MANAGING THE ETHICAL DIMENSIONS OF BRAIN-COMPUTER INTERFACES IN EHEALTH: AN SDLC-BASED APPROACH

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ABSTRACT

A growing range of brain-computer interface (BCI) technologies is being employed for purposes of therapy and human augmentation. While much thought has been given to the ethical implications of such technologies at the 'macro' level of social policy and 'micro' level of individual users, little attention has been given to the unique ethical issues that arise during the process of incorporating BCIs into eHealth ecosystems. In this text a conceptual framework is developed that enables the operators of eHealth ecosystems to manage the ethical components of such processes in a more comprehensive and systematic way than has previously been possible. The framework's first axis defines five ethical dimensions that must be successfully addressed by eHealth ecosystems: 1) beneficence; 2) consent; 3) privacy; 4) equity; and 5) liability. The second axis describes five stages of the systems development life cycle (SDLC) process whereby new technology is incorporated into an eHealth ecosystem: 1) analysis and planning; 2) design, development, and acquisition; 3) integration and activation; 4) operation and maintenance; and 5) disposal. Known ethical issues relating to the deployment of BCIs are mapped onto this matrix in order to demonstrate how it can be employed by the managers of eHealth ecosystems as a tool for fulfilling ethical requirements established by regulatory standards or stakeholders' expectations. Beyond its immediate application in the case of BCIs, we suggest that this framework may also be utilized beneficially when incorporating other innovative forms of information and communications technology (ICT) into eHealth ecosystems.

Keywords*:* *eHealth ecosystems; brain-computer interfaces (BCIs); systems development life cycle (SDLC); health care ethics; business ethics; IT management; technological innovation*

INTRODUCTION

A diverse and growing array of brain-computer interface (BCI) technology is being employed for purposes of therapy and, increasingly, human augmentation. Much thought has been given to the ethical aspects of BCIs; however, such ethical analyses typically view BCIs from the perspective of policymakers who must decide whether or not such technologies should be legal or of individual users for whom a BCI creates new opportunities and risks. Relatively little attention has been given to the ethical aspects of BCIs from the perspective of the managers of eHealth ecosystems who are charged with successfully incorporating new forms of information and communications technology (ICT) like BCIs into those environments. Such a lack of research and best practices is problematic, given the fact that managers who handle the practical details of implementing BCIs within eHealth ecosystems may discover ethical issues that were not foreseen by policymakers and which ordinary end users are not able to fully appreciate and resolve due to a lack of technical expertise.

In this text we seek to formulate a tool that can aid such managers in their work of incorporating BCIs and other innovative new forms of ICT into an eHealth ecosystem in a way that systematically diagnoses and addresses the unique ethical questions that are relevant for each stage of such a process. We begin by defining eHealth ecosystems and presenting an overview of BCIs and the roles that they can fill in such ecosystems. The ethical aspects of BCIs are then investigated by means of a novel two-dimensional framework that surfaces and analyzes ethical issues relating to ICT in eHealth ecosystems through the lens of a systems development life cycle (SDLC) approach to technology management.

DEFINING EHEALTH ECOSYSTEMS

It is difficult to identify a single universally accepted definition of 'eHealth.' Pagliari (2005) cites 36 definitions of eHealth found within the scientific literature and other sources. While those definitions differ greatly, many of them include a number of common themes, including an emphasis on the use of Internet-based and other networked ICT (as opposed to standalone technologies such as non-networked scanning equipment); telemedicine; and the creation, transmission, and analysis of digital data to enhance both the provision of medical treatment and the performance of administrative tasks. Having considered many such definitions of eHealth, Whitehouse and Duquenoy (2008) cite as especially useful the definition contained in the European Commission's *Action Plan for a European e-Health Area* (COM (2004) 356 final, p. 4), which states that eHealth "describes the application of information and communications technologies across the whole range of functions that affect the health sector."

An eHealth 'ecosystem' can be understood as a networked environment of actors, devices, and information systems involved in the provisioning of eHealth services that display both autonomy and mutual dependencies and which interact in such complex ways that they can 'evolve' in a manner analogous to that of a natural biological ecosystem (Benedict and Schlieter, 2015; Guedria et al., 2014). Such ecosystems can incorporate actors such as patients, primary care professionals, public hospitals,

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private outpatient clinics, diagnostic and imaging facilities, nursing homes, pharmacies, universities, research laboratories, insurers, and national and local government agencies (Nollo et al., 2014). These actors interact through the use of ICT that includes medical devices housed in dedicated facilities (such as fMRI machines), mobile health devices (such as wearable heart monitors), home fitness equipment, cloud-based health care information systems, and general-purpose communication tools such as social media, email, and telephones (Guedria et al., 2014; Nollo et al., 2014). Such tools are used to deliver business outcomes including real-time telemonitoring and teleassistance, patient education, management of patient care, and financial processing (Guedria et al., 2014).

In order to be viable, an eHealth ecosystem must possess legal, organizational, semantic, and technical interoperability among its constituent devices, processes, and systems (Guedria et al., 2014; COM (2010) 744 final, Dec. 2010). When implemented on the smallest scale, it is possible for such an ecosystem to constitute a 'personal' eHealth ecosystem (Harno, 2013) that connects all of the implantable, wearable, mobile, or ambient devices involved with the provision of health care to a single individual. When implemented on a larger scale, such ecosystems may operate at a municipal, national, or international level and include millions of patients as members. Bourquard (2011, p. 84) notes, for example, that the development of pan-European eHealth ecosystems will require successful agreement on international standards such as the EU eHealth Interoperability Framework envisioned by the European Commission (Van Langenhove et al., 2013), development of a consensus implementation roadmap by service providers, creation of testing platforms, and creation of certification regimes to enforce convergence and consistency.

OVERVIEW OF BRAIN-COMPUTER INTERFACES AND THEIR (POTENTIAL) ROLES IN EHEALTH ECOSYSTEMS

Brain-computer interfaces (BCIs) comprise a diverse and expanding range of sophisticated neurotechnologies whose use is expected to increasingly impact spheres of human activity including health care; interpersonal relationships and sociality; creativity and the arts; science, education, and knowledge management; commerce, work and organizational life; and defense, law enforcement, and personal security (Gladden, 2016). BCIs are devices that "involve real-time direct connections between the brain and a computer" (Glannon, 2014, p. 1) and which "provide a direct communication pathway between the human brain and an external device" (Lance et al., 2012, p. 1586). A BCI can be classified as 'invasive,' 'non-invasive,' or 'partially invasive' depending on whether the device physically extends into the tissue of its user's brain (Gasson, 2012, p.14; Panoulas et al., 2010; Gladden, 2015). Non-invasive BCIs (e.g., utilizing EEG or fMRI technology) may involve sensors temporarily affixed to a user's scalp, while invasive BCIs (e.g., for deep brain stimulation) may incorporate hundreds of electrodes or other stimulators or sensors surgically implanted in a user's brain (Glannon, 2014, p. 1; Bostrom and Sandberg, 2009). BCIs are employed for functions including neurofeedback, neurostimulation, and neural control of remote devices (Haselager et al., 2009, p. 1352).

There is a wide variety of roles that BCIs are already playing or can potentially play within eHealth ecosystems. Perhaps the most obvious role for BCIs is in the direct provision of care to treat a medical condition. For example, some kinds of cochlear implants (Bostrom and Sandberg, 2009, p. 321) and artificial retinas (see Thanos et al., 2007) can interface directly with the brain to provide sense data from the external environment to users who would otherwise be unable to hear or see. Deep brain stimulation (DBS) is used to treat motor disorders such as Parkinson's disease, dystonia, and essential tremor (Clausen, 2011, p. 495). BCIs can also potentially be employed to predict or stop epileptic seizures (Drongelen et al., 2005; Fountas and Smith, 2007). New kinds of BCIs are being envisioned in the form of cognitive neuroprostheses that can support, regulate, modify, or replace neural processes relating to memory, imagination, emotion, identity, and consciousness (Gladden, 2016).

BCIs can also allow patients suffering from particular medical conditions to control computerized systems that are external to their bodies. For example, BCIs can be utilized to control motorized wheelchairs and robotic artificial limbs, which can be used by paralyzed patients for self-feeding and other important tasks (Clausen, 2011, pp. 498-99; Glannon, 2014, p. 1). BCIs can also be directly employed by patients as a means of communication. For example, a BCI can be used by a paralyzed individual to control a cursor on a computer screen (Glannon, 2014, p. 1) in order to compose messages. BCIs can also be employed to communicate with patients suffering from paralysis or locked-in syndrome (LIS) who would otherwise be unable to communicate (Haselager et al., 2009, p. 1353; Glannon, 2014, p. 1).

Increasingly, though, BCIs will be used not for the therapeutic purpose of treating a medical condition but in order to augment and enhance the cognitive and physical capacities of healthy human beings (Gasson, 2012, p. 25). This is expected to create radical new possibilities for incorporating BCIs into the activities of eHealth ecosystems. For example, it is anticipated that in the future, medical personnel could use BCIs as a replacement for smartphones to engage in real-time, hands-free, direct brain-to-brain communication with one another or to check online medical reference texts with a mere thought (Lance et al., 2015; Gladden, 2015). Medical personnel could also use BCIs as a means of authenticating their identity and accessing restricted services and data within eHealth ecosystems – including financial and administrative data, patients' medical histories, and real-time data from monitoring devices, as well as remotely controlling diagnostic equipment, drug delivery systems, implantable medical devices, and robotic surgical systems (Thorpe et al., 2005; Van Erp et al., 2012; Gladden, 2015).

THE LACK OF TOOLS AND APPROACHES FOR MANAGING THE ETHICAL DIMENSIONS OF INCORPORATING BCIS INTO EHEALTH ECOSYSTEMS

The use of BCIs raises many complex ethical and legal questions relating to safety and risk, privacy, personal identity and agency, equity and social justice, and the nature and future direction of the human species. Many works have explored such ethical dimensions of BCIs, including those by Nijboer et al. (2006), McGee and Maguire (2007), Wolpe (2007), Bostrom and Sandberg (2009), Haselager et al. (2009), Tamburrini (2009), Kotchetkov et al. (2010), Clausen (2011), Vlek et al. (2012), Jebari (2013), Nijboer et al. (2013), Glannon (2014), and McCullagh et al. (2014). However, such works typically focus either on the ethical issues that are relevant at a societal level (e.g., evaluating whether certain kinds of BCIs should be banned by the government) or at the personal level (e.g., considering the impact of a BCI on the privacy and autonomy of an individual patient). Significant attention has not yet been given to ethical issues that arise at the organizational level when managing the implementation of BCIs – and in particular, scholars have not yet systematically identified or considered unique ethical issues that might arise when managing the incorporation of BCIs into eHealth ecosystems.

This lack of research and established best practices relating to the ethical management of eHealth technology implementation concerns not only BCIs but innovative forms of ICT more generally. For example, numerous works have explored the ethical aspects of eHealth, including those by Rippen and Risk (2000), Anderson (2007), Whitehouse and Duquenoy (2008), Liang, Mackey, and Lovett (2011), Kluge (2011), Whitehouse, George, and Duquenoy (2012), Duquenoy, Mekawie, and Springett (2013), Miesperä, Ahonen, and Reponen (2013), Wadhwa and Wright (2013), Habib (2014), Jumelle and Ispas (2015), and Rissanen (2015). However, as broad investigations of ethical issues in eHealth, such texts do not provide operators of eHealth ecosystems with comprehensive frameworks for surfacing and managing the spectrum of unique ethical considerations that arise at each stage of the process of incorporating new ICT into such ecosystems.

FORMULATING AN SDLC-BASED ETHICAL FRAMEWORK FOR MANAGING THE INCORPORATION OF INNOVATIVE ICT INTO EHEALTH

In order to address this lacuna in the fields of BCI implementation and eHealth management, we propose a conceptual framework for managing the incorporation of innovative ICT into eHealth that is based on a systems development life cycle (SDLC) approach and which can be applied directly to the case of BCIs. Our two-dimensional framework encompasses: 1) key ethical dimensions relevant to the management of eHealth ecosystems; and 2) stages in the process of incorporating a new kind of ICT into an eHealth ecosystem. This framework is described in more detail below.

First Axis: Ethical Dimensions of Incorporating Innovative ICT into an eHealth Ecosystem

A review was conducted of the two dozen texts cited above that discuss the ethical dimensions of BCIs or of the incorporation of innovative forms of ICT into eHealth ecosystems. Within the constraints of this text, it is not possible to describe and compare in detail the contents of those texts; however, by analyzing and synthesizing such works, it is possible to delineate five key ethical dimensions that must be successfully addressed when incorporating innovative ICT into eHealth ecosystems; these are: 1) *beneficence*, 2) *consent*, 3) *privacy*, 4) *equity*, and 5) *liability*.

Second Axis: SDLC Stages of Incorporating Innovative ICT into an eHealth Ecosystem

Incorporating insights from the systems development life cycle (SDLC) approach to technology management, the second axis of our framework describes five key stages of implementing new ICT in an eHealth ecosystem. Wager et al. (2013) review a range of SDLC frameworks that have been employed to manage the development of health care information systems; they observe that most approaches can be summarized as comprising the four stages of planning and analysis, design, implementation, and support and evaluation. Similarly, Benedict and Schlieter (2015, pp. 236-37) identify four stages in the creation of the infrastructure for an open eHealth ecosystem: analysis, design, implementation and testing, and utilization. Meanwhile, an SDLC developed by the US National Institute of Standards and Technology with an emphasis on information security similarly describes the four phases of initiation, development/acquisition, implementation, and operations/maintenance, along with an additional phase of disposal (*NIST SP 800-100*, 2006, pp. 19-25): information systems do not last forever, and it is important that once they reach the end of their service life their components are disposed of in a manner involving appropriate information preservation and media sanitization. This is especially critical in the case of health care information systems that contain personal medical data subject to stringent legal and ethical requirements (Gladden, 2015, pp. 180-81).

By synthesizing such SDLC frameworks, we can describe the five relevant stages of incorporating ICT into an eHealth ecosystem as comprising: 1) *analysis and planning*; 2) *design, development, and acquisition*; 3) *integration and activation*; 4) *operation and maintenance*; and 5) *disposal*.

ETHICAL DIMENSIONS OF ICT IN EHEALTH ECOSYSTEMS

SDLC STAGES OF INCORPORATING ICT INTO EHEALTH ECOSYSTEMS

	Beneficence	Consent	Privacy	Equity	Liability
Analysis and planning	Determining whether a BCI is inherently harmful or too risky to be utilized	Developing policies, practices, and roles to ensure consent in all SDLC phases	Developing policies, practices, and roles to ensure privacy in all SDLC phases	Identifying relevant stakeholders and involving them early in the process	Determining liability for the program as a whole
Design, Development, and Acquisition	Designing BCI-ecosystem integration (e.g., failure modes) to minimize harm	Ensuring consent of test subjects for experimental BCI integration into ecosystem	Building information security safeguards into hardware and software	Ensuring that BCI integration is designed to work well for different types of users	Clarifying liability of BCI designers, manufacturers, providers, and operators
Integration and Activation	Ensuring that BCI integration does not disrupt existing institutional ICT systems	BCIs may not be installed, integrated, or activated without users' consent	Privacy of BCI users must be safeguarded during BCI integration and activation	Ensuring that provisioning of BCI integration to institutions and individuals is equitable	Clarifying liability for problems during BCI integration or activation
Operation and Maintenance	BCIs must respond to real-time conditions to optimize service and risk levels	Mechanisms for verifying users' ongoing consent must function effectively	Ensuring privacy of user data generated, sent, received, or stored by BCIs	Ensuring that BCIs do not grant illegal or unjust benefits to users at others' expense	Responsibility to immediately identify and correct harm being caused by BCIs in use
Disposal	BCIs should not be disconnected if this would result in harm to users	Ensuring users' consent before terminating BCI services, insofar as possible	Permanently maintaining privacy of user data even after termination of BCI services	Fairness and impartiality in deciding which BCI services to discontinue	Liability for harm caused by disconnection of BCIs from eHealth ecosystem

Figure 1. *Figure 1. Our proposed framework for managing the ethical dimensions of incorporating innovative ICT into eHealth ecosystems, as applied to the case of brain-computer interface technologies. Shown are examples of issues relating to all five ethical dimensions at each of the five stages of the system development life cycle (SDLC) when incorporating a new BCI technology into an eHealth ecosystem.*

Combining the Two Axes to Yield a Matrix of Ethical Issues for Each Stage of the SDLC

When combined, the axes described above yield a matrix of the sort reflected in Figure 1. It defines an array onto which can be mapped ethical issues relating to a particular form of ICT. We would suggest that such a framework can potentially be used as an effective management tool for surfacing, classifying, and addressing unique ethical issues that should be considered during each stage of the process of incorporating innovative ICT into an eHealth ecosystem.

APPLYING THE ETHICAL FRAMEWORK TO MANAGING THE EHEALTH IMPLEMENTATION OF BCIS

Having formulated this framework, we can apply it to the particular case of incorporating BCI technology into an eHealth ecosystem. A number of ethical questions that have been raised (sometimes in an *ad hoc* fashion) in the literature on BCIs and eHealth ecosystems; in Figure 1, we have populated our matrix with such issues by assigning them to the relevant location within the two-dimensional space. In the following sections, the ethical issues related to each SDLC stage will be discussed in more detail, illustrating the manner in which this framework might aid eHealth ecosystems' operators in managing in a systematic and comprehensive way the ethical dimensions of integrating BCI technologies into such ecosystems.

SDLC Stage 1: The Analysis and Planning Stage

In this stage, key ethical questions may be addressed by international, national, and local policymakers in consultation with the program managers who would ultimately oversee the incorporation of BCI technologies into an eHealth ecosystem. To begin with, the ethical dimension of *beneficence* is important in this stage: decision-makers must assess whether incorporating BCI technology into an eHealth ecosystem is likely to do significant good (and acceptably minimal harm) for its users. For example, use of an invasive BCI that requires implanted electrodes is inherently risky; it can cause brain trauma and hemorrhage in otherwise healthy patients (Clausen, 2011, p. 499). If the benefits generated by the BCI do not outweigh this risk (perhaps, e.g., in the case of BCIs used to grant enhanced communication capacities to healthy human beings (Clausen, 2011, p. 499)), it may be decided not to endorse, encourage, or allow the use of such BCIs by facilitating their incorporation into an eHealth ecosystem.

The element of users' *consent* is also relevant at a systemic level even in this first stage. Decision-makers must consider the extent to which the incorporation of BCIs into an ecosystem is being driven by users' legitimate needs and desires and to what extent users may have been manipulated by device manufacturers (e.g., through advertising campaigns) to feel as though they 'need' a BCI in order to be happy or successful (Bostrom and Sandberg, 2009, p. 324). If the best and most effective health care systems employ widespread BCIs for the provisioning of care, individuals may feel pressured to utilize such technologies in order to access adequate care. If it is apparent that users of a BCI technology will not be truly free to grant or withhold consent, it may be inadvisable to proceed with its incorporation into an eHealth ecosystem.

During this stage, the ethical element of *privacy* is addressed by developing effective policies, practices, and roles to ensure that users' data will be protected throughout the later stages of the SDLC. The element of *equity* is addressed by identifying relevant stakeholders (including ethicists, legal scholars, biomedical experts, hospitals, potential device users, and device manufacturers) and gathering their input before any major programmatic commitments are made. Many BCI technologies are quite expensive: decision-makers must consider how their incorporation into eHealth ecosystems may unfairly advantage those who can afford to purchase them and may increase disparities between financially privileged and disadvantaged individuals within society (Bostrom and Sandberg, 2009, p. 329) or between wealthier and poorer countries. Decision-makers must also consider the impact that incorporation of a BCI will have on those within the eHealth ecosystem who choose not to utilize such technologies: if BCIs become an important element of an ecosystem, then unwillingness to use a BCI might effectively deprive a patient of full access to the health care system (Bostrom and Sandberg, 2009, p. 329). Decision-makers must also ask whether BCIs are being used as an easy means of controlling or pacifying patients that avoids addressing broader medical or societal issues (Bostrom and Sandberg, 2009, p. 324).

Issues of *liability* must also be discussed at a systemic level, to clarify who will bear responsibility for all decisions and actions taken throughout the incorporation process. Moreover, in addition to addressing ethical concerns that are unique to the analysis and planning stage, during this stage decision-makers must also conduct a preliminary analysis of all of the ethical issues that are expected to arise during later stages – to be sure that none of those ethical issues is so severe that it warrants abandoning the BCI incorporation at this first stage.

SDLC Stage 2: The Design, Development, and Acquisition Stage

During the design, development, and acquisition stage of the SDLC, *beneficence* is addressed, for example, by ensuring that BCIs and the mechanisms incorporating them into an eHealth ecosystem possess appropriate failure modes that will minimize harm to users in the case of software errors, mechanical failures, or other problems (Gladden, 2015, p. 259), as well as testing BCIs to ensure that they do not generate unexpectedly harmful side-effects (Bostrom and Sandberg, 2009, p. 323). *Consent* includes obtaining the informed consent of all individuals who serve as test subjects during design and testing of the BCI incorporation. *Privacy* involves not only safeguarding the privacy of such test subjects but also ensuring that BCIs and their system connections are built to include adequate management, operational, and technical controls for information security (Gladden, 2015, pp. 205-304).

Questions of *equity* include ensuring that BCIs and their connections to an eHealth ecosystem are designed to work equally well for diverse kinds of users and that they do not unfairly advantage specific device manufacturers or users who possess a particular socioeconomic status, place of residence, or set of mental and physical characteristics. Issues of *liability* include specifying liability for any accidents that might occur during testing of BCIs and their incorporation into eHealth ecosystems and developing clear liability frameworks for later stages in the implementation process.

SDLC Stage 3: The Integration and Activation Stage

The integration and activation stage involves connecting BCIs to an eHealth ecosystem and its services for the first time or activating features within the eHealth ecosystem that allow BCI users to individually connect to the system. In this stage, the dimension of *beneficence* involves ensuring that the initial integration of BCIs into the ecosystem does not cause harm to the BCIs' users or other participants in the ecosystem (e.g., through a lack of bandwidth or computer resources needed to simultaneously support the BCIs and all other ecosystem components). *Consent* requires that the BCIs of individual users not be accessed by or functionally integrated into an ecosystem (e.g., through remote management or participation in cloud-based services) without users' knowledge and agreement. The ability of minors and those with cognitive disorders to give informed consent for integration of their BCIs into an ecosystem may be nonexistent (Bostrom and Sandberg, 2009, p. 324). Clausen (2011, pp. 498-99) notes the special ethical issues raised by BCIs that are used to establish communication with patients who are otherwise unable to communicate, such as those suffering from locked-in syndrome: by definition, such patients are unable to express their consent before a BCI is installed and activated. While activating such a BCI – especially an invasive one – without a patient's consent could be considered unethical, refusing to apply such a beneficial life-enhancing technology because the patient is unable to express consent in advance might also be considered ethically inappropriate.

During the integration and activation stage, *privacy* requires not only that an ecosystem appropriately safeguard the particular data generated by a user's BCI but also that the mere fact that someone possesses a BCI and has become a member of the ecosystem be kept confidential. *Equity* requires that the order and robustness with which classes of BCIs and individual users' BCIs are incorporated into an eHealth ecosystem be determined in a manner that is just and not unlawfully discriminatory. Questions of *liability* are addressed by ensuring that clear legal frameworks and particular agreements are in place before an institutional or individual operator of BCIs or provider of BCI-related services is allowed to access an eHealth ecosystem.

SDLC Stage 4: The Operation and Maintenance Stage

During this stage, BCIs participate fully in an eHealth ecosystem while being actively employed by their operators and users for a range of therapeutic and augmentative tasks. Here, *beneficence* requires that both BCIs and other components of the eHealth ecosystem (including any centralized management systems) respond effectively to changing real-time conditions to optimize service and risk levels, maximize the benefit, and minimize the potential of harm for BCIs' users. For example, eHealth ecosystem operators may need to monitor BCI users to detect whether use of the devices is generating addictions or harmful personality changes (Clausen, 2011, p. 499). Even non-invasive BCIs designed for seemingly harmless purposes may be employed by their users in ways that raise ethical questions for an ecosystem's managers. For example, BCIs ostensibly designed for educational purposes may yield more knowledgeable users but can also potentially generate negative effects such as increased selfishness, extremism, confusion, or manipulability (Bostrom and Sandberg, 2009, pp. 322-23). Moreover, if BCIs are used to link human minds to create a 'collective intelligence' of direct brain-to-brain communication, an ecosystem's operator may be responsible for preventing such interaction from erupting into the sort of 'flame wars' and trolling that are commonly found on the Internet and which can cause "stress and unpleasantness for everyone involved" (Bostrom and Sandberg, 2009, p. 322) – especially given some BCIs' powerful ability to force incoming communications into a user's immediate conscious awareness.

Bostrom and Sandberg note that economic competition and the need to secure and maintain a job might eventually force individuals to utilize BCIs who would otherwise never voluntarily choose to use them (Bostrom and Sandberg, 2009, p. 328; Gladden, 2016). Similarly, if the best and most effective health care ecosystems employ widespread BCIs for the provisioning of care, individuals may feel pressured to utilize such technologies in order to access adequate care. This raises questions of *consent* that must be monitored and addressed by an eHealth ecosystem's operators.

Moreover, BCIs in use generate large quantities of sensitive information (e.g., about a user's mental states, physical activities, social interactions, location, and environment) whose *privacy* must be safeguarded within an eHealth ecosystem. For example, even BCIs that do not typically create a permanent recording of a patient's electroencephalographic signals may do so during a device's training phase (e.g., when a patient is learning to control a motor prosthesis); Clausen (2011, p. 498) raises the ethical question of whether employers and insurers should be allowed to access such information. BCIs can also potentially be utilized by criminal hackers and other adversaries as a new and more effective tool for accessing or manipulating the data of an eHealth ecosystem's members – including those who do not possess BCIs (Gladden, 2015).

Ensuring *equity* in this stage involves guaranteeing that the providers of BCIs or BCI-related services do not take advantage of their possession of sensitive user data or users' physical and psychological dependency on such devices (Bostrom and Sandberg, 2009, p. 323) to unjustly exploit or extort their

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users. Issues of *liability* are also important; for example, a BCI that allows a paralyzed patient to steer a motorized wheelchair must continuously detect and interpret the patient's brain signals, and the system will inevitably make errors that occasionally cause the wheelchair to move in an unintended manner, thereby potentially causing accidents that harm persons or property. Clausen (2011, p. 499) notes that a majority of surveyed BCI experts would attribute responsibility for such accidents to a system's user (Nijboer et al., 2013), but insurance companies or other participants in an ecosystem might instead be assigned responsibility.

SDLC Stage 5: The Disposal Stage

The ethical factor of *beneficence* requires that before managers and decision-makers permanently remove or limit the existing connection of BCIs to an eHealth ecosystem, they first ascertain whether such actions may cause immediate or future harm to the users of those devices (Gladden, 2015, p. 175). Given the fact that both the use of certain kinds of BCIs as well as the discontinuation of their use can have profound psychological and physical effects on their users, it may be necessary to obtain the *consent* of individual BCI users before changes are made to an eHealth ecosystem that result in a loss of BCIs' ability to interface with the system and utilize its services. In some cases, it may be unethical to disable or disconnect a BCI against its user's will, even when the device no longer serves the medical purpose for which it was originally prescribed (Clausen, 2011, p. 499).

In this stage, the ethical dimension of *privacy* involves ensuring that sensitive user data generated by BCIs' interaction with the eHealth ecosystem and stored within the system is permanently safeguarded, even after the BCIs' ability to participate in the ecosystem has been terminated. The ethical dimension of *equity* involves determining in a fair and impartial way which BCI services and interfaces are to be discontinued – e.g., as a result of budgetary constraints in managing an ecosystem. The ethical dimension of *liability* is reflected, for example, in questions of financial and legal responsibility for any harm occurring to individual users or their property due to actions by an ecosystem's operators that result in the disconnection or disabling of BCIs participating in the system (Bostrom and Sandberg, 2009, p. 323).

CONCLUSION

When seeking to incorporate innovative forms of ICT like brain-computer interface technologies into eHealth ecosystems, the operators of such ecosystems must grapple with a complex array of ethical questions that are not directly and comprehensively addressed by existing approaches within business ethics, health care ethics, and the ethics of BCIs. By utilizing a framework such as the one formulated in this text, managers can systematically identify ethical issues relating to BCIs and understand them as

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questions of *beneficence*, *consent*, *privacy*, *equity*, and *liability* which can be addressed as they become relevant during the SDLC stages of *analysis and planning*; *design, development, and acquisition*; *integration and activation*; *operation and maintenance*; and *disposal*. It is hoped that this framework may facilitate the incorporation of beneficial BCI technologies into eHealth ecosystems in ways that fulfill ethical demands arising from regulatory requirements and the expectations for best practices on the part of stakeholders including patients, medical personnel, government policymakers, taxpayers, device manufacturers, and ecosystem operators. The application of this management tool in the case of BCIs may also lay the groundwork for its use when integrating other forms of innovative ICT into eHealth ecosystems. Giving the growing social and economic significance of advanced health care within aging societies, the expanding role of BCIs in facilitating the provision of high-quality health care, and emerging possibilities for the use of BCIs in human augmentation, the importance of conceptual frameworks that can assist eHealth ecosystem operators in managing the ethical dimensions of such sophisticated technologies is only likely to grow in the coming years.

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