BNCI Horizon 2020

The Future of Brain/Neural Computer Interaction: Horizon 2020

Appendix C End Users

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http://bnci-horizon-2020.eu/

C End Users

C.1 Sources

C.1.1 The UCD approach

Although BCI systems are ultimately designed for what might be called independent home use, much research still takes place within the comforts of a well-equipped psychophysiological laboratory. Thus, there exists a translation gap, which manifests itself in a lack of knowledge about end users of BCI technology and the biological, psychological, and social aspects of human-computer interaction (HCI) (Kübler et al., 2014).

The user-centred design (UCD) process is a viable approach to close this gap and to bring BCI technology to the market. This framework is derived from the consortium's long standing experience and is mirrored in several recent publications (Kübler et al., 2014; Schettini et al., 2015*;* Riccio et al., 2011; Zickler et al., 2011). It is based on the user-centred design approach, which posits "early and continuous involvement of potential users, understanding of user requirements and the whole user experience, and iterative processes between developers and users" (Kübler et al., 2014). These principles can be implemented using a four-stage development mode (see Table 1), which focus on understanding and specifying the user's needs, defining the context of use, evaluating prototypes against these specifications, and developing ever-more refined prototypes to meet these requirements (see Figure 1).

Table 1. Principles of user-centred design and their application for BCI technology (from Kübler et al., 2014).

Principle	Application
Understand the user, the task and environmental requirements	Chose appropriate metrics - apply interviews/questionnaires for first definitions
Encourage early and active involvement of users	Interaction between users and developers to define the first version of a prototype
Be driven and refined by user-centred evaluation	Valid evaluation metrics
Include iteration of design solutions	Continuous interaction between developers and end users in their home environment leading to several prototypes
Address the whole user experience	Evaluation metrics that covers all aspects of ‘‘usability’’, i.e. effectiveness, efficiency, satisfaction
Encourage multi-disciplinary design	Continuous involvement of experts of relevant fields

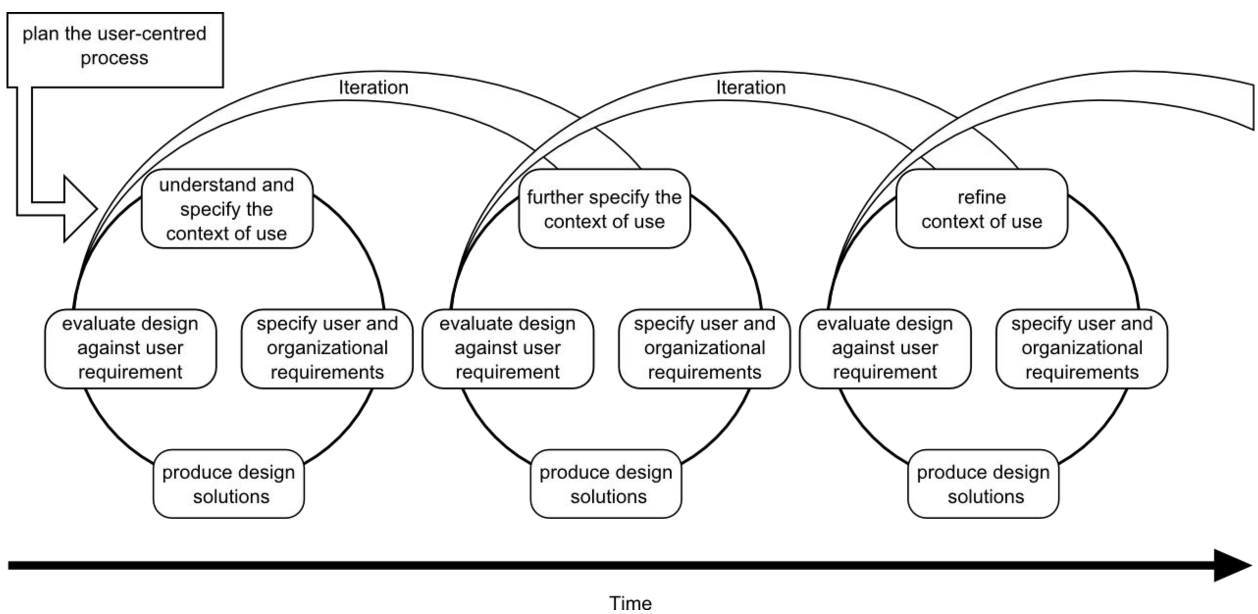

Figure 1. The User-Centred Design Process.

These principles and stages derive from the concept of **usability**, which ISO standard 9241–210 defines as the ‘‘extent to which a […] product […] can be used by specified users to achieve specified goals with *effectiveness*, *efficiency* and *satisfaction* in a specified *context of use*’’ (p. 3). Whereas *effectiveness* refers to the accuracy with which a user can accomplish a given task, *efficiency* relates effectiveness to invested costs (time and personal efforts). Earlier conceptualizations of *user satisfaction* defined this to mean the perceived comfort and acceptability while using a BCI product, e.g. a BCI-controlled application (Kübler et al. 2014). Here, its focus is broadened to also include satisfaction with using BCI technology components. Finally, *context of use* refers to users, tasks, equipment (e.g. hardware and software, materials), and the physical and social environments in which a product/technology is used.

In the UCD process, participants should be selected from the **intended end user population**, even if this may mean spending substantial efforts in recruiting these participants (e.g. involvement of motor impaired individuals). In addition, prototype evaluation always refers to evaluating a product based on **actual experience**. Asking participants to imagine how to interact with a (fictional) product does not suffice and may even be impossible for end users. Finally, tasks selected for evaluation need to be representative of actual product use, as restricting evaluation to subsets of tasks may severely limit generalizability beyond the sampled tasks.

C.1.2 Literature

UCD

To define the state-of-the-art (SoA) of UCD in the BCI field, we searched the available scientific literature on the topic by carrying out a PubMed search with the terms “brain computer interface” and “usability” or “user-centered design”/“user-centred design”; 64 papers resulted from this search. Only journal papers and book chapters related to BCI and considered relevant for the purpose of this review were included. In particular, we considered papers applying either the complete UCD cycle or specific aspects such as the collection of users’ needs, the involvement of users as testers and those including a usability evaluation on behalf of users. After this critical revision, 25 papers were considered for the SoA, including five review papers. Six more papers were added for their particular relevance for the topic of interest, including one review paper. Altogether, a total of 31 papers including six reviews were considered for the SoA.

Ethics

In order to provide a comprehensive review of the literature on ethical and social aspects of BCI technology, we first summarized the main results reported in the Future BNCI roadmap, then we performed a PubMed search with the terms “brain computer interface” and “ethics”. Only journal papers that were not cited in the Future BNCI roadmap have been selected for the review.

C.1.3 Previous projects

We summarized the main results of previous research projects that have dealt with ethical issues about BCI technology and more generally neurotechnology. In particular, we analysed the results of the EU projects TOBI and NERRI and the Nuffield Council on Bioethics Report.

C.1.4 Consultation of users

Within previous research projects, users have been interviewed about their needs and expectations about BCIs using different methods (questionnaires, well-validated scales, interviews). In the context of the BNCI Horizon 2020 project, we preferred the focus group approach because, with respect to other methods, it allows to obtain a larger amount of data of excellent quality. Furthermore, although a focus group is usually planned and structured in advance, it is still flexible and allows to deepen the topics discussed. One of the aims of the BNCI Horizon 2020 project is to foster synergies between different fields (HCI, industries, researchers, professional users), in this regard group discussion, involving different classes of users, facilitates the expression of new views and information. Moreover, the heterogeneity of groups allows to collect new information with respect to previous users surveys (Kitzinger, 1995). Within the whole consortium, a focus group has been carried out for each application scenario by identifying an institution leader for each group according to its background and skills. In a few cases where a focus group was not feasible, structured interviews were held addressing the same topics of the focus groups. Structure and main topics were thus aligned among partners to obtain comparable results.

With respect to participants recruitment, we decided to include people not directly involved in the BCI field in order to obtain new and unbiased opinions. Each focus group involved 6-10 participants with different (professional) backgrounds. Each group discussion was focused on a specific use case (see Appendix D) and aimed at collecting information about current solutions and technologies applying to the specific use case, opinions and suggestions about the proposed device, user's expectations, and possible ethical and social issues.

C.2 Summary of the state-of-the-art

C.2.1 User definition and matrix (identification/stratification according to UCD)

As stated above, UCD is an iterative process in which specific phases can be identified. Once the context of use has been identified, the iterative process consists of three main stages that are repeated until a user-adapted product can be released: (*i)* specify the user requirements; (*ii)* produce design solutions to meet user requirements; and (*iii)* evaluate the designs against requirements.

In the UCD approach three types of users can be identified:

- End users (or primary users): persons who actually use the product;
- Secondary users: persons who will occasionally use the product or those who use it through an intermediary;
- Tertiary users (professional users or other stakeholders): persons who will be affected by the use of the product or make decisions about its purchase.

The UCD cycle usually applies to a given product. In the BCI field, instead of a single specific market product, we refer to the BCI application scenarios described in the roadmap (adapted from Wolpaw & Wolpaw 2012): Replace, Restore, Enhance, Improve, and Research.

The Enhance application scenario is arguably most closely related to be used by healthy users (for example people working in extremely demanding environments). It includes BCI gaming and entertainment applications in which the brain could benefit from an enhanced control channel. Nevertheless, disabled people could also profit from attention monitoring during the execution of particularly demanding tasks (e.g. during rehabilitation therapies) or could opt for a BCI-controlled gaming system, regardless of their own disability. The Research application scenario is transversal to all other applications in the sense that it shifts the target from the external world (i.e. communication, control of devices, regain of a specific function etc.) to the brain itself. With a certain degree of overlap, this classification scheme comprises nearly all conceivable BCI scenarios in the short-term, mid-term and long-term perspective (note that the Supplement scenario described in Wolpaw & Wolpaw 2012 was not further analyzed in this Roadmap).

It is also helpful to define current and future BCI user classes. For this purpose, we propose a classification matrix (Table 2) with applications in columns and user classes in rows. In this table, we propose examples of identified user classes in the different application scenarios. In comparison to what we described above (where professional users are classified as *tertiary users*), we believe that at this stage of BCI development some professional categories might be considered *secondary* or *tertiary users* depending on the scenario. Indeed, at the current state of BCI technology and especially in some newer application scenarios, BCIs cannot properly be considered a market product. For these reasons, some professional users (e.g. researchers testing BCI prototypes on people with disabilities at home, therapists testing BCI prototypes for rehabilitation) might fall under the secondary users category, i.e. using the product through an intermediary, while others (e.g. insurances) might better fit in the *tertiary users* category, i.e. making decisions about the purchase of the product. Nevertheless, once BCIs become mature market products, professional users - now identified as “secondary users” (e.g. therapists) - could also be considered *tertiary users*.

Table 2. Classification matrix for BCI users and application scenarios.

			Scenarios					
			Replace	**Restore**	**Enhance**	**Supplement**	**Improve**	**Research**
		Function of BCI	Assistive product (Communication, Interaction with the environment)	Prosthesis, Orthosis, Exoskeletons	Alert monitoring, neurofeedback to relax	Extra effector	Rehabilitation tool	Conditioning paradigm, Investigation of human brain functions
Users	**Primary Users**	**End users**	Persons with functional deficits	Persons with functional deficits needing prostheses	Healthy people performing demanding tasks, gamers	Healthy people performing tasks in extreme environments	Persons with functional deficits that can be improved	Researchers
	Secondary Users	**Non-Professional Users**	Family, Caregivers, Persons interacting with the user	Caregivers, Persons interacting with the user	Persons benefiting from the user's performance	Persons benefiting from the user's performance	Family, Caregivers, Persons interacting with the user	Persons benefiting from research results
	Secondary/ Tertiary Users	**Professional users**	Manufacturers, AT professionals, IT managers, Researchers	Manufacturers, AT professionals, IT managers, surgeons, other MDs	Industry benefiting from the user's performance, military institutions	Industry benefiting from the user's performance, military institutions	Therapists, Medical doctors, Researchers	Researchers, Academics, Companies
		Other stakeholders	Insurances, Public health system	Insurances, Public health system	Manufacturers	Manufacturers	Insurances, Public health system, Industry	Funding agencies, Publishers

C.2.2 UCD instantiation in BCIs

For the SoA of UCD in the BCI field, papers were classified first according to the BCI application scenario. Subsequently, the target end user category was identified with the description of the functional deficit and its etiology (where applicable). The BCI paradigm used or discussed in the paper was also considered. As specific descriptors of the usability aspects, we identified three phases of users' involvement: *(i)* needs and requirements, (*ii)* testing, and *(iii)* evaluation.

The majority of papers were related to the Replace scenario (Table 3). Nevertheless, among these papers, the majority referred to communication scenarios (see Figure 2). In our interpretation, such prevalence of the Replace application is due to historical reasons, since this can by far be regarded as the original and oldest BCI application, in which most of the ethical and user-related issues have been at least identified and somewhat explored in the literature. Among papers included in the review, in one single case (Plass-Oude Bos et al., 2011) the authors applied the complete UCD cycle: from the collection of needs and requirements (by means of interviews) through the testing of a specifically designed BCI-controlled gaming system, to the evaluation phase (questionnaires and interviews). Very few papers report users' involvement in the early phases of development of BCI paradigms and prototype (5%), and this was done by means of interviews, focus groups and workshops. Among studies targeting disabled end users (21 papers), only 57% actually involved such a user group in the testing procedures. As for the usability evaluation, a few approaches have been consistently applied in BCI studies (87% of the selected papers), which include: effectiveness, efficiency, workload, and satisfaction assessment.

Table 3. Classification of Original Research (OR) papers, Reviews (R) and Book Chapters (BC) applying either the complete UCD cycle or specific aspects such as the collection of users' needs, the involvement of users as testers, and a usability evaluation on behalf of users. Rows highlighted in orange indicate papers that were added for their particular relevance for the topic of interest. Not defined fields have been assigned with n/d.

Title	Scenario	End User	Paradigm	Needs and requirements	Testing	Evaluation
Aloise, et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300 - Covert attention	n/d	Healthy subjects	Effectiveness and efficiency
Blain-Moraes, et al. 2012. (OR)	Replace	Persons with functional deficits - primary users Stakeholder - secondary users	P300	Focus Group	n/d	Focus Group
Blankertz, et al. 2010. (R)	Enhance	Persons without deficits (i.e. "healthy") - primary user	n/d	n/d	Healthy Subjects	Effectiveness and efficiency
Carabalona, et al. 2009. (R)	Improve	Persons with functional deficits - primary user	n/d	n/d	Healthy Subjects	Usability evaluation
Carabalona, et al. 2012. (OR)	Replace	Persons with functional deficits - primary users	P300	n/d	Disabled End Users	Usability evaluation, users feedback
Combaz, et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300/SSVEP	n/d	Disabled End Users	Usability evaluation
Ekandem, et al. 2012 (OR)	Research	Persons without deficits (i.e. "healthy") - primary user	Other	n/d	Healthy Subjects	Users feedback
Fazel-Rezai et al. 2012. (R)	Replace	Persons with functional deficits - primary users	ERP/P300	n/d	Disabled End Users /Healthy subjects	Effectiveness, efficiency, workload, users feedback
Felton, et al. 2012. (OR)	n/d	n/d	SMR	n/d	Healthy subjects vs Disabled End users	Workload
Friedrich, et al. 2013a. (OR)	n/d	n/d	SMR, Other	n/d	Healthy Subjects	Effectiveness
Friedrich, et al. 2013b. (OR)	n/d	n/d	SMR, Other	n/d	Healthy Subjects	Effectiveness, Users Feedback
Grychtol, et al. 2010. (OR)	n/d	n/d	SMR	n/d	Healthy Subjects	Effectiveness
Höhne, et al. 2011. (OR)	Replace	Persons with functional deficits - primary users	ERP - auditory	n/d	Healthy Subjects	Effectiveness - Efficiency

Holz, et al. 2013. (OR)	Replace Enhance	Persons with functional deficits - primary users	SMR	n/d	End Users	Usability evaluation
Huggins, et al. 2011 (OR)	Replace	Persons with functional deficits - primary users	n/d	Interview	n/d	n/d
Kaufmann, et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300 - auditory, visual, tactile	n/d	End Users (case study)	Effectiveness
Kubler, et al. 2013a. (BC)	Replace	Persons with functional deficits - primary users	n/d	n/d	End Users	Usability evaluation
Kübler, et al. 2013b. (R)	Replace	Persons with functional deficits - primary users	n/d	n/d	End Users	Usability evaluation
Lee et al. 2013. (OR)	Improve Enhance	Persons with/without functional deficits which might be improved - primary user	Other	n/d	End Users	Safety, Usability and Acceptability
Liao et al. 2012. (OR)	Enhance	Persons without deficits (i.e. "healthy") - primary user	Other	n/d	Healthy Subjects	Effectiveness
Lopez-Gordo et al. 2012.(OR)	Replace	Persons with functional deficits - primary users	Auditory	n/d	Healthy Subjects	Effectiveness, efficiency
McCullagh et al. 2010. (OR)	Replace	Persons with/without functional deficits - primary users	n/d	Surveys, Workshops	n/d	n/d
Millán et al. 2010. (R)	n/d	n/d	n/d	n/d	n/d	n/d
Nijboer et al. 2014. (OR)	Replace	Professional - Secondary	n/d	Focus Group, Interview	n/d	n/d
Plass-Oude Bos et al. 2011 (BC)	Enhance	Persons without deficits (i.e. "healthy") - primary user	Other	Interview	Healthy Subjects	User Feedback
Pokorny et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300 - Auditory	n/d	Disabled End Users /Healthy subjects	Effectiveness
Riccio et al. 2011. (OR)	Replace	Persons with functional deficits - primary users	P300	n/d	Healthy subjects	Usability evaluation
Scherer et al. 2008. (OR)	Replace Enhance	Persons with/without functional deficits - primary users	SMR	n/d	Healthy subjects	Effectiveness
Schreuder et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300 - auditory, visual	n/d	End Users (case study)	Effectiveness, Workload
Zickler et al. 2013. (OR)	Replace	Persons with functional deficits - primary users	P300	n/d	End Users	Usability evaluation

Zickler et al. 2011. (OR)	Replace	Persons with functional deficits - primary users	P300	n/d	End Users	Usability evaluation

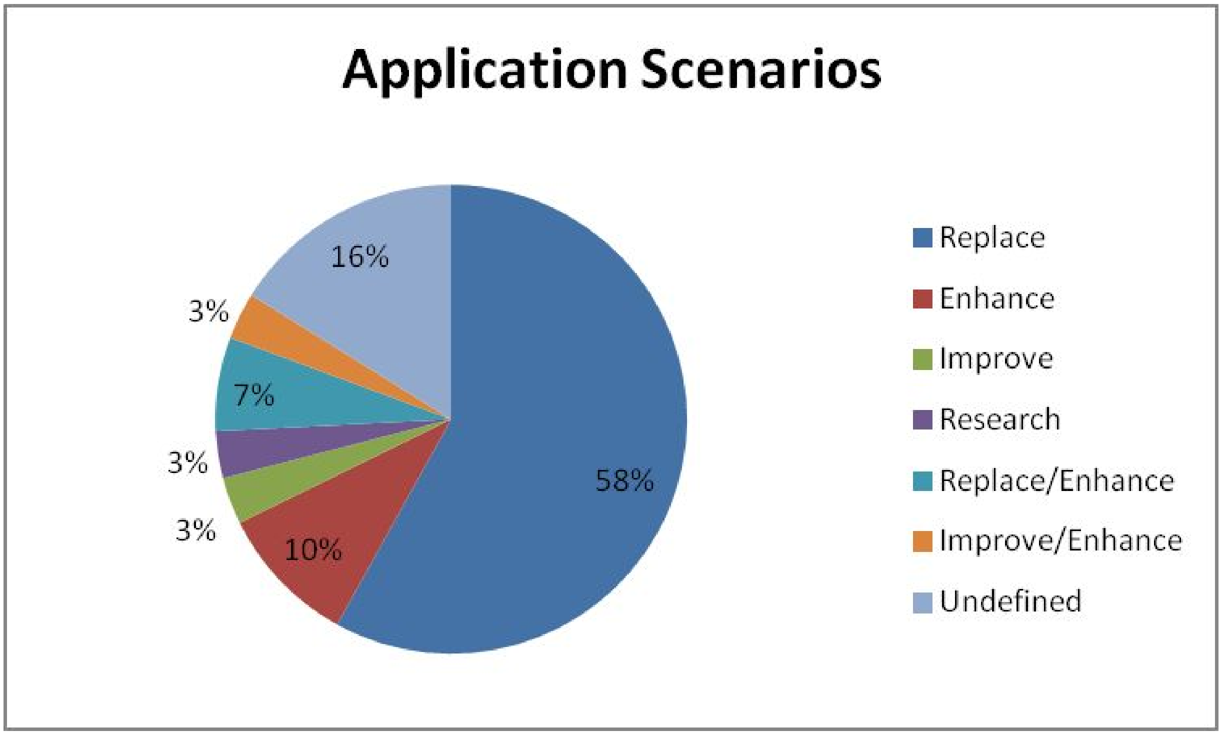

Figure 2: Distribution of reviewed papers among the identified BCI application scenarios. Most of the BCI literature addressing usability issues is found in the Replace scenarios.

C.2.3 Ethical issues in BCIs

Future BNCI Roadmap Post-Mortem Analysis

In this section, a summary of the most important findings on Ethical, Legal, and Social Issues of the Future BNCI project is provided.

Brain-Computer Interfacing promises to reduce the boundaries between humans and technologies, which raises 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 the society as a whole. However, it was noted that despite the multitude of potential topics (see Table 4), ethical aspects or issues brought up in the ethical debate are often not integrated into BCI research, possibly because many BCI 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, a universal set of BCI-specific guidelines that are generally accepted are much needed and wanted (Nijboer et al.,

2013). For example, questions arise of how informed consent (or, at least, informed assent) can be obtained from patients with difficulties to communicate (Haselager et al., 2009). Also, no guidelines exist on how to communicate possible side effects (physical or psychological risks) of BCI use. Further, little is known of how BCI technology affects the daily life of users. Such questions need to be answered using long-term empirical studies. The Future BNCI report also noted that despite neurotechnology projects benefitting from intense funding, only few projects have dedicated work packages related to ethics. They therefore miss the opportunity to foster progress in the successive formulation of an ethical framework in neuroengineering involving the society as a whole. At the same time, several projects are dedicated to Ethical, Legal, and Social Issues (ELSIs) of applied neuroscience and bioengineering. However, these projects have only few connections to neuroengineering or BCI projects.
Based on an analysis of several ELSI projects, the Future BNCI 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. educate PhD students on neuroethics; and
6. foster research on BCI use as an assistive technology with special attention to ELSI issues.

Table 4. Ethical issues in BCI use.

Research & Development	Daily life of users	Society as whole
● 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	● Consequences of BCI technology for end users and caregivers ● Personal responsibility ● Personhood ● Risk of excessive use therapeutic applications	● Mind-reading and privacy ● Mind-control ● Selective enhancement and social stratification ● Mental integrity ● Bodily integrity

Literature

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 (Glannon 2014). The more recent literature increasingly addresses also ethical dimensions of BCI technology (Clausen, 2014; McGie et al., 2013; Carmichael & Carmichael, 2014; Schermer, 2009; Evers & Sigman, 2013). While major interest lies in the ethics of medical BCI applications (McGie et a,l. 2013; Hildt, 2010), also potential military use (Kotchetkov et al., 2013) or applications in the entertainment industry (Attiah & Farah, 2014; Ahn et al., 2014) 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 (Nijboer et al., 2013; Nijboer et al., 2014). 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". For example, when to ceise life support under certain conditions, or how to obtain informed consent in advanced stages of neurodegenerative 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. For example, the availability of means to communicate despite CLIS confronts many caretakers, physicians or legal representatives with very concrete questions (Vlek et al., 2012). Similarly, implantation of BCI systems can be associated with specific ethical concerns (McGie et al., 2013). There are also studies with more anticipatory character, e.g. addressing the issue of mind reading (Evers & Sigman, 2013) raised in the context of the Human Brain Project (Rose, 2014). 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 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 offer the opportunity to foster larger societal discourse on various dimensions of BCI 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 BCI meetings over the last years showed to be instrumental in providing a platform for advancing discourse on the ethical, legal and social aspects of BCI systems.

The TOBI lesson

The EU project TOBI (www.tobi-project.org) devoted a work package (WP) to ethical issues of BCIs. General ethical issues relevant for the use of and research in BCI were categorized and discussed as follows: (*i*) issues relevant but not unique to the BCI field (e.g. risks of invasive methods, obtain informed consent from LIS patients, team responsibility in interdisciplinary research, communication with the media and confidentiality, integrity and availability of neuro-technological devices); (*ii*) issues directly related to 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 mainly focused on benefits and risks for users participating in research studies, while distinguishing between therapeutic and nontherapeutic research, self-interested and non-self-interested research, as well as participants' medical state.

Aspects of informed consent in BCI research were addressed by analyzing difficult yet frequent problems surrounding participation of completely locked-in patients (CLIS), e.g. obtaining consent, evaluation of risks and benefits, privacy, or data protection. 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 were collected 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 volitionally 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, i.e. the 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 of identifying 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 recovery rather than promoting it. 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 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 BCI researchers. With respect to ethical issues, surveyed people were not overly concerned with moral, social or legal issues that could be involved in making the tested BCI devices widespread used solutions in everyday life or standard solutions in rehabilitation. Another survey involved BCI professionals;

results pointed to the concern that research participants might be frustrated, exposed to unnecessary stress or given wrong hopes (Grübler et al., 2014).

NERRI Project

NERRI (Neuro-Enhancement: Responsible Research and Innovation) is a three-year FP7 EU project that started in March 2013 (www.nerri.eu). The project aims to apply the concept of Responsible Research and Innovation (RRI) (Schomberg & Rene, 2011) 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 (Maslen et al., 2014). The role of the project is to bring the ethical debate to different stakeholders. The project is still in progress.

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 focuses on 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, for example surgery complications for invasive BCIs and alteration of 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 is identified, i.e. safety, privacy, autonomy, accessibility, 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 - Schomberg & Rene 2011) 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 neuro-devices 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. 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.

Table 5. Ethical issues in BCI projects or projects about neuro-ethics.

Project	Focus
Future BNCI Roadmap	● Research & development of BCI technology; ● Use of BCI technology in daily life; ● Potential impact of BCI technology on society as a whole
TOBI	● Issues relevant but not unique to the BCI field; ● Issues directly related to the BCI technology itself: ● Aspects related to the meaning of BCI for ethics as a philosophical discipline
NERRI Project	● Neuro-enhancement technologies
Nuffield Council on Bioethics	● Principles: beneficence and caution. ● Interests: safety, privacy, autonomy, accessibility and trust. ● Virtues: inventiveness, humility and responsibility.

C.3 Future outlook

C.3.1 Evaluation framework

An important aspect in the UCD approach is the definition of **valid evaluation metrics**. Generally, these metrics should be as reliable as possible, but care should be taken not to sacrifice external validity. In addition, perceived performance of a BCI application might strongly depend on the task and software ecosystem so application and user specific information can be gathered even using simple face valid measures. Following the definition of usability, the next section presents possible metrics for effectiveness, efficiency, and satisfaction (see Table 6).

Table 6: Evaluation metrics (from Kübler et al., 2014).

Aspect of usability	**Application to BNCIs**	**Example metrics**
Effectiveness	Accuracy	% correct response
Efficiency	Information transfer rate	bits/min
	Utility metrics	Correct responses per unit of time
	Workload questionnaire	NASA-TLX (Hart & Staveland 1988)
Satisfaction	perceived reliability, learnability, speed, aesthetic design	Single item measures
	Match between product and user	ATD-PA (Corradi et al., 2012)

Effectiveness refers to measures of how accurate and complete users can accomplish a given task using a BCI, i.e. how often the intended output can be achieved. Thus, accuracy, as a measure of effectiveness, can be calculated by relating the number of successful selection to the total number of attempted selections.

Measures of effectiveness do not address the frequent need to balance the trade-off between accuracy and speed. Therefore, measures of **efficiency** relate the costs, i.e. effort and time, invested by the user to effectiveness. An **objective measure of efficiency** is the information transfer rate (ITR) and its modifications with regards to error probability, accuracy, and practicality. However, even systems showing a high information transfer rate can be impractical to use if the number of errors is high. Thus, more global measures, such as **utility metrics** (e.g. number of correctly spelled letters per unit of time) have emerged, but are not often used. In addition, **subjective measures of efficiency**, e.g. workload (the perceived "costs incurred by a human operator to achieve a particular level of performance", Hart & Staveland, 1988) should be used.

User satisfaction is defined with reference to the perceived comfort and acceptability while using a product. Depending on the context of use, different metrics, e.g. referring to aspects of a device, or face valid questions on overall satisfaction may be used. However, the ultimate proof of user satisfaction may lie in its **actual daily use**. Unfortunately, few institutions have enough equipment available for extended home use so this requirement often remains unmet.

C.3.2 Ethical guidelines

C.3.2.1 Medical Applications

In medical BCI applications, the principle of "respect for persons" implies first that the process of obtaining informed consent is carried out diligently and carefully, taking into account all relevant aspects. These aspects 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. Furthermore, there is awareness among researchers on improving communication of risks and benefits related to the participation in BCI studies (Haselager et al., 2009).

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); (*iii)* 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); (*iv)* agency, safety, and responsibility in the case of unintended/uncensored actions; (*v)* privacy issues ranging from mere data sharing between research groups 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. Currently, the psychological risk of patients’ disappointment is almost entirely placed 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.

In accordance with the Helsinki Declaration (article 34), each ethical proposal should include plans for “what to do when the study ends”. In principle, researchers, host countries, and sponsors should “provide” participants with access to devices (as well as treatments) that work satisfactorily when a study ends. 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 information be 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 be carried out by the neuroprosthesis/communication device? Or is there some inhibition in the system (Nijboer 2013)? 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?) (Nijboer 2013).

C.3.2.2 Non-Medical Applications

The current ethical debate in non-medical BCI applications is somewhat less developed than that related to disabled people. The apparent reason could be that non-medical applications are related to more futuristic scenarios.

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 maladaptive plasticity 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 focus on coercion and selective enhancement issues. Privacy, personhood and mindreading are relevant issues, especially if we consider the possibility of sharing data through the Internet and storing large amounts of data for long periods of time. For example, future research might reveal new unexpected information from old brain signal recordings. Another important aspect for BCI application in healthy people is the issue of safety and responsibility for unwanted/uncensored actions. Concerns are raised about 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, the BCI field 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-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.

C.3.2.3 Ethical Issues in the Use Case selection

In the following table (Table 7), we list ethical issues relative to six Use Cases. The table contains issues derived from the current ethical debate as well as ideas emerged from the consultation of end users throughout the focus groups (see also Appendix D).

Table 7. Ethical Issues across Use Cases.

Use Case (related scenario)	Ethical Issues
Unlocking the locked-in (Replace)	● Informed Consent from CLIS patient and caregiver ● Privacy issues ● Long-term risks and challenges 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 robot assistant (Replace)	● Privacy Issues, Personhood, Embodiment 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
Spinal cord stimulation for reach and grasp (Restore)	● Risks related to implant/surgery ● Risk related to maladaptive plasticity ● Frustration related to malfunctioning/reduced technical assistance at the end of the study ● Inform the patient in advance about the details of the device ● Agency, safety and responsibility of unwanted/uncensored actions ● Equal opportunities across countries and social status
Home independent rehab after stroke: an hybrid BCI driven FES system for upper limb (Improve)	● Risk related to maladaptive plasticity ● Straightforward communication both to patients (false expectations) and to policy makers ● Frustration related to malfunctioning/reduced technical assistance at the end of the study ● Equal opportunities across countries and social status
A hybrid BCI for use in an adaptive learning environment (Enhance)	● Privacy Issues, Personhood, Embodiment of Technology ● Risks related to excessive use ● Enforce the transition to an extremely achievement-oriented society ● Equal opportunities across countries and social status (selective enhancement)
Research tool for cognitive neuroscience (Research)	● Privacy Issues, Personhood, Embodiment of Technology

C.3.3 Conclusions

In conclusion, we recommend the following steps:

- Develop BCI-specific guidelines and regulations for BCI use in medical, commercial and legal context and disseminate these across the BCI community;
- Investigate issues that are specific to BCI use in terms of sharing data and privacy against the background of general EU and US privacy regulations; and
- Debunk myths about BCIs by obtaining and presenting facts, and promote dissemination of such information to media and society.

Note that the BCI Society is intended to represent the voice of the BCI community and to contribute to the formulation of guidelines, standards and position statements

C.4 References

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