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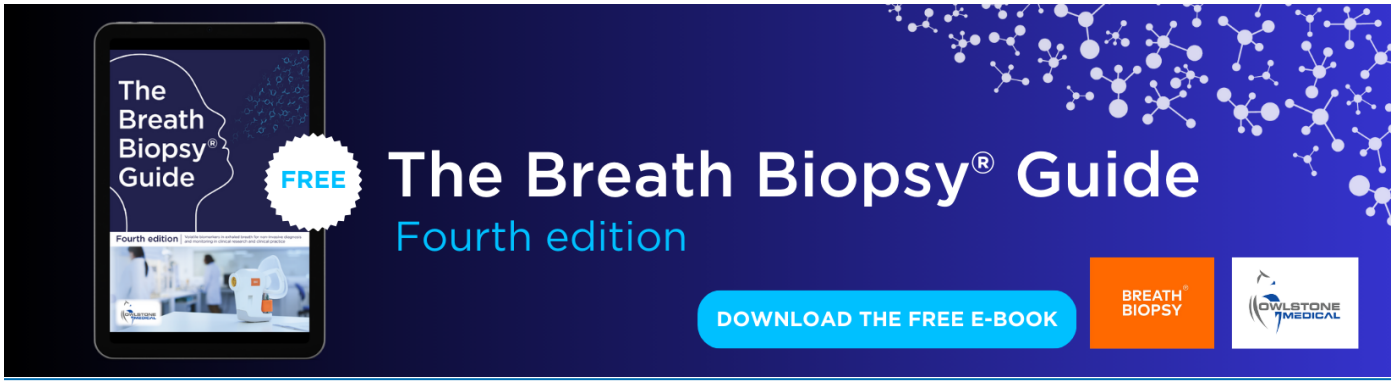

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TUTORIAL

Applying the IEEE BRAIN neuroethics framework to intra-cortical brain-computer interfaces

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Abstract

Objective. Brain-computer interfaces (BCIs) are neuroprosthetic devices that allow for direct interaction between brains and machines. These types of neurotechnologies have recently experienced a strong drive in research and development, given, in part, that they promise to restore motor and communication abilities in individuals experiencing severe paralysis. While a rich literature analyzes the ethical, legal, and sociocultural implications (ELSCI) of these novel neurotechnologies, engineers, clinicians and BCI practitioners often do not have enough exposure to these topics. *Approach*. Here, we present the IEEE Neuroethics Framework, an international, multiyear, iterative initiative aimed at developing a robust, accessible set of considerations for diverse stakeholders. *Main results*. Using the framework, we provide practical examples of ELSCI considerations for BCI neurotechnologies. We focus on invasive technologies, and in particular, devices that are implanted intra-cortically for medical research applications. *Significance*. We demonstrate the utility of our framework in exposing a wide range of implications across different intra-cortical BCI technology modalities and conclude with recommendations on how to utilize this knowledge in the development and application of ethical guidelines for BCI neurotechnologies.

1. Introduction

In the past decades, there has been a strong drive to develop neurotechnologies such as brain-computer interfaces (BCIs) that can restore the ability to communicate or improve motor function in individuals experiencing paralysis [1–7]. In the United States alone, 5.4 million individuals experience paralysis derived from a variety of neurological disorders and diseases of the central and peripheral nervous system, including stroke (33.7%), spinal cord injury (27.3%), and multiple sclerosis (18.6%) [8]. Particular attention has been paid to developing technologies for people experiencing significant speech and motor impairments, as occurs in amyotrophic lateral sclerosis (ALS), which impacts roughly thirty thousand people in the US and two hundred thousand worldwide [1, 9]. ALS often results in locked-in syndrome (LIS), which substantially limits a person's ability to perform voluntary movements.

BCIs (or brain-machine interfaces) refer to a class of technology that records and interprets a user's brain activity and then reacts to that activity in

some way, creating a functional connection or interface between the brain and artificial devices [3]. For the purposes of this article, we will focus on implantable BCIs for two medical research applications, used by individuals with conditions impacting motor ability and/or communication. While BCIs are developing at a rapid pace, ethical guidelines have failed to keep up with new challenges, implications, and opportunities [10–18]. In particular, despite the existence of multiple works highlighting the ethical implications of neurotechnologies, there is a lack of accessible, concrete frameworks that can deliver guidance for addressing the many ethical challenges [14, 18]. In this piece, we apply a neuroethics framework that is being developed by IEEE BRAIN (IEEE Neuroethics Framework [19]) to practically assess the ethical, legal, sociocultural and sociotechnical[10] implications of different BCI medical research applications and technology modalities. We argue that this framework is sufficiently wide in scope to cover such implications across different devices at the design, testing, implementation, and post-implementation stages. The framework emphasizes the contextual nature of ethics and urges technologists, clinicians, and other stakeholders to consider issues from early development to regulatory approval to commercialization, and across the lifespan of the device, ensuring attention and accountability at all stages.

This work complements and expands the existing neuroethics literature by considering iBCI usage through the IEEE Neuroethics Framework, the product of an interdisciplinary, multiyear collaboration between engineers, scientists, clinicians, ethicists, lawmakers, sociologists, entrepreneurs and other stakeholders, including those with lived experience. We present the ethical recommendations in a manner that is accessible to practitioners, including engineers, clinicians and developers, which we believe is a crucial step towards the development of practical solutions. This unique collaboration has led to broader perspectives as well as specific ethical considerations.

First, we will provide an overview of the IEEE BRAIN Neuroethics Framework and the methodological steps involved in its development. Second, we will introduce BCI technologies in greater depth, with a focus on invasive devices that are implanted intracortically for medical research applications. We focus on intra-cortical BCIs (iBCIs) to narrow the scope of the analysis and to exemplify how to apply our framework to a specific neurotechnology type. However, the ethical implications of other neurotechnologies (i.e. non-invasive BCIs for commercial applications) are as important and as vast as for iBCIs. Third, we will exemplify how to apply our framework to obtain an in-depth and comprehensive ethical analysis of iBCI neurotechnologies across applications and modalities. Finally, we will present two iBCI case studies[11], as two concrete examples that can be compared through our framework: one covering recording iBCIs for communication applications and one covering recording and stimulating closed-loop iBCIs for motor control. Through this analysis, we demonstrate the flexibility and adaptability of this framework, which allows us to identify the ethical, legal, and sociocultural implications (ELSCI) across a wide spectrum of iBCI applications and modalities. We note that many of these implications apply to other BCI neurotechnologies (and neurotechnologies in general), but through our analysis, we could identify ethical considerations that are particularly relevant for iBCIs. We close with recommendations for further enriching ethical guidelines for the responsible development of iBCI neurotechnologies.

1.1. Method for developing the IEEE BRAIN neuroethics framework for medical neurotechnologies

The IEEE Brain Neuroethics Framework is an international, multiyear, volunteer-led initiative by IEEE BRAIN, bringing together engineers, scientists, clinicians, ethicists, lawmakers, sociologists, entrepreneurs, and those with lived experience to develop a comprehensive ethical framework covering a wide range of existing and anticipated neurotechnologies. Volunteers are spread across nine working groups: Medical, Wellness, Education, Work and Employment, Military/National Security, Sports and Competitions, Entertainment, Analytics, and Legal, each with its own ethical and technical leads[12] (figure 1(A)). As we write in the Framework's preamble: 'This document has set a foundation for the ongoing development of socio-technical standards with a focus on neurotechnology (IEEE SA P7700) for engineers, researchers, applied scientists, practitioners, and neurotechnology companies that will help ensure the responsible development and use of new neurotechnologies.' [19].

While this framework shares themes with a number of recent neuroethical frameworks [20], several elements distinguish the IEEE Neuroethics

[10] The term sociotechnical, emerging from the field of science and technology studies, refers to the inextricable links between social and material structures, where one is not derived from the other, but they are mutually co-constituted.

[11] In this context, case study refers to an examination of a specific neurotechnology, rather than an analysis of a specific user's experience.

[12] While there is some inevitable overlap between these categories, particularly Medical and Wellness Applications, we delineate medical neurotechnologies as those that align with the US Food and Drug Administration's definition of 'medical device' under section 201(h)(1) of the Food, Drug, and Cosmetic act. Further, the use of such devices outside of traditional clinical instances or for 'off-label' and 'gray' areas is relegated to the Wellness application. Finally, we do not cover devices that enhance human capabilities beyond the normative state.

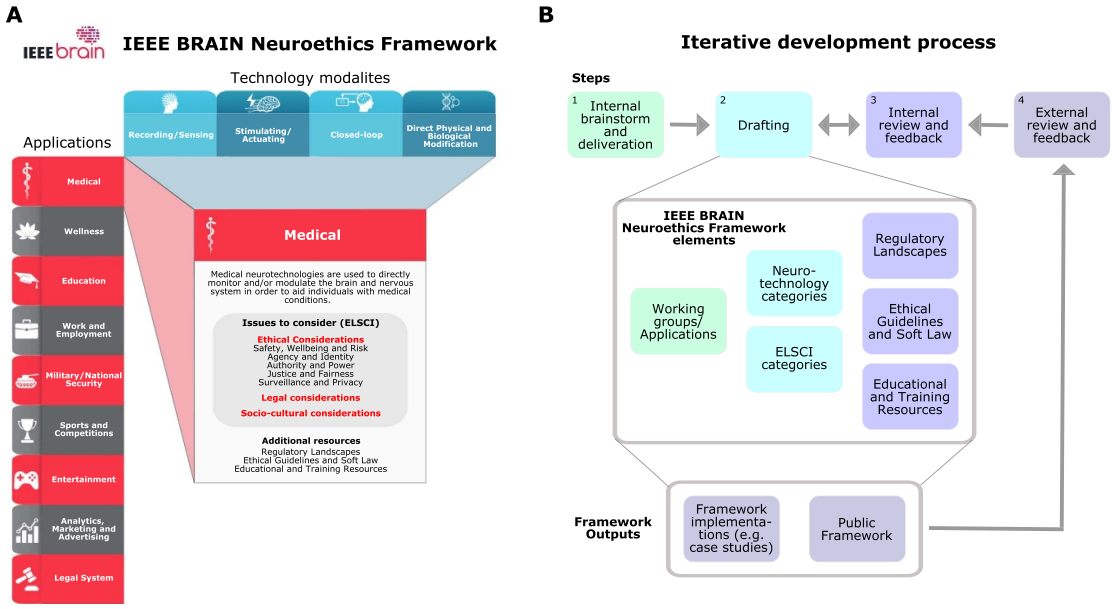

Figure 1. The IEEE BRAIN Neuroethics Framework. (A), The Framework establishes a matrix of applications and technology modalities. Each application of the Framework includes an analysis of ELSCI considerations of neurotechnologies for a respective application (in this case, medical applications) as well as additional resources regarding the regulatory landscape or other guidelines. (B), Framework iterative development process. Top, Framework development steps. Middle, Framework key elements. These are drafted after initial internal brainstorming and deliberation across all working groups. They are later refined iteratively through an internal review and feedback process. The Framework produces outputs, e.g. by applying the framework to particular neurotechnology case studies in order to analyze ELSCI considerations, or by sharing it to the public as a live resource open to public feedback. The Framework outputs are externally reviewed and the feedback is used to further refine the Framework. Green to dark blue shadings indicate chronological progression. The image in panel (A) is adapted from an image courtesy of IEEE Brain.

Framework. First, it brings together a wide array of stakeholders across many different fields, disciplines, and geographic areas, integrating technical and ethical knowledge so as to be of practical value to engineers and technologists. As Michelle Pham and colleagues assert in a chapter comparing five recent neuroethics frameworks [20], cross-cultural comparisons are both rare and necessary for neuroethical guidance, allowing assessments of both cultural biases embedded in technological design and varying public responses to neurotechnologies. Our international approach has involved soliciting feedback from experts and health and technology organizations from around the world. Second, the framework attends to the full life cycle of neurotechnologies, from bench research to clinical trials to commercialization. For the medical working group, this, alongside the incorporation of volunteers with clinical backgrounds and lived experience, allows us to address another area frequently underaddressed in neuroethical frameworks: user treatment and experience before, during, and after research participation [20]. Third, the framework is unique in its simultaneous attention to neurotechnologies across a wide (and ever-expanding) range of applications. Conversations across application domains allow for comparative analyses not otherwise possible. Finally, it is a living document that will grow and respond to input from users and stakeholders as neurotechnologies continue to advance.

The process of developing the IEEE Neuroethics Framework involved multiyear deliberation within and across working groups (figure 1(B)). Volunteers currently number over 60 and are diverse in terms of geographic location, expertise, and career stage. Ethical and technical leads facilitated conversation and initial brainstorming within their working groups to define the boundaries of each application domain (e.g. Medical, Wellness, etc), identify existing and potential technologies within that use case, and highlight emergent ethical, legal, and sociocultural concerns, regulatory landscapes, and supplementary resources. Working group leads then came together to develop a shared 'matrix' across all nine applications (figure 1(A)). In this matrix, neurotechnologies are broken into four discrete categories (recording/-sensing; stimulating/actuating; closed-loop; and direct physical and biological modification), and ethical considerations are divided across five domains (safety, risk and well-being; agency and identity; authority and power; justice and fairness; and surveillance and privacy). Legal implications include individual consumer protections, such as data privacy and ownership, and device regulation systems. Sociocultural implications refer to attitudinal, political, and infrastructural implications, including those

across and between cultures. Importantly, due to the diverse sets of expertise that contributed to the development of the framework, we have also identified and emphasized several sociotechnical, psychosocial, and socio-economic issues within sociocultural considerations.

Using this template, each working group wrote an initial draft of their application's neuroethical framework, with care given to inter- and transdisciplinary translation. For example, we avoided terminology specific to medical bioethics, which may be unfamiliar to engineers as well as those working on neurotechnology in nonmedical applications. Each subgroup developed its own consensus process with oversight from the Framework's chair, and often sought external feedback through workshops, presentations, and invited reviews. Additionally, a task force of volunteers across all working groups ensures agreement across applications to avoid conflicting guidance or definitions.

The authors of this paper are members of the Medical Application working group (figure 1(A)) and developed the study presented here to identify and describe unique challenges and implications in the development and use of neurotechnologies in specific medical settings, as well as to demonstrate the flexibility and adaptability of the framework applied to the field of iBCIs. We aim for the framework to operate as a descriptive-analytical tool, flexible enough to address current and anticipated ethical, legal, and sociocultural issues across various applications.

The IEEE Neuroethics Framework is designed to be a public live document that actively welcomes inputs from diverse stakeholders. This approach ensures that the framework remains adaptable and reflects the evolving ethical landscape surrounding neurotechnological advancements. By actively involving diverse stakeholders, including users, in the ongoing discourse surrounding neuroethics, we can foster a collaborative environment where more perspectives are heard and integrated into the ethical guidelines that govern the development and deployment of neurotechnologies. We aim, with this approach, to continually refine and expand the framework to ensure understandability and usability across stakeholders. The work presented here provides not only an example of applying the IEEE Neuroethics Framework but also an invitation to contribute to the Framework's ongoing development.

1.2. Overview of BCI technologies

This section provides a brief historical overview of BCIs, focusing on iBCIs, the details of how this technology functions, and the current modalities.

History

Humans have long imagined controlling devices using the mind [21–23]. However, it was not only until the early 2000s that the first example of reliable multi-dimensional cursor control using a population of motor cortex neurons was reported in a human with tetraplegia [1, 24]. This user could move a 2-dimensional computer cursor, use it to play *Pong*, and even control a rudimentary prosthetic arm. The same technology was later used by people with ALS to operate a virtual keyboard, showcasing its potential to restore communication [1, 25].

More recently, iBCIs have allowed people experiencing paralysis to control more sophisticated robotic arms, autonomously accomplishing complex tasks such as drinking from a bottle [1, 26] or eating without external human assistance [1, 27]. Another recent development has been the incorporation of artificial stimulation of the brain and body parts driven by motor signals recorded intra-cortically [1, 8, 28]. In particular, direct brain stimulation of somatosensory areas in the human brain has been performed to artificially deliver sensory information into the brain and, with this, restore proprioception, facilitating motor control [29]. Finally, state-of-the-art iBCIs have been recently developed for communication via direct speech translation, achieving unprecedented levels of accuracy in mapping thought to speech [5, 30, 31].

Despite such a long history of development and nearly two decades of work on the ethical implications of this technology [18, 32–36], there has been little progress translating such understanding into actionable guidance [14, 18].

Technology

BCIs work by recording brain signals that reflect ongoing cognitive processes and obtaining information from them to operate artificial devices. BCIs can be passive devices (for instance to predict epileptic seizures or for sleep monitoring) or provide feedback to the users to improve their brain state and/or behaviour. For instance, in motor BCIs, signals conveying motor intentions are recorded and translated into commands to control external devices, while feedback is provided to the users about how their intentions are transformed into actions [2].

BCIs have three main components: a sensor to record neural activity, a decoder that converts neural activity into a command signal, and a device such as a computer cursor or robotic arm that performs an action related to the recorded signal [1]. In iBCIs, the sensor records the electrical activity of groups of neurons measured using penetrating electrodes implanted in cortical areas within the brain of the users. The decoder is an algorithm trained to read

out physiologically relevant signals from the recorded neural activity and to use those signals to control the device. A fourth component can be added to electrically stimulate the user's brain or body parts.

Applications

Here, we summarize the different iBCIs applications we have previously discussed. In medical research settings, iBCIs have been commonly applied for:

Motor control: in individuals that have lost control of their body parts due to neurological conditions or injury leading to severe paralysis.

Communication: in individuals that have lost their ability to speak or to communicate in any other form, due to neurological conditions or injury leading to severe paralysis.

Modalities

BCIs can be classified into one or more of the following technology modalities:

Invasive/Implantable: if they require the surgical implantation of the device within the human body (i.e. iBCIs). Invasive BCIs incorporate electrodes implanted in the brain of the user to record neural signals and can potentially modulate brain activity through electrical stimulation.

Non-invasive/Wearable: if they do not require any surgical procedure and can be simply worn by the user (e.g. electroencephalography (EEG) and functional near-infrared spectroscopy (fNIRS) headsets).

Closed-loop: if they incorporate feedback to the user. This can be sensory feedback provided to the user to adjust their own brain signals (i.e. a human-in-the-loop setting, see below) or can be a direct stimulation of the user's nervous system from the device itself to change the brain state (i.e. a bidirectional setting, see below). In 'closed-loop' systems the feedback is based on measurements of the system's own state, and it is used to automatically regulate the system. Note that from a neurophysiological standpoint, the sensory feedback setting can be considered 'closed-loop', given that the users can auto-regulate their own neural activity based on the sensory feedback received to achieve better device control. However, from a strict control theory engineering perspective, this is only true for BCI systems that use closed control loops integrated into the device itself to automatically modulate the BCI output (i.e. in a bidirectional setting). Because of this, BCIs that are considered 'closed-loop' only from a neurophysiological standpoint are sometimes referred to as 'human-in-the-loop' systems. In this study, however, we will keep the broader definition and simply refer to them as 'closed-loop' systems.

Open-loop: if they do not provide feedback to the user. In this case, brain signals are passively read out to obtain information about brain states without using the information to alter such states or provide information to the user about the task status (e.g. the position of the controlled prosthesis).

Bidirectional: if they incorporate direct brain or peripheral nervous system stimulation. These are closed-loop devices that can typically 'read out' from and 'write in' information into the brain. For instance, the 'writing' of information can be performed by electrically stimulating sensory areas in the brain responsible for touch perception and proprioception. In this case, the stimulation is designed to deliver sensory information artificially into the brain from robotic effectors' sensors. BCIs that incorporate functional electrical stimulation (FES) of peripheral muscles and nerves can also be considered bidirectional. These devices are designed to activate the muscles of paralyzed limbs during external effector control.

2. Applying the IEEE neuroethics framework to iBCIs

Here, we exemplify how to apply our framework to analyze the ELSCI of iBCI neurotechnologies for medical applications. We first describe in more detail the two iBCI applications our study focuses on: iBCIs for communication and motor control. Next, we briefly explain the steps that lead to the implantation of such iBCI devices in a clinical setting. Then, we extensively discuss the ELSCI that can arise during this process and beyond across different iBCI applications and modalities. Finally, we introduce two case studies as concrete examples of iBCIs of a particular medical application and technology modality and compare ELSCI considerations between them.

2.1. iBCIs for communication applications

Communication iBCIs allow individuals to communicate with others using their brain signals. This technology is particularly useful for people who have limited voluntary movements and difficulty communicating due to a neurological condition or injury. A prominent example is LIS, where the affected person can make very few, if any, voluntary movements but remains fully conscious [35, 37]. LIS is usually caused by the interruption of motor pathways in the ventral pons, but other important causes of LIS include trauma, tumours, and ALS, also known as motor neuron disease, which causes rapid loss of muscle control and eventual paralysis. As ALS

advances, before arriving at complete paralysis or LIS, individuals with ALS are affected by dysarthria, a motor speech disorder causing slurred speech, reduced articulation precision, changes in voice quality, and a slower speech rate [38]. Contrary to what many people might assume, individuals with LIS often report a satisfactory quality of life [39]. However, this often depends on their ability to communicate and express their needs and desires [40]. The ability to engage in direct personal communication and hold conversations are the most desirable applications expected from a BCI by users with LIS [40]. People with LIS have very limited capacity to control typical devices for alternative and augmentative communication, given their highly reduced or null mobility. This is why BCI devices that can directly translate brain signals to speech are desirable. In particular, invasive devices such as iBCIs are often considered, given that signal quality recorded from the brain is higher and more stable than from non-invasive recordings [1]. With higher signal quality, the speed and accuracy of the BCI increase, allowing the user to communicate more efficiently. However, recording iBCIs require surgical implantation into the brain. Therefore, the risk-benefits of such an intervention must be thoroughly discussed, as well as other ELSCI considerations, such as potential legal and sociocultural implications.

2.2. iBCIs for motor control applications

Motor control iBCIs allow individuals with paralysis to control external devices, such as a computer cursor or a robotic effector, using their brain signals. End-users can experience different degrees of mobility impairments, from paraplegia to tetraplegia to full-body paralysis such as LIS [41]. Particular attention has been paid to the two latter groups, given the limited range of movements they can perform to control assistive devices. The goal of motor control BCIs is to allow individuals to perform tasks that require effector control, such as grasping or operating a computer, by using their thoughts to control an external device. These devices operate in a closed-loop setting, given that the users receive visual feedback about the position of the effector or computer cursor, which they can use to adjust their own brain signals from moment to moment to achieve better control. As with communication BCIs, there is an advantage of implanting the device intra-cortically since brain signals can be accessed that provide higher spatial and temporal resolution about motor intentions [1]. Besides recording brain activity to decode motor commands, BCIs can use these signals to stimulate the brain or parts of the body to restore or facilitate motor control. As discussed in the previous application, the risks of invasive iBCI interventions must be thoroughly discussed, together with other possible ELSCI considerations.

2.3. Steps of receiving an iBCI

It is important to remark that currently, all iBCIs are only available in the context of clinical trial research; there are no non-investigational iBCIs that are available yet for clinical purposes, and accordingly, no iBCI has yet received Food and Drug Administration approval for clinical use, although several have received investigational device exemptions to be studied in the context of clinical trials (see supplementary table 1 for a list of known commercial entities in Europe and US who are developing iBCIs) [42] While iBCIs are currently mainly confined to the research domain, the ongoing advancements in technology and neuroscience indicate that BCIs will eventually transition into the clinical domain. This will enable clinicians to offer them to individuals who are at risk of losing or have already lost their ability to communicate and/or move [43]. The process of providing an iBCI to a user, currently in the context of a research study, is complex and requires a multidisciplinary approach involving healthcare professionals, BCI specialists, the user, and their support system. The process involves multiple steps, such as:

Assessment: The first step is to assess the potential user's condition to determine if they qualify to be recruited for an iBCI research study. This involves an initial evaluation of symptoms by a referring neurologist, and a psychological assessment by a neuropsychologist to determine the potential user's level of cognitive function (e.g. the ability to concentrate and understand the instructions that are given to successfully control the iBCI system). The assessment will also include a neurosurgical evaluation to determine if the person is an appropriate surgical candidate and can tolerate the surgery. This is particularly the case for those with complex neurological conditions such as advanced stages of ALS.

Consultation and informed consent: Once it is determined that an iBCI is a viable option, the user and identified members of their support system, such as caregivers, should have a consultation with a qualified healthcare professional (e.g. a neurosurgeon) with appropriate expertise. Then, the research team needs to clearly explain and discuss with them the study aims, the risks of the technology and research participation, as well as the user's goals and preferences. Potential users and/or their legally authorised healthcare proxy (surrogate) must also have the capacity to understand, appreciate, and make a reasoned decision to enrol in a research study, and the decision to participate in a research study must be voluntary and free of undue influence. The final step of the process is obtaining informed consent [44].

Surgical delivery and recovery: This step includes preparations for surgery, which may include preoperative testing and health evaluations. Following surgery,

there is a monitor and recovery phase to allow the body to recover from the surgery and any wounds to heal.

Training and Acclimatization: Before the user can begin using the iBCI, they will need to undergo training to learn how to use the system effectively. Training can involve practising with the device and learning how to control it using their brain signals. Additionally, because of the embodied, invasive nature of iBCI, users experience an acclimatization period as they adjust to new modes of embodiment and functioning.

Calibration and customization: The system must be customized to meet the user's needs and preferences, within the constraints of the research study. Customization can involve programming the system to recognize the user's specific brain signals and configuring the device to work with any other technology the user may be using, if they do not interfere with the clinical evaluation.

Re-calibration and support: Ongoing support and maintenance will be necessary to ensure that the iBCI continues functioning properly and meeting the user's needs over time.

During this process, several issues can arise that impact the user. To minimize the negative effects of an iBCI intervention, several ELSCI considerations need to be thoroughly discussed. In the research context, personal benefit to the user is not as highly prioritized as it might be in a clinical context; rather, the primary benefit in the research context is to advance scientific knowledge that can perhaps eventually translate into a clinically integrated iBCI device and help people in the future. Therefore, the ELSCI considerations discussed may vary depending on the clinical context.

2.4. ELSCI of iBCIs

In this section, we discuss the potential ELSCI that can arise during the usage of iBCI technologies across different medical research applications and technology modalities.

2.4.1. Ethical implications

Here, we elaborate on possible ethical considerations that fall into five broad categories concerning Safety, Well-being and Risk; Authority and Power; Justice and Fairness; Agency and Identity; and Surveillance and Privacy.

2.4.1.1. Safety, well-being and risk

The most direct safety concern of iBCI usage arises from the fact that these are invasive neurotechnologies. Even though these devices offer higher precision and speed of BCI control than non-invasive alternatives, given that the quality of the recorded neural signals is higher [1], they require the surgical implantation of the device into the brain, for which open brain surgery is often needed[13]. The risks of undergoing such a potentially dangerous intervention are disclosed and clearly explained to the users [48, 49]. For instance, users are well aware of the risk of infection during surgery. However, future complications can arise due to tissue inflammation, gliosis, and encapsulation of the device, which shortens the durability of the implanted electrodes and, with this, limits the benefits derived from it over time [49, 50]. Thus, different BCI device options should be clearly presented to the candidate user, including both invasive and non-invasive options, explaining each solution's potential advantages and disadvantages, highlighting risks in the short and long term, and reflecting on the degree of reversibility of each neurotechnology. In particular, for invasive devices, it should be made particularly clear that discontinuing their usage might not be a readily available option, given that it would require explanting the device, which needs a careful medical evaluation [51].

Additional risks arise in bidirectional iBCIs that incorporate brain stimulation, such as in motor control applications. Even though the stimulation is designed to avoid tissue damage, the long-term effects of continued stimulation are poorly understood [52]. For instance, there may be a risk of triggering plastic changes in the tissue that might render the area hyperexcitable or induce structural changes at a network level with unknown functional consequences. Even less understood, and often not thoroughly discussed with the user, is the impact on mental health and well-being that the usage of such neurotechnologies can have [53]. There are reports of deep brain stimulation users experiencing stimulation-induced changes in personality (e.g. increased impulsivity, hypermania) [54, 55]. Even without stimulation, as in communication BCIs, the simple usage of the device can induce plasticity due to learning [52]. Finally, candidates must be made aware of how or indeed whether they will have long-term access to the device. At this time, most iBCIs are only made available to users in the context of a clinical trial, which raises questions about the enduring responsibilities of investigators to maintain the device after the trial ends [56].

2.4.1.2. Agency and identity

iBCI neurotechnologies may have a strong impact on the sense of agency and identity of the users. The

[13] Minimally invasive iBCIs have been recently developed which do not require open brain surgery, e.g. inserted into the brain endovascularly, [45]. Note that the term 'invasive' may be ambiguous or contentious, since a consensus on the exact definition of 'invasiveness' is lacking [46, 47]. Therefore, care must be taken when using this term to avoid misinterpretations. In this work, when we refer to 'invasive' devices we specifically mean 'physically invasive' devices.

learning and usage of the device can lead to psychological changes, which could be positive or negative. In particular, the embodied nature of iBCI, as opposed to assistive technologies used externally, may factor into changes in identity and self-perception.

In a study documenting the experience of BCI users, 'What is it like to use a BCI?' [41], a user experiencing spinocerebellar ataxia, which severely impacts motor coordination, balance, and speech [57], had an iBCI implanted in her motor cortex and was trained to use it in order to control a robotic arm. She was very enthusiastic about participating in the study, and very early on in the training, she developed a strong sense of agency and started thinking of the robotic arm as her own: 'Yes. I think it was the second day of training when [the robotic arm] became my arm. I started saying, 'I moved my arm'. I felt like it was part of me.' Participating in the trial had a very positive impact on the user. It gave her a sense of purpose and empowerment and made her realize that she was much more than only her body: 'My brain had not forgotten' and 'I was able to make a contribution [to society]'. However, leaving the research program removed that sense of purpose and identity. 'I miss the training with [the robotic arm]. What I miss even more is having the job'. When users are engaged in clinical trials, this social and psychological aspect of iBCI usage should be considered, as should the impacts of leaving those trials, which often include losing access to their iBCIs and social networks developed with practitioners, as noted above. In general, there is a pressing need to carefully consider continued care and support for iBCI users when clinical trials conclude.

The experience of this user raises several additional questions regarding agency. Given her strong sense of agency and her eagerness to contribute to society, how would the user feel if something went wrong with the robotic arm? What if the arm accidentally hit a doctor as imagined by Yuste and colleagues [13]? Would the user feel accountable for that? In this case, the notions of agency and identity may be profoundly affected, potentially resulting in a negative psychological impact. These potential negative aspects of iBCI usage have been discussed in scholarly circles since at least a decade ago [14, 18, 58–60], and yet they might still be unknown to some physicians, engineers, and funding agents developing iBCI neurotechnologies.

A way to control for potential emerging issues in this domain would be to incorporate test trials designed to evaluate the psychological response of the user in a diverse range of scenarios—and not only focus on success rates to solve specific tasks. For instance, in standard motor tasks, researchers could evaluate the user's emotional impact in the face of device control failures that have harmful consequences for others. This could be done by embedding the test trials in a virtual reality setting, where the users control a virtual arm in an environment where they can interact with virtual agents. This touches on an important aspect of clinical trial design. All the study participants welcomed the technology and concluded that the benefits outweighed the potential harms [41]. However, their experiences occurred in highly controlled lab research settings. This raises the question of their experiences when operating the device in external environments and potentially alone. The proposed virtual test trials might help predict some of these experiences.

Finally, all users felt they were in control of the technology, and because of that, they had a sense of responsibility for BCI-generated actions [41]. However, some users felt that some wrongful actions (e.g. failing to grab an object) arose due to technical errors. Some of the self-attributed failures were perceived as arising from being overexcited or not too focused. The users found it hard to control emotions because these could drive the machines in unexpected ways. The investigation team should document and better understand how the participant's emotional state impacts BCI control and how BCIs impact a user's psychosocial experience [60]. In addition to collecting this data, investigative teams must have adequately diverse expertise to appropriately interpret this information to benefit users; this means including social scientists, psychologists, and others with psychosocial expertise in iBCI research as well as in clinical settings.

2.4.1.3. Authority and power

As with issues of safety, well-being, and risk, issues concerning authority and power also often relate to matters of informed consent. However, what differentiates these categories of analysis is that issues of authority and power explicitly consider coercion, social pressures, and socio-technical systems that create power imbalances in and out of the clinic. For users eager to have abilities restored, consent for a specific intervention might be granted by the user without a complete understanding of the implications of the intervention. Users might not fully consider the negative aspects and dangers in light of the promise of the potential benefits and, thus, might not be well positioned to assess the risk-benefits thoroughly. They might also not be fully aware of the potential impact on their psychological integrity and the cultural and societal implications of BCI usage. In research settings, investigators should endeavour to avoid the therapeutic misconception, whereby participants believe the primary function of the research is personal rather than societal benefit. Further, clinicians are in a position of power when describing the intervention; when the language used is highly technical or filled with legal and clinical jargon, users may not be able to adequately assess the information in order to make an informed decision.

It is particularly important to ensure that unambiguous consent is obtained in people with significant

motor disabilities. Disabled people are especially vulnerable to abuse and exploitation; in a recent study, interviews of people with disabilities in Denmark, for example, showed that 9.4% of them self-reported physical threats, 15.8% humiliations, and 9.5% physical violence [61]. Thus, researchers and clinicians must maintain a vigilant awareness of the clinical and home environments, seeking to ensure that individuals are not experiencing coercion for iBCI initiation. Candidates for iBCI must be provided with the opportunity to clearly indicate whether or not they consent to start using the device, with care taken to consider their preferred mode of communication, the influence of caregivers and relatives, and other factors that may unduly influence the choice to adopt or reject iBCI. If possible, an external person, e.g. the clinical coordinator, who is not part of the investigation team, should manage the informed consent stage. For those who cannot consent, a legally authorized healthcare proxy (i.e. a surrogate decision maker) may consent on their behalf if they know this to be in line with the person's goals of care. Additionally, Joseph Fins notes that people with what he dubs as disorders of consciousness, such as those in a minimally conscious state, are owed distinct ethical considerations regarding the relative benefit of neurotechnologies that may enable communication even as they are currently unable to consent [62]. Even when consent is obtained clearly and unambiguously, however, analyzing the motives behind an individual's acceptance of an intervention is crucial. For example, if compensation for clinical trial enrollment is offered, researchers obtaining the consent should try to discern whether this offering may have been coercive based on the user's financial needs. This analysis must be conducted within the ethical boundaries of standard research consent practices, allowing participants to express, whenever possible, their motives voluntarily and openly, contributing to a more comprehensive understanding of their perspective.

Therapeutic plans or study design (in cases where the BCI usage is part of a clinical trial) must also consider that some iBCI candidates experience progressive conditions; their communication ability may also deteriorate over time, making it difficult for them to maintain or withdraw consent in typical ways. Having advanced research and health directives, where a person expresses their future healthcare wishes in advance (including those related to participating in clinical research), or having a predetermined surrogate decision maker can help offset this risk[14].

Users should also be informed of the cases when they may lack the authority to obtain or deny interventions. For instance, if there is a risk of medical complications and the device has to be explanted, the user may not feel they have the authority to deny such intervention, even though they might want to take the risk of continuing using it [64]. While legally, many countries have standards and precedents allowing a user the right to refuse medical treatment [65], power imbalances in clinical settings may apply undue pressure on the decision-maker.

User preferences should be respected whenever possible. For instance, deciding when and how to inform the user of BCI possibilities should be analyzed on a user-by-user basis. For example, they could have different preferences about when to be informed about BCI possibilities in their progression of a disease (ALS or multiple sclerosis) or adjustments to living with a chronic condition (stroke or spinal cord injury) (e.g. just after the diagnosis, during the rehabilitation, or for degenerative diseases, at the time when they lose the possibility to communicate). This can depend on the aetiology; for instance, some pathologies such as degenerative neuromuscular disorders (like ALS) bring speech impairments in later stages of the disease progression. In other etiologies, such as brainstem stroke, the onset may be acute and unexpected. Caregivers and researchers usually estimate that users would like to be informed as soon as possible after being diagnosed; however, this assumption may be based on an overestimation of the candidate's level of awareness regarding their condition and the implications of their prognosis [40]. It is important to allow individuals with degenerative neuromuscular diseases to defer discussions about their prognosis and end-of-life decisions until later in their clinical journey, even if that means the window of opportunity for iBCI use closes. In these cases, advanced health and research directives and establishing surrogate decision-makers can ensure individual autonomy as conditions progress. This can be particularly relevant for individuals who are experiencing a great deal of stress or emotional turmoil related to their diagnosis and who may need time to process the information before making important decisions (e.g. people who experienced an acute event, stroke, or injury who may still be going through their emotional journey post trauma). Researchers, caregivers, and clinicians must be sensitive to the opinions of prospective end-users while also taking into consideration that the users need sufficient time to learn how to use the technology and to decide if they want to use it and which one if multiple possibilities are available [43, 66].

iBCI candidates and users need continued care and attention from caregivers and clinicians, which can involve balancing authority and decision-making. Caregivers and clinicians play a crucial role in the decision-making process of iBCI candidates, providing guidance and expertise on the iBCI adoption and usage during the research study. However, it is important to recognize that decision-making autonomy about neurotechnology should ultimately lie with the candidate whenever possible. Providing

[14] For a more in-depth discussion of advanced research directives, see [63].

unbiased and understandable information allows them to make informed decisions regarding iBCI usage, and for this, collaborative decision-making is key. By acknowledging and actively addressing power dynamics, caregivers and clinicians can work together with iBCI candidates to create a supportive and empowering environment when choosing the iBCI type, during the training, and in deciding when to keep the device active and when to switch it off. While these decisions have to be taken within the constraints of the research study, this approach respects user autonomy, ensures informed decision-making, and promotes collaboration in the management of their communication needs.

2.4.1.4. Justice and fairness

In the future, iBCI neurotechnologies promise to improve the lives of many individuals that have been marginalized by society due to their disabilities. However, these technologies might also contribute to widening the gap between different sectors of society and exacerbate socio-economic inequalities. While nearly all iBCI users currently receive their devices through clinical trials, often at no cost or with a reimbursement, future use of iBCI in other contexts will likely be biased toward those with financial means. Access to technology might not be feasible for poor communities in Western countries and many in the global South. The costs of the device, surgical implantation, and long-term maintenance might be too high, or they may face insufficient technical infrastructure or health professional training [67, 68]. Even in current clinical trials, candidate users may be dissuaded or excluded from participating if they are expected to fund their own personal costs, such as transportation and caregiving while participating [69]. Neurotechnology developers and funders should put in place programs that allow potential users to overcome socio-economic barriers limiting their access to these technologies [70].

In the context of iBCIs, the lack of local expertise and resources can create significant hurdles for candidates residing in remote areas. These individuals may face difficulties in accessing healthcare facilities where iBCI clinical trials take place. If in the future iBCI begins to be adopted in clinical practice, the distance and logistical challenges involved in travelling to urban centres or specialized facilities will be prohibitive for many, leading to limited or no access to this neurotechnology, and thus, depriving them of the opportunity to regain communication and motor abilities and experience improved quality of life, simply due to their geographical location. Addressing this issue requires innovative solutions to bridge the geographical gap. Telemedicine, teleneurology, and telerehabilitation programs can play a crucial role in providing remote consultations, assessments, and training [71].

When considering justice and fairness in developing and using iBCIs, it is also important to recognize who is categorically excluded from access, either directly through exclusion criteria in clinical trials or, in the future, indirectly through a lack of evidence to support receiving an iBCI in other settings. For example, due to the visual nature of many iBCI set-ups for communication and motor applications, people who are blind or have low vision are often excluded from clinical trials[15], even though BCIs are often presented as an alternative to people with ALS when eye gaze systems are no longer reliable. Likewise, people with cognitive impairments, intellectual disabilities, and dementia are often excluded from clinical trials, and/or intellectual disability is considered a contraindication for access (see, for example, inclusion/exclusion criteria for studies posted by the BCI Society [72]).

Another issue concerning justice and fairness relates to the way the algorithms needed to operate the devices are designed. For instance, it is known that machine learning algorithms can be endowed with intrinsic biases. These can be embedded in the design process or, concerningly, simply learned from data [13]. Similar issues may arise in BCI neurotechnologies. For instance, future communication iBCIs may leverage the power of large language models (LLMs) to generate speech to improve thought-to-word translation speeds by, for instance, incorporating auto-complete features. However, it has been shown that such models can learn human-like biases and are prone to generating racist, sexist, or otherwise toxic language [73, 74]. Even if such unfair intrinsic biases are mitigated, auto-complete features may result in other types of biases that can end up being a source of frustration for the iBCI user. An LLM model's predicted output is computed based on the most likely candidate word, given the millions of example sentences the model is trained on. This prediction, however, might not align with the actual word wanted to be conveyed by the iBCI user. Given their limited communication capabilities, instances like this might be very hard to correct by the iBCI users, causing a great deal of frustration. Thus, caution should be taken on the type of algorithms that are chosen to be deployed on iBCIs to ensure that these devices generate unbiased and fair behaviour, as well as that they respect user preferences.

2.4.1.5. Surveillance and privacy

A major concern within this ethical category is data access and ownership. Policies should be put in place that protect the right of users to keep their own data private [13]. This might not always be possible, for instance, in clinical trial settings, where researchers may need to analyze and reuse the data.

[15] This exclusion does not apply to implants targeting the visual cortex for visual restoration applications.

In this setting, users might become uncomfortable with the fact that researchers are closely inspecting their neural signals, or in other words, 'reading out their thoughts'. However, even in the context of clinical trials, there are many decisions to be made by researchers, in partnership with participants, regarding which neural data will be recorded and studied, whether the neural data collected will be shared beyond the direct research team, and if so, how. Without robust data protections, iBCI lends itself to contributing to discrimination and control made possible through 'neurosurveillance' [75].

In iBCIs, and especially in communication iBCIs, it might be challenging to guarantee privacy during and after communication. An iBCI device raises important risks associated with privacy of thought, resulting from recording, using, and storing a variety of neural signals. Since brain signals are recorded, they can contain sensitive information related to the individuals' emotions, psychology, or intent. It must always be clear to the iBCI user who will see the actions or phrases formulated using the device while they are using the system (online communication) and after the usage. This is particularly important for users for whom the privacy enabled by iBCI (as opposed to speech control systems) may be a determining factor in choosing this intervention. In many cases, it is important to store both the brain signals and the behaviour generated, for instance, to fine-tune the controller of the device to improve its accuracy. The user has to be aware of and in control of devices for managing the collection, use, and sharing of personal neurodata, guaranteeing him/her the right to mental privacy [76–79]. This right is intended to protect 'private or sensitive information in a person's mind from unauthorized collection, storage, use or even deletion' [12], therefore protecting the information before it materializes (before it is written, spoken, or generally expressed), thereby also protecting the source and thus providing stronger protection than current privacy rights. These concerns are particularly timely, given that many companies perform the mining of social media and consumer data to influence consumer behaviour.

A major concern is that this mental data could be hacked by malignant entities that seek to manipulate or coerce. Security breaches compromise user health, safety, and privacy. Therefore, the generated data from the iBCI has to be protected from unauthorized access and misuse, employing best practices for security and privacy when storing, sharing, and processing neurodata, including appropriate privacy enhancing technologies, sensitive personal neurodata encryption, and appropriate security measures to combat bad actors [80].

2.4.2. Legal implications

Legal issues might stem from many of the discussion points touched on above. For instance, knowing how to attribute agency and accountability to iBCI users might be difficult [81]. For example, consider the case that an iBCI user harms someone with a robotic arm. It may be hard to prove that the harm was intended, as opposed to derived from a malfunctioning of the device [82]. Another issue concerns authority and power, as well as privacy. Imagine an entrepreneur approaching an iBCI user, convincing them to release their data to develop a very advanced brain interface, with the promise that they will have access to it. Can the recipient sell their data to them? Can they decide to make their data exclusive to the recipient of the data and ban researchers from using it? Some scholars propose that stringent regulations should be put in place to control the commercialization of neural data, and that international treaties should be put forward to ban neural interfacing in exchange for monetary rewards [13]. There could be legal issues in post-trial or early termination cases, too. For instance, if a BCI company chooses to discontinue device development before or at the end of a clinical trial, it may ask for participants to undergo explantation and return proprietary device hardware. If a participant refuses to undergo surgery, explantation as a coercive medical intervention would require a strong legal justification (e.g. to avert impending harm to self or others) [83].

2.4.3. Sociocultural implications

The short- and long-term social and cultural implications of iBCI usage are poorly understood. Having access to such technologies might undoubtedly provide users with many benefits, like accomplishing many complex motor tasks that they could not do before or re-gaining the ability to communicate with their loved ones. However, psychosocially, the way others perceive the users might emotionally impact them. For instance, they might experience discrimination from people who question their 'bionic' nature and are afraid of what they might be able to do by interfacing directly with machines. Media hype around iBCIs might exacerbate such negative views [64, 84]. Additionally, cultural perceptions of the self, the brain, and the acceptability of interventions on the brain will impact the relative desirability of iBCIs across different cultural contexts.

The possible side effects of an iBCI on users' personal interactions are unclear. There are concerns about possible social pressure on those to use the technology and how iBCIs could limit the users' control over communication. For instance, it can be hard to ascertain that certain observed (BCI-mediated) expressions coincide with the users' endorsed actions. Does 'Yes' always mean 'Yes', or is it sometimes a mistake of the device? This becomes particularly important in circumstances in which miscommunication or malfunction could have devastating or irremediable consequences. For instance, incorrectly communicating requests for support could have serious implications for safety or dignity [85].

Further, as Leuthard, Moran, and Mullen discuss [86], how a BCI user is perceived by others or interprets their own appearance may have a bearing on whether they pursue invasive or noninvasive BCIs. They note that users may prefer more physically invasive options, despite the higher risk due to implantation because noninvasive options may be 'aesthetically unpleasing, unreliable, or difficult or embarrassing to use.' Societal standards for beauty and ability may hold more weight in a potential user's decision than clinical risk.

The focus on restoring motor or communication abilities through technology may inadvertently reinforce the notion that people with disabilities are obligated to pursue medical intervention. Potential users may face social consequences for choosing not to adopt BCIs, ranging from judgment and blame to an inability to access infrastructure designed for and by nondisabled people [87, 88]. Conversely, some people who choose to adopt neurotechnologies experience postoperative psychological and social burdens related to restoring previously lost functions. The phenomenon has been described elsewhere as the 'burden of normality' [64]. Should a user wish to discontinue BCI use for this or any other reason, then the procedure is straightforward for a non-implanted device, while an implanted one will likely stay in place or be explanted through another surgery.

Further, as we write in the framework, 'Consideration must be given to inter-cultural tensions, particularly with the importation of Western biomedical perspectives alongside biomedical technologies into non-Western contexts. For true global humanitarian benefit, and to avoid imperialism, international and cross-cultural collaborations are required [. . .]' [89]. Relatedly, BCI neurotechnologies could amplify social and socio-economic inequalities within and across geographic and social contexts. In the future, iBCI devices might become an accessory medical procedure similar to Lasik surgery, but in this case, used to restore lost or diminished physical and cognitive functions other than vision. If the technology were only accessible to the higher socioeconomic classes, this could magnify the gap between the rich and the poor [90].

2.5. Identifying ELSCI across particular iBCI case studies

As part of our methodology, the IEEE Neuroethics Framework uses case studies to help identify a diverse set of ELSCI considerations, as well as to isolate important idiosyncrasies among applications and technology types. In practice, we find that many of the identified ELSCI considerations are generally applicable to most neurotechnologies. However, some ELSCI considerations are particularly relevant to iBCIs as a category, as well as to specific iBCIs. In this section, we briefly compare ELSCI considerations across two case studies representing two types of iBCIs for medical applications: iBCIs for recording brain activity to restore communication and closed-loop iBCIs for recording and stimulating brain activity to restore motor control.

In both cases, the iBCI devices present similar risks to well-being due to their invasive nature. However, motor iBCIs that incorporate stimulation might pose additional risks due to possible tissue damage or unknown plastic changes within the brain [52]. Regarding the impact on agency and identity, motor iBCIs that operate in a closed-loop fashion might induce a stronger sense of ownership and agency over the device, which can have profound implications on identity and self-perception. This is particularly true for intra-cortical devices since they have access to neural signals at a very high temporal and spatial resolution, which allows them to provide closed-loop motor-related feedback with very short latencies [1], increasing the sense of motor control and agency. ELSCI considerations can vary depending on the particular medical application the iBCI is used for. In communication applications, legal and sociocultural issues might arise if the iBCI fails to accurately convey the intended meaning of an end-user's speech. In motor applications, translation errors can result in failures to control external robotic effectors, which can physically harm the user or others. This has legal implications derived from ill-defined notions of accountability in case of accidents under iBCI control. The lack of control can also disrupt the sense of agency and identity, which can lead to unknown psychological impairments. The two iBCIs have several common ELSCI implications. Both types of iBCIs may be particularly vulnerable to data ownership and privacy violations, which in this case might be highly sensitive due to the uniqueness of the data, which is recorded intra-cortically. A major concern of both iBCI neurotechnologies regarding justice and fairness is that they could exacerbate socioeconomic inequalities if access to technology is not made fair and equitable. Finally, particularly relevant for iBCI devices are post-trial considerations. In future commercially available iBCIs, the companies manufacturing the devices may go bankrupt. This could pose a high risk of abandonment and device obsolescence, which would be exacerbated by the need for explantation surgery. While non-invasive BCIs pose concerns regarding device abandonment, such as sudden loss of access to communication, they do not present the same problems, because surgical explantation would not be required. Similarly, other invasive medical neurotechnologies such as Deep Brain Stimulation (DBS) would not suffer from these issues to the same extent, given that DBS devices are clinically established and widely manufactured, and can be removed at most urban university hospitals [60].

3. Conclusions and future directions

BCI neurotechnologies have the potential to revolutionize the medical field, offering treatment for highly impairing conditions such as paralysis. BCIs also promise to fundamentally change the way individuals interact with the world, allowing users to communicate with others or control devices by simply using their thoughts. As such, concerns have been raised about the ethical implications that these and other neurotechnologies might have on individual users and society, in general, [10–18, 20, 32–34, 87]. Here, we applied the IEEE Neuroethics Framework to iBCIs devices and identified particular ELSCI challenges associated with this neurotechnology that have implications on safety, well-being and risk; agency and identity; authority and power; justice and fairness, and surveillance and privacy; as well as legal and sociocultural implications.

The application of the IEEE Neuroethics Framework across different iBCI medical applications and technology modalities illustrates some potential issues that might arise in developing and deploying BCI neurotechnologies. We hope our study will motivate neurotechnology researchers, engineers, funders, and other stakeholders to take steps in order to mitigate these potential challenges when designing and developing BCI neurotechnologies. Adopting this type of ethical analysis throughout all stages of technology development, and by both funders [91], [Larrivee *et al under review*] and engineers [13], could greatly help mitigate potential problems. Assessing end-user p [92] might remove some of the issues concerning well-being and mental health. These individuals possess unique insights into the practical implications of ethical guidelines as they directly engage with these technologies. Their lived experiences and concerns are invaluable in shaping ethical frameworks that are robust in theory and responsive to the realities of those utilizing these interfaces. We believe that our framework can be combined with other initiatives to help define global neuroethics guidelines, which should go in tandem with country-based legislation to account for cultural differences [13, 17]. The authors in [17], for example, brought together a multidisciplinary and multinational team of scholars and policymakers in a Global Neuroethics Summit to define a set of cross-cultural neuroethical imperatives, which they are now working to implement through the International Brain Initiative (Kavli Foundation, 2017). Pulling together all these different efforts, we can account for limitations that each initiative alone might have, including ours. For instance, other frameworks have more strongly emphasized public engagement and/or the intersection of technology modalities, their stage of development, and different ELSCI considerations [91].

As described above, the IEEE Neuroethics Framework is an interactive, collaborative document that actively welcomes input from diverse stakeholders. In doing so, we aim to create a practical, accessible, and living document that will increasingly serve the needs of BCI practitioners, including engineers, clinicians, researchers, ethicists and users. As such, we end with an invitation to contribute to the ongoing development of this framework, with the hope of defining a regulatory landscape that guides the development of future BCI neurotechnologies for the benefit of all.

Data availability statement

No new data were created or analyzed in this study.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

Ethical statement

No new data were created or analyzed in this study, leading to no ethical protocol requirement.

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