

Ethical Challenges Associated with the Development and Deployment of Brain Computer Interface Technology

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Received: 21 December 2012 / Accepted: 12 July 2013 / Published online: 28 July 2013
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Abstract Brain Computer Interface (BCI) technology offers potential for human augmentation in areas ranging from communication to home automation, leisure and gaming. This paper addresses ethical challenges associated with the wider scale deployment of BCI as an assistive technology by documenting issues associated with the development of non-invasive BCI technology. Laboratory testing is normally carried out with volunteers but further testing with subjects, who may be in vulnerable groups is often needed to improve system operation. BCI development is technically complex, sometimes requiring lengthy recording sessions to achieve the necessary personalisation of the paradigms, and this can present ethical challenges that vary depending on the subject group. The paper contributes to the on-going ethical discussion surrounding the deployment BCI outside the specialist laboratory

and suggests some tentative guidelines for BCI research teams, appropriate to those deploying the technology, derived from experience on a multisite project. Any tension between deployment and technical progress must be managed by a formal process within a multidisciplinary consortium.

Keywords Neuroethics · Brain-Computer-Interface · Non-invasive · Development · Deployment

Introduction

The starting point for any ethical consideration can be reduced to the statement that net benefits (including new knowledge) should outweigh net harm or inconvenience. The four canons of autonomy, beneficence, non-maleficence and justice, first introduced 30 years ago (see [1]) continue to act as a guiding framework today. These principles are helpful, but require further consideration to adequately capture the complex nature of development and deployment of emerging technology. For technology whose application has been predominantly in the research laboratory, the link between knowledge acquisition and improving subject experience in the real world may seem to be tenuous or far off.

The intricate functioning of the human brain is still not fully understood. An initiative to unlock its mysteries, denoted BRAIN, was announced by President Obama in April 2013 [2]. The project, ‘Brain Research Through Advancing Innovative Neurotechnologies’, to begin in 2014, will utilize a plethora of imaging

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techniques and computational models, to study the brain in action and better understand how humans think, learn and remember. Ethical considerations have been emphasized in this initiative. In 2012, the Nuffield Council on Bioethics, launched a consultation on the ethics of new technologies and devices that intervene in the human brain [3]. Three important areas were identified as: brain computer interfaces (BCI), neuro-stimulation and neural stem cell therapy. This activity highlights that brain interaction technologies are beginning to advance beyond specialist laboratories and are being considered by the mainstream clinical and scientific communities. As our understanding of brain function advances, ethical issues regarding the interface between technology and people arise and need to be further addressed [4]. Vlek et al. [5] highlights the importance of topical discussions on the ethical challenges, stating that, “*These ethical debates may substantially influence public acceptance of BCIs and related neurotechnologies*”.

Ethical issues are addressed in this paper according to the authors’ experience with BCI development and deployment during the EU Framework Programme 7 BRAIN project [6] (FP7-BRAIN, 2012 – not to be confused with the aforementioned Obama initiative). The project’s primary aim was to promote inclusion for people with brain injury by deploying a robust, non-invasive BCI [7]. The project achieved technological advances in hardware and with the development of novel software, and had many interactions with participants. Over 200 subjects were investigated in five countries using a variety of BCI protocols, many with repeated sessions, giving insight into practical issues with deployment.

As part of project management an Ethics Advisory Board (EAB) comprising a representative from each research partner was set up. The EAB had responsibility for implementing and managing the ethical and legal issues in the project, particularly in obtaining ethical permission for recording and reporting under a research governance framework [8]. Some of the routine ethical issues were anticipated at the outset, informing the initial ethical application (consent, recording and storage of data). Others arose during the work with users, which were categorised into four main groups (research investigators, healthy volunteers, general public volunteers and people with a brain injury), see Fig. 1. The EAB facilitated communication among partners regarding user interaction. An ethics

manager and external ethics advisor were appointed to lead the administration and provide an authoritative unbiased external viewpoint, respectively. The role of the EAB was to foresee, reduce and address any subject specific concerns regarding deployment of the technology. Potential conflicts were resolved, during management meetings. An ethical report was high on the agenda during annual European Commission reviews of project progress.

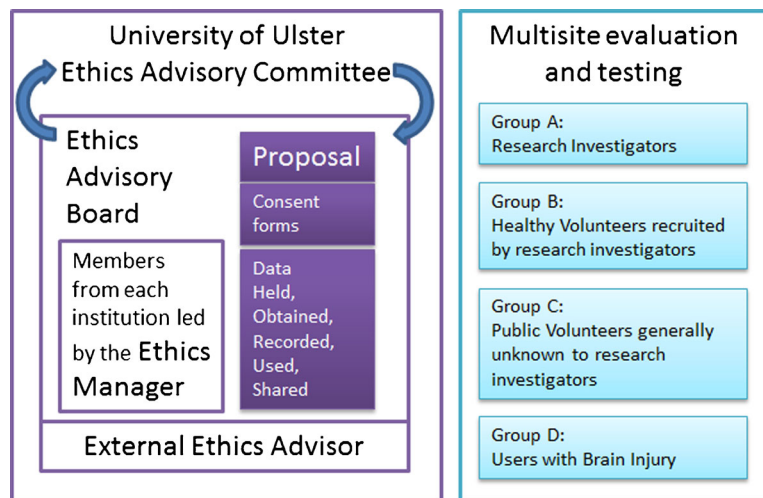
The perspective of this paper is from the *ethics manager*, *external adviser* and *technologists* in the team; the contrasting technical roles are firstly the *developer* and secondly those responsible for the *technology transfer and deployment* to the users. Issues arose as BCI research and development is complex, often requiring lengthy recording sessions to achieve the necessary personalisation of the paradigms, and hence this presents user challenges and the need for an ethical judgement depending on the participant group.

We explore the ethical issues identified in BCI, first through critical appraisal of background evidence and secondly through experience with project deployment. Section 2 provides some general background information on BCI recording. Previously documented ethical issues raised for BCI are discussed in Section 3. Anticipated issues are examined in Section 4, together with discussion on further BCI-related issues encountered in FP7-BRAIN. Some tentative guidelines which may be of use to other BCI teams are provided in Section 5. These of course need further ratification by the BCI community. Some reflection is provided in Section 6, with conclusions in Section 7.

Brain Computer Interface

BCI offers potential control and communication for people without the use of peripheral muscular control [9–11]. It is the subject of scientific interest as an additional communication channel in the world of computer gaming and virtual reality [12]. Capture of the electroencephalogram (EEG) for BCI can take the form of invasive implanted electrodes or non-invasive surface electrodes. Pioneering advances have demonstrated invasive BCI to be appropriate to long term use [13]; a Locked-in Syndrome (LIS) patient used a BCI with good accuracy (83 %) for over 2 years. Research is underway in areas such as stroke rehabilitation [14] and autism [15]. Sensory stimulation is sometimes

Fig. 1 Structure of the Ethical Advisory Committee and the subject groups involved in multisite testing



required to alter or modulate brain activity and is normally delivered visually (Steady State Visual Evoked Potential, known as SSVEP), often requiring the user to engage with a task. In another approach the user is expected to attempt to alter their own brain electrical activity (aided by visual feedback), by concentration and active thought, e.g. a task could be to “*think about moving your left hand*”. This is known as motor imagery (MI).

The scope of BCI research has been extended more recently by the realisation that brain activity can be combined with other neural activity to provide a Brain-Neural-Computer-Interface (BNCI), which could prove more robust. In addition, approaches could be combined or BCI could be used with another assistive technology such as ‘eye tracker’ systems to provide a more usable hybrid solution [16]. However with regard to more widespread clinical application, BCI technology is still predominately in the research phase, not yet a widely accepted therapeutic tool. BCI is classified in the ‘technology trigger’ phase of the Gartner’s Hype Cycle of Emerging Technologies, with the perspective of being adopted by the mainstream in the next decade [17]. This slow speed of deployment itself raises the ethical charge of injustice as those who might benefit are denied BCI technology.

Ethics and BCI

Research into the advancement of BCI technology is heavily reliant upon the active participation of users. The need for informed consent by subjects, engagement

with an experimental protocol which may often seem monotonous, the need for sustained attention and/or concentration, and allocating sufficient personal time, often for repeated recording sessions, means that BCI investigation is particularly demanding on the motivation of the subject, who may become fatigued or even exasperated by poor achievable results. The British Psychological Society [18] proposed principles to be considered in research involving human subjects; ensuring fully informed consent, that there is no coercion to participate and that a participant has the right to withdraw. The principle has been well documented in other areas where subjects may be vulnerable [19]. These principles serve to protect the participant autonomy.

A significant community of BCI researchers has been established, and the ethical debate has been initiated [20, 21]. Nijboer and Broermann [22] emphasises the complexity of ethical considerations of BCI and the need for further discussion. The BNCI Roadmap [23] highlights some of the ethical, legal and social issues identified by stakeholders. A key challenge has arisen in the transition from pure research to realising useful applications; ranging from entertainment packages, wheelchair navigation control systems through to neuro-feedback therapies. The amount of personal information that could potentially be streamed from a participant’s engagement with BCI, highlights the importance of privacy and data protection. Guidelines and standards need to evolve to reflect the differing needs in each of these applications.

Tamburrini [24] identifies issues posed by research studies as: obtaining informed consent, jeopardy to human dignity (a challenge to autonomy), responsibility

(which may include a duty to care) and liability (as a function of justice). Ethics committees traditionally scrutinize the process of informed consent (Unesco Chair [25]) and protection of human dignity, issues which are shared by all research studies. Reduced capacity for communication by a participant can make the process of obtaining fully informed consent complex and this puts the onus on researchers to ensure that consent is on-going and that dignity is preserved. Enough time should be provided for the information to be assimilated, understood and an autonomous response made by potential subjects. Furthermore a vulnerable participant may not wish to continue with a recording session on a particular day, but may be unable to communicate this effectively.

Vlek et al. [5] provides scenarios to highlight the considerations around informed consent. For those in need of a legal representative it may be the case that those closest to the subject may not be impartial to the decision making process. They may put their desire to communicate with the subject above the realistic expectations from the user's involvement. Kübler and Birbaumer [26] highlights that to fully inform the user, information may be needed regarding the temporal progress of any disease process. Could BCI performance be the first evidence to the user that their condition has deteriorated? In this light, an ethical guideline may be made for routine clinical review of such systems in addition to technical support.

Managing user expectation can be compromised by the appetite for and representation of BCI by the media [27, 28]. There is, of course, a responsibility of researchers to disseminate responsibly, but today's media culture often demands an attention-grabbing headline, and is often penned by a journalist for wider public consumption [29]. However, when engaging with potential users of a BCI it is of utmost importance that they understand the significant limitations of the technology as part of the consent process [30]. Vlek et al. [5] comments on this confusion between research and therapy; they remind researchers of the need to understand the motivations of the user and their carers.

There also needs to be consideration given to the subjects's needs post-research. Did he/she expect to receive reliable BCI technology package (and support) home with them? If this does not happen, could this lead to a negative impact on wellbeing? Ethical guidelines should assist the researchers on how to manage all aspects of the project from initiation to completion. It is

important to recognise that the non-scientist will have little understanding of the process of research and development. They are unlikely to understand the long development time and the huge investment required before this technology can become routine.

Grübler [31] explores the issues of responsibility and liability, which can have a subtle effect in BCI. When a BCI approach is unsuccessful, it may not be clear where a failure occurred; within the technology or with the subject? For example, is there a fault with the recording setup, did the subject engage or has he/she a specific physical or psychological deficit which impairs performance? With such close integration it may not be possible to determine, for example, if unconscious actions or background brain activity could create an unintended (but from a purely signal processing perspective) appropriate and valid classification and enactment. Thus technologies must be at least 'mostly' reliable with a minimum level of reliability defined for applications, determined by a risk assessment. A communication system may have less associated risk than guiding a wheelchair, for example. Training is required for both user and carer responsible for BCI setup, and thus usability of the system is crucial. However BCI is inherently a complex process and complexity is often the enemy of usability.

Nijboer et al. [28] raises the issue about team responsibility, with 73 % of respondents to a survey agreeing to the concept of a "common code with rules and regulations for team responsibility issues". It can be difficult for researchers to discharge the duty of care to their subjects who volunteer to assist with system testing and development. In addition, user confusion may be caused by the differing experience and opinions of the researchers. Haselager et al. [27] cites the diverse understanding of BCI across research groups due to the heterogeneous skill-set, "with a fragmented understanding of the overall picture". Interdisciplinary development must be integrated sympathetically for the user of the system, with accountability for participant safety: keeping in mind the non-maleficence principle.

Other risks include selective enhancement and social stratification [23]. Vlek et al. [5] comments "*if brain enhancement does become effective and popular, there could be pressure to enhance one's brain to keep up with the competition*". Farah [32] adds "*As used in the neuroethics literature, brain enhancement refers to interventions that make normal, healthy brains better, in*

contrast with treatments for unhealthy or dysfunctional brains". Recently golfer Jason Day used brain training based on wireless EEG for 1 month to aid the mental side of his game. "If the computer shows I'm using my right brain then I know I am focused", Day claimed [33]. Nijboer et al. [34] discusses potential negative side effects; "the possibility of BCI-induced changes in cognitive capacities, psychological continuity or personal identity needs to be considered". Side effects on the alteration of brain activity, possibly long term, are not well understood. Could these interventions possibly change mood, alter memory retention or result in changes in personality, for example?

Ethical consideration demands that we predict likely risks and protect against them. The ethicist does not expect the impossible or expect preparation for the totally unexpected, only that a rigorous risk assessment is performed and expected risks are fully managed. These ethical aspects need further consideration as the results of more end-user studies become available.

Ethical Considerations in FP7-BRAIN

The issues highlighted in Section 3 demands ethical awareness, sensitivity and high standards to be applied and monitored by the research team. Whilst researchers strive to adhere to these principles, necessary on-going development of hardware and analysis software puts added strain on the research team and the subjects. FP7-BRAIN recording experience was with the non-invasive EEG based BCI, using Steady State Visual Evoked Potential (SSVEP) [35] and Motor Imagery (MI) paradigms ([36]).

The BCI development process involved interaction between hardware and software developers and a system integrator. Software drivers, integration software and a user interface, with virtual applications were all required in the integration process for producing a BCI system. Software that may appear straightforward and intuitive to the developer in a laboratory can appear complex and unpredictable to the experimental investigator and participant in the 'real world'. Researchers responsible for recording sessions will not welcome upgrades and bug fixes that require significant re-testing. These problems can be exacerbated in a multi-site development, where the software developers may be remote from user trials. Indeed in a multidisciplinary consortium, the different stakeholders may often

have insufficient appreciation of the role and demands of their partners. Thus hardware and software developers may not appreciate the impact upon experimenters and subjects in terms of time and effort. Paradoxically, end users may not appreciate the technology developer's real need for data to improve and personalise classification algorithms, the aim of which is to ultimately improve the user experience and advance the science. In order to obtain the maximum benefit from the process, effective teamwork and communication are required.

Anticipated Issues

The research data were anonymised to guarantee privacy according to local and European regulation and law. Existing medical data (e.g. patient history, symptoms) were not accessed or subsequently recorded. The EEG data were stored in a computer, identifiable by an index, which was stored securely by a senior investigator, for circumstances in which the EAB agreed that personal information should be extracted, e.g. to remove the person from the study in accordance with Data Protection legislation. This did not occur in the study. Identifiable data from individuals were not shared with partners or external organizations (although this proved to be limiting later in the project as data could not be share with the community). The data were later uploaded to a server for analysis, accessed only by researchers. All data were accompanied by sufficient explanations, in order to be used appropriately.

Our research aim was to demonstrate the use of BCI 'outside the traditional laboratory' and hence provide a BCI that could be used by non-experts. A number of user groups, posing varying levels of vulnerability, were involved at various stages of the software development and study. This included researchers, students, the general public, and vulnerable people with brain injury. Table 1 provides a high level description of the profile of participants in BCI investigation.

FP7-BRAIN gathered experience from Groups A-D. The project did not involve any participants with learning disabilities. Some subjects had significantly restricted communication, but were able to give fully informed consent. Qualified professionals working with subjects confirmed this [37]. Thus, whilst investigators had to obtain informed consent from people with significant

Table 1 Ethical challenges and the motivation for subjects

Subjects	Profile : Motivation/Observation	Main Potential Ethical concerns
Group A. Research investigator as subject. N=10 approximately across the various participating sites.	This participant will be fully committed to the research project. He/she will normally have no physical or EEG impairment. The participant may however be biased and unduly motivated and cannot be taken as representative of other volunteers. Hence performance results obtained could be optimistic for the wider community.	Data security.
Group B. Healthy volunteers: i) Undergraduate student as investigator/subject. (N=20 approximately across the various participating sites) ii) Postgraduate student or research company volunteer as subject (N=20 approximately across the various participating sites)	(i) This participant will be partially committed to the project, but this may be time limited. He/she may need to obtain results from a small experiment as part of an undergraduate qualification. However when this goal has been achieved, the participant is unlikely to be available, say for re-testing. (ii) This participant will usually have some scientific interest and commitment to research. He/she may be induced by a small stipend for taking part. The participant will normally be cooperative and fully engage with the experiment. The duration of the recording sessions may impinge upon the participant's valuable time. This can adversely influence willingness for re-testing.	Data security; Coercion by a supervisor or need to participate should be addressed.
Group C. Public volunteers as subject N=86, SSVEP (age: 25.8±7.8, 10 females) Hannover Fair 2010 [35] N=71 volunteers (age 29.3±10, 7 female) CEBIT 2011 N=23 Telefonica, Spain	This participant may be recruited as a control for the intended user group under study. They may be in an older demographic (over fifty, for example age-matched). As such they may have little computer or experimental experience and could find the process unpleasant and possibly tiring or stressful. Alternatively, this participant may be reached at a scientific exhibition (e.g. CEBIT). In this case it is imperative that the protocol minimises time interaction.	Data security. Additional ethical issues will depend on the volunteer, e.g. privacy may well be an issue.
Group D. Vulnerable subjects Brain injured participants: (e.g. acquired brain injury, stroke, etc.) i) living in sheltered 'smart home' accommodation, N=5 at Cedar, Belfast ii) living independently in the community N=10 (3 for repeated training sessions) at Cedar, Belfast	This participant may have varying commitment to the project. He/she may participate with initial enthusiasm. If results are not positive, then frustration can reduce motivation. A carer may be involved in the ethical process for consent.	There are many potential ethical issues to deal with, such as confidentiality, privacy, raised expectations, and stress and fatigue associated with recording. Obtaining fully informed consent and the right to remove consent for participation becomes important, and this should be actively managed.

communication impairment, they did not have to overcome the more difficult communication problems associated with 'Locked-in syndrome'. Haselager et al. [27] discusses an interview protocol for addressing this concern, to ensure continued assent from the LIS patient for the ongoing study. However diminished ability for subjects to readily communicate places extra responsibility on the researchers to ensure that any discomfort (with attachment of electrodes and/or cap) or additional stress

(e.g., due to long training sessions) is properly managed. Thus the subjects from Group D provided the FP7-BRAIN researchers with valuable insight to other vulnerable groups.

Testing was required by each research partner and site with initial integration testing on Groups A, B, and C. When the hardware and software were sufficiently stable, users in Group D were introduced. The BCI prototype was still however in an exploratory phase

as there was a requirement to fine-tune software. However this is not a software ‘debug’ phase, but a necessary part of the software development process.

Safety and comfort issues were addressed by employing a physiological measurement technician (20 years’ experience) for interaction with vulnerable subjects. The technician was able to use experience to put the subject at ease while applying electrodes. Difficult to treat infections such as Methicillin-Resistant *Staphylococcus Aureus* (MRSA) could potentially be passed on through electrodes or caps. Clinically accepted sterilization procedures were adopted, to reduce any possibility of cross infection. This approach built confidence and facilitated comfort and safety of the subjects. This level of expertise was not required for the volunteers (Groups A to C), although appropriate safety and hygiene approaches were adopted. Indeed a primary motivation was that the technology should be transferred to and used by ‘non-experts’, in addition to taking place outside normal controlled laboratory conditions. A standard EEG cap was used, which allowed quicker placement of the electrodes, by the non-expert. This was not uncomfortable, but recording sessions sometimes left a residue of gel in the participant’s hair, which was reported as an unpleasant side effect of participation. All recording equipment was CE-marked to ensure appropriate electrical safety standards. By assuring safety and comfort of the participants, risk was minimized.

Additional Considerations

As the project progressed, ethical and user issues were reviewed regularly and revisions made, as necessary. Discussion raised a number of user issues and the consortium devised technical solutions, influenced by the end user experience. Good relationships and frequent interaction, promoted by the EAB and efficient communication tools (which provide remote access to a computer running the BCI software, with concurrent audio and video channels) were crucial in order to address development issues in a multi-site, multi-disciplinary consortium.

Set-up

FP7-BRAIN developed novel electrodes based on ‘wet’ sponges and small high impedance amplifiers for recording the electroencephalogram (EEG) [38]. This provided less clutter and easier application and

clean-up, which was appreciated by users. The ‘water-based’ electrodes in particular had little appreciable degradation on the quality of the EEG signal [39].

Recording Issues

SSVEP: The flickering of a visual stimulus below 30Hz produces a readily detectable component in the EEG. However it can be annoying to the subject and in some cases flashing lights could induce a seizure. FP7-BRAIN investigated visual stimulus protocols at a higher frequency (30-40Hz) in order to provide a more agreeable stimulus [40]. At these rates the components are much smaller and significant additional processing must be used to detect them. However the temporal stability of these higher frequency components has not been established, requiring recalibration for each session, which is significant a drawback.

MI: Practical considerations that became apparent such as elongated session recording time were fed back to the developers to influence successive iterations of prototype development. In particular for the MI paradigm [41], the calibration software was partitioned to allow rest breaks every 20 min. This required additional software to reassemble the calibration files, but it proved a useful work around, to keep within the ethical guidelines.

Privacy

The user evaluations were carried out according to principles respecting user privacy. No image compromising dignity or privacy of the subjects and carers, was initially used. However, upon interaction with participants (Groups B, C, D) it became apparent that there was a need for fuller documentation of the interviewing process and recording of the experimental procedure in order to obtain a richer description of the background of each individual; to illustrate the subject’s ability or difficulty in interacting with the paradigms and to support dissemination to the investigators, consortium, and wider scientific community. The ethics manager thus sought and received a favourable ethical opinion for the use of audio, video and photography for storage of this information. This information was stored securely, as was the case for data.

The use of audio and, in particular video raised an issue with regard to anonymity and hence potentially preserving dignity. For volunteers with no disability,

the anonymity requirement was waived if full consent for this was obtained, so that fuller dissemination could be facilitated. Initially it was planned to anonymise the faces of all vulnerable people in the study. After representation from members of this group, however, it was decided that for true equality, both healthy volunteers and vulnerable participants could opt to have anonymity preserved or waived. Indeed some of the vulnerable group were enthusiastic about dissemination of this activity, as it allowed them to actively support research, which could assist people with a similar condition.

Technology Transfer

BCI development provides a paradox. From an ethical perspective, paradigms should only be tested on Group D subjects when robust and successfully tested on other groups. However for the MI paradigm in particular, it was necessary for the software developers to analyse the data, to assess whether the imagery strategy was indeed having any effect on brain electrical activity, see feedback loop in Fig. 2.

In practice schedules often get squeezed by the need to adhere to deadlines, as dictated by project management. Thus experimental investigators require a stable reliable system, whereas research developers need data to tune, debug and update algorithms. This dilemma is exacerbated by the need for personalization of features. Indeed where the developers are remote from the

experimental investigators, the problem can be difficult to solve. There is a requirement for quality assurance of hardware and software. There should be a requirement to test new algorithms with volunteers first to prove efficacy. In some cases it may be necessary to test with Group D subjects shortly after this to meet deadlines or concurrently where personalisation of algorithms is required. However these subjects should never be used to ‘debug’ software/systems.

Discussion

The Need for Communication

Enhancing the communication mechanisms for those at the greatest risk from social exclusion is an important responsibility. Blain-Moraes et al. [42] highlights the importance of effective communication to the human self.

“the existence of the human-self hinges on successful interaction with others; those who cannot engage in communicative interaction are, consequently, at risk of not being accorded personhood by others. While there are many discourses on the topics of personhood and humanness in the context of disability, personhood is herein defined as *a standing or status that is bestowed upon one human being by others, in the context of relationship and social being*”

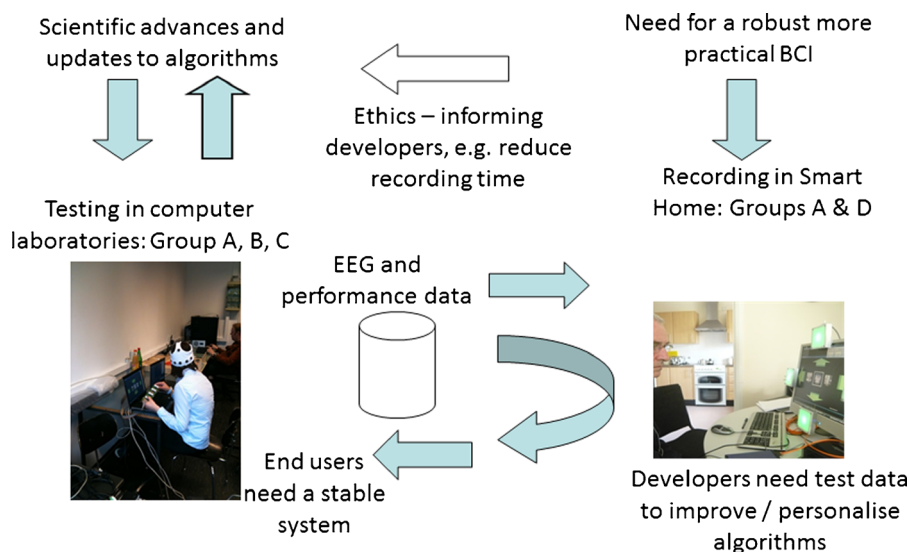


Fig. 2 Role of ethics: recording and feedback from subjects to inform the development of algorithms and updates to protocol

This has been evidence by individuals such as Jean-Dominique Bauby who have gone to extraordinary lengths to achieve communication [43]. BCI technology potentially provides a communication channel for people, for whom communication is difficult or impossible. Secondary to technology per se but nonetheless high profile ethical and legal debates concern the fundamental rights of LIS patients. Could the communication possibility offered by BCI control lessen immediate concerns, e.g. if a sufferer knew that he/she could readily indicate a requirement for higher level pain relief, would this improve their wellbeing? If BCI was commonplace would more LIS patients accept life prolonging treatment? [22, 44].

Distributive Justice

BCI technology is becoming available directly to the public. Gtec have released a public facing BCI system for spelling, computer control and painting by thoughts [45]. This demonstrates promise for wider deployment. BCI mediated games devices and application development toolkits have become available in the last 2–3 years. It could be that either spelling for communication or alternatively computer gaming becomes the ‘killer app’, forcing BCI technology further into the mainstream. However there is also a justice consideration, in that those in the greatest need for such technologies often cannot gain access, due to the individualised nature of the technology and the subsequent care support package needed. This has been recognised by the Brain Communication Foundation [46], which aims to target the technology to the demographic that may be overlooked as they provide the least commercial gain.

Appropriateness of Technology

The use of BCI is tiring and it may be difficult to use for long duration or over long periods without recalibration. It is difficult to see how BCI technology in its current form would be the assistive technology of choice for participants from Group D, but it is may be the only option for LIS patients. Current developments in BNCI and hybrid BCI may improve the robustness and reliability of this technology and eventually achieve the desired breakthrough (see Roadmap, [23]).

User Centre Design and a Vulnerable ‘Lead’ User

An objective within research is to include user involvement throughout the project lifecycle to provide user informed development [47]. However, early involvement of the users in FP7-BRAIN raised issues due to the early instability of the BCI system. Yet, user involvement is essential to fully understand the complexity of issues to be solved. At what point within a project is it ethical to include a vulnerable user group? This needs to be a team responsibility, which again can pose a challenge in creating an understanding for the need for caution when there is also a real enthusiasm to deploy the technology under development to the target user. If standard guidelines in policy and practice were available then this could help to assist in such issues within interdisciplinary teams and provide a more objective viewpoint.

Technology Transfer

Technology transfer is a well-known problem in medicine. Frustrations initially encountered within FP7-BRAIN included deploying software in which errors only came to light remote from the developer, sometimes in a recording situation; physical complexity of system with significant setup time; and consequently an inability to promote a widespread understanding of the significant upheaval to the user.

Managing User Expectations

As with many emerging technologies, there are significant risks in BCI around managing user expectations. As part of the consent process such discussions took place, but in retrospect it was difficult to portray the complexity of the development process required for BCI to the non-technical user. Furthermore, this was initially compounded by the unrealistic expectations of the researchers themselves. The pace of such developments could have a negative effect on the user, as it might have been their belief that such a technology might have become readily accessible to them. There should be some responsibility post-project to keep interested users informed of the status of the development.

A cause for concern in BCI is the effect of a negative trial result on the user. Recordings demonstrated that users with brain injury had a lower accuracy than the healthy volunteers. Thus the people for whom the

technology was intended were less likely to successfully apply it. With negative recording sessions it could be a concern that this would adversely impact the user. Initial calibration trials provided classification accuracies with Group D users, many of which were not promising. However, as the project progressed the same users were asked to navigate through an interface and perform certain tasks. At this stage a level of frustration was obvious and it was necessary to stop this phase of the work. An ethical override stating a minimum level of accuracy before the vulnerable user should continue may be appropriate. In our experiments we found the usability needed to be greater than 75 % (Ware et al. [48]) for users to continue to engage. But a dilemma then occurs; by excluding users, how would improvements be made without further involvement from them?

Technology Risk

If BCI technology was deployed to the home setting then the risk factors would need to be assessed, as with all assistive technologies. Gröbler [31] discusses the importance of minimum reliability depending on application and as such the BCI system would need to categorise the applications that could be supported by the user depending on their ability. FP7-BRAIN's applications ranged from media control to smart home device control. The later involves higher risk devices and hence a greater need for reliability to promote safe use (e.g., front door opening).

Ethical Guidelines for BCI Development and Deployment

As neuroscience advances, ethical issues regarding the interface between technology and people need be addressed. In 2009, [49] (University of Mainz, Section of Neuroethics) proposed a European network with the following remit (abridged).

“The network is designed to the raising of awareness; the systematization of ethical issues; the prescription of ways and approaches to deal with them; ...and the establishment of general guidelines for good practice in BCI research and use.”

Unfortunately, the network was not realised, but the issues raised are still relevant. From the FP7-BRAIN experiences it is clear that a more detailed and

standardised set of guidelines is needed, when deploying BCI technology within vulnerable user groups that goes beyond data protection, and informed consent. In this section we provide some tentative guidelines according to the experience of the authors which confirms and augments the work of existing research contributors to the debate. Solutions which do not take account of ethical limitations are unlikely to be successful outside the laboratory.

Governance Structures

- In a consortium, establish an Ethical Advisory Board with participation from each partner and a trusted external adviser. Where internal agreement cannot be reached the external adviser should have a final say on ethical matters that impact upon subjects.
- Enforce team responsibility so that any user issues are reported via the EAB. This includes reporting of any negative side effects with users.
- Ensure that the EAB reports at consortium meeting and review meetings.

The Consent Process

As part of the consent process, the following should be disseminated to the user (and their representative, if in a vulnerable group) to manage user expectation:

- Emphasise the research nature of BCI study. Indicate that some of the work is exploratory in nature, to allow new algorithms and approaches to be developed and tuned.
- Do not raise expectations unduly. BCI is complex and does not work for everyone. Explain that, at this stage, the BCI may not perform consistently, and possibly not at all.
- FP7-BRAIN experience has shown that BCI is less likely to work for a person with brain injury. This should be made clear to potential subjects, although the issues for this performance are complex.
- Confirm that BCI is not a therapy (at this stage of development).
- Ensure that user knows that they can halt the experiment at any time if desired and have an agreed way that a communication impaired user can signal this. This should address continued consent.

- If possible, achieve consent for image, video and audio data to be recorded. Image data may be anonymised to preserve privacy.
- If possible, achieve agreement for anonymous data to be made available to the wider BCI community. This requires clearance early on in the process, which can be difficult to achieve. However, it can help justify the effort put into the research and potentially advance the state of the art, by leveraging expertise outside the consortium.
- Confirm that BCI equipment or support package will or may *not* be available after the termination of the study.

Knowledge Transfer

Training is required for both participant and carer responsible for BCI setup, and thus usability is clearly crucial.

- Make the recording procedure as straight forward as possible, from the perspective of the users. Software that requires complex libraries (e.g., for signal processing) should be automated by use of an installation wizard, for example [50].
- Provide quality documentation. This should include a list of all components within any deliverable, with version number and updates noted; supplied with a user guide document for the system component. Video guides should also be considered and this can be aided by screen capture software.
- Remove features that have no relevance to those conducting experiments (i.e., debug information).
- Utilise appropriate communication tools (remote desktop control and videoconferencing) for frequent interaction between sites.
- Provide continued technical support to those conducting experiments with limited understanding of the scientific process.

Experimental Issues

Recording non-invasive EEG has been undertaken in laboratories for decades, and the approach has been standardised with regard to electrical safety and infection control. For widespread deployment, set up time, subject comfort and aesthetics all become relevant

issues. Some experiments evoke a response in the EEG, to facilitate BCI interaction. The user may view flashing stimuli (SSVEP) for example. This requires exclusion criteria for subjects with epilepsy, for example. For MI, a number of training sessions are required and will be time consuming and tiring to the user. The user invests a significant level of commitment to the training process before any gauge of future ability can be determined. This could be demotivating to the user. However it is important to reduce any possible distress that the stimulus could cause by restricting recording time.

- Build ethical requirement into the experimental specification. These include comfort of the subject, duration of the setup time and duration of a recording session (which may be tailored to the needs of the user group).
- Design software to facilitate user rest breaks.
- Determine a minimum level of reliability for using with vulnerable subjects. Proven stability and effectiveness is needed using evaluations with Groups A-C before experimentation can involve Group D.
- There is a need for a stable system for data capture. Don't allow project deadlines to result in premature delivery of software.
- Software may need to be tuned to a subject, but it should never be 'debugged' on a vulnerable subject.
- A minimum user accuracy should be established in calibration, e.g. 75 % before more complex interaction, e.g. with a virtual environment (to reduce potential user frustration).
- Clinical hygiene standards should be employed to guard against infection (e.g., cleaning of electrodes, disposable sponge electrodes)

Consequences of Success or Failure

Consideration is needed concerning the expectation of the user. If a level of competency is achieved great disappointment could occur if the technology was not available to the user long term. Conversely failure of system software or hardware will produce frustration to the user and waste time of all involved. Particularly, failure to achieve sufficient control after a number of training sessions in the MI protocol, will cause disappointment due to the time already invested. Low accuracy achieved shows evidence of unsuitability of BCI

paradigm for the subject. It is important that this is determined as soon as possible.

- Efficient screening to identify subjects who are more likely to benefit from the use of BCI technology.
- Establish guidelines prior to evaluation to help establish the point at which experimentation should be halted due to low performance and determine how this should be managed.
- Indicate that failure to use a BCI successfully is not a reliable indicator of the subject's medical condition.
- However decline in performance of a user may require reporting to a suitable profession for a clinical review. This could even be viewed as 'incidental decline' [51].

Mitigation of Risk

Once a level of BCI control and interaction has been achieved a user may be able to command some level of interaction with devices (e.g., speller; entertainments package; web browser, domotic control). At the research stage the interaction would be performed under experimental protocol. The key risks depend on the application, ranging from low to high depending on any physical dangers for example, domotic control.

- Predict likely risk and adopt procedures to protect against the risk wherever possible.

Conclusion

Research projects have many outputs and beneficiaries. Publication is important for researchers, and new software algorithms and advances in hardware are both important in advancing the science and competitive industry. Participants in research studies are increasingly seen as partners in the research, and as such many give their time and commitment largely for altruistic reasons. Figure 1 illustrated that the both volunteers and vulnerable groups need to participate in the tuning of algorithms and design of the interface. There was significant time commitment given from subjects in FP7-BRAIN, both healthy volunteers and those with brain injury.

The technologists are part of the overall multidisciplinary team, but often a dominant part at this stage of

BCI evolution. The viewpoints of *developer* and those responsible for *technology transfer* are both compatible and sometimes competing, and the roles of the ethics manager and external ethics adviser are to ensure that the viewpoints are influenced by other consortium members, including of course the end users. The EAB seeks consensus on user issues at consortium meetings. However, an experimental issue (such as unduly long recording duration) could be agreed by a voting process in a consortium. In such a case the external ethics advisor should intervene and provide an appropriate judgement.

The legacy of BCI research, a widely deployable BCI, will depend on the success of follow on research projects and further innovations from manufacturers to deliver solutions to those in most need (group D) and those who wish to use such technology for leisure and gaming. Research poses more questions requiring additional study (e.g., 'Back Home' [52] whose goal is to move BNCIs from laboratory devices for healthy users toward practical devices used at home by people in need) and opens up new lines of inquiry. The tension between ethical deployment and technical progress must be managed by a formal process within a multi-disciplinary consortium. The timeline to wide scale BCI deployment is difficult to evaluate due to the large set of experimental variables, and lack of standard hardware, software and protocol, but good progress is undoubtedly being made and mature ethical guidelines should evolve to accompany this.

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