

Technology to unlock the mind: citizen science and the sandbox approach for a new model of BCI governance

Fiorella Battaglia
Department of Human Studies
University of Salento
Lecce Italy
Faculty of Philosophy,
Philosophy of Science and
Religious Studies
Ludwig-Maximilians-University

Munich Germany
Fiorella.Battaglia@unisalento.it
ORCID 0000-0002-0559-7892

Giuseppe Di Vetta
Institute of Law, Politics and
Development, Dirpolis
Sant'Anna School of Advanced
Studies
Pisa Italy
Giuseppe.Divetta@santannapisa.it

Abstract— The benefits and harms of Brain-Computer Interfaces (BCIs) deserve to be explored in depth. The evaluation of the fundamental conceptual, ethical and legal questions associated with BCI applications should be scrutinized. Finally, the resulting insights should be leveraged to benefit both medicine and society. We will perform this exploration with two focuses: the first one will look at the epistemic and ethical impact of the peer-production of knowledge (citizen science) and the second one will look at the legal criteria that should inform the introduction of a novel form of regulation which is envisioned by the sandbox approach [1].

With a view to complying with a translational research approach, it is required to foster co-creation of knowledge and therefore to include the active participation of patients, their families, clinicians, healthy users and the public in the process aimed at the regulation of the use of BCIs.

Citizen science is emerging as an important policy orientation but is still largely unknown [2]. Users are holders of practical knowledge which should be emphasized in a translational approach. There

is a close connection between the emergence of a new model of governance of BCIs, which takes into account the issues of epistemic injustice and the deep and profound implications on science as a discipline, a profession, and as a practice, foreseen by the policy orientation of citizen science [3]. Moreover, considering the user as merely a passive participant amounts to an injustice done to someone specifically in their capacity as a knower [4].

This part of the special session is about providing a state-of-the-art account of what is going on in co-creation theory, which is the necessary premise for designing co-creation activities in the framework of the sandboxes. How is the co-creation of knowledge possible? Why does co-creation of knowledge matter? These questions are central in the epistemology of the co-creation and have significant effects on a number of dimensions (implementation, benchmarking, and regulation), which are the specific themes of this special session.

According to the European legal framework, it is required that all high-risk AI informed devices must be tested for legal

conformity. This test can often be performed by the provider itself. The Proposal for a Regulation of the European Parliament and of the council encourages EU member states to create regulatory ‘sandboxes’, in which firms can try out novel services without fear of being hit by a penalty [5].

During the temporary suspension of current regulations that would prevent the use of the BCI, all interested stakeholders are requested to participate in the experiment aiming at testing the devices.

This test has two different kinds of requirements: the technical constraints responsible for the feasibility of the devices and the norms for the legal regulations. In between is the role of patients, users, families and the public.

Firstly, we will address the understanding of co-creation and provide the reasons for adopting a co-creation approach beyond the immediate evidence of benefit that is proceeding from the engagement in participatory practices in the production of goods, services, and knowledge. It is a theory that is capable of both explaining and formulating the epistemic and ethical reasons behind these processes, in order to enhance well-functioning practices and avoid possible shortcomings in their implementation, especially during the last step, that of the regulation.

Secondly, we will discuss why a ‘sandbox’ should be considered the most efficient regulatory environment to allow a real co-creation dynamic in BCIs innovation, considering the strict liability regime foreseen by European AI regulation. As known, a regulatory sandbox should be a safe space for both discovery and application, or for both BCI innovation and regulation. In that sense, while the sandbox approach can be conceived to improve proactive publicness in tech science, significant criticisms are raised. Discussing the legal implications of the sandbox regulatory approach, the paper will address many of these criticisms, especially regarding the consistency between a strict liability regime and a sandbox approach, as designed by EU regulators and the condition of legal-safe operating. This approach in terms of adaptive governance needs to be examined further. What are the rules for experimentation? How should these rules be characterized? Are the envisioned rules tools of soft law? Lastly,

we will discuss the regulatory learning effect of the sandbox approach: could it be real? Examples will be given from FinTech Regulation, where the sandbox approach has already been experimented with; that regulatory experience should be taken into consideration.

Keywords— Brain-computer interfaces, Neuroethics, Deliberation in Science and Technology, Risk Regulation

I. INTRODUCTION

Brain Computer Interfaces are characterized by both a strong public interest and the sensitive nature of the field. This combination requires particular attention regarding public communication. It is mandatory to avoid inaccurate or incomplete accounts and high expectations. While most of the scholars engaged in the ethical debates on the BCIs are concerned with ethical questions regarding the impact of the BCI technology on some ethical dimensions such as autonomy, authenticity, agency and the like [6; 7], this paper takes a different path. It argues for a radical citizens' engagement and participation in determining which ethical issues are at stake and covers the governance of BCIs. It is an approach characterized in terms of both citizen science and sandbox regulation. Such an approach requiring citizen engagement is typically resorted to in the event of an emergency situation in public health. The citizen science approach usually concerns those situations characterized by a high risk of infringing rights, or even after those rights have been infringed. On the contrary, we claim that such a participatory attitude of the citizen science approach in the field of BCIs is required to generate compliance not only with the results of the research in this field, but also to supplement knowledge informed policies with collaborative scientists-and-citizens' knowledge.

II. FOUNDATIONAL REMARKS CONCERNING ETHICS

Classical approaches in terms of ethical principles have their own shortcomings [8]. Their methodological reference is to abstract principles that are taken from academic sources and then applied to the case under question [9]. For instance, analyses on some normative principles, when faced with the variety of meanings of autonomy, result in choosing one rather than another academic philosophical norm in a way that is entirely arbitrary and not really related to the use of the technology in question. On the contrary, according to some of the most influential ethical theorists we argue that the starting point of ethics is based on moral beliefs. Moral beliefs in turn relate to what is good, what is morally impermissible, and what can be regarded as fair distribution etc. There are moral beliefs of higher generality, which we are not ready to give up, just as there are specific behaviors that we want to see characterized as immoral. On the one hand, the ethical theory attempts to develop general criteria for what is good, right, and just, which are consistent with individual moral convictions that appear to be non-negotiable. On the other hand, ethical theory provides guidance for the cases in which our moral conceptions are uncertain or even contradictory.

III. THE ETHICS OF BCIs AND THE CITIZEN SCIENCE APPROACH

Human action has always been intertwined with technologies. Given this social aspect, the domain of life sciences and technology is not a matter of individualistic ethics. Rather it includes the construction of a more integrated political society. For these reasons a modern analysis of the ethical impact of BCIs must encompass an idea of how to deal with emerging technologies with a view of making room for a stronger civic hand in shaping our future. Because of these epistemological and methodological considerations, it is not excluded that for different areas of human practice there are different normative appropriate criteria, which cannot be reduced to a single system of moral rules and principles. At least it appears heuristically appropriate that larger complexes of human practice, each of which has specific characteristics (such as Brain-Computer Interfaces research and applications), undergo an independent normative analysis. Typical involvement of patients collaborating as "peers" in creating knowledge (or peer-production of knowledge) will establish cooperation on multiple fronts. Valuable tools are questionnaires and surveys. In the case of BCIs, the questionnaires and surveys will include both open-ended questions for qualitative evaluation of patients and relatives and questions regarding the sessions' setting. Patients' performance will be evaluated quantitatively not only by the clinicians but also by the relatives. This methodology will allow a comprehensive participatory research process. Normative theory and empirical research are believed to be separate branches of ethics, but this attitude has been sharply criticized [10]. We suggest that empirical research can be guided and improved by normative theory. This pragmatic approach will become particularly evident in a two-step Ethical Analysis based on: 1) literature reviews and normative philosophical analysis, 2) qualitative surveys, anticipated by exploratory interviews with a view to grounding questionnaires to main participant categories 1) health care professionals, 2) technicians, 3) relatives, and 4) patients. These qualitative inquiries will be filled out during the activities according to the research method of Participant Observation, where the researcher is immersed in the day-to-day research activities. What is more, patients' organizations will be active not only in the Ethics Monitoring committees, but also actively participate in the surveys whose results will drive the research process. It is essential that a series of exploratory interviews with relatives, clinicians, engineers, and computer scientists will be conducted in advance in order to make the following drafting of the questionnaires grounded [11]. The different questionnaires will be made out of a mix of quantitative closed questions (about 70%) and open questions (about 30%). One of the objectives of this kind of inquiry is to explore the attitudes of participants with respect to the use of BCIs through a descriptive statistical analysis. Moreover, it will be interesting to compare attitudes in different countries. Not all forms of participation are equal. Participation may in fact result in a mere passive attitude tending exclusively to provide the data. However, it can generate a more participative attitude which entails the right to establish the purposes of the research and the boundaries of technological development. In the case of BCI, an interpretation of participation as described may correctly identify the achievement of common good. More specifically, in the case of the BCI, the general aim is to develop

a peer-production of knowledge with a view to improving patients' health, parents-patients relationships, and health care personnel relationship with patients and relatives. Moreover, such an approach may also contribute to the placement in the market and the putting into service of the BCIs because it ensures the economical sustainability by means of a techno-economic assessment. Eventually, the characterization of our approach in terms of participation and co-creation of knowledge turns out to also be beneficial in addressing the governance of BCI.

IV. THE REGULATORY SANDBOX APPROACH IN THE HEALTHCARE SECTOR

The Regulatory sandbox approach has first been launched in the financial sector (FinTech) in order to promote business innovation (by developing disruptive innovative financial products or models) and to ensure consumer safety. Then this kind of regulatory approach has moved beyond the FinTech towards the other sectors where new technologies should be tested and implemented [8]. According to the UK's Financial Conduct Authority (FCA) sandbox approach can be described as "a safe space in which businesses can test innovative products, services, business models and delivery mechanisms without immediately incurring all the normal regulatory consequences". Moving from this definitional account, sandbox approach is designed to be an epistemological and regulatory comfortable environment in which industry, innovators and civil society stakeholders can test innovative technologies and develop methods, procedures and product standards ensuring safety and social/economic benefit [9]. From a theoretical point of view, sandbox approach could be traced back to the *anticipatory* regulatory strategy. Armstrong and Rae have explained that regulation is seen as a support tool for safeguarding responsible innovation across multiple sectors rather than a fence preventing it. In that sense, sandbox approach has primarily to be conceived as a *reflexive* (or procedural) mode of technology regulation (TechReg); in that sense, sandboxes are aiming to ensure firms and producers not only to test the compliance with the relevant regulatory framework, before implementing the innovative technology in the wider sector. Yet, as real "testing" environment, sandboxes allow producers and consumers to find and discuss the better tactics, principles, and standards according to which policymakers could define (legal) regulation. Reflexive or procedural orientation characterizing sandbox approach underlines also its democratic, communicative, and experimental habit, that makes it appropriate to be implemented as regulatory approach with regard to the BCIs technologies. Scholars have also pointed out the inclusive, collaborative, future-facing, proactive, iterative, and experimental features of the regulatory sandbox approach [9]. Considering these features, in the sandbox, environment ethics assessment or experimentalism could be implemented and well managed. Patients and other ethics stakeholders (like relatives) should be engaged in the real-world test environments enabling them to cooperate in the regulatory outcome procedures. As we already said, regulatory sandbox approach is moving across multiple sectors. In the health and social care sectors, sandbox was

widely experimented, as a meta-analysis study have showed: health-care regulatory agencies have adopted sandboxes concerning the regulation of new healthcare innovations; reports and literature review are supporting that sandbox could be useful to draw regulatory schemes and standards for innovative healthcare technologies [10]. However, such innovative paradigm necessarily needs adaptive efforts to adequate the regulatory framework and liability regimes (civil or criminal) in a way allowing sandbox environments to be effective safe harbors for regulatory experimentalism and testing. That point is crucial to provide a sandbox safe space for BCIs technologies responsible innovation and developing. For the moment, the European lawmaker has not still adopted a formal regulatory benchmark or guidelines being able to steer and induce healthcare industry and other stakeholders to undertake BCI sandbox experiment. In the "Conclusions on the Regulatory Sandboxes and the experimentation clauses" (16 November 2020), the European Council have just addressed the need to enhance the EU regulatory strategies by improving experimental and anticipatory regulation. According to the mentioned Conclusions, sandboxes are considered as "as concrete frameworks which, by providing a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place". Thus, providing sandbox approach is designed to advance the European regulatory approach making it more flexible, experimental, cooperative, proof-oriented, and evidence-based. In that sense, sandbox tools, because of its proactive regulatory orientation, can enable regulators to "gain better regulatory knowledge and to find the best means to regulate innovations on real-world evidence" (as the Council has suggested), in a way consistent with the need to prevent as soon as possible uncertainty-related risks and ethics challenges. Precautionary principle and ethics/social sustainability may be considered the normative reference points which have to shape the *European* regulatory sandbox approach even in the BCIs context. The Council hence have called the Commission to "organise an exchange of information and good practices regarding regulatory sandboxes between Member States". This exchange of information and best practices should be aimed to collect data and evidence concerning the use of regulatory sandboxes in the EU; to select and discuss experiences "regarding the legal basis, implementation and evaluation" of those regulatory tools; to investigate "how learning form regulatory sandboxes at national level can contribute to evidence-based policy making at EU-level". It seems that Council has not paid attention to the potential ethics empowerment of the sandbox approach especially with regard to the technology or innovation fields where social, cultural and human criticism can arise.

V. EMPOWERING THE REGULATORY SANDBOX APPROACHES WITH CITIZEN SCIENCE

In our view, citizen science and sandbox approaches form a continuum in terms of (i) co-creation; (ii) openness; and (iii) experimentation with knowledge. More specifically, the two approaches differ in respect of whether they answer the question about if BCIs pose a challenge to some characteristic human properties, or whether they can be best regulated by complementing a strict liability regime with a sandbox approach [11]. Both questions are of crucial relevance to ethics as a whole, and in particular to ethics of technology, as well as to the discussion about risk regulation. As in the case of the reasons in favor of embracing a citizen science approach which includes both peer-production of knowledge and empowerment of citizens, sandbox regulation comes up with the opportunity of curbing the development of BCIs with relation to both the protection of citizens and society and to the promotion of innovation. The main reason offered in favor of experimenting on BCI applications within the sandbox is that control of the BCIs and knowledge about the BCIs is made possible at the same time. More specifically, it is possible to understand the impact of the BCIs on the market and society [1]. On a more general level, even this approach may strengthen the common good in society because the procedures envisioned to identify and determine the considerations relevant to the decision regarding the ethical appraisal of the BCIs and their governance are aligned with the main values of the deliberative democracy. In the case of the citizen science ethical approach of BCIs and their governance by means of a sandbox approach we can state that deliberation, understood as “decision making by discussion among free and equal citizens” [12] broadens the set of practical knowledge, ideas and information. It may help us to produce a better understanding of different perspectives - economical, technological, individual, and societal which are informed by the practical knowledge that the various actors may have. More importantly, deliberation and its procedures may help us to come to terms with forms of disagreement, to avoid discrimination and to promote justice.

V. CONCLUSION

The ability to communicate is a fundamental characteristic of human beings. BCIs have an affordance that make it possible even for individuals that lack that capacity to ensure the vital coexistence among other humans by means of technological devices. The focus on this hybrid connection – able to unlock the mind – is necessary to sort out the competing interests connected with this innovation crucial in the health sector but also sensitive in the field of regulation and business. We have been arguing for an approach that does support in terms of political and institutional pattern the participatory approach against one focused merely on some ethical principles. The main objective of this paper is therefore to establish an alternative route in terms of citizen science and sandbox approach for more inclusive and pluralist forms of governance. Citizen science is a strategic orientation with immense potential, which has barely been explored with a view to its epistemological and ethical significance, when it comes to analyze the impact of BCIs on private and public life. Also the

sandbox approach has barely been explored with a view to its participatory and experimental value, when it comes to the governance of new devices such as the BCIs in the sector of public health. What is more, both approaches in our view may be investigated along with their implications in terms of techno-economical assessment. As a result, the political-institutional twist of combining the two approaches is the unprecedented move taken by this paper. The model of governance envisioned by this paper is inclusive at the most extreme level because it includes all the relevant stakeholders considered not only as mere data holders, but rather as subjects owning some kind of practical knowledge which is relevant for framing the debate about the technological development, its societal deployment and finally for the most suitable kind of regulation. This paper makes a new use of the participatory approach, which is conceptualized, explored, and enacted for health care ends. Moreover, the project makes room for sketching out inclusive societies of the future, which will prevent conflicts by adopting a respectful attitude toward the most radical differences. This version of inclusive research inspired by theoretical in-depth analysis and participatory approaches has not been explored, tested, and deployed so far neither in ethics, nor in political philosophy nor in qualitative social research. This is why, this approach will establish an alternative and critical perspective on the governance of emergent technologies committed to create a common language among disciplines; this shared language will realign political, scientific and technical research with the needs that individuals and communities develop in their own fields to foster social inclusiveness and technological development. One of the main obstacles to a better alignment is the persistence of some sorts of dualisms such as culture/nature, human/technological and more generally, some process of growing apart between technological development, societal implications and regulation considered as not related spheres of human life. Our approach is related to a groundbreaking technology. Accordingly, the time is ripe to explore the strategic orientations coming from different fields that envision new stories of bringing different perspectives such as socio-technical visions of future and legal frameworks into deliberative discussion. Under this respect, this interdisciplinary paper brings to unconventional exchange the methodologies of different fields. As a result, a highly innovative approach in ethics of technology and legal studies will be introduced. The lynchpin idea is to exploit the productive tensions between their very different methodological perspectives and fields of application. It argues for a new model of governance whose newsworthiness lies mainly in their combination. It includes: 1)the translational approach, moving in a circle from normative analysis to the empirical study of real-world use to theoretical reflection and back to real-world use, 2)the patient- and parent-oriented approach, eliciting the perspectives of these rather forgotten, but crucial stakeholders as compared to researchers and ethicists. Foundational work includes: (i) Ethical, scientific and technical expertise complementing each other and leading to a

shared explanatory framework; (ii) A review of the normative and technological landscapes; (iii) Integration of the disciplines to accommodate BCIs in a broader combination of provinces of science and technologies based on common taxonomies understandable horizontally and vertically across-disciplines and society (iv) Finding a way to have a stronger civic hand in shaping our future; (v) In-depth analysis of philosophical concepts and legal theories.

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