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Abstract: In this deliverable we report WP4 contribution to Roadmap across the whole project. The main outcome of WP4 activities flowed into Appendices C and D (Focus Groups results), which will be shortly summarized here.

Keywords: Brain-Computer Interface, User-Centered Design, Ethics, Roadmap.

[1] Public
[2] Restricted to other program participants
[3] Restricted to a group specified by the consortium
[4] Confidential, only for members of the consortium

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1 Introduction

This WP focuses on users of BCI systems. Our activities were organized in four tasks. Task 4.1, Updated State of the Art, aimed at identifying current and future classes of users by adapting principles of User Centered Design (UCD) to BCI applications. Task 4.2, End-Users and BNCI solutions, was carried out by directly addressing different classes of users by means of Focus Groups and structured interviews in order to identify future developmental issues and valorize synergies. Task 4.3, Societal and Ethical Aspects included a critical review of the literature and previous experiences (projects) whose results were incorporated into the Roadmap Structure (Application Scenarios and Use Cases). Finally, in Task 4.4, Quality Assessment of BNCI Applications, we proposed a framework of procedures and metrics to validate BCI applications. Our activities mainly converged into Appendix C, End-Users and Appendix D and Focus Groups section of the Roadmap.

2 Appendix C - End-Users

2.1 Sources

2.1.1 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 fill this gap and to bring BCI technology to the market. The UCD approach posits "early and continuous involvement of potential users, understanding of user requirements and the whole user experience, and iterative processes between developers and users". These principles can be implemented using a four-stage development process (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) (see also (Kübler et al., 2014; Riccio et al., 2011; Schettini et al., 2015; Zickler et al., 2011).

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". 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-controlled application (Kübler et al., 2014). Here, its focus is broadened to also include satisfaction with 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 assessing a product based on actual experience. 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.

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

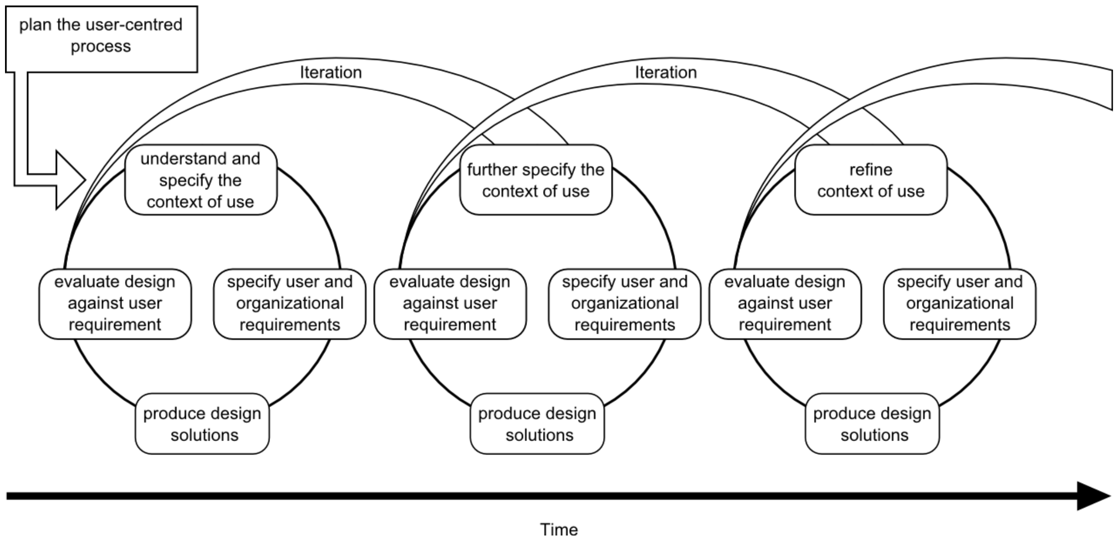

Figure 1. The User-Centred Design Process.

2.1.2 *Literature and Previous Projects*

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 users’ assessment of usability. After this critical revision, 25 papers were considered for the SoA, five of which were review articles. 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.

To provide a comprehensive review of the literature covering 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.
Furthermore, we gathered and summarized the main outcomes from two previous EU projects (e.g. TOBI and NERRI) and the Nuffield Council on Bioethics Report that have dealt with ethical issues about BCI technology and neurotechnology in general (please refer to D4.3).

2.1.3 Consultation of Users

Within previous research projects, users have been interviewed about their needs and expectations on BCIs using different methods (questionnaires, well-validated scales, interviews). Within the BNCI Horizon 2020 project, the consortium agreed to adopt a focus group approach because, with respect to other methods, it allows a larger amount of data collection through the real and spontaneous interaction of different classes of users. Furthermore, although a focus group is usually planned and structured in advance, it is still flexible and allows deepening 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). To this extent, the group discussion, involving different classes of users, has the advantage to easily convey different point of views and new 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 (see also D4.2).

2.2 Summary of the State of The Art

2.2.1 User definition and stratification

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 and Wolpaw, 2012)): Replace, Restore, Enhance, Improve, and Research.
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. It is also helpful to define current and future BCI user classes. For this purpose, we proposed a classification matrix (Table 2) with applications scenarios in columns and user classes in rows. We propose examples of user classes identified in the different application scenarios. In comparison to what we described above (where professional users are classified as *tertiary users*), we believe that at the current 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
Users	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
Users	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
Users	Secondary/ Tertiary Users	Other stakeholders	Insurances, Public health system	Insurances, Public health system	Manufacturers	Manufacturers	Insurances, Public health system, Industry	Funding agencies, Publishers

2.2.2 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 and in particular to communication scenarios. 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 (see also D4.1).

2.3 Future Outlook

2.3.1 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. Thus, 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 3).

Table 3: 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. 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 and 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.

2.3.2 Ethical Guidelines

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 the BCI-based options available for 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 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 et al., 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 , e.g. in 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 et al., 2013).

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 users' age 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.

3 Appendix D - Focus Group results

3.1 BCI-controlled neuroprosthesis (TUG and GUTT)

Consultation of end users for this use case was carried out through an online questionnaire and a focus group (Figure 2).
As for the questionnaire, participants agreed that a BCI-controlled neuroprosthesis might be useful for a specific group of patients. However, it is not clear how large this target population is, because there might be severe exclusion criteria (such as SCI patients with denervated muscles, and people who mainly work with a computer). A major factor besides technical feasibility will be the cost. If such a device is very expensive and not covered by insurance, it will probably hamper widespread use.
Finally, all potential benefits must be proven. At the moment, the list of advantages looks like a wish list. In particular, two therapists were skeptical and could not really assess how realistic a successful implementation is.
The FG included a representative group of patients, caregivers and clinicians. All participants had the opportunity to share their opinions with respect to the UC. They very much appreciated being involved in the early phases of system development.
Clinicians were less skeptical with respect to the system and in general tried to imagine how it would work. Their main concerns were about the different individualization of the solution to be adapted to the different patients’ needs. A caregiver was open to adopt a system like this, although she also found it difficult to imagine in real contexts. She insisted on the importance of testing it to get to know the functioning of the system. Patients were the most skeptical. In general they would not use it unless it provided a huge leap in functionality and usability if compared to what they are currently using.
None of the participants found any ethical concern with respect to the instrument.

Figure 2: Focus Group participants at the Guttman Institute.

3.2 Research tool for cognitive neurosciences (UMCU)

Considering the international character of the group of participants to this FG the focus group was held as a Skype Meeting. Participants agreed on the interest for the proposed tool. They pointed out the need for individualization of the tool (not a completely fixed off-the-shelf system), as well as user-friendliness. The success of BCIs will depend on signal acquisition techniques such as fMRI and EEG, and that these techniques by themselves suffer from some problems (spatial, temporal resolution for example), the solution of which is considered a highly important step forward.

3.3 Neurotutor (TUB, UNIWUE)

Online interviews have been carried out for this use case involving six experts in the field of e-learning, applied Neuroscience/Neurotechnology and Education.
All experts see long-term potential of BCIs in adaptive learning platforms. However, practical problems as well as methodological requirements were reported which indicate that a commercially viable and scientifically convincing product is not expected within the next years. While the market size is generally expected to be large, the unique added value of a BCI is still unclear. It remains an aspect of future research to investigate the effectiveness of mental state monitoring during learning.

3.4 BCI-controlled robot assistant (GTEC,EPFL)

One focus group with 5 participants and two single skype interviews have been carried out.
All participants liked the presented idea, though one participant was skeptical about the its feasibility. It was agreed that the presented mockup would provide big benefits, compared to current solutions. The control needs to have context awareness so that high level commands

can be used. Research onto embodiment itself also needs to be done to investigate how this would influence the user's perception.

3.5 Hybrid BCI-driven FES for rehabilitation (FSL)

A FG was held with 8 participants, including one chronic stroke patient, two medical doctors, two therapists with experience in stroke rehabilitation, one health care provider with a medical education, two engineers representative of two different biomedical companies (see Figure 3).

Figure 3. Focus Group participants at FSL premises.

All participants' opinions were positive about the proposed Use case. As the primary user stressed out, such device could reinforce the enthusiasm and could be very useful in the chronic phase (at home) to maintain the benefits achieved in the rehabilitation clinic in the subacute phase. The possibility to follow a rehabilitation program at home would allow to save economic resources. This is very important considering the increasing number of stroke survivors needing rehabilitation in the future (aging population). However it should not be considered as a substitute of the rehabilitation therapist but as a support to the standard therapy. More research and clinical trials are still needed in order to define therapy details (duration, quantity, indications,…) as well as to contain patients' and policy makers' expectations.

3.6 Unlocking the locked-in (EKUT, UNIWUE)

The consultation of users was organized in different steps including one-to-one interviews, a group discussion and retrospective commenting of the transcripts.

The focus group concluded that BNCI technology would play a major role to replace lost functions in a variety of disorders. The use case should be revised in some points to avoid misunderstandings (e.g. decoding of "inner speech") and opened to replacement of other functions, e.g. movement, vision or other sensory qualities. Also, the technique used for recording the required brain signals should not be specified too well in order to account for future advancements and technical innovations.

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