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Main author: Febo Cincotti (FSL), Donatella Mattia (FSL), Floriana Pichiorri (FSL), Francesca Schettini (FSL).
Other authors: Ruben Real (UNIWUE), Eloy Opisso (FPING), Surjo Soekadar (EKUT), Mariska Van Steensel (UMCU), Maria Laura Blefari (EPFL).
Abstract: In this deliverable we deal with ethical aspects of BCI research (Task 4.3). First, a survey of existing reports and recent literature was carried out in order to clarify how ethical issues have been instantiated in the BCI community so far (Overview of the ongoing Ethical Debate). A conclusive chapter is dedicated to general recommendations drawn from a critical revision of the survey in the context of medical and non-medical BCI applications. Finally, we identified ethical issues specific to six Use Cases relative to each application scenarios. The issues related to short- mid- and long- term UCs will be addressed during the consultation of end-users (Task 4.2). The result of such consultation will be part of the final roadmap.
Keywords: Brain-Computer Interface, BCI, Ethics, Use-case, Roadmap.

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Table of contents

1	Introduction	3
2	Overview of the ongoing Ethical Debate	3
2.1	fBNCI Roadmap Post-Mortem Analysis	3
2.2	Literature update.....	4
2.3	Other sources	5
2.3.1	The Tobi lesson	5
2.3.2	NERRI Project.....	6
2.3.3	Nuffield Council on Bioethics Report	6
3	Contribution to Roadmap	7
3.1	Medical Applications.....	7
3.2	Non-Medical Applications	7
3.3	Ethical Issues in the Use-Case selection.....	8
4	References	9

1 Introduction

The Belmont Report is a report created in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [1]. It summarizes ethical principles and guidelines for research involving human subjects. Three core principles (respect for persons, beneficence, and justice) are identified in the report, which can be referred to three main areas of application (informed consent, assessment of risks and benefits, and selection of subjects). Ethical issues regarding BCI research in humans can be organized according to such framework [2]:

- Respect for persons: autonomy of individuals participating to the research must be protected, i.e. informed consent must be obtained from subjects;
- Beneficence: the potential benefits of the research far outweighs its risk to the subjects involved, i.e. the "do no harm" principle;
- Justice: benefits and burdens of the research should be fairly distributed in the population, i.e. principle of equality.

These principles apply to the two main BCI categories: i) BCI research aimed at helping people with disabilities to obtain a functional status that is equal to that of people who are not disabled (Restore, Replace and Improve scenarios, i.e. medical applications); ii) research aimed at the general population (Supplement, Enhance and Research scenarios, i.e. non medical applications).

2 Overview of the ongoing Ethical Debate

2.1 fBNCI Roadmap Post-Mortem Analysis

In this section a summary of the most important findings from the Future BNCI project regarding Ethical, Legal, and Social Issues is provided [3].

Brain-Computer Interfacing promises to reduce the boundaries between humans and technologies raising significant ethical questions related to 1) research & development of BCI technology, 2) use of BCI technology in daily life, and 3) the potential impact of BCI technology on society as a whole.

However, it was noted that despite the multitude of potential topics (see Table 1), ethical aspects or issues brought up in the ethical debate are often not integrated into BCI research, possibly because many BNCI researchers prefer to work within an accepted framework of ethical guidelines rather than actively participating in fundamental ethical debates or making these sensitive and often controversial topics part of their research. Although BCI research & development projects are bound by national and international regulations, and most projects do include ethical managers, an universal set of BCI specific guidelines that are generally accepted are much needed and wanted [4]. For example, questions arise of how informed consent (or, at least, informed assent) can be obtained from patients with difficulties to communicate [5]. Also, no guidelines exist on how to communicate possible side effects (physical or psychological risks) of BCI use. Further, little is known of how BCNI technology affects the daily life of users. Such questions need to be answered using long-term empirical studies. The fBNCI report also noted that despite neurotechnology projects benefitting from intense funding, only few projects have dedicated work packages relating to ethics, thereby missing the opportunity to foster progress in the successive formulation of an ethical framework in neuroengineering involving society as a whole. At the same time, several projects are dedicated to ethical, legal, and social issues (ELSI) of applied neuroscience and bioengineering, however, these projects have only little connections to neuroengineering or BNCI projects.

Based on an analysis of several ELSI projects the fBNCI report closed with the following (abbreviated) recommendations: 1) foster cooperation between BCI and ELSI projects, 2) new BCI projects should be required to address ethical, legal, and societal issues, 3) communicate results to the public, 4) encourage citizen participation in BCI projects, 5)

educating PhD students on neuroethics, 6) research on BCI use as an assistive technology with special attention to ELSI issues.

Research & Development	Daily life of users	Society as whole
<ul style="list-style-type: none"> • Informed consent from people having difficulties communicating • Risk/benefit analysis • Shared responsibility in BCI teams • Side-effects • Ethics in translational research from animal models to humans • Human dignity • Regulating safety • Communication to the media 	<ul style="list-style-type: none"> • Consequences of BCI technology for end-users and care-givers • Personal responsibility • Personhood • Risk of excessive use therapeutic applications 	<ul style="list-style-type: none"> • Mind-reading and privacy • Mind-control • Selective enhancement and social stratification • Mental integrity • Bodily integrity

Table 1. Ethical issues in BCI use

2.2 Literature update

As the scientific community increasingly recognizes the relevance and need to investigate the ethical, legal, and social aspects of BCI systems, a growing number of scientific articles were published in the last years. A few years back, most articles on ethical aspects of neurotechnology were focusing on *brain stimulation* e.g. the issue of neuro-enhancement, identity or undesirable side effects [6], the more recent literature increasingly addresses also ethical dimensions of BMI technology [7]–[11]. While major interest lies in the ethics of medical BCI applications [8], [12], also potential military use [13] or applications in the entertainment industry [14], [15] are being targeted. Importantly, large surveys on stakeholders’ opinions on ethical issues related to BCI systems were pursued to identify main controversial topics crucial for promoting societal acceptance and adequate policies[4][16].

A major topic in the ethics of BCI systems used for communication in paralysis, particularly in complete locked-in syndrome (CLIS), is the question of how to handle “advanced directives”, e.g. when to seize life support under certain conditions, or how to obtain informed consent in advanced stages of neuro-degenerative disorders, such as amyotrophic lateral sclerosis (ALS) given that novel technological measures are available allowing for reliable communication even in complete paralysis [Soekadar et al. 2015, in press].

While some articles stress that ethical issues related to BCI systems are often not different from other assistive or restorative technologies, such as brain stimulation or use of neuropharmacological agents, there is agreement that some ethical aspects are very specific to BCI systems and require broader societal discourse. E.g. the availability of means to communicate despite CLIS confronts many caretakers, physicians or legal representatives with very concrete questions [17]. Similarly, implantation of BMI systems can be associated with specific ethical concerns[8]. But there are also studies with more anticipatory character, e.g. addressing the issue of mind reading [11] raised in the context of the Human Brain Project [18]. In summary, the recent literature reflects that more and more academic and non-academic groups develop awareness of BCI technology’s ethical and legal dimensions and the ethical challenges ahead. Unfortunately, this is not yet reflected in the number of publications in high-impact and high-visibility scientific and non-scientific media outlets. Interest of editors in large-scale research projects like the Human Brain Project or the BRAIN Initiative [19] offer the opportunity to foster larger societal discourse on various dimensions of BNCI systems. While most articles conclude that a broader societal discourse is needed, such discourse may be different from region to region as it highly depends on the cultural context. The formation of regular international and regional BMI meetings over the last years

showed to be instrumental in providing a platform for advancing discourse on the ethical, legal and social aspects of BNCI systems.

2.3 Other sources

2.3.1 *The Tobi lesson*

The EU project TOBI (www.tobi-project.org) devoted a work package (WP) to the ethical issues of BCI. General ethical issues relevant for the use of and research in BCI were categorized and discussed as follows: i) Ethical aspects *in* BCI, issue **relevant but not unique for the BCI field** (e.g. risks of invasive methods, obtain informed consent from LIS patients, team responsibility in interdisciplinary research, communication with media and confidentiality, integrity and availability of neuro-technological devices); ii) Ethical aspect *of* BCI, issues **directly related to the BCI technology** itself (e.g. the problem of shared control, moral responsibility in case of unintended results, access to BCI devices, use of unconscious features, unintended side-effects coming from repetitive use of stereotyped brain signals, meaning of BCI use for a person's self-image and self-perception); iii) aspects related to the meaning of **BCI for ethics as a philosophical discipline** (e.g. integration of the device into own body representation, re-arrangement of competences by routinely using a BCI device, alienation from true personal interactions due to technology).

In the TOBI project, the ethics WP contribution mainly focused on benefits and risks for users participating in research studies, while distinguishing between therapeutic and non-therapeutic research, self-interested and non-self-interested research as well as participants' medical state.

The aspect of the **informed consent** in BCI research was addressed by taking into account the issues of borderline examples among participants (e.g. CLIS), benefits and risks for participants in the studies, privacy and data protection problems. A template for the informed consent form was provided; the template contains sentences and text blocks that can be combined to tailor the form to the specific study. Moreover, during the first part of the project, international guidelines, national laws and other relevant rules have been gathered and evaluated to give the partners concrete advice on how to deal with ethical committees or internal review boards. Concerning legal aspects, the TOBI project referred to the national laws applying to medical devices and medical profession.

Concerning the use of BCI technology for rehabilitation (i.e. to enhance hand function recovery in stroke patients or to volitional modulate brain activity to reduce seizure frequency or improve ADHD symptoms), two main ethical issues were discussed in the project: the possibility of **iatrogenic effects** (undesirable potentiation of maladaptive brain activity) and difficulties in addressing cognitive/behavioral performance in an uncontrolled loop. The former issue is due to the impossibility to identify beneficial or desirable "brain activity" to train for optimal recovery of a damaged brain. As a consequence the BCI could sustain or augment brain activity that inhibits rather than supports recovery. The second issue emerges when BCIs are used to guide the recovery of cognitive functions like attention or speech since the application of these "objective" approaches to areas like emotion, affection, and aggression is obviously less direct. The idea that an individual can modify his or her emotional state or aggressiveness by training neural activity and that this can be achieved by the use of a machine that reads someone's thoughts and redirects them, might have a considerable impact on the general public and in the general perception of this therapy.

Throughout the TOBI project, the topic of BCI and philosophy has been extensively discussed. With respect to technological human self-enhancement, the experiences of current or future BCI users can provide information on how the inclusion of technology in everyday life affects the human being both in impaired and healthy users. With regard to BCI ethics as a new domain of applied ethics, the most pervasive moral problems in BCI at the moment seem to be the question of **agency and responsibility**, the **assessment of communicative processes in locked-in and non-responsive patients** via BCI and the **claim for public funding**.

The ethics team of the TOBI project carried out a survey involving research subjects. With respect to ethical issues participants were not overly concerned with moral, social or legal issues that could be involved in making the tested BCI devices widespread used solutions in every-day life or standard solutions in rehabilitation. Another survey involved BCI professionals and results pointed to the concern that research participants might be frustrated, exposed to unnecessary stress or given wrong hopes [20].

2.3.2 NERRI Project

NERRI (Neuro-Enhancement: Responsible Research and Innovation) is a three-year FP7 EU project that started in March '13 (www.nerri.eu). The project aims to apply the concept of **Responsible Research and Innovation** (RRI) [21] in the field of **neuro-enhancement** (ENHANCE scenario), shaping a normative framework underpinning the governance of neuro-enhancement technologies.

For instance, cognitive enhancement devices (e.g. TMS, tDCS, Neurofeedback), when purchased outside the clinical setting are unregulated [22]. The role of the project is to bring the ethical debate to the different stakeholders. The project is still in progress.

2.3.3 Nuffield Council on Bioethics Report

The Nuffield Council on Bioethics is an independent body that examines and reports on ethical issues in biology and medicine.

This report [23] focuses on the new methods, which involve interventions in the brain, and looks at the benefits and risks presented by the development and use of a number of novel **neurotechnologies** taking into account ethical, legal and societal aspects.

In particular, the report highlights some risks with respect to BCIs, which are commonly present in other reports, those are: surgery complications for invasive BCIs and changing brain structure and functioning in non-invasive BCIs since these employ a highly repetitive use of certain pathways.

The document proposes an **ethical framework** which articulates all these ethical and social concerns. The ethical framework is based on three stages:

First, two common foundational principles set the grounds for the framework, i.e. the principle of **beneficence** and **caution**. Second, in articulating these principles, a cluster of five interests are identified, i.e. **safety, privacy, autonomy, equity** and **trust**. Finally, and in favor of these interests, there are three virtues that are specially relevant, i.e. **inventiveness, humility** and **responsibility**. In addition, the report is also in favor of the adoption of the elements of the **responsible research and innovation** (RRI) [21] which provide a tool that complements the ethical framework.

With respect to the **patients and participants'** interests, the report also highlights the importance of the potentially serious impact of withdrawal of neurodevices at the end of research studies. The report proposes that submissions to research ethics committees must detail the information and support that will be provided to participants as part of consent procedures and at the conclusion of the study.

On **regulatory** aspects, the report highlights the levity in considering the risks related to medical devices (especially for non-invasive) and to devices for non-therapeutic applications in Europe (see also [24]). Although this may support innovation, the report proposes to narrow the arguments in which novel neurotechnologies can be relying on pre-existing evidence. Uncertainty about the benefits, risks and mechanisms by which some novel neurotechnologies achieve their effects presents one of the central ethical challenges in this field. Therefore, the regulation of medical devices should not encourage collection of extensive clinical evidence but should be focused on transparency in the regulatory system. Only through proportionate regulation, innovation in neurotechnologies can be promoted and in turn deliver safe and effective therapies and services.

3 Contribution to Roadmap

3.1 Medical Applications

In medical BNCI applications, the principle of “respect for persons” implies first that the process of obtaining the informed consent is carried out diligently and carefully, taking into account all relevant aspects. These include the issue of obtaining informed consent from people with reduced or unreliable communication means (as well as patients with cognitive impairment), the need to involve caregivers and obtain their consent to the participation in long-term, home-based studies. Also, there is awareness among researchers on improving communication of risks and benefits of the participation to BCI studies [5].

Such communication of risks and benefits is the core of the “beneficence” principle, which is in theory fulfilled in medical application as they aim at replacing, restoring or improving a lost function. Nevertheless the following risks emerged as relevant from our survey: i) physical risk with invasive BCI research; ii) the risk of inducing unwanted changes in the brain with excessive, repetitive use (e.g. maladaptive plasticity); ii) psychological risk of disappointment when the BCI device is not working sufficiently well (frustration) or excessively well (as most of the studies are time limited and the device is withdrawn from the participant); iii) agency, safety and responsibility in the case of unintended/uncensored actions; iv) privacy issues ranging from the mere data sharing among research group to the less tangible “mind reading issue”. As for risks connected to invasive BCI studies, lessons should be drawn from other fields such as deep brain stimulation in movement disorders. Large controlled studies are needed in the improve/restore scenarios to address the issue of possible detrimental changes in the brain (i.e. maladaptive plasticity). Such studies should include extensive clinical and neurophysiological assessments to fully evaluate risks and benefits. The psychological risk of disappointment is currently almost entirely lying on the researchers shoulders. In this sense, BCI researchers must establish clear guidelines for the straightforward communication of possibilities and limitations of current BCI based options in medical applications. Each ethical proposal should include plans for 'what to do when the study ends': in principle, researchers are not allowed to take away devices (as well as treatments) that work satisfactorily when a study ends (Helsinki Declaration). This issue, however, has important implications for the period after the study and should be considered in grant proposals (it could be associated with further costs to the proposing entity). The issue of agency, safety and responsibility is especially relevant to the Replace and Restore scenarios: how reliably can the information delivered through the BCI channel (in the case of a communication device) or the action resulting from the BCI (in the case of a prosthetic device controlled through a BCI) be used? Will all intentions carried out by the neuroprosthesis/communication device? Or is there some inhibition in the system? [25] Answers to this question imply considerations on safety and assignment of responsibility in the case of unwanted results. Another relevant facet of this topic is that communication through a BCI device in e.g. CLIS patients might deal with ethically relevant topics per se, such as advanced directives (“life will” decisions).

The principle of “justice” or equality in medical applications is currently mostly the researchers’ responsibility. In particular, researchers must be prompt and honest in responding to appeals of the general population asking to participate in BCI studies or simply requiring more information on the ongoing research (e.g. emails sent from laypersons getting information on ongoing or past projects through the internet). In this regard, communication with the media should be responsible and possibly regulated by common guidelines. Research results should be shared among research groups to promote fast advancements and reach the widest number of patients in different geographical regions. The issue of equal opportunities across countries and social statuses will become relevant with the commercialization of BCI devices for medical applications. Similarly, social implications of BCI use will become relevant with commercialization and wide distribution of the devices (e.g. who will put this on my head? will this add burden to my caregivers? how will this make me look, will it further exclude me from society?) [25].

3.2 Non-Medical Applications

The current ethical debate in non-medical BCI applications (Supplement, Enhance, Research) is somewhat less developed than that related to disabled participants. The apparent reason could be that non-medical applications are related to more futuristic scenarios. Given the potentially wide impact of such applications (larger number of target end-users), ethical issues related to the healthy population will be widely addressed in the roadmap (consultation of end-users Task 4.2).

The principle of “respect for persons” appears less relevant for gaming and daily life applications since the use of a BCI device in these contexts implies a voluntary decision. However, in the case of gaming BCI applications, minor age users will need to be considered. The principle of “beneficence” here is again less definite since we deal with the healthy population; however the possibility of inducing unwanted changes in the brain or even causing damage with excessive use or misuse of BCI devices in daily routine should be considered. In military applications or other specific situations related to e.g. employment decisions, lawsuits etc., the ethical debate could imply coercion and selective enhancement issues. Privacy, personhood and mindreading are relevant issues for the Enhance, Supplement and Research scenarios especially if we consider the possibility of sharing data through the internet and storing large amounts of data for long periods of time (future research might reveal new unexpected information from old brain signal recordings). Another important aspect for BCI application in healthy (Enhance and Supplement scenarios) is the issue of safety and responsibility for unwanted/uncensored actions. Concerns raise about the risks related to invasiveness in non medical BCI applications, however no conclusions can be drawn at the moment given the futuristic facet of these scenarios; in this context, BCI might learn from areas that deal with invasive procedures without medical need (e.g. esthetic surgery).

The issue of “justice” is probably relevant here, given the high cost of current BCI and BCI-related technologies which could limit the accessibility of such devices for the general population. However, the wide range of possible future applications limits the current discussion.

3.3 Ethical Issues in the Use-Case selection

In the following table we list ethical issues relative to six Use-Cases that will be analyzed in detail in the roadmap (one for each application scenario). The table contains exemplary outlines of the consultation of end-users (Task 4.2) with regard to ethical issues. Such task will be carried out throughout focus groups relative to each application scenario in which relevant issues will be discussed with different classes of users. Hence, synergies with other fields ranging from neuromodulation (invasive and non invasive), assistive technologies, gaming, social networking, human-computer interaction, will be exploited in order to address common ethical issues.

Use Case (related scenario)	Ethical Issues
Unlocking the completely locked-in (Replace)	<ul style="list-style-type: none"> • Informed Consent from CLIS patient and caregiver • Privacy issues • Risks related to implant • Frustration related to malfunctioning/reduced technical assistance at the end of the study • Equal opportunities across countries and social status
BCI-controlled neuroprosthesis (Restore)	<ul style="list-style-type: none"> • Risks related to implant • Risk related to maladaptive

	<p>plasticity</p> <ul style="list-style-type: none"> • Frustration related to malfunctioning/reduced technical assistance at the end of the study • Agency, safety and responsibility of unwanted/uncensored actions • Equal opportunities across countries and social status
Hybrid BCI-driven FES for rehabilitation (Improve)	<ul style="list-style-type: none"> • Risk related to maladaptive plasticity • Frustration related to malfunctioning/reduced technical assistance at the end of the study • Equal opportunities across countries and social status
Neurotutor (Enhance)	<ul style="list-style-type: none"> • Privacy Issues, Personhood, Embodiement of Technology • Risks related to excessive use • Equal opportunities across countries and social status (selective enhancement)
BCI-controlled robot assistant (Supplement)	<ul style="list-style-type: none"> • Privacy Issues, Personhood, Embodiement of Technology • Risks related to excessive use, maladaptive plasticity • Frustration related to malfunctioning • Safety and responsibility of unwanted/uncensored actions • Equal opportunities across countries and social status
Research tool for cognitive neuroscience (Research)	<ul style="list-style-type: none"> • Privacy Issues, Personhood, Embodiement of Technology • Risks related to excessive use, maladaptive plasticity

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