advancement. According to a RAND report, if a military mission were to involve use of BCIs, service members may be unlikely to volunteer, especially without clear privacy policies

regarding the extracted brain signal data.[46]

- **Changing conceptions of humanity and personhood.** Some people with lived experience may consider their BCIs as part of their person or self. For example, one BCI user with paralysis, who uses a BCI to control a computer, video games, and a robotic arm, considers himself a cyborg.[47] Some may consider such changes to the concept of personhood undesirable.

Experts told us that policymaking regarding BCIs should consider input from a diverse group of stakeholders and the public, and that it should balance individual and societal interests. Experts suggested that when considering regulations and policies, a fundamental question needs to be asked: Is this the society we really want to live in?

Implantable Brain-Computer Interface Collaborative Community (iBCI-CC)

In March 2024, stakeholders convened the Implantable Brain-Computer Interface Collaborative Community. Some of its members include the Food and Drug Administration (FDA), BCI developers, patient advocacy groups, and professional societies. The community seeks to address challenges related to ethics, implantable BCI applications, user preferences, and public messaging and education, among others.[a]

Source: GAO. | GAO-25-106952

[a]iBCI Collaborative Community, https://www.ibci-cc.org/, accessed Nov. 13, 2024.

We developed two policy options to help address ethical challenges, shown in table 6.

[46]Brain-Computer Interfaces: U.S. Military Applications and Implications, An Initial Assessment. https://www.rand.org/pubs/research_reports/RR2996.html, accessed Aug 21, 2024.

[47]This Man Set the Record for Wearing a Brain-Computer Interface, https://www.wired.com/story/this-man-set-the-record-for-wearing-a-brain-computer-interface/, accessed Aug 21, 2024.

Table 6: Policy options that may help address ethical challenges to the use of brain computer interfaces (BCI)

Policy options	Opportunities	Considerations
Conduct or support studies on potential unethical and inequitable outcomes related to BCIs which could include the perspectives of stakeholders and the public. *Potential implementation approaches:* *Government or nongovernment stakeholders with the appropriate expertise could consider undertaking such a study.* *The Implantable Brain-Computer Interface Collaborative Community, or other groups that include a diverse range of stakeholders, could develop a set of ethical guidelines.*	• Could help establish a framework that promotes ethical development and use of BCIs. • Experts including bioethicists told us that such studies would provide an opportunity to better understand the perspectives of the American people.	• May require a considerable amount of time and taxpayer resources. • Depending on the study methodology, citizen perspectives may not be generalizable. • What constitutes ethical development and use is subjective, so it may be difficult to reach consensus.
Maintain the status quo.	• Could save resources.	• The likelihood of unethical development or use of BCIs could increase as the technology matures.

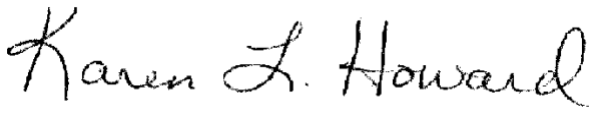
Source: GAO. | GAO-25-106952

4 Agency and Expert Comments

We provided a draft of this product to the Department of Health and Human Services' FDA, National Institutes of Health, Office for Civil Rights, and Centers for Medicare & Medicaid Services; the Department of Defense; the Department of Commerce's National Institute of Standards and Technology and Bureau of Industry and Security; and the Federal Trade Commission. The Department of Defense concurred without comment. The other agencies and some participants from our expert meeting provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or HowardK@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.



Karen L. Howard, PhD
Director,
Science, Technology Assessment, and Analytics

Appendix I: Objectives, Scope, and Methodology

Objectives

We prepared this report under the authority of the Comptroller General to assist Congress with its oversight responsibilities, in light of broad congressional interest and the potential high value of brain-computer interface (BCI) technologies. We examined: (1) BCI technologies available or in development, along with their potential benefits, and (2) challenges to the development and use of BCIs, and (3) options policymakers could consider to help address the challenges.

Scope and methodology

To address all three of our objectives, we assessed available and developing BCI technologies and approaches that may enable people to direct their brain signals to control computers, robots, or other devices, whether worn in the form of a tight-fitting cap or headband or implanted in or near the brain. For all of our objectives, we reviewed peer-reviewed scientific literature and other documents describing current and developing technologies; interviewed federal agency officials and other experts from government, academia, industry, nonprofit organizations, and end user groups. We also reviewed federal agency guidance on the development and deployment of relevant technologies, such as Food and Drug Administration (FDA) guidance on the device license applications process and Federal Trade Commission (FTC) guidance on deceptive acts and practices, and security for biometric data. We provide more details on these methodologies below.

Limitations to scope

The list of key technologies discussed in this report is not intended to be exhaustive. Based on our review of the literature and discussions with federal agency officials and other experts, we selected technologies currently in use or under development by researchers to enable people to direct their brain signals to control computers, robots, or other devices. Though BCI technologies may be developed or used internationally, the policy options we identified represent possible actions U.S. policymakers and stakeholders could take.

Literature search

To gain insight into BCI technologies' applications, potential benefits, challenges, and considerations, we conducted a literature search, reviewed federal agency guidance, and other documents. We conducted scientific searches using search terms that included, "brain-computer interface," "brain-computer interface security," "brain-computer interface intracortical array human," "brain computer interface electroencephalogram (EEG)," "brain-computer interface electrocorticography (ECoG)," "brain computer interface functional near-infrared spectroscopy (fNIRS)", "brain computer interface stentrode," "brain-computer interface ethics," and "brain-computer interface policy".[48] For the scientific

[48]Electrocorticography (ECoG) electrodes provide a highly reliable signal from the human brain surface, and these signals have been used to decode movements, vision, and speech. ECoG-based BCIs are being developed to provide increased options for treatment and assistive devices for patients who have functional limitations. Functional near infrared spectroscopy (fNIRS) is a noninvasive optical technology able to measure changes in blood flow within the brain. When paired

literature review, we considered articles that were published from 2020 to 2024 and excluded articles that were not relevant to our objectives, used animal models, and were published in languages other than English. We identified additional, relevant articles through snowball methods, either though articles from the initial literature search, or through recommendations from our interviews.

Interviews

We interviewed federal agency officials as well as nonfederal experts with a diverse set of perspectives on the science and application of these technologies. The federal officials included individuals from the Department of Health and Human Services (HHS), including representatives from FDA, the National Institutes of Health (NIH), Office for Civil Rights (OCR), and the Centers for Medicare & Medicaid Services (CMS); the Department of Defense (DOD), including representatives from the Defense Advanced Research Projects Agency (DARPA); the Department of Commerce, including representatives from the National Institute of Standards and Technology NIST) and the Bureau of Industry and Security (BIS); and the Federal Trade Commission (FTC).

We also interviewed experts from technology companies, universities, and research institutes that use or develop BCI technologies and experts that represent national advocacy organizations, such as the BCI Pioneers Coalition and Neurotech Network. We invited representative from several prominent companies of which several participated, but one declined and another didn't respond. We selected experts based on their expertise in at least one area related to our objectives. We interviewed these experts to establish a base understanding of BCI technologies that are either available or in development and the potential benefits and challenges associated with the development and use of BCIs. To obtain an understanding of the key challenges identified in our initial interviews, we convened small groups of experts to engage in a cross-sectoral discussion on scientific and technical challenges, data privacy and cybersecurity challenges, regulatory challenges, and various ethical and societal issues. These experts are listed in appendix II.

In addition to evaluating experts on the basis of their expertise, we evaluated them for any conflicts of interest. A conflict of interest was considered to be any current financial or other interest, such as an organizational position, that might conflict with the service of an individual because it could (1) impair objectivity or (2) create an unfair competitive advantage for any person or organization. Of the 17 experts who participated in the cross-sectoral discussions, some were affiliated with companies, a government agency, universities, or nonprofit advocacy organizations. We took these affiliations into consideration as potential conflicts of interest when conducting our analysis and preparing our report. We determined that these experts' affiliations were unlikely to bias our overall reporting.

with electroencephalography (EEG), fNIRS allows provides a noninvasive and portable way to detect brain signals. A stentrode is a small stent-mounted electrode array permanently implanted into a blood vessel in the brain, without the need for open brain surgery.

Policy options

Based on our research, we developed a series of policy options. These are not listed in any particular order, nor are they inclusive of all possible policy options. Policy options are intended to represent possible options policymakers can take to address a policy objective. We consider policymakers to include Congress, federal agencies, state and local governments, academia, and industry. For each policy option, we discussed potential opportunities and considerations. We limited policy options to those that fit the objective and fell within the report scope.

To develop our policy options, we compiled a list of possible options over the course of our work based on review of the literature, interviews with government officials, stakeholders, and experts. We further refined and assessed these options to ensure they were adequately supported by the evidence we collected, could be feasibly implemented, and fit into the overall scope of our work. We then analyzed the information we collected to identify potential benefits and considerations of implementing each policy option. We did not conduct work to assess how effective the options may be and express no view regarding the extent to which legal changes would be needed to implement them. The policy options and analyses were supported by documentary and testimonial evidence.

We conducted our work from July 2023 to December 2024 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. Consistent with our quality assurance framework, we provided the relevant agencies and experts with a draft of our report and solicited their feedback, which we incorporated as appropriate. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Appendix II: Expert Participation

To conduct our work, we identified experts from technology companies, universities, and research institutes that use or develop brain-computer interface (BCI) technologies or represent national advocacy organizations. We selected these 17 experts based on their expertise in at least one area related to our objectives. The experts who participated in these discussions are listed below. Some of these experts provided additional assistance by sending material for our review or reviewing our draft report for accuracy.

Matt Angle

Paradromics

Daniel Berrick

Future of Privacy Forum

Charles Binkley

Hackensack Meridian Health

Ian Burkhart

North American Spinal Cord Injury Consortium

Jennifer Collinger

University of Pittsburgh

Nita Farahany

Duke University

Jennifer French

Neurotech Network

Brian Green

Markkula Center for Applied Ethics at Santa Clara University

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Tom Oxley

Synchron

Leo Petrossian

Neurolutions

Benjamin Rapoport

Precision Neuroscience

Jameson Spivack

Future of Privacy Forum

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Cognixion

Rafael Yuste

Columbia University, NeuroRights Foundation

Appendix III: GAO Contact and Staff Acknowledgments

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Staff acknowledgments

In addition to the contact named above, the following STAA staff made key contributions to this report:

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