Responsible Research and Innovation for Communication by Brain-Computer Interfaces in Severe Brain Damage

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Abstract

Motivation and problem definition: Severe brain damage frequently leads to a loss of communicative abilities. For example, patients with chronic disorders of consciousness do not consistently respond to external stimuli, become completely dependent on nursing care, and prove unable to use verbal and classic nonverbal means of communication. Nevertheless, neuroscientific analysis of the patients' brain activities reveals that a subgroup still possesses the capability to willfully modulate brain signals, e.g. by imagining activities. This phenomenon could be utilized to restore communication. The interdisciplinary German research project NeuroCommTrainer aims at this goal, relying on an electroencephalography-based brain-computer interface. Since patients with severe brain damage constitute a highly vulnerable research population, the integration of social, normative, and ethical considerations into the project assumes great importance.

Approach and methodology: Social and ethical aspects in the project are assessed by a variety of empirical methods. For example, project stakeholders participate in a structured discussion regarding predefined normative dimensions, which are drawn from the literature on the ethics of technology and applied to the specific contexts of the project.

Results: Regarding beneficence, the research setting is viewed as one component in a holistic care approach that takes the patients' biographies into account. Autonomy means that patients' acute needs and desires are honored, as far as they can be perceived at all in the patients' devastating and secluded states. Safety and security mean, on a fundamental level, that humans are at the center of attention. The principle of justice results in a fair and transparent allocation of research resources, e.g. concerning the limited number of brain-computer interfaces during the early research phase. Privacy includes data protection. Restoring communication has the potential to contribute to the patients' participation in society again. Reasoning from the dimension of self-image means to offer the opportunity to the patient to feel like a whole, complete, and accepted person again.

Conclusion: The empirical method of structured stakeholder discourse on social and ethical issues aids in defining goals and processes in the project. Such an integrative view on research and innovation will likely improve acceptance and acceptability of technology in the delicate field of care for vulnerable populations.

Keywords

Severe brain damage; chronic disorders of consciousness; brain-computer interfaces; electroencephalography (EEG); communication; ethical, legal, and social implications (ELSI)

I. INTRODUCTION

Severe brain damage significantly diminishes survival and quality of life. Both internal and external trauma, among others due to strokes and accidents, can lead to chronic disorders of consciousness. In the unresponsive wakefulness syndrome (UWS; also commonly known as the vegetative state), patients do not visibly respond to any external stimuli; no reaction is perceived at the bedside in nursing settings. In the minimally conscious state (MCS), a few reactions, such as eye movements, can be elicited. Although most patients stay in these states permanently, some patients recover late, more than twelve months after onset [1]. Several studies have shown that a patient subgroup is still capable of willfully modulating their brain activity, despite no discernible response at the bedside [2].

Therefore, brain-computer interfaces promise to restore communication with such severely physically challenged patients. For this purpose, a brain-computer interface based on electroencephalography (EEG) will be developed and utilized in the project Training and Communication System for Nursing-Dependent Patients with Severe Brain Damage (i.e. "Ein Trainings- und Kommunikationssystem für schwer hirngeschädigte pflegebedürftige Patienten" in German, abbreviated as NeuroCommTrainer) [3]. This NeuroCommTrainer device may be combined with online signal processing [4], sensor and actuator toolkits [5], and sonification [6]. The partners involved in the project represent disciplines as diverse as psychology, cognitive science, medicine, nursing, computer science, and engineering in this interdisciplinary and multicenter approach.

II. Background and Aims

Patients with severe brain damage and chronic disorders of consciousness constitute a highly vulnerable population in clinical care and research [7]. Therefore, it is paramount to consider their interests early on in the research process. For this purpose, ethical, legal, and social implications or issues (ELSI) are discussed from the beginning in the project NeuroCommTrainer. One approach to promote discourse on applied social and ethical questions is to use the model for the ethical evaluation of sociotechnical arrangements (i.e. "Modell zur ethischen Evaluation soziotechnischer Arrangements", also known as MEESTAR) [8]. It builds on the four widely-known principles in applied biomedical ethics [9], i.e. respect for the autonomy of patients, nonmaleficence, beneficence, and justice [10]. In MEESTAR, these principles have been differentiated, for the application to technology use, into the seven dimensions of beneficence, autonomy, safety and security, justice, privacy, participation, and self-image [8]. Moreover, MEESTAR distinguishes chances and risks on the three classic sociological perspectives of the micro-, meso-, and macro-levels [8].

III. Methods

An ELSI workshop, i.e. a workshop that is centered on ELSI topics, was conducted within the first six months of the research and development project NeuroCommTrainer, which is 36 months long in total. Ten project partners participated in the workshop as well-informed and highly interested stakeholders. The workshop contained a section that was dedicated to the application of MEESTAR to this project. Its structured and moderated discourse followed a predefined sequence:

(1) plenary introduction

(1.1) to ELSI and

(1.2) to MEESTAR;

(2) individual and group work regarding the dimensions and levels in MEESTAR, concerning

(2.1) general characteristics of the model and

(2.2) its applications to the specific project;

(3) group presentations of the results from the previous step;

(4) plenary discussions about the project-specific topics according to the MEESTAR dimensions and levels with all workshop participants regarding breadth and relevance;

(5) written summary (which was prepared after the workshop) in the format of theses, dissemination of the summary, and adjustments according to the feedback;

(6) further discourse after the workshop.

The results presented in section IV largely correspond to the summary in step 5, and the discussion in section V constitutes an outcome of further reflection akin step 6.

IV. Results

Beneficence

Regarding beneficence, the patients' biographies should be well known in both clinical care and research on the micro-level. The patients' abilities in their former lives should be considered in order to assess their full potentials to respond in communication. The NeuroCommTrainer device should improve their quality of life. On the meso-level, the nursing home where the patients live takes responsibility for care, including that in research contexts. The technological device should not divert attention of the nursing staff away from the patients. On the macro-level, public awareness for the devastating conditions in severe brain damage and chronic disorders of consciousness should be increased.

Autonomy

Concerning autonomy, the approach to restore communication is an excellent way to promote autonomy on the micro-level. Eventually, the patients themselves should be able to initiate and end communication sessions. On the meso-level, the organizational settings should enable patients to use the novel communication device as much as possible. Ultimately, the resources for this need to be guaranteed. On the macro-level, the autonomy in a vulnerable group should be increased by way of improved communication.

Safety and Security

Considering safety and security, data protection for the individual patient is important on the micro-level. Both hardware and software need to prove secure. On the meso-level, the complex interplays between humans and technological devices need to be considered. For example, technology may or may not lead to increased personal interaction between nurses and patients, and this may have diverse effects on the patients' objective degrees of and subjective senses of safety and security. The NeuroCommTrainer device may eventually help to recognize emergencies. On the macro-level, data protection laws have to be followed.

Justice

In a reflection on justice, each patient's right to utilize the novel communication device needs to be assessed. On the meso-level, decisions have to be justified as to which patients, who live together in one nursing home that specializes in severe brain damage, will first receive the limited resources of a scarce research apparatus. The criteria for selection have to be made transparent, both within the research group and towards the patients and their relatives in the nursing home. On the macro-level, questions of access in the health care system need to be addressed eventually. Depending on the research successes, the communication device to be developed may receive reimbursement within the public health insurance system or may have to be paid for out of pocket.

Privacy

The patients' privacy may be severely restricted by a brain-computer interface on the micro-level because brain responses are directly measured and reactions cannot be modulated like

in the usual ways of verbal and nonverbal communication. On the meso-level, this tendency needs to be considered to protect privacy in the data analysis steps. On the macro-level, data protection laws need to be considered.

Participation

The NeuroCommTrainer device promises to improve participation in society again on the micro-level, liberating patients from their secluded and isolated states by communication. On the meso-level, patients' communication skills, when enhanced by technology, empower them to influence the care that they receive in their nursing home. On the macro-level, patients as a vulnerable group may gain public awareness again when they are able to make their concerns and interests known themselves.

Self-Image

The communication device may possess ambivalent effects on patients' self-images on the micro-level. On the one hand, patients may experience themselves as valuable and complete humans again. On the other hand, they may see this effect as artificially mediated by technology. On the meso- and macro-levels, these phenomena may also be observed in the nursing home or in society. The patients may be seen as fully human again or as pitifully dependent on technology.

V. Discussion und Outlook

Concerning the MEESTAR dimensions, numerous synergistic ideas could be observed among them. For example, communication possesses the potential to improve both autonomy as a person and participation in society. Quality of life can be enhanced as an aim in the framework of beneficence and as part of participation. Data protection is an important factor both for privacy and for safety and security. At the same time, conflicts between dimensions may arise. For example, considerations from privacy, safety, and security could limit advances in autonomy and participation.

The dimension of justice is particularly relevant in research and development projects because patient subjects do not only share risks regarding novel technologies, but also limitations in the access to potentially beneficial treatments. Resources are scarce, and only a subset of patients is allowed to participate in studies with the novel NeuroCommTrainer device, although a generally high level of interest in such promising research studies can be observed in the community for brain damage survivors, at least in the nursing home that is part of the NeuroCommTrainer project. The conditions and requirements for study participation need to be made transparent within the project, and they have to be clearly communicated to the legal decision-makers, the relatives, and the nursing home administration.

Self-image, as a MEESTAR category, evokes ambivalent associations in this project. While the aim is to improve the patients' situation again in a straightforward way, this intention is pursued by sophisticated technological means. It remains unclear whether the patients who eventually benefit from the communication device fully accept the technology on which their improvement rests. This question needs to be addressed with empirical studies, once a clear-cut communication success is indeed achieved in the project.

In addition to several social and ethical dimensions, MEESTAR takes different sociological levels into account. Potentially contradictory interests on the micro-, meso-, and macro-levels may result in obstacles. The perspectives to be considered stem from patients, relatives, health professionals, nursing home administration, special interest groups, health organizations, and society at large, among others.

MEESTAR also offers a third axis of assessment, in addition to the first axis of the seven dimensions and the second axis of the three sociological levels. The third axis includes a scale for the final social and ethical judgment on all ELSI issues that are identified in analysis and discourse. So far, this assessment has not been applied in the NeuroCommTrainer project for two reasons: First, the project is continously evaluated regarding its ELSI implications during its three-year course. Second, the phrases for the third axis appear to be rather stationary and not dynamic, and this fact is in contrast to the developmental character of a research project. Both aspects preclude a seemingly final assessment prior to the end of the project. The third MEESTAR axis is open for improvement, in the sense that it could be construed in a more adaptable and accommodating way.

Within the context of a social and ethical assessment for a research project, the MEESTAR dimensions and levels aid to structure discourse on the potential advantages and disadvantages of future technology in health care. The MEESTAR approach was developed for, and is particularly suited to, discuss technology for practical purposes, leaving aside complex philosophical and sociological theories.

The workshop character, in which the MEESTAR model was applied to the research and development project NeuroCommTrainer, provides an appealing approach and introduction to the assessment of ELSI topics for novices. The results could have been more in-depth and far-sighted, if the workshop had been longer or prepared in advance, for example by having the participants read ELSI or MEESTAR literature beforehand.

A limitation might be the fact that workshop participants also were project partners. This may have resulted in conflicts of interest and lack of neutrality in the ELSI assessments. Nevertheless, this fact may also be seen as an advantage because the project partners plan the project and are therefore the chronologically first and the most knowledgeable stakeholders to reflect on ELSI topics that are specific to the project. Moreover, the workshop results will be put into perspective by obtaining views from external experts in order to obtain a more comprehensive picture.

Regarding future steps, the results will be used to continue the discourse on ELSI topics within the project. Specific recommendations will be deduced and adapted as the project progresses and both successes and obstacles challenge its course. In conclusion, the ELSI workshop, and in particular the perspective on technology from the MEESTAR model, are valuable to find a common language regarding normative

decisions in technology-oriented research and development projects.

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