

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

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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.

TECHNOLOGY ASSESSMENT

Brain-Computer Interfaces Applications, Challenges, and Policy Options

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/Colorilfe/Good Studio/Ico Maker/Macrovector/Robu_s/Svitlana/victorbillvyse/ VRTX/stock.adobe.c (images). | GAO-25-108952

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 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). <i>This policy option could help address</i> <i>uncertainties in data ownership and control.</i>	 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. 	 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.
	 May increase protection for other types of sensitive data. 	• 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	 Options that protect brain signal data could also protect other types of biometric data. 	 May place additional burdens on stakeholders to coordinate.
(report p. 19). This policy option could help address uncertainties in data ownership and control.	 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 require additional resources to evaluate potential effects of a unified framework.
Prioritize device maintenance and support for users (report p. 24).	 Could reduce potential physical or psychological harms to participants following conclusion of a clinical trial. 	 Developers may lack resources or willingness to fund post-trial support for participants.
This policy option could help address the challenge faced by users who may lose access to, or support for their BCI.	• 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.	• 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	 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). 	 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
challenge of CMS coverage decision processes being a potential key hindrance to adoption.	 Could encourage new products and may speed up the review process. 	device is tested in humans.
	 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. 	

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

Source: GAO. | GAO-25-106952