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“The future is already here — it's just not very evenly distributed.”

William Gibson

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II. Extended Abstract

Intelligent computing is rapidly reshaping healthcare. In light of the global burden of population aging and neurological disorders, dementia and elderly care are among the healthcare sectors that are most likely to benefit from this technological revolution. Trends in artificial intelligence, robotics, ubiquitous computing, neurotechnology and other branches of biomedical engineering are progressively enabling novel opportunities for technology-enhanced care. These Intelligent Assistive Technologies (IATs) open the prospects of supporting older adults with neurocognitive disabilities, maintain their independence, reduce the burden on caregivers and delay the need for long-term care (*1, 2*). While technology develops fast, yet little knowledge is available to patients and health professionals about the current availability, applicability, and capability of existing IATs. This thesis proposes a state-of-the-art analysis of IATs in dementia and elderly care. Our findings indicate that advances in intelligent technology are resulting in a rapidly expanding number and variety of assistive solutions for older adults and people with neurocognitive disabilities. However, our analysis identifies a number of challenges that negatively affect the optimal deployment and uptake of IATs among target users and care institutions. These include design issues, sub-optimal approaches to product development, translational barriers between lab and clinics, lack of adequate validation and implementation, as well as data security and cyber-risk weaknesses. Additionally, in virtue of their technological novelty, intelligent technologies raise a number of Ethical, Legal and Social Implications (ELSI). Therefore, a significant portion of this thesis is devoted to providing an early ethical Technology Assessment (eTA) of intelligent technology, hence contributing to preparing the terrain for its safe and ethically responsible adoption. This assessment is primarily focused on intelligent technologies at the human-machine interface, as these applications enable an unprecedented exposure of the intimate dimension of individuals to the digital infosphere. Issues of privacy, integrity, equality, and dual-use were addressed at the level of stakeholder analysis, normative ethics and human-rights law. Finally, this thesis is aimed at providing evidence-based recommendations for guiding participatory and responsible development in intelligent technology, and delineating governance strategies that maximize the clinical benefits of IATs for the aging world, while minimizing unintended risks.

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IV. List of Tables

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VI. List of Abbreviations

- AAL: Ambient Assisted Living
- ACC: Anterior Cingulate Cortex
- AD: Alzheimer's Disease
- ADL: Activities of Daily Living
- AI: Artificial Intelligence
- ALS: Amyotrophic Lateral Sclerosis
- AR: Augmented Reality
- AT: Assistive Technology
- ATM: Automatic Teller Machine
- BCI: Brain-computer Interface
- BRAIN Initiative: Brain Research through Advancing Innovative Neurotechnologies
- BWC: Biological Weapons Convention
- CANE: Camberwell Assessment of Need in the Elderly
- CDR: Clinical Dementia Rating
- CE: Cognitive Enhancement
- CoE: Council of Europe
- CPU: Central Processing Unit
- CWC: Chemical Weapons Convention
- DARPA: Defense Advanced Research Projects Agency
- DBS: Deep Brain Stimulation
- DIY: Do-It-Yourself
- DoH: Declaration of Helsinki
- DTI16: Dementia Technology Index 2016
- ECG: Electrocardiogram
- ECHR: European Convention on Human Rights
- ECT: Extended Cognition Thesis
- ECtHR: European Court of Human Rights
- EEG: Electroencephalography
- EGEP: Essentials of Good Epidemiological Practice

- EKNZ: Ethics Committee Northwest/Central Switzerland
- ELSI: Ethical, Legal and Social Implications
- EM: Extended Mind
- EMBS: Engineering in Medicine and Biology Society
- EMG: Electromyography
- ERP: Event-related Potential
- eTA: Ethical Technology Assessment
- EU: European Union
- EU CFR: European Charter of Fundamental Rights
- FDA: Food & Drugs Administration
- FES: Functional Electrical Stimulation
- fMRI: Functional Magnetic Resonance
- GABA: Gamma-Aminobutyric Acid
- GB: Gigabyte
- GDPR: General Data Protection Regulation
- GEPND: General Elderly Population with Neurocognitive Disabilities
- GP: General Practitioner
- GPS: Global Positioning System
- HBP: Human Brain Project
- HIPAA: Health Insurance Portability and Accountability Act
- HMI: Human-Machine Interface
- HRI: Human-Robot Interaction
- HRSI: Human-Robot Safe Interaction
- HRQoL: Health-Related Quality of Life
- IAT: Intelligent Assistive Technology
- ICCPR: International Covenant on Civil and Political Rights
- ICD: International Classification of Diseases and Related Health Problems
- IDI: In-depth interview
- ICMS: Intracortical Microstimulation
- ICT: Information and Communication Technology
- ICU: Intensive Care Unit
- IDHGD: International Declaration on Human Genetic Data

- IEEE: Institute of Electrical and Electronics Engineers
- IHL: International Humanitarian Law
- IOCTA: Internet Organised Crime Threat Assessment
- IoT: Internet of Things
- IRB: Institutional review board
- MCI: Mild Cognitive Impairment
- MEG: Magnetoencephalography
- MPC: Model Penal Code
- Near-infrared Spectroscopy
- NIA: Neurotechnology for Intelligence Analysts
- NIH: National Institutes of Health

  NSA: National Security Agency
- NTC: NeuroTechnology Center
- OECD: Organization for Economic Co-operation and Development
- PD: Parkinson's Disease
- PDA: Personal Digital Assistant
- PED-ART: Proactive Ethical Design for Assistive & Rehabilitation Technology
- PIA: Privacy Impact Assessment
- PIN: Personal Identification Number
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- PSR: Potential Support Ratio
- PTA: Post-Traumatic Amnesia
- PUC: Pervasive and Ubiquitous Computing
- QoC: Quality of Care
- QoL: Quality of Life
- RCT: Randomized Controlled Trial
- RESNA: Rehabilitation Engineering and Assistive Technology Society of North America
- SAL: Smart Assistive Living
- SAR: Socially Assistive Robot
- SORM: System for Operative Investigative Activities
- SST: Steady State Topography
- STS: Sit-to-Stand

- TA: Technology Assessment
- TACS: Transcranial alternating current stimulation
- tDCS: Transcranial Direct Current Stimulation
- TEU: Treaty of the European Union
- TMS: Transcranial Magnetic Stimulation
- UC: User-centered
- UCD: User-centered Design
- UDHR: Universal Declaration of Human Rights
- UDHGR: Universal Declaration on the Human Genome and Human Rights
- UK: United Kingdom
- US: United States
- VaD: Vascular Dementia
- VR: Virtual Reality
- VS: Value-sensitive
- VSD: Value-sensitive Design
- WHO: World Health Organization
- WIA: Wearable Impact Assessment

VII. Intellectual Property Disclosure

This thesis is the cumulative product of collaborative research. While sections one, three, four and five are entirely written by the PhD candidate (MI), many original contributions presented in section two have shared intellectual property. Full authorship disclosures are presented at the beginning of each Chapter.

VIII. Methodology

This thesis summarizes the main findings and implications of a 3-year research project conducted at the University of Basel between September 2014 and August 2017. The study obtained an official waiver (*Unbedenklichkeitserklärung*) from the Ethics Committee Northwest/Central Switzerland (EKNZ). The Committee motivated that the study was “ethically unobjectionable” (*ethisch unbedenklich*), hence did not require further approval from EKNZ. The protocol synopsis submitted to EKNZ is presented in Appendix 6.

The project was structured modularly and articulated into three main Modules.

Module 1: Systematic Literature Review and Technology Index

In the first Module, a systematic review of the relevant literature on IATs for dementia and elderly care was conducted. A literature search was performed for English language articles indexed in the following search engines and bibliographic databases: IEEE, PubMed, Scopus, PsycINFO, and Web of Science. The following query logic was developed and pilot-tested (see Tab. 1). Whenever necessary, the query was modified to adapt to the language used by each engine or database.

LOGICAL OPERATOR	AND	AND	AND
OR	assistive technolog*	Intelligent	Alzheimer*
OR	assistive device	Adaptive	dementia
OR	assistive application	Computer	ag*ing
OR		Robotic	Elder*

Tab. 1- Query logic for systematic literature review

Inclusion Criteria: In order to be included into the quantitative synthesis, retrieved articles had to meet the following inclusion criteria:

- Were published in the format of original articles, book Chapters or conference proceedings. Reviews, commentaries, letters to the editors, and opinion articles were not considered;
- Were written in English;

- Were published in the period between January 1, 2000 and April 12, 2016;
- Presented the (a) design and development, or (b) assessment and evaluation of one or more intelligent assistive systems with current or potential applications to dementia

Filtering: Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (*3*), four steps of filtering were performed: duplicates removal, eligibility assessment, in-depth review of full-text articles, and screening and further review of secondary sources. In the first phase of filtering, duplicates were removed using both the ENDNOTE tool for duplicate detection and manual techniques. Second, eligibility assessment was performed on the remaining papers to remove sources that did not meet the review's inclusion criteria (*4*). Third, in-depth review was performed on the full-text articles of the remaining entries included in the synthesis. Fourth, additional records were identified by reviewing the references of all articles included in the synthesis and underwent in-depth review. For a detailed visualization of the filtering process see flow diagram presented in Fig. 2. Two reviewers performed all stages of filtering independently, and only the papers rejected by both reviewers were removed from the working corpus.

Clustering: In order to produce an informative and logically consistent technology index, retrieved IATs were clustered according to the following main characteristics: (I) technology type, (II) application, (III) function assisted, (IV) user-centered design, (V) primary target-user population, (VI) evidence of clinical validation, and (VII) and ethical values in product design.

Characteristics I-VI and VII were organized in two distinct datasets and analyzed separately from each other in order to explore two distinct research questions:

(I-VI) Assessing the number, availability, capability and applicability of current IATs for dementia and elderly care.

(VII) Investigating the prevalence and distribution of value-sensitive approaches and ethical considerations in IAT design.

Research question A is addressed in Chapter 2.1 of this thesis, whereas B in Chapter 2.2. While clusters I to VI were analyzed using quantitative analysis (e.g. frequency distribution), cluster VII was analyzed using both quantitative and qualitative (qualitative content analysis and disclosive computer ethics) methods.

Module2: Qualitative Interviews with Health Professionals

In the second Module, qualitative interviews with relevant stakeholders were conducted. The goal of this qualitative Module was to generate original information on the views, attitudes and needs of health professionals concerning the use of IATs in dementia and elderly care. This research strategy was employed to generate person-centered insights on the use and applicability of IATs in the clinical setting (both institutional and home care) and to explore possible barriers to the clinical implementation of current IATs.

Study sample: The study participants for this Module included health professionals from Switzerland, Germany and Italy. The rationale for that stems from the fact that these three countries have among the highest longevity and lowest birth rate in the world, hence are particularly exposed to population aging. The study participants were actively working within the fields of geriatrics, psychiatry, neurology, neuropsychology, gerontology, nursing, and healthcare management. In addition, they had direct experience and were actively working within the field of dementia and elderly care.

Participants were purposively selected based on their professional profiles and recruited through personal communication at research institutions or e-mail communication. Such purposive sampling strategy was adopted from previous research in order to obtain a diverse selection of stakeholders from both private and public health institutions with varying professional experience.

A total of 18 stakeholders were selected but one respondent dropped out from the study due to health issues. Therefore, a total of 17 interviews were completed. The invitation message contained the following information: (i) title of the study: *"Health professionals' views on Intelligent Assistive Technology for Dementia and Elderly Care"*, (ii) study rationale, design and purpose (iii) interview methodology and approximate length, (iv) safeguards employed for the protection of confidentiality and anonymization of the collected data, (v) contact details of the research team, as well the (vi) informed consent form.

Informed consent: Following international research ethics guidelines, written informed consent was obtained from research participants prior to enrolling them in the study. A template of the informed consent form used in this study is presented in Appendix 5.

Interview guide: The inquiry method used in this Module was semi-structured interviews (*5*). Interviews examined the critical needs, wishes and attitudes of health professionals regarding the opportunities and challenges of IAT in dementia and elderly care. Together with participants' experiences and perceptions, the interviews sought to understand what critical physical and psychosocial needs arise as a consequence of diminishing health and how technological solutions could empower patients and allow them to have some level of healthy aging. Finally, the interview questions sought to identify critical barriers to IAT adoption in the clinical setting. In addition to open-ended questions, this semi-structured interview guide also contained several closed ended questions based on the results obtained in Module 1 (*6*).

Interview and analysis: The interviews were carried out by the PhD candidate author of this thesis. Interviews were recorded and transcribed verbatim using the *f4transkript* software[1]. Interview transcripts were analysed using content analysis. The following qualitative analytic strategy was employed: multiple readings of interview responses and reflective process notes followed by thematic coding. Data analysis was performed with the assistance of the MAXQDA software for computer-assisted qualitative analysis (release 12.3.1)[2].

Module 3: Conceptual and Normative Analysis of Ethical, Legal and Social Implications (ELSI)

Our systematic review results (see Module 1) revealed which ethical considerations are most neglected in current IAT design. This information was triangulated with our interview results (see Module 2), which delineated a number of clinical needs and technical features that should be prioritized in IAT development. The triangulation of these results and further literature review identified which ethical gaps in IAT design require urgent assessment to guarantee the safe and responsible clinical implementation of these technologies. Four ethical themes emerged as primary salient: privacy, data security, autonomy and justice.

1 For a full description of software specifications see: https://www.audiotranskription.de/english/f4.htm

2 MAXQDA is a property software developed and distributed by VERBI Software. See: http://www.maxqda.com/

Subsequently, conceptual, normative and legal analysis was performed to explore the major ethical, legal and social implications (ELSI) associated with the use of IATs in relation to these four major themes. First, conceptual analysis (*7*) in conjunction with literature review was employed to delineate a theoretical framework for machine and cyborg ethics that could account for the interaction between humans and machines enabled by IATs. Second, normative ethical analysis in conjunction with literature review and argumentative technology assessment (*8*) was employed to investigate the implications of IATs for the four ethical themes described above. Third, legal document analysis in conjunction with literature review and standard technology assessment was employed to investigate the implications of IATs for the legal entitlements associated with the four themes described above.

Finally, the normative evaluations resulting from this Module of the study were used to provide a set of recommendations for relevant stakeholders (health professionals, policy-makers and regulatory bodies) in relation to the responsible use of IATs.

This this third and last Module of the thesis configures as an ethical Technology Assessment (eTA) of intelligent technology. An eTA is an ethics-focused form of technology assessment serving as "a tool for identifying adverse effects of new technologies at an early stage" (p.543) (*9*). The eTA presented in this thesis is designed to anticipate possible adverse effects of advancing intelligent technology and inform responsible innovation in this emerging field. Methodologically observed, this thesis complies with the nine-point checklist developed by Palm and Hansson as a guiding reference for eTA (ibid).

Part 1: General Introduction

"Today's AI is about new ways of connecting people to computers, people to knowledge, people to the physical world, and people to people."

Patrick Winston

1.1. The Global Burden of Population Aging and Dementia

1.1.1. Population Aging

Today, humans are living longer than ever in history. Most people currently alive can expect to live into their sixties and beyond (*10*). As the median age in the world population increases, human societies are facing a global phenomenon known as *global population aging* (*11*). Due to a demographic regime characterized by rising life expectancy and/or declining fertility rates, over 900 million people worldwide were reported in 2015 to be over the age of 60, comprising approximately 12% of the world's population. In the next three decades, this proportion is predicted to double and the overall number of people aged 60 years and older is expected to reach two billion (*12*).

This demographic trend is particularly recognizable in the European continent. Forecasts predict that the proportion of individuals older than 65 years in Europe will reach 27.5 % by 2050 (*13*). In parallel, the relative proportion of the oldest-old is set to increase at a faster pace than any other population segment. As a consequence of that, the share of people aged 80 years and older in the European population is projected to increase from 5.4 % to 12.7 % in the next few decades (*14*).

This relative increase in the share of older people in the total population is particularly accentuated in countries characterized by higher life expectancy at birth and lower fertility rates. People living in European countries like Switzerland, Italy and Germany have among the world's highest life expectancy at birth (Switzerland 83.4; Italy 82.7; Germany: 81.0) and the lowest fertility rates (Italy 1.43 births/woman; Germany: 1.44; Switzerland: 1.55) (*15*). In these countries, people aged 60 years and over already account for nearly one fourth of the total population (Italy: 28.6; Germany: 27.6; Switzerland: 23.6%) and are expected to account for approximately one third by 2030 (*16*).

Global population aging is associated with a number of profound societal transformations. One of these is the declining share of working-age persons in the population. The old-age dependency ratio[3] for the EU-28 zone was 29.3 % in 2016, meaning that there were nearly four persons of working age for every senior person. In countries like Italy (34.3%),

[3] The old-age dependency ratio is a metrics used to measure the level of support given to younger and/or older persons by the working age population. This ratio is expressed in terms of "the relative size of younger and/or older populations compared with the working age population" 14. Eurostat. (European Commission Luxembourg, 2017).

Switzerland (33.3%)[4] and Germany (32%) this dependency ratio has already shrunk to only three working age people for every person aged 65 and older (*14*). With the increasing number of senior citizens who are no longer in working age, this phenomenon will likely result in an increased financial burden on retirement plans and national pension systems (*13*). This is feared to jeopardize the long term sustainability of the solidarity-based European health care (*17*).

Concurrently, the expansion of the old-age dependency ratio will likely result in a shortage of caregivers as the number of older people who need care is growing at a faster pace than the number of younger people who can provide (either formal or informal) care and assistance (*18*). Caregiver shortage is particularly alarming in light of the fact that the probability of becoming physically or cognitively disabled significantly increases with age. Cross-sectional comparisons show that increased age is associated with lower levels of cognitive performance, with some cognitive functions beginning to decline already in young adults and then worsening dramatically after the age of 60 (*19, 20*). In light of their higher risk of physical and cognitive disability, older adults often require assistance and care (*21*).

1.1.2. Aging and the Burden of Neurological disorders

Global population aging brings forth a number of health-related concerns since age is the main risk factor for the most prevalent diseases of developed countries: cancer, cardiovascular disease and neurological disorders[5] (*23*). Neurological disorders are disorders of the central nervous system (*24*). These include those conditions that are caused by progressive neurodegenerative disease such Alzheimer's and Parkinson's disease (PD) or traumatic injury.

Neurological disorders affect hundreds of millions of people worldwide –approximately one in six individuals– and their prevalence strongly correlates with advancing age (*22*). For example, Alzheimer's disease (AD) affects less than 1% of the population under the age of 59, almost 4% of the population segment aged 60-79, and over 11% of those aged 80-89 (*25*). With the ageing of the global population, the number of people with AD worldwide is expected to

[4] Swiss Federal Statistical Office (FSO): https://www.bfs.admin.ch/bfsstatic/dam/assets/349257/master

[5] In this thesis, the term "neurological disorder" and its definition are used in accordance with the World Health Organization's report *"Neurological Disorders: Public Health Challenges"* 22. WHO, "Neurological disorders: public health challenges," (World Health Organization, Brussels/Geneva, 2006).. Further information about the use of this term is available here: http://www.who.int/features/qa/55/en/

nearly triple by 2050 (*26*). By 2050, there will be 135.5 million people with AD worldwide, 1 in 85 people globally (*27*).

AD is not the only neurological disorder whose risk and prevalence increase with age. Research indicates that advancing age is "the biggest risk factor" also for PD, as age-related decline causes increased neuronal loss within this disease (*28*). The same goes for vascular dementia (VaD) (*29*). Age is widely acknowledged as a major risk factor not only for progressive neurodegenerative disorders but also for stroke. Evidence shows that the risk of stroke increases with advancing age, as its incidence doubles with each decade after the age of 45 years (*30*). Over 70% of all strokes are reported to occur above the age of 65 (*31*).

Many neurological disorders determine chronically disabling and incurable conditions whose effects may continue over long periods of time (years or decades). For example, AD causes an irreversible neurodegeneration whose disabling effects dramatically increase over time and are eventually fatal (*26*). As the brain is the principal site of human cognition, emotion and behavior, neurological disorders ─including neurodegenerative diseases as well as traumatic injury and stroke─ can result not only in physical but also in cognitive, emotional, and behavioral symptoms. In addition, they are a major cause of permanent physical and neurocognitive disability (*22*). Some neurological disorders such as AD and PD can lead to a degree of decline in cognitive and other mental function that is severe enough to interfere with daily life. *Dementia* is the overall term used to describe this general condition of neurocognitive disability ─e.g. decline in memory, reasoning, judgment, attention, language and other cognitive functions─ and the wide range of associated symptoms[6].

Old age is also associated with what has been *multimorbidity* (*21*). This includes higher rates of mental health morbidity. According to the WHO, one in four older adults worldwide experiences some mood disorder including depression and anxiety disorders (*32*). Such trends are particularly concerning in light of the fact that current preventative services for this population are limited and, as the WHO reports, only one-third of older adults with mental health problems receives treatment. The high number of untreated seniors with mood disorders results in poor health outcomes, higher health care utilization, increased disability and impairment, compromised quality of life, increased caregiver stress, increased mortality, and higher risk of suicide. In fact, people aged 85+ reportedly have the highest suicide rate of any age group (*33*).

6 For a detailed definition of dementia see the Alzheimer's Association's pamphlet *"What is Dementia?"*: http://www.alz.org/what-is-dementia.asp

The rising proportion of older people and the associated prevalence of neurological disorders are placing an upward pressure on overall health care spending in several countries. According to a recent review, neurological disorders represent a major social and economic burden globally. Their yearly costs in the sole European continent were estimated around 800 billion euros and the number of afflicted people reached 179 million (*22*). Based on the facts, researchers have concluded that neurological disorders "are an unquestionable emergency and a grand challenge for neuroscientists" (*34*).

Within the domain of neurological disorders, AD and other dementias are considered to be a major component of the global burden of disease and among the most expensive diseases in human societies, with an average price tag in 2013 of around $160 billion (*35*). According to the World Alzheimer Report, the estimated global cost of dementia –including both formal and informal care- was $818 billion in 2015 (*36*). These significant costs arise primarily from long-term care at nursing homes and other health-care institutions, whose burden affects not only public finances but also older patients, their non-professional caregivers (e.g. spouses and relatives) and the health-care system. At the family level, the problem of population ageing results in a caregiving burden on informal carers (*36*). In most countries, care, assistance and support for elderly and disabled adults are primarily provided by their informal caregivers, who are mostly family members such as spouses, children and grandchildren (*37*). This informal caregiving service is highly time consuming and requires great effort from caregivers in terms of physical and mental energy. The provision of caregiving services frequently comes at high socioeconomic cost for caregivers, who often need to give up jobs, leisure time, and social activities to effectively take care of their loved ones (*38*). As research increasingly shows (*38-40*), the informal caregiving burden for elderly and disabled people is a significant source of psychological distress for carers, worsened mental health functioning, anxiety, perceived stress, and depression (*38*). As most caregivers of elders with physical or cognitive disabilities are themselves growing older (average age 63), and one third of them are reported to be in fair to poor health (*41*), the reduction of caregiving burden is expected to contribute to the promotion of healthy and successful ageing within society at large. In spite of this multi-domain burden, informal care is neither accounted for nor reimbursed in many national healthcare economies (*42*). Finally, at the individual level, older adults with dementia or other age-related cognitive decline are reported to experience diminished quality of life, reduced autonomy, independence, and work productivity (*26*).

For these reasons, the WHO and the Lancet Commission on dementia prevention, intervention and care, have recently described global ageing and the consequent increasing prevalence of AD and other dementias as a “priority for public health” (*41, 43*) and called for urgent strategies to tackle this global problem. This call echoes previous warnings, such as those of the Working Party on Biotechnology of the Organization for Economic Co-operation and Development (OECD), which back in 2013 defined dementia a “grand global challenge” which requires the development of a multi-national plan (*44*).

1.2. Intelligent Technology in the Aging World

1.2.1. Computers in Medicine: Current and Emerging Trends

In response to the global burden of age-related neurological disorders and in absence of significant progresses in pharmacological therapy, coordinate and innovative solutions are increasingly required to tackle this national and global crisis. Among these innovative solutions, the integration of advanced Information and Communication Technology (ICT) and biomedical engineering into standard care is rapidly emerging as a viable strategy to optimize healthcare expenditures, enhance care provision and improve the quality of life of patients.

In particular, four emerging trends in ICT and biomedical engineering have shown a potential from the perspective of dementia and elderly care: robotics, Pervasive and Ubiquitous Computing (PUC), neurotechnology and Artificial Intelligence (AI).

Robotics is the branch of computer technology that deals with the design, development and application of autonomous or semi-autonomous machines called *robots*. In recent years, the use of robots in healthcare has increased in number, magnitude and variety. Today, machines capable of automatically carrying out a complex series of actions are available to complement and enhance standard care for a variety of medical applications including telesurgery (*45*), disinfection (*46*), pharmacy dispensing (*47*), telepresence as well as assistance and rehabilitation (*48*).

PUC is the embedment of computing capabilities in various devices, formats and locations with the purpose of making computation available anytime and anywhere. While traditional personal computers were physically confined to the desktop site, PUC trends enabled to “move the site and style of interaction beyond the desktop and into the larger real world where we live and act" (*49*). Today, computing capabilities are increasingly embedded in everyday objects (from clothing to cars and home appliances) and in a variety of settings, including healthcare. Medical uses of PUC include ambulatory care, home/mobile care, emergency medicine and rehabilitation (*50*).

Neurotechnology is a trend in biomedical engineering concerned with the development of technologies that can directly monitor, visualize, measure, restore and even improve neural function. Neurotechnologies include brain measurement technologies like electroencephalography (EEG), neuroimaging techniques (e.g. functional magnetic resonance - fMRI), electric or magnetic neurostimulators (e.g. transcranial direct current stimulation -tDCS), brain-computer interfaces (BCIs) and neural implants. These tools can be used for a variety of clinical purposes including prevention, diagnostics, functional restoration and neurorehabilitation. Neurotechnologies can be either invasive or non-invasive. Invasive neurotechnologies monitor, measure, restore and modulate brain functions through surgical implantation on brain tissue. In contrast, non-invasive neurotechnologies enable the accomplishment of those tasks via electrodes or other components placed outside the skull. The massive deployment of clinical neurotechnologies is often considered a promising complementary strategy to drug therapy to tackle the global burden of neurological disorders and associated mental health issues (*51-53*). For this reason, several countries are pushing research in neurotechnology to the frontline of their scientific agenda. For example, the US White House has launched in 2013 the BRAIN Initiative (Brain Research through Advancing Innovative Neurotechnologies Initiative), a generously funded (current annual budget over $300 million) aimed at developing and applying innovative technologies that can improve the understanding of brain function and tackle neurological disorders[7]. Researchers have argued that efforts need to be made to internationalize this neurotechnology-oriented research agenda (*54*).

In order to provide flexible and adaptive solutions in care settings, robots, embedded systems and neurotechnologies all need to perceive their environment, classify information and take action in a specific context in a manner that maximizes their chances of success at some goal. For this reason, they need to exhibit some degree of intelligence. The capacity of computers to exhibit intelligence or "act intelligently […] in increasingly wider realms" (*55*) is called Artificial Intelligence (AI). Chief examples of AI include the ability of robots to manipulate objects, navigate spaces, plan motion or process natural language as well the ability

[7] For further information see: https://www.braininitiative.nih.gov/

of PUC systems to inductively predict aspects of their environment from sensor inputs. Similarly, neurotechnologies increasingly use AI to classify the information generated from neural recordings (*56*). In a more narrow sense, however, AI refers to the hypothetical capacity of machines to flexibly simulate human cognitive functions such as learning, reasoning and knowledge representation ─an hypothesis known as *strong AI* (*57*) or *artificial general intelligence* (*58*). Authors have introduced the notion of *superintelligence* to refer to the possibility that AIs might surpass human brains in general intelligence. Since machine intelligence is not subject to the same physical and biological constrains of human intelligence, this possibility is considered by many researchers a realistic outcome of linear development in AI and general computing (*59, 60*).

Besides robotics, PUC and neurotechnology, clinical applications of AI include medical assistance. The data flows generated by PUC-enhanced care environments, robots, neurodevices as well as other digital information (e.g. digital medical records and patient dossiers) can now be aggregated into comprehensive datasets and *mined* using intelligent technology to discover medically relevant patterns. Intelligent medical assistants use AI to enable predictive analysis of large data volumes and can enhance medical decision making at various levels including prevention, diagnosis, therapy, care delivery and care management. These tools – especially those using machine learning such as IBM Watson (*61*) – are showing a great potential in optimizing and guiding medical decision making as well as delivering personalized solutions to patients (*62*). Successful applications of this technology could identify clinically significant patterns among large volumes of heterogeneous medical records and other health information and deliver patient-centered solutions that maximize clinical efficacy and optimize resource allocation. AI can also be used to improve device performance. In fact, robots, PUC systems and neurotechnologies increasingly use aspects of AI to improve their precision, accuracy, reliability and flexibility (*63, 64*).

This thesis will use the umbrella term *intelligent technology* to refer to the wide realm of ICT applications described above. The common denominator of these technologies, in fact, is the capacity to process information and simulate aspects of human intelligence such as sensing, perception, memory, planning, problem-solving, inductive and deductive reasoning, as well as adaptive behavior. It is worth noting that the adjective *intelligent* in intelligent technology is not used in this thesis in its narrow denotation, i.e. exclusively to refer to machines capable of passing the Turing test[8]. Rather, it is used in the broad sense of "simulating aspects of human intelligence", regardless of whether they do it in a manner that outperforms human ability.

1.2.2. Intelligent Technologies for the Aging Brain

Dementia and elderly care are among the divisions of healthcare provision that are expected to benefit the most from this technological revolution (*1*). The reasons are multifold. First, given the high relative costs of formal and informal care (*66*), technological systems capable of delaying or obviating the need for long-term care could reduce healthcare costs and secure the provision of institutional services among a rapidly growing ageing population (*67*). Second, given the erosion of the old age support and the caregiver-to-patient ratio (*68*), the massive deployment of technology-assisted care could supplement the incipient shortage of human caregivers and complement current care provision, hence reduce the burden on unpaid caregivers and improve the quality of care (*2*). Third, in the absence of effective therapeutic solutions for many age-related neurological disorders such as AD, medical AI, wearable devices, and assisted-living solutions have the potential to reveal insights from large amounts of unstructured data, hence spark innovation in prevention, diagnostics, personalized therapy and care management (*69*). Fourth, the incorporation of computing and, in particular, AI into care platforms and care environments could favor the delivery of personalized, adaptive and patient-centered care solutions (*70*). This would have a twofold consequence: (i) helping patients fulfill their wish to live autonomously and age in place and (ii) improve their quality of life. Finally, wearable PUC devices, digital phenotyping and neuromonitoring technologies enable remote monitoring and continuous collection of electrophysiological data (*71*, *72*), hence open new possibilities for the self-assessment of patients' physical and mental activity and the early detection of anomalies.

1.2.3 What Is an Intelligent Assistive Technology?

Older people and patients with dementia require increased physical and cognitive assistance compared to younger and healthy individuals. Therefore, a primary task of dementia

[8] The Turing test, firstly developed by Alan Turing in 1950 65. A. M. Turing, Computing machinery and intelligence. *Mind* **59**, 433-460 (1950)., is a theoretical procedure to test whether a machine has the ability to exhibit intelligent behavior equivalent to, or indistinguishable from, that of a human.

and elderly care is to provide assistance to this population in need. Research shows that trends in computing and biomedical engineering are creating new opportunities for the development of technologies that can deliver such assistance (*73-75*).

Assistive technology (ATs) is the umbrella term used to encompass the wide and heterogeneous domain of technological applications in healthcare for assistance purposes. The UK Royal Commission on Long Term Care (*76*) defines AT as "any device or system that allows an individual to perform a task that they would otherwise be unable to do, or increases the ease and safety with which the task can be performed". In the context of dementia and elderly care, ATs allow to "increase, maintain or improve capabilities of individuals with cognitive, physical or communication disabilities" (p.9) (*77*). Consequently, robots, PUC-environments, neurotechnologies and AI-systems qualify as ATs as long as they are used to help people with disabilities to increase, maintain or improve their (cognitive, physical, emotional and behavioral) capabilities.

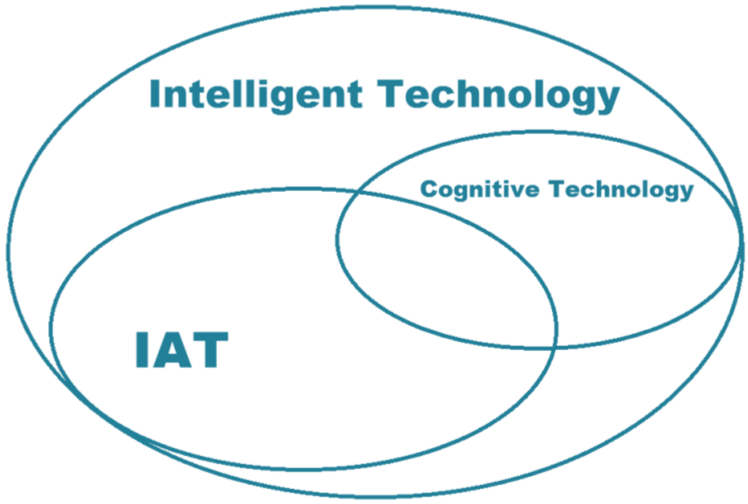

Figure 1- Conceptual and semantic relationship between different concepts (set and subsets)

In recent years, researchers have introduced the notion of Intelligent Assistive Technology (IAT) to differentiate purely mechanical ATs from technologies that incorporate computing capabilities like those described in the previous paragraph (*2*, *6*, *67*, *78*), especially aspects of artificial intelligence. In short, IATs are intelligent technologies used for assistive purposes. Unlike traditional assistive aids such as crutches, walking canes and pill dispensers, IATs have own computing capacity, can carry out complex series of actions in an automatic or semi-automatic manner and may exhibit aspects of intelligent in relation to a variety of tasks. Heterogeneous hardware technologies such as distributed systems[9], integrated sensors, handheld

[9] A distributed system is a "model in which components located on networked computers communicate and coordinate their actions by passing messages" 79. G. F. Coulouris, J. Dollimore, T. Kindberg, *Distributed systems: concepts and design*. (pearson education, 2005)..

devices (e.g. smartphones and tablets), digital assistants, robots, powered exoskeletons and wheelchairs, may all qualify as IAT.

In a few occurrences, this thesis will also use the notion of *cognitive technology*, a term firstly introduced in 2005 by Dascal & Dror (*80*), to designate the subset of intelligent technologies that assist, augment or simulate cognitive processes. This characteristic is particularly prominent in BCI and other technologies that directly interface the nervous system. However, virtually any intelligent technology can be regarded as cognitive technology if it is used in relation to cognitive processes. In addition, cognitive technologies can be regarded as IATs if they are used for assistive aims (e.g. memory support or other cognitive assistance). A visual overview of these notions and their conceptual and semantic relationships is presented in Figure 1 and Table 2.

Concept	Definition	Technological types encompassed
Intelligent Technology	Any ICT that simulates aspects of human intelligence	Robots, distributed systems, wearables, handheld devices, neurotechnologies, software and mobile apps, powered mobility aids, intelligent digital assistants
Intelligent Assistive Technology (IAT)	Any intelligent technology used for assistive aims	All of the above if used for assistive aims
Cognitive Technology	Any intelligent technology that deals with cognitive processes	All of the above if used to assist, augment or simulate cognitive processes (esp. BCI)

Tab. 2- Conceptual and semantic relationships between different concepts (synoptic view)

1.3 A Comprehensive Taxonomy of IATs for Dementia & Elderly Care

While the clinical use of IAT is increasingly raising the attention of researchers, no up-to-date comprehensive and systematic knowledge about cutting-edge IATs for the aging society was available prior to this study. Previous studies had not been systematic (*73*), limited their scope only to specific subsections of the IAT domain (*81*) or date back to the past decade, hence are not up-to-date given IAT development rates (*2*). Given the increased need for IATs in dementia and elderly care and the reported translational delay in their clinical implementation (*82*), a comprehensive technology index would be critical to orient health professionals, people in need and other stakeholders involved in the provision or reception of dementia and elderly care services (*6*). In addition, systematic and replicable approaches are highly required to organize the wide and heterogeneous IAT domain into a rigorous taxonomy or system of classification.

To this purpose, the first Module of the present study was concerned with conducting a meta-analysis of existing IATs and producing a first comprehensive index and taxonomy of the IAT domain. The methodology used in this Module of the study was a systematic review of the relevant literature and following data analysis according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (*3*). A detailed description of the study methodology is presented in Chapter 2.

Our review identified 539 IATs with current or potential applications to dementia and elderly care and revealed a linear expansion of the IAT spectrum over time, with the total number of available IAT experiencing a six-fold increase between 2006-2010 and a fifteen-fold increase in the period 2011-2016. The IAT spectrum appeared to encompass seven main technological types or families: distributed systems, robots, mobility and rehabilitation aids, handheld and multimedia devices, software applications, wearables and human-machine interfaces. Existing IATs showed applicability in a variety of domains of dementia and elderly care including: support in the activities of daily living (ADL), monitoring, physical and cognitive assistance, interaction, engagement, rehabilitation and emotional assistance. With regard to end-user populations, most devices were designed for the general elderly and disabled population, whereas smaller fractions were specifically targeting people with dementia and mild cognitive impairment (MCI). Very few IATs appeared to be exclusively designed for people with AD. A visualization of the main characteristics of the IAT spectrum is presented in Tab. 3.

Type		**Application**	**Target-user Population**
	Distributed Systems	ADL	General senior and disabled population
	Robots	Monitoring	People with AD
	Mobility & Rehabilitation Aids	Cognitive Assistance	People with MCI
	Handheld & Multimedia Devices	Physical Assistance	
	Software & Mobile Apps	Interaction/Engagement	
	Wearables	Emotional Assistance	
	Human-machine Interfaces		

Tab. 3- A Taxonomy of IATs for Dementia and Elderly Care (type, application & target-user population)

A detailed quantitative description of the study results is presented in Chapter 2.1. This Chapter also contains the state-of-the-art index of IATs for dementia and elderly care and provides an analytic discussion of the study results including their implications for clinicians, developers, healthcare services and policy makers.

1.4. Designing IATs: Current Stand & Possible Improvements

As any other (biomedical) technology, the clinical applicability of IATs is highly influenced by their process of design and development. In fact, design and development are critical phases of the production of a new technology. Design is the "specification of an object, manifested by an agent, intended to accomplish goals in a particular environment, using a set of primitive components, satisfying a set of requirements, subject to constraints" (*83*). In the subsequent development phase, such specification is programmed, built, documented and tested. The process of design and development usually results in a new *technological product*.

Research has shown that the approach to design and development adopted by technology producers highly influences the future success of a technological product (*84*). In particular, growing evidence shows that top-down approaches ─where the design and development is driven by producers─ tend to correlate with lower acceptance of IATs among users and lower chance for IATs to fulfill care needs. In contrast, bottom-up approaches ─where end-users are involved in the design and development process on an equal footage─ seem to correlate with higher acceptance and better chances for IATs to fulfill care needs (*85-87*).

An encouraging approach to improving the design and development of IATs is *user-centered design* (UCD). UCD is a strategy "based on the needs and interests of the user, with an emphasis on making products usable and understandable" (*88*). Through UC approaches, end-users' (e.g. patients' and caregivers') needs and wishes are "elicited correctly, reflected properly into the system requirements, and verified thoroughly by the tests" (ivi). In the context of IATs for elderly and dementia care, UC approaches make sure that the needs and wishes of patients, their caregivers and health professionals are (i) elicited correctly through bottom-up and participatory approaches, (ii) reflected properly into the IAT requirements, and (iii) verified thoroughly by tests and adequate clinical validation. User-centered approaches are particularly desirable in the context of IATs for AD and other dementias. In fact, one of the eight core principles for advancing Alzheimer's treatment and care postulated by the Ware Invitational Summit is precisely to engage patients and family caregivers in the decision-making process (*89*).

In order to assess current approaches to the design and development of IATs for dementia and elderly care, our meta-analysis also controlled for the prevalence of UC approaches across the IAT spectrum (n=539). Our results show that only 40.1% of reviewed IATs are explicitly designed, developed, or assessed in a user-centered manner (see Fig. 7). In addition, the slight majority of existing IATs (50.65%) did not receive any clinical validation through studies involving human subjects. These findings indicate that the clinical efficacy and safety of current IATs as well as their capacity to fulfil end-users' needs are not adequately verified at present. Even the subset of IATs that was subject to testing and clinical validation studies appeared to be affected by small sample sizes (less than 20 participants) and extremely low prevalence of randomized-controlled trials (1,1%).

However, a positive trend could be detected as the results of a logistic regression showed a statistically significant increase in UC approaches to IAT design and assessment over time. If such trend persists, most IATs are expected to be developed through UC approaches in a non-distant future.

Chapter 2.1 presents a detailed quantitative analysis of current trends in IAT design and development. In addition, it provides evidence-based recommendations about how to improve future IAT production in a manner that increases acceptance among end-users, facilitates adoption and clinical implementation, and improves the clinical validity of existing tools.

1.5. Value-Sensitive and Ethical Design in IAT

Involving end-users into the design and development process through UC approaches is not the only strategy for improving the production of IATs for dementia and elderly care. Besides transitioning to UC approaches, there is a growing consensus among researchers that IATs should account for human values, especially the ethical values of stakeholders (*90*). These considerations have led researchers in engineering and ethics of technology to develop a theoretically grounded approach to the design and development of (biomedical) technologies called value-sensitive design (VSD). Through VSD approaches, human values are incorporated into technology design "in a principled and comprehensive manner and throughout the whole process" (*91, 92*). Among these values, the moral values of direct and indirect stakeholders are often believed to play a central role. Moral values (also called *ethical values*)[10] are values related to the moral domain, i.e. the domain of life concerned with how individuals and machines "ought to behave in relation to others and themselves and how society should be organized as to promote the right course of action" (*90*). Examples of moral values include justice, equality, freedom, autonomy and privacy. Researchers have argued that the

[10] In line with the relevant literature, the terms "moral value" and "ethical value" are used interchangeably in throughout this thesis.

consideration and incorporation of moral values is a critical requirement for preventing harm, improving "human situations"(*93*) and guaranteeing responsible technology development. This ethics-focused version of VSD is often called *ethical design*. According to Karr, ethical design allows to prevent various forms of harm to technology users and other stakeholders including interpersonal (e.g. risk of stigmatization), psychological (e.g. discomfort and distress), and social/societal harm (e.g. exploitation and injustice)(*93*).

At core of the advocacy of ethical design as a strategy for technology development there is a twofold theoretical assumption. First, research in Science and Technology Studies (STS) has promoted the view that technology, its application, the practices it generates and the contexts in which it is used, are not morally neutral but raise significant ethical implications (*94*). Second, the so-called *embedded values approach* has underscored that technological artifacts "can have built-in tendencies to promote or demote particular values" (*90*). When a technological specification or other characteristic is built-in in a certain technological product to promote the realization of a (moral) value, such specification can be said to incorporate an *embedded value* (*90*). The promotion of embedded values in technology development is a central feature of ethical design.

In relation to IATs for dementia and elderly care, ethical design prescribes that IATs should account for the ethical values of elderly people (including people with a diagnosis of dementia), their caregivers as well as of health professionals involved in the delivery of care services (*30*). In compliance with VSD requirements, ethical considerations and values should be incorporated early on into IAT design "in a principled and comprehensive manner throughout the design process" (*95*).

While many experts agree that VSD and ethical design would massively benefit progress in IATs for the aging world (*96, 97*), yet information about these trends in relation to psychogeriatric care is scant. To our knowledge, no study had evaluated the prevalence of ethical values in current IATs for dementia and elderly care prior to the present research project. In absence of such studies, assessing the prevalence of VSD approaches and the ethical sensitivity of current IATs for dementia is tempered by insufficient evidence. This is significant because the lack of ethical values and considerations has been identified as a major barrier for technology transfer of IATs (*98*). In addition, healthcare professionals have urged developers to thoughtfully consider ethical and socio-cultural issues throughout the design process (*99*).

To fill this gap in the literature and corroborate decision-making on this topic with extensive evidence, we have investigated the prevalence of embedded moral values in current

IATs. As embedded (moral) values are the atomic constituents of VSD and ethical design, this study component also provided information about the frequency of these approaches in current IAT design. Chapter 2.2 presents the key findings of this analysis and provides a set of recommendations for facilitating the transition to VSD and ethical design in IAT for dementia and elderly care. Our results show that the vast majority of (67%) current IATs are developed in absence of explicit ethical considerations and values, hence not in compliance with VSD and ethical design requirements. Consequently, the current prevalence of VS and ethically-informed approaches to the design of IATs for dementia and elderly care appear rare. Furthermore, the distribution of ethical values within the subset of value-sensitive IATs appeared not uniform. In fact, values like independence and safety appeared significantly more prevalent than the values of interdependence, privacy and justice. The latter three appeared indeed remarkably rare (<10%). Based on this evidence, recommendations for designers and developers were proposed. These include the prioritization of affordable and open-source technology, a closer and more systematic cooperation between IAT designers and information security experts, as well as the incorporation of encryption, data security and other privacy-enhancing strategies. For a detailed analysis see Chapter 2.2.

The approach to the study of embedded (ethical) values in technology design employed in this study component is called *disclosive computer ethics* (*100*). The goal of disclosive computer ethics is to "uncover values and moral decisions embedded in ICT artefacts" (*90*). In most technological products, in fact, ethical values or devalues are not directly manifest to the average user, hence the ethical significance of these products remains largely undetermined. In technical terms, they are said to be *morally opaque* (*90*). This moral opacity may be due to many reasons including a lack of ethical awareness among product designers and technological complexity ─i.e. when understanding the basic features or operations of a certain technology requires sophisticated expertise in computer science and engineering, hence is hard to achieve for the layperson. IATs that involve highly complex AI features such as deep learning are even more likely to be morally opaque since the algorithms through which they operate might be inscrutable even to the engineers who created them and, in most cases, cannot be traced back (*101*). The higher the moral opacity, the higher is the risk that ethically relevant technical or emergent biases unknowingly enter the system. This could have a negative impact on end-users, a risk that is particularly problematic in relation to IATs for dementia and elderly care since their end-users belong to frail and vulnerable population segments. Through disclosive approaches such as the one presented in this study, the moral opacity of the technologies under investigation is reduced. Consequently, *moral transparency* is promoted because extensive information is provided to end-users and other stakeholders about what (moral) values are at stake in relation to those technologies.

1.6. A Framework for Ethical Design: the PED-ART Framework

The issue of addressing ethics in technology design is a relatively recent concern. Until recently, most research at the intersection between ethics and medical engineering was focused on the post-production assessment of IATs. Rather than investigating ethical values at the level of product design, previous studies were primarily concerned with assessing the compatibility of existing IAT products with ethical norms, especially as a consequence of ethical conflicts arising from the sub-optimal use of such IATs. This approach to the ethics of technology can be labeled as *reactive* because the ethical analysis is urged as a reaction to ongoing ethical or social conflicts associated with the use of IATs. However, the reported low frequency of ethical values at the level of IAT design jointly with repeated calls for VSD, have led researchers to advance the thesis that ethics should not be introduced only at the end of product development but incorporated early in the design and development process. For example, Feng (2000) has argued that there is a need for "addressing ethical concerns early on in the design of a technology", hence "bringing ethics back into design" (*102*). In Chapter 2.3, we propose a framework for the introduction of ethical values early on in IAT design with the purpose of increasing the clinical effectiveness, acceptance and ethical sustainability of this technological family. The Chapter suggests that to achieve this goal a conceptual shift is required: reactive approaches to the ethics of (bio)medical technology need to be complemented with what we called *proactive* approaches. Instead of merely reacting to existing ethical problems, proactive approaches enable the anticipation of future potential uses, requirements, and unintended consequences of new technologies before they generate ethical conflicts or other problems.

To facilitate this conceptual shift, Chapter 2.3 proposes a framework for ethical design and development in IAT. We called this framework the *Proactive Ethical Design* (PED) framework for assistive and rehabilitation technology. The PED framework is characterized by the convergence of UC and VSD approaches to technology design through a proactive mode of ethical evaluation (*103, 104*). The realization of the PED-ART framework relies on four basic normative requirements: minimization of power imbalances, compliance with biomedical ethics, translationality and social awareness. See Chapter 2.3 for a detailed characterization of this framework.

In addition, this Chapter provides an ostensive and operative model of the PED-ART framework: the Cybathlon, i.e. an international competition organized by ETH Zurich for disabled competitors allowed to use IATs (see Figure 2).

Figure 2- Photographic reports from the first edition of the Cybathlon competition. Zurich, Switzerland, October 2016. Photo credit: g.tec medical engineering GmbH.

1.7. Attitudes and Views of Health Professionals

While our review results show that the spectrum of IATs with possible direct application to dementia and elderly care is rapidly expanding in number and variety, the clinical implementation and adoption rates of these technologies are still reportedly low (*105*, *106*). Lower-than-expected acceptance and use of IATs in elderly and dementia care has been reported in a number of countries including Germany, Norway, England, France and the United States (*107*, *108*). In brief, IAT is developing at a much faster rate than patients and healthcare professionals are willing to adopt.

Investigating the views of key stakeholders involved in dementia and elderly care is gaining momentum as an effective strategy for acquiring valuable insights about possible barriers to the successful adoption of IATs in the institutional and home-care setting (*107*). Co-determinant of lower-than-expected acceptance might include demographic, socioeconomic and sociocultural factors. In addition, they might depend on the specific needs, wishes and attitudes of direct and indirect stakeholders, such as elderly people (including people with dementia), their informal caregivers and health professionals. The latter category is particularly relevant to understand barriers to the implementation of IATs in the institutional setting, as health professionals are critical decision-makers in the adoption of new medical technologies in healthcare facilities. In addition, they also have a critical advisory role in the use of IATs in the homecare setting. To date, most research has focused on the views and attitudes of direct stakeholders, especially elderly people, people with dementia and their informal caregivers (*109, 110*). More research is needed to complement existing knowledge with quantitative and qualitative evidence on the views and attitudes of health professionals towards IATs. Such studies are particularly needed in the countries that are most affected by current trends in population aging.

To this purpose, in the second Module of this PhD project, qualitative interviews with health professionals were conducted to explore the promises and challenges of IATs for dementia and elderly care. This study component involved semi-structured interviews conducted with health professionals in three among the countries with the highest longevity and lowest birthrate (Switzerland, Germany and Italy), hence particularly exposed to aging-related health burden (for a detailed description of the study methodology see Chapter 2.4). Results show that healthcare professionals identify two major barriers to adoption: (a) limitations in the design, development clinical implementation of current IATs, and (b) perceived collateral risks and obstacles in the translation of research results from the designing lab into the clinics. In addition, the study reveals an insufficient information transfer between, on the one hand, designers and developers and, on the other hand, clinicians. This is confirmed by the fact that interactions and information exchanges between the two groups appeared very rare, with less than one in five health professionals reporting active interactions with designers, developers or marketers of IATs for clinical purposes. This study Module also explores issues such as current limitations in elderly and dementia care, perceived opportunities and challenges associated with clinical applications of IATs and the future of dementia and elderly care in light of current trends in digital technology. Our qualitative data analysis identified six main themes and seventeen associated subthemes. An overview of the main themes and subthemes emerging from the interviews is presented in Tab. 6 in Chapter 2.4. This Chapter also provides a detailed analysis of the key findings emerging from this second Module of the PhD project.

1.8. Ethical, Legal and Social Implications (ELSI)

Involving direct and indirect stakeholders in the design of new IATs through UC design and incorporating values in product design through VSD approaches (e.g. the PED-ART framework) might not be sufficient to develop *ethical* IATs. In fact, while VSD prescribes the incorporation of values in product design, it remains an open normative question *which* values should be incorporated. Documentary research and empirical research with stakeholders are important strategies to *inform* these normative evaluations, but cannot *determine* them. The reason for that stems from two major theoretical impediments. First, as postulated by Hume's law (also known as *Hume's guillotine*), normative statements (i.e. statements about what ought to be) cannot be deduced from positive or descriptive statements, i.e. statements about what is (*111*). Therefore, normative statements about which ethical values and considerations ought to be implemented into IATs for dementia cannot be deduced from descriptive analyses of which values and considerations are being implemented in current products. Second, as illustrated by Moore's open-question argument (*112*), moral properties are not identical to natural properties such as desirability. Therefore, it would be fallacious to deduce which moral properties should be addressed in IATs from what stakeholders consider desirable. It is important to consider that these two theoretical impediments do not make descriptive research invalid but simply demarcate its epistemological validity. In fact, Hume's law and Moore's argument do not rule out that descriptive research can very useful to inform and orient normative analyses. In contrast, they indicate that descriptive research alone is not sufficient to address normative problems, hence needs to be complemented with (empirically informed) normative approaches.

For this reason, the third Module of this PhD project was concerned with the normative dimension of IATs for dementia and elderly care. Key findings emerging from this third Module are presented in Chapters 2.4 to 2.15. In particular, these Chapters provide:

- A theoretical foundation of normative ethical analysis in the context of assistive technology and human-machine interaction (including IAT)
- A normative evaluation of the major ethical implications associated with IAT development and adoption. These include issues of autonomy, privacy, cybersecurity, and dual-use.
- A normative evaluation of the major implications of IATs from the perspective of international human rights law.
- Recommendations for clinicians, developers and other stakeholders to guide the responsible development of IATs with special focus on specific IAT subfamilies: BCIs, AALs, wearables, and assistive robots.

1.8.1. Theoretical & Normative Foundations of Human-Machine Interaction

Normative ethics is the branch of ethics concerned with questions related to how one ought to act. As such, it is distinct from descriptive ethics since the latter is concerned with the empirical investigation of moral properties in biological and artificial agents. The first Chapters of this thesis addressed descriptive ethical questions related to IATs for dementia and elderly care. These included the analysis of embedded moral values in current IATs and the empirical investigation of health-professionals' views and beliefs in relation to ethically relevant factors. The next sections, in contrast, will address normative questions. The common objective of these sections is to outline a comprehensive normative ethical assessment of IATs for dementia and elderly care, anticipate or early detect ethical risks, and provide empirically informed and normatively justified recommendations for relevant stakeholders.

It is worth noting that the normative analysis contained in these pages is *applied* in character. In fact, this thesis will not discuss which features make a technology or an action right or wrong. In contrast, it will discuss through an evidence-based and practice-oriented approach which characteristics or applications of IATs are ethically more sustainable than others in a specific context. Applied ethics, in fact, is a branch of ethics concerned with the study of particular ethical issues in particular contexts. In ethics typologies (*113*), applied ethics is further classified into main sub-disciplines based on context or area of application of the ethical analysis. IATs for dementia appear to intersect at least three main sub-disciplines of applied ethics: biomedical ethics[11], machine ethics and cyborg ethics. Biomedical ethics is concerned with ethical issues emerging from biomedical research and clinical practice. This subdomain intersects IATs for dementia and elderly care as these technologies are being developed in the context of biomedical research for the achievement of clinical aims, i.e. the assistance of elderly people and people with dementia. Machine ethics (also called computational ethics) is concerned with the moral features and behavior of intelligent machines (*114*) as well as with ethical issues emerging from their development and application. This subdomain intersects IATs for dementia as these technologies qualify as intelligent machines (some of which also exhibit autonomous behavior) and generate a number of novel ethical issues in the context of development and use. Finally, cyborg ethics is concerned with the moral features and behavior of human-machine integrated systems called *cyborgs*[12] (*116*) as well as with the ethical issues

[11] In this section, the phrase "biomedical ethics" is used to comprehensively refer to the study of ethical issues in biomedicine, hence encompasses subdisciplines such as medical ethics, neuroethics and research ethics.
[12] The term cyborg to denote human-machine integrated systems was also used in relation to the Cybathlon competition (see section 1.6), which was often labeled as "Cyborg Olympics" in the media

emerging from human-machine interaction. This subdomain intersects IATs for dementia as these technologies operate in close interaction with the people they assist and, in some circumstances, augment or compensate for their impaired biological functions (e.g. memory, locomotion, biosensing) with mechatronic ones.

While biomedical ethics as a professional and academic discipline originated in the early seventies (*117*) and can now rely on relatively solid principled theoretical foundations (*118-120*)[13], machine and cyborg ethics are more recent endeavors in applied ethics. As a consequence of their novelty, these disciplines are grounded on less widely accepted theoretical foundations[14]. Literature reviews show that a number of different and mutually conflicting foundational approaches co-exist, as there is no consensus within the research community about which (if any) approach should be prioritized (*123*).

For this reason, prior to moving to the analysis of the major ethical implications associated with the use of IATs, Chapter 2.5 provides a contribution to the theoretical foundations of machine and cyborg ethics. This contribution attempts to propose an alternative macroethical framework for machine and cyborg ethics by linking the foundations of these disciplines with a general theory of cognition[15]. In fact, while machine ethicists have investigated the cognitive requirements for attributing moral status to intelligent machines and cyborg ethicists have discussed the ethical implications of man-machine hybrid systems, yet it remains an open question which theory of cognition should set those cognitive requirements and address those implications. This latter question is *foundational* in the sense that, as Himma (2007) described, "it is more abstract and basic" than the former two and necessary for their solution (*124*). The Chapter proposes to base machine and cyborg ethics upon an active

and scientific literature. See *Nature*, 536/7614: 20-22: 115. S. Reardon, Welcome to the Cyborg Olympics. *Nature* **536**, 20-22 (2016)..

13 For the sake of completeness, not every researcher in bioemedical ethics agrees on the disciplines' theoretical foundations. Controversy around the principlist approach is widespread. However, the wide prevalence of principlist foundational approaches in medical curricula 121. P. Schröder-Bäck, P. Duncan, W. Sherlaw, C. Brall, K. Czabanowska, Teaching seven principles for public health ethics: towards a curriculum for a short course on ethics in public health programmes. *BMC medical ethics* **15**, 73 (2014). indicates a much broader common theoretical ground compared to machine and cyborg ethics.

14 According to Floridi and Sanders (p. 2), debates on the theoretical foundations can be viewed as "a metatheoretical reflection on the nature and justification of computer ethics" 122. L. Floridi, J. W. Sanders, Mapping the foundationalist debate in computer ethics. *Ethics and information Technology* **4**, 1-9 (2002)..

15 Based on Floridi and Sanders model for mapping foundational issues in computer ethics, the approach presented in this thesis belongs to what they call *innovative approaches* as opposed to, respectively, *radical* and *conservative* approaches 122. L. Floridi, J. W. Sanders, Mapping the foundationalist debate in computer ethics. *Ethics and information Technology* **4**, 1-9 (2002)..

externalist approach to the study of cognition in, respectively, human beings (e.g. older people with dementia), human-machine hybrid systems (e.g. older people with dementia as users of integrated IATs), and artificially intelligent systems (e.g. the IATs themselves). This approach is based on the notion of *extended mind*, i.e. an hypothesis in theoretical cognitive science according to which cognitive states and processes do not locate exclusively in human nervous systems (*125, 126*) but might be "hybrids, unevenly distributed across biological and nonbiological realms" (*127*) if certain conditions are satisfied. The extended mind model is proposed as a useful approach to investigate information processing across human users and intelligent technologies (especially cognitive technologies) and to elegantly describe their mutual interaction.

For the reasons delineated above, Chapter 2.5 is aimed at contributing to laying down the theoretical foundations of machine and cyborg ethics, hence providing a more solid conceptual ground for the applied normative analysis presented in the next Chapters.

1.8.2. Privacy and Data Security

Like any other computer system and network, IATs collect, store and share information, usually in digital format. The rapid increase in the number and types of IATs for dementia and elderly care (as reported in Chapter 2.1) is causing a parallel increase in the quantity and variety of information collected, stored and shared by those devices. This trend is part of a broader socio-technological phenomenon, namely the digitalization of various aspects of human life, healthcare included. This *digitalization of healthcare* (*128*) is accompanied with a number of intricately related sub-trends such as the digitalization of medical records (*129*), the leveraging of the information contained in those records and its combination with other data sources (*62*), the multiplication of data-generation and data-access points facilitated by PUC trends, the application of AI for predictive purposes, and the increasing use of automation to complement or replace care tasks. As healthcare becomes digitalized, more and more healthcare-related data are being generated. Studies show that the size of healthcare and biomedical data volumes is approximately doubling every year (*130*). By 2025, a ten-fold increase in worldwide data is predicted with an annual data creation rate of 16.3 zettabytes[16] (*131*).

[16] One zettabyte (ZB) is one trillion gigabytes (GB).

In addition to this quantitative increase, healthcare data are expanding in variety as well. IATs are co-responsible for this trend. Current IATs can collect, store and share various and very heterogeneous types of healthcare-related data, as described in Tab. 4.

Information type	Data sources	IATs enabling collection and sharing	Privacy sensitivity
Environmental	- Video recordings of private spaces - Optical and photoelectric information - Gas levels (e.g. smoke detectors)	- AALs - Sensorics	
Behavioral	- Video-recorded behavior - Voice recordings - Tracked physical activity (e.g. podometrics)	- AALs - Wearables - Care robots	
Medical records	- Disease chronicles - Surgical history - Family history - Demographics - Genetic data	- Electronic medical records (EMRs) - Healthcare data platforms - Intelligent digital assistants	
Physiological	- Real-time heart rate - Glucose levels - Neural information (e.g. EEG-recordings)	- AALs - Physiological monitoring devices - BCIs & other neurodevices	

Tab. 4- Types of privacy-sensitive information collectable via IAT and relative risk

Thank to AI and predictive analytic, these different data types and sources can be aggregated into large data sets to generate comprehensive insights on the person whose data are being recorded (and his/her environment). The increasing availability of these various data sources and their subsequent analyzability are predicted to benefit the delivery of dementia and elderly care services worldwide (*132*). In fact, they are likely to enable more targeted, personalized and optimized care solutions for the affected individuals as well as novel insights for care providers (*62*). At the same time, however these trends will produce an unprecedented quantity and quality of patient data to be introduced into the digital ecosystem. IATs will increasingly make end-users' medical records electronically available to service providers, permanently track their activities, monitor their behavior and record their physiological parameters. This raises a fundamental ethical question: Are our current digital infrastructures and, legal and ethical safeguards, adequate for this upcoming data explosion? This question acquires particular ethical significance in relation to private and sensitive data. In fact, research increasingly shows that novel breaches of privacy violation are emerging from IAT use, a consequence of the fact that privacy and data security are not prioritized in IAT design (*133*). As described in Chapter 2.2, privacy and data security are among the least prevalent considerations in IATs design in spite of the fact that stakeholders perceive them as critical requirements for responsible IAT use.

Some of the breaches for privacy violation emerging from IAT use are instances of already known ethical challenges in technology-mediated healthcare. For example, the disproportionate tracking and monitoring of behavioral activities of users (e.g. via camera-based monitoring and GPS tracking) has been largely addressed in the literature as a major risk for the physical and informational privacy of end-users (*134-137*). Other breaches are, however, qualitatively novel and directly enabled by emerging IAT types. Among these, BCIs and other cognitive technologies are critical. BCIs for device-control and/or self-monitoring such as those based on EEG-measurements enable the access to highly private and sensitive data sources, namely the neural correlates of mental processes such as interests, intentions, moods and preferences (*138*). These data are only partly under voluntary conscious control, contain personally identifiable signatures, and can be aggregated by data-handlers to capture or predict fundamental elements of health status, preferences and behavior. In absence of adequate safeguards at the level of design, the increasing pervasiveness of BCIs and other IATs is raising the probability of unauthorized disclosures of neural information and related privacy violations. These violations are facilitated by the reported unpreparedness of existing digital and regulatory infrastructures. In fact, phenomena such as data storage and sharing across unsecured channels as well the absence of privacy-protecting safeguards in products' terms of service highlight an urgent need to develop adequate safeguards for neural data.

To this purpose, Chapters 2.10 and 2.11 present a detailed analysis of emerging privacy issues associated with the increasingly pervasive use of IAT types that enable the collection, storage and sharing of private and sensitive information. Chapter 2.10 focuses primarily on BCI and other neurotechnologies. Chapter 2.11, in contrast, focuses on AAL, wearable computing and robotics. After describing the technological peculiarities of these IAT families, the Chapters present a number of breaches for privacy violation opened by these technologies. In addition, the Chapters review current privacy safeguards and identify an urgent need to increase the privacy and security of the neurophysiological and behavioral data processed by IATs. Based on this analysis, the Chapters propose a number of privacy-protecting recommendations at three levels: individual users, technology producers or service providers, and policy and regulatory bodies.

1.8.3. Dual-Use

As described in Chapter 2.10 and 2.11, breaches for privacy and data security violation can emerge from the pervasive diffusion of certain IAT types and from the exponential proliferation of IAT-generated data. In addition, challenges for privacy, security and other ethical values can emerge from the misuse of IATs for malevolent purposes. In fact, research shows that several IATs, even though they were originally designed for beneficial clinical purposes, can be coopted for nefarious aims by malevolent agents. In ethical terms, they hold a dual-use potential: the same technology "has the potential to be used for bad as well as good purposes" (*139*). This generates an important ethical dilemma in relation to the governance of these technologies. In fact, while it is important to maximize the clinical and social benefits of IATs among end-users and their caregivers, it is equally important to minimize collateral risks associated with the misuse of these technologies.

Chapter 2.7 provides a detailed review of dual-use dilemmas emerging from the use and misuse of IAT types such as BCI and other neurotechnologies as well as neurally-controlled robotics. As the Chapter illustrates, dual-use dilemmas for these IAT-types primarily arise in two contexts: cyber-criminality and the military. The Chapter presents a detailed list of dual-use possibilities in the IAT context and takes a normative stance in the debate over their governance. In light of the current global burden of population aging and dementia, the Chapter suggests that regulatory approaches should be calibrated in a manner that maximizes clinical benefits for older people and people with cognitive disabilities. Therefore, the Chapter suggests that a global ban or moratorium on military IAT research should be discouraged since it could delay the development and administration of clinically effective solutions for the people in need. The reason for that stems from an important characteristic of dual-use dynamics in the IAT context:

the fact that technologies originally developed by the military for national security purposes often spillover into the civilian sector with beneficial impact on healthcare (*140*). This characteristic, known as *reverse dual-use*, is illustrated in Chapter 2.7 through various examples.

In addition, the Chapter calls for the development of a biosecurity framework specific to neurotechnology. This framework, which is called *neurosecurity* framework, consists of calibrated regulatory interventions, ethical guidelines and awareness-raising activities within the neuroscience community.

1.8.3.1. A Paradigmatic Example of Dual-Use Risk in IAT: the Case of Malicious Brain-Hacking

As Chapter 2.7 illustrates, BCIs are among the IAT-types with the highest dual-use potential. In addition to being researched and tested in the military context, these technologies also are a potential target for criminality. Research shows that BCI headsets can be experimentally coopted by malevolent agents for nefarious purposes and turned against their users. In particular, they have been used to extract sensitive information from the user's EEG-recordings without their consent and even awareness (*141-143*). These experimental results demonstrate the actual feasibility of performing targeted attacks against BCI users and denote an emerging dual-use risk called *malicious brain-hacking*. Similarly to malicious computer hacking, malicious brain-hacking involves the unauthorized extraction and sharing of sensitive information for malevolent purposes. Unlike traditional computer hacking, however, it enables the direct extraction of information from neural recordings, hence a more direct access to a person's mental states. This unique feature of malicious brain-hacking raises a new set of ethical questions related to the degree of control that individuals should exercise over their brain data, the private status of their mental information and the implications for their autonomy and personhood resulting from the unprecedented possibility of direct external manipulation of their brain activity. To explore this new domain of ethical issues, a component of the third Module of this PhD study was devoted to the ethical assessment of malicious brain-hacking. This assessment was aimed at anticipating possible risks for end-users, clarifying the spectrum of ethical issues associated with this novel opportunity for technology misuse, and providing guidance for stakeholders (end-users, BCI developers & designers, clinicians, and cybersecurity experts).

1.9. Intelligent Assistive Robots: Recommendations for Clinicians

BCIs are not the only type of IAT that is believed to raise ethical challenges. Authors have argued that socially assistive robots (SARs) are also particularly problematic from a moral perspective since they raise a number of ethical challenges including the risk of deception (*144*), a feeling of objectification, and a loss of privacy, personal liberty and human contact (*145*). SARs are "robots that provide assistance through social, rather than physical, interaction". These robots are aimed "to address critical areas and gaps in care by automating supervision, coaching, motivation, and companionship aspects of one-on-one interactions with individuals from various large and growing populations, including stroke survivors, the elderly and individuals with dementia, and children with autism spectrum disorders" (*144*). Thank to advances in AI, SARs are expected to provide increasingly flexible and adaptive responses to end-users' care needs, hence to provide care standards that will ultimately match or even outperform those of human caregivers. At the same time, however, their technological novelty and semi-autonomous behavior generate ethical uncertainty among experts.

The ethical significance of SARs in the context of dementia and elderly care has elicited coordinate responses from institutions. A paradigmatic example is a workshop on the "Ethics and Policy of Robots in Healthcare"[17] organized by the Foundation for Responsible Robotics at The Hague Institute for Social Justice, The Netherlands. The author of this thesis was among 15 experts invited by the organizers to create a white paper on the governance of healthcare robots and a roadmap of guidelines for Human-Robot Interaction (HRI) in healthcare settings.

In light of this need for ethical guidelines and governance strategies, an important portion of the third Module of this PhD project was the development of a set of recommendations for clinicians and engineers regarding the ethically responsible application of SARs in the dementia and elderly care setting. A detailed analysis of this study segment and a full description of these recommendations is presented in Chapter 2.12.

[17] For further information about this workshop see: http://responsiblerobotics.org/2017/04/29/ethics-and-policy-of-robots-in-healthcare-workshop/

1.10. Implications for Human Rights

In normative analysis, ethical evaluations often intersect or even overlap with legal and social ones. To underscore this contiguity between these three domains, the acronym ELSI *(Ethical Legal and Social Implications)* is often used in the literature as semantic tool to demarcate the domain of normative analyses related to science and technology (*146-148*).

In the context of IATs, legal implications at the level of fundamental rights are of primary relevance. As Sullins has observed, there are “global challenges that revolve around human rights and ICTs”, and these are “one of the primary concerns of our time” (p.130) (*149*). In fact, many of the values that were identified as ethically relevant and/or neglected at the level of product design (see Chapters 2.10 and 2.11) do not only qualify as moral values but also as legally protected human rights. A typical example is the notion of privacy. Privacy, as we have seen, configures an important and often neglected ethical requirement of IATs for dementia and elderly care. In addition, it is also protected as fundamental human right under the The Universal Declaration of Human Rights (Art. 12), the 1950 European Convention on Human Rights (Art. 8) and the 2000 EU Charter of Fundamental Rights (Art. 7 and 8).

Human rights are “equal and inalienable rights of all members of the human family” regardless of sex, ethnicity, nationality, religion, and other biological or sociocultural variables (*150*). Such rights arise from ethical principles and moral norms. However, to become regularly protected as legal rights in municipal and international law, these principles or norms need to “reflect a fundamentally important social value (…), be consistent, but not merely repetitive, of the existing body of international human rights law, (…) be capable of achieving a very high degree of international consensus”, and “be sufficiently precise as to give rise to identifiable rights and obligations” (*151*).

The primary importance of human rights analyses within ELSI studies on computing technology has been stressed by many authors. For example, Sullins has underscored how every technology-mediated activity leaves a trail of information, a so-called *digital footprint*, to emphasize that individuals should “pay close attention to the forces that access and manipulate that information” (p.118). In the digital era, he argued, the access to or manipulation of digital information can result in fundamental rights violations because it can “critically alter” the ability of people “to operate in the social world” (*149*). This risk is particularly evident in relation to technology misuse. As we have seen in relation to malicious brain-hacking, “the wrong information in the wrong hands” (ibid.) can significantly affect a person’s informational privacy, autonomy or even identity. Floridi and associates at the Oxford Internet Institute have established an even closer link between computer technology and human rights, observing that digital information has an "ontological force in the construction of our personal identity" (*149*), hence it should be "a fundamental and inalienable right" (*152*).

In most cases, the implications for human rights raised by novel intelligent technologies are accounted for by previously codified rights. In other cases, however, when advances in intelligent technology open novel and unprecedented technological capabilities (e.g. novel opportunities for monitoring, interfacing and controlling human behavior), there is uncertainty on how human right law should cope with such advancements. In fact, as data-security experts have argued, new technologies can open *breaches*, meaning "sudden new opportunities for offending that opened as a result of changes in the technological or social environment" (*153*). These breaches "are often the result of a defective legal or regulatory coverage", hence might require the development of novel regulatory mechanisms. For example, as we have seen in Chapters 2.8, 2.9, 2.10 and 2.11, the neurotechnology segment of the IAT spectrum opens unprecedented possibilities for accessing, collecting, sharing and manipulating information from the human brain. In such cases, it is possible that existing human rights may not be normatively sufficient to respond to these emerging issues. The reason for that stems from the fact that those rights emerged in times and historical contingencies where the challenges currently posed by new technologies where not technically possible or even imaginable. For example, the right to privacy was originally formulated in the late 19th century as a response to "deep-seated abhorrence of the invasions of social privacy" triggered by the massive diffusion of newspapers and other mass media (*154*). However, at that time and for many decades to come, the only three types of information that could be protected under privacy rights were written, verbally uttered and behaviorally observable information. With advances in neurotechnology and BCI, information about a person's mental states can be directly decoded from neural recordings in absence of verbal utterances or observable behavior (see Tab. 4 at p. 49). This new technological opportunity, as we have seen in Chapters 2.8, 2.9 and 2.10, can be used to enable new types of privacy violation and can be coopted by malevolent agents for personal gain and privacy-threatening malevolent purposes (e.g. unauthorized disclosure of mental information).

Based on these considerations, Chapters 2.13 and 2.14 discuss the implications of new intelligent technologies for fundamental rights, with a special focus on cognitive technologies. Taking a first step from Sullins' "concern for our rights of citizens in the world of information" (*149*), the Chapters use literature review and comparative legal analysis to assess whether existing rights are enough normatively equipped to account for novel advances at the brain-machine interface. Based on this analysis, we advance the proposal that evolutionary interpretations of human rights or even the creation of brand new rights might be required to face the challenges posed by novel cognitive technologies. Possible candidates are the rights to cognitive liberty, mental privacy, mental integrity and psychological continuity.

Further research is required to assess the implications for human rights of other disruptive trends in IATs such as autonomous and emotionally intelligent robots, big-data analytics, strong AI and superintelligence (*59*), as well as the so-called *Internet of Everything* (*155*).

1.11. Governance of Cognitive Technology: Responsible Enhancement and the Need for Democratization

The third and last Module of the present PhD projects ends with two contributions to the governance of intelligent ─especially cognitive─ technologies in light of the contextual factors presented in the previous sections of this thesis (e.g. global burden of dementia and population aging, dual-use potentials, cybercrime, risks for privacy and related rights). The focus of these contributions is twofold. The first contribution focuses on the governance of intelligent technology from the perspective of public health policy. After reviewing new evidence about the role of cognitive technology in maintaining cognitive performance among senior and cognitively disabled citizens, this contribution suggests that the responsible use of technology-mediated cognitive enhancement should be carefully considered by policy makers as a possible public health strategy to tackle the global burden of population aging and dementia. The underlying assumption of this contribution is that the clinical potential of intelligent technology does not restrict exclusively to assistive purposes, but can be redirected to fulfil preventive and enhancement-related aims. This assumption is grounded on new longitudinal evidence such as the newly released findings from the 10-year long Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) study, which showed that computer-based technologies can not only augment cognition but also reduce dementia risk among older adults (*156*). Chapter 2.6 presents a detailed description of this proposal and a preliminary discussion of its moral significance. After reviewing a number of possible objections against public health applications of cognitive enhancement, the Chapter submits that the most substantive ethical issues arise in relation to cost, fair access and paternalism. This is consistent with previous considerations presented in this thesis emphasizing the moral centrality of guaranteeing fair technology access, preventing digital divides and protecting the cognitive liberty of individuals. Therefore, the Chapter concludes that public health programs involving cognitive technology should prioritized the most disadvantaged population segments such as the oldest-old and the lowest socioeconomic classes. In addition, cheap and unobtrusive cognitive technologies such as those enabling environmental enrichment and those implementable on low-cost hardware should be prioritized *ceteris paribus* over more expensive ones, unless significantly different outcomes are evidenced. The Chapter also stresses the so-called *recursive nature of cognitive enhancement* to underscore how the improvement of cognitive performance might result in more positive overall health outcomes among older citizens.

The second contribution focuses on the governance of intelligent technology from the perspective of deliberative democracy. Unlike other contributions presented in this Module, this last section is not simply concerned with a normative ethical and legal assessment of IATs, but with a concrete policy deliverable: a practical proposal for the governance of cognitive technologies at the governmental and non-governmental level. This proposal originates from the observation of the paradigm-shifting effect (*157*) that these technologies can exert on human cultural evolution, not only in the medical context. In fact, the potential of cognitive technology to map, interface and simulate human cognition and its vulnerability to misuse urge the development of governance strategies that align the future of IATs with the basic principles of liberal democracy in free and open societies. For example, Ess and Thorseth (2010), have argued that the global diffusion of intelligent technology urges the development of "a global, not simply local, information and computer ethics", especially in relation to the issues of "global deliberation and deliberative democracy" (*158*). Similarly, Ienca and Jotterand have suggested the development of a "procedural ethics grounded on a deliberative democracy approach" to shape the discourse on the ethics of neurotechnology (*159*).

For this reason, Chapter 2.15 provides a preliminary description of an approach to the governance of IATs called the *democratization* approach. This governance strategy is aimed at aligning intelligent technology with the protection fundamental liberties and the basic principles of an open and democratic society. This approach is based on seven inter-related normative principles: avoidance of centralized control, pervasiveness, openness, transparency, inclusiveness, user-centeredness and convergence. This contribution is designed to achieve a more universal and even distribution of the potential benefits of IATs in a manner that avoids the exacerbation digital and/or socioeconomic inequalities and mitigates the risks for individuals and groups associated with the misuse of such emerging technologies. To quote Neuralink CEO, Elon Musk, "If everyone has AI powers, then there's not any one person or a small set of individuals who can have AI superpower"[18]. Global empowerment of individual technology users is proposed to achieve this goal. The Chapter also presents a number of examples and concrete suggestions for the practical realization of this governance strategy.

[18] Quote reported in *Forbes*, December 13, 2015: https://www.forbes.com/sites/theopriestley/2015/12/13/does-elon-musk-and-openai-want-to-democratise-or-sanitise-artificial-intelligence/#7b6712fad754

Part 2: Original Research Contributions[19]

[19] All research contributions presented in this section have been published, in modified form, in peer-review academic journals or edited volumes. Information about the relevant publication outlet is presented in the cover page of each contribution. The in-text citations and references for this section have been formatted to suit the general style of this thesis.

Module 1

*2.1. - Intelligent Assistive Technology for Alzheimer's Disease and Other Dementias: A Systematic Review**

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Abstract

Intelligent Assistive Technologies (IATs) have the potential of offering innovative solutions to mitigate the global burden of dementia and provide new tools for dementia care. While technological opportunities multiply rapidly, clinical applications are rare as the technological potential of IATs remains inadequately translated into dementia care. In this article, the authors present the results of a systematic review and the resulting comprehensive technology index of IATs with application in dementia care. Computer science, engineering, and medical databases were extensively searched and the retrieved items were systematically reviewed. For each IAT, the authors examined their technological type, application, target population, model of development and evidence of clinical validation. The findings reveal that the IAT spectrum is expanding rapidly in volume and variety over time, and encompasses intelligent systems supporting various assistive tasks and clinical uses. At the same time, the results confirm the persistence of structural limitations to successful adoption including partial lack of clinical validation and insufficient focus on patients' needs. This index is designed to orient clinicians and relevant stakeholders involved in the implementation and management of dementia care across the current capabilities, applications and limitations of IATs and to facilitate the translation of medical engineering research into clinical practice. In addition, a discussion of the major methodological challenges and policy implications for the successful and ethically responsible implementation of IAT into dementia care is provided.

Introduction

The increasing prevalence of dementia poses a major challenge for global health at multiple levels. At the financial level, Hurd and colleagues (2013) calculated that dementia and specifically AD are among the most expensive diseases for Western society, with a price tag per year of around $160 billion (*35, 36*). As the greatest relative cost increases are occurring in low-income African and in East Asia regions (*160*), the provision of dementia care services will be seriously exposed to danger due to pre-existing limitations of local national budgets.

Long-term care at nursing homes and other healthcare institutions is a major component of this societal and economic burden whose impact affects not only public finances but also the provision of healthcare services. In addition to institutional care, a large proportion of dementia care is provided by informal caregivers (usually family members). In the U.S., more than 15 million Americans provide unpaid care for family members affected by AD and other types of dementia (*161*). At the individual level, these informal caregivers often experience psychological burden, with more than 40% of them reporting emotional stress and 74% reporting concern about maintaining their own health since becoming a caregiver (*161*). In 2014, this unpaid informal contribution provided an estimated 17.9 billion hours of medical and social assistance, hence providing an overall value nearly equal to the costs of direct U.S. medical and long-term care of dementia (*35*). However, this crucial component of dementia care provision is expected to rapidly shrink as a consequence of demographic trends. Currently, the Potential Support Ratio (PSR) ─ defined as the number of people aged 20-64 divided by the number of people aged 65 and over ─ is under 4 in most North American and European countries (*160*). By 2050, at least 35 countries will have PSRs below 2, hence having fewer than two people under 65 for each senior person. In the context of dementia, the caregiver-to-patient ratio is expected to reduce accordingly (*162*). This progressive scarcity of human caregivers will put additional financial and logistic pressures on the healthcare systems. Finally, due to the highly disabling condition of their disease and the increasing limitations to the provision of care, the growing population of older adults with dementia and their caregivers will face major challenges to quality of life (*36*).

In response to this emerging global scenario, technological innovation is likely to be a critical factor. Recent advancements in Artificial Intelligence (AI), Pervasive and Ubiquitous Computing (PUC), robotics, and mobile computing combined with new developments in wireless networking and Human-Computer Interaction open the prospects of reshaping dementia care with intelligent technology. In fact, the pervasive deployment of Intelligent Assistive Technologies (IATs) for dementia may have a disruptive impact on dementia care (*67*). IATs could (i) mitigate the burden on public finances through the delay or obviation of institutional care, (ii) reduce the psychological burden on formal and informal caregivers, (iii) compensate for the progressive scarcity of human caregivers while enhancing and optimizing quality of care, and (iv) empower older adults with dementia and thereby improving their quality of life.

Assistive technology is the umbrella term used to describe devices or systems which allow to "increase, maintain or improve capabilities of individuals with cognitive, physical or communication disabilities" Marshall (*77*). IATs are assistive technologies with own computation capability and the ability to communicate information through a network. Most of them display the ability to sense the external environment or digital ecosystem and provide adaptive responses in a manner that maximizes the benefits for the users (e.g., increasing safety). IAT encompasses a wide spectrum of technological applications currently used or in-development with potential application to dementia care. These include self-contained devices (e.g., tablets, wearables, personal care robots etc.) and distributed systems (e.g., smart homes, integrated sensor systems, mobile platforms etc.), as well as software applications (e.g., mobile or web-based apps). While AI provides systems capable to simulate aspects of human intelligence, PUC embeds intelligent microsystems into everyday objects and homes whose friction with the user is progressively mitigated by advancements in Human-Computer Interaction. In parallel, intelligent service robots can assist users in a variety of dimensions including personal care, companionship, social and emotional support.

Although IATs open up promising prospects for the future of dementia care, yet their adoption is still lower than expected (*2*). This has been attributed to suboptimal information transfer and dissemination across technology development and medical implementation (*107*) as well as to the lack of solid and highly generalizable clinical validation of many IATs (*163*). Clinicians and other health professionals are often unaware of new IATs and their applicability to dementia care as little cooperation has occurred between technology development and medical implementation. In addition, a mismatch between the user's cognitive profile and the prescribed IATs has been reported as a consequence of top-down approaches to technology design (*164*).

Concomitantly, the prevalence of participatory and user-centered (UC) approaches to technology design is reportedly low (*2*). The "user-centered" or "patient-centered" approach is a framework for the design and development of new products or for the assessment and evaluation of existing products in which the needs, wishes, and limitations of end-users of the IAT are given extensive attention at each stage of the design or assessment process (*165*, *166*). Such low prevalence of participatory and UC approaches to technology design has been observed as a co-determinant of low adoption rates since it obstacles the incorporation of end-users' needs, desires and wishes into product development (*167*). Finally, clinical studies designed to validate IATs are often affected by structural limitations and methodological weaknesses including small sample-size, high drop-out rates, low statistical significance and inadequate adjustment for multiple comparisons (*163*). This lack of solid and highly generalizable clinical validation might contribute to the slow translation of emerging IATs from the designing labs into the clinics.

While the number of publications in this area has been significantly growing in the past few years (*168*), yet a comprehensive and up-to-date index of IATs with possible application into dementia care has not been produced. Given the pace of innovation in medical technology and the reported translational gap between bench and bedside, the production of a comprehensive index is highly needed to orient health professionals, affected individuals and other operators involved in the provision of dementia care across this rapidly emerging domain. Such a state-of-the art index will provide comprehensive information for relevant stakeholders about current IAT possibilities and limitations hence contributing in raising awareness about the pros and cons of their integration into care. While one study recently reviewed dementia-focused assistive technologies (*169*), their review did not result in the production of a technology index. A cognitive function based review of assistive technologies for cognitive impairment retrieved only 13 studies with direct focus on assistive technologies for dementia, hence covering a very small portion of the currently estimated technological spectrum (*170*). In addition, both studies failed to distinguish IAT from other assistive technology (e.g. tools without computing capacity), thus underestimating the specificity of intelligent technology and its potentially game-changing role in the clinical setting. Other previous reviews have either not been systematic (*73*) or have limited their scope to a subsection of assistive technology for dementia such as "assistive devices for the hours of darkness" (*171*). The latest comprehensive list of IATs (especially cognitive orthotics and advanced integrated sensors) with potential applications to dementia care dates seven years back (*75*). As technology evolves fast, a new up-to-date index is urgently needed to keep up with advancing innovation, guide health professionals across emerging technological opportunities, and contribute towards adequate uptake of potentially useful tools to improve the lives of older adults with dementia.

In order to facilitate the successful implementation of emerging intelligent assistive technologies into dementia care, such index should address six critical questions: (i) How large is the current IAT spectrum and what is its growth rate over time? (ii) What types of device are currently available? (iii) What cognitive or physical functions can be assisted through IAT? (iv) Which patient population segments are targeted as end-user groups? (v) Which is the current level of clinical validation of existing IATs? (vi) What approach is prevalent in the design and development of such devices?

In the following we address these critical questions by presenting the results of our systematic review and aggregate such information into a comprehensive technology index. This index is designed to provide comprehensive information to clinicians, researchers, patients, caregivers and other stakeholders involved in dementia care about the current possibilities and limitations of intelligent assistive technology for dementia.

Methodology

Data search and extraction

A literature search was performed for English language articles indexed in the following search engines and bibliographic databases: IEEE, PubMed, Scopus, PsycINFO, and Web of Science. We searched title, abstract, and keywords for the terms: ("assistive technolog*" OR "assistive device" OR "assistive application") AND ("intelligent" OR "ICT" OR "adaptive" OR "computer" OR "robotic") AND ("Alzheimer*" OR "dementia" OR "ag*ing" OR "elder*). Query logic was modified to adapt to the language used by each engine or database. Studies included in the synthesis had the following features: (I) original articles, book Chapters or conference proceedings, (II) written in English; and (III) published between January 1, 2000 and April 12, 2016. Additionally, studies included in the synthesis must present the (a) design and development, or (b) assessment and evaluation of one or more intelligent assistive systems with current or potential applications to dementia care. Reviews, commentaries, letters to the editors, and opinion articles were removed.

Intelligent assistive systems included into the technology index met the following inclusion criteria: (I) had their own computing capability[21], (II) had direct applicability to dementia care, and (III) could assist or compensate for one or more functional impairments associated with AD or other age-related dementias (e.g. memory loss and executive dysfunction). Reviewers excluded non-intelligent systems (i.e. without own computational capacity, such as walking canes or printed cognitive training books) as well as systems developed for the support of non-progressive traumatic brain injuries with limited applicability to the cognitive, emotional and physical deficits specific of AD and other age-related dementias.

A total of 617 papers were initially identified. Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria ***(3)***, four steps of filtering were performed (See Fig. 2). First, additional 167 records were identified by reviewing the references of all initially retrieved articles. Second, duplicates were removed using the ENDNOTE tool for duplicate detection. Additional duplicates were removed manually after reviewing the abstracts. A total of 5 duplicates were detected. Second, eligibility assessment was performed on the

[21] Devices with own computational capacity are those that enable the collection, processing and transfer of information without external support.

remaining 779 papers to remove sources that did not meet the review's inclusion criteria. Further 208 publications were rejected at this stage of filtering. Third, in-depth review was performed on the full-text articles of the remaining 571 entries included in the synthesis. Fourth, articles were clustered according to the categorization criteria described below. Two reviewers performed all stages of filtering independently, and only the papers rejected by both reviewers were removed from the working corpus.

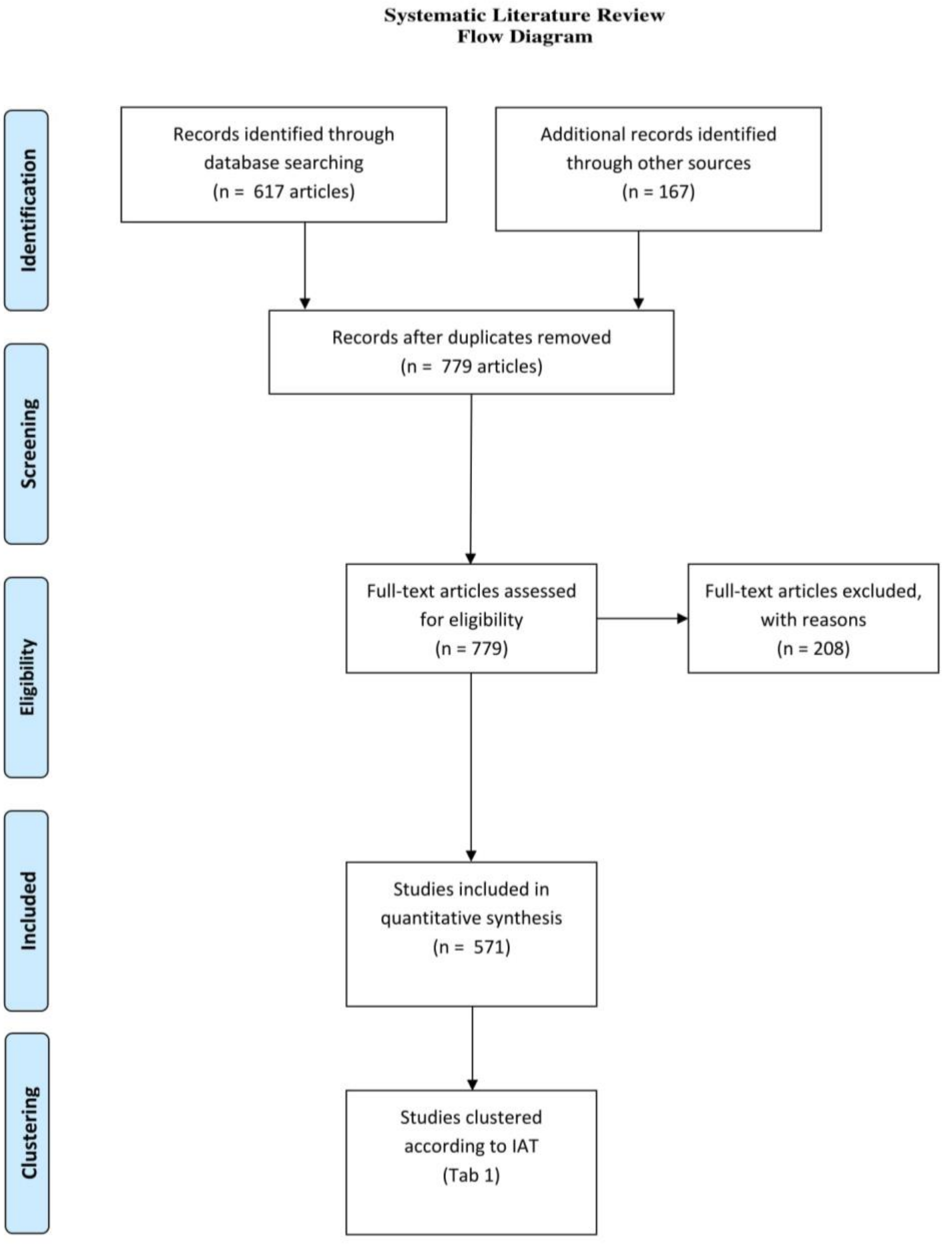

Figure 3- Systematic Review Flow Diagram

Categorization

In order to produce a systematic technology index, retrieved technologies were clustered according to the following main characteristics: (I) technology type, (II) application, (III) function assisted, (IV) user-centered design, and (V) primary target-user population, and (VI) evidence of clinical validation. For already marketed products the official commercial names were adopted. In contrast, prototypes without commercial name were listed according to the names or descriptions that the study authors used.

Technological types categorize IATs according to their hardware or software architecture, composition (single device vs distributed system), and type of human-machine interaction (e.g., wearables vs hand-held devices). We grouped them into seven major categories: distributed systems, robots, mobility and rehabilitation aids, hand-held multimedia devices, wearables, human-machine interfaces, and software applications. A distributed system is defined as a system composed of several sensing and processing sub-systems, which communicate through a computer network, "hosting processes that use a common set of protocols to assist the coherent execution of distributed activities" (*172*). This category includes Ambient Assisted Living (AAL) systems, i.e., distributed assistive systems based on the Ambient Intelligence paradigm that shape the user's environment in a manner that is sensitive, adaptive, and responsive to their needs. When AAL systems are used to reshape and augment the user's home (e.g. with sensors, wireless networks and software applications for healthcare monitoring), this is called a *smart home*. Personal robots are autonomous service robots designed for the use and benefit of individuals. These include domestic service robots that support Activities of Daily Living (ADL), robotic cognitive assistants, as well as companionship and socially assistive robots that support, respectively, the relational and social dimension of patients. While robots are autonomous individual agents, mobility aids are mobile machines (e.g. powered wheelchairs) or worn assistive systems (e.g. exoskeletons) that can facilitate mobility, limb movement and control for users with physical disability. Hand-held multimedia devices are mobile devices having a display screen with touch input and/or a miniature keyboard, hence usable with hand control. These include smartphones, Personal Digital Assistants (PDAs), tablets and other multimedia technologies capable of generating text, audio, images, animation, video and interactive content. Finally, wearable devices are technologies incorporated into items of clothing and accessories worn by the user, hence represent the most intimate and closed-up form of non-invasive human-computer interaction.

Applications categorize the primary type of activity supported by the system and its primary functionality. In contrast, the category "function assisted" determines the specific functional impairment caused by or associated with AD or other dementias to which the IAT provides compensation or assistance. When IATs were designed for the compensation of more than one single cognitive, emotional or physical deficit, they were categorized as *general-purpose* systems.

Finally, the target user category indexes IATs according to the specificity of the primary end-user population targeted by researchers when designing the system. In fact, although all IATs included in the index had direct application as compensatory tools for one or more functional impairments associated with AD or other age-related dementias, some of them may not be designed exclusively for AD patients but with a more inclusive population target.

In addition, the reviewers determined for each IAT whether it was developed and designed following a user-centered approach and including participatory design techniques. Since UC design has often been considered a major predictor of social adoption and a crucial factor of ethically sustainable technology development (*37, 75, 167*), we investigated what proportion of the entire spectrum of IATs for dementia incorporates such approaches. A logistic regression was performed on the correlation between time and the frequency of user-centered models of technology design with the purpose of testing if the adoption of user-centered models is increasing over time. Finally, following several reports on the lack of evidence-based studies on the clinical effectiveness of IATs for dementia (*168, 173*), the reviewers investigated if each IAT had been preliminary validated via clinical studies on human subjects.

Results

Our review identified 539 IATs with current or potential applications to dementia care. These systems are included into the technology index summarized in Tab. 5 and analyzed according to the previously listed core categories. For each IAT, their technological type, function, assisted deficit, a user-centered design, primary end-user population, and evidence of clinical validation are presented.

IAT	**Technology type**	**Application**	**Function Assisted**	**User-Centered design**	**Primary Target Population**	**Evidence of Clinical Validation**	**References**
2D motion coordination enhancement	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No (only test on 1 healthy	Tsagarakis et al. (2008)

						subject)	
3D infrared sensor anti-collision system for powered wheelchair	Distributed system	ADL	Cognition (Orientation)	No	Dementia	No	Viswanathan et al. (2008)
3D SLAM	Distributed system	ADL	Perception	No	GEPND	No	Lili et al. (2014)
3D VFT for iAT environments	HMI	Monitoring	General-Purpose	Yes	AD	Yes (30 healthy young adults aged 25-40, 30 healthy adults of aged 65+, and 30 patients with mild AD)	Kosmidou et al. (2014)
3G-based assistive network	Distributed system	Care & Rehabilitation	General-Purpose	No	GEPND	No	Fong et al. (2013)
6-DOF Jaco robotic arm	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Bassily et al. (2014)
AAL system	Distributed system	Monitoring	General-Purpose	Yes	AD	Yes	Cavallo et al. (2015)
ABLE	Distributed system	ADL	General-Purpose	No	GEPND	No	Giokas et al. (2014)
ACTION	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Magnusson et al. (2012)
Active synchronized motion control for comfortable walking support	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Pervez et al. (2007)
Activity board	Software	Cognitive Assistance	Cognition (Reasoning)	No	Dementia	Yes	DeOliveira et al. (2010)
Adapted Smart TV	Distributed system	Engagement	Social interaction	Yes	GEPND	No	Alaoui et al. (2013)
Adaptive equipment	Distributed system	ADL	General-Purpose	No	Dementia	No	Gitlin et al. (2006)
ADL Monitor	Distributed system	ADL	General-Purpose	No	Dementia	Yes	Ando et al. (2015)
Affective Robot	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	GEPND	No	Carelli et al. (2009)
Affectively aligned cognitive assistant	Distributed system	Cognitive Assistance	Cognition	No	AD	No	Luyan et al. (2014)
AIBO	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	GEPND	Yes	Broadbent et al. (2009)
AILISA	Mobility & Rehabilitation Aid	Monitoring	Motor	No	GEPND	Yes	Broadbent et al. (2009)

ALADIN prototype	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Schulke et al. (2010)
ALiFE	Wearable	Engagement	Perception	Yes	GEPND	No	Mahadi et al. (2008), Werda et al. (2007)
ALLT	Distributed system	Engagement	Perception	No	GEPND	No	Attarwala et al. (2013)
Alziminder	Handheld/Multimedia	Cognitive Assistance	General-Purpose	Yes	AD	No	Xenadikis et al. (2014)
Ambient Assistant application	Software	ADL	General-Purpose	No	GEPND	Yes	Lee et al. (2011)
Ambient monitoring system for activity recognition	Distributed system	Physical Assistance	Motor	No	GEPND	Yes (trial on 100 households)	Chiriac et al. (2011)
AMIGA prototype	Distributed system	Emotional Assistance	Emotion	Yes	GEPND	Yes	Reis et al. (2012)
AP@LZ	Distributed system	Cognitive Assistance	Cognition (Memory)	No	AD	Yes (2 participants with AD)	Imbeault et al. (2014)
App for mobile technology	Software (mobile app)	Interaction	Communication	Yes	GEPND	Yes	Isaacs et al. (2013)
App-based issue reminders	Software (mobile app)	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes (cohort with 9 participants)	Hartin et al. (2014)
Arm-Balancer	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Miyawaki et al. (2010)
ARMin robot	Robot	ADL	General-Purpose	Yes	GEPND	Yes (7 healthy subjects and 3 chronic stroke patients)	Guidali et al. (2011)
ARVK	Wearable (VR)	Cognitive Assistance	General-Purpose	No	GEPND	No	Ong et al. (2012)
Ashley	Robot	ADL	General-Purpose	Yes	GEPND	Yes (29 older adults aged 70+)	Spiekman et al. (2011)
ASIBOT	Robot	ADL	General-Purpose	No	GEPND	Yes	Heute et al. (2012), Jardon et al. (2012)
Assisting mat system for wheel-chair	Distributed system	Physical Assistance	General-Purpose	No	GEPND	No	Nagamachi et al. (2014)
Assistive communication robot	Robot	Interaction	Communication	No	GEPND	No	Khosla et al. (2010)

Assistive exoskeleton	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Hirota et al. (2016)
Assistive household robot	Robot	ADL	General-Purpose	No	GEPND	Yes	Kantorovitch et al. (2014)
Assistive mobile application	Software (mobile app)	Interaction	Communication	Yes	GEPND	Yes	Madeira et al. (2015)
Assistive mobile robot	Robot	Physical Assistance	Motor	No	GEPND	No	Duy et al. (2016)
Assistive motorized hip orthosis	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Olivier et al. (2013)
Assistive rehabilitation hand device	Mobility & Rehabilitation Aid	ADL	Motor	No	GEPND	No	Huang et al. (2008)
Assistive robot	Robot	ADL	General-Purpose	Yes	GEPND	No	Moreno et al. (2015)
Assistive robot for gait training	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes (RCT with 41 patients with PD)	Picelli et al. (2012)
Assistive robot prototype	Robot	ADL	General-Purpose	No	GEPND	No	Znagui et al. (2011)
Assistive robotic agent for pedestrian mobility	Robot	Physical Assistance	Motor	No	GEPND	No	Wasson et al. (2001)
Assistive smart environment	Distributed system	ADL	General-Purpose	No	GEPND	No	Manning et al. (2008)
Assistive system for smart homes based on the analysis of electrical load signatures at the steady-state	Distributed system	ADL	General-Purpose	No	Dementia	Yes	Belley et al. (2014)
Assistive system prototype	Distributed system	Interaction	General-Purpose	Yes	Dementia	No	Colonius et al. (2010)
Assistive videomonitoring	Distributed system	Monitoring	General-Purpose	Yes	GEPND	No	Edgcomb et al. (2013)
ASTROMOBILE	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Cavallo et al. (2013)
ATLEC personalised mobile application	Handheld/Multimedia	ADL	General-Purpose	Yes	GEPND	Yes (thoroughly tested with people with disabilities, teachers, trainers, carers and	Papavasiliou et al. (2014)

						professionals: 29 people in Belgium, 20 in Greece, 20 in Italy, 20 in the UK)	
Attendant propelled wheelchair	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Suzuki et al. (2012)
Attentional guidance system	Software	Cognitive Assistance	Cognition (Attention)	Yes	GEPND	No	Stork et al. (2009)
Audio and video signal processing for a multimodal environment	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Karpov et al. (2014)
Automatic fall detection system with a rgb-d camera	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Dubois et al. (2013)
Autonomous assistive robot	Robot	ADL	General-Purpose	No	GEPND	Yes	Meng et al. (2006)
AVICENA	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes	Gomez-Sebastià et al. (2016)
AXO-SUIT	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	O'Sullivan et al. (2015)
Bandit II (humanoid torso mounted on the Pioneer mobile base)	Robot (Socially Assistive)	ADL	Social interaction	No	Dementia	Yes	Nestorov et al. (2014), Tapus et al. (2009)
Basic doorbell system	Distributed system	ADL	General-Purpose	Yes	moderate AD	Yes (7 patients with AD)	Lancioni et al. (2013)
Basis B1 Smartwatch	Wearable	Monitoring	General-Purpose	Yes	Dementia	Yes (1 patient with dementia)	Boletsis et al. (2015)
Bath support device	Robot	ADL	General-Purpose	No	GEPND	No	Nagamachi et al. (2014)
Bayesian plan recognition for IWS	Software	ADL	Motor	No	GEPND	No	Huentenmann et al. (2007)
BCI controller for Assistive Robot	HMI	Interaction	General-Purpose	No	GEPND	Yes	Krishna et al. (2013)
BCI for AT	HMI	Interaction	Motor	No	GEPND	Yes	Cincotti et al. (2008)
BCI wheelchair	HMI	Physical Assistance	Motor	No	GEPND	No	Carlson et al. (2012)

Biofeedback based portable device	Wearable	ADL	Motor	Yes	GEPND	Yes (6 older people with Parkinson's Disease and 3 age-matched control subjects)	Mancini et al. (2009)
B-Live	Distributed system	ADL	General-Purpose	No	GEPND	No	Santos et al. (2007)
BMI for hand exoskeleton	HMI	Interaction	General-Purpose	No	GEPND	Yes	Witkowski et al. (2014)
BMI-control for smart homes	HMI	Interaction	Communication	Yes	GEPND	Yes	Ogawa et al. (2015)
Brain Machine Interface System Automation	HMI	Interaction	General-Purpose	No	GEPND	Yes	Penaloza et al. (2014)
Brian 2.0	Robot (Socially Assistive)	Cognitive Assistance	Cognition	No	Dementia	Yes	Chan et al. (2010), McColl et al. (2013)
Brian 2.1	Robot (Socially Assistive)	Cognitive Assistance	Cognition (Reasoning)	Yes	GEPND	Yes (survey with with 46 elderly adults)	Louie et al. (2014)
CACA	Handheld/Multimedia	Cognitive Assistance	Cognition (Reasoning)	No	GEPND	No	Jednoralski et al. (2011)
Calendar	Software	Cognitive Assistance	Cognition (Consciousness)	No	Dementia	Yes	DeOliveira et al. (2010)
Calendar Clock	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	Yes	AD	Yes	Yuginovich & Soar et al. (2014)
CamBadge	Wearable	Monitoring	Emotion	No	GEPND	No	Blythe et al. (2004)
Camera system	Distributed system	Monitoring	General-Purpose	No	Dementia	No	Sugihara et al. (2012)
Candoo	Software (mobile app)	Cognitive Assistance	General-Purpose	Yes	AD	No	Yamagata et al. (2013)
CARA (Context Aware Real-time Assistant)	Distributed system	ADL	Cognition (Reasoning)	No	GEPND	No	Bingchuan et al. (2014)
CARDEAGate	Distributed system	Cognitive Assistance	Cognition (Orientation)	No	GEPND	Yes	Guerra et al. (2014)
Care Media	Distributed system	Monitoring	General-Purpose	No	AD	No	Carrillo et al. (2009)
Care-O-bot	Robot	ADL	Motor	No	GEPND	Yes	Broadbent et al. (2009)
CDSS for mobile	Handheld/Multimedia	Care &	Cognition	Yes	CARE	No	Roy et al.

devices		Rehabilitation	(Decision-making)			(only feasibility study via simulation)	(2014)
CDSS for smart home services	Distributed system	Care & Rehabilitation	Cognition (Decision-making)	Yes	CARE	No (only feasibility study via simulation)	Roy et al. (2014)
CIRCA (Computer Interactive Reminiscence Conversation Aid)	Software	Interaction	Communication	Yes	Dementia	Yes (3 patients with dementia and 1 conversation partner)	Purves et al. (2015)
CIRCA I	Distributed system	Engagement	Cognition (Memory)	Yes	Dementia	Yes	Alm et al. (2009)
CIRCA II	Distributed system	Engagement	Cognition (Memory)	No	Dementia	Yes	Alm et al. (2009)
Cloud architecture for family recognition	Software	Cognitive Assistance	Cognition	Yes	AD	Yes	Fardoun et al. (2015)
COAALAS	Robot (Socially Assistive)	Interaction	General-Purpose	No	GEPND	No	Moreno et al. (2013)
COACH	Distributed system	ADL	General-Purpose	No	Dementia	Yes	Boger et al. (2010)
COGKNOW	Distributed system	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes	Meiland et al. (2012), Nugent et al. (2008)
COGKNOW Day Navigator Version I	Distributed system	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes	Droes et al. (2010), Meiland et al. (2010)
Collaborative patient-carer system	HMI	Cognitive Assistance	Cognition (Memory)	Yes	AD	Yes	Beattie et al. (2015)
Collaborative reading of digital books	Handheld/Multimedia	Cognitive Assistance	Perception	No	GEPND	No	Snelgrove et al. (2010)
Communication interface and protocol for robotic assistive device	HMI	Physical Assistance	Motor	No	GEPND	No	Lubecki et al. (2012)
Compact Assistence System prototype	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Yamada et al. (2013)

CompanionAble	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	Dementia	No	Nestorov et al. (2014), Kerssens et al. (2015), Merten et al. (2012), Gross et al. (2011), Pastor et al. (2009)
Computer based cognitive training	Handheld/Multimedia	Cognitive Assistance	Perception	Yes	MCI	Yes (59 patients with MCI)	Stavros et al. (2010)
Computer vision based sensing agent	Distributed system	ADL	Perception	No	Dementia	No	As'ari et al. (2012)
Computer vision-based fall detection system	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes (15 elderly people in a simulated home environment)	Miao et al. (2012)
Computer-aided program	Software	ADL	General-Purpose	No	GEPND	Yes (6 persons with multiple disabilities)	Lancioni et al. (2015)
Computer-aided program	Software	Cognitive Assistance	Cognition (Memory)	Yes	moderate AD	Yes (16 subjects with moderate AD)	Lancioni et al. (2015)
Computer-aided telephone system	Handheld/Multimedia	Interaction	Communication	Yes	AD	Yes (5 patients with AD)	Perilli et al. (2013)
Computer-based third element to the interaction	Distributed system	Interaction	Communication	Yes	Dementia	No	Alm et al. (2013)
Computerized guidance system using Markov decision processes (MDPs)	Distributed system	Cognitive Assistance	Cognition (Orientation)	No	Dementia	No	Boger et al. (2006)
Context-Aware Distributed Sensor Network System	Distributed system	Physical Assistance	Motor	No	Dementia	No	Aung Aung et al. (2010)
Context-Aware Smart Oven	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Yared et al. (2015)
Conversational agent	Distributed system	Interaction	Communication	No	Dementia	No	Hung-Hsuan et al. (2014)

Conversational robot	Robot	Interaction	Communication	Yes	GEPND	Yes (30 elderly adults)	Heerink et al. (2008)
Cooker Monitor	Distributed system	Monitoring	Cognition (Memory)	No	Dementia	No	Adlam et al. (2004)
CORBYS gait rehabilitation robot	Robot	Care & Rehabilitation	Motor	No	GEPND	No	Grosu et al. (2015)
Corscience CORBELT	Wearable	Monitoring	General-Purpose	No	GEPND	Yes (interviews with 12 older adults)	Ehmen et al. (2012)
Cross platform	Distributed system	Interaction	General-Purpose	No	GEPND	No	Yanyan et al. (2013)
Daily Assistant	Distributed system	Cognitive Assistance	Cognition (Memory)	No	GEPND	No	Duong et al. (2011)
DANAH assistive system	Distributed system	ADL	General-Purpose	No	GEPND	No	Lankri et al. (2009)
DAT Service	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Andrich et al. (2007)
Data logging system with RFID technology	Distributed system	Monitoring	General-Purpose	No	Dementia	No	Sugihara et al. (2012)
Decision making support	Distributed system	Cognitive Assistance	Cognition (Decision-making)	No	GEPND	No	Lin et al. (2009)
Decision support for AD patients in smart homes	Distributed system	Cognitive Assistance	Cognition (Decision-making)	No	AD	Yes	Shuai et al. (2008), Zhang et al. (2008)
DIADEM application	Software (WEB)	ADL	Cognition (Reasoning)	Yes	GEPND	No	Money et al. (2011)
Digital Photo Diary	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes (survey with 408 professionals)	Harrefors et al. (2012)
Digital Sign System for Indoor Wayfinding	Wearable	Cognitive Assistance	Cognition (Orientation)	No	GEPND	No	Tjan et al. (2005)
Distributed Adaptive Control (DAC)	Software	Interaction	General-Purpose	No	GEPND	No	Stoelen et al. (2014)
Distributed cognitive aid	Distributed system	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes	LoPresti et al. (2008)
Domeo	Robot (Socially Assistive)	ADL	Emotion	Yes	GEPND	No	Zsiga et al. (2013)
Dress (Develop a Responsive Emotive Sensing System)	Distributed system	Physical Assistance	General-Purpose	No	AD	No	Tung et al. (2013)
Dusty	Robot	ADL	Cognition	Yes	GEPND	Yes	King et al.

							(2012)
Dynamic Pointing Assistive Program (DPAP)	Wearable	ADL	Perception	Yes	GEPND	Yes	Shih et al. (2011)
E-assessment tool	Software	Cognitive Assistance	Cognition (Decision-making)	Yes	CARE	Yes	Nilsson et al. (2014)
Ed	Robot	ADL	Cognition	Yes	AD	Yes (10 participants with AD)	Rudicz et al. (2015)
EEG-based BCI for assistive wheelchair	HMI	ADL	Motor	No	GEPND	Yes	Li et al. (2013)
E-JUST assistive device (EJAD)	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Salah et al. (2013)
Electric lifting chair with hip-up function	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Ju-hwan et al. (2011)
Electronic guidance system	Wearable	ADL	Perception	No	GEPND	No	Agarwal et al. (2015)
Embedded platform for fall detection	Distributed system	Monitoring	Motor	Yes	GEPND	No	Kwolek et al. (2014)
Emergency Call System	Distributed system	Monitoring	Cognition	Yes	AD	Yes	Yuginovich & Soar et al. (2014)
EMG-controlled Rehabilitation Robot	Robot	Physical Assistance	Motor	No	GEPND	No	Akdogan et al. (2011)
EMG-Controlled Robotic Elbow Prosthesis	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Kumar Kundu et al. (2007)
Emotionally intelligent cognitive assistant I	Robot (Socially Assistive)	Cognitive Assistance	General-Purpose	No	AD	No	Lin et al. (2014)
Emotionally intelligent cognitive assistant II	Robot	Cognitive Assistance	Emotion	No	AD	No	Luyuan et al. (2014)
Engaging Platform for Art Development (ePAD)	Handheld/Multimedia	Engagement	Cognition (Reasoning)	Yes	Dementia	Yes (6 patients with mild to moderate dementia)	Leuty et al. (2013)
ePAD	Handheld/Multimedia	Engagement	General-Purpose	No	AD	No	Tung et al. (2013)
ePAD I for Art	Handheld/Multimedia	Engagement	Emotion	Yes	Dementia	Yes	Mihailidis et

therapy							al. (2011)
ePAD II for Art therapy	Handheld/Multimedia	Engagement	Emotion	Yes	Dementia	Yes	Mihailidis et al. (2011)
ePAD III for Art therapy	Handheld/Multimedia	Engagement	Emotion	Yes	Dementia	Yes	Mihailidis et al. (2011)
Epitalk	Distributed system	ADL	General-Purpose	No	Dementia	Yes	Mei et al. (2006)
EpiTalk advisor system	Distributed system	Monitoring	General-Purpose	No	AD	Yes	Sun et al. (2006)
eWALL	Distributed system	Monitoring	General-Purpose	Yes	Dementia	No	Mihovska et al. (2014)
eWALL	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Kyriazakos et al. (2016)
Exertion games	Distributed system	Engagement	Emotion	No	GEPND	No	Gerling et al. (2010)
Exoskeleton for ankle propulsion	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Wiggin et al. (2011)
Exoskeleton Robot for Human Forearm and Wrist Motion Assist	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Gopura et al. (2008)
EXPOS	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Kyoungchul et al. (2006)
ExPress Play	Software	Cognitive Assistance	Cognition (Memory)	No	Dementia	Yes	Alm et al. (2011)
ExpressPlay	Distributed system	Engagement	Cognition (Memory)	No	Dementia	Yes	Alm et al. (2011)
Eye-contolled multitask gadget	Wearable	Cognitive Assistance	Perception	No	GEPND	No	Gandhi et al. (2010)
EyeSEC	HMI	Interaction	Perception	No	GEPND	No	Moita et al. (2012)
Face recognition app for Android OS	Handheld/Multimedia	Cognitive Assistance	Cognition	No	Dementia	No	Doukas et al. (2010)
FALL DETECTION SOLUTION for smarphone	Software (mobile app)	Monitoring	General-Purpose	No	GEPND	No	Zhuang et al. (2013)
FOOD Smart Kitchen	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Grossi et al. (2014)
Framework for context-aware online physiological monitoring	Software	Monitoring	General-Purpose	No	GEPND	No	Shuai et al. (2011)
Friendly Rest Room (FRR)	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Magnusson et al. (2011)
Fusion of machine vision and an	Distributed system	Monitoring	General-Purpose	No	Dementia	No	Matic et al. (2009)

RFID system							
Fuzzy Control for Electric Power-Assisted Wheelchair	Software	Cognitive Assistance	Motor	No	GEPND	No	Seki et al. (2012)
Fuzzy controller for automatic microphone	Distributed system	ADL	Perception	No	GEPND	No	Gonzalez-Delgado et al. (2014)
Gait analysis protocol for walk assistive device	Software	Physical Assistance	Motor	No	GEPND	Yes	Martins et al. (2013)
Gait assistive device	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Das et al. (2014)
Gait Trainer (GT)	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Regnaux et al. (2008)
GAL technology	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes (79 apartments with senior citizens)	Haux et al. (2014)
Gamification tool	Wearable	Emotional Assistance	Emotion	No	GEPND	Yes	Korn (2012)/13/14) et al. (2014)
Garmin premium heart rate monitor	Wearable	Monitoring	General-Purpose	No	GEPND	Yes	Ehmen et al. (2012)
Gator Tech Smart House	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Helal et al. (2009), Davenport et al. (2007)
Gaze pattern based mobile eye tracking system for user authentication	Wearable	ADL	Cognition (Memory)	No	GEPND	No	Koceijko et al. (2012)
Geriatric Software	Software	Cognitive Assistance	Cognition (Memory)	No	Dementia	Yes	DeOliveira et al. (2010)
Giraff	Robot (Telepresence)	Monitoring	Communication	Yes	GEPND	Yes	Boman et al. (2013)
Giraffplus	Robot (Telepresence)	Monitoring	Social interaction	No	GEPND	Yes	Coradeschi et al. (2013)
GiraffPlus-mobile (GP-m)	HMI	Monitoring	General-Purpose	No	GEPND	No	Palumbo et al. (2014)
Global Public Inclusive Infrastructure (GPII)	Distributed system	Interaction	General-Purpose	Yes	GEPND	No	Vanderheiden (2012)/14) et al. (2014)
Graphical user interface (GUI) for service robot	HMI	Interaction	General-Purpose	Yes	Dementia	Yes (11 subjects with MCI and	Pino et al. (2012)

						11 elderly with normal cognition)	
Graphical user interface for drag and drop	HMI	Interaction	General-Purpose	Yes	Dementia	Yes	Vella et al. (2011)
Gravity-balanced assistive device for sit-to-stand tasks	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Fattah et al. (2004)
Guido robotic walker	Robot	Physical Assistance	Perception	Yes	GEPND	Yes (45 elderly participants)	Rentschler et al. (2008)
Hair-washing Robot	Robot	ADL	General-Purpose	Yes	GEPND	Yes	Wan-Ling et al. (2013)
HAL Exoskeleton	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Sczesny-Kaiser et al. (2015)
Hand tracker for COACH	Wearable	Monitoring	General-Purpose	No	Dementia	Yes	Czarnuch et al. (2015)
Handheld technology	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	No	AD	Yes	Becker et al. (2007)
Handwashing gudance tool	Distributed system	Physical Assistance	General-Purpose	No	Dementia	Yes	Von Bertoldi et al. (2008)
HAPPY AGEING system	Distributed system	ADL	General-Purpose	No	GEPND	No	Marcelini et al. (2011)
Haptic Touchscreen Interface	HMI	Cognitive Assistance	Perception	No	GEPND	Yes	Nishino (2010)/11) et al. (2011)
Haptic user interfaces (HUIs) for computer navigation	HMI	Cognitive Assistance	Perception	Yes	Dementia	No	Kim et al. (2011)
Haptic web browser	Software	Cognitive Assistance	Perception	No	GEPND	Yes	Nishino et al. (2012)
Health care information system	Handheld/Multimedia	Monitoring	General-Purpose	No	GEPND	Yes	Stefanos et al. (2008)
Health monitoring system	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Schilling et al. (2009)
HicMo ICT platform for active aging	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Peruzzini et al. (2014)
Highly-integrated system for behavioral analysis	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Liciotti et al. (2014)
Home automation system for elderly care	Distributed system	ADL	General-Purpose	No	GEPND	No	Grossi et al. (2008), Mann et al. (2007)
Home health	Distributed system	Monitoring	General-	No	GEPND	No	Sabarivani et

assistive system			Purpose				al. (2015)
Home health monitoring system	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes (Survey with 673 older persons with chronic physical conditions)	Mann et al. (2007)
Home robot companion for people with mild cognitive impairment	Robot (Socially Assistive)	Cognitive Assistance	Emotion	Yes	MCI	Yes	Gross et al. (2012)
Home solution for medication management and communication I	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Lee et al. (2011)
Home solution for medication management and communication II	Distributed system	Interaction	Communication	No	GEPND	Yes	Chaiwoo et al. (2011)
HomeCare Hub	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Ashford et al. (2007)
HomePUI	Distributed system	ADL	General-Purpose	No	Dementia	Yes	Burns et al. (2008)
Hopis	Robot	Physical Assistance	General-Purpose	No	GEPND	Yes	Broadbent et al. (2009)
Hug	Robot (Socially Assistive)	Interaction	Emotion	No	GEPND	Yes	Broadbent et al. (2009)
Human activity and health monitoring system prototype	Wearable	Monitoring	General-Purpose	No	GEPND	No	Oniga et al. (2014)
Human Emotion Management System (HEMS) add on LAGUNTXO	Software	Emotional Assistance	Emotion	No	Dementia	No	Martinez et al. (2010)
Human-driven spatial language robot system	Robot	ADL	General-Purpose	Yes	GEPND	No	Carlson et al. (2014)
Humanoid domestic robot	Robot	ADL	General-Purpose	Yes	GEPND	Yes	McGinn et al. (2014)
Humanoid robot	Robot	Cognitive Assistance	Social interaction	No	Dementia	No	Simou et al. (2015)
Humanoid robot for AT evaluation	Robot	ADL	General-Purpose	No	GEPND	Yes	Miura et al. (2013)
iARM	Robot	Physical Assistance	Motor	No	GEPND	Yes	Oyama et al. (2012)

iCane	Robot	Physical Assistance	Motor	No	GEPND	No	Pei et al. (2012)
iCat	Robot (Socially Assistive)	Emotional Assistance	Emotion	Yes	Dementia	Yes (29 older adults aged 70+)	Nestorov et al. (2014), Spiekman et al. (2011), Broadbent et al. (2009)
iGrocer	Handheld/Multimedia	Interaction	General-Purpose	No	GEPND	No	Shekar et al. (2003)
i-Locate LBS monitor	Wearable	Cognitive Assistance	Cognition (Orientation)	Yes	GEPND	Yes (86 older adults)	Thomas et al. (2013)
Indicator-based Smart Glasses	Wearable	Cognitive Assistance	Cognition (Orientation)	No	Dementia	Yes	Forouzian et al. (2015)
Indoor Wayfinding System Based on Passive RFID	Wearable	Monitoring	Cognition (Orientation)	No	Dementia	No	Chang et al. (2008), Yao-Jen et al. (2008)
Information support for PaPeRo	Software	ADL	Communication	No	Dementia	Yes (5 participants with dementia)	Inoue et al. (2012)
Informationally Structured Room for Robotic Assistance	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Tsuij et al. (2015)
Infrared Sensor Anticollision System	Wearable	ADL	Motor	No	Dementia	Yes	Mihailidis et al. (20079
In-home monitoring system (IMS)	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes	Larizza et al. (2014)
INHOME platform	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Vergado et al. (2010)
In-home robotic agent	Robot	Cognitive Assistance	Cognition	Yes	Dementia	No	Fauconau et al. (2009)
INREDIS Cloud-based Assistive Technology Service	Distributed system	ADL	General-Purpose	No	GEPND	No	Murua et al. (2011)
Integrated Platform for Ambient Assisted Living	Distributed system	ADL	General-Purpose	No	GEPND	No	Rossi et al. (2014)
IntelliCare	Software	ADL	General-Purpose	No	GEPND	No	Valente et al. (2010)
Intelligent aging-	Distributed system	Care &	General-	No	GEPND	No	Song et al.

in-place home care web services platform		Rehabilitation	Purpose				(2015)
Intelligent powered wheelchair	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	Dementia	Yes	Mihailidis et al. (2007)
Intelligent robotic system	Robot	ADL	General-Purpose	No	GEPND	No	Jarvis et al. (2009)
Intelligent speed adaptation (ISA)	Distributed system	Cognitive Assistance	Cognition	Yes	Dementia	Yes	Klarborg et al. (2012)
Intelligent Sweet Home (ISH)	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Lee et al. (2007), Jung et al. (2005), Jin-Woo et al. (2005)
Intelligent system with a monitoring infrastructure	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Casas et al. (2008)
Intelligent toilet prototype	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes (trial in a day activity centre over a period of 2 months with 29 primary and 12 secondary users)	Panek et al. (2009)
Intelligent total access system (ITAS)	HMI	Interaction	Social interaction	No	GEPND	No	Scott et al. (2004)
Intelligent walking-aid	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Mederic et al. (2005)
intelligent walking-aid robot	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Xu et al. (2015)
Intelligent WC	Distributed system	ADL	General-Purpose	No	GEPND	No	Nagamachi et al. (2014)
Intelligent Wheelchair System (IWS) I	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Boucher et al. (2013)
Intelligent Wheelchair System (IWS) II	Mobility & Rehabilitation Aid	ADL	Motor	Yes	Dementia	Yes	How et al. (2013)
Interactive digital television (iDTV)	Distributed system	Engagement	Emotion	Yes	GEPND	Yes	Bures et al. (2012)
Interactive entertainment system	Distributed system	Engagement	Emotion	Yes	Dementia	Yes	Alm et al. (2007)
Interactive	Distributed system	Monitoring	Cognition	Yes	AD	No	Al-Muhanna

multimedia system			(Memory)				et al. (2011)
Interactive screen-based Augmented Exercise Biking with Virtual Environments	Mobility & Rehabilitation Aid	Physical Assistance	General-Purpose	Yes	GEPND	No	Bruun-Pedersen et al. (2014)
Interactive visual multiple choice question game	Distributed system	Cognitive Assistance	Cognition (Reasoning)	No	Dementia	Yes	Chilukoti et al. (2007)
Interface for Assistive Robot	HMI	Interaction	Communication	Yes	GEPND	No	Broz et al. (2015)
Interface for Assistive Robot Based on Growing Neural Gas	HMI	Interaction	General-Purpose	No	GEPND	No	Yanik et al. (2014)
Interface for joints exoskeleton robots	HMI	Physical Assistance	Motor	No	GEPND	No	Kizilhan et al. (2015)
Internet Browser Interface I	HMI	Cognitive Assistance	General-Purpose	No	Dementia	No	Pai Hsun et al. (2014)
Internet browser interface II	HMI	Cognitive Assistance	Cognition (Reasoning)	No	GEPND	Yes	Chen et al. (2014)
IoT enabled cross-platform	Distributed system	Interaction	general-purpose	No	GEPND	No	Konstantinidis et al. (2015)
iPad Hub for Smart Homes	Handheld/Multimedia	ADL	General-Purpose	No	GEPND	No	Alvseike et al. (2012)
iPhone-based portable brain control wheelchair	HMI	ADL	Motor	No	GEPND	No	Jiang et al. (2012)
iRobot Roomba	Robot	ADL	General-Purpose	Yes	GEPND	Yes	Wan-Ling & Sabanovic (2013), Broadbent et al. (2009)
IRT Home-Assistant Robot	Robot	ADL	General-Purpose	No	GEPND	No	Yamazaki et al. (2012)
ISISEMD system	Distributed system	Care & Rehabilitation	General-Purpose	Yes	Dementia	Yes	Mitseva et al. (2012)
iTutorials	Handheld/Multimedia	ADL	General-Purpose	No	Dementia	Yes	Rubio et al. (2011)
iWalker	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Cortes et al. (2008)
Jungle App	Software (mobile app)	ADL	Emotion	Yes	AD	No	Yamagata et al. (2013)
Kannon	Distributed system	ADL	General-Purpose	No	GEPND	No	Zao et al. (2006)
Keep- In-Touch	Distributed system	Interaction	Communication	Yes	GEPND	Yes (6-month pilot study in a clinic)	Kieffer et al. (2011)
KOBIAN	Robot	ADL	General-	Yes	GEPND	No	Zecca et al.

			Purpose				(2009)
Kompaï robot	Robot (Socially Assistive)	Cognitive Assistance	Cognition	Yes	Dementia	Yes (6 older adults with cognitive impairment)	Nestorov et al. (2014), Wu et al. (2014)
KSERA	Robot (Socially Assistive)	ADL	General-Purpose	Yes	GEPND	Yes	Johnson et al. (2014)
LAGUNTXO	Distributed system	ADL	Emotion	Yes	Dementia	No	Martinez et al. (2010)
Leap Motion	Mobility & Rehabilitation Aid	Care & Rehabilitation	Motor	No	GEPND	No	Kin Fun et al. (2014)
Leap Motion Controller	HMI	Physical Assistance	Motor	No	GEPND	No	Bassily et al. (2014)
Light-based alarm for general smart building system	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Jarvinen et al. (2012)
Lightweight walking assistant	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Li & Hashimoto (2016)
Living Lab	Distributed system	Engagement	Cognition (Decision-making)	Yes	GEPND	Yes	Panek et al. (2007)
Localization and safety monitoring cane	Handheld/Multimedia	Physical Assistance	Motor	No	GEPND	No	Lee et al. (2015)
Lokomat (LOKO)	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Regnaux et al. (2008)
Louise	HMI	Monitoring	Cognition (Consciousness)	Yes	Dementia	No	Wargnier et al. (2015)
Lower limb exoskeleton I	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Miranda-Linares et al. (2015)
Lower limb exoskeleton II	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Tang et al. (2014)
LUCAS Robot	Robot	Interaction	Perception	No	MCI	No	Behan et al. (2005)
MaKey MaKey	Handheld/Multimedia	Engagement	Emotion	Yes	GEPND	Yes	Rogers et al. (2014)
Matilda	Robot (Socially Assistive)	Interaction	Communication	No	Dementia	Yes	Khosla et al. (2014)
MATS	Robot	Physical Assistance	Motor	No	GEPND	No	Balaguer et al. (2006)
Memory assistant companion	Distributed system	Cognitive Assistance	Cognition (Memory)	No	Dementia	No	Hung-Hsuan et al. (2012)
Memory karaoke	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes	Tang et al. (2007)
MEMS-based intelligent	Distributed system	ADL	General-Purpose	No	GEPND	No	Zao et al. (2006)

sensor/actuator Modules							
Microsoft Kinect	Distributed system	Monitoring	General-Purpose	Yes	GEPND	No	Znagui et al. (2011), Cunha et al. (2014)
Microsoft's Speech Application Programming Interface (SAPI)	HMI	Interaction	Communication	No	GEPND	No	Luo et al. (2011)
Mobile app for speech recording	Software (mobile app)	Interaction	Communication	No	Dementia	No	Chai et al. (2015)
Mobile AR system (tablet)	Handheld/Multimedia	Interaction	Social interaction	Yes	GEPND	Yes (48 participants including elderly people, caregivers and experts)	Saracchini et al. (2015)
Mobile AR system (wearable)	Wearable	Interaction	Social interaction	Yes	GEPND	Yes 48 participants including elderly people, caregivers and experts)	Saracchini et al. (2015)
Mobile assistive technology (MAT)	Handheld/Multimedia	Care & Rehabilitation	General-Purpose	No	Dementia	No	Zerth et al. (2012)
Mobile Conversational Agent	HMI	Engagement	Communication	Yes	AD	No	Griol et al. (2015)
Mobile device for remote monitoring	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Havlík et al. (2012)
Mobile phone-based video streaming system	Handheld/Multimedia	Interaction	Communication	Yes	Dementia	No	Shuai et al. (2013)
Mobile robot	Robot	ADL	General-Purpose	No	GEPND	No	Ballantyne et al. (2009)
Mobile touch screen based assistive tool	Distributed system	Cognitive Assistance	General-Purpose	Yes	Dementia	No	Mayer et al. (2013)
Mobile translation system (Speech Language to Hand Motion Language)	Handheld/Multimedia	Interaction	Communication	Yes	GEPND	No	Rekha et al. (2014)
Mobile-compatible home robot system	Distributed system	ADL	General-Purpose	No	GEPND	No	Benavidez et al. (2015)
Mobility Assistant	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Krieg-Brückner et al.

							(2010)
MOBOT*	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Ho Hoang et al. (2015), Khai-Long et al. (2015)
Model of activity recognition in smart homes	Distributed system	Cognitive Assistance	General-Purpose	No	Dementia	Yes	Roy et al. (2011)
Modular Elder Service Zone	Distributed system	ADL	General-Purpose	No	GEPND	No	Zao et al. (2006)
Mon Ami™	Mobility & Rehabilitation Aid	Monitoring	General-Purpose	No	GEPND	Yes	Balog et al. (2012)
Monitoring Memory Streams (MMS) iPad application	Handheld/Multimedia	Monitoring	Cognition (Memory)	Yes	AD	Yes	AlMazrua et al. (2013)
Motor imagery based BCI	HMI	Interaction	General-Purpose	Yes	GEPND	Yes	Jiralerspong et al. (2014)
Mouse driver	Wearable	ADL	Perception	Yes	GEPND	Yes	Shih et al. (2011)
MOVAID	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Broadbent et al. (2009)
MPVS system	Handheld/Multimedia	ADL	General-Purpose	No	AD	No	Zhang et al. (2014)
Multi-agent system for assistive social network	Distributed system	ADL	General-Purpose	Yes	GEPND	No	Barruè et al. (2015)
Multi-function mobility assistive device	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Asker et al. (2015)
Multimedia contents for remote assistance	Distributed system	Emotional Assistance	Emotion	Yes	Dementia	Yes	Hamada et al. (2009)
Multimedia convergence user interface for smart home	HMI	Interaction	General-Purpose	No	GEPND	Yes (7 people aged from 60 to 93)	Jenko et al. (2007)
Multimedia verbal instructions	Handheld/Multimedia	ADL	General-Purpose	Yes	Moderate AD	Yes (11 patients with AD)	Lancioni et al. (2010)
Multimodal interactive system	Distributed system	ADL	General-Purpose	Yes	Dementia	Yes	Mokhtari et al. (2012)
Multimodal Robot/Human Interface	HMI	ADL	General-Purpose	No	GEPND	No	Jarvis et al. (2009)
Multimodal sensor system	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Schumm et al. (2010)
Multiple sensor	Distributed system	Cognitive	Cognition	No	GEPND	No	Mustapha et

based Obstacle Detection System (ODS)		Assistance	(Orientation)				al. (2014)
Multipurpose robotic system	Robot	ADL	General-Purpose	No	GEPND	No	Irene Cavallaro et al. (2012)
Multiuser indoor localization system	Distributed system	Cognitive Assistance	Cognition (Orientation)	Yes	GEPND	Yes	Veronese et al. (2014)
Music choice program	Software	Engagement	General-Purpose	Yes	moderate AD	Yes	Lancioni et al. (2014)
Music therapist robot	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	AD	Yes	Tapus et al. (2009)
My Life (Digital Reminiscence Therapy Software)	Software (WEB)	Cognitive Assistance	Cognition (Memory)	Yes	Dementia	Yes	Hellman et al. (2014)
Nabaztag	Robot (Socially Assistive)	ADL	General-Purpose	Yes	GEPND	Yes (29 adults aged 70+)	Spiekman et al. (2011)
Nadine robot	Robot (Socially Assistive)	Interaction	Social interaction	Yes	GEPND	No	Magnenat-Thalmann et al. (2014)
Nao	Robot	ADL	General-Purpose	Yes	GEPND	Yes (29 adults aged 70+)	Spiekman et al. (2011)
Navigation system for powered wheelchairs	Distributed system	ADL	Cognition (Orientation)	No	GEPND	No	Fioretti et al. (2000)
Network System	Distributed system	Interaction	General-Purpose	No	GEPND	No	Houde et al. (2015)
Neural control for robot	HMI	Interaction	Motor	No	GEPND	No	Masse et al. (2011)
NFC Interface for smart environments	HMI	Interaction	General-Purpose	No	GEPND	Yes	Spinsante et al. (2015)
NFC-based monitoring system	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Jara et al. (2014)
NFC-based video system	Handheld/Multimedia	Engagement	Cognition	No	GEPND	No	Rafferty et al. (2014)
Night Light	Distributed system	Monitoring	Motor	No	Dementia	No	Adlam et al. (2004)
NIRS-based experimental smart house	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Ogawa et al. (2015)
NOCTURNAL	Distributed system	ADL	General-Purpose	Yes	Dementia	Yes (8 people with dementia)	Martin et al. (2013), Martin et al. (2013)
Noninvasive monitoring	Distributed system	Monitoring	General-Purpose	Yes	GEPND	No	Leone et al. (2013)

platform based on 3D sensors							
Novel Point-select Technique for Assistive Robots	HMI	Interaction	General-Purpose	No	GEPND	No	Williams et al. (2007)
Nursebot	Robot	Interaction	General-Purpose	Yes	GEPND	Yes	Matthews et al. (2004)
Ontology-based pervasive M2M healthcare environment	Distributed system	ADL	General-Purpose	No	Dementia	No	Chellouche et al. (2013)
Organizational centered multi-agent system (OCMAS) Architecture for Ambient Intelligence	Software	ADL	General-Purpose	No	Dementia	No	Roy et al. (2012)
OSGi-based service platform	Distributed system	ADL	General-Purpose	No	Dementia	Yes (controlled trial with 10 participants aged 25-30 and 10 aged 75-85)	Qiang et al. (2012)
Palm Tungsten T3	Handheld/Multimedia	ADL	Cognition (Memory)	Yes	GEPND	Yes	Siek et al. (2005)
PAMAID (Personal Adaptive Mobility Aid)	Wearable	Physical Assistance	Perception	Yes	GEPND	Yes	Rumeau et al. (2012), Mac Namara et al. (2000)
PaPeRo	Robot (Socially Assistive)	ADL	General-Purpose	No	Dementia	Yes	Inoue et al. (2012)
Paro	Robot (Socially Assistive)	Emotional Assistance	Emotion	Yes	Dementia	No	Nestorov et al. (2014), Wan-Ling et al. (2013)
PASS	Distributed system	Cognitive Assistance	General-Purpose	No	GEPND	No	Siddiqi et al. (2008)
Pattern recognition based system	Distributed system	Monitoring	Motor	No	GEPND	No	Sasidhar et al. (2013)
PDA	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	Yes	GEPND	Yes (673 older persons with chronic physical conditions)	Mann et al. (2007)
Pearl	Robot	Cognitive Assistance	Cognition (Memory)	No	GEPND	Yes	Broadbent et al. (2009)

Personal amplifying device	Wearable	Cognitive Assistance	General-Purpose	Yes	AD	Yes	Yuginovich & Soar et al. (2014)
Personal Social Assistant.	Handheld/Multimedia	Cognitive Assistance	General-Purpose	No	Dementia	No	Verstockt et al. (2009)
Pervasive ZigBee network	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Cavallo et al. (2009)
PhonAge	Handheld/Multimedia	ADL	Cognition (Memory)	Yes	GEPND	No	Abdulrazak et al. (2013)
Physiotherapeutic Assistive Trainer (PAT) for Nao	Robot	Physical Assistance	Motor	No	GEPND	No	Bhuvaneswari et al. (2013)
PIA system	Handheld/Multimedia	Cognitive Assistance	General-Purpose	Yes	Dementia	Yes	Hellman et al. (2014)
Pictorial instruction program	Software	ADL	General-Purpose	Yes	moderate AD	Yes	Lancioni et al. (2013), Lancioni et al. (2014)
Picture Album	Handheld/Multimedia	Cognitive Assistance	Perception	No	GEPND	No	Duong et al. (2011)
Pilot ICT service	Handheld/Multimedia	Interaction	Communication	Yes	AD	No	Stancic et al. (2011)
Platform for muscle fatige monitoring	Distributed system	Monitoring	Motor	Yes	GEPND	No	Tatarisco et al. (2012)
Play System for Elderly Therapy (PSET)	Handheld/Multimedia	Emotional Assistance	Emotion	Yes	GEPND	No	Zviel-Girshin et al. (2011)
Plug-&-play integration for Gator Tech Smart House (GTSH)	Distributed system	ADL	General-Purpose	No	GEPND	No	Abdulrazak et al. (2006)
Pocket Buddy	Wearable (VR)	Interaction	Communication	No	AD	No	Carrillo et al. (2009)
Polar wear link coded R	Wearable	Monitoring	General-Purpose	No	GEPND	Yes	Ehmen et al. (2012)
Power assistive device for self-supported transfer motion	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Nagai et al. (2002)
Power-assisted transport wheelchair	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Chi et al. (2013)
Predictive location-aware algorithm for assurance systems	Software	ADL	General-Purpose	No	Dementia	Yes	Vuong et al. (2011)
Prompts	Distributed system	Cognitive Assistance	Cognition	Yes	AD	Yes	Lapointe et al. (2013)

Prototype development of an overhead robot arm	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Suzuki et al. (2000)
Prototype Intelligent Power Wheelchair (IPW)	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes (12 older users, 4 caregivers and 12clinicians)	Rushton et al. (2015)
Public Domain Dataset	Software	Monitoring	General-Purpose	Yes	GEPND	No	Bruno et al. (2014)
Queensland Smart Home Initiative (QSHI)	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Soar et al. (2009)
RAPUDA	Robot	ADL	Motor	No	GEPND	Yes	Oyama et al. (2012)
Reading Assistive Computer System	Handheld/Multimedia	Cognitive Assistance	Perception	No	GEPND	No	Se-Yeol et al. (2014)
Real-time detection system for water flow detection	Distributed system	ADL	General-Purpose	No	AD	No	Taati et al. (2010)
Recognition scheme based on the Growing Neural Gas (GNG) algorithm	Software	Interaction	General-Purpose	No	GEPND	No	Yanik et al. (2012)
Rehabilitation shoes	Wearable	Care & Rehabilitation	Motor	No	GEPND	No	Simsik et al. (2012)
Remote mobile healthcare monitoring	Distributed system	Cognitive Assistance	Cognition (Orientation)	No	Dementia	Yes	Vuong et al. (2011)
Remote monitoring system	Distributed system	Monitoring	General-Purpose	Yes	Dementia	Yes (real-life test in nursing home)	Schikhof et al. (2008)
Remotely controlled robot	Robot	Monitoring	General-Purpose	No	MCI	No	Devaux et al. (2011)
Remotely controlled robot with video-communication capability	Robot	Interaction	Emotion	Yes	GEPND	No	Seelye et al. (2012)
RFID Localization System for smart homes	Distributed system	Monitoring	Cognition	No	Dementia	Yes	Fortin-Simard et al. (2012)
RFID-based assistive platform	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Alvarez et al. (2007)

RFID-based system for assisted living	Distributed system	ADL	General-Purpose	No	Dementia	No	Symonds et al. (2007)
RIBA	Robot	Care & Rehabilitation	General-Purpose	Yes	GEPND	Yes	Wan-Ling et al. (2013)
Ri-man	Robot (Socially Assistive)	ADL	General-Purpose	No	GEPND	Yes	Broadbent et al. (2009)
ROBADOM	Robot	Cognitive Assistance	Cognition	No	MCI	No	Wu et al. (2012)
RobAlz	Robot (Socially Assistive)	Cognitive Assistance	Cognition	Yes	AD	No	Salichs et al. (2016)
RoBOCARE	Distributed system	ADL	general-purpose	No	GEPND	Yes	Cesta et al. (2007)
Robot for mealtime monitoring	Robot (Socially Assistive)	Monitoring	General-Purpose	No	GEPND	Yes	McColl et al. (2014)
Robot vacuum cleaner	Robot	ADL	General-Purpose	Yes	AD	Yes	Yuginovich & Soar (2014)
Robotic assistive technology for locomotion	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Riviero et al. (2015)
Robotic bed	Robot	Physical Assistance	Motor	No	GEPND	No	Vazquez-Santacruz et al. (2016)
Robotic cane	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Ady et al. (2013)
Robotic dog AIBO	Robot	Physical Assistance	General-Purpose	No	GEPND	Yes	Naganuma et al. (2013)
Robotic fitness coach	Robot	Physical Assistance	Motor	No	GEPND	No	Gorer et al. (2013)
Robotic Home Environment	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Güttler et al. (2015)
Robotic stand-up assist system	Robot	Physical Assistance	Motor	No	GEPND	No	Miyake et al. (2014)
Robotic system	Robot	ADL	General-Purpose	Yes	Dementia	Yes	Begum et al. (2013)
Robotic walker	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	Dementia	Yes	Morris et al. (2003)
Rosetta system	Distributed system	ADL	General-Purpose	Yes	Dementia	Yes	Meiland et al. (2014)
Routine organizer	Software	Cognitive Assistance	General-Purpose	No	Dementia	Yes	DeOliveira et al. (2010)
SALIG device	Handheld/Multimedia	Cognitive Assistance	Cognition	Yes	Dementia	Yes	Boman et al. (2016)
SAM (Smart Autonomous Majordomo)	Robot	ADL	General-Purpose	Yes	GEPND	Yes	Leroux et al. (2013), Lebec et al. (2013)
Scooter	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Schilling et al. (2009)

Self-monitoring ability-reactive technology (SMART)	Distributed system	Care & Rehabilitation	General-Purpose	Yes	Dementia	No	Hakobyan et al. (2014)
Self-transfer robotic facility	Robot	Physical Assistance	Motor	No	GEPND	No	Hari Krishnan et al. (2015)
SEMG acquisition system for assistive robot	HMI	Interaction	General-Purpose	No	GEPND	No	Shuang et al. (2012)
Semi-autonomous wheelchair controlled using head-mounted sensors	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	Yes	Rönnbäck et al. (2006)
SenseCam (Microsoft)	Wearable	Monitoring	Cognition (Memory)	No	Dementia	No	Barnard et al. (2011)
Sensor Fusion-Oriented Fall Detector I	Distributed system	Monitoring	Motor	No	GEPND	No	Cagnoni et al. (2009)
Sensor Fusion-Oriented Fall Detector II	Wearable	Monitoring	Motor	No	GEPND	No	Cagnoni et al. (2009)
Sensor Mat	Distributed system	Monitoring	General-Purpose	Yes	AD	Yes	Yuginovich & Soar et al. (2014)
Sensor network for multi-person smart spaces	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Biswas et al. (2011)
Sensor system for mobility monitoring	Distributed system	Monitoring	Motor	Yes	GEPND	No	Marques et al. (2013)
Sensor-based in-home monitoring system	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Bradford et al. (2013)
Service Architecture for Assistive Robot	Software	Care & Rehabilitation	General-Purpose	No	Dementia	Yes	Khosla et al. (2013)
Service connection device (SCD)	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Chien et al. (2014)
SHARE-it	Distributed system	Interaction	Motor	No	GEPND	No	Cortes et al. (2008)
Sharioto	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Huentenmann et al. (2007)
Simple sensor network	Distributed system	Monitoring	General-Purpose	No	Dementia	Yes	Lofti et al. (2012)
SIMPLE-use (Set for Intuitive Movement and Proximity Logging	Wearable	Cognitive Assistance	General-Purpose	No	GEPND	No	D'Angelo et al. (2014)

for Everyday)							
Simplified e-mail interface	HMI	Cognitive Assistance	Cognition (Reasoning)	Yes	Dementia	Yes	Sohlberg et al. (2003)
Simplified hardware infrastructure for assisted living	Distributed system	ADL	General-Purpose	Yes	Dementia	Yes	Mokhtari et al. (2015)
SJOBOKS	Software (WEB)	Cognitive Assistance	General-Purpose	Yes	GEPND	Yes	Heijkers et al. (2013)
SLIDE FLEX	HMI	Physical Assistance	Motor	No	GEPND	Yes	Nihei et al. (2012)
Smart Assistive Living (SAL) platform	Distributed system	ADL	General-Purpose	No	Dementia	No	Zhang et al. (2014)
Smart augmenting walker in ubiquitous-computing environment	Distributed system	Physical Assistance	Motor	No	GEPND	No	Chen et al. (2008)
Smart chair to assist sit-to-stand transferring	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Lu et al. (2014)
Smart environment	Distributed system	ADL	General-Purpose	No	GEPND	No	Kerbler et al. (2014)
Smart garment system	Wearable	ADL	General-Purpose	No	GEPND	No	McCann et al. (2008)
Smart Glasses for E-health support	Wearable	ADL	Cognition	Yes	Dementia	No	Zhao et al. (2015)
Smart grab bars	Distributed system	ADL	General-Purpose	No	GEPND	Yes (69 older adults)	Guitard et al. (2013)
Smart Hoist	Robot	Physical Assistance	General-purpose	Yes	GEPND	No	Dantanarayana et al. (2014), Ranasinghe et al. (2014)
Smart home device	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Cho et al. (2014)
Smart home healthcare system utilizing assistive technology	Distributed system	Cognitive Assistance	General-Purpose	No	Dementia	No	Fong et al. (2012)
Smart Home IRIS	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes (59 persons with disabilities and elderly people)	Ocepek et al. (2013)
Smart home pilot	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes	Melkas et al. (2013)

Smart home system via Wireless Bluetooth	Distributed system	ADL	General-Purpose	No	GEPND	No	Ramlee et al. (2012)
Smart household control system	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Franco et al. (2013)
Smart kitchen environment featuring workflow technology	Distributed system	Monitoring	General-Purpose	No	Dementia	No	Sarni et al. (2013)
Smart mobile walker	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Kiwan et al. (2014)
Smart Mobile Walker (SMW) I	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Kim et al. (2011)
Smart Mobile Walker(SMW) II	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Inho et al. (2011)
Smart Mote-based Wireless Medication Management System	Distributed system	Care & Rehabilitation	Cognition (Memory)	No	Dementia	No	Fook et al. (2008)
Smart prompt-generator	Robot	Cognitive Assistance	Cognition	Yes	Dementia	Yes	Bewernitz et al. (2009)
Smart robotic assisted healthcare tool	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Gilham et al. (2012)
Smart rollator	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Chan et al. (2008)
Smart skirt	Wearable	Monitoring	General-Purpose	No	Dementia	No	Culen et al. (2014)
Smart Voice Messaging System (SVMS)	Handheld/Multimedia	Interaction	Communication	Yes	Dementia	No	Sugihara et al. (2014)
Smartbrain	Software (mobile app)	Cognitive Assistance	Cognition (Reasoning)	Yes	AD	No	Yamagata et al. (2013)
SmartCane	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Au et al. (2008)
Smart-chair for sit-to-stand transfer	Mobility & Rehabilitation Aid	Physical Assistance	Motor	Yes	GEPND	No	Hang et al. (2014)
Smarter Safer Homes (SSH) platform	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes	Dodd et al. (2015)
Smart-home based activity recognition	Distributed system	Monitoring	General-Purpose	Yes	AD	Yes	Belley et al. (2013)
SmartPal humanoid service robot	Robot	ADL	General-Purpose	No	GEPND	Yes	Tsuij et al. (2015)
Smartphione	Handheld/Multimedia	Cognitive	Cognition	Yes	Dementia	Yes	Brankaert et

Interface		Assistance					al. (2014)
Smartphone Application I	Software (mobile app)	Cognitive Assistance	Cognition (Memory)	Yes	AD	Yes	De Leo et al. (2011)
Smartphone application II	Software (mobile app)	Monitoring	General-Purpose	Yes	AD	Yes	Armstrong et al. (2012)
Smartphone application III	Software (mobile app)	Monitoring	General-Purpose	Yes	AD	Yes	Armstrong et al. (2012)
Smartphone application IV	Software (mobile app)	Monitoring	General-Purpose	Yes	AD	Yes	Armstrong et al. (2012)
Smartphone-based monitoring system	Handheld/Multimedia	Monitoring	General-Purpose	Yes	AD	No	Megalingam et al. (2014)
Smartphone-based prompting system	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	No	Dementia	No	Das et al. (2012)
SmartSenior system	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes (35 apartments with 35 older adults)	Gövercin et al. (2014)
Socially Assistive Robot	Robot (Socially Assistive)	Engagement	Social interaction	Yes	GEPND	No	Frennert et al. (2013)
Socially assistive robot (SAR) system	Robot (Socially Assistive)	Engagement	General-Purpose	No	GEPND	Yes	Fasola et al. (2012)
Socially-Assistive Humanoid Robot	Robot (Socially Assistive)	Emotional Assistance	Emotion	Yes	GEPND	Yes (8 elderly people)	Torta et al. (2014)
Software architecture for assistive robots	Software	Monitoring	Cognition (Reasoning)	No	Dementia	No	Saunders et al. (2013)
Software tool for smart homes	Software	Monitoring	General-Purpose	No	GEPND	No	Poland et al. (2009)
Sophie	Robot (Socially Assistive)	Interaction	Emotion	Yes	GEPND	No	Magnenat-Thalmann et al. (2014)
Speach interface for Ed	HMI	Interaction	Communication	Yes	AD	Yes (10 older adults with AD)	Rudicz et al. (2015)
SPIDer	Robot	Care & Rehabilitation	General-Purpose	Yes	GEPND	No	Moreno et al. (2013)
Spoken dialogue interface to intelligent cognitive assistant	HMI	Interaction	Cognition	Yes	Dementia	No	Wolters et al. (2015)
Standing assistance system	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	No	Chugo et al. (2012)
Standing assistance system for an elderly	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Chugo et al. (2012)

person							
Stereo based system for Assessment of Sit-To-Stand Movement	Distributed system	Monitoring	Motor	No	GEPND	Yes	Allin et al. (2009)
Steward robot for smart home	Robot	Interaction	General-Purpose	No	GEPND	No	Park et al. (2008)
SWEET-HOME system	Distributed system	ADL	General-Purpose	Yes	GEPND	Yes	Vacher et al. (2015)
System for automated recognition of ADLs	Distributed system	ADL	General-Purpose	No	GEPND	Yes	Sim et al. (2010)
System for the control of autonomous assistive robots	Software	Interaction	General-Purpose	No	GEPND	Yes	Meng et al. (2004)
Tablet-based participatory tool	Handheld/Multimedia	Cognitive Assistance	Cognition (Decision-making)	Yes	GEPND	Yes	Buman et al. (2013)
Tactile Sight Inc.	Wearable	Monitoring	Cognition (Orientation)	No	AD	No	Carrillo et al. (2009)
TeleCalmPlus	Distributed system	Monitoring	General-Purpose	Yes	GEPND	No	Budai et al. (2015)
Telemedicine system for supporting optimal palliative care at home	Distributed system	Emotional Assistance	Emotion	Yes	GEPND	No	Levy et al. (2011)
Teleoperated Home Care Mobile Robot	Robot	Care & Rehabilitation	General-Purpose	No	GEPND	No	Zeng et al. (2007)
Telephone support service	Distributed system	Interaction	Communication	No	GEPND	Yes	Johansson & Becker (2011)
Telerobot	Robot (Telepresence)	ADL	General-Purpose	Yes	GEPND	Yes	Michaud et al. (2010)
Teletechnology for multifactorial in-home rehabilitation	Distributed system	ADL	general-purpose	Yes	GEPND	Yes (14 rehabilitation patients)	Hoenig et al. (2006)
The eHealthCom platform	Distributed system	Care & Rehabilitation	General-Purpose	No	GEPND	No	Ferreira et al. (2012)
Toothbrush Handles	Handheld/Multimedia	ADL	General-Purpose	No	GEPND	Yes (RCT with 16 elderly participants)	Kammers et al. (2015)
Touch-screen videophone mock-	Handheld/Multimedia	ADL	Communication	Yes	Dementia	Yes (4 persons	Boman et al. (2014)

up for persons with dementia						with dementia and their significant others)	
Tread-Walk 1	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Nihei et al. (2008)
Tread-Walk 2	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Nihei et al. (2008)
TUG	Robot	ADL	Cognition (Orientation)	Yes	GEPND	Yes	Wan-Ling et al. (2013)
Ubiquitous Robotic Companion (URC)	Robot (Socially Assistive)	ADL	general-purpose	No	GEPND	No	Helal et al. (2008)
Ubiquitous sensors for smart environment	Distributed system	Monitoring	General-Purpose	No	Dementia	Yes	Bilodeau et al. (2014)
Ultrasound sensors for anti-collision systems of powered wheelchairs	Distributed system	Physical Assistance	Motor	No	GEPND	No	Dutta et al. (2015)
Upper-limb assistive device	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Gu et al. (2014), Gwang et al. (2014)
Upper-limb exoskeleton system	Mobility & Rehabilitation Aid	ADL	Motor	No	GEPND	No	Latt et al. (2014)
User-friendly Elders' PDA	Handheld/Multimedia	ADL	General-Purpose	No	GEPND	No	Zao et al. (2006)
Verbal and non-verbal human to TV-based application voice interaction	Distributed system	Monitoring	General-Purpose	Yes	GEPND	Yes	Bures et al. (2012)
Video conference system for Alzheimer's patients at home.	Distributed system	Interaction	Communication	Yes	AD	Yes (8 persons with AD)	Carrasco et al. (2009)
Video Monitoring System for Activity Recognition and Fall Detection	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Schulze et al. (2009)
Virtual Agent prototype	Handheld/Multimedia	Cognitive Assistance	Cognition (Memory)	Yes	AD	Yes	Yaghoubzadeh et al. (2013)
Virtual Butler	Robot	Interaction	General-Purpose	Yes	GEPND	No	Costa et al. (2014)

Virtual development environment	Distributed system	ADL	General-Purpose	No	GEPND	No	Driessen et al. (2003)
Vision based interface system	HMI	Interaction	Motor	No	GEPND	Yes	Ju et al. (2009)
Vision based interface system for hands free control	HMI	ADL	Motor	No	GEPND	Yes	Jin-Sun et al. (2009)
Vision-based door detection technique	Software	Cognitive Assistance	Cognition (Orientation)	No	GEPND	No	Shalaby et al. (2014)
Visual Interaction System for Aldebaran NAO	Robot	Interaction	Cognition	Yes	Dementia	No	Carcagni et al. (2015)
Visual interface for home telecare system	Distributed system	ADL	General-Purpose	Yes	AD	Yes (30 patients with MCI)	Mehrabian et al. (2015)
VitalTrack	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Reyes et al. (2012)
Voice activity detection driven acoustic event classification	Distributed system	Monitoring	general-purpose	No	GEPND	No	Hollosi et al. (2010)
Voice and graphical -based interfaces for interaction with a robot	HMI	Interaction	Communication	No	GEPND	Yes (11 elderly persons with MCI)	Granata et al. (2010)
Voice interface for Sweet Home	HMI	ADL	General-Purpose	Yes	GEPND	Yes	Vacher et al. (2015)
Wakamaru	Robot (Socially Assistive)	ADL	General-Purpose	No	GEPND	Yes	Broadbent et al. (2009)
Walker assistant	Mobility & Rehabilitation Aid	Physical Assistance	Motor	No	GEPND	Yes	Martins et al. (2013)
Waseda Bioinstrumentation system No.1 (WB-1)	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Zecca et al. (2007)
Water supply telemonitoring system	Distributed system	Monitoring	General-Purpose	No	GEPND	Yes	Tamura et al. (2002)
Wayfinding assistant based on sensorimotor representation	Software	Cognitive Assistance	Cognition (Orientation)	No	AD	No	Zetzsche et al. (2012)
Wearable computer-based orientation and	Wearable	Cognitive Assistance	Cognition (Orientation)	No	GEPND	Yes	Ross et al. (2001)

wayfinding aid							
Wearable inertial measurement units (IMUs)	Wearable	Monitoring	General-Purpose	No	GEPND	Yes	Trkov et al. (2015)
Wearable Knee Assistive Instrument (WKAI)	Wearable	Physical Assistance	Motor	Yes	GEPND	Yes	Yong et al. (2012)
Wearable lower-limb assistive device	Wearable	ADL	Motor	No	GEPND	Yes	Hasegawa et al. (2013)
Wearable pervasive platform	Wearable	Monitoring	Motor	No	GEPND	No	Pioggia et al. (2010)
Wearable soft-robotic glove	Wearable	Physical Assistance	Motor	Yes	GEPND	No	Radder et al. (2015)
Web-based non-intrusive ambient system	Distributed system	Monitoring	General-Purpose	Yes	AD	Yes (10 healthy participants and 1 AD patient)	Stucki et al. (2014)
Web-page presentation	Software	Engagement	General-Purpose	Yes	GEPND	Yes	Kurniawan et al. (2006)
Whole-body emotion expression humanoid robot	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	GEPND	Yes	Endo et al. (2008)
Willow Garage's PR2 robot	Robot	ADL	General-Purpose	Yes	GEPND	No	Mitzner et al. (2014)
Wireless Architectures for Heterogeneous Sensing	Software	Monitoring	General-Purpose	No	GEPND	No	Viani et al. (2013)
Wireless Intelligent Healthcare Gadget	Wearable	Monitoring	General-Purpose	No	GEPND	No	Megalingam et al. (2011)
Wireless Sensor Network (WSN)	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Aleksander et al. (2015)
Wireless sensor network based assistive system (WASN)	Distributed system	Interaction	Perception	No	GEPND	No	Ren et al. (2006)
Wrist wearable unit (WWU)	Wearable	Monitoring	General-Purpose	No	GEPND	Yes	Ahanathapillai et al. (2015)
Wrist-worn wearable	Wearable	Monitoring	General-Purpose	Yes	GEPND	No	Bruno et al. (2014)
WWW-based home care system	Distributed system	Care & Rehabilitation	General-Purpose	No	GEPND	No	Nambu et al. (2002)
Yorisoi Ifbot	Robot (Socially Assistive)	Emotional Assistance	Emotion	No	GEPND	Yes	Broadbent et al. (2009)

Zephyr bioharness BT	Wearable	Monitoring	General-Purpose	No	GEPND	Yes	Ehmen et al. (2012)
ZigBee	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Bing et al. (2010)
Zigbee-based Disease Monitoring device	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Zhang et al. (2010)
Zigbee-based Personal Wellness Monitoring Device	Distributed system	Monitoring	General-Purpose	No	GEPND	No	Zhang et al. (2010)

Tab. 5- A Full Index of IATs for Dementia (stand 2016)

Expansion of the IAT spectrum (2000-2016)

Results show the number of IATs is rapidly increasing over time, hence confirming the progressive expansion of the IAT trend in dementia care. As represented in Figure 4, the number of IATs with application to dementia care has increased by over 6 times in the period 2006-2010 as compared to 2000-2005 and has even increased by a factor of 15 in the period 2011-2015 (since the literature review was carried until April 12, 2016, only approximately one-third of the IATs published in 2016 are captured in Figure 4).

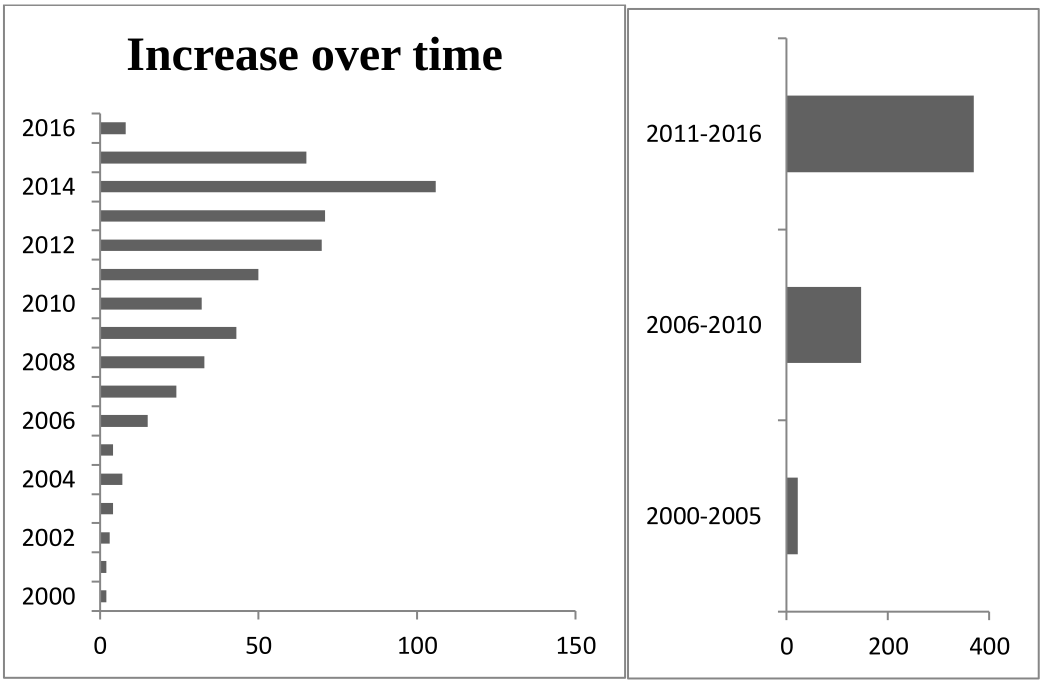

Figure 4- Increasing number of IATs over the time period of 2000 – 2016

Of the total, the majority of systems were distributed systems (n=194), followed by robots (n=97), and mobility and rehabilitation aids (n=62). System goals were determined based on their primary capability according to the intent of the manufacturer. Most IATs were designed with the purposes of supporting users in the completion of ADLs (n=148), monitoring users and their environment (n=100) or providing, respectively, physical (n=88) and cognitive assistance (n=85). Assisted deficits were determined according to the primary cognitive or physical deficit associated with dementia to which the IAT provides compensation. Of the total, most devices were general-purpose, i.e. non-modular but broadly applicable across psychophysical domains, without specialized features exclusive for a particular domain (n=250). Devices exclusively programmed for specific deficits include motor function (n=109), impaired cognition (n=140), and mood and emotional disturbances (n=31). The category “end-user population” was determined according to the end-user segment explicitly targeted by the researchers. Our review identified four end user types according to the specificity of the target population chosen by the researchers: general elderly and disabled population, people with dementia, AD, and specific stages of AD. Models of design and development or assessment and evaluation were screened to identify the proportion of IAT adopting user-centered design and assessed through clinical studies. The variation over time of UC approaches was also examined. Results reveal that the prevalence of UC approaches to IAT design and development is significantly increasing over time and that half of the IAT spectrum received preliminary clinical validation. In the following, we present these findings in detail.

Technological Type

With 194 items, distributed systems represent the largest proportion of IATs for dementia (Fig. 4). These include smart service platforms and Ambient Assisted Living technologies, i.e. distributed assistant systems “for the constitution of intelligent environments” that “aim to compensate predominantly age-related functional limitations of different target groups” (*174*). An example of AAL distributed system is Zhang and colleagues’ (2014) Smart Assistive Living (SAL) platform. This platform is designed to support the delivery of telehealth and telecare services to older people suffering from dementia, and can enable them to stay at home longer and more independently (*175*). The digitalization of the domestic and residential environment is also accelerated by the application to healthcare of the Internet of Things (IoT) technology, another important subcategory of distributed systems (n=24).

With rapid advancements in medical robotics, personal care robots represent the second most common technological type (n=97). While most reviewed robots are domestic service robots (n=62), i.e., autonomous systems that assist users in the completion of practical activities such as house maintenance, alarming, telehealth etc., an interesting growing portion of robots (n=31) is being designed to assist the emotional and social dimension of older people with dementia. Robots of these type are called Socially Assistive Robots (*37*, *144*). A successful example is robot PARO, developed by AIST (See: http://www.parorobots.com/; last accessed: June 2, 2016). Designed to stimulate patients with AD and other cognitive disorders by providing emotional assistance and companionship, PARO has been effectively applied as part of standard occupational therapy (*176*) and revealed a positive effect on the residents' quality-of-life and pleasure scores (*177*). All reviewed robots including PARO presented some degrees of AI such as the ability to learn and remember their own name, and to learn when their behavior results in positive responses of the user.

The relative frequency of hand-held multimedia devices (n=50) is presumably facilitated by the availability of these devices among the general population as everyday communication tools, as a consequence of the growing importance of such mobile devices in our societies. These technological types: include smartphones, tablets, PDAs, and other mobile devices, co-evolving with a rapidly growing digital ecosystem of compliant mobile apps and other software applications (n=50). At the software level, in fact, most hand-held devices were designed to run specific assistive mobile or web applications programmed for people with dementia. For example, the SmartBrains mobile app was developed to provide cognitive enhancement for people with AD (*178*) and was reported to "greatly augment" the "traditional psychomotor stimulation" (*179*).

Wearable devices (n=44) accounted for a slightly smaller portion of the IAT spectrum, possibly as a consequence of the most recent growth of this technological trend. However, since the number of wearables is increasing rapidly over time, it is reasonable to predict that such applications will play an increasingly prevalent role in technology-assisted dementia care. One promising application is the incorporation of a wrist wearable unit into an Android smartwatch to monitor the physical activity of the user and enhance independent living (*180*). Neurowearable devices such as Virtual Reality (VR) and Augmented Reality (AR) systems composed a smaller proportion of the IAT spectrum.

Finally, Human-Machine Interfaces broadly encompass the realm of hardware and software systems (n=42) designed to establish a direct connection pathway between the human user and an external computer device. Among those, particular interest from the perspective of neurocognitive rehabilitation is raised by brain-computer interfaces (BCIs), as they allow users to control external devices solely with brain activity (usually via EEG-recordings), hence bypassing the peripheral nervous and muscle system (*181*). Since BCI applications are usually based on instrumental learning and require users to self-regulate their brain activation —a task whose completion is very limited among elders with dementia, they were considered for many years not suitable for compensating the cognitive deficits in AD patients (*182*). However, recent advancements in the detection of involuntary brain signals (e.g. related to emotional states) are enabling the development of new BCI solutions (n=7) with possible application to dementia care, including BCIs for early diagnosis, computerized cognitive training and communication (*182*, *183*).

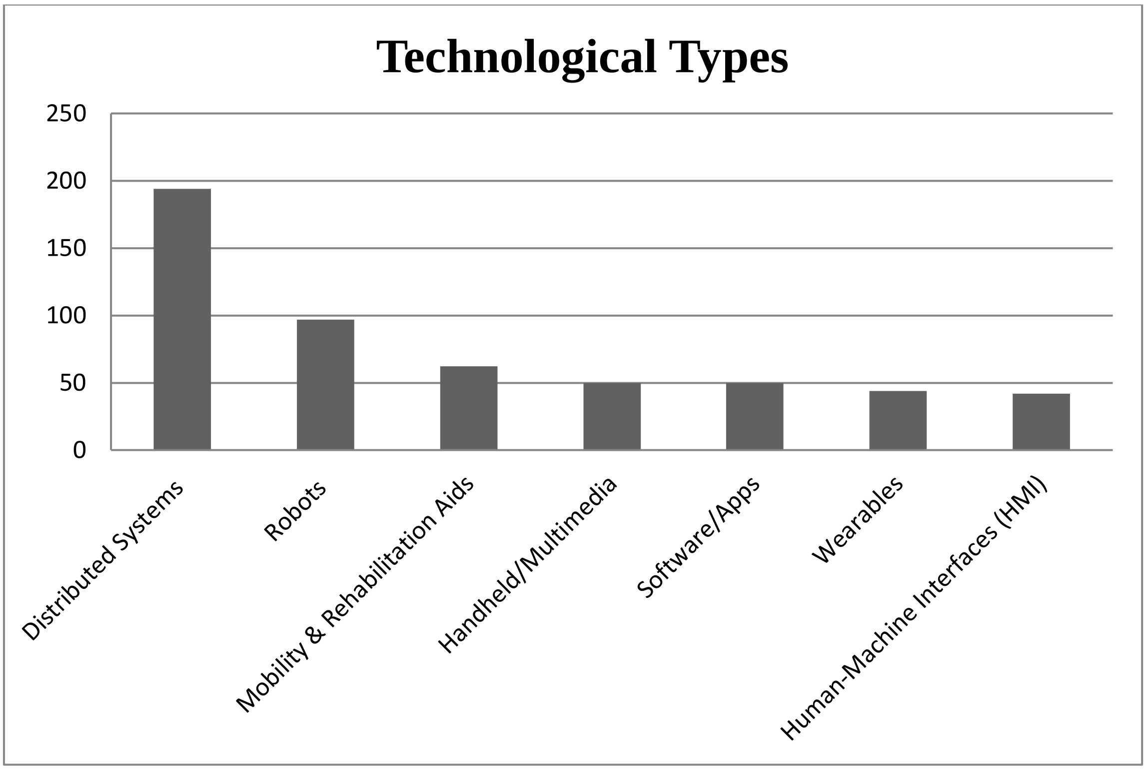

Figure 5- Technological Types in IATs for Dementia & Elderly Care

Application

IATs are currently being implemented into dementia care for a variety of purposes (Figure 6). Our review results reveal that the most common application of IATs in dementia care is supporting older adults with dementia in the completion of ADLs (n=148) such as eating, bathing, dressing, toileting, and continence. These results reflect the oft-stated wish of elders with dementia to enhance their independent living and the need for healthcare systems to delay or obviate institutional care, hence age-in-place (*184*). With 100 systems, *monitoring* is the second most common application. Monitoring is a key function for enhancing a person's safety as it allows identifying patterns of abnormal behavior, prompting responses from caregivers in case of danger and collecting data for other connected applications. Physical (n=88) and cognitive assistance (n=85) also compose an important proportion of the overall applications of IAT to dementia care. Cognitive assistants are intelligent devices capable of supporting or augmenting cognitive functions in cognitively impaired individuals, functioning as external cognitive processors. These include memory aids and other cognitive orthotics. An example is the COGKNOW Day Navigator, a digital prosthetics to support persons with mild dementia in their daily lives, with memory, social contacts, daily activities, and safety (*185*). In contrast, physical assistants compensate for motor and locomotive deficits associated with dementia-related disability. An example is the MOBOT, an intelligent physical assistant to support elderly patients with mobility disabilities during gait and sit-to-stand (STS) transfer (*186*). Emotional support and assistance represents a smaller (n=15) but rapidly developing portion of IAT application. Finally, promoting interaction (n=64) and engagement (n=22) as well as facilitating care and rehabilitation complete the picture of possible applications enable by current IATs for dementia.

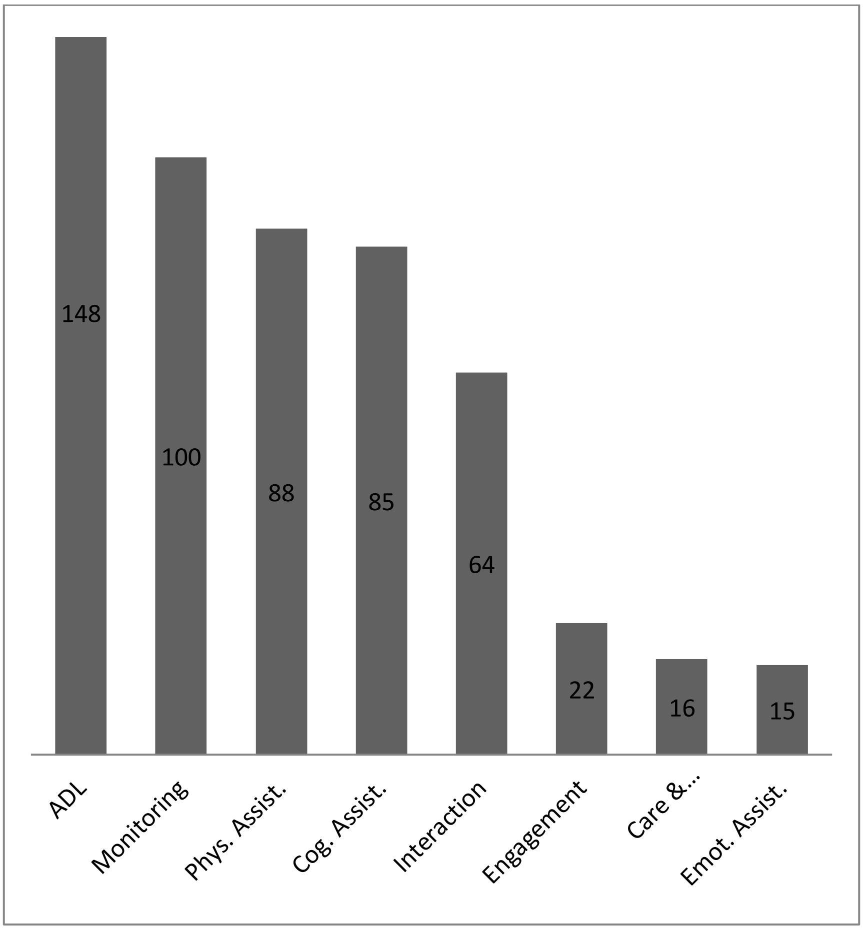

Figure 6- Most common IAT applications

Function Assisted

Most reviewed systems appeared to be general-purpose (n=250), showing how the complex disabling condition of dementia affects in parallel various components of a person’s psycho-physical dimension (Figure 7). With 140 items, the cognitive dimension (encompassing not exclusively executive function but also perception and communication) is the component of dementia-induced disability most commonly assisted via IAT. Among these cognitive faculties, memory predictably scores first (n=33), followed by communication (n=28), orientation (n=18), reasoning (n=12), and decision-making (n=8). Physical assistance such as assistance in mobility, navigation, and motor control represents the third most common category of deficits assisted by IATs. Dementia-associated disturbances of the emotional and affective sphere are supported by a significant portion of IATs (n=31), revealing an increasing effort to compensate through intelligent technology an often-neglected component of care provision for older adults living with dementia. Finally, a significantly smaller number of IATs (n=9) can provide assistance to the social dimension of elderly adults with dementia by reducing isolation and facilitating social interaction.

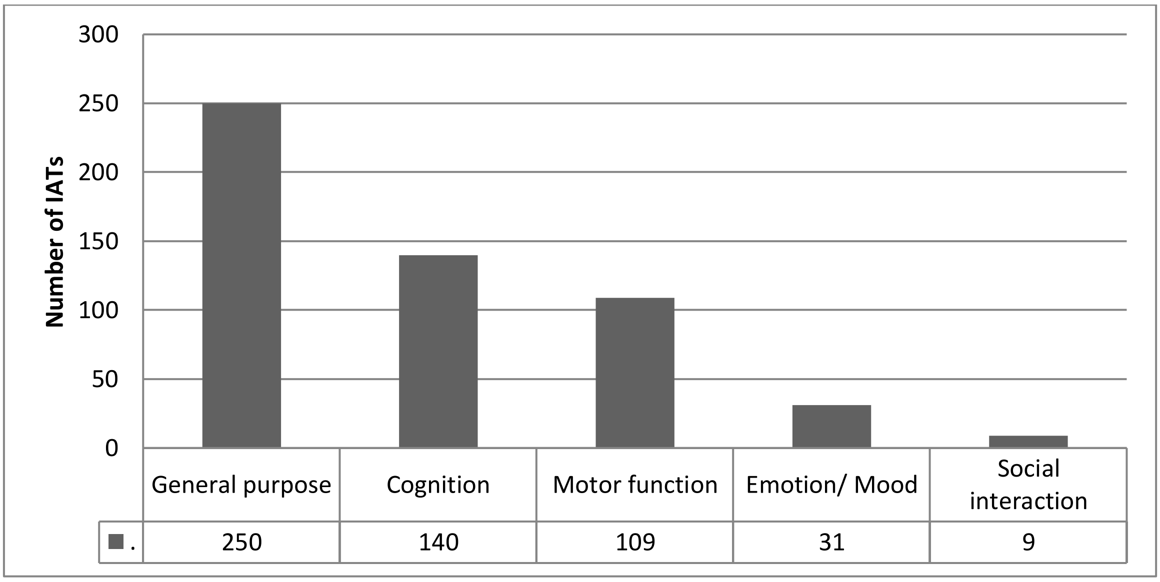

Figure 7- Functions assisted by IAT

User-centered Design

Results show that, to date, only 40.1 % of reviewed IATs are explicitly designed, developed or assessed through UC approaches (see Fig. 8). Among those, cooperative design and participatory design approaches are often recognizable, with researchers and users being involved on an equal footing in the various stages of the design process (*187*). However, the results of our logistic regression show a statistically significant correlation between time and the frequency of user-centered models of technology design and assessment ($b = 0.21$, $Wald(1) = 6.17$, $p < .01$). Therefore, this correlation predicts that the prevalence of UC approaches will become majoritarian in IAT design and development in the near future.

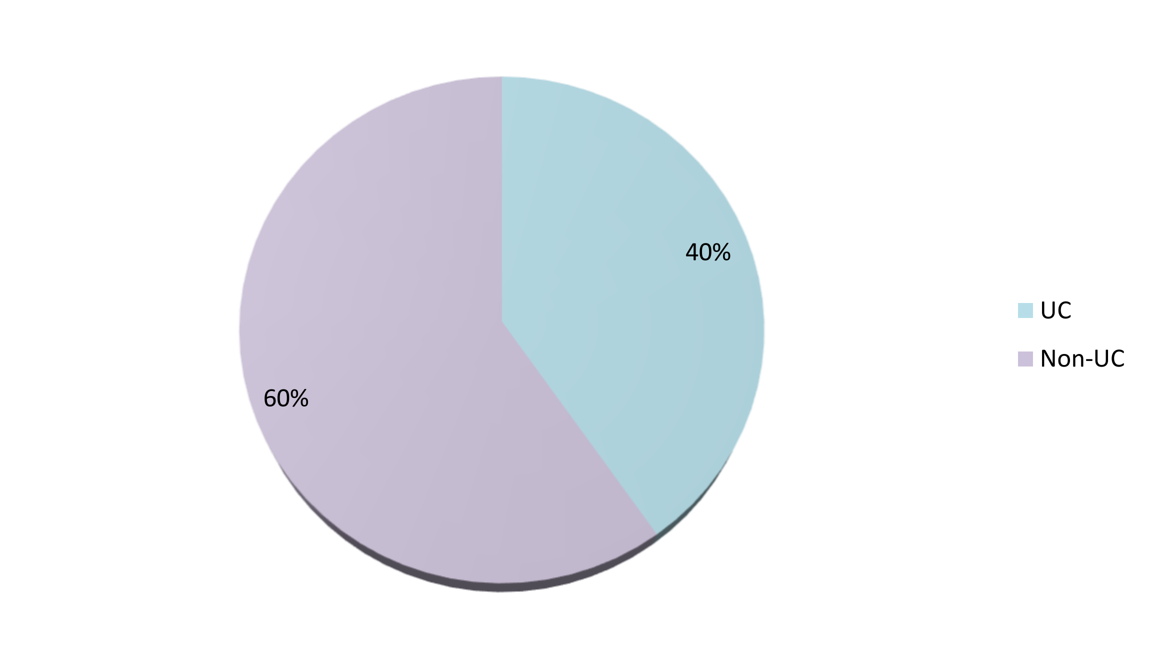

Figure 8- Prevalence of User-centered (UC) Design in IATs for Dementia & Elderly Care

Primary Target Population

As different forms of dementia and different stages of the disease progression may present inherently specific symptoms and care requirements, we looked at the level of selectivity adopted by the technology designers in determining the end-user population of each IAT. While all reviewed IATs could assist or compensate for one or more functional impairments associated with AD or other dementias, most of them were not exclusively designed for people with AD or other forms of dementia but also for the general elderly population with neurocognitive disability (n= 362). A significantly smaller portion (n= 115) of intelligent systems was more selectively designed to primarily target people with dementia, or the specific cognitive, physical, and behavioral symptoms of people with AD (n=51). Finally, only nine devices were specifically designed to target either specific stages of AD (n=5) or Mild Cognitive Impairment (MCI) (n=5).

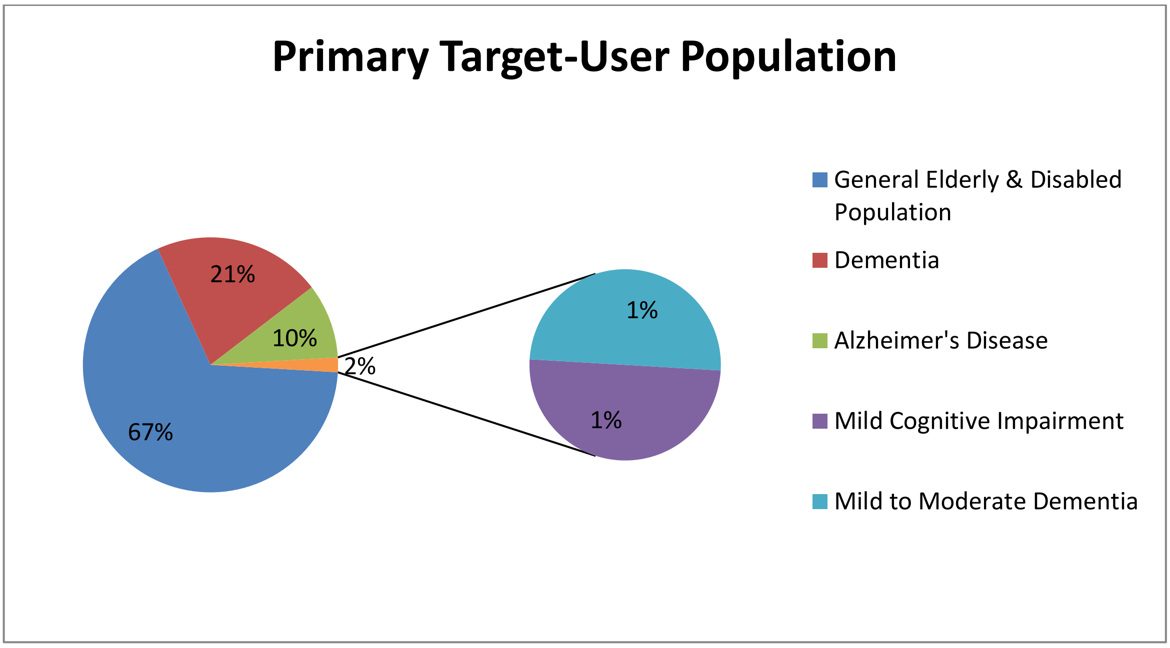

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Figure 9- Selectivity of end-user population targeted by IAT designers/producers

Clinical Validation

Our analysis of the clinical validation of IATs for dementia shows that little more than half of them (50.65%) did not receive clinical validation through clinical trials with human subjects. Among the subset IATs that received clinical validation (n= 266; 49.35%), most validation studies (n=254) were conducted with small sample sizes (<20 participants). Randomized-controlled design was reported in only 1.1% of clinical trials, that is 3 studies.

Discussion

In comparison to previous reviews (*2*, *170*), our review's results show that the spectrum of IATs for dementia is expanding fast in volume, variety, and potential applications. Since the number of IAT applications is approximately doubling every five years, IATs are likely, in the near future, to become a ubiquitous trend in dementia care. In addition, as the overall processing power for computers is increasing linearly over time and rapid advancements in micro-computing are accelerating the miniaturization of IAT systems (*188*), the expansion of the IAT spectrum will be accompanied by a coordinated performance potentiation. Such computing trends will generate novel possibilities for people suffering from dementia to live more independently, autonomously, and safely, and will facilitate the delivery of care to this growing patient population.

At the level of product development, the large proportion of AAL technology and other distributed systems attests an ongoing *smart-environment* trend in healthcare. As our results report, pervasive and ubiquitous computing techniques are being increasingly used to incorporate automation into domestic and residential environments with the purpose of delivering services, improving efficiency, performing or facilitating daily activities, and improving the wellbeing of their residents. After the Internet of Things has already incorporated computer technology into everyday objects such as televisions and other electronic appliances (*189*), the transition to smart homes could represent the next disruptive change in domestic environment. Although these trends are not exclusive to healthcare but common to various aspects of modern societies – i.e., through the creation of *smart cities* or *cybervilles* -, their application to dementia care is particularly promising since it could delay the need for long-term care and institutionalization, hence result in significant cost - reduction for healthcare finances and improved quality of life for the senior population (*2, 67*). In fact, such distributed assistive systems have the potential to prolong the safety and independence of older adults with dementia, preventing accidents, assisting them during the completion of ADLs, facilitating caregiver supervision, and triggering alarm in case of emergencies (*190*).

Hand-held multimedia devices are also likely to play an important role in the future of technology-assisted dementia care. In the light of their widespread use as everyday technologies in modern society, smartphones and other hand-held devices are often recognized by users as familiar tools, therefore requiring a lower level of training —especially among baby-boomers, who are often smartphone savvy (*191*). This is likely to result in higher social adoption, in particular if combined with coordinated advances in mobile software technology. In parallel, the recently increasing frequency of wearable devices underscores the need for a more widespread distribution of friction-free, non-invasive tools since non-obtrusive use is a reported priority among elders (*135, 192*). Although the concept of wearable device dates back to the 80s, only recent progress in miniaturization, micro-computing, and reduction of form factors allowed a significant development of wearables for commercial and medical purposes. However, while commercial applications of wearable technology are becoming increasingly popular among general users, the assistive and medical application of this technological type has not reached yet a sufficient level of maturity. In the next few years, a new generation of low-cost, friction-free, and information secure wearable devices is expected to add further opportunities to the current IAT spectrum. In contrast, assistive robots seem to have already reached a relatively high degree of commercial maturity, with several assistive robots ─ such as PARO (Daiwa

House Industry), NAO (Aldebaran Robotics), Pepper (SoftBank), and PALRO (FUJISOFT) ─ already being commercially available in Japan, Europe, and the United States. Future advances in robotics, especially the use of adaptive intelligence and the problem-resolution at the human-machine interface, are likely to increase even more the distribution of these IAT types.

The high distribution of IATs for facilitating human-to-human interaction and human caregiving shows that some reported worries about the potential risk of "dehumanizing care" with assistive technology (*193*) are rather unjustified. In fact, technology-enabled care is not alternative to human-delivered care but complementary. For example, telepresence robots such as Giraff (Giraff Technologies AB), allow caregivers to virtually enter the home of a person with dementia from their computer via the Internet, hence supervising, monitoring, communicating, and conveying their presence as if they were physically there.

With the rapid erosion of the caregiver-to-patient ratio, the proportion of intelligent assistance to be integrated into general care is bound to expand significantly. This will require not only advancing the development of IATs for cognitive and physical assistance but for emotional support as well. As our results show, intelligent emotional assistants represent a minor proportion of IATs currently developed for compensating psychophysical deficits associated with dementia. However, developments in Artificial Emotional Intelligence could dramatically accelerate the successful integration of IATs into standard care. As people with dementia often present emotional disturbances such as anxiety, depression, agitation, and distress (*194*), IATs programmed to learn "when and how to display emotion in ways that enable the machine to appear empathetic or otherwise emotionally intelligent" will be crucial for the future of care (*195*).

As the list of current applications shows, IATs are not only increasing in number but also in variety. While the first generation of IATs was primarily focused on promoting safety through tracking, alarm prompting, and remote monitoring (e.g., fall detectors and GPS trackers), current IAT applications are designed to support a number of activities including communication, telecare, and entertainment. In addition, the high number of applications for supporting ADLs shows that the main focus of most current IATs is not simply monitoring older adults with dementia, but empowering them by promoting the autonomous and successful completion of daily activities and the support of their psychosocial dimension (e.g. entertainment, engagement, and communication). Since emotional and psychosocial factors are recognized as important to stabilize mental health (*196*), this emerging holistic trend in IAT has the potential to achieve greater outcomes than earlier trends in technology-assisted dementia care.

From the perspective of the specific dementia-related deficits compensated for or assisted by IATs, the large prevalence of general-purpose systems (46.3% of the total) attests the complex and multifaceted condition experienced by elderly people with dementia. Since the disabling condition of dementia encompasses various components of a person's physical, cognitive, and behavioral dimension, IAT solutions are often required to provide a holistic and multi-level support to their users. Therefore, advances in adaptive intelligence and other trends in AI are expected to be of extreme benefit for dementia care.

When defining the product's end-user population, there is a need for a more narrow focus on the specific needs of each category of end-users. As our results show, many IATs tend to be targeting a vast and clinically heterogeneous end-user population including people with various forms of dementia and general neurocognitive disability. This fact may reflect the commercial advantage for producers to maximize the number of possible end-users for each marketed product. In contrast, the proportion of devices selectively designed to support specific stages of dementia is currently low. This lack of specificity could represent a significant obstacle towards the massive adoption of IATs for dementia and could add an additional reason to the limited uptake of IATs. In fact, patients suffering from different stages of AD may present specific needs and limitations that may be qualitatively and/or quantitatively different than those of people with other age-related cognitive disturbances or disabilities (*197*). Also, people with mild AD often present different needs and limitations than people with moderate or advanced dementia and *vice versa* (*198*). Future IATs should be adaptive to each specific form of dementia and, within the same form of dementia, to each specific stage of progression of the disease in order to better reflect the specific needs of each end-user group and sub-group.

Another limitation of current IATs emerging from the review is the scarcity of clinical trials assessing the clinical effectiveness and safety of each product. As every second IAT for dementia lacks clinical validation, health professionals and institutions may be reasonably reluctant to introduce IATs into standard care. In addition, among the subset of IATs with reported preliminary validation, several clinical studies reported major limitations in terms of sample-size, drop-out rates, statistical significance and adjustment for multiple comparisons. While technical feasibility and usability were successfully tested via simulations in approximately all reviewed IATs, well-designed, statistically-significant and highly generalizable randomized controlled studies with older adults with dementia are lacking.

Policy Implications

While the IAT ecosystem is expanding rapidly and creating novel opportunities for technology-assisted dementia care, policy makers must seek to harmonize such developments and remove or prevent administrative, regulatory, and infrastructural obstacles that could delay the integration of IAT into standard care. In addition, they also have the responsibility to address situations and conditions that could potentially undermine the successful and ethically appropriate adoption of IATs among end-users. As recently addressed by the Working Party on Biotechnology of the Organization for Economic Co-operation and Development (OECD), the global challenge of AD and other dementias requires the development of a multi-national plan that could harmonize technology development, facilitate the process of technology transfer, establish a framework for public-private partnerships for innovative projects, and create new models for multinational governance (*44*).

Since the increasing availability of IATs is disproportionally exceeding the number of tools currently used in clinical practice, a more effective commitment to accelerating translational research and pioneering responsible adoption is highly needed. *Technology transfer* is paramount to address this challenge. There is an urgent need for accelerating the translation of clinically effective technological innovation into clinical and commercial applications. This transfer will require cooperative work at the intersection between technology development and healthcare, the creation of multidisciplinary platforms for information exchange, and increased investments for innovative research as well as product development and marketing. To favor such cooperation, increased interaction between manufacturers and clinicians is required; with the former taking into account more closely the clinical needs of their end-user populations and the latter increasing their awareness of available technological applications. With the number of IAT prototypes more than doubling every five years, clinicians should monitor this rapidly expanding realm of assistive solutions, keep track of the novel technological availabilities, and supervise their responsible implementation. At the same time, manufacturers should be incentivized to adapt new prototypes more closely to the needs of patients, involve them constructively and in a participative manner into the design of future products via UC design and seek clinical validation of their prototypes through clinical trials run on larger sample sizes. Clinical effectiveness is a critical factor not only for technology adoption but, most importantly, also for guaranteeing the efficacy of technological products to improve care. Feasibility and usability tests via simulation are critical preliminary indicators of successful implementation.

However, in absence of large-scale, well-designed and statistically significant clinical trials, the clinical effectiveness of IATs cannot be presumed nor generalized across various geographical or clinical contexts. In particular, studies that evaluate IAT-derived functional improvements in patients via randomized controlled design are essential. In addition, there is still a great need for outcome studies on the effectiveness of IAT interventions in non-institutional real-life settings, such as studies with home-dwelling older adults with dementia during the completion of ADL tasks. Responsible translation in IAT for dementia should follow an evidence-based strategy that prioritizes systems with demonstrated clinical effectiveness and facilitates their responsible introduction into care.

In parallel, health policies and business strategies that promote and facilitate the responsible uptake of IATs must be encouraged to prevent this reportedly large technological potential from remaining underused. To this respect, the significant increase over time of UC approaches shows that a first step in this direction is already being taken. Since the delayed transition to UC approaches to technology design and assessment has often been recognized as one of the major causes of the lower-than-expected uptake of IATs for dementia (*199, 200*), the increasing prevalence over time of such approaches reveals an ongoing transition in product development that is likely to ultimately result in increased societal adoption. UC approaches, in addition, are predicted not only to increase technology acceptance, but also to reduce marginal risks, increase effectiveness and maximize benefits for the end-user population (*37, 167*). As UC approaches give extensive attention to the needs, wishes, and limitations of end users at each stage of the design or assessment process, IATs will be increasingly more capable to match the needs, wishes, and limitations of people with dementia. This can also result in promoting the autonomy of end-users since they are given an active, prototype-shaping role, becoming co-developers instead of being simply considered passive users of predetermined artifacts.

While AI-modulated human-to-machine interaction is a critical pathway for empowering older adults with dementia and overcoming social isolation, human-to-human interaction should be pursued too. The need for more AI-modulated human-to-human interaction is particularly important for older patients who are not digital natives.

At the ethical and social level, a number of considerations must be included into the design of new products to guarantee responsible and successful development. While the often stated goal of IAT researchers is to maximize older adults' capacity for independent living and delay the need for institutional care (*201-203*), issues of privacy and information security should also be early considered during product development. Because various types of IATs could be used to access private and sensitive user-related information (*204-206*), privacy and security breaches should be anticipated and prevented. With security by design being hard to achieve, measures for securing sensitive (e.g., behavioral, personal or physiological) information should be implemented at the level of product development, institutional use as well as in-home use.

Finally, cost-related and access-related considerations should be addressed to avoid the risk that IAT adoption will be impeded by socio-economic factors or could even exacerbate existing socio-economic problems. To prevent this risk, the massive adoption of IATs for the aging population should be coordinated with health policy plans and health insurance programs to minimize the emergence of adverse unintended societal consequences. For instance, reimbursement plans, government incentives, and the promotion of low-cost and open-sourced IATs are crucial strategies to promote access to technological innovation and avoid the emergence of a digital divide between older adults with dementia who could afford IATs and those who could not. Such a divide, in fact, could exacerbate existing socio-economic inequalities (*207*).

Conclusion

Intelligent technology is reshaping the world we live in. Its application into dementia care has a great potential for older persons and our society. Based on our systematic review, we produced a comprehensive and up-to-date index of IATs developed for assisting older adults living with dementia. This index provides health professionals with a comprehensive and up-to-date picture of the current availabilities of IATs for dementia, their major trends, limitations and possible applications into dementia care. As technology is rapidly advancing, future research should closely monitor this rapidly expanding technological spectrum and more extensively test their clinical effectiveness. In parallel, healthcare services and policies should keep up with advancing technology and facilitate the successful adoption of IATs into standard care in a manner that benefits patients, their caregivers, and society.

*2.2. Ethical Design of Intelligent Assistive Technologies for Dementia: A Descriptive Review**

*A version of this article was published in *Science and Engineering Ethics*[22]
Full reference: Ienca, M., Wangmo, T., Jotterand, F., Kressig, R. W., & Elger, B. (2018). Ethical design of intelligent assistive technologies for dementia: a descriptive review. Science and engineering ethics, 24(4), 1035-1055.

Abstract

The use of Intelligent Assistive Technology (IAT) in dementia care opens the prospects of reducing the global burden of dementia and enabling novel opportunities to improve the lives of dementia patients. However, with current adoption rates being reportedly low, the potential of IATs might remain under-expressed as long as the reasons for suboptimal adoption remain unaddressed. Among these, ethical and social considerations are critical. This article reviews the spectrum of IATs for dementia and investigates the prevalence of ethical considerations in the design of current IATs. Our screening shows that a significant portion of current IATs is designed in the absence of explicit ethical considerations. These results suggest that the lack of ethical consideration might be a codeterminant of current structural limitations in the translation of IATs from designing labs to bedside. Based on these data, we call for a coordinated effort to proactively incorporate ethical considerations early in the design and development of new products.

Introduction: A Technology Revolution in Dementia Care?

The information technology revolution in healthcare is transforming the delivery, administration and management of healthcare services worldwide. Advances in robotics and medical engineering are rapidly multiplying opportunities for technology-assisted therapy, surgery, and rehabilitation. In parallel, advances in Pervasive and Ubiquitous Computing (PUC) are increasingly embedding computational capabilities (e.g. prompting, sensing and information sharing) into traditional domestic and institutional environments, as well as worn items. These trends are expected to increase patient safety and the pervasiveness of care delivery (*2, 208*). In parallel, with the digitalization of patient records and the exponential increase in medical data

[22] Current Impact Factor: 2.229 (2016)

worldwide, predictive analytics and data mining strategies enable the extraction, aggregation and analysis of large volumes of data.

Dementia care is one of the branches of the health care industry that is most likely to benefit from such technological revolution. The reasons are manifold. First, with the high relative costs of formal and informal dementia care (*66*), technological solutions that can delay or obviate the need for long-term care could alleviate the burden on public finances and offer a viable path for the otherwise endangered provision of institutional services among a rapidly expanding elderly population (*67*). Second, given the erosion of the caregiver-to-patient ratio (*68*), the massive deployment of robot-assisted care could complement current care provision, reduce the burden on unpaid caregivers and improve the quality of care (*2*). Third, with effective pharmacological solutions still not in sight, big-data platforms can improve prevention, diagnostics, therapy and care management by revealing insights from large amounts of unstructured data (*69*). Fourth, the incorporation of computing and, in particular, artificial intelligence (AI) into care agents and care environments could favor the delivery of personalized, adaptive and patient-centered care solutions (*70*). This would not only help fulfill the wishes of patients but also empower them and improve their quality of life. Finally, neuromonitoring/neuromodulation technology and brain-computer interfaces (BCIs) are opening new possibilities for the monitoring and purposeful modulation of the patients' brain activity as well as for external device control using both invasive and non-invasive means (*71, 72*).

A number of Assistive Technologies (ATs) of these diverse types have been developed to date with direct or indirect application in dementia care. AT is the umbrella term used to describe technological devices or systems which allow people with physical or cognitive disabilities to perform tasks "that they would otherwise be unable to do", or to increase "the ease and safety with which a task can be performed" (*209*). Bharucha et al. (2007) have introduced the notion of Intelligent Assistive Technologies (IATs) to distinguish ATs with own computational capacity from mere mechanic tools (e.g. walking canes). The spectrum of IATs is wide and encompasses a variety of devices and systems including handheld devices (e.g. tablets, PDAs, GPS trackers), mobility aids (e.g. powered wheelchairs and electronic canes), distributed systems (e.g. smart homes, integrated sensor systems, mobile platforms etc.), wearable devices (e.g. fitness trackers), humanoid robots, brain-computer interfaces (BCIs), and software applications (e.g. mobile or web-based apps). Ienca et al. have systematically reviewed the entire spectrum of IATs with current or possible application into dementia care and provided the first comprehensive index of IATs for dementia. Their results show that the number of IATs for dementia is exponentially increasing over time, with an average five-year increase of 400%. As for the technological type, the most common IATs in dementia care are distributed systems, especially Ambient Assisted Living technologies (AALs), followed by humanoid robots and handheld devices. Most of these devices have been developed for supporting older adults with dementia during the completion of ADLs; other applications include monitoring, cognitive assistance and physical assistance (*210*).

The Ethics of IATs for Dementia: Time for Proactive Approaches

Due to their pervasive and ubiquitous character, IATs do not exclusively affect the clinical dimension of patients but their emotional, psychosocial and relational dimensions as well. IATs such as GPS trackers and videomonitoring technologies can enhance and partly replace the need for continuous human caregiver supervision (*211*). Personal care robots and Ambient Assisted Living (AAL) technologies can help older adults with dementia achieve greater independence in their home environment and autonomously perform routine activities (*212*). Cognitive assistants and patient-oriented handheld devices can support the cognitive dimension of patients and partly compensate for the cognitive deficits caused by the progression of their disease (*213*). Neurodevices and BCIs can enable better preventive diagnostics through brain activity tracking and favor interaction through the brain-control of external devices (*214*, *215*). Finally, companionship robots can assist the emotional dimension of patients, alleviate agitation, loneliness, social isolation and improve their emotional wellbeing (*216*). As such, IATs open the prospects of becoming intimately intertwined in the psychosocial dimension of elders with dementia. In fact, the pervasive dissemination of IATs across various domains of life has the potential not only to enhance care delivery, but also to affect the psycho-social dimension of patients. Concomitantly, due to the technological novelty and complexity of IATs for dementia, the introduction of such systems into standard dementia care raises a number of ethical and legal issues.

For example, Felzmann et al. (2015) argue that the switch from human care to technology-assisted care could have an unintended impact on the subjective experience of older people with dementia (*217*). Other common normative ethical evaluations related to the use of IATs in dementia care include the appropriate obtainment of informed consent (*96*), the protection of the patients personal privacy from unconsented surveillance (*218*), the protection of patients from restraint (*219*), and the normative status of "justifiable benevolent deception" when using socially assistive robots (*220*).

A recent literature review has comprehensively evaluated the ethics of AAL technologies for people with dementia (*221*). This review identified various types of ethically relevant issues which should be systematically addressed as part of the development of new devices. These include user involvement in product development, informed consent, social isolation and data security (*221*). In a similar comprehensive fashion, Zwijsen et al. have reviewed the relevant literature to identify the ethical implications associated with the use of ATs in the care for community-dwelling elderly people, including people with dementia (*137*). Their results identified ethically relevant themes including privacy, autonomy, social stigma, affordability and safety.

Ethical concerns of key stakeholders, especially informal caregivers, have also been at focus of investigation. Mulvenna et al. (2017) examined the views of caregivers of people with dementia on the use of camera-based surveillance ATs, with special focus on ethically relevant values such as autonomy, freedom and privacy. Their results indicate a general willingness among caregivers to make use of camera technology, with some significant caveats around the risks of invading the patients' privacy or reducing their freedom and autonomy (*222*). Such studies of stakeholder perspectives are crucial to overcome barriers and fine-tune new prototypes of IATs to the end-users' needs in order to guarantee the ethically sustainable introduction of ATs into standard dementia care.

It has been observed, in fact, that the absence or inadequate translation of ethical considerations is a major obstacle towards the successful adoption of assistive technologies (*2*, *210*). Ethical concerns have been observed to be a major predictor of suboptimal user acceptance and were reported as cause of skepticism towards technology among elderly adults with dementia and their caregivers. For example, Boise et al. (2013) investigated the acceptance of in-home and computer monitoring among elderly adults with mild cognitive impairment (MCI). Their results show that a majority of participants (60%) reported ethical concerns related to privacy and security (*223*).

Most ethical literature on IAT deals with the ethical evaluation of existing products with the aim of establishing standards or norms on how to use and apply new IATs in an ethically adequate manner. Consequently, ethics, in the context of IATs, plays primarily a *reactive* role: it reacts to pre-determined technological products and services by assessing their compatibility with existing ethical values and principles, and eventually making prescriptive judgments about the appropriate implementation of such technologies. For example, Perry et al. (2009) have investigated the impact of current IAT and telecare solutions for people with intellectual disabilities through the lenses of the four principles of biomedical ethics (*224*). The goal of their analysis was to assess whether present products and prototypes align or conflict with those ethical principles.

In the last two decades, a growing number of researchers have called for incorporating ethical considerations early on in the design process through approaches to product design such as user-centered and value-sensitive design (*102, 225, 226*). For example, Van den Hoven has called for "a way of doing ethics that aims at making moral values part of technological design, research, and development"(*226*). Value-sensitive design is "a theoretically grounded approach to the design of technology that accounts for human values in a principled and comprehensive manner throughout the design process" (*95*). According to this approach, human values should be proactively incorporated at the level of design instead of being discussed only at the end of the technology development process. Among these values, ethical values play a critical role. In fact, researchers have argued that the consideration and incorporation of ethical values is a critical requirement for preventing harm, improving "human situations" (*93*) and guaranteeing responsible technology development. This ethics-focused instance of VSD is called *ethical design* (*102*). According to Karr, ethical design allows to prevent various forms of harm to technology users and other stakeholders including interpersonal, psychological, and social harm (*93*). For this reason, authors have called for "addressing ethical concerns early on in the design of a technology" and "bringing ethics back into design" (*102*).

While value-sensitive approaches are increasingly raising the attention of IAT researchers, little knowledge is available regarding the current prevalence of ethical values in IATs. In particular, no study to our knowledge has investigated whether and which ethical values are being currently incorporated into the designs of IATs for dementia.

In this paper, we fill this gap by providing a comprehensive analysis of the spectrum of ethical values and considerations incorporated into the design of current IATs for dementia. This analysis is relevant for a twofold reason. First, it will provide a quantitative description of current trends in value-sensitive design for IATs for dementia, including evidence about the presence and prevalence of ethical values at the level of product design. In addition, this analysis can inform with empirical evidence normative approaches to the ethical co-design of future products. For example, it could help determine what ethical values are currently underestimated, hence must be more carefully considered in the future to reduce the risk of drawbacks such as low social adoption, breaches for insecurity, and unintended ethical and social consequences. With the rapid introduction of intelligent systems into healthcare, working out how to build ethical systems is "one of the thorniest challenges in artificial intelligence" (*227*). Therefore, it is important to investigate whether and how current systems are meeting this challenge, in particular in the context of intelligent systems used in the care of vulnerable populations, such as people with dementia and neurocognitive disabilities (*225*).

Methodology

Data search and extraction

A systematic literature review was performed to retrieve a comprehensive and up-to-date list of IATs with application to dementia care. Original research articles and application protocols were searched for the period 2000-2016 in the following search engines and bibliographic databases: IEEE, PubMed, Scopus, PsycINFO, and Web of Science. The following query logic was developed, pilot-tested and, whenever necessary, adapted to the language used by each engine or database: *("assistive technolog*" OR "assistive device" OR "assistive application") AND ("intelligent" OR "ICT" OR "adaptive" OR "computer" OR "robotic") AND ("Alzheimer*" OR "dementia" OR "ag*ing" OR "elder*)*. Based on the inclusion criteria, IATs included into the analysis met the following requirements: (i) had own computing capability; (ii) showed direct applicability to dementia care, and (iii) could be used to assist or compensate for the functional impairments associated with dementia. A total of 617 papers were initially identified. Subsequently, three steps of filtering were performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria (*3*): additional records identification through secondary sources, duplicates removal (both software-assisted and manual), and eligibility assessment. To minimize subjective biases, each stage of review was performed by at least two authors independently from each other.

Data Analysis and Synthesis

In-depth review of full-text articles included in the synthesis (n=571) was performed. Such systematic review resulted in the production of the *Dementia Technology Index 2016 (DTI16)*. 539 IATs with direct application to dementia care were identified and included in the DTI16 (*210*). Subsequently, the DTI16 was analyzed with the purpose of retrieving the full list of ethical considerations addressed in the design, development or assessment of each indexed technology. Our content analysis of the document consisted of three sequential steps. First, for each IAT, we screened the presence of ethically-relevant considerations. During this phase, ethically relevant keywords and statements were searched in the full texts of all reviewed articles. This process was performed by two authors using both software-guided keyword search (software used: Endnote X7) and unguided full-text review. Second, we clustered all retrieved ethical considerations into main categories following Constas' account of the categorization process (*228*). Based on thematic affinity, our analysis identified six main ethically relevant considerations: (I) Autonomy, (II) Privacy, (III) Beneficence, (IV) Non-Maleficence, (V) Interdependence, and (VI) Justice.

The *nomination* phase of this categorization process was partly derived from the framework of the principles of biomedical ethics (*118*) and adapted to the specific context of assistive technology for dementia. In particular, given the distinctive nature of privacy issues in information technology (*229*), we classified privacy as an independent category rather than a sub-component of respect for autonomy. This is in accordance with growing literature supporting the conceptual distinction between privacy and autonomy (*230-233*) and the oft stated suggestion that the physical and informational privacy of elderly adults with dementia should be seen as a primary consideration especially in relation to surveillance technology for in-home monitoring (*234*). In addition, ethical considerations related to the caregiver and care-receiver relationship in dementia care were indexed under the category of *interdependence* based on the body of literature on this topic (*235, 236*).

Each thematic family was further classified into sub-families relative to specific sub-components of the main ethical theme. The nomination of subthemes was partly derived and expanded from the classifications provided by Novitzki et al. (2014) and Zwijsen et al. (2011). Based on interpretative orientation (*228*), we chose to separate safety-oriented considerations from the family of justice considerations since safety and risk-reduction represent critical components of the non-maleficence principle in biomedical ethics and have little in common with justice-oriented considerations (*118*). This classification was also informed by Friedman et al.'s list of human values (with ethical import) often implicated in system design (*95*).

Thematic families and subfamilies in this ethical taxonomy were categorized in the following manner:

Autonomy

The principle of autonomy was understood as the capacity of the person to deliberate or act on the basis of one's own desires, that is the ability to act freely in accordance with a self-chosen plan (*237*). Subcomponents of the autonomy principle in relation to IATs for dementia are: independence, ageing-in-place, and user-centeredness. In fact, the ability for autonomous action and deliberation entails that the person's activity is not exclusively dependent on contingent limitations or manipulative and distorting external forces. Therefore, independence (e.g. independent living) is an essential component of autonomy. In the context of dementia care, independence is strictly related to the wish of elders to *age-in-place* (*2*). The U.S. Centers for Disease Control and Prevention defines *aging-in-place* as "the ability to live in one's own home and community safely, independently, and comfortably, regardless of age, income, or ability level" (*238*). In addition, the respect for autonomy entails that the IAT is designed upon and to better meet the user's needs. Personal autonomy is maximized when users are not passive objects of top-down designs but when the IATs are adapted upon their needs. This notion of autonomy entails both a right that should be respected and a capability that should be promoted.

Privacy

The principle of privacy was defined as the ability and the legal right of an individual or group to seclude themselves, or information about themselves. Two subtypes of privacy could be distinguished: physical and informational privacy. Physical privacy pertains to the capacity to demarcate one's personal physical space. This includes ethical considerations related to the invasiveness, intrusiveness and obtrusiveness of IATs into the intimate and private sphere of elders with dementia. Informational privacy pertains to the capacity to seclude sensitive, confidential or private information. This includes ethical considerations on the protection of sensitive information about the users and the risk of disproportionate data collection. As a necessary prerequisite of informational privacy is the security of information and the protection of private data (e.g. personally identifiable data), these two are also included as a subtheme.

Beneficence

The principle of beneficence postulates the promotion of the benefit and welfare of the person, and is often considered the main end of medicine. While narrow definitions of beneficence have linked this principle exclusively to the end of healing and not to any other form of benefit (*239*), a growing consensus in biomedical ethics considers beneficence holistically, hence encompassing the notions of quality of life (QoL), care (*240*), and enhancement (*241, 242*). QoL is a complex, multidimensional construct defined by the World Health Organization as '*individuals' perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns*'(*243*). Care-related principles such as empathy, dignity and the protection of vulnerability categorized in the beneficence family, together with ethically relevant aspects of a person's emotional and psychological well-being. Finally, enhancement refers to the augmentation of human physical or cognitive capacities beyond therapy, that is in relation to or pursuit of non-therapeutic aims.

Non-Maleficence

The principle of non-maleficence postulates a moral obligation to avoiding or, at least, minimizing the causation of harm (*118*). While every intervention – including technology assisted interventions in dementia care- involves some possible degree of harm, even if minimal, the non-maleficence principle maintains that the harm should not be disproportionate to the benefits of the intervention. This category thus includes ethical considerations incorporated into IAT for risk-prevention and risk-minimization – for example, smart smoke and fall detectors. Relatedly, it includes considerations for the improvement of safety, i.e. the protection from or reduced likelihood of danger or injury.

Interdependence

IATs enable elderly adults with dementia to maintain, restore, reacquire, or support social relations and the capacity to interact with the external social, digital and natural environments. This relational dimension, often articulated as a dialectic of human independence and dependence which is described as *interdependence* (*235*), is of particular relevance in the caregiver-care receiver relationship as well as in the relationship between care receivers and their significant others (*244*). This category encompasses subthemes related to the relational dimension of elders with dementia including the problem of social inclusion, the risk of loneliness and the loss of human contact.

Justice

The principle of justice postulates a fair distribution of benefits, risks and costs of technology. In the context of health technology, justice articulates into three major subfamilies: equality, fair access and openness. Equality considerations are concerned with enabling patients with equal conditions to use a technology equally. Fair access considerations strive to maximize access to technology and consequent adoption for all socioeconomic classes while affordability considerations are concerned with the development of low-cost IATs with the purpose of preventing technological divides that may exacerbate pre-existing socioeconomic divides. Finally, openness issues refer to the availability to anyone and for any purpose of the software's source codes, licenses, or even hardware components.

Results

Results show that the majority of current IATs (n=361; 67%) are developed in absence of any explicit ethical consideration (Figure 10).

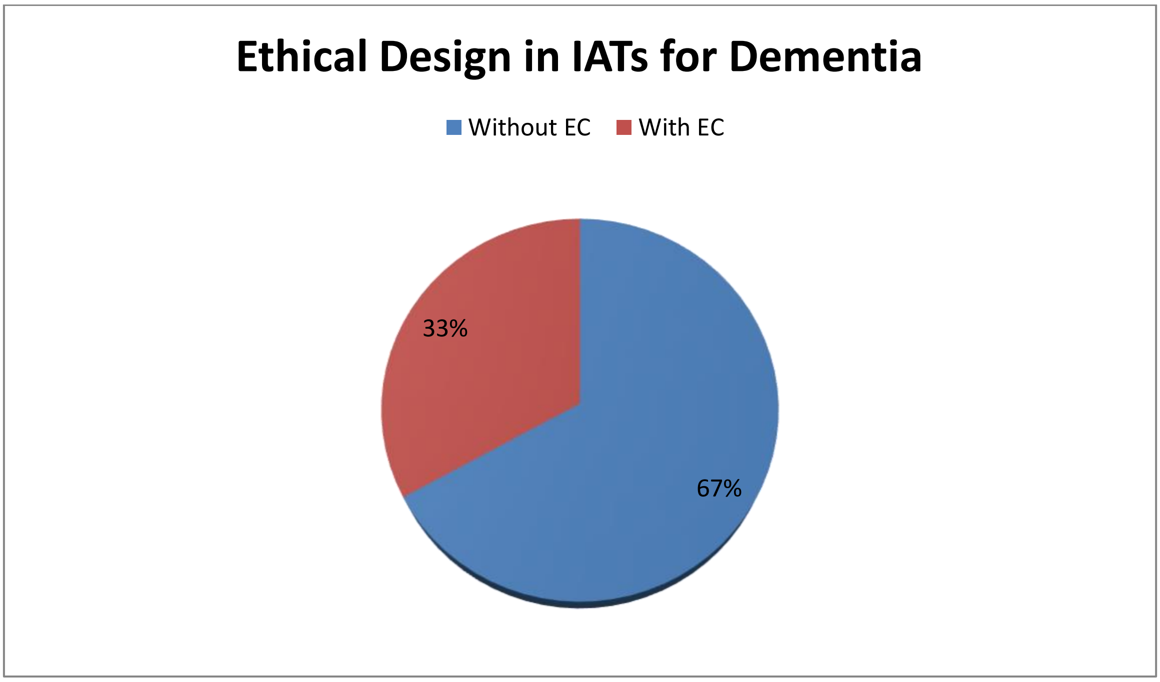

Figure 10- Prevalence of value-sensitive ethical design in IATs for Dementia

In the remaining portion of the IAT spectrum (n=178; 33%), ethical considerations at the level of design were detected and analyzed. As several IATs presented multiple considerations (i.e. more than one ethical theme), we detected in total 257 ethical considerations, as presented in Fig. 11. Among these, autonomy (n=99; 38.5%) was by far the most frequent family of ethical considerations, followed by non-maleficence (n=52; 20.2%) and beneficence (n=50; 19.4%). In contrast, justice (n=24; 9.3%), interdependence (n=19; 7.4%) and privacy (n=13; 5%) considerations appeared rare.

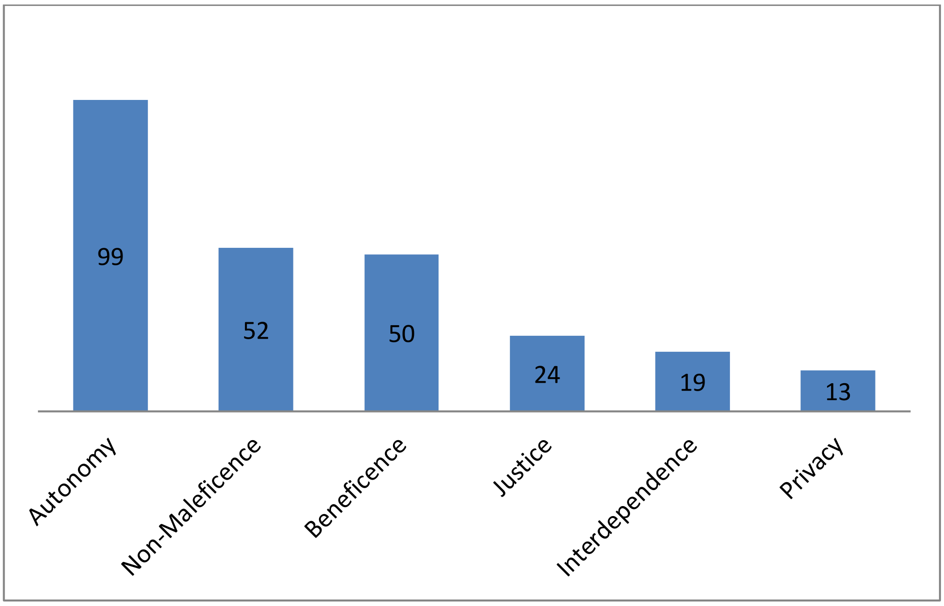

Figure 11- Distribution of Ethical Considerations in IATs for Dementia by Thematic Family (n=257)

Results by Subfamily

Autonomy and Independence

Results show that autonomy, broadly conceived, is the primary and most common concern in current IAT designs. While some IATs (n=26) incorporated *cognitivist* conceptions of autonomy as self-determination ─i.e. the ability to deliberate and act in accordance with a self-chosen *plan* (*237*), the most common subtheme within this thematic family was independence (n=52) during the completion of daily activities. The prevalence of independence considerations occurs across all technological types of IATs. For example, assistive robots such as PaPeRo (*245*), smart mobile apps such as Smartbrain (*178*) and mobility assistants such as iWalker (*246*) were all designed with the purpose of supporting *independent living* among persons with dementia. However, independence considerations appeared particularly prominent among distributed systems such as AAL platforms, smart-home prototypes and other advanced integrated systems. For example, the assistive platform iWall (*247*), the home sensing environment INHOME (*248*), the smart house Intelligent Sweet Home (*249*) and the ICT infrastructure LAGUNTXO (*250*) had the common objective of promoting or enhancing the degree of independence of older adults with dementia. In contrast, considerations of autonomy as self-determination were more relevant among cognitive assistants such as the information system SJOBOKS (*251*).

In addition, issues of user-centeredness and adaptation of IAT to the user needs also covered a significant portion of the technological spectrum (n=21). These include issues of individualization and personalization of IAT applications according to the users' needs and personal choices, as well as issues of non-patronization. For example, robot SAM's (Smart Autonomous Majordomo) advanced assistive functions were designed to be user-friendly and adaptive to the user's needs (*252*). Similar considerations were detected also in distributed systems like ISISEMD (*253*) and assistive software like DIADEM (*254*). Service robot ROBADOM was the only IAT explicitly designed with the concern of not patronizing its users (*255*).

Beneficence

With regard to beneficence-oriented considerations, the major concern in current IAT designs is the promotion of the QoL of elder adults with dementia (n=28). Such QoL-oriented considerations appear frequent across all IAT types. For example, multimedia system ePAD (*256*), AAL system ASTROMOBILE (*257*), and domestic smart environment RoBOCARE were all designed with the explicit purpose of improving "the quality of life of patients, their relatives, and their caregivers" (*257*). QoL considerations appeared particularly focused with the physical wellbeing of elderly adults with dementia. However, a small portion (n=5) focused on the proactive promotion of their emotional wellbeing (n=5). For example, a cloud architecture for family recognition was designed with the purpose of "improving their self-esteem and stimulating the patient with novel technology" (*258*). This characteristic was mostly exhibited by assistive systems exhibiting emotional intelligence features.

Care-related considerations also compose an important portion of this thematic family (n=20). These include the promotion of quality of care, the alleviation of caregiving burden, issues of dignity, frailty and vulnerability, or the empowerment of elderly adults with dementia through technology use and the integration of social intelligence features into intelligent systems. For example, the ABLE platform (*259*) was designed with consideration of the condition of frailty and vulnerability typical of elderly adults with dementia, whereas the design of a robotic home environment addressed the problem of protecting the dignity of users (*260*). Finally, issues of cognitive and physical enhancement appear relatively rare (n=2).

Non-Maleficence, Safety and Risk Reduction

No-harm considerations represent another important portion of ethical considerations incorporated in current IATs and are largely expressed in the form of risk-reduction strategies (n=13) and safety-promoting (n=38) considerations. For example, a number of mobility assistants, such as SmartCane (*261*), and ambient assisted living technologies, such as the FOOD Smart Kitchen (*262*), were designed to reduce domestic risks such as falls and fire. An even greater portion of systems including intelligent powered wheelchairs (*263*, *264*), robotic walkers (*265*), and assistive robots such as Domeo (*266*) were designed to assure the safety of their elderly users.

Interdependence

In spite of the rapid increase in technical opportunities for human-machine interaction in dementia care, ethical considerations associated with the relational dimension of users and the relational capabilities of IATs still represent a small portion of the ethical IAT spectrum. Among them, the problem of social inclusion and the proactive reactivation of the user's relational capacities are a dominant theme (n=13). For example, a number of IATs including intelligent agent Coaalas (*267*, *268*), robot KSERA (*269*), cognitive prosthetics COGNOW (*270*), distributed system NOCTURNAL (*271*) and intelligent ebook ALLT (*272*) had the shared objective of favoring social inclusion by creating new opportunities for social exchange, supporting social activities and reducing social isolation. In parallel, a smaller number of devices (n=5) including the Monitoring Memory Streams (MMS) iPad application were designed for facilitating interactions between caregivers and people with Alzheimer's disease (*273*). Finally, issues of loneliness and the ethical concern that the expansion of technology assisted care will thereby cause a loss of human contact are considered by a very small portion of intelligent systems (n=1).

Justice

Justice and equality considerations compose another small portion of ethical considerations in current IATs for dementia. Among these, issues of affordability and cost-control are dominant (n=18). In particular, several IATs are designed with the explicit wish of achieving low-cost products, which could be afforded by a large number of elderly adults with dementia from virtually all socioeconomic classes instead only by the wealthy. These attitudes could be detected among IATs employing low-cost hardware — especially monitoring systems, home automation services and rehabilitation tools. Concomitantly, issues of universal access and fair distribution are considered only in five IATs, with special focus on delivering care in spite of accessibility barriers as in the case of the cloud-based INREDIS service (*274*). Finally, open design (both open-source hardware and software) considerations, where information about the hardware/software is easily discerned to enable other people to reproduce it, were detected in only one occurrence: a freely available dataset of acceleration data coming from a wrist-worn wearable device (*275*).

Privacy

Privacy considerations encompass the smallest portion of ethical considerations in current IATs. Among these, issues of physical privacy (n=7), especially in the form of non-invasiveness, non-intrusiveness and non-obtrusiveness of IAT into the physical private dimension of elders with dementia, are considered. Issues of informational privacy compose a slightly smaller fraction of ethical coverage (n=5) and are mostly associated with tracking and monitoring technologies. For example, the Clinical Decision Support Systems (CDSS) for mobile device incorporated privacy concerns in a context where it interacts with smart homes (*276*), while the user-centered design of an in-home monitoring system (*277*) addressed the problem of privacy of the information obtained through monitoring. Finally, issues of information security and data protection are proactively considered only in one IAT.

A detailed summary of results by family and subfamily is presented in Table 6.

Autonomy (n=99)	***Non-maleficence (n=52)***	***Beneficence (n=50)***	***Justice (n=24)***	***Interdependence (n=19)***	***Privacy (n=13)***
Independence (n=52)	*Safety (n=38)*	*Quality of Life (n=28)*	*Affordability (n=18)*	*Social Inclusion (n=13)*	*Physical Privacy (n=7)*
Self-determination (n=26)	*Risk-reduction (n=13)*	*Care (n=20)*	*Access (n=5)*	*Interaction (n=5)*	*Informational Privacy (n=5)*
User-centeredness (n=21)		*Enhancement (n=2)*	*Openness (n=1)*	*Loneliness & Loss of Human Contact (n=1)*	*Data Protection/ Information Security (n=1)*

Tab. 6- Prevalence and Distribution of Ethical Values in IATs for Dementia (Themes and Subthemes)

Discussion and Recommendations

The finding that the vast majority of IATs for dementia (67%) is designed and developed in absence of explicit ethical values or considerations suggests that the current prevalence of value-sensitive approaches in IATs for dementia is still low. In addition, since addressing values in design in a principled manner is believed to increase the benefits and reduce the harms of a technology among a stakeholder group (*92*), it is possible that the low prevalence of ethical values in IAT design might negatively affect the adoption and use of IATs by people with dementia.

These results confirm previous research findings showing the persistence in the IAT community of conceptual and practical barriers to the incorporation of ethics into the design phase (*102, 278*). Closer collaboration among ethicists and engineers might be required to build IATs for dementia that can account for the values of end-users, hence favor effective and responsible clinical use.

The recurrence of issues of *independence* reveals the often stated goal of IAT designers of maximizing the capacity for independent living of older adults with dementia (*2*). Independence and independent living are critical factors in IAT research, in particular from the perspective of public health and health economy. In fact, technologies that can protract in-home independent living of older adults with dementia will delay or obviate the need for institutionalized care, hence alleviate the financial burden of dementia for health care systems. In addition, the greater independence elders with dementia can maintain at home or in skilled facilities the lower the need for both formal and informal care. This is likely to mitigate the burden on caregivers and may improve the well-being of both care receiver and care providers. However, while independence is crucial, other considerations should be carefully included too.

In particular, the low frequency of justice and access-related considerations highlights a major societal challenge in the future of IATs for dementia. With the limited number of low-cost and open-source devices and the frequent failure of researchers to address issues of fair and universal access to technology, there is a risk that the adoption of IATs will be limited by socio-economic factors or could even exacerbate existing socio-economic problems. To compensate for this problem, the massive adoption of IATs among the ageing population should be coordinated with health policy plans that minimize the emergence of adverse unintended societal consequences. For example, reimbursement plans and government incentives are crucial strategies to promote fair access to technological innovation and avoid the emergence of a digital divide between elderly adults with dementia who could afford IATs and those who could not. Such a divide, in fact, could exacerbate existing socio-economic inequalities. In addition, since the prevalence of dementia is not dependent on socioeconomic factors, the benefits of IAT for dementia should be shared among all socioeconomic classes, not only among the wealthy people who can afford such technologies. This is particularly relevant from a global health perspective. In fact, since the greatest relative cost increases are occurring in low-income African and in East Asia regions (*279*) it is critical to deploy low-cost IATs that can be afforded by low-income populations in the developing world. While access and affordability are critical predictors of technology adoption, open-source designs should be also pursued. Open design in IAT for dementia would assure that the hardware and software of future IATs is developed in a collaborative manner and can be distributed to anyone without copyright restrictions. This would facilitate the fair distribution of and access to IAT across different world regions and socioeconomic classes and guarantee the *democratization* of such technological trend.

The dramatically underrepresented frequency of privacy considerations, especially of those related to informational privacy, raises a major ethical concern. In fact, it has been observed how various types of IATs could be used to access private and sensitive information (*204, 264, 280, 281*). Our results show that value-sensitive approaches to accounting for privacy considerations, particularly *privacy by design* (*282*), are not a priority in current IATs for dementia. We argue that protecting the privacy of older adults with dementia as well as the security of their identifiable information should be a structural requirement of future products. This can be achieved by enhancing the security of future products and integrating tools that *prevent unconsented extraction of private information or* filter it out from the information flow processed by the IAT. To achieve this, closer collaboration between IAT designers and information security experts may be required. Ideally, this would result in increased attention to principled approaches to privacy and data protection and in the integration of encryption and jamming technology. However, with security by design being difficult to achieve, measures for securing sensitive (e.g. behavioral, personal or physiological) information should be implemented not only at the level of product development but also of individual use and regulation. With regard to data ownership, older persons with dementia should be legally entitled to claim ownership over the content and the form of their data, either directly, through advanced directives or via proxy. Since the degree of information security decreases with the amount of awareness of the user, older people with dementia are in principle ideal targets for cybercrime or unauthorized data extraction. For example, when using a smartphone app for cognitive assistance and training, they might not have enough knowledge or awareness about what privileges the app is requiring from their device. This could open breaches for insecurity. The problem of privacy and security breaches is exacerbated by the fact that several IATs are not FDA certified —since they are not classified as medical devices, and do not fall under the HIPAA rule (*283*). Consequently, they are not required to hold the same privacy and security standards of medical applications.

The high prevalence of independence, risk-reduction and safety considerations indicates that the priority of IAT designers is to assist elders with dementia during the completion of their ADL. While the successful and autonomous completion of daily task is a major leap towards the empowerment of older adults with dementia, designers should look more carefully also at the emotional and cognitive underpinnings of behavior. In fact, although a certain IAT may be extremely successful at enabling users to independently perform task X, yet users might still not perform X because of their state of distress and agitation or due to forgetfulness. Therefore, there is a need for considering more carefully at the design level how IATs can be used to improve the emotional and cognitive dimension of elderly adults. In parallel, strategies should be developed to increase end-users' trust in the system.

Finally, conflicting ethical principles should be balanced in a weighted manner. For example, as observed by Nestrorov et al., promoting patient autonomy and reducing caregiver burden through intelligent technology may cause a loss of human contact (*284*). Similarly, minimizing invasiveness and obtrusiveness may result in sub-optimal accuracy of the device in sensing or tracking the user or collecting user data, hence conflict with benefice-oriented principles of health optimization. Therefore, a weighted balance among conflicting values should be pursued in a case-by-case manner through a cooperative effort involving not only designers and ethicists but also end-users and their caregivers.

Limitations and Future Research

This study presents several limitations. First, it is possible that ethical considerations might be addressed at the level of technology design in an implicit manner, i.e. without being reported in the study protocols or without the use of the explicit terminology. Although the value-sensitive framework prescribes that values in design should be addressed "in a principled and comprehensive manner" (*95*), unprincipled and implicit considerations might also relevant be in assessing IATs. To minimize this risk, software-guided keyword search was complemented with full-text review. This phase of review was performed independently by two researchers. In addition, the lack of ethical considerations at the level of technology design might not necessarily lead to unethical technology. In fact, the absence of ethical values in product design does not necessarily imply poorer ethical outcomes in the application of a certain IAT. A clear distinction between intended ethical values in product design and ethical outcomes is important to avoid this conceptual confusion. Finally, the absence of ethically relevant considerations might not be exclusive to IATs for dementia but common to other trends in medical technology. Some of the findings and implications of this study are likely to apply to IATs designed for different target user populations.

In spite of these limitations, the methodology employed in this study constitutes a valuable strategy to investigate the prevalence of value-sensitive approaches in IAT design and test whether and which ethical values are actually incorporated in current products. In addition, research in value-sensitive design has shown that addressing ethical values in a principled manner at the design level can result in increased benefits and reduced harms for technology users (*92*). Therefore, it is possible that mapping the prevalence of ethical values in IAT design might help develop strategies for the clinically successful and ethical responsible use of IATs among people with dementia.

Further research is required to investigate the ethical values addressed in IATs designed for different target populations such as people suffering from brain and spinal cord injury. In addition, further research is needed to explore the relationship between ethical design and technology acceptance among end-users. One possible strategy is to compare these review results with interview studies or surveys involving people living with dementia and their formal and informal caregivers. This triangulation would be particularly relevant in a cross-cultural context, since preliminary findings have revealed that elderly people from different world regions have different degrees of reservations about ethical issues (*285*).

Conclusion

The technology revolution in dementia care opens the prospects of reducing the global burden of dementia worldwide and enabling novel opportunities to reengineer the lives of elderly people with dementia and maximize their wellbeing. However, with current adoption rates being reportedly low, the potential of IAT in dementia care risks to remain under-expressed or even misused if ethical considerations are not addressed. This article investigated the presence and prevalence of ethical values and considerations in current IATs for dementia. Our screening revealed that the vast majority of IATs are designed in absence of explicit ethical values and considerations. This raises concerns about the current prevalence of value-sensitive approaches to IAT design and the level ethical sensitivity of current products. As the lack of ethically relevant considerations has been described as a predictor of sub-optimal user acceptance (*210, 286, 287*), future IATs should incorporate more extensively such considerations in a cooperative and proactive manner. In addition, as issues of justice and equality as well as privacy and information security torn out to be the most ignored, more research is required to make future prototypes affordable and fairly accessible across all socioeconomic classes of users, as well as more secure and protective of users' information, in particular in the context of private and sensitive data. Additionally, in order to match public expectations, technology designs should rely less on market-driven and inherently paternalistic approaches to product development and integrate factors and values that are considered relevant by end-users. This requires a transition to user-centered approaches to product development and more extensive needs-assessment research among end-users. Given the largely reported failure of top-down approaches to technology design in medical technology, user-centered and value-sensitive approaches should be prioritized.

As ethically designed and successfully implemented IATs open the prospects of improving the lives of people living with dementia, designers and developers have a moral obligation to incorporate ethical evaluations in their products and engage in a proactive debate with ethicists, clinicians, end-users and their caregivers. In this context, participation is critical for responsible development. At the same time, ethicists have a parallel obligation to being proactive instead of merely reactive. Instead of restricting their analysis solely on post-development evaluations of existing products, they should proactively cooperate with designers and developers to the responsible creation of ethically sustainable products.

Declaration of interest

Conflicts of interest: none.

*2.3. - Proactive Ethical Design for Neuroengineering, Assistive and Rehabilitation Technologies: the Cybathlon Lesson **

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Structured Abstract

Background

Rapid advancements in rehabilitation science and the widespread application of engineering techniques are opening the prospect of a new phase of clinical and commercial maturity for Neuroengineering, Assistive and Rehabilitation Technologies (NARTs). As the field enters this new phase, there is an urgent need to address and anticipate the ethical implications associated with novel technological opportunities, clinical solutions, and social applications.

Main idea

In this paper, we review possible approaches to the ethics of NART, and propose a framework for ethical design and development, which we call the Proactive Ethical Design (PED) framework.

Conclusion

A viable ethical framework for neuroengineering, assistive and rehabilitation technology should be characterized by the convergence of user-centered and value-sensitive approaches to product design through a proactive mode of ethical evaluation. We propose four basic normative requirements for the realization of this framework: minimization of power imbalances, compliance with biomedical ethics, translationality and social awareness. The aims and values of the CYBATHLON competition provide an operative model of this ethical framework and could drive an ethical shift in neuroengineering and rehabilitation.

Keywords: Ethics of assistive technology – proactive ethical design- user-centered- value sensitive design- neuroethics- Cybathlon –

Main Text

Background

With rapid advancements in rehabilitation science and the widespread application of engineering techniques for the restoration, compensation, assistance and enhancement of human neural systems, the field of neuroengineering is entering a new phase of clinical and commercial maturity. The first pioneering research prototypes of the 80s and 90s have evolved into an increasingly mature technological spectrum with direct clinical applications and corroborated efficacy. Over the past two decades, assistive and rehabilitation technologies have increased in number and variety. Concurrently, many invasive and non-invasive neurotechnologies have become available for assistive and rehabilitation aims. This expanded technological domain might be regarded as Neuroengineering, Assistive and Rehabilitation Technology (NART). NARTs have been developed with the main purpose of mitigating several morbidities associated with diseases and traumatic injuries to the human nervous system. Today, this evolving spectrum encompasses five major technological families: devices for robot-assisted training, functional electrical stimulation (FES) techniques, neuroprosthetics, brain-computer interfaces (BCIs) and powered mobility aids, many of which were listed as competing disciplines in the CYBATHLON 2016 (*288*).

Many of these applications have shown efficacy in improving neurological care and neurorehabilitation in relation to a number of functional domains. For example, randomized controlled trials performed on robotic devices for post-stroke therapy and rehabilitation showed that NARTs can enable significant improvements in the therapeutic outcomes compared to usual care (*289*), especially with respect to motor function (*290*) and quality of life (*291*). In parallel, at the commercial level, several neuroengineering tools for assistance and neurorehabilitation have made their way onto the market and are now available as effective tools for neurological care and rehabilitation. The InMotion ARM™ robot, for instance, allows the efficient delivery of personalized intensive sensorimotor therapy to neurologic patients who need upper-limb rehabilitation while the Lokomat® powered robotic gait trainer has shown effectiveness in improving locomotor gait-training for patients with incomplete spinal cord injury.

As the field of NART enters a new phase of clinical and commercial maturity, many authors have urged to address the ethical implications of this emerging field.

In a recent report based on the outcomes of a joint workshop between the US National Science Foundation and the German Research Foundation on “New Perspectives in Neuroengineering and Neurotechnology”, a group of international experts identified key technological, social and ethical challenges to the adoption of neuroengineering applications in the clinical setting. They concluded that the envisaged progress in NARTs requires a careful reflection on the ethical and social implications, in particular in relation to issues such as safety, security, privacy, public acceptance and respect for autonomy (*292*). In a similar fashion, participants of an interdisciplinary symposium at the NeuroTechnology Center (NTC) at Columbia University have advocated for the integration of ethics into neurotechnology and recommended the development of ethical guidelines for developers and users of novel products (*103*). This need for ethical guidelines has not been advocated only by researchers and scientists but also by rehabilitation professionals. Nijboer et al. have investigated the views of rehabilitation professionals and other stakeholders on the use of BCIs (one of the six disciplines featured in the Cybathlon) as assistive technologies. Their findings show that professionals are urging developers to carefully consider ethical and socio-cultural issues at the level of design (*99*). In addition, the lack of ethical consideration is increasingly seen as a major barrier for technology transfer of BCIs as assistive technology in neurorehabilitation (*98*).

Although it has only recently become an object of empirical and normative investigation, the need for ethical analysis in clinical neuroengineering is not a new demand but one that is deeply rooted in the neurorehabilitation practice. In fact, ethical significance is inherent to the very objectives and mission of the neuroengineering enterprise. As the goal of clinical neuroengineering and neurorehabilitation is to restore, repair, assist and enhance the capabilities of people with neurological conditions, its very mission is of primary ethical relevance and implicitly incorporates moral principles such as promoting end-user's autonomy, wellbeing and independence, empowering them across a wide range of activities and reducing their social isolation. This predominantly beneficence-oriented and autonomy-oriented ethical goal is well captured by the mission of the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA). RESNA's mission statement, in fact, emphasizes the aim of improving the potential of people with disabilities to achieve their goals through the use of technology.[24] An ethics-laden language is also at core of the Cone Health Neurorehabilitation Center, where a stroke support group was recently established for newly diagnosed patients "to make certain they feel *empowered* to take charge of their health and wellness to live a *full life*".[25]

In addition, the clinical implementation of NART raises ethical attention because the end-user population of these technologies is largely composed by vulnerable individuals with neurological conditions and other functional variabilities that, in virtue of their vulnerability, are often entitled to extraordinary ethical protection. For example, clinical BCIs can be used by individuals with advanced neuromuscular disorders, including patients with locked-in syndrome

24 See: http://www.resna.org/ (last accessed: 02/28/2017)

25 See: http://www.conehealth.com/app/files/public/3030/Empowering-Parkinsons-and-stroke-patients.pdf

(*293*), while robot-aided rehabilitation provides effective support during the recovery process of patients following a stroke (*294*).

Finally, as the pace of development of new technological products is reportedly faster than their social adoption and ethico-legal assessment, there is a risk that the beneficial potential of clinical neuroengineering and neurorehabilitation technology remains under-expressed if social, ethical and legal implications remain unaddressed. This is particularly relevant for potentially disruptive sociotechnological trends such as assistive robotics as well as for technologies ─such as invasive BCIs─ that establish direct connection pathways with the human brain, hence raising delicate ethical questions about integrity, mental privacy and personhood (*206*). A recent review about responsibility in rehabilitation robotics (including neurorehabilitation robots, robotic prostheses, and even next-generation personal assistance robots), has observed that most devices operate in close proximity or direct physical contact with patients, manipulate instruments inside their bodies or directly move their impaired limbs, and have invasive or non-invasive connections with the human nervous system (*295*). This raises the need for high ethical attention. While there is an increasing consensus among scientists, engineers and clinicians that ethics is relevant for NART, several conceptual and practical obstacles prevent the successful incorporation of ethical factors into product design and development.

First, at the conceptual level, it is often unclear what ethical considerations should be prioritized and at what level of the technology development process (e.g. design, clinical trials, or post-commercialization assessment).

Second, at the practical level, ethical guidelines and ethics-oriented clinical recommendations remain rare. For example, the RESNA Strategic Plan 2014-2018 does not address ethical considerations and even the RESNA Code of Ethics provides only eight general integrity guidelines to guide the conduct of members and service providers but remains silent on how to incorporate ethics into technology or how to maximize ethical values through their applications.[26] Similarly, the IEEE Engineering in Medicine and Biology Society (EMBS), the world's largest international society of biomedical engineers, provides a set of rules for ethical conduct in research but does not address substantive ethical considerations associated with technology use. In other words, existing guidelines focus on how to ethically develop assistive

[26] See: http://www.resna.org/get-certified/code-ethics/code-ethics (last accessed: 02/19/2017).

technologies. However, little guidance is available to engineers and researchers on how to develop ethical assistive technologies, that is technologies that promote ethical values.

Third, in many assistive domains such as the support and rehabilitation of elderly adults with physical or cognitive disabilities, ethical design remains reportedly sporadic while ethical assessment and compliance with guidelines are often perceived by developers and manufacturers as delay factors in the process of development and commercialization of new products (*6*).

In this paper, we review possible approaches to the ethics of neuroengineering and neurorehabilitation technology and propose a framework for ethical design and development, which we call the Proactive Ethical Design for Assistive & Rehabilitation Technology (PED-ART) framework. We also suggest that the aims and values of the Cybathlon competition provide an ostensive and operative model of this ethical framework.

It is important to highlight that the ethical challenges raised by assistive and rehabilitation technology are not necessarily unique but might apply also to other sectors of medical technology. Nonetheless, the repeated calls for ethical guidelines advocated by experts' committees and the relative infrequency of ethical guidelines in professional codes indicate a need for a proactive and collaborative framework that could facilitate the successful design, development and implementation of assistive and rehabilitation technology in an ethically responsible manner.

Reactive vs. Proactive Ethics of Assistive Technology

The ethical aspects of NART can be approached either reactively or proactively. Reactive approaches focus on the critical ethical evaluations of novel products and the assessment of their compatibility with existing normative ethical principles. In reactive ethics, ethical conflicts or problems are addressed as they arise, which usually occurs only at the end of the development process when the finished system is being implemented. For example, authors have performed ethical assessment of commercially available consumer-grade BCIs and argued that their security vulnerabilities may conflict with the principle of informational privacy (*206, 296*).

In contrast, proactive approaches are characterized by the development of strategies and solutions before a new technology becomes a source of potential ethical confrontation or conflict. Instead of merely reacting to an existing ethical problem, proactive approaches anticipate future potential uses, requirements, and unintended consequences of new technologies before they become ethical issues. For example, Bonaci et al. (2015) have anticipated an operative solution to the privacy problem of commercial BCIs described above and developed a system called *BCI Anonymizer* that integrates privacy safeguards into the BCI headset (*297*), hence proactively promoting the ethical principle of respect for privacy.

The notion of proactive ethics was independently coined in the fields of, respectively, business ethics and clinical ethics consultation. In business ethics, the notion "proactive" is used when a business introduces ethical measures (e.g. transparency, accountability and communication) before the eruption of crisis situations, rather than in response to the crisis (*298*). Similarly, in clinical ethics consultation, this notion is used to describe a process-oriented approach to ethics consultation (e.g. in ICUs) where communication and planning begin prior to crises (*299*). Pavlish et al. (2013) have further developed this notion into a Proactive Ethics Framework, that is a comprehensive set of proactive, ethics-specific, and evidence-based strategies for mitigating ethical conflicts in the clinical setting (*300*). This framework included sequential key action points, beginning with the creation of an ethics-minded culture, and continuing with the implementation of risk reduction strategies and the response to early indicators.

Reactive and proactive approaches are not necessarily mutually exclusive but can be complementary. As the example above shows, they can be two sequential phases of a continuing technology assessment process: first, in the reactive phase, ethical conflicts are identified and assessed; concurrently, in the proactive phase, further ethical considerations are anticipated and ethically relevant solutions are incorporated into the design of novel products.

The advantage of reactive approaches to the ethics of neuroengineering is that they allow ethicists and engineers to optimize their efforts and focus on concrete problems rather than on the anticipation of possible future scenarios that are often hard to foresee. However, reactive approaches ─if not in conjunction with concurrent proactive considerations─ present several disadvantages. First, they are structurally postdated since they provide ethical advice, by definition, only at the post-development level (*301*), that is at a stage when there is little or no room for modification of an assistive technology or rehabilitation device. Second, in several domains of cognitive and physical disability such as dementia and age-dependent frailty, the lack of proactive ethical and social considerations has been inferred as a determinant of low adoption and acceptance of technology (*2, 302*). In fact, if the impact of ethically relevant factors is not anticipated, products might not match the end-users' needs and wishes, hence result in sub-optimal uptake, implementation lag and delayed clinical or social benefit. Third, there is a risk that lack of proactive ethical considerations may cause negative public perceptions or even unjustified Luddite fears among end-users, caregivers and other relevant stakeholders (*303*). This risk is particularly concrete in relation to advanced technologies such as those that incorporate or embed Artificial Intelligence, as their underlying mechanisms and functionalities are often unclear to users (*304*). Finally, reactive approaches are a possible source of antagonism and conflict between designers and developers, on the one hand, and ethicists and policy makers, on the other hand. The reason for that stems from the fact that, in a reactive context, engineers and ethicists may engage in a competitive dynamic where the work of the former professionals is being constantly questioned and judged by the latter. By contrast, in a proactive approach, all parties are encouraged to work together. It is worth considering, however, that even though proactive approaches encourage interaction among ethicists and engineers, they are not *necessarily* conductive to collaborative approaches.

Modes of Proactive Ethics: User-centered and value-sensitive design

In most circumstances, the type of approach to the ethics of neuroengineering and neurorehabilitation technology chosen by manufacturers is influenced by the process of product design. For example, the increasing prevalence of bottom-up and user-driven approaches to the design of assistive technologies has been often observed to "move a step further to the ethics of the user" (*305*), reduce usability problems or conflicts ─since these can be identified and resolved before the systems are launched, and facilitate the incorporation of ethical considerations in the design process (*6*). This suggests that the type of technological design adopted by manufacturers is not morally neutral but determines the possibilities of an assistive technology and has consequences for human wellbeing (*301*).

The "user-centered" (sometimes also referred to as "patient-centered") approach is a framework of processes for the design and development of assistive technologies in which the needs, wishes, and limitations of end-users are given extensive attention at each stage of the design process (*166*) (Fig. 12).

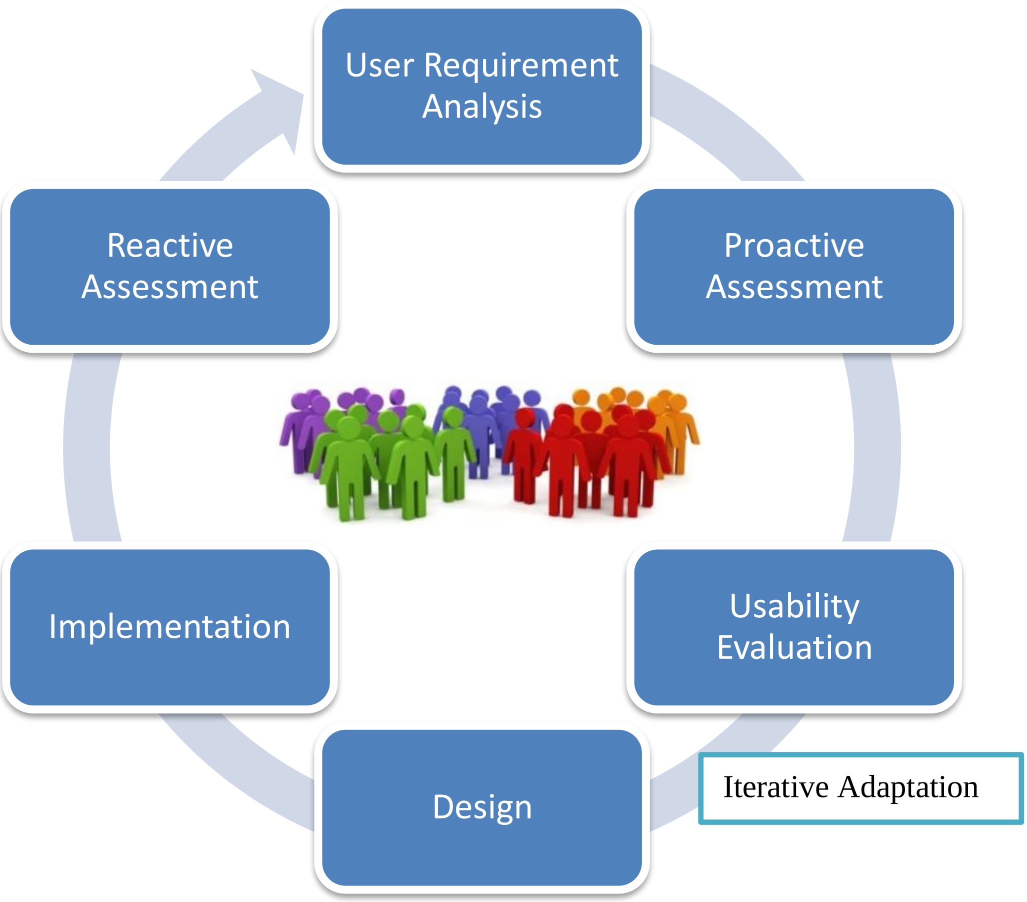

Figure 12- A Visual Representation of the Iterative Dynamics of User-Centered Design (UCD)

The user-centered (UC) family encompasses a number of methodologically contiguous approaches including cooperative design (where designers and users are involved on an equal footing), participatory design (where users are involved through active and participative processes) and contextual design (where the participatory process occurs in the actual context or environment). For example, the Us'em wearable device, a rehabilitation tool for motivating stroke patients to use their impaired arm-hand in daily life activities, was designed and developed using an user-centered process during which stroke patients, therapists, rehabilitation researchers, and interaction design experts were actively involved (*306*).

UC approaches are being increasingly considered a necessary requirement for ethical design of assistive and rehabilitation technology (*37, 98*). The reason for that is twofold.

First, by putting users at the center of design and development, UC approaches shift the location of power in the research process (*307*). Through this approach, users are no longer conceptualized as passive recipients of a new product who are implicitly coerced to change their behavior to accommodate the new technology. In contrast, they are empowered at each stage of the design and development process (requirement analysis, pre-production models, mid-production and post-production). In addition, they are no longer subordinated to designers in the decision-making process regarding a new technology, but actively involved in a cooperative dynamic and on a potentially equal footing.

Second, at the practical level, UC approaches facilitate the translation of new assistive technologies into standard rehabilitation practice and care, hence accelerate and maximize the social and clinical benefits of technological innovation. In fact, the translation of new technologies from the designing lab to the rehabilitation clinic can best be accomplished if a patient-centered focus is incorporated throughout the research and development continuum and changes are made so that biomedical innovation serves the broadest needs within the shortest period of time (*308*). This societal outcome is consistent with multiple ethical principles and theories. For example, it is consistent with Stuart Mill's principle of aggregate utility, the foundational ethical tenet of classic utilitarianism according to which people desire happiness — the utilitarian end— and where general happiness is considered "a good to the aggregate of all persons" (*309*).

Third, in determining this shift in the location of power, UC approaches inherently promote ethical principles, especially the respect for autonomy, which is one of the four fundamental principles of biomedical ethics (*118*). At least two components of personal autonomy are promoted through UC design: decisional autonomy and executional autonomy (*310*). Decisional autonomy is the capability to make decisions without restraint from other actors or pre-imposed designs. This capability is promoted if users are actively involved in the decisional process of product design and enabled to make choices or suggestions based on their wishes and needs. Executional autonomy is the capability to act according to a desired course of action. This capability is promoted if users can successfully use assistive technologies tailored around their needs and wishes, hence become able to perform tasks that they might not be able to perform otherwise.

However, authors have argued that decisional and executional autonomy might not be sufficient to guarantee full autonomy and participation of users in rehabilitation. Rather, another component of the autonomy concept is required, that is self-realization (*310*). According to this notion, users should not only be granted the capability to make free decisions and act independently, but should also be able to shape their life "into a meaningful existence which expresses individuality" (p. 972). Patients who need assistive and rehabilitation technologies may be experiencing a reduction in their capacity to act as autonomous persons along all these three dimensions (decisional, executional and self-realization). Therefore, assistive and rehabilitation technologies may compensate for such reduced capacity and boost patient autonomy.

Considerations of this kind have led researchers to complement the user-centered framework with values of psychological and ethical significance. The resulting systematic approach is called value-sensitive design (VSD) and is characterized by the embedment of human values into technology design. In the VSD approach values are defined as the “principles or standards of a person or society, the personal or societal judgment of what is valuable and important in life” (*311*).

According to the VSD approach, assistive and rehabilitation technologies should embody and account for ethical, social and psychological values “through a theoretically grounded approach in a principled and comprehensive manner throughout the design process” (*312*). VSD has often been described by engineers, clinicians and ethicists as a successful strategy to incorporate ethics in the overall design process of assistive and rehabilitation technology (*301, 313*). In light of this, VSD approaches have raised increasing interest among researchers, a phenomenon confirmed by a fivefold increase in research papers in the field of human-computer interaction mentioning “human values” during the past ten years (*314*).

Recently, ethicists of healthcare technology have tried to operationalize the principles of VSD in the context of assistive and rehabilitation technology. For example, van Wynsberghe has used the blueprint of VSD “as a means for creating a framework tailored to care contexts”. These efforts are motivated by the need of guaranteeing that assistive and rehabilitation technologies enter the clinical domain in a manner that “supports and promotes fundamental values” in healthcare (*313*).

While having the merit of enhancing the ethical sensitivity of emerging assistive technology, neither the UC nor the VSD approach are anchored by default on a specific normative grounding or ethical theory (*315*). Rather, they can be realized through multiple normative principles or ethical theories. In addition, it has been observed that differences exist between designers’ values and users’ values (*316*). This raises the question of how to implement VSD approaches in a multi-cultural society where people could reasonably disagree on important values. While we recognize the importance of the problem, in this paper we refer to VSD as a method “that can be applied in principle to any set of values” and not as the “methodological instantiation of a particular set of values” (*314*). Future ethical research should discuss which ethical values (e.g. universal vs. culturally-relative) should actually be instantiated in emerging technologies.

While we remain agnostic about the specific instantiation of ethical values in the strong sense, in the following, we propose a UC and VSD approach to ethical assistive and rehabilitation technology based on four basic normative requirements. We call this approach the Proactive Ethical Design for Assistive & Rehabilitation Technology (PED-ART). Finally, we refer to the experience of the Cybathlon competition as an ostensive and operative model of this ethical framework.

A Framework for Proactive Ethical Design

There is an increasing consensus that UC and VSD are necessary requirements for ethically sustainable development of assistive and rehabilitation technology (*6, 98, 99*). However, little analysis is available on the prerequisites of successful adoption of such approaches. Based on the inherent goals and objectives of UC and VSD described above, we argue that four basic normative requirements are necessary for the successful implementation of ethical NART.

Minimization of power imbalances: Both UC and VSD presuppose the minimization of power imbalances in decision-making and a certain degree of inclusiveness and democratization in the design process. This shift in the location of power across the technology design continuum is best achieved through a goal-oriented cooperation among designers, developers and end-users. This principle implies that in order to be involved on an equal footage in the design process, all stakeholders should be incentivized to share common goals that could be pursued through coordinated and cooperative efforts. In fact, in absence of common goals or even in presence of mutually conflicting objectives between different stakeholders (e.g. designers vs users), no successful cooperation within the UC and VSD framework is likely to occur. An example of conflicting objectives between different stakeholders is the observation that designers and developers of assistive and rehabilitation technology often prioritize the effectiveness of a new technology whereas users often prioritize usability. Effectiveness refers to the accuracy and completeness with which end-users can achieve certain goals in a certain environment. Usability is the easiness and extent to which a technology can be used by users to effectively achieve these goals. This discrepancy between effectiveness and usability has been particularly investigated in the context of assistive BCI, one of the technologies featured in the CYBATHLON 2016. For example, a review of BCIs as access pathways for people with severe disabilities has shown that most current prototypes are developed with focus on speed and accuracy instead of usability (*317*). These conflicts of objectives can have detrimental consequences for rehabilitation as they could concur in the phenomenon of technology abandonment. This refers to the fact that users of an available assistive or rehabilitation technology might stop using it after an initial phase, a phenomenon that is particularly common with technologies for home use. Scherer has reported that about one third of all assistive technologies are abandoned, and many others might continue to be used sub-optimally due to unease and discomfort. As she states: “we have no information about the number of people who continue to use devices they are unhappy or uncomfortable with because they cannot abandon them without facing more severe consequences”(*318*). In addition, the absence of common objectives among different stakeholders involved in the design and development of assistive and rehabilitation technologies is likely to cause the so-called “problem of many hands” (*319*). This problem denotes the risk that in complex process where multiple stakeholders are actively involved errors can be made although no class of stakeholders acted in an explicitly reckless or negligent way.

To overcome this problem, there is a need for harmonizing the objectives of all relevant stakeholders involved in the design process through an iterative and dialogic confrontation. This could be achieved by creating cooperative scenarios where all stakeholders are incentivized to pursue a common goal or objective.

Compliance with biomedical ethics: The second requirement for the successful implementation of ethical assistive technology in rehabilitation is compliance and coherence with biomedical ethics. NARTs are integral part of biomedicine and biotechnology. Nonetheless, their degree of ethical scrutiny by biomedical ethicists is often lower compared to other domains of biomedicine and biotechnology such as pharmacological interventions. This is probably due to many factors including the relative novelty of assistive and rehabilitation technology, a less stratified history of misuse and different risk-related perceptions among professionals.

We argue that successful technology development via UC and VSD presupposes the compliance with biomedical ethics. As we said before, this requirement can be fulfilled through compliance with multiple approaches and values in biomedical ethics such as utilitarianism, Kantianism or virtue ethics. Among others, one viable and, according to some, easy-to-implement approach is principlism, a practical approach for *ethical* decision-making that focuses on four common-ground moral principles: beneficence, non-maleficence, autonomy and justice. Research shows that the principlist approach has the largest circulation among health professionals and the highest prevalence in ethics curricula for health science students (*104, 121*). This fact could, ceteris paribus, guarantee better acceptance and easier implementation among health professionals. However, it is important to highlight that, at any rate, referring to any specific ethical theory in a predetermined manner risks to preempt normative input from users. Therefore, it is important that, at any rate, ethical theories or principles are chosen based on the needs and values of users, and adapted to these needs and values through an iterative and flexible process. In other words, the investigation of the users' needs and values should determine which ethical content is most suitable for a certain technology in a certain patient population, not vice versa.

Principlism, uses a "common morality" approach and "mid-level" prima facie principles: beneficence, non-maleficence, respect for autonomy and justice (*118*). Beneficence is the promotion of the wellbeing of people with disability through the successful implementation of assistive and rehabilitation technology. As we have seen above, the field of assistive and rehabilitation technology urges a broad concept of beneficence that is not only focused on the effectiveness of new technologies but also on their usability.

Non-maleficence is the principle of preventing or minimizing harms associated with the use of assistive and rehabilitation technology. This principle is promoted through the implementation of safeguards for the safe and secure use such as the precautionary approach, namely the idea that technologies whose consequences are difficult to predict should be first investigated in a safe setting (*301*). Neurorehabilitation experts have tried to systematize the principle of non-maleficence in relation to robot-assisted neurorehabilitation (*320*). Their model is based on the postulation of three fundamental laws called the laws of neurorobotics in rehabilitation, a re-elaboration of Asimov's laws of robotics (*321*):

(I) A robot for neurorehabilitation may not injure a patient or allow a patient to come to harm.

(II) A robot must obey the orders given it by therapists, except where such orders would conflict with the First Law.

(III) A robot must adapt its behavior to patients' abilities in a transparent manner as long as this does not conflict with the First or Second Law.

The first law postulates that rehabilitation robotics should be safe not only in terms of movement, but also from other medical points of view. This can be achieved by designing new products in accordance with the international standards such as ISO 13482:2014 (*322*) and through careful consideration of unintended harms, where harm is understood as any "possible damage to patients" including discomfort and time spent on ineffective rehabilitation. The second law postulates that assistive technologies should not replace therapists, but rather complement existing treatment options. Therapists should always be on the loop of robot-assisted rehabilitation and maintain a position of control in relation to the adjustment of technological parameters, the avoidance of harmful compensation strategies and identification of trade-offs between rehabilitative goals and the psychological dimension of patients. Risks of reduced control over technological parameters such as is the discrepancy between the desired and actual values of some parameters of the electromechanical Gait Trainer (*323*) should be prevented. At the same time, based on the third law, automatic features and artificial intelligence might be used to support rehabilitation therapists by performing all the control changes required for a successful therapy.

The principle of respect for personal autonomy, as stated above, should not be seen exclusively as the promotion of decisional and executional autonomy, but of self-realization as well. To achieve that, UC approaches should not only involve the active participation of end-users and investigate their perceptions only in relation to quantitative parameters such as effectiveness and usability, but should proactively incorporate user-driven ethical and psychological factors in product design. Given the requirements of context-sensitive design, this attempt to "materializing morality" (*94*) through assistive technology should be dependent on the specific context and environment of end-users.

Finally, justice is the principle of biomedical ethics that requires assistive technologies to be fairly accessible to users, affordable across various socioeconomic classes, and evenly distributed across rehabilitation clinics in various world regions. While this principle can be incorporated into product design by favoring scalable, low-cost and pervasive technologies, yet design alone might be insufficient. In addition to that, justice-promoting policies should be pursued at various levels of health-technology regulation. Reimbursement policies and State incentives have been advocated elsewhere as possible justice-promoting regulatory interventions (*37*).

Translationality: The third requirement is translationality. In fact, the ethical goal of maximizing wellbeing for all individuals with disability through the use of assistive and rehabilitation technology is highly dependent on the process of translating research from the designing lab to the rehabilitation center. In order to maximize the societal benefits of assistive and rehabilitation technology, we need to ensure that new technologies actually reach the patients or population for whom they are intended and are implemented correctly (*324*). Slow or incomplete translation across bench, bedside and community ─ which the European Society for Translational Medicine calls the “three main pillars” ─ is likely to reduce the beneficial impact of assistive technology on the global healthcare system. According to the Institute of Medicine's Clinical Research Roundtable two distinct phases in the translational process are in particular need of improvement: the first translational block (T1) prevents basic research findings from being tested in a clinical setting; the second translational block (T2) prevents proven interventions from becoming standard practice.[27]

Social awareness: Finally, the fourth requirement is raising social awareness and favoring knowledge dissemination across society. The public is often skeptical or reluctant regarding the use of new technologies because of lacking knowledge on the technology and its applications (*325*). Sociologists have identified historical patterns and dynamics of opposition to technological innovation”. For example, Juma has explored the multi-layered dimensions of socio-political resistance to various types of technological innovation including biomedical technology. These include established social norms, financial considerations, health implications, social disruption, as well as prejudices or human ignorance (*325*). Patterns of resistance to new technologies have also been observed in the specific context of healthcare technology (*326*). This opposition seems to be particularly significant in relation to technologies that enable proximity to the human body such as wearable devices and neural prosthetics. A 2014 Pew survey showed that 53% of Americans think it would be a bad thing if “most people wear implants or other devices that constantly show them information about the world around them.” In contrast, just over one third (37%) think this would be “a change for the better” (*327*). Since many NARTs operate in close proximity or direct physical contact with patients, and have invasive or non-invasive connections with the human nervous system, they are likely to be affected by these negative public perceptions.

The media, a major catalyzer of attention and knowledge on novel technological possibilities, have started only recently to properly cover the domain of rehabilitation technology. Concurrently, since NARTs are still in an initial phase of the technology life cycle, their

27 See: https://ncats.nih.gov/about

pervasive implementation might still be limited by enduring habits of health professionals, financial limitations and issues of resource allocation or conservative managerial decisions —all phenomena that have already been observed in other sectors of healthcare technology (*328-330*). If improving the effectiveness, usability and ethical potential of assistive technology is the grand challenge for neuroengineering, raising social awareness on assistive technology is the corresponding challenge at the level of society. It is worth stressing that these requirements should not be seen as values *per se*, but as *conditions of possibility* for the consideration and incorporation of values through UC and VSD (see Fig. 13).

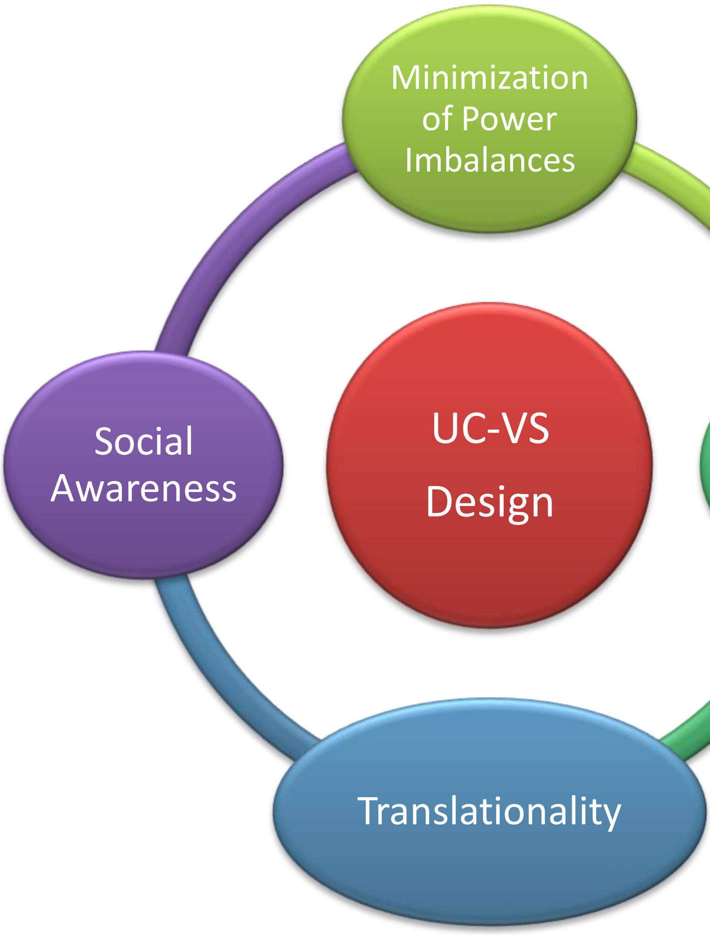

Figure 13- A Framework for the Proactive Ethical Design (PED) of assistive & rehabilitation technologies

In fact, we hypothesize that UC and VSD approaches cannot be properly implemented if: (i) major power imbalances persist, (ii) biomedical ethics is ignored, (iii) prototypes are not adequately translated into viable products for users and (iv) there is a lack of social awareness about the clinical benefits. However we recognize that this causal relationship can be bidirectional as: (i) the 4 normative requirements enable UC & VSD, but, in parallel, (ii) the adequate realization of UC & VSD guarantees the fulfillment of the four normative requirements.

Proactive Ethical Design: The Cybathlon Lesson

In October 2016, ETH Zurich organized in Switzerland the first edition of the CYBATHLON, an international championship for competitors with disabilities using bionic assistive technologies. The competition featured six disciplines – a FES bicycle race, a Powered Leg Prosthesis Race, a Powered Wheelchair Race, a Powered Exoskeleton Race, a Powered Arm Prosthesis Race, and a BCI neurogaming race.

We argue that this innovative event represents an ostensive and operative model of the ethical framework delineated in this paper. The reason for that stems from the fact that the Cybathlon embodies all four required approaches for the successful implementation of ethical assistive technology in rehabilitation.

First, the Cybathlon fulfills the first requirement by providing an ideal setting for a goal-oriented cooperation among different stakeholders. During the CYBATHLON 2016 competition, designers, developers and end-users have not only engaged in cooperative dynamics on an equal footage (as required by the UC approach) but also shared a common goal. This created a goal-converging dynamic where the success in the race of the user (the competing athlete) corresponds to the success of the designing team. Such gamification creates a fruitful and possibly reproducible setting for harmonizing the objectives of all relevant stakeholders involved in the design process. Concurrently, it shifts the location of power by putting the user (the individual athlete with disability) at the center of the arena. This centrality of the user in the competition is an ultimate form of empowerment: instead of being a passive recipient of technology-assisted rehabilitation, the person with disability becomes the protagonist of a cooperative process.

Second, the CYBATHLON model fulfills the second requirement by proactively anticipating compliance and coherence with the principles of biomedical ethics. The day prior to the competition, a roundtable discussion involving end-users, patient and industry representatives also hosted a prominent ethics researcher. In addition, the creation of a goal-oriented cooperation between designers and athletes facilitates the promotion of beneficence, non-maleficence and patient autonomy by giving them the possibility to request adaptations of the prototypes according to their wishes and needs at every stage of the process. This iterative process of need assessment and product adjustment exemplifies the ideal feedback-loop between designers and users that should be pursued in the research setting according to the UC and VSD frameworks. While beneficence is captured by the need of increasing efficiency, effectiveness and usability in order to win the competition, and the non-maleficence principle is embodied by safety-enhancing safeguards, the autonomy of users is maximized by their physical and decisional centrality in the process. As a factor of limitation, the justice principle appeared more sporadically during the competition due to multiple facts: (i) high-performing technologies are likely to be financially expensive; (ii) the competition took place in one of the world' most affluent countries; (iii) most competing teams were from affluent and highly industrialized countries. However, future editions of the competition may compensate for this omission and incorporate the justice principle by creating a component of the competition involving low-cost technologies, hosting the event in non-European and non-North American countries and encouraging participation of research teams from emergent and developing countries.

Third, the CYBATHLON competition fulfills the translationality requirement by enabling a smooth and accelerated translation of innovative research in assistive technology for the benefit of individual users and the community. Each competing team in the CYBATHLON championship is a small-scale translational round-block that translates research findings into utilizable technology and assesses them in a public arena together with real end-users. This translational power is corroborated by the possibility that through the CYBATHLON competition many technologies originally designed for a small-sized group of people with disability may found an application in larger markets including people with similar functional disabilities or even able-bodied people. From a business perspective, this possibility, jointly with the commercial relevance of the CYBATHLON, could expand the market of assistive technologies from a small-scaled niche that creates little incentives for the industry to pull the technology onto the market into a broader, more mature and pervasive domain of technological innovation.

Finally, the surprising media coverage and societal attention raised by the CYBATHLON could become a critical catalyzer to raising social awareness on disability and assistive technological solutions. Several international media including the British BBC, the German Deutschlandfunk, the Swiss SRF, and the Canadian CTV provided live coverage and subsequent analysis of the competition. This degree of international coverage in mainstream media could be a ground-breaker in the effort of raising social attention and awareness about novel technological possibilities in rehabilitation. In addition, the possibility of watching real-time successful applications of current assistive technologies may contribute in changing negative societal perceptions on these products and disseminate information and knowledge about this ever-evolving technological domain across society.

Conclusion

As the fields of assistive technology and neuroengineering are entering a new phase of clinical and commercial maturity, there is an increasing need to address the ethical implications associated with the design and development of novel assistive and rehabilitative technological solutions. After reviewing various ethically-sensitive approaches to the design of NART, we proposed a framework for ethical design and development, which we call the Proactive Ethical Design (PED) framework. This framework is characterized by the convergence of user-centered and value-sensitive approaches to product design through a proactive mode of ethical evaluation. Four basic normative requirements are necessary for the realization of this framework: minimization of power imbalances, compliance with biomedical ethics, translationality and social awareness.

Cooperative efforts of researchers, end-users, clinicians and societal stakeholders are necessary to drive assistive and rehabilitation technology towards the PED framework and maximize the benefits of neuroengineering for individual users and society at large. The innovative paradigm of the CYBATHLON competition provides a promising operative model of this ethical framework and could drive an ethical shift in neuroengineering and rehabilitation. In fact, the CYBATHLON establishes a platform for exchange and cooperation among various stakeholders including people with disabilities, researchers, developers, funding actors, media and the general public. In addition, it encourages a convergence of goals between researchers and end-users, promotes compliance with ethical considerations, facilitates successful translation of new technology and raises social awareness on assistive technology and disability.

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Author's contribution

MI has conceptualized the ethical framework, conducted the literature review and drafted the manuscript. RWK supported the study design, revised the manuscript and contributed to the figures. FJ supported the study design development and revised the manuscript. BE supported the study design development and contributed to write and revise the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors have no conflict of interest to declare.

Ethics approval and consent to participate

Not applicable.

Module 2

*2.4. - Health Professionals' and Researchers' Views on Intelligent Assistive Technology for Psychogeriatric Care**

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Abstract

Intelligent Assistive Technologies open the prospects of alleviation the global burden of population aging and dementia. However, their translation from designing labs to the clinical setting appears suboptimal. This study aims at obtaining more detailed knowledge on the clinical translation of IATs by exploring the views and attitudes of key health professionals involved in dementia and elderly care. Qualitative data were gathered in three among the countries with the highest longevity and lowest birthrate (Switzerland, Germany and Italy), hence particularly exposed to aging-related health burden. Our findings provide a qualitatively rich picture of the current opportunities and challenges of using IATs in the clinical setting. In addition, we indentify a number of possible barriers to the adequate translation of IATs into the clinics.

Introduction

Today over 900 million people worldwide are aged 60 years and over as a consequence of rising life expectancy (*331*). In many countries increased longevity is being accompanied by declining fertility rates causing a rapid increase in the proportion of older people to the total population. This trend is particularly recognizable in Western European countries such as Italy, Germany and Switzerland, characterized by extremely high life expectancy (Switzerland 83.4; Italy 82.7; Germany: 81.0) and low fertility rates (Italy 1.43; Germany: 1.44; Switzerland: 1.55) (*15*). In these countries, people aged 60 years and over constituted more than one fifth of the total population in 2015 (Italy: 28.6; Germany: 27.6; Switzerland: 23.6%), a number that is expected to increase by an additional 8-9% by 2030 (*16*). These demographic trends pose a major challenge to public health since older age is associated with rising incidence of non-communicable chronic diseases, increased disability and higher healthcare costs. A major component of health burden among older population in those countries is represented by Alzheimer's disease (AD) and other age-dependent dementias. People with dementia experience major cognitive and physical disabilities, hence need constant care during basic activities of daily living (*331*). This is reported to create a "heavy economic and social burden" (*332*), primarily as a consequence of the high financial and social costs of long-term medical care, informal care provided by families, and social care provided by community care professionals.

Gerontechnologies that can help older adults and people with dementia remain mobile and independent, hold the promise of mitigating this global health challenge by decreasing the costs for long-term care to families and society, alleviating caregiving burden, facilitating the delivery of medical care, and increasing the quality of life of this vulnerable population (*2*, *67*). Intelligent Assistive Technology (IAT) is the umbrella term used to comprehensively describe the broad spectrum of gerontechnological solutions (both hardware and software) designed to assist elderly adults and people with dementia in the homecare and institutional setting (*2*). A recent review has shown that the number of IATs with application to dementia and elderly care has nearly tripled in the last 5 years and even increased by a factor of 15 compared to beginning of the new millennium (*6*). The same review shows that the IAT spectrum appears to encompass a large variety of computing solutions including distributed systems such as ambient assisted living technologies, care robots, mobility and rehabilitation aids, handheld devices, apps, wearables and human-machine interfaces. The common denominator of these otherwise different technologies is their capacity to use intelligent computation to support psychogeriatric care. IATs are being developed for a variety of clinical and social-care purposes including assistance during the completion of activities of daily living, health and behavioral monitoring, physical and cognitive assistance, facilitated interaction and engagement, care delivery and rehabilitation, as well as emotional support (*6*).

While technology is developing fast, studies assessing the clinical and social effectiveness of IATs remain scarce and significantly vary in number and level of generalizability depending on the specific IAT type. Bemelmans et al. have shown that socially assistive robots such as Paro can have a positive effect on mitigating the mood scores of patients in various stages of dementia (*333*). This positive effect is particularly recognizable in long-term care setting (*334*). However, large-scale cohort studies are rare for this IAT type. Other IAT types such as ambient assisted living (AAL) technology have been investigated more extensively. For example, the UP-TECH project involved a randomized control trial with 438 patient-caregiver dyads to validate an integrated package of AAL solutions in Italy. Nonetheless, experts have emphasized the need for improved evaluation methods, "particularly feature-focused scenario-based evaluations" (*335*). Furthermore, cross-national and cross-cultural studies appear still rare.

Besides validation, one further challenge is adoption. Research shows that adoption rates of IATs in dementia and elderly care are still low (*107*). Investigating the views of key stakeholders involved in dementia and elderly care is gaining momentum as an effective strategy for acquiring valuable insights about possible barriers to the successful adoption of IATs in the institutional and home-care setting. In 2014 a German interview-study investigated the views of dementia caregivers and identified a lack of awareness and unsuccessful information transfer across relevant stakeholders (*107*). A UK study involving people with dementia and their caregivers enriched such qualitative evidence and suggested that lack of information and cost-related considerations might play a role in determining adoption rates (*336*). To date, researchers have indicated a number of possible barriers and obstacles to adoption including lack of robust evidence for the cost-effectiveness of IAT solutions (*337*), low-prevalence of user-centered approaches to technology design (*6*), information gaps at the cross-section of technology development and healthcare (*107*), high costs of IATs and absence of viable reimbursement plans (*336, 337*), as well as unaddressed ethical considerations, privacy in particular (*191, 225*). A few studies investigated the perspective of health professionals on the use of IATs for dementia and elderly care. A recent study in the UK explored the views on IATs of GPs, people with dementia and their caregivers (*338*). Their results indicate moderately high awareness among GPs about IAT solutions but show persistent obstacles in the dissemination of adequate information and support (*338*). As health professionals are critical decision-makers for the adoption of new medical technologies, more research is needed to investigate their views and attitudes towards IATs, especially in light of current trends in population aging.

To this purpose, our study aims at obtaining more detailed knowledge on the views and attitudes towards IATs of key health professionals involved in dementia and elderly care. Qualitative data were gathered in three among the countries with the highest longevity and lowest birthrate (Switzerland, Germany and Italy), hence particularly exposed to aging-related health burden. Furthermore, it aims at producing qualitative, experience-based and clinically-oriented knowledge that can be used by gerontechnologists to inform future development and implementation studies involving IATs in psychogeriatric care. As IATs compose a numerically considerable (*210*) and ethically challenging (*1*) component of gerontechnology, cross-national expert assessments of IAT can provide useful information not only for IAT designers and developers but also for ethicists, health professionals, policy makers and gerontechnologists.

Methods

Study sampling and recruitment

We conducted and analyzed open-ended qualitative interviews with health professionals and researchers working in Switzerland, Germany and Italy. Interviewees were conducting research and/or actively working within the fields of geriatrics, psychiatry, neurology, neuropsychology, gerontology, nursing, and healthcare management. They had direct research experience in the field of gerontechnology and/or in the professional care for psychogeriatric patients including people with dementia and other age-dependent disability. Purposive sampling was adopted according to positions, expertise, research background and years of experience to obtain a diverse selection of stakeholders from both private and public health institutions with varying disciplinary affiliation and professional experience. A total of 21 stakeholders were purposively selected from the homepages of the research institutions according to their professional profile or recruited through subsequent snowballing. The initial sample was adopted based on previous qualitative studies assessing IAT use among caregivers of persons with dementia whose sample sizes were comprised between 10 and 25 (*339-341*). Snowball was interrupted once theoretical saturation was achieved. Participants were contacted via e-mail outlining the research and invited to participate in the study. Three respondents declined the invitation due to conflicting commitments while one respondent dropped out from the study after initial acceptance due to health issues. A total of 17 interviews were completed (see Tab.7). The overall response rate was 85%. The invitation message contained the following information: (i) title of the study: *"Health professionals' views on Intelligent Assistive Technology for Dementia* and *Elderly Care"*, (ii) study rationale, design and purpose (iii) interview methodology and approximate length, (iv) safeguards employed for the protection of confidentiality and anonymization of the collected data, (v) contact details of the research team, as well the (vi) informed consent form. Prior to recruitment, the study obtained a waiver from the Ethics Committee Northwest/Central Switzerland (EKNZ).

Country	**n (%)**
Switzerland	10 (59)
Germany	4 (23)
Italy	3 (18)
Professional Experience	
Gerontology	1 (6)

Geriatrics	2 (13)
GP	1 (6)
Neurology	2 (13)
Neuropsychology	3 (19)
Nursing	1 (6)
Nursing Home Management	1 (6)
Psychiatry	5 (31)
Gender	
Male	10 (59)
Female	7 (41)

Tab. 7- Interviewees' Distribution (N=17)

Data collection

Semi-structured interviews were carried out and the research team designed an interview guide. Using the interview guide, we sought to explore healthcare professionals' (a) expectations, needs and perceptions regarding the clinical application of IATs, and (b) practical experiences with the clinical use of these technologies. Additional questions were also added to understand the issues of effectiveness, clinical evaluation, care needs, interactions with designers, developers and other stakeholders, as well as issues related to the governance and management of IATs. Finally, interviewees were invited to provide recommendations for IAT designers and developers based on their clinical experience and perceived clinical needs with the purpose of improving IAT use for the benefit of end-users. The interview guide was pilot-tested and adapted during the first few interviews. Whenever useful to orient the conversation or provide tangible technological examples, participants were presented with the latest comprehensive index of IATs for dementia and elderly care known to the interviewer, encompassing the following IAT types: distributed systems, robots, mobility and rehabilitation aids, handheld/multimedia, software/apps, wearables and human-machine interfaces (*6*).

Fifteen interviews were conducted face-to-face at the interviewees' institutions or at a location of their choice. Two interviews were conducted via video-call upon request from the participant. The first author conducted all the interviews in the time period between October 2016 and April 2017 and they were digitally recorded. The interviews lasted approximately between 21 and 55 min, with an average duration of 33 min. The recorded audio files were transcribed verbatim in the original language of the interviewees (English, German, or Italian) using the *F4transkript* software.

Data checking and data analysis

To ensure respondent validation (*342*), study participants were given the opportunity to review their interview transcripts. Two participants made use of this option. Thereafter, thematic analysis (*343*) was used for systematically identifying, organizing, and offering insight into, patterns of meaning (themes) across a dataset. All data were read thoroughly by two researchers (MI, ML) in the language of the interview, and thereafter coded openly with the support of the data analysis software *MAXQDA 12*. Data analysis included three sequential steps. First, a code system was developed based on thematic relations using both inductive and deductive reasoning. Second, major themes were identified and categorized independently by two researchers. Finally, emerging themes were analyzed and compared within the code system, and adaptations were made to increase logical consistency. Discrepancies in interpretation were discussed and revised at various phases until a consensus was reached among all members of the research team.

Results

Our analysis identified six main recurrent themes:

(I) IAT-use in response to current challenges in elderly and dementia care

(II) Personal experience and clinical implementation

(III) Expected benefits of IAT-use

(IV) Barriers to adoption of IAT

(V) Recommendations for designers and developers

(VI) The future of dementia and elderly care in the digital era.

Each of these core themes was further analyzed in detailed. An overview of themes and subthemes is presented in Table 8.

Themes	**I. IAT-use in response to current challenges in dementia and elderly care**	**II. Personal experience and clinical implementation**	**III. Expected benefits of IAT-use**	**IV. Barriers to adoption of IAT**	**V. Recommendations for designers and developers**	**VI. Future of DEC in the digital era**

Subtheme 1	Lack of resources: Technological Financial Human	Awareness	Improving QoC	Mismatch between patients' needs and IATs	Clinical validation	Holistic approaches- IAT in conjunction with: Pharma. therapy Early diagnosis Human care
Subtheme 2	Caregiver burden	Actual utilization of IATs	Reducing caregiver burden	Technical limitations	Technical requirements: Portability Reliability User-friendliness	Personalized care
Subtheme 3	Communication	Need for open-minded and evidence-based approaches	Improving communication and social interaction	Translational problems	User-centeredness	
Subtheme 4	AD diagnostics		Improving HRQoL of patients			

Tab. 8- Overview of interview themes and subthemes

IAT-use in response to current challenges in elderly and dementia care

Interviewees repeatedly discussed IATs in the context of current challenges in dementia and elderly care. In particular, they identified the lack of technological support, together with the scarcity of financial and human resources, as a major obstacle towards the successful delivery of elderly and dementia care services at their institutions. The lack of adequate technological equipment and digital infrastructures was perceived as a possible cause of sub-optimal care delivery jointly with the shortage of skilled healthcare workers, especially skilled nurses with specific training in the care of elderly people with dementia.

P15, Neurologist, Female, Italy: "In our hospital we don't have much technological support. Often it happens that a patient wanders away and this creates problems, even though there are guardians. But it still happens that patients wander away."

P4, Psychiatrist, Male, Switzerland: "The main problem, in my view, is the lack of trained healthcare professionals, and financially viable… and, of course, also of (technological) instruments, individual devices… of course… we are better off but this is a big problem in nursing homes and other institutions… we receive more and more questions about this."

IATs were also presented in relation to the problem of limited therapeutic opportunities for various forms of dementia, especially AD, and the rapid erosion of the caregiver-to-patient ratio.

Caregiver burden among formal caregivers was perceived as a major source of problem at the interviewees' institutions.

P3, Nursing Home Manager, Female, Switzerland: "Yes, they (caregivers) are always overburdened. So, we always have to check that they are still here, that they don't get sick."

In light of unmet expectations with pharmacological therapy and in view of caregiver shortage and budget limitations at healthcare institutions, interviewees hypothesized that IAT support could mitigate the burden of disease and its associated financial problems before adequate therapeutic solutions are developed. The increasing need for skilled caregivers and persistent budget limitations at care institutions appeared hardly reconcilable unless smart technology-mediated solutions are deployed.

P6, GP, Male, Switzerland: "I think that in the future (IATs) are the only way to overcome the dilemma between the lack of caregivers and the lack of money. "

Some interviewees identified a special challenge in their communication with patients with dementia, which was thought to be an important component of the doctor-patient relationship. Consequently, strategies that could facilitate or improve communication between patients and health professionals were perceived of primary importance.

P7, Geriatrician, Female, Switzerland: "This is the greatest challenge: approaching patients and communicating with them".

Finally, in the specific context of AD, interviewees addressed the problem of late diagnosis and the lack of adequate tools and strategies for the early and accurate diagnosis of the disease. In this respect, health professionals expressed hopes that advances in personalized mHealth such as wearable health monitoring or portable brain and eye imaging could lead to better diagnostic outcomes, especially in the form of self-assessment.

P2, Neuropsychologist, Male, Switzerland: „The big challenge, I think, is that we should become able to tell what it is as early as possible and as reliably as possible. [...] We should get to a point where we can develop various examinations that patients can perform autonomously because the features of the device are so easy to grasp that they become self-explanatory."

Personal experience and practical implementation

Reference to personal experience in relation to the clinical utilization of IATs was a common thematic pattern. Our findings show that most health professionals were aware of the existence and clinical availability of various types of IATs for elderly and dementia care including ambient assisted living technologies (AALs), personal care robots, handheld devices and activity trackers.

P8, Geriatrician, Female, Switzerland: "I know many GPS systems, alarm systems, and all these types of wearables, and then I know these intelligent beds (...) and security systems, sensors…"

P13, Gerontologist, Male, Germany: "We have been working on projects involving assistive devices, smartphone based, and glasses… smart glasses for people with mild cognitive impairment"

P16, Psychiatrist, Female, Italy: *"Yes, I've heard about these (social robots)"*

However, only less than one third of them reported having actually used such technologies at their institutions to enhance care. Concurrently, interactions between health professionals and technology producers appeared rare, with less than one in four healthcare professionals reporting active interactions with designers, developers or marketers of assistive technologies for clinical purposes even though such interaction was often perceived as necessary to enable clinical translation.

P15, Neurologist, Female, Italy: "No, nobody ever came here to show or propose some products to us… maybe because we are just ambulant clinics… but at regional level either… nothing."

P14, Psychiatrist, Female, Germany: "Having a look at what's technologically possible. And in the help-desk kind of study, clinicians would not refer to that, they would not feel like "oh let's have a look at what is available nowadays"... clinicians wouldn't do that. So it really has to be presented to them. There are some people who are more interested and they, on conferences for example, would go to stands and see what's new... but most clinicians wouldn't. So if it's not presented to them, they wouldn't get in touch with it."

Results show that interviewees had mixed but mostly positive views about the use of IATs in elderly and dementia care. Such positive attitudes were often associated with the idea that the assessment of new medical technologies should require open-minded attitudes to technological novelty and evidence-based approaches to technology evaluation. Most interviewees argued that prejudices against technological innovation could harm medical progress and delay the delivery of better healthcare services for patients. At the same time, interviewees felt that the efficacy of technology-mediated interventions should be carefully assessed and that the risks of hype or unintended effects should be prevented. As multiple interviewees reported:

P5, Psychiatrist, Male, Switzerland: "Of course, you need to have a critical mindset but you shouldn't be anti-technology. I think there is a lot of hostility towards new technologies, I was affected by it myself. When I first saw this robot seal I said: "please, spare me this crap!" but then I realized this was a stupid attitude. You shouldn't be hostile. You should first try and then judge ".

P6, Neuropsychologist, Female, Switzerland: "I don't have anything against them (IATs). I think they are a 'must' in the future."

P17, Psychiatrist, Male, Italy: "I am absolutely in favor of any therapeutic-technological device that can benefit the patient. Our hospital is full, completely full of geriatric patients, so are the emergency wards, so any tool that can help prevent hospitalization would be good."

<u>Expected benefits of IATs</u>

Positive attitudes towards IATs were largely dependent on optimistic expectations regarding the potential of these technologies to improve care delivery and ultimately benefit elderly patients. These attitudes appeared associated with recurring subthemes:

First, improving the Quality of Care (QoC) was perceived has a major opportunity enabled by IATs as these technologies were perceived as able to gather more and better information about patients, hence deliver more personalized care solutions;

P10, Psychiatrist, Male, Switzerland: "I think the environment and the type of dementia care… an individualized care closely dependent on the stage of the disease and as adapted as possible to the personal needs (of the user)…"

Second, participants expected that IATs will reduce the burden on formal and informal caregivers, which was often reported by interviewees as a major challenge in current dementia and elderly care;

P4, Psychiatrist, Male, Switzerland: "I see these technologies especially useful among patients with advanced dementia as a relief for caregivers… as they can undertake certain mechanical functions…"

P14, Psychiatrist, Female, Germany: "I think where I see a potential is in assistive functions, so apps that can, for example, monitor motivation and the general psychological condition of relatives, support it and maybe even automates first aids or starts a conversation"

P6, Neuropsychologist, Female, Switzerland: "Of course they can reduce the burden on caregivers if they are adequately implemented"

Besides caregivers, elderly patients with dementia were also considered primary beneficiaries of the clinical application of IATs. In fact, participants perceived that IATs have the potential to improving the health-related quality of life (HRQoL) of patients and increase their safety and security;
P10, Psychiatrist, Male, Switzerland: "Through technology you can obtain targeted alleviation of burden and workload or, under certain circumstances, increase the safety of patients, or in other circumstances… where you can transfer care tasks to technology."

P14, Psychiatrist, Female, Germany: "I think the issue of safety/security is the one that is best addressed through IATs"

P15, Neurologist, Female, Italy:" I think that the priority is to care about the safety of people. Precisely because care is so hard, so hard. So I would welcome those (IATs)"

Fourth, IATs were perceived as enablers of novel opportunities for patient-caregiver communication, hence capable of digitally enhancing the patient-health professional and patient-relative relationships. This possibility appeared particularly useful in the context of multilingual communities.

P14, Psychiatrist, Female, Germany: "I have tested tracking devices and telephone hotlines and I had a positive experience with them. Even though the devices sometimes weren't so good, but my impression was that the care workers were well sensitized. Of course, there are always *barriers with such media tools. But if I have somebody over the phone and through such devices… when a relative asks for support, in such circumstances having the chance to rely on devices that can process information, or navigate… videoconferences, videochats, videos that can give me an understanding of the situation, or that you can have a consultation with…"*

P6, Neuropsychologist, Female, Switzerland: "In Switzerland we have so many foreign care workers and they are not able to converse with patients with dementia in their native language. So, I would envision conversational robots that can say something or translate sentences."

Finally, IATs were expected to maintain or even improve the social relations of patients. This expected benefit was often perceived in conjunction with the capacity of these technologies to reduce loneliness and social isolation;

P16, Psychiatrist, Male, Italy: "It could be a success. Because robots can talk, relate, interact, so patients maybe don't feel lonely… maybe patients, from this point of view, don't feel abandoned. Especially because these patients are very fragile. Every small thing can (help). It may sound silly but I have experienced many times that some patients have pets and that these pets can make them feel much better. So, this can improve their quality of life."

Barriers to adoption of IATs

Barriers to adoption from the perspective of health professionals appeared strongly associated with both (i) current limitations in the design, development clinical implementation of IATs, and (ii) perceived collateral risks and obstacles in the translation of research results into the clinics. Three subthemes could be identified:

Frist, low technology acceptance among elderly patients was often attributed to a mismatch between patients' needs or abilities and design characteristics of currently available products. According to the interviewees, the specific cognitive and physical limitations of elderly adults, especially those of people with AD, are not adequately addressed by current IATs, resulting in a number of usage-related difficulties from the perspective of patients. These difficulties included: low familiarity among older users with advanced computing technology, the problem of adapting to unintuitive interfaces, excessive cognitive workload required by the IAT during everyday use, long training times required or the presence of visible features that can lead to social stigma;

P13, Gerontologist, Female, Germany: "These are people that no longer use any technology in *their daily life, except for a light switch…very few can use a coffee machine, so it's very difficult to approach..."*

P11,Nurse, Male, Germany : "Sometimes you have one button and many lights, and that makes it difficult even for a technology-savvy man like me to unambiguously understand which lights correspond to which alarm or what kind of signal…"

P1, Neuropsychologist, Male, Switzerland: "Programming a reminder is way too complicated… the cognitive impairments of these patients do not allow them to do that… so patients can't benefit from it (app-based cognitive assistant)."

P12, Gerontologist, Female, Germany: "Ahm… acceptance is influenced by… you know, products are too big, or not adapted to their target population, or too clunky, or not enough unobtrusive and not enough user-friendly."

P11, Nurse, Male, Germany: "I think that many technologies, as they are today, are still made in a manner that can generate visual stigma."

Second, technical limitations and low efficacy of certain IATs were also widely reported. Interviewees identified technical challenges in the IATs they used at their institutions. These challenges included poor quality of hardware and software, unoptimized interfaces, low reliability, low accuracy and others. These issues were perceived to negatively affect the utilizability of these technologies among end-users and even jeopardize the entire IAT market. In fact, the presence in the IAT market of numerous poorly designed, clinically ineffective and insufficiently validated devices was often presented as a risk factor that could harm the reputation and credibility of the entire market.

P12, Gerontologist, F- Germany: "In most cases we're talking about devices that are not so valuable. The specifications and materials are awful."

P6, Neuropsychologist, F- Switzerland: "Once you have a negative image, this will negatively affect the future production of truly helpful robots"

P1, Neuropsychologist, M- Switzerland: "A really, truly helpful assistive technology… I've experienced that rarely…"

Besides technical considerations, critical problems in the successful translation of research prototypes from the designing labs to the clinical setting were identified. These translational problems included a knowledge gap between technology producers and clinicians due to insufficient interaction among these stake-holders groups, lack of time or absence of mediators that can enable information transfer across these groups, and difficulties associated with interdisciplinary collaborations between engineers and clinicians;

P14, Psychiatrist, Female, Germany: "There was only once a research project... proposed... but it was really difficult to imagine how that could, in the very end, translate into clinical relevance so we didn't follow up on that."

P13, Gerontologist, Male, Germany: "I have experienced this myself with security sensorics that worked very well theoretically, still worked well in the lab but then in reality didn't work properly anymore."

P11, Nurse, Male, Germany: „There are language barriers between medicine and engineering."

P11, Nurse, Male, Germany: „This is of course a big problem. How can a clinic, how can a health professional, how can patient associations transfer knowledge to the engineers that are responsible for creating a new device?

P8, Geriatrician, Male, Switzerland: "I can't meet with all (IAT) companies. I just don't have the time!"

These considerations led many interviewees to advocate the creation of intermediary platforms that could bridge the gap and facilitate information transfer across relevant stakeholders.

P9, Psychiatrist, Male, Switzerland: "People in the clinics have just a general idea of what can be done, but very few ideas, not so much understanding of what that technologically means. I am sure that a mediation (between clinicians and tech-producers) is very important."

Recommendations for IATs producers

Based on their clinical experience, interviewees provided recommendations for IAT producers on how to adapt technological designs and development strategies to their clinical needs with the purpose of increasing clinical effectiveness and acceptance among end-users. One major subtheme in this respect was clinical validation. Most interviewees argued that a cause of reluctance towards the introduction of IATs in their clinical praxis was the insufficient clinical validation of current products and the lack of sufficient and generalizable data about their safety and effectiveness.

P10, Psychiatrist, Male, Switzerland: "So I looked into the studies and saw that the evidence is very poor. (…) There are studies that say „it works" and others that say "it doesn't work". But evidence is currently small. Until there is a lack of evidence any discussion with industrial partners is difficult".

Concurrently, interviewees argued that study results in design labs and other experimental settings should be complemented with studies in real-world scenarios:

P12, Gerontologist, Female, Germany: "You should definitely get out from the lab and back into reality! There should be more every-day studies… there is certainly not enough."

This recommendation appeared strongly linked with the theme of persistent translational barriers as interviewees reported the difficulty of replicating in the field research results previously obtained in controlled laboratory settings:

P13, Gerontologist, Male, Germany: "I have experienced this myself with security sensorics that worked very well theoretically, still worked well in the lab but then in reality didn't work properly anymore."

Other interviewees, however, proposed to distinguish minimally invasive IATs such as activity trackers and monitoring technologies from other devices and argued that the former might be entitled to faster clinical validation given their low invasiveness and risk. In such circumstance, a conflict appeared between the physician's need for clinical validation and the need for accelerating the development of new products for the benefit of patients.

P14, Psychiatrist, Female, Germany: "Actually with devices that only show that they are (...) helpful and they are not invasive, I wouldn't mind too much about it going quicker to the market. Because that's the thing: in this field the consumer will then very easily show if a product is *good or not by using it, buying it, or especially using them or not. So I would not insist on a big dataset beforehand".*

Frequently associated with the theme of clinical validation was the problem of identifying "signal-from-noise" in the IAT market. Interviewees largely shared the view that it is hard for them to detect truly effective tools in the large and ever-evolving IAT market, hence recommended to divert more efforts from the design of new prototypes to the clinical implementation of existing ones.

P12, Gerontologist, Female, Germany: "The money shouldn't be invested for even more new hyperhigh prototypes, in contrast we should place more research funds in the implementation."

In order to increase technology acceptance among end-users, interviewees recommended ameliorating the technical specifications of current IATs and prioritizing the principles of reliability, portability and user-friendliness. Reliable functioning was perceived as a necessary requirement to guarantee that users can trust and safely rely on and their assistive tools in their daily activities.

P14, Psychiatrist, Female, Germany: "Reliability is key. So this is an experience we made with GPS systems: very frequently they are just not working. And that's not helpful for the patients or the caregivers if the devices frequently have issues with the battery or no signal or something like that. That leads to frustration and then they don't use it at all. So reliability is very important."

The importance of portability (i.e. the ability to be easily carried, worn or moved) was associated with the problem of forgetfulness, which is particularly prominent among elderly people with AD and other dementias.

P14, Psychiatrist, Female, Germany: "So it would be a device that can be carried on the body, and would not have to be remembered to take with you. So, it can be a watch on the wrist or around your neck. So probably it would be a good kind of device for cognitive assistance."

Virtually all interviewees highlighted the importance of user-friendly, cognitively easy and behaviorally effortless interfaces to increase acceptance and efficacy among end-users. This theme appeared strongly linked with consideration of unintuitive and cognitively demanding interfaces as a major barrier to adoption and acceptance among elderly users.

P14, Psychiatrist, Female, Germany:" One thing that's really important is that the device should not have too many buttons or too many functions because patients wouldn't be able to use them anyway in most cases and it would be confusing for them. So where there is like one button to record something and one button to play probably it would be the easiest way and most likely to be used then."

Finally, a general consensus could be identified among interviewees regarding the importance of pursuing user-centered approaches to technology design. In addition to patient-centered approaches, inclusive approaches favoring the involvement of caregivers were also positively evaluated.

P10, Psychiatrist, Male, Switzerland: "It's absolutely important that engineers closely work together with clinicians as well as patients and their relatives, and that these can tell engineers what dementia is and what the needs of these patients are."

P4, Psychiatrist, Male, Switzerland: "It's not sufficient to simply involve patients in the process. You also have to involve their caregivers, relatives etc…. because sometimes their needs might be different".

The future of elderly and dementia care in the digital era

A significant subset of coded themes was associated with views, expectations and predictions about the future of elderly and dementia care in the digital era. Interviewees expected that with advances in robotics and the progressive digitalization and automation of healthcare, IATs will become increasingly ubiquitous.

P7, GP, Male, Germany: „I cannot foresee if in 20 years robots will be regularly utilized, but I'm very confident that they will."

However, all interviewees agreed that IATs should integrate and complement human-delivered care but not replace it altogether.

P3, Nuring Home Manager, Female, Switzerland: "Technology is an added value, a support, but I don't think that it can replace human care."

P4, Psychiatrist, Male, Switzerland: "I think that these instruments should remain assistive tools and shouldn't replace medical examinations, diagnoses or therapies. I find this a risky trend: if doctor-patient contact is abolished and everything runs via apps… I think this is *dangerous…"*

This consensus about the integrative but not substitutive nature of technology-mediated care was often associated with the idea that assistive robots and other IATs cannot adequately support the social dimension of the patient-caregiver dynamic and replicate eminently human abilities such as empathy, companionship and human contact.

P5, Psychiatrist, Male, Switzerland: "This (IAT) is a support but if it ends up replacing human care entirely then we will be deprived of this… human contact, humanity… this empathy and emotional exchange."

Interviewees indicated IATs as one of the strategies that should be pursued to tackle "the grand challenge" of global aging and dementia. Additionally, they called for holistic approaches consisting of coordinated strategies including prevention, early diagnosis, better pharmacological therapies, personalized care and IATs.

P16, Psychiatrist, Male, Italy: "Raising awareness and investing more resources and funds for the establishment of interdisciplinary teams that can support the patient not only clinically but also socially."

From their perspective, various parallel approaches will be required to mitigate the global burden of population aging and dementia and IATs are likely to become part of a multi-strategic roadmap for dementia and elderly care in the upcoming decades.

Limitations

This study has several limitations. While the use of a qualitative method allowed exploring a multifaceted topic in depth, such qualitative design prevents representative and generalizable conclusions. The study sample may not have represented the full range of experts' views from the field of dementia and elderly care in the three target countries, since it was limited in regards to sample size, recruitment strategy as well as geographical and cultural variation. However, since the interviewees came from three countries characterized by large proportions of psychogeriatric population and worked at internationally renowned healthcare institutions with direct experience with gerontechnology development and testing, we believe that their views and perspectives provided valuable insights on IAT use in light of current trends in population aging.

In addition, there may be selection biases due to the recruitment process. In order to provide participants with adequate information, a brief summary of the project description was included in the invitation email (see methods section). This could have stimulated participants to reflect on the topic before the actual interview. Despite these limitations, the obtained findings show a variety of well-differentiated attitudes which add significant knowledge about how health professionals' and researchers' attitudes towards IATs for elderly and dementia care. Further research is required to provide (i) quantitative data on health professionals' awareness, views and attitudes regarding IATs, (ii) qualitative insights from different cultural settings, and (iii) a more detailed assessment of the ethical issues at stake from a clinical perspective.

Discussion

Awareness, clinical utilization and translational issues

Participants appeared very aware of current trends in IAT and gerontechnology. However, the small number (less than one third) of experts who reported having actually used IATs in the clinical setting denotes insufficient transfer at the cross-section between technology development and clinical implementation. This is confirmed by the recurrent report of unresolved challenges in the translation of prototypes into clinically viable products. In contrast, the general open-mindedness and positive attitude about IATs of interviewees seems to challenge the elsewhere reported hypothesis (*344*) that lower-than-expected adoption might be caused by conservative attitudes towards technology among stakeholders.

This insufficient information transfer seems to be confirmed by the fact that interactions between health professionals and technology producers are reportedly rare, with only few interviewees reporting active interactions with designers, developers or marketers of assistive technologies for clinical purposes. Interviewees indicated as possible causes of such missing interaction the lack of time and interest of health professionals (especially physicians) in engaging with IAT producers, and the absence of mediators that can enable information transfer across these groups. Based on this evidence, increasing investments and strengthening efforts for the adequate implementation of IATs, as many interviewees suggested, seem to be an urgent priority. To facilitate such implementation, there is a need for creating new intermediary and consulting services at the cross-section between the lab and the clinics. While all interviewees acknowledged such need, and called for the creation of intermediary and consulting services, there was disagreement and uncertainty about which stakeholders should be responsible for such intermediation.

Strictly linked to the problem of insufficient transfer at the cross-section between technology development and clinical use is the frequently reported presence of unresolved problems in the translation of research prototypes into viable clinical tools. Translation is a fundamental mechanism for leveraging the benefits of IATs for dementia (*345*). In light of our findings, three main translational challenges need to be addressed. First, producers should improve the technical reliability of their products in order to provide health professionals with more reliable tools. Second, the clinical validity of current IATs needs to be increased through larger and better designed studies, especially studies involving (i) larger population samples of (ii) elderly adults with specific forms/stages of cognitive impairment (iii) in real-world settings (e.g. homecare). As hypothesized in previous studies (*2, 210*), our results show that technical reliability and clinical validity are predictors of trust in IAT among health professionals, hence might positively influence final adoption into clinical practice. Large-scale randomized control trials were often perceived as a privileged method of clinical validation. Furthermore, our results support the claim by Kearns et al. (2016) that proof of concept studies in gerontechnology are useful but not sufficient (*346*).

Promises and challenges

Overall our findings seem to identify a positive match, from the health professionals' perspective, between the perceived challenges in elderly and dementia care and the perceived capacity of IATs to address such challenges. In fact, our findings show that assistive technologies that can (i) alleviate caregiving burden, (ii) provide new tools for self-assessment and early diagnosis, (iii) optimize financial expenditures by providing more targeted and cost-effective interventions, (iv) facilitate doctor-patient communication and (v) supply for the imminent shortage of human caregivers, are perceived by health professionals as capable to fulfill the major challenges in elderly and dementia care.

At the same time, however, results indicate a general wish to inscribe IATs into a broader and multi-strategic roadmap for tackling the grand challenge of population aging and dementia. Our findings show a strong consensus that IATs should not replace human care, diagnostics and therapy but complement these human activities by providing mechanical and informational support for the benefit of patients and their caregivers. Particularly, interviewees hypothesized the impossibility of replicating via IATs (e.g. care robots) putatively human aspects of care such as empathy, human contact and emotional intelligence. While it remains an open empirical question whether advances in emotional intelligence can achieve such human-like features (*347*), our findings suggest that preserving (aspects of) human care will increase the likelihood of IAT-interventions to be accepted by health professionals. Concurrently, our results indicate a need for harmonizing efforts in IAT development and implementation with other long-term strategies for enhancing elderly and dementia care, including prevention, pharmacological therapy, diagnosis and end-of-life support.

Validation and Assessment

The open and positive attitude of interviewees towards IATs denotes an incentive for future technological development in this field. These results confirm previous findings corroborating the positive potential of IATs for improving elderly and dementia care (*67*). However, our interviewees recommended that the focus in IAT-research should be shifted from the development of new prototypes to their validation and successful implementation. This is consistent with recent review results (*6*) showing that the IAT market is rapidly expanding in size and variety but is still affected by inadequate clinical validation, slow implementation and outdated models of technology design. Our findings indicate a need for supporting physicians in the process of filtering signal from noise in the IAT market, that is identifying safe, clinically effective, adequately validated and socially beneficial devices and distinguishing them from devices that do not meet these requirements. While consumer preferences and market dynamics could, on the long term, enable such filtering process, proactive designs and calibrated regulatory interventions could help accelerate and maximize the benefits of IATs in the short-to-medium term. In addition, even though there is general agreement that "adequate implementation" is pivotal (see P6), it remains open what kind of implementation qualifies as "adequate", i.e. which criteria and methods are required. It is worth observing that calibrated regulatory interventions and adequate implementation strategies can contribute not only to accurately identifying safe and effective products within the chaotic IAT domain, but also, and most importantly, to accelerate responsible innovation and the sharing of clinical benefits among psychogeriatric patients.

User-centered design

To this respect, our findings confirm health professionals' preference for user-centered approaches to technology design and indicate room for cross-disciplinary collaboration among designers, developers and healthcare professionals with the aim of involving end-users in the process and better adapting future products to their specific needs. Since review results show the almost half IATs for dementia and elderly care are developed in absence of user-centered approaches to product design (*6*), more efforts are needed to roots such approaches in technology development. In addition, interviewees often associated the lack of user-centered approaches with higher risk of technical limitations such as unintuitive, demanding or inflexible interfaces, which were identified as major barriers towards adoption. Consequently, a shift to user-centered approaches has the potential to initiate a virtuous circle where the early involvement of end-users in the design phase results in better products that obtain higher adoption rates among end-users, hence creating an incentive for companies to pursue user-centered approaches.

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Module 3

*2.5. - Cognitive Technology and Human-Machine Interaction: The Contribution of Externalism to the Theoretical Foundations of Machine and Cyborg Ethics**

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Abstract

Machine ethics is the branch of ethics concerned with the behavior of artificially intelligent systems. Cyborg ethics is the related field of investigation concerned with the ethics of human-machine hybrid systems. While these areas of ethical investigation are experiencing rapid growth urged by disruptive advances in artificial intelligence, robotics and human-machine interaction, yet their theoretical foundations continue to elude consensus among researchers. In fact, most attention in machine and cyborg ethics has been devoted to normative and applied ethical questions concerning the moral status of artificially intelligent systems, the moral permissibility of their application in specific contexts, and the normative principles governing the interaction between artificially intelligent systems and humans. While cyborg ethicists have discussed the ethical implications of integrating man and machines, machine ethicists have long debated on whether artificially intelligent systems have the cognitive capacities necessary for the attribution of moral status. It remains unexplored, however, what theory of cognition is best placed to explain and assess these cognitive capacities or competent

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actions, especially in relation to human-machine interaction. This contribution aims at harmonizing the theoretical foundations of, respectively, machine and cyborg ethics and argues that an externalist account of cognition based on the notion of extended mind might offer a valid substrate for such harmonization.

Cognition and the Problem of Moral Status

Machine ethics is the branch of ethics concerned with the behavior of artificially intelligent systems. A basic problem in machine ethics is determining which artificially intelligent systems possess the cognitive capacities necessary for attributing moral status and moral responsibility. The answer to this problem is strictly dependent on another problem, often addressed in cognitive psychology and theoretical artificial intelligence, namely that of determining which mechanism realizes cognition in living organisms and artificial systems. In fact, in order to determine which systems possess capacity X (where X = cognitive capacity necessary and sufficient for the attribution of moral status and moral responsibility), we first need to explain what X is. In accordance with the requirements of modern science, this explanation should ideally be in functionalistic and mechanistic form.

The default position in neuroscience is that cognitive processes in living organisms are largely implemented by the brain. The reason for that stems from the fact that the brain functions, in all vertebrate and most invertebrate animals, as the center of the nervous system, where center is meant in two ways. First, the brain is the functional center of information processing, which continuously receives sensory information in input, and then, after rapidly analyzing this information, responds by producing outputs which serve to control virtually all bodily actions and functions. Second, the brain is the necessary component of the nervous system, in absence of which no computation-like information processing connecting from sensory inputs would take place. Given these two characteristics, the analogous of the brain in artificial intelligent systems is often described as a central processing unit (CPU) in a serial processing digital computer.

This idea is well rooted in the observation that the brain of humans is a particularly complex organ. Although it has the same general structure as the brains of other mammals (*348*), it is over three times as large as the brain of a typical mammal with an equivalent body size. It has been estimated to contain 50–100 billion (10^{11}) neurons (*349*), of which about 10 billion (10^{10}) are cortical pyramidal cells (*350*). Most of the expansion of the human brain with respect to the brain of other mammals comes from the cerebral cortex, a convoluted layer of neural tissue that covers the surface of the forebrain, which plays a key role in putatively cognitive processes such as thinking, reasoning, memory, attention, consciousness, language and perception.

These cortex-enabled capacities are usually considered by ethicists as co-determinants of moral status. Therefore, the possession of such cognitive capacities among artificially intelligent systems would justify the attribution of moral status to these artifacts. For example, according to Kant, only beings with the capacity for practical rationality have moral standing (Kant 1788). In a similar fashion, Bentham (1823) proposed sentience as a discriminant of morality. Other intellectual capacities that have been proposed as grounding full moral status include intentionality (*149*), self-awareness , and future-oriented planning (*351*).

For a theoretically well-founded machine and cyborg ethics, however, it is not sufficient to know what cognitive capacities are associated with moral status. Another foundational question is determining how these cognitive capacities can be realized in humans, machines and interactive human-machine systems. Consequently, developing a consistent theory of how cognition can be realized should cast light on how morality-enabling cognitive capacities can or should be realized in, respectively, humans, machines and interactive human-machine systems. Additionally, addressing the question about the realization of cognitive capacities would provide a more solid metaethical foundation to machine and cyborg ethics. Developing a theory of how morality-enabling cognitive capacities are realized at the functional level would cast light on what cognition means in relation to functions or processes that enable (the attribution of) moral properties.

Internalism vs Externalism

According to a position in cognitive science which obtained significant success in the '70s and 80s, the relation between the brain and the cognitive processes it implements basically resembles the relation between computer hardware and system software: the brain, on the one hand, is hardware, i.e. the physical part of the computer; the mind, on the other hand, is software, i.e. a set of programs and related data installed in the hardware in order to provide instructions for the hardware to accomplish tasks (Block 1995)[30].

[30] In recent times, the brain-computer metaphor has become increasingly controversial as many authors have criticized this analogy based on anti-representational approaches to cognitive science. See, among others, Epstein (2016).

The traditional view regarding the role of external (e.g. bodily or ecological) factors in cognitive processes admits that these factors play a causal role in determining which input patterns will be processed by the nervous system, in particular by the brain, through a finite number of internally defined successive states and manipulated to produce an output. However, this view does not attribute to environmental factors any constitutive role in the information processing itself. According to the traditional view, indeed, cognitive processing in biological organisms corresponds to information processing in the form of electrochemical signaling within the neural circuits of the nervous system.

In the past 20 years, findings in findings in cognitive psychology (*352*), biolinguistics , artificial intelligence (*353*) and philosophy of mind (*125*) that the functioning of cognition might intimately depend on external (e.g. bodily and environmental) resources. In particular, these findings have led some cognitive scientists to formulate two related (even though not self-implicating) hypotheses: (i) that cognitive processes in humans, non-human animals, AI systems and cyborgs (defined as human-machine integrated systems) might be actively influenced by external (e.g. bodily and environmental) factors (an hypothesis known as 'embedded cognition'), and (ii) that cognitive processes might partly capitalize on (indeed, be partly constituted by) information being stored and elaborated in natural or artificial representational systems located outside the organism or artificial system (an hypothesis known as 'extended mind'). These findings, as well as their conceptual implications, have questioned the default brain-centered paradigm of neuroscience according to which cognition is computation-like information processing which is exclusively realized inside the brain.

In this contribution, I will describe this externalist account of cognition by presenting its major theoretical components: embodied cognition, ecological cognition, distributed cognition and situated artificial intelligence. Subsequently, I will argue that this family of externalist approaches might offer a viable contribution to the theoretical foundations of machine and cyborg ethics in the era of human-machine interaction.

Forms of Externalism

Embodied Cognition

Embodied cognition is the view according to which “cognition is deeply dependent upon features of the physical body of an agent, that is, when aspects of the agent's body beyond the brain play a significant causal or physically constitutive role in cognitive processing” (*354*).

For example, findings in the cognitive psychology of perception (*355*) have shown that internal bodily states affect distant perception. Participants were randomly assigned by the researchers to three groups: high-choice (or freedom of choice), low- choice (experimenter choice), and control conditions. They were also asked to walk across a certain area. At the conclusion of the experiment, each participant was asked to estimate the distance she walked. The results showed that the high-choice participants perceived the distance walked as significantly shorter than participants in the low-choice and control groups, even though they walked the same distance. These results show the ability of internal states to influence perception of physical distance moved. This illustrates the reciprocal relationship of the body and mind in cognitive processing. Similarly, findings in the cognitive psychology of vision (*356*) have shown that bodily orientation can affect information processing in visual search, thus supporting the view that vision is often action-guiding, and bodily movement and the feedback it generates are more tightly integrated into at least some visual processing than has been anticipated by traditional models of vision (*357*). Experimental findings in support of the causal role of bodily factors in cognitive processing have been reported with regard to many other cognitive processes, including memory (*358*), language (*359*), and moral cognition (*360*).

Such findings have also encouraged AI researchers to bring embodiment theory into Artificial Intelligence. The resulting approach is called Nouvelle AI. Whereas traditional AI (sometimes referred to with the acronym GOFAI, Good Old-Fashioned Artificial Intelligence) has by and large attempted to build disembodied intelligences whose only way of exhibiting human-like cognitive performances is to process symbolic information (regardless of the morphology of the robot that these processes are implemented by), Nouvelle AI attempts to build embodied artificial intelligences in which structural and morphological factors of the robot play a causal role in driving cognitive processes. To the representational and symbolic stance of traditional AI, which was ultimately aimed at simulating human general intelligence, nouvelle AI approaches oppose an embodied stance aimed at emulating the behavior of evolutionarily simpler organisms such as insects.

Ecological Cognition

Research in embodied cognition has shown that bodily factors external to the nervous system of a living organism can play a significant causal or physically constitutive role in cognitive processing. Therefore, this approach has extended the boundaries of cognition from the nervous system of a living organism to its entire body. The ecological cognition approach attempts to further expand the class of factors that are causally relevant for cognition as to include factors localized outside the organism, i.e. in the local environment where the organism lives and with which it interacts. According to this view, cognition is not exclusively realized by the brain but might, under certain conditions, emerge at the interplay between the brain, the rest of the body and the external environment. This view is succinctly captured by James Gibson's motto: "Ask not what's inside your head, but what your head's inside of" (*361*).

Distributed Cognition in Human-Machine Interaction

According to the distributed cognition approach, cognitive information-processing does not occur entirely within an individual cognizing organism but is distributed across a cognitive continuum involving the agent and the physical or social structures with which it interacts (*362*). This interaction chiefly occurs in symbolic form. Accordingly, a cognitive state, say a perceptual state, is a distributed state that includes the perceiving organism as well as elements in the perceiving organism's environment (*363*).

Distributed cognition has turned out to be a useful approach for analyzing social aspects of cognition (socially distributed cognition) as well as cognizing in the digital technology era. Cognizers in a digital environment tend to offload some of their cognitive functions onto cognitive technologies such as personal computers and the internet, thereby extending their performance capacity beyond the limits of their own brain power (*359*)[31]. A prime example of cognitive technology is search engine technology. Sparrow et al. (2011) have shown that if people rely on internet-stored information which they expect it would be accessible later in time, they were worse at remembering the actual trivia, but better at remembering *whether* it would be accessible (*364*). These results suggest that (i) processes of human memory adapt to the digital environment of computing and communication technology; and that (ii) external cognitive technologies do not merely determine instrumental and quantitative changes, but can rather have qualitative effects on how information is processed. In the light of the two considerations, proponents of the distributed cognition approach think that such types of phenomena are better understood by redesigning human cognition as not confined to the individual cognizing organism but distributed across the organism and its (digital and

[31] While Dror and Harnad’s research on cognitive technology emphasizes the causal role of external artifacts in cognitive processing, these authors surprisingly reject “extended” approaches to the ontology of the mind. See Dror and Harnad (2008, p. 2).

social) environment. In this context, distributed means that the operation of the cognitive system involves (i) various internal and external components and (ii) a functional coordination between these components.

Today, a number of cognitive technologies are available for supporting cognitive processing among people with cognitive disorders or disabilities. For examples, an increasing number of intelligent devices is being developed for providing external cognitive assistance (especially memory assistance in the form of adaptive prompts and reminders) to people with Alzheimer's disease and other dementias (*5*). Cognitive technologies do not include exclusively digital artifacts but brain-dependent cognitive faculties too. For instance, language itself is often understood as a form of cognitive technology that (I) allows cognizing organisms to offload some of their cognitive functions onto the brain of other cognizers (social environment), and (ii) extends organisms' individual and joint cognitive performances, distributing the load through interactive cognition (*363*).

Situated Artificial Intelligence

The role of external factors in driving cognitive processes has also been highlighted by recent research approaches in Artificial Intelligence (AI). For example, the situated approach in contemporary AI is aimed at designing artificial agents that are situated in a given environment and are capable of behaving successfully in it. The cognitive architecture of situated artificial systems is commonly referred to as a *'subsumption architecture'* (*365*). Whereas classical architectures for artificial systems rely on a central processing unit (CPU), i.e. an hardware unit that carries out the instructions of a program by processing the basic operations of the system through serial processing, subsumption architectures have multiple parallel computing elements, with no one unit considered the "center", and process the information by a distributed interconnected set of processors. Each processor is specified as a layer of networks of augmented *finite state machines* (*353*). Such architecture implies that the cognizing agent does not rely on an internal, symbolic description of the environment, but rather on a non-representational model of the interactions between the agent and its local environment. Simulating artificial agents in a natural or virtual environment requires AI loops, i.e. simulation technologies of the entire process that goes from perceiving an environmental stimulus to an action on the environment. The role of external factors in driving cognitive processes implemented by situated robots is twofold:

1. They causally affect the robot's sensory system without involving intermediate levels of representation, thus influencing the robot's internal information processing and behavior.

2. They can be manipulated or modified through the robot's behavior, for they are linked with the robot in a dynamic interaction loop.

The most significant characteristics of situated artificial systems as compared to classical AI are (i) a refined internal organization, in particular in terms of computational cheapness and information-processing speed; and (ii) a refined capacity of behaving and acting in a dynamic environment. Similar characteristics can be detected also in environment-dependent cognizing in living organisms. For instance, heuristic-based decision-making has turned out to be computationally less expensive and to produce faster and more accurate behavioral patterns than classic computational decision-making (*366*).

At the Origins of Cognitive Externalism: Evolutionary Hypotheses

Characteristics like optimization and output accuracy, have led authors such as Rowlands (2003), Clark (2002, 2008), and Gigerenzer (2007) to advance the hypothesis that embodied and ecological cognition are adaptations, i.e. phenotypical traits evolved by natural selection. Geary (2005) and Striedter (2005) have set a list of adaptive criteria that a certain cognitive faculty should meet in order to make its selection evolutionary predictable. These include, among others, optimization in system internal organization, optimization in input processes, and positive feedback on other system faculties.

Internal organization is central not only in the assessment of the evolutionary predictability of a cognitive process but also in the assessment of its functional organization. From an evolutionary perspective, both in the sense of evolutionary biology and evolutionary computation, the ability to extend some cognitive processes to the external environment might determine an optimization in our internal system organization in three important ways. First, it may produce a better metabolic equilibrium.

Cognitive systems are dissipative systems that get pushed into operation by harnessing energy from a variety of metabolic pathways. The human brain, in particular, is one of the most dissipating system of the biosphere, for it claims only 2% of our body mass, but is responsible for approximately 20% of our body oxygen consumption (*367*). For a cognitive system, therefore, energy must be constantly available for work (e.g. mechanical work) or for other processes (such as chemical synthesis and anabolic processes). However, energy is not always easily available for a system. Food, for instance, humans' best resource to assimilate some of the essential nutrients that our cells convert in energy, is often scant. For this reason, authors have argued that evolution might have favored those organisms capable to spark their life-maintaining processes with the lowest possible expenditure of chemical energy. According to a principle in bioenergetics, all living systems try to execute their biological processes with the smallest effort/profit ratio, namely to obtain the best possible outcome with the lowest possible energy expense (*368*). One possible way for the nervous system to reduce such effort/profit ratio might have been by transferring some processes from neurons or single processing units to external resources, as the latter do not draw on internal energy supplies.

Optimization of the internal organization does not operate exclusively at the biochemical level, but at the functional level too. In order for a system to be functionally optimized in evolutionary terms, and thus to have a high statistical probability of propagating itself to future generations, it must be able to (i) execute more functions than its unoptimized matching system; (ii) execute the functions of its unoptimized matching system more efficiently. In the case of environment-dependent cognition both conditions seem to be satisfied. In the first place, through extending to the external environment, the cognitive system might be able to execute more cognitive functions than if it were confined within the original boundaries. This functional advantage might not only pertain to couplings with sophisticated technologies, but also to simple artifacts and even to parts of the physical body too. For instance, McClelland (1989) and Clark (1989) observed that, thanks to the use of pen and paper, students can perform complex arithmetical and geometrical operations that they could not solve if they would only lean on internal resources (*369*).

The same goes for children counting fingers on their own hand (*370*). In addition, extended systems have sometimes been observed to be more efficient than non-extended ones, as they are able to process information faster and to produce more accurate outcomes. Kirsh & Maglio (1994), for example, calculated that the physical rotation of a shape in the computer game Tetris goes about three times faster than the mental rotation of the same shape, precisely 300 milliseconds of 1000 milliseconds to rotate the same shape through 90 (*371*). This reveals external processing to be, at least under some conditions, dramatically faster than internal processing. The same can be said, again, for mathematical operations. If one compares the performance of mathematical exercises both with and without a calculator (or pen and paper set), one would suddenly notice a dramatic difference in the time it takes to work them out.

In addition, leaning on external supports might not only increase the processing speed, but the outcome accuracy too. This phenomenon is particularly common among people with cognitive disorders, especially older adults with dementia. In fact, deficits in the accuracy of beliefs caused by insufficient internal cognitive resources have been observed in patients with Alzheimer’s disease and frontotemporal dementia (*372*). In these patients, memory reduction caused by loss of neurons and synapses in the cerebral cortex systematically leads to a deficit in belief accuracy. For example, a patient more prone to forget, say, the name of his daughter Amy, will also be more prone to have the false belief that his daughter's name is Laura.

The Extended Mind

Extended Mind (hereafter EM) is the thesis, first proposed by Clark & Chalmers (*125*), according to which the mind should not be limited to internal information-processing in the nervous system of cognizing organisms (or internal hardware of an artificial system) but extended to include some functionally isomorphic processes whose local position is outside the nervous system, and even the body of cognizing organisms, or internal hardware of an artificial system. More succinctly, EM is the view according to which the mind of a biological organism or artificial system may extend outside that organism or system.

From the perspective of EM, the only parameter that defines the components of a cognitive process is the act of playing a causal role in a cognitive network, regardless of whether these components are physically located inside or outside the organism or artificial system (*373*).

Not all external (bodily, technological and environment-dependent) processes count as mind-constituent. Rather, in order to be considered extensions of the mind, external processes must satisfy two basic conditions: (I) functional equivalence, and (II) reliability of coupling. Let us see what this means.

According to a basic principle of EM, called 'Parity Principle', if an external system performs a process functionally equivalent to a process that (i) could be executed by an internal cognitive system, and (ii) if executed by an internal cognitive system would be regarded as cognitive without doubt, then the external process should be regarded as cognitive as well. Therefore, according to this view, cognition is not bounded by the nervous system of the organism, but may extend into processes that are realized by systems physically located outside that organism. The boundary of the nervous system becomes thus arbitrary and explanatory vacuous in determining the boundary of the implementation medium of cognition, as cognition might be implemented by entities located outside the nervous system of the organism. As Clark and Chalmers (1998) famously put it:

„If, as we confront some task, a part of the world functions as a process which, were it done in the head, we would have no hesitation in recognizing as part of the cognitive process, than that part of the world is (so we claim) part of the cognitive process. Cognitive processes ain't (all) in the head!“ (*125*).

The reliability of coupling criterion introduces a further restriction to the EM cases. According to this criterion, not all external processes that are functionally equivalent to internal cognitive processes should be regarded as mind-constituent. Rather, functionally isomorphic processes are considered mind-constituent only if they couple with the internal cognitive processes that they are isomorphic to in a reliable way. Reliability is a complex property. In the EM debate, it is commonly thought to involve the following sub-properties: availability, portability and design.

Availability requires the external process to be coupled with the internal one in a manner that the external process can be easily and quickly accessed by the internal system. An example of an external process that meets this requirement is the use of smartphone technology, as these external resources provided by these handheld devices are usually constantly available to the cognizing human being during her every-day-life.

Portability requires the external process to be coupled with the internal one in a manner that is easily transferable in space and over time. An external process is said to be portable if it does not get decoupled when the internal system changes its local position in space nor when minor alterations affect the local environment itself. Sun-based communication in honey bees meets this requirement too, as the sun position continues to be coupled with the sun also when the bee changes its local position. A human-scale example is the use of wearable technology (e.g. smart watches), as these resources can be taken with the cognizing human beings who wear them in a more reliable and robust manner compared to other device types such as desktop computers. In fact, their portability is guaranteed even in case of macroscopic changes in the user’s local position or minor environmental changes (e.g. seasonal change or change in weather). It is worth considering that portability is not an all-or-nothing property but a continuum. For example, handheld devices are more portable than desktop computers, wearables are more portable than handheld devices and implants are more portable than wearables. The element of portability is particularly important for assistive technologies developed for people with memory impairments. In fact, these patients often forget to bring their devices with them, hence need devices that exhibit a high degree of frictionless portability.

To these two criteria, which are widely discussed in the literature, I add a third requirement, i.e. design. Design requires that the internal-external coupling is not random, but designed to execute the cognitive function that it actually executes. For instance, hardware and software interfaces are non-random in the strong sense that they are designed, built and programmed by technicians precisely to execute the function that they actually execute. Similarly, smartphone technologies are designed, built and programmed precisely to provide an accessible, portable and useful support to internal cognition in humans. Of course, in order to be designed, external objects do not necessarily need to be artifacts or manipulated objects, such as tools. Non-manipulated objects in the natural environment can be also regarded as cognitive extensions, as long as they are co-opted by the cognizing organism for the function they actually execute in the integrated cognitive loop. This cooptation is multiply realizable, as it does not necessarily involve the physical modification of the object, but simply a change of function. For instance, the sun is coopted by the honey bee as vehicle of meaning regarding the position of food resources. Similarly, a tree can be coopted by humans as an external memory support (e.g. as a path-tracker sign).

Some authors (*125, 126*) suggest a stronger criterion of design. According to this stronger criterion it is not sufficient that the external system is designed by the internal system to be coupled with it and execute the function it actually executes in the integrated cognitive loop. Rather, the internal system should also be designed to be coupled with external systems and integrate them in the cognitive loop. In other words, the dependence relation between the internal and the external system should not be unidirectional (from the internal to the external system) but bidirectional (form the internal to the external system and the other way round). This stronger criterion of design is self-evidently satisfied by artificial agents, such as situated intelligent robots. These agents do not simply redesign external objects in order to co-opt them for cognitive functions useful to the robot and couple them with the internal system, but they are themselves designed, built and programmed to couple with external objects and co-opt them for cognitive functions useful to the robot (*374*). According to Clark & Chalmers (*125*) and Rowlands (*126*) the strong criterion of design is satisfied by living organisms too. Based on the evolutionary explanations summarized in the previous section, these authors claim that the cognitive systems of living organisms are designed by (in the sense of 'selected for') natural selection to couple with external objects in the environment and co-opt them for cognitive functions useful to organism. This conjecture is logically linked to the empirical hypothesis of environment-involving processes to be adaptations. If this hypothesis turns out to be empirically correct, then cognizing living organisms satisfy the strong criterion of design too.

As we have seen, the reliability of coupling is a crucial criterion to provide EM with a valuable ontology of the mind. In the absence of it mind-attribution would be ubiquitous (*125*).

Extended Mind as a Theory of Human-Machine Interaction

EM is particularly appealing to describe the class of cognitive interactions between humans and technological devices, hence the behavior of human-machine integrated systems. One classic example that EM proponents usually refer to is the every-day use of smartphones and personal computers to store and retrieve or simply access information. For instance, consider the case of a market trader saving on her smart-phone's phone-book her customers' phone numbers, a child searching on a web dictionary the meaning of the word 'idiosyncrasy', a student using a calculator to do her math homework, a teen googling the lyrics of a song she can't recall, a teacher using an electronic calendar to memorize the course program, a tourist using geolocation to find her Hotel in Paris or a virtual translator to communicate with her French waiter. In all these cases, the internal cognitive system of the subject establishes an interaction with some external electronic devices that play an active causal role in driving a certain cognitive process - respectively, in the cases mentioned above: memory storage, recall, learning, calculation, spatial navigation, language. Moreover, in all these cases the process executed by the external device is functionally equivalent to a process, or at least a phase of a process, executed, or that could be executed, by an internal cognitive system such as the human nervous system. Finally, the coupling between the internal and the external system satisfies the condition of reliability, which is a critical requirement for the successful integration of human and machine. Other classical examples focus on the role of non-electronic technologies and cultural artifacts such as writing instruments, books, codes, etc.; and bodily components such as the hands when they are used to support mental calculation. From the point of view of EM, when people count along their fingers (process known as dactylonomy) there is no theoretical impediment to claim that this external calculation becomes part of a broader calculation process executed by the extended cognitive system composed by the nervous system and the hand. Similarly, when people use notebooks, books and encyclopedias to store or recall information, these external artifacts are regarded as processing units of an extended memory process (*364*).

One further privileged field of application of EM are clinical cases of impaired general or modular cognitive ability (*125*). Dementia patients, such as Alzheimer's disease or vascular dementia patients, tend to compensate for their loss of cognitive ability by using external resources. For example, Alzheimer's patients in the early and moderate stage of the disease, typically display cognitive inabilities such as inability to build new memories or to recall vocabulary (*375*). For this reason, they tend to note down the information that their brain is unable to store and recall it via external resources such as electronic devices or simple notebooks. Today, a broad spectrum of intelligent assistive technologies is available to provide and enhance such external cognitive assistance (*6*).

From the point of view of EM, these external tools get integrated by the cognizing subject in such a way that they literally become constitutive components of the cognitive system responsible for the execution of the cognitive task. In the case of tool-using Alzheimer's patients, therefore, cognitive processes such as forming new memories or recalling vocabulary are not exclusively realized by the nervous system, but extend into the external resources exploited by the patient. In fact, the way intelligent assistive devices and notebooks perform (stages of) the memory process in Alzheimer's patients is functionally equivalent to cognitive processes that, in normal subjects, are usually executed by the brain (*125*).

Externalism as a Framework for Cognitive Science and Artificial Intelligence

In virtue of its high level of generalization across the human-machine continuum, the various externalist approaches described in above, have been proposed as a new paradigm or theoretical framework for the cognitive sciences (*125, 126*). The reason for that stems from the fact that these approaches appear particularly suitable for integrating and making sense of the body of evidence in cognitive science and artificial intelligence regarding the role of external factors in cognition. In addition, they offer a suitable common ground for the many areas of cognitive science including cognitive neuroscience, cognitive psychology, AI, cognitive linguistics and philosophy of mind. As a broad theoretical framework, externalism encompasses a large constellation of theoretical and empirical perspectives, which all recognize the causal (and, in the case of EM, even constitutive) role of external resources in driving, supporting or enhancing the internal cognitive capacity of biological organisms.

From a theoretical point of view, externalism appears to unify virtually all approaches and perspectives to the study of cognition that do not underestimate the causal role of environmental factors in driving cognitive processes. In particular, externalism is thought to integrate the embodied cognition approach, as, according to EM, cognition (particularly cognition that leads to competent action in the world) is not confined within the brain but extends to components whose local position is outside the brain and even the entire nervous system of a cognizing organism. Since the embodied cognition approach assumes cognition not to be restricted to information-processing in the brain but to extend to bodily components such as the musculoskeletal system and the sensory- motor mechanisms that are external to the organism's nervous system, then embodied cognition is inherently externalist. More specifically, certain accounts of embodied cognition qualify as special instances of EM if such bodily factors are constitutively relevant to cognition.

In addition, externalism is able to integrate all approaches and perspectives that recognize the causal role of external factors in driving cognitive processes. In particular, externalism is able to integrate the embedded, the situated and the distributed approach to cognition. All these approaches assume cognition not to be restricted to information- processing within the cognizing organism but to extend to processes partially implemented by objects in the organism's local environment, or at least to emerge out of the interaction between the organism, the intelligent machine and their local environment.

Externalism as a Framework for Machine and Cyborg Ethics

While there is a growing consensus that various forms of externalism might offer a valuable framework for the cognitive sciences, it is less intuitive to see how externalist approaches might valuably contribute to strengthening the theoretical foundations of machine and cyborg ethics.

As we have previously stated, machine ethics is the branch of ethics concerned with the behavior of artificially intelligent systems. This discipline deals with problems such as determining the moral status of intelligent machines and designing machines that exhibit moral behavior. I argue that an externalist approach to cognition can provide a scientifically informed and philosophically innovative substrate for addressing these ethical questions. The reason for that stems from a twofold consideration.

First, while many authors recognize that cognitive faculties are critical for the attribution of moral status and moral responsibility (*149, 351*), yet the field of machine ethics lacks both (i) a uniform meta-ethical theory of what cognition is and (ii) a theoretical characterization of how cognition is realized in intelligent machines. I argue that the externalist framework is epistemologically well-equipped to fill these gaps in the foundations of machine ethics.

From an externalist perspective, cognition can be best understood as information processing that emerges out of the interplay between a cognizing agent (human or intelligent machine) and its physical, digital or social environment. This meta-ethical characterization is general enough to encompass both human and machine cognition, hence can harmonize the meta-ethical foundations of machines ethics with those of moral psychology and applied ethics. This also emphasizes how moral status is supervenient on the level of complexity of cognitive systems, i.e. it is a variable that can be gradually increased or decreased on a continuous scale based on the cognitive system's degree of complexity.

Additionally, since externalism admits that cognition is realizable through distributed systems consisting of various cognitive components (extended cognition), it provides a theory of realization that accounts not only for standalone intelligent agents but also for parallel and distributed systems. This characterization is particularly fruitful to frame the debate over the moral status and responsibility of emerging trends in computing and AI such as parallel and distributed computer systems (consisting of various networked and communicating components), distributed artificial intelligence and multi-agent systems (i.e. systems composed of multiple interacting intelligent agents within an environment). These types of intelligent machines, in fact, in virtue of their distributed organization, are not accounted for by meta-ethical theories that define cognition only in terms of mental representations implemented by an internal processor (e.g. the human brain or equivalent in silico).

Second, externalist approaches provide a fruitful and informative scientific substrate for designing and developing intelligent machines that exhibit moral behavior. While traditional approaches to the design of moral machines have primarily focus on producing moral behavior by intervening on the internal cognitive resources, externalism poses the accent on the interplay between the machine and its environment. This theoretical shift and expansion is particularly valuable to account for intelligent machines such as social and companionship robots as well conversational agents. In fact, in these types of machines, the ability to competently interact with the social, digital and physical environment is absolutely critical. This increased attention on the interactive and interpersonal dimension is particularly valuable for social and assistive robots used for assisting frail seniors or people with cognitive disabilities as these patients are often vulnerable individuals, hence ensuring the moral behavior of care robots in an interactive dynamics is a priority (*36*).

With regard to cyborg ethics, the epistemological advantage of shifting the focus on extended cognitive networks is even greater. The reason for that stems from the fact that cyborgs are, by definition, cognitive agents consisting of both organic and mechatronic components. Therefore, the field of cyborg ethics is highly in need of a theoretical foundation that can account for the entire bio-mechatronic continuum, without arbitrary restrictions in the attribution of moral status and responsibility based on the type of physical realization of cognition within each component. Externalist approaches to the theoretical foundations of cyborg ethics have the advantage of providing a solid and comprehensive foundation to the ethics of all human-machine integrated systems, regardless of the physical realization of their components. Instead of focusing on the hardware architecture of each part of the cyborg, they can provide a comprehensive framework that encompasses the entire human-machine continuum. This epistemological shift is particularly important to account for the increasing use of integrated assistive technologies among people with physical or psychological disabilities such as brain-computer interfaces and neural prosthetics. Additionally, it can account for emerging phenomena where the relevant cognitive processing occurs across a reliable coupling of human and machine (e.g. information search across the brain-smartphone continuum).

Additionally, at a more practical level, authors have noted that an externalist approach to the theoretical foundations of cyborg ethics can broaden our normative conception of harms to technological equipment and provide increased legal protection in the era of human-machine interaction (*376*). In their view, to the extent that externalist approaches are prioritized, intentional harm towards technological devices that have been appropriately integrated, should not be simply regarded as property damage, but as “extended personal assault” (ivi). In fact, the role played by these technologies within the extended cognitive process initiated by the user is such that their damage by malevolent third parties might qualify as personal assault. This normative advantage is particularly helpful to account for emerging dual-use risks in cognitive technology, such as malicious brain-hacking (*377*). With the pervasive diffusion of intelligent computing and its progressive integration into human life, ethics is increasingly required to provide a coherent normative ground to orient society across this historical transformation. Externalism is well positioned to accomplish this task and harmonize not only the theoretical foundations of, respectively, machine and cyborg ethics, but also the interoperability of these theoretical foundations as part of normative human-machine continuum. Authors have observed that technological innovation at the human-machine interface urges a new ethics of the post-human or “more-than-human” moral world (*378*). As the boundaries between humans and machines progressively blur, theories of cognition and moral status that rely on internalist, realization-specific accounts slowly become explanatory inadequate. In contrast, externalists approaches enable a shared and common grounding that accounts for all components and modes of realization of the human-machine entanglement.

Conclusions

Although machine and cyborg ethics are experiencing rapid growth ─urged by disruptive advances in artificial intelligence, robotics and human-machine interaction, yet their theoretical foundations remain undefined or even affected by conceptual muddles. In fact, most attention in machine and cyborg ethics has been devoted to normative and applied ethical questions concerning the moral status of artificially intelligent systems, the moral permissibility of their application in specific contexts, and the normative principles governing the interaction between artificially intelligent systems and humans. Machine ethicists have largely discussed whether artificially intelligent systems have the cognitive capacities necessary for the attribution of moral status as well as whether these systems are able to perform competent actions. However, it remains unclear what theory of cognition should better explain and assess these cognitive capacities or competent actions, especially in relation to human-machine interaction. This contribution has described an account of cognition in artificially intelligent systems and living beings from an externalist perspective.

Given its capacity to explain cognition across the entire human-machine continuum, this externalist account of cognition provides a viable foundation for machine and cyborg ethics. In providing an elegant theory of how cognition is implemented in biological and artificial systems, this account also provides a more solid meta-ethical description of what cognition means in relation to functions or processes that enable (the attribution of) moral properties in artificial or hybrid intelligent systems. Functions or processes that enable (the attribution of) moral properties, in fact, can be realized not only via biological organisms (such as humans) but also by artificially intelligent systems and human-machine integrated systems. For this reason, the externalist account of cognition proposed by advocates of the extended mind thesis offers a more suitable and epistemically informative foundational framework for machine and cyborg ethics.

*2.6 - Cognitive Enhancement for the Aging World: Opportunities & Challenges**

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Abstract

Population ageing and the global burden of dementia pose a major challenge for human societies and a priority for public health. Cognitive enhancement, i.e. the targeted amplification of core cognitive abilities, is raising increasing attention among researchers as an effective strategy to complement traditional therapeutic and assistive approaches and reduce the impact of

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age-related cognitive disability. In this paper, we discuss the possible applicability of cognitive enhancement for public health purposes to mitigate the burden of population ageing and dementia. After discussing the promises and challenges associated with enhancing ageing citizens and people with cognitive disabilities, we argue that global societies have a moral obligation to consider the careful use of cognitive enhancement technologies as a possible strategy to improve individual and public health. In addition, we address a few primary normative issues and possible objections that could arise from the implementation of public-health-oriented cognitive enhancement technologies.

Introduction: Global Ageing and Dementia

Today, approximately 12 per cent of the world's population is over the age of 60; by 2050 this proportion is expected to have more than doubled (*12*). This trend is particularly recognizable in Europe as the proportion of individuals older than 65 years is estimated to increase from 16.1 per cent in 2000 to 27.5 per cent by 2050, while the proportion of the population aged over 80 years (3.6 % in 2000) is expected to reach 10 per cent by 2050 (*13*). This demographic trend brings multiple health-related concerns, one of which is the rise in the number of older persons living with neurocognitive disabilities or experiencing age-related cognitive decline. In fact, the probability of becoming cognitively impaired significantly increases with age. Cross-sectional comparisons have consistently demonstrated that increased age is associated with lower levels of cognitive performance, with some cognitive functions beginning to decline already in young adults and then worsening dramatically after the age of 60 (*19*). In addition, the prevalence of dementia-causing neuroprogressive disorders also correlates significantly with advancing age. For example, Alzheimer's disease (AD), the most frequent type of age-related dementia, affects less than one per cent of the population under the age of 59, almost four per cent of the population segment aged 60-79, and over 11 per cent of those aged 80-89. With the ageing of the global population, the number of people with AD worldwide is expected to nearly triple by 2050 (*26*).

Global ageing and the consequent increasing prevalence of cognitive decline pose a "priority for public health" in terms of financial management and caregiving burden (*43*). Estimates indicate that dementia and specifically AD are among the most expensive diseases for Western societies (*35*). According to the World Alzheimer Report 2015, the annual societal and economic cost of dementia in the US has reached $818 billion, a 35 per cent increase compared to 2010. By 2018, it is expected to skyrocket to a trillion dollar (*331*).

These significant costs arise primarily from long-term care at nursing homes and other health-care institutions; their burden affects not only public finances but also senior citizens, their non-professional caregivers (e.g. relatives) and the health-care system. At the family level, the problem of population ageing results in a caregiving burden on informal carers. In most countries, the primary source of care, assistance and support for older and disabled adults is informal caregivers, who are mostly family members such as spouses, children and grandchildren. This informal caregiving service is highly time-consuming and requires great effort from caregivers in terms of physical and mental energy. The provision of caregiving services frequently comes at high socioeconomic cost for caregivers, who often need to give up jobs, leisure time, and social activities to effectively take care of their loved ones. As research increasingly shows (*38-40*), the informal caregiving burden for older and disabled people is a significant source of psychological distress for carers, worsened mental health functioning, anxiety, perceived stress, and depression (*38*). As most caregivers of seniors with physical or cognitive disabilities are themselves growing older (average age 63), and one third of them are reported to be in fair to poor health (Administration on Ageing 2004), the reduction of caregiving burden could play a major role in the promotion of healthy and successful ageing within society at large. In spite of this multi-domain burden, informal care is neither accounted for nor reimbursed in the healthcare economy in most countries (Bhimani, 2014). Finally, at the individual level, older people with dementia or age-related cognitive decline experience diminished quality of life, reduced independence, and low work productivity (*331*).

Cognitive Enhancement

Cognitive Enhancement (CE) refers to the "amplification or extension of core capacities of the mind through improvement or augmentation of internal or external information processing systems (p.311" (*379*).

Philosophers and scientists have long debated on what degree of improvement or augmentation of internal or external information processing systems qualifies as cognitive enhancement. Some authors, for example, have argued that a line can be drawn between *enhancement* and therapy (*380*), with the former only denoting improvements beyond the norm[33] and the latter denoting improvements aimed at restoring lower-than-normal function. In recent years, however, researchers have underscored the "elusive nature" of this line (*382*) and expressed skepticism regarding the conceptual validity (*383*) and "practical significance" (*379*) of the enhancement-therapy distinction. While a detailed description of the semantic and conceptual debate over enhancement is beyond the scopes of this article, our analysis will use the notion of CE to define any amplification of core mental capacities, encompassing interventions aimed at both restoring function towards the norm and improving it beyond it.

CE via augmentation of internal information processing systems usually occurs through interventions that target the underlying neurobiology of the cognizing agent. This can occur either chemically or electronically. Chemical enhancement usually consists on the administration of cognition-enhancing pharmacological treatments. For example, the nootropic drug Piracetam, a cyclic derivative of GABA, has demonstrated benefits in treating neuro-degenerative diseases such as Alzheimer's disease by improving alertness and memory (*384*), and is also prevalent amongst college students seeking cognitive performance boosts (e.g. during exams preparation)[34]. Internal electronic enhancement usually occurs through the use of technologies that interface the brain of the cognizing agent. Neural prostheses are devices that can repair, replace or enhance motor, sensory or cognitive capacities that might have been damaged as a result of an injury or a disease (*385*). These include sensory prosthetics such as cochlear implants,[35] motor-prosthetics such as bladder control implants[36] and cognitive neural prosthetics *stricto sensu*. The latter are capable of recording the cognitive state of the subject, rather than just signals strictly related to motor execution or sensation. Using high-level cortical signals, cognitive prostheses can partly compensate for declining cognitive functions including intention, motor imagery, decision making, forward estimation, executive function, attention, learning, and multi-effector movement planning (*386*). Restoration of function after brain damage using a neural prosthesis. Cognitive neural prosthetics *stricto sensu* need to be

[33] It is worth noting that much debated has also focused on the definition of normality. See for example: 381. N. Daniels, Normal functioning and the treatment-enhancement distinction. *Cambridge Quarterly of Healthcare Ethics* **9**, 309-322 (2000).

[34]See: https://www.newswithviews.com/Howenstine/james182.htm
and http://ieet.org/index.php/IEET/more/nicholas20120320

[35] Surgically implanted electronic devices that provide auditory function in persons who are profoundly deaf or severely hard of hearing in both ears.

[36] Devices implanted over the sacral anterior root ganglia of the spinal cord, controlled by an external transmitter, which deliver intermittent stimulation to improve bladder emptying.

distinguished from technologies that non-invasively (i.e. from outside the skull) enhance internal information processing, like non-invasive neuromodulation (*387*).

Augmentation of external information processing systems usually occurs through interventions that do not directly target the underlying neurobiology of the cognizing agent but rather non-invasively modify the environment within which the cognizing agent interacts, alter the agent's habits or provide external cognitive resources to support cognition from outside the skull. For example, after their extensive review of the literature, Halperin and Healey have concluded that strategies of "environmental enrichment", i.e. environmental manipulations of the natural and social environment with the purpose of improving the agent's cognitive capacities, have a powerful influence as cognitive enhancers (*388*). In fact, studies have shown that an array of neurodevelopmental processes facilitate efficient neurotransmission and are highly responsive to environmental influences. These influences include modifications of air pollution levels, urban planning strategies, home design, quality of parenting, creation or protection of large and reliable social networks such as family and friends etc. Interventions targeting the agent's habits have also demonstrated effectiveness in enhancing cognitive functions. These include optimal amount of sleep, healthy nutrition, drug avoidance, regular physical exercise and sports, reading, brain-training etc. Finally, several digital (both hardware and software) systems are increasingly usable as external cognitive support tools or cognitive extensions in modern societies. A paradigmatic example is the smartphone which is pervasively used as additional memory storage space, spatial orientation and navigation assistant (through the use of mapping services and GPS-tracking apps), task reminder, activity planner, and verbal communication tool, hence supplementing critical intracranial cognitive functions (*389*). Today, a number of external hardware (e.g. robotic assistants) and software (e.g. mobile apps) applications "routinely give human beings effective cognitive abilities that in many respects far outstrip those of biological brains (p. 312)" (*390*). For example, cognitive processes such as arithmetic calculus and geolocalization are now prevalently and more effectively performed in humans through external software than through internal information processing (*391*).

With advances in cognitive neuroscience, clinical neurology, neural engineering, and computer technology, the number of cognitive capacities that can be augmented through improvement of information processing systems (both internally and externally) is increasing. These include memory, sensory, perception, attention, language.

CE raises a number of ethical questions. In 2008, an article appeared in *Nature* raised awareness among scientists about the ethical implications of CE and called for an evidence-based approach to the cost-benefit analysis of cognitive enhancers. The authors identified three major ethical issues: safety, fairness and coercion (*392*). Since then, the ethical debate over CE has largely focused on the theoretical permissibility of cognitive-enhancing interventions rather than on the applicability of CE to specific population segments to improve public health. As Shaw (2014) observes (p. 389), the CE literature "has focused on cosmetic neurology and *restoring* those of sub-par ability to the normal range", paying very little attention to developing strategies for improving the physical and psychological health of the public via CE (*393*). One exception is represented by pediatric neuroenhancement, as some studies have explored the ethics of health-improving applications of CE. For example, Singh and Kelleher have proposed that the primary care clinic should be the relevant site where young people's use of enhancement technologies can be safely and objectively managed in a manner that maximizes the benefits of these technologies while minimizing the risks (*394*).

In spite of the growing prevalence of age-related cognitive decline, the applicability of CE for public health purposes remains largely unexplored. In this paper, we conduct a narrative review of the existing literature on CE solutions for older people and propose an ethical stance for the safe and effective implementation of CE in light of global population ageing. We argue that, in light of the current clinical, financial, and organizational burden of ageing and dementia, global societies have a moral obligation to consider the careful use of "cognitive enhancement technologies" (*395*) as a strategy to improve individual and public health. In addition, we address a few primary normative issues that could arise from the implementation of public-health-oriented CE interventions with the purpose of preparing the normative ethical terrain for such future interventions. Finally, we respond to possible objections against the use of CE among seniors.

Cognitive Enhancement for the Ageing World: Opportunities

Research shows that the calibrated application of CE technologies has the potential to alleviate the global burden of population ageing and age-dependent cognitive decline. Recent findings in clinical neuroscience have demonstrated that neural and cognitive functions in older adults can be enhanced using cognitive training techniques (*396*). For example, several studies have focused on establishing the impact of exercise on the nervous system and the associated cognitive benefits. Daily aerobic exercise over a long period of time has been observed to increase oxygen transport and energy resources by maintaining blood vessels of the brain and improving the growth and function of brain cells (*397*). Based on this evidence, Korean researchers have developed a CE gymnastics program for older people with dementia and verified its effects. Their results show that such enhancement programs improve gait capability, balance sense and the performance of activities of daily living in people with AD or vascular dementia (average age, 80.93±5.19 yr) (*398*). Similarly, European researchers have developed and tested a physical activity program that can significantly slow cognitive decline and improve quality of walking in older persons suffering from dementia (*399*). Besides physical training, environmental interventions have shown great potential too. In their extensive review, Park and Bishof (2013) have concluded that engagement in an environment that requires sustained cognitive effort facilitates cognitive function in older adults and that modifications of the social environment such as social participation and engaged lifestyle increase behavioral performance on executive function tasks (*396*). In parallel, randomized controlled trials involving pharmaceutical neuroenhancers have also achieved promising results. A double blind trial involving 140 older individuals with Mild Cognitive Impairment (MCI) for a period of 6 months has shown that a cholinesterase inhibitor called *donepezil* improves gait performance and reduces the risk of falling (*400*, *401*). Finally, advancements in micro-computing, mobile technology and artificial intelligence are also producing positive results. For example, tablet-based tools have shown effectiveness as cognitive assistants for the augmentation of decision-making capacities among senior citizens (*402*), reminiscence (*403*) and social interaction (*404*). Last year, the release of the 10-year findings from the Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) study showed that computer-based CE technologies can not only augment cognition but also reduce dementia risk among older adults (*156*). Through a large randomized-controlled design (2,785 participants at six trial sites in the U.S.) researchers detected a 33 per cent reduction (p=0.012) in the risk of developing cognitive decline or dementia over the next 10 years.

Such rapid advancements in CE for senior citizens are particularly promising in the light of the current limited possibilities in geriatric medicine. Today, in spite of some promising applications of stem-cell-based epigenetic regulation in human cell line (*405*), reversing ageing is still scientifically impracticable. In addition, most neurogeriatric disorders such as Alzheimer's and Parkinson's disease are currently incurable. Available therapeutic strategies can either delay disease progression or temporarily remediate to contingent symptoms (*331*). Given the current demographic regime of global population ageing, the consequent increased prevalence of age-dependent neurocognitive disorders, and current limited therapeutic possibilities in geriatric medicine, the global burden of ageing is predicted to increase over the next few decades (*331*).

As findings show that CE could be of great benefit for elderly and dementia care, we argue that there is a moral obligation to consider CE as one additional strategic avenue for addressing the global burden of population ageing worldwide and improve the lives of senior citizens. In fact, the careful and calibrated use of CE interventions could complement existing preventive and therapeutic strategies, resulting in better public-health outcomes. CE technologies, in fact, could help amplify core mental capacities of senior citizens in a manner that restores function towards the norm or even improves it beyond it.

Challenges

Four considerations are important in relation to this proposal. First, CE interventions are not and should not be intended to replace prevention and therapy. In contrast, they are and should be designed with the purpose of complementing existing strategies as part of a comprehensive public-health enterprise. Effective CE interventions that can mitigate cognitive decline, reduce the risk of neuroprogressive disorders and contribute to the promotion of healthy and successful ageing among senior citizens could successfully complement and enhance existing public health strategies.

This continuity between CE and public health is confirmed by the consideration that, in the context of elderly care, the line between enhancement and treatment is, as previously observed, hard to draw. This is particularly evident in geriatric medicine. As Bostrom and Sandberg observed, CE of a person X with poor biological memory could leave that person with a memory that is still worse than that of a person Y who has retained a fairly good memory despite being recently diagnosed with an identifiable pathology, such as mild cognitive impairment or early-stage AD (*379*). In addition, as the ACTIVE study shows, CE strategies such as long-term computer-based cognitive training among healthy older adults, may be effective in preventing neurogeriatric pathologies (*156*).

Second, the implementation of CE technologies should be guided by a procedural, evidence-based approach that prioritizes those interventions that have demonstrably higher clinical effectiveness and safety over other interventions. In addition, interventions that involve low financial costs should be prioritized over more expensive interventions, provided all other parameters (clinical effectiveness and safety) are equal. For example, easy-to-implement and inexpensive measures such as environment modifications and low-cost brain-training programs should be prioritized -*ceteris paribus*- over costly high-tech interventions.

Third, interventions should be non-coercive (*406, 407*). Mentally competent older adults should have the right and liberty to choose whether to use CE technologies or refuse to do so. Following public-health campaigns based on traditional CE technologies such as healthy nutrition and physical exercise, citizens should be thoroughly informed about the clinical and non-clinical benefits of adapting their habits to public-health goals. While under some circumstances, seniors may be implicitly oriented towards these goals through nudging, financial incentives, and other promotional strategies, we argue that CE interventions, unlike other forms of human enhancement such as immune enhancement via vaccination, should not be mandatory as a default position. The reason for that is twofold. First, because ageing and most neurological disorders that can be alleviated via CE are not communicable: in absence of any equivalent of herd immunity, the group of individuals that will choose to enhance will not increase in any significant sense the protection of those individuals who cannot do it. Second, because CE interventions should respect the individual right to cognitive liberty, an emerging fundamental right that comprises two intimately related principles: the right of individuals to use CE technologies, and the protection of individuals from the coercive and unconsented use of such technologies. Cognitive liberty has often been presented by scholars as the fundamental level of self-determination (*408*), because "the right and freedom to control one's own consciousness and electrochemical thought processes is the necessary substrate for just about every other freedom" (*406*). It is worth noting, however, that the right to cognitive liberty may not be an absolute but a relative right. Therefore, while no form of coercion should be accepted as a default position, *soft-paternalistic* strategies (*409*) could be morally acceptable under certain circumstances. The use of nudging and soft paternalism ─use of maps on the floor and environmental alarm systems to avoid wandering installed in absence of explicit consent─ is currently accepted in the care of people with advanced dementia when this is considered in the best interest of patients. Similarly, temporary limitations to cognitive liberty for the purposes of CE might be morally accepted if these are in the best interest of patients (e.g. proportionally reducing suffering in absence of relevant adverse effects). However, we argue that soft paternalism may become ethically problematic if it leads to situations where CE is not mandatory but refusal of it leads to punitive financial consequences in terms of providing for one's own care.

Fourth, CE strategies should be justice-oriented and prevent the exacerbation of pre-existing socioeconomic inequalities. Shaw (2014) has examined the prospect of improving health outcomes through CE among sections of the population where health inequalities are particularly pronounced. He called this enhancement of the population health through CE 'neuroenhancing public health' (*393*). In light of the considerations described above, elderly care might be at the core of this public health enterprise.

Possible Objections

The proposal of neuroenhancing public health measures to alleviate the global burden of population ageing and cognitive decline might be opposed on various grounds. First, it might be argued that it represents a form of ageism, i.e. discrimination against older people. For example, Hertogh has argued that the focus on successful ageing is a form of ageism that works out as a negative incentive to the care for the oldest-old (*410*). The reason for that stems from the consideration that CE strategies aiming at promoting successful ageing might fail to recognize the inevitable nature of ageing and age-dependent frailty or psychophysical decline. In addition, at the pragmatic level, focusing on preventing or delaying age-dependent decline might result in reduced support for frail older adults that need care. In response to this concern, we argue that CE technologies that aim to prevent or mitigate the cognitive effects of ageing are not more ageist than preventive or therapeutic interventions in geriatric medicine that aim to prevent or cure physical age-dependent disorders. Therefore, objecting to CE on this ground would thereby imply that geriatric medicine itself is ageist in character. Second, CE interventions that can help older adults maintain their cognitive capacities, physical skills, and social relationships can thereby empower them and protect their individual autonomy. Instead of being a form of discrimination, CE would enable seniors to maintain greater independence and promote their freedom to make choices and select courses of actions according to their intended plans, with fewer external constrains and limitations. Finally, as it may delay or partly obviate the need for institutionalized care (*2, 67*), CE is predicted to alleviate the burden on the healthcare system. In a time when the provision of institutional care for the ageing population is increasingly threatened by financial and logistical limitations[37], CE strategies might actually help allocate the available resources to those population groups −such as the oldest-old or elders with advanced dementia− that are in greater need of institutional care and skilled support. It could even be

[37] The Guardian: https://www.theguardian.com/australia-news/2016/may/03/aged-care-funding-nursing-homes-cut-federal-budget (last accessed 10/27/16).

argued that it would actually be discriminatory to deny older people access to CE, given the disproportionate burden of mental problems that affects this group – particularly if CE for health reasons becomes more widespread among other age groups.

The point about resources is closely related to the possibility that CE plans for older people might be economically impracticable in a world where 12 per cent of the population is over the age of 60 (*411*). While this is an empirical question that can only be answered based on existing data and statistical predictions, it is worth considering that the costs of CE should not be considered in absolute terms, but proportionally to the costs that could be potentially saved on healthcare budgets through the effective implementation of CE strategies. In light of current to demographic trends, the rapid erosion of the caregiver-to-patient ratio, and the consequent financial and practical unsustainability of long-term institutional care for a growing older population in the near future, CE could offer a valuable complementary solution to existing public-health strategies. It is possible, however, that long-term care costs might actually increase if CE delays entry into care but prolongs time in care overall. Future research should assess the financial sustainability of this proposal in the light of current and future demo-economic variables.

Some authors have observed that most common views on CE are paternalistic (*412*), a problem that might become even more evident if these views are expressed through public-health initiatives. However, we think that this risk applies only to cognitive enhancement plans that involve hard paternalistic and coercive measures or are misimplemented in a manner that illegitimacy violates the individual right to cognitive liberty.

A more substantial concern is the risk that unevenly distributed CE technologies could generate a neurotechnological divide which might exacerbate pre-existing socioeconomic inequalities. In fact, while ageing and age-related cognitive decline are common to all socioeconomic classes, there is the latent risk that only certain socioeconomic groups could afford, and hence benefit from, CE technologies. This risk will be discussed in the following section.

Preserving Fairness in Cognitive Enhancement

In regard to costs and fairness, two considerations are important. First, several forms of CE for senior citizens with reported effectiveness such as physical exercise and environment modification do not involve costly equipment. Therefore, they could be implemented in a manner that minimizes socioeconomic divides. Second, with the average cost of care in an assisted living facility in the United States reaching $3,293 per resident per month[38], the current state of long-term care is a major threat to socioeconomic inequality in the ageing world. In fact, the negative impact of age-dependent cognitive and physical decline is greater among low-middle class people who hardly face the costs of institutional long-term care, or whose carers have to give up jobs and leisure time to care for their beloved ones instead of paying for skilled facilities. This problem has global relevance given that the greatest relative cost increases related to elderly care and age-dependent cognitive disorders are occurring in low-income African and in East Asia regions (*413*) where the provision of elderly care services will be seriously threatened due to the existing limitations of national budgets. In this global context, even the most sophisticated CE strategies are likely to improve current cost-effectiveness ratios if they have demonstrated efficacy.

While prioritizing low-cost CE interventions might be an ethically sound kick-off strategy, there is a collateral risk of delaying the benefits of effective but higher-priced CE solutions. High-tech electronic neurodevices such as BCIs and portable neuromodulators have prices starting from over a hundred US dollars, pharmacological enhancers such as Donepezil cost over one US dollar per single pill, and app-based cognitive programs can be often free to download but require expensive hardware (smartphones or tablets) to work; assistive robots including cognitive assistants such as SoftBank's Pepper (*414*) and companionship robot Paro (*415*) have prices ranging between two and six thousand US dollars[39]. In the absence of governmental interventions via targeted reimbursement plans there is a risk that high-tech CE tools might be accessed solely by middle-to-upper class citizens of industrialized countries. It might be observed that this unequal distribution is not an exclusive characteristic of enhancement, but common to the entire healthcare landscape; while this is likely the case, it is not a moral justification of inequality at the policy level. However, CE should not aggravate current geographical and socioeconomic inequalities but seek to mitigate them.

To avoid the exacerbation of socioeconomic inequalities, we suggest that strategies that could maximize universal access by fair opportunity should be pursued. These include both technical and policy strategies. First, at the technical level, efforts need to be made to reduce hardware costs and promote open-software initiatives in the development of computer-based CE

[38] U.S. Department of Health and Human Services: http://longtermcare.gov/costs-how-to-pay/costs-of-care/ (last accessed 10/27/16).
[39] See: https://www.ald.softbankrobotics.com/en/Launch_Sales_of_Pepper; http://www.technorms.com/37552/top-10-awesome-robots-you-can-buy-today (last accessed 10/27/16).

devices. Open platforms such as Open-BCI and open source repositories for the development of m-health solutions for people living with dementia (*416*) are positive examples of these efforts. In parallel, inclusive health policies that maximize access, availability and distribution of effective and safe CE solutions across all socioeconomic groups should be designed. These policies might involve governmental subsidy and reimbursement schemes for health-promoting CE solutions, the inclusion of CE tools into basic health insurance plans, and financial incentives (e.g. tax reductions and credits) for virtuous developers.

In developing such policies, those people who are socioeconomically most disadvantaged should be prioritized. As Shaw explains, this is because the greater beneficial impact of CE is likely to occur among the cognitively worse-off. In contrast, "those who already make good health decisions might benefit only slightly (p. 391)" (*393*). Such prioritization of the most disadvantaged shows that CE could not only avoid the aggravation of pre-existing socioeconomic inequalities, but holds the potential of reducing such inequalities by delaying or obviating the need for unequally accessible and geographically unevenly distributed services. As Shaw puts it (p. 391), successful CE "would ultimately mean that the cognitive gap between the most and least cognitively able citizens would decrease, just as health inequalities would decrease" (*393*).

This aspect is particularly relevant in the light of what we call the *recursive nature of cognitive enhancement*. In fact, clinical evidence shows that lower intelligence (broadly defined), worse cognitive performance and poor health literacy are predictors of lower health outcomes and reduced longevity (*417-422*). Therefore, increasing intelligence and cognitive performance via CE will not simply improve public-health by reducing the global burden of age-dependent cognitive decline and related disorders; in addition, such measures are also predicted to recursively improve general health outcomes in a number of domains including cardiovascular disease (*419*), blood pressure (*423*), mental health (*424*), and others. This recursive character of CE acquires special ethical significance in relation to socioeconomic parameters. In fact, people with lower overall cognitive performance are more at risk of lower socioeconomic status, which recursively increases their risk of lower health literacy and, consequently, negative health-outcomes. For example, Morrow et al. have observed that functional health literacy scores are lower among older and less educated citizens, in particular when they had more comorbidities, or scored lower on all cognitive ability measures (*425*).

Therefore, CE technologies that prioritize the most socioeconomically disadvantaged are likely to interrupt this cycle of "income inequality leading to educational inequality leading to health inequality" (*426*) and initiate a virtuous circle in which cognitive enhancement leads to increased socioeconomic equality and, consequently, increased health equality. As recently stated by The Lancet Commission Dementia Prevention, Intervention, and Care (p. 53), "we are a long way from achieving equity" (*427*). Consequently, CE should reduce inequities, not aggravate them.

Conclusion

In this paper, we have argued that CE should be seriously considered as one viable solution to tackle the increased prevalence of age-related cognitive decline and promote healthy ageing. In light of the current clinical, financial, and organizational burden of ageing and dementia, we argue that global societies have a moral obligation to consider the careful use of CE technologies as a strategy to improve individual and public health. There do not appear to be any strong arguments against offering CE technologies on a voluntary basis to ageing citizens, especially those affected by or likely to be affected by dementia. The only substantive ethical issues arise with regard to cost, paternalism and fair access. First, it is possible that long-term care costs might actually increase if CE delays entry into care but prolongs time in care overall. Second, lightly paternalistic measures such as nudging may be ethically problematic, if they lead to situations where CE is not mandatory but refusal of it leads to punitive financial consequences in terms of providing for one's own care. Finally, in order to avoid the exacerbation of a technology divide, effective deployment of CE technologies should aim at maximizing universal access and prioritizing the most socioeconomically disadvantaged.

*2.7 - From Healthcare to Warfare and Reverse: Regulating Dual-Use Neurotechnology in the Aging World**

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Abstract

Recent advances in military-funded neurotechnology and novel opportunities for misusing neurodevices show that the problem of dual-use is inherent to neuroscience. This paper discusses how the neuroscience community should respond to these dilemmas and delineates a neuroscience-specific biosecurity framework. This *neurosecurity* framework involves calibrated regulation, (neuro)ethical guidelines and awareness-raising activities within the scientific community.

Introduction: Dual-use Neurotechnology

In ethics of (bio)technology, the dual-use problem refers primarily to the cooptation of civilian technology for military aims. This expression is also used to refer to the possibility of utilizing the same technology for both beneficial (e.g. clinical) applications and harmful misuse (e.g. bioterrorism). While nearly any technology holds a potential for dual-use in the broad sense, recent reports for the British Royal Society and the Dutch Research Council have provided a

40 Current Impact Factor: 14.024 (2016). As the author of this Elsevier article, I retain the right to include it in a thesis or dissertation, provided it is not published commercially. Permission is not required, but please ensure that the journal is referenced as the original source.

narrower definition and distinguished "intentional misuse" from the general domain of repurposing activities with unintended harmful consequences. Dual-use technologies are originally designed and developed for a wide spectrum of civilian purposes, among which biomedical research and healthcare often play a prominent role.

Until recent times most attention to dual-use technology emerged in the fields of molecular and cell biology, especially in those areas involving research on pathogens such as virology, bacteriology, and other subdivisions of microbiology. Security-sensitive research in these fields of science is classified as Dual Use Research of Concern (DURC). DURC is a United States Government's oversight label identifying research in the life-sciences that can be anticipated to provide informational or technical resources for the development of threats to public health, individual safety or national security. The DURC label was introduced to prevent the malicious application of life science research, and although this framing has recently faced criticism among researchers (e.g. for not clearly demarcating the range of dual-use applications and providing only limited oversight), it is still in place as a guidance mechanism among national and international organizations.

In the past two decades, new concerns have been raised as several emerging neurotechnologies have shown dual-use potential, causing the inclusion of various areas of neuroscience into the DURC-domain. Tennison and Moreno (2012) have extensively reviewed the domain of neurotechnology tools with applications in both civilian and national security contexts with special focus on projects funded via the Pentagon's Defense Advanced Research Projects Agency (DARPA). Their state-of-the-art review identified three main categories of dual-use neurotechnology: brain-computer interfaces (BCIs), neurotechnologies for warfighter enhancement, and neurotechnological systems for deception detection and interrogation (*428*). The first category encompasses systems that establish a direct connection channel between the human brain and an external computer device, bypassing the peripheral nervous and muscular system. Medical applications of BCI have shown clinical effectiveness in repairing, assisting or augmenting cognitive or sensory-motor functions in patients experiencing neurological impairments including spinal-cord injury, stroke, motor neuron disease and, more recently, even though with significant limitations, age-related cognitive decline and Alzheimer's disease (AD). Outside the clinics, non-invasive direct-to-consumer BCIs are gaining increasing popularity as portable (often smartphone-compatible) tools for device control, self-neuromonitoring and personalized entertainment.

Using the same technological paradigm, national security uses of BCI include the acquisition of neural information gathered from warfighters' brains to adaptively modify their equipment and the development of Threat Warning Systems that convert subconscious, neurological responses to danger into consciously available information (*429*). Warfighter enhancement applications include pharmacological and non-pharmacological (especially transcranial direct current stimulation-tDCS) technologies for selective cognitive enhancement in targeted brain-areas. Finally, the deception detection domain encompasses devices such as the so-called "brain-fingerprints" capable to access concealed information in response to a stimulus. While these applications, especially those based on functional-magnetic resonance (fMRI) and electroencephalography (EEG) hold a great potential for medical diagnostics, they are powerful surveillance and enhancement tools for national security, judicial and military purposes due to their dual-use character. Although no deception detection technology is being currently used in official security operations, several devices are either directly DARPA-commissioned or are able to market their services to national security and law enforcement agencies (http://www.truthfulbrain.com/martkets/).

The dual-use problem is often presented as an ethical dilemma since it identifies a conflict between two fundamental ethical duties: the promotion of good and the prevention of possible collateral harm, e.g., between the promotion of health through effective clinical applications and the provision of resources for the killing of civilians through military operations. Marchant and Gullant have noted that, in some research contexts including neurotechnology, the complexity of the dual-use dilemma is increased by its bidirectional character. While classical dual-use problems are concerned with the cooptation of beneficial, civilian technology for military or nefarious purposes, neurotechnology also raises the reverse problem as several neurotechnologies developed by the military for national security purposes are likely to spill over into the civilian sector with a disruptive impact on healthcare, communication or other fields (*430*).

The dual-use character of neurotechnology makes it also a potential target for non-State actors. In fact, as many neurotechnologies are based on computation and information processing, they are potentially vulnerable to cyber-risks. Even though there are no confirmed cases of malicious attacks in non-experimental settings, information security researchers have experimentally demonstrated the actual feasibility of performing side-channel attacks and extracting private information from users of EEG-based BCIs without their authorization (*431*). These experiments have shown that neurotechnology is subject to similar privacy vulnerabilities and cyber-risks as other computer systems. In response to that, neuroengineers have called for enhancing the security of current neurodevices and incorporating protective measures such as encryption technology into the product design (*142*).

The Bidirectional Character of Dual-Use in Neurotechnology

As dual-use appears inherent to neurotechnology, the progressive increase in the number of civilian ─both clinical and consumer-grade─ neurotechnology applications, will likely determine a proportionate increase in dual-use opportunities.

With global population aging, an important portion of neurotechnological applications is being developed with the purpose of assisting or providing novel therapeutic, diagnostic and assistive solutions for older adults with cognitive or physical disabilities. Researchers have observed that the number of technology applications for older adults and people with dementia is nearly tripling every five years (*6*). In parallel, a growing number of portable diagnostic tools are under development. For example, virtual reality techniques and mobile apps (http://www.seaheroquest.com/site/en/) can be used to detect navigational deficits in cognitive aging and AD.

Many technologies currently used for seniors and the cognitively disabled have a dual-use potential. Notably, near-infrared spectroscopy (NIRS) is used in medical and physiological diagnostics to assess loss of functional hemispheric asymmetry or verbal fluency in AD, as well as to comparatively measure cognitive function in, respectively, normal cognitive aging and prodromal dementia. Similarly, transcranial magnetic stimulation (TMS) techniques can help enucleating the neurophysiological profile of vascular dementia and understanding the role of different neurotransmission pathways. Today, DARPA-funded NIRS applications are being tested for military purposes to detect deficiencies in a warfighter's neural processes and feed that information into a device utilizing in-helmet or in-vehicle transcranial magnetic stimulation (TMS) to suppress or enhance individual brain functions (*428*).

Vice versa, given the bidirectional character of dual-use in neurotechnology, several applications have shown reverse dual-use potential. A paradigmatic example is the DARPA-funded Restorative Encoding Memory Integration Neural Device (*REMIND*) program. Under this program, researchers were able to detect patterns of functional brain connectivity in the hippocampus and prefrontal cortex associated with successful memory encoding and retrieval. After identifying hippocampal firing patterns associated with correct encoding of a specific event, they translated these outputs into electrical stimulation in animal models with rodents. Their results show that, when applied to the hippocampus during memory encoding, the stimulation significantly improved the ability of rodents to subsequently remember an event (*432*). These promising results, obtained in the context of military-oriented neuroengineering research, hold the potential of leaking into the civilian sector with beneficial impacts. With recent unmeet expectations in pharmacological research on memory restoration, neurostimulation studies could complement or even create new avenues of therapeutic research for memory disorders such as AD and other dementias, post-traumatic amnesia, and even normal aging.

In some circumstances, dual-use in neurotechnology can generate a circular dynamic. As mentioned previously, several non-invasive, direct-to-consumer BCIs have made their way onto the consumer market. However, as Miranda et al. (2015) observed, "the signal-to-noise ratio of these systems is often too low to reliably detect many EEG components of interest for neuroscience efforts aimed at improving human training and performance, particularly when single trial analysis is required" (*429*). DARPA-funded programs such as the CT2WS *aim precisely at developing reliable EEG-based BCIs* for applications such as threat detection and non-invasively recording of operators' neural activity (*429*). These efforts are an example of a civilian technology that is coopted for military research and may subsequently spillover into the civilian sector through more reliable clinical or commercial applications.

A Global Ban on Dual-Use Neurotechnology? From Applied Ethics to Policy

The problem of dual-use in neurotechnology is exacerbated by the fact that national-security and military applications are not the only way to repurpose civilian neurotechnologies. As mentioned before, misuse by malevolent individuals or groups is likely to become a concrete risk in the near future. Proliferation of both civilian and military neurotechnology is increasing the chances that neurodevices could land in the wrong hands. As neuroethicist James Giordano put it: "It's not a question of if non-State actors will use some form of neuroscientific techniques or technologies, but when, and which ones they'll use" (*433*). Malevolent uses of neurotechnology could be potentially performed not only by individual actors, but also in the context of organized criminality, terrorist organizations and other State and non-State actors, hence raising global security concerns.

The emerging risks associated to dual-use issues in neurotechnology have led scholars to take a critical stance against national defense and security involvement in neuroscience research. For example, it was argued that '[m]ost rational human beings would believe that if we could have a world where nobody does military neuroscience, we'll all be better off'' (*434*). These evaluations have led policy makers to consider the possibility of introducing a moratorium against military neuroscience. For example, in 1999 the European Parliament Committee on Foreign Affairs, Security and Defence Policy (rapporteur: Maj Britt Theorin) called for a global ban of research "which seeks to apply knowledge of the chemical, electrical, (…) or other functioning of the human brain to the development of weapons which might enable any form of manipulation of human beings". However, given the reverse dual-use potential of neurotechnology, the claim that we would be better off in a world without military neurotechnology is likely to be an inaccurate prediction. Defense-funded research enables increased funding opportunities for accelerating development in neurotechnology, and can spillover into civilian applications for the benefit of society. It cannot be ruled out *a priori* that military neurotechnology could follow a similar historical trajectory as geographic positioning system (GPS) surveillance and the Internet—examples of originally military-oriented technologies that eventually leaked into the civilian sector and today "pervade society's daily life, mostly with beneficial impacts" (*430*). Risks of misuse are common to nearly all ICTs, including those that are regularly used in daily activities such as mobile computing and social media. The long terms effects of these technologies might be hard to predict. In addition, these systems can be realistically repurposed for malicious activities including cyberwarfare and cyberterrorism. Nonetheless, a global ban on these technologies would likely be perceived by many as a disproportionate policy response as their foreseeable benefits outweigh the conceivable harms. A global ban on military neurotechnology would prevent any spillover-effect into civilian applications and could delay technological innovation for people in need including older people and patients with neurological disorders.

In light of population aging, the global burden of neurological disorders and the bidirectional dynamics of dual-use issues in neurotechnology, we identify a strategic and global health benefit in continuing research in defense-funded neurotechnology to successfully meet the grand challenges ahead in mental health and neurological care.

The Need for a Neurosecurity Framework

Although a global ban or moratorium on military neurotechnology appears ethically unjustified at present, softer and more calibrated regulatory interventions might be necessary to mitigate the risks of a disproportionate *weaponization of neuroscience*. In particular, we identify an urgent need for increased monitoring and careful risk-assessment in the context of dual-use neurotechnology. Even though, at the moment, benefits seem to outweigh the risks, preventive mechanisms should be in place to promptly detect future variations in the risk-benefit ratio. Building upon the experience of biosecurity frameworks developed in other areas of the life sciences might be a viable strategy to tackle the emerging problem of dual-use in neurotechnology. However, adaptive adjustments to the specific challenges of neuroscience and neurotechnology are required. The reason for that stems from the fact that the misuse of neurotechnology might have a more direct impact on the mental dimension of individuals, hence pose specific ethical, legal and social challenges. As neurodevices have the capacity to access and modify the neural correlates of mental processes, their misuse by malevolent actors could expose individuals to greater risks associated to their mental dimension.

To this purpose we identify a need for developing a neuro-specific biosecurity framework, the *neurosecurity* framework. Following biosecurity strategies in cell biology and other life sciences, such neurosecurity framework should be designed and implemented to maximize security across the whole translational continuum between scientific research and society (and reverse). Furthermore, it should be particularly sensitized to anticipate and promptly detect neurotechnology-specific threats, especially those that concern the mental dimension. This neurosecurity framework should include, at least, three main levels of safeguard: calibrated regulatory interventions, codes of ethical conduct and awareness-raising activities. In the following, we provide a non-exhaustive characterization of these requirements.

First of all, calibrated and neuro-specific regulatory approaches are needed to ensure neurosecurity for individuals and groups. Currently, military neurotechnology falls into a regulatory chasm. The two existing U.N. treaties —the Biological Weapons Convention (BWC) and Chemical Weapons Convention (CWC)— that *de iure* should limit abuses within the neurotechnology domain, only focus on biological and chemical bioweapons but contain no provisions for electrophysiological applications (*435*). Additionally, the CWC does not prohibit the use of chemical weapons in riot control, leaving open the possibility that riot control tools might be coopted as neurochemical weapons for offense. These regulatory gaps and loopholes could allow opportunities for misuse and offence, especially in war zones. Experts have already emphasized the limited scope of the CWC and called for their urgent update, warning the treaty's exclusive focus on national authorities and neglect of individuals, revolutionary groups, factions in civil wars and terrorist cells that can exert a detrimental influence on global security (*436*). Such expansion of the weapons conventions should also aim at preventing detrimental misuses of neuroelectric applications. Legal scholars have argued that certain neuroweapons might be incompatible with International Humanitarian Law (IHL) as they "ultimately disrupt the premise of responsibility under IHL" (*437*). Consequently, national governments and international organizations are under obligation to consider how neuroweapons would relate to IHL norms. Similarly, it should be considered how dual-use neurotechnology relates to human rights such as autonomy, privacy and mental or physical integrity.

In the context of nefarious misuse by State and non-State actors, emerging collateral risks associated with the widespread use of neurotechnology such as malicious hacking, neuroimaging-based intelligence interrogation as well as hazardous uses of medical neuromodulation are likely to require neurospecific security safeguards. Adequate regulatory responses by governmental and intergovernmental organizations might require the evolutive interpretation of existing rights (e.g. updating privacy rights to account for *mental privacy*) or even the creation of new neuro-specific rights (*407*). A possible candidate is the protection of *mental integrity*. Although mental integrity is protected by the EU's Charter of fundamental rights (Article 3), this right is conceptualized as a guarantee for accessible mental health services. No specific protection, however, is stipulated against unauthorized intrusions into a person's neural computation through the use of neurotechnology, even if such intrusions result in physical or mental harm to the victim. Other possible candidates include the right to *psychological continuity*, which intends to protect the continuity of personal identity from unconsented exogenous alteration (*407*). These regulatory updates could be operationalized within the general schemes set by existing declarations such as the Universal Declaration on Bioethics and Human Rights adopted by UNESCO, but with specific focus on the challenges raised by neurotechnology –similarly to how the *Universal Declaration on the Human Genome and Human Rights* or the *International Declaration on Human Genetic Data* addressed specific normative issues raised by genetic testing and engineering.

Second, codes of ethical conduct need to be developed to maximize the benefits of military neuroscience while minimizing the risks for individuals and communities. If research on selective memory manipulation (restoration or erasure) will ever reach human experimentation, it must guarantee the highest safety and research ethics standards. In particular, clinical trials must (i) be preceded by corroborated evidence of safety and effectiveness in animal, in vitro and computational models, (ii) prioritize subjects with treatment-resistant conditions, whose symptoms elude conventional therapies, (iii) demonstrably exclude unintended collateral consequences on non-targeted brain functions, and (iv) follow rigorous procedures for the obtainment of informed consent and IRB approval. Furthermore, to protect the autonomy of users, military neurotechnology applications, including those that leak into the civilian domain, should be non-coercive. Soldiers and civilians should keep their right to cognitive liberty, i.e. the right to competently choose or refuse to use neurodevices. In the context of military applications, it should be determined whether defense bodies and armed forces can legitimately require combatants to use brain-altering or brain-reading neurodevices as part of the Uniform Code of Military Justice, which requires soldiers "to accept medical interventions that make them fit for duty" (*428*). This question is particularly sensitive since the principle of cognitive liberty protects not only from explicitly coercive uses but also from "implicit coercion", namely when an individual is not directly forced to use a technology by formal coercive rules but is compelled to conform to a social equilibrium in which not using that technology creates a significant disadvantage. At the same time, in order to fulfill the need for responsible innovation in neurotechnology, data security measures should become a critical component of neurotechnology design and development. To this purpose, regulations should incentivize manufacturers to equip neurotechnologies with encryption, especially those technologies that can record and/or manipulate privacy-sensitive aspects of neural processing.

Finally, a neurosecurity framework should raise awareness among neuroscientists, neuroengineers and clinicians about dual-use. In fact, although several neurotechnology applications, including applications in geriatric neurology and psychiatry, have demonstrated dual-use potential, yet awareness of dual-use is reportedly low among researchers. As Tennison and Moreno have observed, although "they may receive funding from national security agencies, neuroscientists may not consider how their work contributes to warfare" (*428*). This consideration is consistent with the observation that the two-volume, 200-page report on the ethical implications of the BRAIN Initiative, does not include the terms "dual use" or "weaponization" (*433*), in spite of the fact that the initiative receives significant funding from

DARPA for defense and military applications. Further research, especially in the form of survey questionnaires and interviews, is required to monitor and accurately assess the level of awareness of dual-use issues in neurotechnology among researchers and clinicians. Concurrently, potential conflicts of interest linked to military funding should become a deontological concern also among neuroscientists and must be systematically disclosed at the level of research funding, IRB approval and scientific publication. In parallel, public engagement strategies such as citizen science initiatives, hackathons and open-development platforms like Open BCI (http://openbci.com/) must be sustained and incentivized.

A first promising step in the direction of awareness-enhancing strategies is the recent participation of representatives of the European Commission flagship initiative Human Brain Project (HBP) in a webinar on "dual-use and neuroscience. HBP researchers recognized that "a significant proportion of modern neuroscience research (not the research conducted by the HBP partners) receives funding from sources associated with the military", hence requires ethical and policy assessment.

Another positive example is a pledge drafted in 2010 and signed by neuroscientists in 17 different countries. The pledge was designed "as a course of action" for neuroscientists who share dual-use concerns. Their signers commit to two programmatic obligations:

I. "Making themselves aware of the potential applications of their work and that of others to applications that violate basic human rights or international law such as torture and aggressive war"
II. "Refusing to participate knowingly in the application of neuroscience to violations of basic human rights and international law" (*438*)

In addition, the pledge emphasizes the importance of raising awareness in the neuroscience community "through education and discussion", for example by introducing neuroethics courses into neuroscience curricula, as well as through the creation of appropriate regulatory bodies such as "committees or working groups" that might provide guidance or advise to neuroscience projects with identifiable dual-use potential (*438*). In February 2012, a committee of the British Royal Society issued a report on "Neuroscience, Conflict & Security". The main tenet of the report was that "neuroscientists have a responsibility to be aware from an early stage of their training that knowledge and technologies used for beneficial purposes can also be misused for harmful purposes" (*439*). Additionally, the report included ten specific recommendations for oversight of neurotechnology applications to military and law enforcement agencies. While the British example is encouraging, more needs to be done to expand this paradigm to other countries and to better root it in the neuroscience community, especially among "neuroscientists at an early stage of their training" (*439*).

The International Neuroethics Society (INS) can play a key role in raising awareness and promoting responsible innovation in an international context. The mission of the INS is precisely to "encourage and inspire research and dialogue on the responsible use of advances in brain science".

Conclusion

Dual-use dilemmas are inherent to neuroscience. Building upon the experience of biosecurity frameworks developed in other areas the life sciences might be a viable strategy to tackle the emerging problem of dual-use neurotechnology. However, adaptive adjustments to the specific challenges of neuroscience and neurotechnology are required. While a global ban of neurotechnology appears ethically unjustified, dual-use trends in this domain require increased monitoring, careful risk-assessment, and evidence-based normative interventions. A neurosecurity framework could help anticipate future threats and maximize security in the neurotechnology domain through calibrated regulatory interventions, (neuro)ethical codes of conduct and awareness-raising activities across the scientific community and the public.

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Declaration of Interests

The authors declare no competing interests.

Author Contributions

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*2.8. - Neuroprivacy, Neurosecurity and Brain-Hacking: Emerging Issues in Neural Engineering**

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Keywords: Neuroprivacy, Neurosecurity and Brain-Hacking: Dual-Use Dilemmas in Neural Engineering

Nearly 1 in 6 of world's population suffers from neurological disorders. Disorders of the nervous system, from Alzheimer and other dementias, Parkinson disease, multiple sclerosis and epilepsy to strokes, brain and spinal cord injuries, affect people in all countries, irrespective of sex, education or income. The global prevalence of neurological disorders poses a major problem for public health and the health-care services in terms of care provision, caregiving burden and financial management. Availability of appropriate care is frequently constrained by the effectiveness and limitations of present neuropharmacological treatments, and the non-integration of neurological care into primary care. Informal caregivers who assist chronically disabled neurological patients are reported to face a major physical, psychological and financial burden. Health-care systems face correspondingly high economic costs. These include not only the cost of treatment, but also the lost productivity of patients and their caregivers. Only in Europe, the total cost of neurological disorders is estimated to be 798 billion per year (of which 60% was attributable to direct costs and 40% to lost productivity) - twice the estimated cost of cancer.

A promising approach in response to this global crisis is the development and deployment of cutting-edge neural engineering devices for the treatment, rehabilitation and assistance of neurological patients. With the current capability in microtechnology and computational neuroscience, there is the opportunity to develop devices that can effectively

[41] No Impact Factor currently available for this journal.

establish a connection pathway between the human nervous system and interfaced electromechanical systems. Brain-controlled computer systems, robotic limbs, neuroprostheses, brain-stimulators, cognitive orthotics, memory aids, hearing and visual implants, are no longer domain of science-fiction; they are already commercialized medical technologies or well-corroborated research prototypes. These devices could provide a triple-win effect as they could: (I) provide more rapid and effective treatment, rehabilitation and assistance, thus improving the quality of life of patients; (ii) reduce caregiving burden; (iii) save significant costs to the healthcare system. While neural engineering can have a groundbreaking impact on neurological care and radically improve the quality of life of neurological patients, it raises the issues of dual-use and information security. The reason for that stems from the fact that neural devices, similarly as personal computers, are potentially vulnerable to be manipulated by malicious actors for nefarious purposes. This emerging breach for information insecurity can be labeled as *neurocrime* since it enables criminal activity which target neural information.

Neurosecurity

In order to establish a communication pathway with the nervous system, neural devices such as brain stimulators and brain-computer interfaces are designed to allow computer systems to access and process neural computation. While the accessibility of neural information is crucial for the effective functioning of the device, this feature raises the issue of privacy and information security, as neural information is carrier of private and sensitive data whose access or manipulation by malicious actors may cause significant physical (including life-threatening), psychological or social harm to technology users. With the rapid increase in distribution of neural devices it is expected that neural information will irrigate the digital ecosystem from innumerable sources with an unprecedented quantity of data flows and at an unprecedented velocity. Neural implants for clinical patients, at-home neurostimulators for cognitive enhancement, brain-computer interfacing applications for smartphone and a myriad of other devices are becoming access points of neural information, often connected to the internet. This will also multiply the quantity of data and the number and type of devices that are potentially exposed to neurocriminality.

Brain-Hacking

Neurocrime can target neural information either indirectly or directly. Indirect crime is when the attack is aimed at limiting, modifying or disrupting function in the devices that interface brain information -with neural computation from the users' brain not being accessed or manipulated in any significant sense. This type of risk is already critical at the current level of deployment of neural engineering technologies. With neurally controlled devices (e.g. brain stimulators and brain-computer interfaces) being available as medical technologies as well as commercialized products, present neurocriminals may abuse of the users by disrupting or terminating function in their devices without the users' permission or consent. For example, already commercialized brain-computer interfacing headsets for smartphones could be mechanically destroyed by malicious actors. Direct crime is when the attack cracks the users' neural computation to access and/or manipulate neural information for criminal purposes. I call this special type of neurocrime *"brain-cracking"* or "*brain-hacking"* as it exploits the neural device to get illicit access to and eventually manipulate information in a manner that resembles how computers are hacked in computer crime.

Some forms of brain-hacking have proven to be actually feasible in experimental setting. Studies have shown that brain-computer interfaces can be coopted to detect concealed autobiographical information from users with a significantly high accuracy rate (*440*). More strikingly, brain-computer interfaces to reveal private and sensitive information about the users such as their pin codes, bank membership, months of birth, debit card numbers, home location and faces of known persons (*441*). In addition, first proto-examples of brain-hacking have been also reported outside the experimental setting. A striking case is the so-called Cody's Emokit project through which the hacker Cody Brocious managed to crack encrypted data directly from a consumer-grade brain-computer interfacing headset (*442*). A sci-fi future where people can access and manipulate information in other people's brains is approaching at a very high speed and their prodromes are already here. Therefore, all direct and indirect implications of this emerging trend should be urgently assessed.

The dual-use dilemma of neural engineering

The peculiar dual-use dilemma of neural engineering can be summarized as follows: the same neural device has the potential to be used for positive (e.g. assisting cognitive function in neurological patients) as well as negative purposes (e.g. identity theft and other forms of brain-hacking). It is worth noting, that the attributes "positive" and "negative" with regard to technology use are hardly definable in an objective and non-contextual way. While the disambiguation of these terms remains an open philosophical question, a minimal characterization of positive in terms of "intended by design" and negative in terms of "unintended by design" may be helpful to address the issue. Unlike dual-use dilemmas in personal computer technology, the dual-use dilemma of neural engineering is more radical as the object of dual-use (especially in the case of brain-hacking) is neural computation. Neural computation underlies life-maintaining processes (such as nutrition and respiration) as well as faculties such as consciousness, perception, thinking, judgment, memory and language and is primarily responsible for our behavior and our self-identification as persons – all the things that make us human. Therefore, misusing neural devices for cybercriminal purposes may not only threaten the physical security of the users but also compromise fundamental faculties of human beings, influence their behavior and alter their self-identification as persons. This dilemma is primarily faced not only by researchers and technology developers, but also by governments as they are committed to promoting health and security of their citizens.

Neuroprivacy, Neuroconfidentiality and Information Security

The possibility of extracting private and sensitive information from the brain of users represents a significant treat to privacy and data protection. Users that are victims of brain-hacking may lose the ability to seclude confidential or inherently sensitive information about themselves, thus experience an intrusion of their private sphere. For example, hackers could extract information about the character traits or sexual preferences of users. This sensitive type of information is potentially of interest not only to criminals involved in harmful activities such as blackmail but also to employers and insurances. For example, health insurance companies may be interested in extracting information about the medical records of the user to accept or reject her enrollment into an insurance plan or to determine her insurance premiums. This ethical problem is particularly significant because privacy is a priority issue in a free society, closely linked to civil liberties, democracy and human rights (see, for instance, the American Bar Association 2004). A famous adagio in information and computer security states: "the best antivirus software is your brain". This is meant to stress that the conscious choices made by the user are the most important determinants of the security of the user's computer system. The possibility of brain-hacking questions the adagio since it removes precisely this intermediate level of protection between the information and the hacker. In brain-hacking there is no external brain exerting control over the information through rational choices since that brain consists of the exact same type of information under potential attack: neural information. The users choices are exposed to the same risks to which is exposed the sensitive information that the user wants to seclude; sometimes they *are* that information.

Autonomy and Personal Identity

The possibility for an external control over the user's future behavior seems to substantially conflict with the moral principles of individual autonomy and agency and may even interfere with the self-determination of personal identity or personhood. Individual autonomy is generally understood as the capacity of someone to deliberate or act on the basis of one's self-chosen plan and not as the product of manipulative or distorting external forces (443). By contrast, potential victims of brain-hacking may see their deliberation and action being constrained, controlled or manipulated by malevolent others. This problem is critical from an ethical perspective as the respect for autonomy is often considered (most notoriously by Beauchamp and Childress 2008) the paramount principle of biomedical ethics. In fact, any notion of moral decision-making assumes that rational agents are involved in making informed and voluntary decisions. Autonomy also plays a key role in several legislations as a prerequisite for liability. For example, the USA Model Penal Code (MPC), Section 2.01, states that a person is not guilty of an offense when his liability is based on an involuntary act such as "a bodily movement that otherwise is not a product of the effort or determination of the actor, either conscious or habitual". Users that are victims of brain-hacking would precisely fit in this description.

Physical and Psychological Safety

Brain-hacking and general neurocrime may not only threaten the security and confidentiality of brain information; they can also result in severe physical and psychological harm (e.g. traumatic experiences) to users. The degree of harm is proportionate to the level of benefit produced by the neural device in assisting the user's physical and psychological performance. For example, patients using BCIs to control wheelchairs may suddenly loose their reacquired spatial mobility and be led back to their original condition of impairment (prior to the BCI). Similarly, robotic limb users and patients using vision BCIs may lose respectively their reacquired motor capacity and visual perception. In addition, sophisticated forms of brain-hacking such the partial or full hijacking of the user's neural computation by the hacker, may cause direct physical and psychological harm to the user as they could result in self-violence and other detrimental activities.

Conclusion

A Matrix-like future where people can access and manipulate information from other people's brain is approaching rapidly. As neural engineering technologies become more and more widespread there is a fiduciary responsibility of experts to educate the population about what is reasonable to do. Collaborative research at the intersection between criminal law, cybersecurity, neurotechnology and neuroethics is urgently required to assess these challenges and protect present and future users of neural devices.

*2.9 - Hacking the Brain: Brain-Computer Interfacing and the Ethics of Neurosecurity**

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Abstract

Brain-computer interfacing technologies are used as assistive technologies for patients as well as healthy subjects to control devices solely by brain activity. Yet the risks associated with the misuse of these technologies remain largely unexplored. Recent findings have shown that BCIs are potentially vulnerable to cybercriminality. This opens the prospect of *"neurocrime":* extending the range of computer-crime to neural devices. This paper explores a type of neurocrime that we call *brain-hacking* as it aims at the illicit access to and manipulation of neural information and computation. As neural computation underlies cognition, behavior and our self-determination as persons, a careful analysis of the emerging risks of brain-hacking is paramount, and ethical safeguards against these risks should be considered early in design and regulation. This contribution is aimed at raising awareness of the emerging risk of brain-hacking and takes a first step in developing an ethical and legal reflection on those risks.

Introduction

The term brain-hacking refers to the emerging possibility of coopting brain-computer interfaces (BCI) and other neural engineering devices with the purpose of illicitly accessing or manipulating neural information from the brain of users. This paper offers an overview of the possible sorts of brain-hacking to which BCIs are or may become subject in the near future and provides an inventory of the specific ethical implications of brain-hacking. We will proceed as follows: first, we will discuss the main features of computer crime. Second, we will discuss the main features of neurocrime and brain-hacking. Third, we will offer a brief description of the BCI cycle. Fourth, we will identify what specific types of brain-hacking can occur at each phase of the cycle. Finally, we will delineate the major ethical implications emerging out of the

42 Current Impact Factor: 1.500 (2016)

phenomenon of brain-hacking. Although the ethical concerns we discuss in relation to brain-hacking may be found in relation to other technologies as well, we suggest that their particular combination with respect to BCI warrants a separate discussion, especially given the current and to be expected progress in BCI research and applications. Therefore, our aim is to provide a systematic treatment of the various ways of brain-hacking in relation to the different components of BCI. This contribution is aimed at promoting a public debate over the potential threats to neurosecurity related to the potentially widespread availability of BCIs among the general public, and takes a first step in developing a systematic ethical and legal reflection on brain-hacking. Future research is required to extend this analysis and to develop a comprehensive ethical, legal and regulatory framework.

Computer Crime

The number and quality of human activities enabled or mediated by computers is increasing rapidly. Emerging trends in information and computer technology such as big data, ubiquitous computing, and the Internet of Things are accelerating the expansion of computer use in our societies. Today, computers are used to perform or facilitate an enormous variety of tasks and activities of daily living including, but not restricted to, banking, trading, scheduling and organizing events, learning, entertaining, gaming and communicating. Computer use does not restrict solely to the social and economic domain. Several activities that are considered inherent to our psychological and biological dimension are now supported or facilitated by computing. Examples include the use of GPS systems in geolocation and spatial navigation, the use of wearables in monitoring bodily processes such as calories intake, heart beat rate, and weight loss, and the use of personal computers in performing cognitive tasks such as arithmetic calculus, writing, and memory.

As the uses of computers in human life have increased both in volume and in richness, the security threats to computing have also increased significantly. Notoriously, computer and information technologies can be used by actors for nefarious purposes such as cracking, fraud, identity theft, financial theft, and information warfare. The broad range of criminal activities that result from misusing computers and networks is referred to as *cybercrime*. Halder & Jaishankar (2011) define cybercrime as: "Offenses that are committed against individuals or groups of individuals with a criminal motive to intentionally harm the reputation of the victim or cause physical or mental harm to the victim directly or indirectly, using modern telecommunication networks” (*444*). Originally, cybercriminal activities were restricted to personal computers and related computer networks. With the dramatic expansion of the digital ecosystem many new opportunities for malicious exploitation should be expected. It is predicted that the current number of devices connected to the Internet will increase from 9 billion in 2011 to 50 billion in 2020, generating a flow of 50 trillion GBs of data (*445*). Devices such as watches, TVs, eye-wears, home-appliances, automobiles and medical devices are increasingly becoming sources of computational information and will irrigate the digital ecosystem with an unprecedented quantity of data flows and at an unprecedented velocity. This will also multiply the quantity of data and the number and type of devices that are potentially exposed to cybercriminality.

Many of the technologies responsible for this dramatic expansion of the digital ecosystem fit in the category of *disruptive technologies* as they make a lasting change to the technological landscape. Although disruptive technologies are designed to positively impact individuals and society, their technological novelty also opens 'breaches' for criminals. These breaches, as Dupont points out, are often “the result of a defective legal or regulatory coverage and provoke rapid increases in offenses” (*446*). In fact, regulation upgrade occurs at a much slower rate than technology upgrade and present security regulations are often incapable to effectively account for the accelerating changes generated by technology in human activities and infrastructures.

In this rapidly changing context, the goals of computer security, namely the protection of the confidentiality, integrity, and availability of information become more difficult to achieve (*296*). This increased difficulty does not arise exclusively from the quantity and velocity of data. Rather, the quality of information introduced into the data flow is crucial too. The more pervasive computing technology becomes, the more intricately it is interwoven into the everyday life. While this has the significant benefit of minimizing interaction friction between humans and machines, hence making computer-use effortless and more personalized, it also multiplies the classes of information that become accessible, hence potentially exposed to cybercriminal risks. Among these classes of information, biological information is critical[43].

43 The notion of biological information is used in this paper to extensively refer to information expressed in the processes characteristic of living organisms at various levels, i.e. at the levels of molecules, cells, organs, circuits etc. This definition is in accordance with the statistical definition of information formulated by Claude Shannon and used in mathematical information theory 447. C. Shannon, The mathematical theory of environments. *The Mathematical Theory of Communication.*

Medical computer technologies such as artificial cardiac pacemakers as well consumer-grade technologies such as wearable heart rate monitors are designed with the purpose of accessing and processing biological information –in this case, information about the beating of the heart. As the use of bioengineering devices is rapidly increasing, the amount of biological information irrigating the digital ecosystem will increase as a consequence. This raises the issue of privacy and information security, as biological information is carrier of private and sensitive data whose access or manipulation by malicious actors may cause significant physical (including life-threatening), psychological or social harm to technology users. An example of this emerging risk was provided by Halperin et al. (2008) who experimentally demonstrated that a hacker could wirelessly compromise the security and privacy of an already commercialized implantable cardiac defibrillator. In their experiment, hackers could use homemade and low-cost equipment to change a patient‘s therapies, disable therapies altogether, and induce potentially fatal processes such as ventricular fibrillation (*449*).

Neurocrime

The problems of technology misuse and security of biological information are particularly critical in the context of neurotechnology as this type of technology applies (either directly or indirectly) to a very important organ in the human body, the brain. The brain not only contributes significantly to life-maintaining processes (such as nutrition and respiration) but also to faculties such as consciousness, perception, thinking, judgment, memory and language and is of great importance to our behavior and our self-identification as sentient-beings or persons. Therefore, misusing neural devices for cybercriminal purposes may not only threaten the physical security of the users but also influence their behavior and alter their self-identification as persons. We call the realm of cybercriminal activities enabled by the misuse of neural devices *neurocrime*.

It is worth noting that neurocrime does not necessarily involve direct access to the brain and to brain information. Rather, neurocriminal activities are most likely to occur, at present, in a manner that affects the brain only indirectly, for example by limiting, modifying or

University of Illinois Press, Urbana, 1-93 (1949). . In Shannon’s sense, “anything is a *source* of information if it has a range of possible states, and one variable *carries* information about another to the extent that their states are physically correlated”. For a comprehensive understanding of the notion of biological information see: 448.P. Godfrey-Smith, K. Sterelny, Biological information. (2007).

disrupting function in the devices that interface brain computation. This type of risk is already critical at the current level of deployment of neural engineering technologies. With neurally controlled devices (e.g. brain stimulators and brain-computer interfaces) being available as medical technologies as well as commercialized products, present neurocriminals may abuse of the users by disrupting or terminating function in their devices without the users' permission or consent. For example, neurally controlled robotic limbs used to compensate for the motor deficits of amputated patients are potentially vulnerable to being mechanically destroyed by malicious actors, which would deprive the users of their re-acquired motor abilities. This type of neurocrime affects the brain only indirectly since the users' neural computation is not directly accessed or manipulated in any significant sense during the attack. Nonetheless, criminal activities of this type may affect significantly the mental life of the victims, because these activities can limit and constrain their behavior, generate emotional responses such as panic, fear, and psychological distress, and leave traumatic memories. In the light of this and in accordance with the previously reported definition of computer crime, we define the emerging phenomenon of neurocrime as offenses against individuals or groups of individuals with a criminal motive to intentionally cause direct or indirect physical and mental harm to the victim as well as harm to the victim's reputation and property by accessing or manipulating neural information through the use of neural devices. It is worth noting that, under some circumstances, the attacker and the target of the attack may be the same person. For example, mentally unstable users of prosthetic limbs may choose to damage their devices in an attempt to perform self-imposed harm.

From the perspective of neurocrime two types of neural devices are particularly critical at present: brain stimulators –especially Deep Brain Stimulation (DBS) and transcranial direct-current stimulators (tDCS)[44]- on the one hand, and brain-computer interfaces (BCIs) on the other hand. The reason for that stems from three basic facts common to both types of neural

44 Deep brain stimulation (DBS) is an invasive neurostimulation technique which involves the neurosurgical implantation of a medical device into the brain. This implanted device sends electrical signals into targeted subcortical areas with the aim of eliciting activity. DBS is an increasingly used therapy for several neurological conditions such as Parkinson's disease, dystonias, essential tremor, and chronic pain syndromes when patients are not responding to less invasive approaches 450. V. M. Tronnier, D. Rasche, in *Textbook of Neuromodulation*. (Springer, 2015), pp. 61-72..
Transcranial direct current stimulation is a neuromodulatory intervention which uses constant, low electrical current delivered to the cortical area of interest via small electrodes placed on the skull with the aim of changing neuronal excitability in that area 451. A. R. Brunoni *et al.*, Clinical Research with Transcranial Direct Current Stimulation (tDCS): Challenges and Future Directions. *Brain stimulation* **5**, 175-195 (2012).. This change of neuronal excitability may influence, and in certain cases enhance cognitive performance for a brief period of time on a number of different cognitive tasks .

device: (i) they potentially enable direct access to neural computation, although in diametrically opposite ways - brain stimulation vs. reading of brain activity; (ii) their use is widespread as they are both available not exclusively as medical technologies but also as commercialized products for healthy users (iii) they have the potential to generate safety and security concerns[45]. Being the only type of neural devices whose hackability has been proven in experimental and real-life settings, BCIs will be the only neural technology at stake in this paper. Further research is required to explore the specific neurocriminal risks associated with DBS, tDCS and other forms of neurostimulation.

Brain-Computer Interfacing

In contrast to neurostimulators, brain-computer interfaces are not used to stimulate the brain but establish a direct communication pathway that allows BCI-users to control an external computer device exclusively with brain activity, bypassing the peripheral nervous and muscle systems (*181*). BCIs originally developed in clinical medicine as a therapeutic or assistive technology for neurological patients. In clinical settings, BCI-applications are directed at repairing, assisting or augmenting cognitive or sensory-motor functions in patients experiencing cognitive or sensory-motor impairments including spinal cord injury, stroke, and motor neuron disease such as amyotrophic lateral sclerosis (ALS) and muscular dystrophy (*181*, *453*). For example, BCI-based motor prostheses have successfully been trialed in animal models and patients to enable direct brain control on artificial limbs, wheelchairs and other devices (*454*). To date, BCI-applications are available not only within clinical settings but also to the general public. Several commercial applications of EEG-based BCI devices have made their way onto the market and are becoming increasingly popular among healthy individuals for gaming and supporting everyday activities. For example, companies *Emotiv (http://emotiv.com/)* and *Neurosky (http://www.neurosky.com)* have pioneered the commercialization of consumer-grade non-invasive and easy-to-wear BCIs for gaming, interactive television, or as hands-free control systems. The electronic telecommunication industry is providing consumer-grade BCIs that are available for potential mass adoption. For

45 See, for example, the following two magazine reviews: 442. M. Conner, Hacking the brain: Brain-to-computer interface hardware moves from the realm of research. *EDN* **55**, 30-35 (2010); 452. E. Strickland, Brain hacking: Self-experimenters are zapping their heads. *IEEE Spectrum* **51**, 23-25 (2014).. Although concerns expressed by popular media may at times be exaggerated, they still may require appropriate responses by scientists and ethicists, if only to diminish or forestall unrealistic worries amongst the general public.

instance, iPhone accessories such as Xwave© allow the headset to plug directly into compliant iPhones and read brainwaves. Meanwhile, prototypes of next-generation Samsung Galaxy Tabs and other mobile or wearable devices have being tested to be controlled by brain activity via EEG-based BCI (*455*) In addition, neuromarketing companies such as Nielsen are using BCI-applications to better assess customer needs and preferences[46]. Given the significant potential benefits of brain control in computing —e.g. immediacy, hands-free control, portability etc.— Yuan and colleagues predict that BCIs will gradually replace the keyboard, the touch screen, the mouse and the voice command device as humans' preferred ways to interact with computers (*456*). Finally, a number of military and warfare BCI-applications are currently in development. The US Defense Advanced Research Projects Agency (DARPA) is currently funding a broad spectrum of BCI projects with two major purposes: (1) restoring neural and/or behavioral function in warfighters, and (2) enhancing training and performance in warfighters and intelligence agents (*429, 457*). For example, the Neurotechnology for Intelligence Analysts (NIA) has developed BCI systems utilizing non-invasively recorded EEG to significantly increase the efficiency and throughput of imagery analysis (*429*).

While the potential benefits and predicted distribution of clinical and non-clinical applications of BCI technology are significant, the neurosecurity risks associated with the widespread availability of this technology remain largely unexplored.

From Neurocrime to Brain-Hacking

Denning et al. (2009) provide prototype-examples of neurocrime. These include the wireless hijacking of a prosthetic limb, the malicious re-programming of neurostimulation therapy (e.g. the wireless alteration of the device settings to generate unsafe brain stimulation) and the eavesdropping of a brain implant's signals to reveal private information. These examples describe very specific neurocriminal phenomena where the attack is not simply directed at disrupting the neural device but at getting direct access to brain information. Neurocriminal activities of this type appear more specific than general neurocrime as (i) can only be performed on neural devices that establish a direct connection pathway with the brain such as tDCS, neural implants and BCI, (ii) involve the direct access to and manipulation of neural information, (iii) influence directly neural computation in the users. We call this special type of neurocrime "*brain-hacking*" as it exploits the neural device to get illicit access to and

46 http://www.nielsen.com/us/en.html (last accessed May 3, 2015).

eventually manipulate brain information in a manner that resembles how computers are hacked in computer crime. As in general neurocrime, also in brain-hacking the attacker and the target of the attack may be the same person. For example, a user may hack his or her own neurostimulation device to self-prescribe elevated moods or increase activation of reward centers in his or her brain (*296*).

Li et al. (2015) have provided an inventory of possible malicious brain-hacking based on the type of BCI application. They distinguish four types of BCI applications: (i) neuromedical applications, (ii) user authentication, (iii) gaming and entertainment, and (iv) smartphone-based application (*458*). For each of these application families they presented the current attack scenario and suggested possible countermeasures. Some forms of brain-hacking have already proven to be actually feasible in experimental as well as in real-life settings. Rosenfeld at al. (2010) have shown that brain-computer interfaces can be coopted to detect concealed autobiographical information from users with a significantly high accuracy rate (*440*). More strikingly, Martinovic et al. (2012) have successfully used brain-computer interfaces to reveal private and sensitive information about the users such as their pin codes, bank membership, months of birth, debit card numbers, home location and faces of known persons (*441*). We will discuss these possibilities in more detail below in section 2.2.1.

A sci-fi future where people can access and manipulate information in other people's brains is approaching and their prodromes are already here. Therefore, unless appropriate safeguards are considered early in the design of the neural devices that will be deployed in the next future (5–20 years), concerns of malicious misuse in the form of brain-hacking could become paramount for public safety.

The BCI cycle

BCIs can be distinguished into two types: invasive and non-invasive. Invasive BCIs record brain signaling via surgical implantation of electrode arrays in or directly connected to the central nervous system. Non-invasive BCIs interface brain signaling via neuroimaging technologies such as electroencephalography (EEG) and electromyography (EMG) that record brain activity through electrodes placed on the outside of the skull. As said previously, both invasive and non-invasive BCIs establish a direct interaction between the user's brain and a computer device. This interaction is usually described as a 4-phase cycle (*459*). See Figure 14: (adopted, with permission, from J. Farquhar/Braingain).

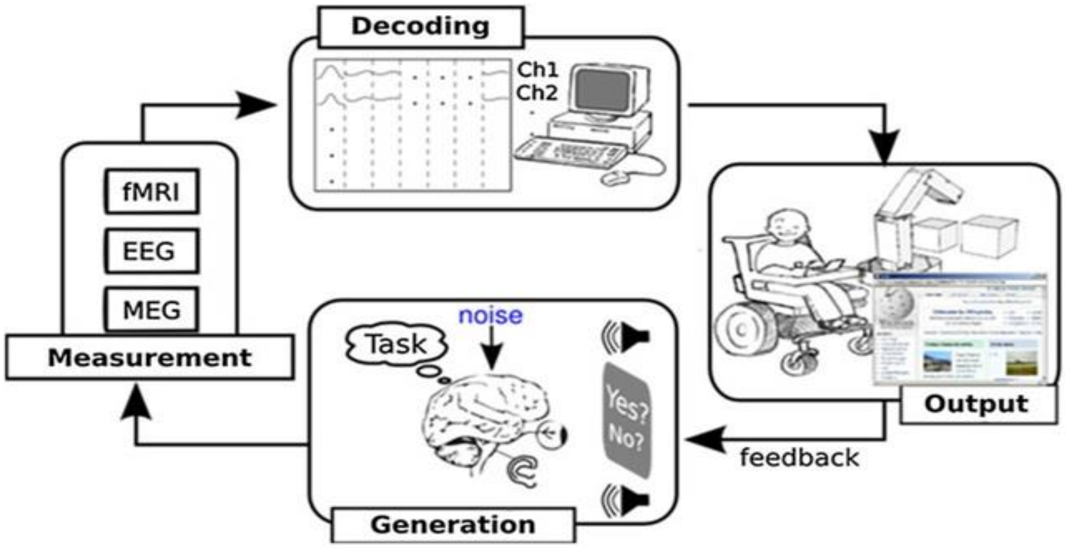

Figure 14- The BCI Cycle

The first phase concerns the input, i.e. the generation of specific brain activity by the user in response to a stimulus. This brain activity is generated when the BCI-user is in a certain cognitive state or performs a mental task. For example, when a BCI user is controlling a wheelchair a matrix of possible itinerary choices is presented on the interface that the user is watching. A frequent brain activation pattern used in BCI are the so-called event-related potentials (ERPs), i.e. measured brain responses that are the direct result of a specific sensory, cognitive, or motor event. Among these ERPs, increasing interest is surrounding the P300 wave, an ERP component usually elicited in the process of decision making(*460*). In our example, when the desired itinerary is presented (e.g. by highlighting or 'flashing' it) at the interface, the user's brain signals will contain a P300 signal that can be picked up by the BCI.

The second phase concerns the measurement and recording of brain activity. At this stage, patterns of brain activity in the user's brain are detected and measured by the interface during a cognitive process or the performance of a mental task. For example, when a certain itinerary option upon which the BCI-user is focusing is flashed (say, a specific end-location, or an instruction to turn left), the BCI can detect the P300 wave elicited at that moment. The measurement can be implemented in several ways according to the type of BCI in use. The most frequent type of BCI is based on electroencephalogram (EEG); other measurement options include magnetoencephalography (MEG), and functional magnetic resonance imaging (fMRI).

In order to be usable for the BCI and generate appropriate outputs (i.e. those expected by the user), the raw data measured in the second phase should be decoded into its main features and classified. This decoding and classifying process typically occurs in the third phase of the BCI cycle. In this phase, data are processed in order to 'clean' the brain signals, namely to increase the signal-to-noise ratio (i.e. a measure of strength of the desired signal relative to background noise) and to filter the most relevant aspects of each signal for further processing. This processing is necessary to extract the relevant features from the signal and distinguish them from non-relevant features, especially from the background noise due to the underlying brain activity that is not directed at the execution of that specific mental task (in our example, the activity that is not directed at moving the wheelchair, e.g. processes involved in color perception).

Once the signals are decoded, they can be translated into output. The output is usually the performance of the action initially intended or desired by, or deemed beneficial for, the user through the control of the applications interfaced by the BCI (in our example, turning left with the wheelchair). Controllable applications include motor devices (e.g. wheelchairs and robotic limbs), sensor devices as well as several software and hardware applications (including apps for smartphones). Once each cycle is completed the user can perceive the feedback resulting from the previous cycle (e.g. notices the wheelchair turning left) and the next cycle can start.

Brain-hacking

Brain-hacking can in principle occur at each of the different phases of the BCI-cycle. In the following, we will provide an overview of the sorts of brain-hacking to which BCIs are subject at present or may be subject in the near future according to the phase of the BCI-cycle at which the attacks may occur. For each sort of attack it will discuss the corresponding criminal activities that can be committed and the type of moral values and norms that are at stake.

Input Manipulation

Brain-hacking via input manipulation occurs when the hacker attacks the BCI user at the moment of providing input, i.e. at the first phase of the BCI cycle[47]. Input information can be

47 It is worth noting that there are two potential meanings of *input* here: (i) the user provides input to the BCI through brain activity; (ii) the interface provides information (e.g. a screen with commands) to the user. To

manipulated by altering the stimuli presented to the user. For example, brain-hackers may preselect target stimuli to elicit specific responses in the user that may facilitate the access the user's neural information. This type of hack has been proven to be actually feasible by recent research in computer security and human-computer interaction. For example, Rosenfeld at al. (2006) and have developed a P300-based protocol to detect concealed autobiographical information from users with a significantly high accuracy rate (*461*). Van Vliet et al. (2010) have used the N400 component of ERP to detect what a BCI user is 'thinking about' without using explicit stimuli (*462*)[48]. Particularly striking are the results by Martinovic et al. (2012). In this study, researchers presented EEG BCI-users with six classes of stimuli: (I) PIN code digits, (ii) photos related to banks, (iii) names of the months, (iv) debit card digits, (v) locations, and (vi) faces. For each class, one target stimulus (i.e. stimulus eliciting sensitive information known to the user) was inserted in the randomly permuted sequence of non-target stimuli (*441*). For example, in the bank experiment, the target stimulus was the picture of an ATM machine from the user's bank whereas the non-target stimuli were a series of pictures of ATMs from other banks. The goal of the study was to detect a P300 signal in response to private and sensitive information about the users (their pin codes, bank membership, month of birth, debit card numbers, home location and faces of known persons) and extract that information. Since this information is usable for monetary transactions, home banking and log-in to private on-line accounts, extracting this information may enable hackers to perform offenses against BCI users. The results show that this sort of input-manipulation can turn the BCI against users in order to reveal some private information with a significant chance of success: in fact, the Shannon entropy of the private information was decreased on the average by approximately 15%-40% compared to random guessing attacks[49] (Martinovic et al. 2013, p. 1). Such sorts of malware resemble the function of computer spyware as they aid in gathering information about a user, in sending it to another entity, or in asserting control over a computer or computer-driven device without the user's permission or consent. Unlike common spyware, however, the malware

disambiguate, in this section we will refer exclusively to the latter as this type of input is the only one whose hackability was proven in the experimental setting.

48 The ambiguous term 'thinking about' is defined by the authors as 'being primed on'. Since the priming effect occurs for many types of stimuli (e.g. words, sounds, and images) the authors assumed that a subject can prime himself by being told to think about an object. See van Vliet et al. (2010, p. 183).

49 In order to quantify the information leak that the BCI attack provides, the researchers compared the Shannon entropies of guessing the correct answers for the classifiers against the entropy of the random guess attack. The entropy difference directly measures the information leaked by an attack; see Martinovic et al. (2012, p. 11).

involved in brain-hacking extracts information directly from brain signaling, hence the name *'brain-spyware'*. The potential set of applications of brain-spyware in future cybercrime is large and may involve several criminal activities such as password cracking, identity theft, phishing and fraud.

An additional breach for brain-hacking via input-manipulation is authentication via EEG signal. Li et al (2015) have reported an attack model by impersonating the thoughts of subjects using EEG generative model based on the historical EEG data from a subject (*458*).

It is worth to point out that at the current level of development of BCI technology three major technical limitations prevent the diffusion of brain-hacking cases outside the clinical setting: (i) measurement accuracy, (ii) processing speed, and (iii) distribution. As we have seen in the previous Chapter, in the decoding phase of the BCI cycle data must be processed in order to increase the signal-to-noise ratio and segregate relevant from non-relevant information. For today's hackers, decoding brain signals with a level of accuracy and at a speed comparable to cracking computer codes is still impossible outside the experimental settings. This is exacerbated, by the limited commercial distribution of portable BCI-applications. Given the limited readability of brain signals and the current level of maturity of the market, for today's hackers the reward may not be worth the risk. However, as technology advances and the BCI-market rapidly expands, brain data will reveal more and more and their level of readability will rapidly increase.

Measurement Manipulation

Brain-hacking can also occur when the hacker attacks the BCI user during the phase of the measurement in order to generate - without the user's permission - outputs that are different from those expected to be generated by regular processing. Attacks of this type may differ with regard to their purpose. Three main criminal purposes are foreseeable: cracking the BCI's raw data, disrupting BCI's function, and hijacking the BCI. A real-life protoexample of BCI-cracking is the so-called Cody's Emokit project, developed by the hacker Cody Brocious. Brocious cracked the encryption of a consumer-grade BCI produced by Emotiv (called EPOC) and built a decryption routine. Subsequently, he created an open-source library for reading encrypted data directly from the headset, and posted about his project on the Emotiv user forum. As Conner explains: "his library of code hacks to the device just pulls raw data from the unit; there's no ability to filter the signals or tell which sensor corresponds to each data stream"(*442*). It is worth to highlight that Brocious' hack had no malicious motive. In contrast, it was designed to open EPOC’s source code and open up the device to development (hence with the ethical purpose of accelerating secure new products and research). However, malevolent agents can use similar strategies to illicitly crack information as a form of dual-use.

Attacks by BCI disruption may occur when the hacker aims at manipulating the measuring process in order to confuse, sabotage or delay the function of the BCI application. The function of a BCI can be disrupted, at the level of measurement, by adding noise to make the measurement inaccurate. Hijacking may occur when the hacker tries to monitor and alter the BCI communication channel with the purpose of diminishing or even replacing the user’s control of the BCI application. During hijacking the system is given other commands than those intended or desired by the user, for the benefit of the hacker. Brain-hackers could manipulate the measurement by adding noise in order to diminish or eliminate control of the user over the BCI application. For example, a frustrated caregiver could hijack a BCI-enabled speech production device to silence a cognitively impaired user or a wheelchair to force the user to follow a certain itinerary. More generally, measurement manipulation by hijacking may result in several criminal activities aimed at limiting, harming or taking advantage of the BCI-users' behavior.

Decoding and Classifying Manipulation

Brain-hacking at the level of decoding and classification is also aimed at generating outputs that are different from those intended or desired by the user, and expected to be generated by regular processing. This criminal goal may be achieved in three ways: (I) by adding noise to simply make the decoding process unduly difficult; (II) by intervening with the machine learning component (so strictly speaking, moving to the feature classification phase) in order to manipulate the classification of the brain signal; or (III) overriding the signal sent by the BCI to the output device[50]. Each of these hacking strategies will have peculiar pros and cons. For example, the noise-adding hack will have the advantages (from the perspective of malicious actors) of being more easily performable and less easily detectable than the other two but it will also make it more difficult for the hackers to have the BCI application do what they want. In contrast, the other two hacking strategies will be more difficult to perform and more easily detectable than the former but they will, in principle, enable the hackers to have more control over the BCI system. Similarly, as in measurement-manipulation, brain-hackers can intervene at

50 It is worth noting that the first strategy (adding noise) is similar to the one discussed at page 210 with regard to measurement manipulation. However, at this level, the consequence we discuss may be different as the aim of the intervention here is to delay or complicate the decoding process.

the level of decoding and classification with the criminal motive of hijacking the BCI-application. The peculiarity of attacks at this phase of the cycle, however, is that the hijacking may not be simply aimed at diminishing or expunging the control of the user over the application, but also at replacing control. Brain-hackers may try to monitor and alter or inject messages into the BCI communication channel with the purpose of replacing the user's control of the BCI application. During hijacking, the system is given other commands than those intended or desired by the user, for the benefit of the hacker. Successful hijacking will result in the hacker having partial or full control over the BCI application and the BCI user having diminished or no control on the application. This would expose the user to perils directly or indirectly induced by the hijacker. For example, a criminal actor could hijack the BCI-controlled smartphone of a BCI-user without the user's permission to extort payments, erase sensitive information or communicate with third parties by masquerading his or her identity under the identity of the user (hence performing offences including fraud, theft and identity theft). In addition, as we have seen before, hijacking strategies could also become sources of threat to the personal safety of third parties, as the hijacked device could harm third parties either accidentally or as an explicit command of the hijacker.

Although no confirmed real-life or experimental reports of hacking via measurement or decoding and classifying manipulation are available at present, these types of brain-hacking deserve particular monitoring in the context of security, surveillance and public health. The reason for that stems from the fact that their potential nefarious outcomes are not exclusively restricted to actions involving the access to sensitive information (e.g. identity theft and fraud) but extend to more detrimental activities involving the physical and psychological harm of the users.

Feedback Manipulation

Brain-hacking by feedback manipulation would occur when the hack is aimed at altering the feedback perceived by the user at the end of each cycle. This type of hack would aim at manipulating the perception that the user has of previous actions performed or the self-perception of previous cognitive states generated through the BCI. The criminal motive underlying these hacks would be to induce –without the user's permission- particular cognitive states or actions in the subsequent cycle of the user for the advantage of the hacker. For example, brain-hackers could perform a sort of "brain-phishing" in which the user is required by the hacker to insert a password or another type of authentication information before the originally intended process can continue (e.g. a user could be asked for a password to actually start the program she has mentally commanded). Through the same mechanism, traumatic experiences could be induced in the user to his or her detriment. Criminal activities performable through this hack may include fraud, phishing, identity theft, and physical or psychological harm.

These different sorts of hack with their related type of malware, and potential criminal activities are presented in Table 9:

Phase	Type of attack	Criminal activity	Ethical problem	Proved feasibility
Input	Providing misleading input	Password/PIN cracking Identity theft Fraud Phishing	Privacy Confidentiality Personal security	√
Measurement	Noise addition Manipulating classification	Disruption Termination Hijacking	Psychological distress Physical harm Diminished agency	–
Decoding	Overriding signal sent to output	Disruption Termination Hijacking	Psychological distress Physical harm	–
Output	Feedback alteration	Disruption Termination Hijacking	Diminished agency Psychological distress Physical harm Uncertain personhood Uncertain moral responsibility	–

Tab. 9- Synoptic view of malicious brain-hacking

Ethical Implications

These four sorts of brain-hacking have several ethical and legal implications. Some of these implications are cross-categorical, i.e. apply to all forms of brain-hacking, whereas some others are peculiar to a specific category of hack. In this section an inventory of the ethical implications of brain-hacking will be provided. Further research is required to develop each of these implications into a detailed ethical and legal analysis to inform future regulatory strategies for the prevention of neurocrime.

The Dual-Use Dilemma of Brain-hacking

Cross-categorical ethical implications involve the general problem of dual-use and the obtainment of informed consent. By dual use it is meant the fact that the same beneficial scientific knowledge or technology can be used for good as well as for nefarious purposes (*463*). Dual-use is a particularly crucial ethical concern in computer, telecommunication and information technology, since computers and networking technologies are frequently used by actors for cybercriminal purposes. Therefore, the ethical implications of dual-use, in particular the dual-use dilemma, also apply to BCI technology and the phenomenon of brain-hacking.

The peculiar dual-use dilemma of brain-hacking can be summarized as follows: the same neural device (e.g. the same BCI) has the potential to be used for good (e.g. assisting cognitive function in neurological patients) as well as bad purposes (e.g. identity theft, password cracking and other forms of brain-hacking). This dilemma is primarily faced not only by researchers and technology developers, but also by companies because of their potential product liability and by governments as they are committed to promoting health and security of their citizens.

At the current level of diffusion and sophistication of brain-hacking, the benefits produced by BCI development for patients and society significantly overwhelm the costs associated to brain-hacking and other neurocrime. Although some mild forms of brain-hacking have been proven feasible in experimental settings or in real-life tests (as in Cody's Emokit project), there is no confirmed report of criminal and/or detrimental activities involving BCI to date. However, the phenomenon of brain-hacking should be constantly monitored and appropriate safeguards should be considered early in the design and deployment of the neural devices as the opportunities for criminal offense and malicious exploitation related to BCI are predicted to significantly increase in the near future. These safeguards may include:

- The development of mechanisms and methods for anonymizing neural signals. A promising example of this is the Brain-Computer Interface Anonymizer (patent US 20140228701 A1), a method to generate anonymized neural signals by filtering features to remove privacy-sensitive information (*464*).

- The deployment and integration of security mechanisms to detect uncharacteristic increase of noise in BCI-processing at the level of measurement as well as at the level of decoding and classification.
- The deployment of feedback mechanisms for users to allow them to signal clearly undesired or uninitiated output of the device. In vulnerable (e.g. physically disabled or cognitively impaired) users these feedback mechanisms may be connected to alarms and/or location services that allow the hacked-users to automatically alert a response center (e.g. their caregivers or public safety authorities) and receive prompt support.
- The deployment of machine learning self-control mechanism for detecting severe inconsistencies in the classification of features. These self-consistency check mechanisms could detect criminal circumstances where the brain-hack occurs at the level of decoding and classification of features.
- The provision of specific training sessions for clinical BCI-users to train the users' resistance to brain-hacking, especially brain-hacking via input-manipulation. These trainings could include the instruction of specific responses to potentially unsafe stimuli such as those related to banking and authentication methods and could be directly provided by the health-care institution where the user is allocated.
- The inclusion of free neurosecurity demos into the BCI-package for general users. Future commercially available BCI-packages may include a small introduction software package containing a brief serious game demo with instructions and safety-guidelines related to brain-hacking.

It is a major role for current neural engineering and information security organizations to call for awareness regarding the dual-use risks associated with brain-computer interfacing and design regulatory mechanisms that could enhance the safety and security of present and future BCI applications. In addition, it is important to raise awareness among the general public on the ethical implications associated with the phenomenon of brain-hacking and to stimulate the understanding and practical application of guidelines aimed at protecting and promoting the privacy, autonomy and integrity of the individual.

Informed Consent

Ethical issues with respect to informed consent for BCI-use interventions especially focus on the ratio between the high expectations that BCI technology may generate and the possible vulnerability of potential BCI users (*465*). For example, in the case of severe neuromuscular patients such as LIS patients, high expectations on the liberating effect of BCI technology may represent a major ethical challenge, since these expectations could undermine patients' evaluation of risks and benefits, including the risks associated with the phenomenon of brain-hacking. Vulnerable patients may be more likely to accept a higher risk of information insecurity, hence become more exposed to brain-hacking. To prevent this, accurate monitoring and reporting of the phenomenon of brain-hacking is recommended not only for scientists and ethicists but also for technology producers and the media. Inaccurate or insufficient reporting may result in generating unrealistic expectations in patients and reducing their perception of risk. In addition, more rigorous procedures for informed consent should be implemented to increase the user's understanding of the risk-benefit ratio. It is worth remembering that getting informed consent is especially challenging when communicating with severely paralyzed target users such as those suffering LIS. Impaired communicative capacities of LIS patients require paying attention also to some characteristics of information and communication that are not reducible to verbal communication (e.g. eye blinking). As Clausen (2011) note, this is especially important for the questions whether the patient understands the information correctly, and whether there are any questions left for him/her (*465*).

Privacy, Confidentiality and Security

Particular ethical problems are posed by each single sort of hacking. Two major ethical problems are associated with hacking through input-manipulation. The first one is privacy. The possibility of extracting private and sensitive information from the brain of users represents a significant treat to privacy and data protection. Users that are victims of this sort of brain-hacking typically lose the ability to seclude confidential or inherently sensitive information about themselves, thus experience an intrusion of their private sphere (*466*). This ethical problem is particularly significant because privacy is a priority issue in a free society, closely linked to civil liberties, democracy and human rights (*467*). The protection of privacy and confidential data is a primary commitment in the United States as well as in the European Union where there is a collaborative push for modernizing the current data protection principles, strengthening the data protection mechanisms, ensuring police and criminal justice cooperation and a proper enforcement of the rules on privacy and confidentiality (*468*).

The second problem is security. As experimentally shown by Martinovic et al. (2012), brain-hacking via input manipulation exposes BCI users to the risk of losing surveillance over their personal and financial security. Additionally, the opening of a breach into private and confidential information implied by input-manipulation also exposes users to physical and psychological insecurity. The reason for that stems from the fact that the sort of information potentially extractable from a user's mind does not limit to financial information but may extend to information about the health condition of the users, their profession, location, psychological capacities, sexual preferences, religious beliefs, routine activities etc. For example, Martinovic at al. (2012) have proved the feasibility of extracting information about the user's place of residence and date of birth, two types of information that are directly involved in personal security. It is expected that other types of equally complex information can be extracted in a similar manner (*466*). This type of information is potentially of interest not only to criminals involved in harmful activities such as blackmail but also to employers and insurances. For example, health insurance companies may be interested in extracting information about the medical records of the user to accept or reject her enrollment into an insurance plan or to determine her insurance premiums. Similarly, employers could extract information about the user’s political views or sexual preferences and commit political or sexual orientation discrimination.

Physical and Psychological Safety

Brain-hacking via measurement-manipulation, decoding-manipulation, and feedback-manipulation pose a problem for physical and psychological safety. These types of hacking may result in severe physical and psychological (e.g. traumatic experiences) harm to users in a way that is proportionate to the level of benefit of the BCI in assisting the user's physical and psychological performance. For example, patients using BCIs to control wheelchairs may suddenly lose their reacquired spatial mobility and be led back to their original condition of impairment (prior to the BCI). Similarly, robotic limb users and patients using vision BCIs may lose respectively their reacquired motor capacity and visual perception. This sort of attacks require immediate monitoring in the context of security, surveillance and public health as they may not need to involve sophisticated malware development, hence can performed also in absence of specific cybercriminal skills.

In addition, BCI users that are victim of these types of attack may experience psychological distress as a result of their incapacity to perform the actions that they are mentally inducing. This distress would be particularly significant in LIS patients who use

BCIs as the only available connection to the external world[51]. As the primary goal of implementing neurotechnologies in health-care is promoting the benefit of the patient, the development of regulatory mechanisms for protecting physical and psychological safety will be required. Equally strict and rigorous regulatory mechanisms should protect healthy people who use consumer-grade BCI for entertainment, gaming and communication.

Autonomy, Agency and Personhood

Particularly critical ethical and legal implications are posed by brain-hacking through decoding and feedback-manipulation. The reason for that stems from the fact that these types of brain-hacking, as previously mentioned, would not simply enable malevolent actors to access information but may cause changes in the user's decision-making and/or behavior. This possibility for an external control over the user's future behavior seems to substantially conflict with the moral values of personal autonomy and free agency and may even interfere with the self-determination of personal identity. Personal autonomy is generally understood as the capacity of someone to deliberate or act on the basis of one's own desires and plans and not as the product of manipulative or distorting external forces (*469, 470*). Autonomous individuals are those that are able to act freely in accordance with a self-chosen plan. By contrast, potential victims of brain-hacking may see their deliberation and action being partially limited, controlled or interfered by malevolent others. From this perspective, the way brain-hackers influence the users' decisions and behavior seems to substantially undermine their individual autonomy. The threat to autonomy posed by brain-hacking will be exacerbated in the clinical context as it would affect an extraordinarily vulnerable class of individuals such as patients with severe neurological disorders. In medical ethics, autonomy, conceived at minimum as a "self-rule that is free from both controlling interference by others and from limitations" (Varelius, 2006), is usually considered a fundamental requirement for the respect of patients and the protection of their dignity (*118, 237*). It is important to stress, however, that although hacked BCI-users with severe neurological conditions would be exposed to the risk of diminished autonomy if compared to non-hacked users with the same condition, they may, nevertheless, achieve greater overall autonomy than equally impaired patients who do not have access to BCI whatsoever. This fact is worth extensive philosophical reflection, since the counterintuitive situation that the

[51] Here too, there is a difference between hacking by disruption and hijacking, as the psychological stress involved in doing something different from what the user intended may differ from the traumatic experience of losing control over oneself.

same technology can both increase and diminish autonomy requires quite detailed analysis of the benefit-risk ratios in different scenarios.

The challenge to autonomy posed by these types of brain-hacking also raises the issue of coercion, i.e the exercise of a constraining power on another party (besides the use of force, violence, and threats thereof) with the purpose of forcing him or her to act in a non-voluntary manner (*471*). As such, brain-hacking could raise a novel, more subliminal (since performed below the victim's threshold of consciousness) form of coercion which adds to extortion, blackmail, torture and other currently performed forms of coercion.

Strictly related to the notion of autonomy is the notion of agency, i.e. the capacity of an agent to act, and the capacity to distinguish between events that are self-initiated versus simply occurring (i.e. experiencing the difference between doing something and having something happening to you). The sense of agency serves to identify the range of one's actions (i.e. activities actively performed by agents) from those events that are passively caused by external forces. For example, jumping into the water is considered an action if the jump is performed by the agent without being caused by external forces (e.g. being forced into the water by another person or by the wind). Similarly, controlling a wheelchair via BCI is an action if it is performed intentionally by the agent. In itself, BCI already contains the possibility to result in considerable uncertainty of the BCI user about whether or not the user actually did or did not perform a BCI mediated action, e.g. in case of error (*472*). When another agent, e.g. a remote hacker, gains control over the application and determines the actions of the user, the agency of the BCI user diminishes and the uncertainty of ascribing the action to the user increases significantly. This is ethically problematic for three major reasons. First, because the detachment of the intention-action causal link prompted by brain-hacking may result in psychological distress and for the user. Second, because it generates uncertainty about the voluntary character of the user's actions. Third and consequently, because in Western jurisprudence the capacity for voluntary control over one's own actions is consider a requisite for legal liability. Therefore, diminished or absent voluntary control over one's own actions would result in diminished or absent legal liability of the user with regard to those actions. This intimate link between agency and legal liability is explicitly expressed by the USA Model Penal Code (MPC), Section 2.01, which states that "(1) a person is not guilty of an offense unless his liability is based on conduct that includes a voluntary act or the omission to perform an act of which he is physically capable". The MPC also provides a list of examples of non-liable acts which includes: "(a) a reflex or convulsion; (b) a bodily movement during unconsciousness or sleep;

(c) conduct during hypnosis or resulting from hypnotic suggestion; (d) a bodily movement that otherwise is not a product of the effort or determination of the actor, either conscious or habitual" (*473*). The performance of an act as a consequence of brain-hacking via output manipulation seems to fit in at least three of the four above mentioned explicative categories, as the act is not a product or determination of the BCI user but of the hacker. Problems of uncertain legal liability are expected to arise. Collaborative research at the intersection between criminal law, cybersecurity, neurotechnology and ethics will be required in the next future to assess these problems in a manner that facilitates the judicial circuit and protects BCI users.

Conclusions

This paper took a first step in addressing the issue of brain-hacking and raising awareness on the ethical and security implications associated with the malicious use of BCI technology. An overview of the possible vulnerability sources of BCIs and their related sorts of brain-hacking was offered. Additionally, an inventory of the major ethical implications of brain-hacking via BCI was provided. Further interdisciplinary investigation is required to extensively analyze those implications and to develop a normative and regulatory framework that allows maximizing the benefits of BCI technology while minimizing its potential risks.

BCI applications have the potential of significantly improving life quality in patients (especially in patients suffering severe neuromuscular disorders) and enabling enhanced and more personalized user experience in communication, gaming and entertainment for general users. However, the potential benefits of this technology may be tempered if security issues and ethical-legal considerations remain unaddressed. Ideally, this debate should involve the collaboration of ethicists, neuroscientists, engineers, computer scientists, cybersecurity experts, lawyers and other significant stakeholders and inform regulators and policy-makers.

Competing Interests

The authors declare that they have no competing interests.

*2.10. - Brain Leaks and Consumer Neurotechnology**

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One Sentence Summary: Greater safeguards are needed to address the personal safety, security and privacy risks arising from increasing adoption of neurotechnology in the consumer realm.

Rapid advances in neuroscience, clinical imaging, digital health and the internet of things (IoT) are propelling neurotechnology from the exclusive domain of the medical clinic to an ever-increasing number of direct-to-consumer (DTC) applications. Today, numerous neuromodulatory devices and brain-computer interfaces (BCIs) are becoming available to consumers, with associated accessories, mobile applications, software frameworks, and online services.

[52] Current Impact Factor: 46.223 (2016). Ownership of copyright in original research articles remains with the Author, and provided that, when reproducing the contribution or extracts from it or from the Supplementary Information, the Author acknowledges first and reference publication in the Journal, the Author retains the following non-exclusive rights: To reproduce the contribution in whole or in part in any printed volume (book or thesis) of which they are the author(s). The author and any academic institution, where they work, at the time may reproduce the contribution for the purpose of course teaching. To reuse figures or tables created by the Author and contained in the Contribution in oral presentations and other works created by them. To post a copy of the contribution as accepted for publication after peer review (in locked Word processing file, of a PDF version thereof) on the Author's own web site, or the Author's institutional repository, or the Author's funding body's archive, six months after publication of the printed or online edition of the Journal, provided that they also link to the contribution on the publisher's website.

DTC headsets allow individuals to engage in various activities without medical supervision, such as monitoring cognitive health and wellbeing, optimizing brain fitness and performance or playing virtual games. Companies, such as Neurosky and Emotiv Systems, offer assortments of smartphone-compatible DTC neurodevices; large electronics and social media companies, such as Samsung (Seoul) and Facebook (Menlo Park), are testing future products controlled via electroencephalography (EEG) detected brain signals.

As neurotechnology becomes more common outside of the clinical sphere and in the consumer market, brain derived data will increase in quantity and will require new solutions that are both capable of effective storage and sharing and that also ensure protection of privacy and security. Brain recordings in connection with other types of online information will add to the increasing proliferation of comprehensive electronic user profiles. These developments raise two fundamental questions for society and the biomedical community: Are our current digital infrastructures adequate for this upcoming proliferation of consumer-generated neurological data? And what legal and ethical safeguards need to be put in place to ensure individual rights, such as privacy and data security, are protected?

An expanding DTC universe

According to a recent review by neurotechnology market research firm *SharpBrains*, the number of patent classifications related to DTC neurotechnology has more than doubled in the past 10 years(*474*). Currently, over 8,000 active patents are focused on neurotechnology, with just as many pending applications. Another market research report by Neurotech Reports projects that the overall worldwide market for neurotechnology products will be $8.4 billion in 2018 and will reach $13.3 billion in 2022. Indeed, at last year's 'NeuroGaming' conference in San Francisco, the hyperbole rose to fever pitch, with delegates heralding the dawn of "the pervasive neurotechnology age" in which everyday wearable technologies will be non-invasively connected to brains.

DTC neuromodulatory and imaging devices open new opportunities for self-monitoring and cognitive training in fields as diverse as mental health and education. And as neurodevices increase in portability and affordability, neurotechnology is likely to become increasingly pervasive. Three types of neurotechnology that are entering the consumer products market pose the greatest concern for privacy and security: BCIs for device control or self-monitoring; devices for non-invasive neurostimulation; and neuromarketing applications of neuroimaging technology.

Self-monitoring, home therapy and neuromarketing

As yet, only a few of these three different types of neurotechnology device relevant to the DTC space have been published in the peer-reviewed literature. We discuss each in turn to exemplify the types of privacy and security issues that arise when applied in the DTC market.

Self-monitoring using BCIs. Portable EEG headsets like Emotiv Epoc+ and Neurosky Mindwave are available in the consumer market with prices ranging between $99.99 and $799.99. These products enable access to raw EEG data with proprietary software subscription for a variety of purposes including monitoring attention levels or controlling virtual objects. However, their privacy and security standards are questionable. In 2013, researchers used a consumer headset to demonstrate that EEG-measurements of an event-related potential elicited in decision making (the ‘P300’) can be successfully used to extract financial and identity-related information from BCI-users without their knowledge or consent(*441*). In this experiment, users were exposed to various classes of visual stimuli (e.g., bank cards, PIN (personal identification) numbers, area of living and the knowledge of known persons) through *ad hoc* designed ‘brain-spyware’; that is, software intentionally designed to extract private information from brain recordings. For each class of stimuli, one target stimulus (i.e., stimulus eliciting sensitive information known to the user) was inserted in a randomly permuted sequence of non-target stimuli. Through the analysis of the captured EEG-signal, researchers were able to detect which of the presented stimuli were related to the user’s private or secret information, such as the user’s home address and PIN code digits. Such information leakage from the user revealed a significant chance of successful extraction of sensitive data. Compared with random guessing attacks, the EEG information can enhance identification accuracy of private information by ~15–40 % on average.

Similarly, researchers at the University of Washington have developed a BCI game, called ‘Flappy Whale,’ in which players are presented with overt visual stimuli while EEG and electromagnetography (EMG) signals are recorded. The results of the experiment confirm the feasibility of extracting private and sensitive information from BCI-users through subliminal stimulation. Although Flappy Whale was designed to measure responses to relatively innocuous information (e.g. logotypes of commercial brands), its creators claimed during the Enigma Conference 2017 in Oakland, CA, that the same model has the potential to extract more sensitive information, such as financial information or even personal beliefs(*475*).

Devices for non-invasive neurostimulation. Security breaches might be also enabled by another type of neurotechnology: transcranial current stimulation (tCS), which encompasses various techniques, such as tDCS (transcranial direct current stimulation), tACS (transcranial alternating current stimulation) and tRNS (transcranial random noise stimulation). Thus far, mechanisms for these approaches have yet to be completely defined: tDCS applies a constant electric field dependent on polarity that is thought to have short-term effects on neuronal excitability likely through cell membrane polarization; tACS applies an oscillatory electric field with a specific frequency and phase that modulates brain oscillations supposedly through 'entrainment'; and tRNS applies white noise (1–640 Hz) to modulate cortical excitability likely though 'stochastic resonance'. A related set of neurostimulatory devices use transcranial magnetic stimulation (tMS) to influence cortical activity.

An increasing number of the above devices are being approved by the US Food and Drug Administration (FDA) for use under prescription. But many of these neurodevices are also being marketed in the DTC realm. Commercial applications of tDCS device kits, such as Neuroelectrics' StarStim8,http://www.neuroelectrics.com/products/starstim/starstim-8/ are of particular concern because they often rely on wireless (Bluetooth) connections between a home-computer and the device, allowing unsecured data transmission that can be intercepted by third parties. For tMS, Neuronetics and eNeura have FDA-approved devices for depression and migraine, respectively; other tMS devices are also entering the consumer market. Other products are available without FDA certification.

In addition to privacy and data security issues, researchers have also questioned the safety of these neurostimulation techniques, arguing that some longer-term side-effects (e.g. build-up of stimulating effects in non-target areas) are poorly known, and expressed concern that the adjective "non-invasive" may mislead non-expert users into the belief that the effect of the technique is by definition mild.(*476*) These concerns become particularly relevant in the context of widespread and unsupervised uses of advertised DTC products, especially when some claims, such as improving cognitive performance and mental wellbeing, are not sufficiently substantiated by validated scientific evidence.(*477*)

Neuromarketing and neuroimaging. The combination of neuroimaging techniques, such as functional magnetic resonance (fMRI), and machine learning also presents new concerns regarding breaches of mental privacy.(*478*) In a study conducted at the University of California, participants were shown movie trailers while undergoing an fMRI scan. Decoding fMRI data, the researchers used a machine learning algorithm to reconstruct the videos(*479*). Although the reconstructed videos remained blurry, researchers effectively proved the feasibility of reconstructing visual content from neural data. Given the self-improving capacity of the algorithm and the increasing accuracy of neuroimaging scans, the brain-reading potential of such technology is likely to increase substantially in the near future.

In parallel, the development of innovative magnetoencephalography (MEG) techniques that do not require superconducting technology could lead, in the near future, to a new generation of lightweight wearable neuroimaging headsets.(*480*)

Although the neuroimaging tools above are not currently applied in the DTC context *stricto sensu* due to their limited portability, the increasing application of similar devices in commercial settings opens new possibilities for collection and analysis of neural information outside the clinical or research domain. This information can be used by neuromarketing research companies to study −and possibly influence−consumer behavior and perception. Neuroimaging applications in commercial settings, especially in neuromarketing, are of particular ethical concern because they are not required to comply with the same ethical guidelines as clinical research. Unlike clinical research, neuromarketing companies are free to conduct neuroimaging studies of humans in the consumer space without formal approval from an ethics committee and rigorous informed consent from study participants. Furthermore, once DTC neuromonitoring becomes sufficiently widespread, big data analytics can be performed on large-scale datasets of user-generated neural data without explicit user consent.

Privacy and information security risks

Historically, at the early stages of technological innovation security risks are common because of a lack of stringent security measures integrated into the technologies and unprepared legal frameworks. Notoriously, “technology innovates faster than the regulatory system can adapt” and disruptive technological advancements can make current privacy and security norms obsolete (*481*).

For example, the frequency of cybersecurity threats has increased substantially with the disruptive emergence of smartphone-controlled pervasive and ubiquitous computing(*482*). Given the high sensitivity of neural information, neurotechnology must not be allowed to follow a similar historical trajectory. Privacy and security breaches should be proactively anticipated and prevented.

The combination of three distinctive features inherent in DTC neurotechnology poses important ethical and legal challenges. First, the expansion of commercial neurodevices and neuromarketing applications produces large volumes of data (both raw EEG data and their associations with user-data, demographics, social media information etc.) in an unprotected and loosely regulated manner. Second, the control of EEG data is only partially voluntary and may be tapped without the knowledge of the subject. Moreover, access to these raw data enables a more direct detection pathway of the neural correlates of mental processes, such as interests, intentions, silent speech, moods and preferences, compared with other digitally available sensor data(*483*). And third, the data collected includes rich and personally identifiable sources of information that could be aggregated by data-handlers to capture or predict elements of health status, preferences and behavior.

The comprehensive collection of both personal and non-personal information is common to most DTC neurotechnology actors. For example, the Emotiv Privacy Policy states that the company exercises the right to gather "personal information" from users that can be associated with them, including their EEG-data, usage information, specific interactions with applications, as well as "information that may be inferred from the foregoing sources, either alone or in any combination".[53] In addition, if Emotiv or Neurosky customers use their social network log-in to create a user-profile, information associated with the social network account, such as demographics, IP address and interests will be collected and linked to the EEG-data.

With the growing proliferation of neurotechnology-related online databases available for analysis and their association with digitally available profiles, it will be increasingly hard for users to selectively isolate intended information (e.g., parameters relevant for cognitive self-monitoring and training) from information that they wish to keep private like preferences, interests or abnormalities. Anonymization techniques are useful but vulnerable to re-identification. Consequently, unintended disclosure of private information is a tangible risk(*484*).

Brain privacy and security risks can arise in multiple ways. First, as the brain-spyware and Floppy Whale examples show, raw neural data, such as EEG-recordings, can be gleaned

[53] https://id.emotivcloud.com/eoidc/privacy/privacy_policy/ (last accessed: Aug 8, 2018)

directly from the neuroheadset through subliminal stimulation, without authorization from the user. These activities are forms of ‘brain-hacking’ and can exploit different phases of the BCI cycle(*377*).

As technology advances, the accuracy and informational richness of hacking primary brain data sources are set to increase, opening novel possibilities for unintended and unconsented decoding of mental information. In non-cybercriminal scenarios, EEG-recordings and neuroimaging data collected in neuromarketing studies can be used to reveal information (e.g. biomarkers of mental illness or personal beliefs) from participants. Similarly, variations in EEG responses to Facebook interests, demographic data and other online activities could be gleaned from users of Internet-connected consumer-grade BCIs, without explicit consent of the user.

What’s more, data can be accessed from platforms of sensor data storage, analysis and visualization. Most DTC companies including Emotiv, Neurosky and Muse Interaxon use private cloud services for data storage in which users outsource their data to an in-house or third-party cloud provider. Notoriously, cloud services are vulnerable both to insider threats and cyberattacks, especially Distributed Denial of Service (DDoS). In addition, they are characterized by lack of customer support, standardization issues (absence of clear-cut guidelines unifying cloud providers), and unclear legal liability in case of security breaches. The attractiveness and therefore risk of hacking data storage sites by nefarious and criminal actors will be greatly increased when large population EEG-databases are stored and linked for analysis to other databases containing medical, social-media or other sensitive information. Even though most DTC companies, anonymize the collected EEG data, these data can be easily combined with other informational sources to re-identify a user. It is notable that DTC neurotechnology companies actively encourage users to outsource their data. For example, if users of most DTC services choose not to upload their data on the cloud, a more limited set of features is made available to them. Most data can also be hacked during transmission from the recording device to other platforms. This breach of security can be facilitated by unsecured uses of data gathering and sharing services. This phenomenon has already been observed in the context of mobile health, with many health professionals sharing patient-related clinical data via unsecured wireless channels like smartphone messaging apps(*485*). Outside the clinical context, in the DTC sphere, the use of unsecured data-sharing services is widespread and the exposure to unauthorized access even higher(*486*).

The risk of unauthorized disclosure of brain information is particularly perilous among people with medical and psychological conditions. For example, the unintended disclosure of information revealing cognitive deficits and neural signatures predictive of disorders (e.g. depression or bipolar disorder), substance addiction or personality traits that the person wants to keep private, can lead to discrimination and social isolation(*484, 487*).

The possibility of brain leaks is not limited to criminal hackers or other malevolent agents, and does not necessarily involve the use of malware. With the growing availability of large datasets of brain-related data, anonymous EEG and fMRI data can be legally mined for commercial and marketing purposes to reveal more information about a certain user group than the individual user intended to provide or share. As long as people accept their terms of use, companies are free to use data-mining and big-data analytics to extract associations between sensor data, demographic information and online behavior or to share the data with third parties for further reuse.

Recycling of user data is a real possibility—and could become highly profitable— for private providers of DTC neurotechnology services. For example, by accepting the terms of use of most direct-to-consumer BCI-providers, users grant the companies a right to re-use and disclose non-personal information to advertisers and other third parties. These data can be used for a variety of purposes including identifying peer groups based on their overall cognitive performance relative to age or other characteristics. When companies like Facebook will be able to collect large volumes of brain-derived data, these policies will allow them to re-use this information for microtargeted psychographic ads or other commercial purposes.

Finally, neuromonitoring techniques are also being tested by national security agencies for surveillance, investigation and predictive policy purposes,(*140, 488*) making governments an additional actor potentially interested in the access and reuse of personal neurological data. This possibility projects a future in which "thoughts and images in our brains could become the target of future government investigations"(*489*). To the extent the information is available in private firms, the government could, in principle, obtain access to the firms' information through search warrant, subpoena, or simple request. This is explicitly reported in Emotiv's and Muse Interaxon's Privacy Policy, where it is stated that the company may be required to share personal information to comply with with applicable law or respond to governmental requests.

Inadequate safeguards

Because of the socio-technological novelty of consumer neurotechnology trends, current ethical and legal safeguards are inadequate to guarantee the protection of brain information in this rapidly changing digital environment. In the United States, federal law protects medical information. And yet, no specific laws or guidelines govern access to brain data outside of the clinical realm. If a consumer neurotechnology or associated app is provided by an hospital or business associate, then HIPAA (Health Insurance Portability and Accountability Act) (*490*) regulation applies. However, HIPAA does not apply if the neuroheadset is just purchased online by an individual without a prescription and the apps are downloaded from an app store, as usual in the DTC realm.

Consumer neurotechnology highlights the problem of regulations focusing on where the data originate rather than the nature and use of such data. In parallel, FDA regulation provides guidance for digital health and mobile medical apps(*491*). However, the current FDA framework has been criticized for creating simultaneously under-regulation and over-regulation. On the one hand, it is relatively easy for DTC manufacturers to elude FDA compliance due to its limited bandwidth. On the other hand, it is difficult for responsible innovators to invest in neurodevices that require a premarket approval path from the FDA due to the significant delays in approving new devices.

It is important to highlight, that expanding HIPAA and the FDA's scope might not be possible without new legislation, because those regulations can only go as far as the statutes (i.e. Congress) allow. Therefore, reforming policies for the digital health era almost certainly requires new legislation and not just agency-initiated changes in regulations.

Indeed, DTC neurotechnology applications often remain in an undefined ethical and regulatory space. For example, while neuroimaging studies in the neuroscience and clinical research setting require institutional review board (IRB) approval and follow specific guidelines for data usage, consumer neurotechnology companies are not subject to the same standards. Neuromarketing companies can run studies involving human subjects without formal approval from an ethics committee, while DTC companies can transmit data to third parties such as social media or other apps. This makes it possible to collect substantial volumes of user-generated data and distribute them to third parties, even when the purpose of such reuse (e.g., marketing analysis) could be different from the intent of the user or the function advertised by the company when selling the product (e.g., self-monitoring of mental wellbeing)(*492*).

With the volume of personal neurological data rapidly increasing and security-by-design not being the focus of companies, such defective legal and regulatory coverage allows unsecure uses of brain information. As stated by Nita Farahany during the World Economic Forum in Davos, Switzerland: "There are no legal protections from having your mind involuntarily read". Not surprisingly, security experts consider BCI and other neurotechnologies to be among the nine disruptive technological trends that "are likely to shape the cybersecurity environment over the next decade"[22].

In light of these inadequate ethical and legal safeguards, the US National Institutes of Health (NIH) has recently released a request for information, soliciting input to identify a set core of ethical issues associated to emerging neurotechnology. These include considerations associated with novel neuromodulation and neuroimaging technologies, informed consent issues in the context of neurotechnology research and the problem of "the evolving breadth of neural data" with associated issues of data ownership, data storage and access, unintended uses of data and privacy concerns; including "protection from discrimination for those whose neural data are shared".(*493*) This is helpful, but is limited to the research setting. More importantly, the NIH has authority to regulate research conducted with its funds, but does not have the authority to regulate the DTC market for neurodevices.

Proposing safeguards

In response to this emerging scenario, a proactive effort is needed to increase the privacy and security of brain-related data outside the medical and research context. Safeguards are needed at three levels: individual users; neurotechnology producers or service providers; and policy and regulatory bodies.

At the user level, robust and valid informed consent is critical. With the growing market of DTC self-monitoring, neurodevices and medical crowdsourcing platforms, individuals will be increasingly motivated to acquire and share their brain data as part of their quantified self, seeking interpretations of the relationship between their data and health variability—a phenomenon that has already been observed with DTC genetic testing. Given the informational richness, versatility, psychological relevance, near-endless reusability and partial voluntary control of brain data, current requests for accepting the service's terms and conditions are insufficient to protect users. In addition, the possibility that users unreflectively trade their brain data for behavior analysis or monetary compensation in neuromarketing or other services must be prevented. Research shows that most users do not fully read online terms of service (ToS)(*494*), hence are likely to click away their data privacy rights in an uninformed manner.

For service providers, standard practice should include the following: adopting procedures and practices similar to routine informed consent for research and stored biological samples, companies must disclose in their terms of use: (1) how and where brain-data are stored; (2) whether and by whom brain-data are re-used and shared; (3) what anonymization and information security measures are implemented; (4) how individuals will be informed if their data are hacked or inadequately transmitted; and (5) who is legally liable under those circumstances. In addition, service providers should give users the ability to easily withdraw or erase their data at any time. This would also require the incorporation into the product's license of a transparency statement of what rights and duties different parties have with respect to the data. Replacing the current click-to-accept modus of ToS with designs that involve bullet summaries of companies' agreements and require users to explicitly consider their options is necessary.

Although companies might be granted a license to use, reproduce, display, and prepare derivative works of the user's brain-related data, they should not be automatically allowed to transmit and distribute those data to third parties. The Facebook-Cambridge Analytica scenario should not be permitted for neuro-derived information. Similarly, the linkage of sensor data with social-media profiles and other online information should be not be permitted by companies through opt-out strategies, but allowed only upon explicit affirmative permission from users via opt-in approaches. Institutional measures including independent IRB for every use of data for non-research purposes should also be considered. As the Cambridge Analytica scandal illustrates, online service providers like Facebook are often unwilling and unable to limit data collection, which makes it possible for third parties to access data no one gave authorization for. This risk could exacerbate when companies will store large datasets of brain-related data.

Data security needs to be a primary concern of manufacturers and sellers of pervasive neurodevices. Proactive safeguards for the selective protection of brain-information should be incorporated into product design. One promising example is the BCI Anonymizer, a system capable of pre-processing neural signals before their transmission and storage with the purpose of removing all redundant information except the specifically intended BCI commands(*142*). Distributed ledger computing (blockchain) and differential privacy techniques should also be considered as ways to improve the security and transparency of data processing. In parallel, recommendations for secured data transmission should be included by service providers in the user manual. An example of the desired standard in terms of use is Soterix Medical, which notifies users to the "risk of relying on a wireless connection with a computer to control and monitor the device". All apps –including both those bundled in the neuroheadset starter kit and those freely downloadable from an app store– should have to comply with data security best practices such as the European Network and Information Security Agency's guidelines. In parallel, as Bonaci *et al.*(*495*) have suggested, "platforms should be immunized for apps that third parties submit" to incentivize policies against abusive apps.

Finally, the often-hyperbolic claims made by some DTC manufacturers need to be substantiated by more solid scientific evidence to avoid generating unrealistic expectations. Currently, companies are not required and have no incentive to wait for their products to go through expensive and time-consuming clinical or performance trials and cybersecurity tests before they market their products and make marketing claims.(*496*) Therefore, regulatory interventions might be required to incentivize evidence-based and user-centered development and facilitate the incorporation of efficacy, safety and security-enhancing capabilities into future prototypes.

Conclusions

In the DTC context, neurotechnology promises to improve the diagnosis and treatment of neurological disease, enable new opportunities for human-machine interaction, open possibilities for training and education, and make brain data accessible for public use. That said, cooperative, interdisciplinary efforts are urgently needed to proactively develop and implement strategies that can help maximize the benefits of pervasive neurotechnology for society at large while minimizing the privacy and security risks.

Like any other digital health subdomain, the market of consumer neurotechnology is global. Therefore, effective governance strategies should be able to harmonize national regulations. A step in the right direction is being taken in the European Union, where a new General Data Protection Regulation (GDPR) became enforceable for all member States on May 25, 2018. The GDPR requires explicit consent (opt-in) for the data collected and the purpose data are used for "in an intelligible and easily accessible form, using clear and plain language" on pain of not being binding (Art. 7,2). It obligates data controllers to meet the principles of privacy by design and by default (i.e. from the onset of the designing of systems) and to notify users in case of data breaches. Organizations in breach of GDPR can be fined up to 4% of annual global turnover or €20 Million (whichever is greater). The positive impact of GDPR on consumer neurotechnology is already visible. For example, some DTC companies such as Emotiv no longer grant themselves an “irrevocable, perpetual license” to use, transmit and distribute user-generated neurological data (as stated in their Terms of Use prior to GDPR) and will inform users about their right to withdraw their consent at any time.

Creating an ecosystem that enables technological innovation while making sure that citizens have control over their data is critical for neurotechnology. All relevant stakeholders including researchers/developers, companies, regulatory agencies and end-users should make security of personalized brain information a priority. Near term solutions include enhancing the privacy and security standards of current hardware and software, fostering evidence-based approaches to product development, reforming consent procedures for DTC products and raising awareness among individual users and developers. Long term solutions include enforcing responsible governance and opening a public debate on what rights individuals are entitled to exercise in relation to their neural domain. Ignoring these issues could not only result in harm to individuals or groups but also fuel public distrust in the entire neurotechnology enterprise. Therefore, proactively securing brain-related data is the clear and present challenge to ensure continuing application of these devices in the consumer sector.

*2.11. - Privacy and Security Issues in Assistive Technologies for Dementia: the Case of Ambient Assisted Living, Wearables and Service Robotics**

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Abstract

The collection of a large volume and variety of physiological and behavioral data is critical for the effective development, deployment and implementation of assistive technologies and for the subsequent effective support of older adults with dementia. Yet it raises privacy and security issues. In this Chapter we review the major privacy and security implications associated with the use of three major families of intelligent assistive technologies for dementia: ambient assisted living systems, wearable devices and service robotics, especially telepresence robots. After exploring a number of both category-specific and cross-categorical ethical and legal implications, we propose a list of policy recommendation with the purpose of maximizing the uptake of assistive technologies while minimizing possible adverse effects on the privacy and security of target users.

[54] Edited volume under contract. Expected release in 2019.

Introduction

A key functional component of most intelligent assistive technologies (IATs) for dementia is the capacity to sense, track and monitor patients and their activities. The process of tracking and monitoring adults with dementia and their activities may have various purposes. These include: alarming in case of detected abnormalities, conveying or facilitating the supervision or intervention of caregivers, generating data flows useful for diagnostics and therapy, favoring a more adaptive and personalized interaction with other assistive technologies. In a nutshell, monitoring and tracking tools are primarily instrumental to collecting relevant information for increasing the patients' safety and enhancing the effective support of users in the completion of activities of daily living (ADLs). The capacity of tracking and monitoring is enabled by sensors, which convert physical parameters (for example: temperature, blood pressure, CO_2 levels, speed, etc.) into a signal that can be measured electrically. Such electrically measurable signals may contain various types of information about the patients, the most common being behavioral and physiological information. Behavioral monitoring technology collects information about the user's behavior, such as movements, actions, and sounds. In contrast, physiological monitoring systems track and record patient physiological data such as heart rate, breathing rates, blood pressure, electrocardiogram (ECG) and electroencephalography (EEG) signals, and blood chemistry information. Both behavioral and physiological records are likely to contain private and sensitive information. Behavioral records, for example, may contain information about the patient's habits, locations and daily activities in their private sphere. Physiological records, on the other hand, may contain information about physiological correlates of a person's health as well as biometric information. While the collection of such private and sensitive information is critical for the effective development, deployment and implementation of assistive technologies and for the subsequent effective support of older adults with dementia, yet it raises privacy and security issues. Having others know intimate details about a person's life such as their behavior or their medical records may infringe that person's right to privacy as well as cause a loss of autonomy.

In this Chapter we will describe and discuss the major privacy implications associated with the use of intelligent assistive technologies in the context of dementia care. In particular, we will focus on the three classes of IATs that most largely rely on the monitoring and tracking of personal data: ambient assisted living systems, telepresence robotics and wearable technology. Both general and class-specific issues will be discussed.

We will proceed as follows. First, we will present the notion of privacy, its role in our current ethical and legal discourse, and its relation to other notions such as medical beneficence and data protection. Second, we will explain how certain classes of IATs may generate novel issues for privacy and data protection. We will focus on three major families of monitoring and tracking technologies for dementia: ambient assisted living, telepresence robots and wearables. Third, we will discuss the implications of defective privacy protection in the context of IATs and highlight the need for unambiguous privacy standards in IATs for dementia care. Finally, we will conclude by providing preliminary insights into privacy-enhancing regulatory solutions.

Informational Privacy, Beneficence and the Goals of Care

The need to set limits to the public dissemination of information relating to a person's private life was firstly defended by Warren and Brandeis (1890). In their seminal analysis, the emergence of novel technologies was seen as an increased risk of intrusion into a person’s private domain and a potential breach for unintended public disclosure of personal information (*497*). The notion of informational privacy, i.e. the control over information about oneself, was further developed by authors such as Westin (1967), Fried (1970) and Parent (1983). Westin, for example, described privacy as the ability to determine for ourselves when, how, and to what extent information about us is communicated to others (*498*). Such an account of privacy became central to the legal discourse after the U.S. Supreme Court explicitly ruled that privacy is a central reason for Fourth Amendment protection. Consequently to that deliberation, informational privacy has been frequently extended as to include the protection against unwarranted searches, eavesdropping, surveillance, and appropriation and misuses of one's communications. With the emergence of digital computers and the Internet, novel debates arose about the privacy and security status of personal records of information. The reason for that stems primarily from the fact that people may not know what information is stored about them or what parties have access to it − a problem that has been recently exacerbated by cloud computing. The possibility for service providers to access and link databases containing personal information, with few controls on how those data are used, shared, or exploited, has hindered individual control over information about oneself in an unprecedented manner.

In the ethics tradition, the notion of privacy has often been attributed moral value based on the argument that it is necessarily associated to certain basic freedom, independence and other moral values. For example, Bloustein (1964) stated that invasion of privacy is best understood, in sum, as affront to human dignity (*499*). In a similar fashion, Allen (1988) has argued that a degree of privacy is required by the liberal ideals of personhood, civil liberty and the participation of citizens as equals (*500*). In the light of the informational privacy account at its interconnectedness to core moral values such as equality, liberty, personhood and dignity, it becomes questionable to what extent it is legitimate to monitor and track activity from older adults with dementia, hence to access control of their physiological and behavioral information. To properly appreciate this philosophical problem, however, it is necessary to balance privacy with another value in the moral spectrum, i.e. the principle of beneficence in biomedical ethics.

Beneficence is the principle of biomedical ethics which requires that any procedure or intervention be provided with the intent of doing the best interest of the patient involved and to promote their welfare. Under some circumstances, privacy and beneficence may be in mutual conflict. One common ethical issue arises when the patient's informational privacy conflicts with the physician's beneficent duty to look out for the patient's best interests. For example, the doctor of a patient with dementia may gain valuable treatment-related information from monitoring the patient's everyday behavioral habits even without the patient's consent. However, this unauthorized monitoring would represent an intrusion into the patient's privacy. In these situations the protection of the patient's informational privacy conflicts with the physician's duty of beneficence and following each principle would lead to different courses of action.

In the light of this complex dynamics among potentially conflicting principles it results clear how the healthcare system and healthcare professionals do have an obligation to prevent or mitigate harms, and weigh and balance possible benefits against other principles (e.g. privacy and autonomy) as well as against possible risks of an action.

In the context of IATs, there is an undisputable obligation to use monitoring and tracking technologies to prevent and mitigate harms. For example, smoke detectors employ sensor technology to detect unusually high levels of carbon dioxide in the home environment and send alarms to prevent harms such as intoxication or fire. Analogously, fall detectors employ sensor technology to detect falls and prevent the arms of delayed assistance. Beyond this undisputable obligation, however, specific clauses on the legitimate conditions for the recording, storage, access, and reuse of behavioral and physiological information remain to be unequivocally determined. In fact, a weighed and balanced calibration of the various moral values at stake would automatically exclude any account that disproportionally sacrifices one value over the other. For example, renouncing to the implementation of monitoring and tracking technology altogether in dementia care on the grounds of privacy rights would dramatically hamper the quality of care, obstacle improvements to the quality of life of the patient and stop technological innovation. At the same time, however, allowing any uncontrolled and unrestricted beneficence-motivated collection and dissemination of highly sensitive physiological, behavioral and other personal information from elders with dementia without their knowledge and consent, would result in harming the patient's privacy and ultimately producing injustice.

Current Legal Coverage on Privacy, Security and Data Protection

Potential benefits of IAT systems for dementia care include (i) extending the time people can live in their preferred environment by increasing their autonomy, self-confidence and mobility; (ii) supporting the preservation of health and functional capabilities of the elderly, (iii) promoting a better and healthier lifestyle for individuals at risk; (iv) enhancing security, preventing social isolation and supporting the preservation of the multifunctional network around the individual; (v) supporting carers, families and care organizations; and (vi) increasing the efficiency and productivity of used resources in the ageing societies. While the long term positive impact of this technological turn in neurogeriatric care is massive, the intrusion into the patient's private sphere enabled by IATs needs to be counterposed to the protection of two main fundamental rights: the right to privacy the right to data protection.

In Europe, there are two legal systems that guarantee the protection of fundamental rights: the European Convention on Human Rights (ECHR), an international agreement between the 47 members of the Council of Europe (CoE); and the European Charter of Fundamental Rights (EU CFR) that became binding and primary law after the Lisbon treaty in 2009 (Art. 6.1 Treaty of the European Union, TEU). Inspired by the article 12 of the Universal Declaration of Human Rights (UDHR), and the article 17 of the International Covenant on Civil and Political Rights (ICCPR), both corpuses protect the "right to respect for his private and family life, his home and his correspondence", so as to say *privacy* (art. 8 ECHR and art. 7 EUCFR respectively). With regard to the processing of personal data, however and unlike the United States, Europe has extensively developed another right, the data protection right either within CoE (through the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, also called "Convention 108" (14)) or within the EU with the 95/46/EC Data Protection Directive [soon to be replaced by the General Data Protection

Regulation (GDPR) and the Directive for the criminal judicial cooperation, two proposals made in January 2012] [55].

Privacy and data protection are "twins, but not identical" (5) and both are narrower and broader than its former at the same time: while privacy extends to the entire private dimension of the person, data protection focuses solely on the processing of personal data; on the other side, personal data may refer to "any information relating to an identified or identifiable individual" (data subject), which makes it broader than privacy because it may encompass information that does not contravene privacy. Indeed, while the process of personal data for a concrete purpose with the obtaining of a valid consent for it would make no interference to the right to data protection, the collection, storage or disclosure of such data could interfere with private life (18).

It is worth noting that although the current data protection directive grants protection "to all persons", it only includes within its scope "living being[*s*]" (23). The rest of persons are covered nowadays by the right to privacy (24). Moreover, this directive does not cover anonymous data even though it may interfere with the private sphere of citizens (25), e.g. data such as traffic and location data – as those increasingly collected by ambient assistive living technologies can infringe the privacy of the citizen, especially when they steer the conduct of the citizens invading their individual's privacy and autonomy (26). In the end, "the processing of data that is not qualified as personal might also constitute an unlawful infringement of the right to respect for private life" (61).

In any case, both rights are not absolute and need to be considered "in relation to its function in society" (19), and they need to be balanced with other rights (20-21), e.g. in the case of dementia care, the degree of intrusiveness of a certain assistive technology should be in proportion to their contribution to achieving the goals of good care and promoting the patient's best interest. Furthermore, interferences to these rights in special occasions (e.g. to pursue terrorist attacks) are lawful if they are "provided for by law and respect the essence of those rights and freedoms [*and*] subject to the principle of proportionality […]" (Art. 52 EU CFR) (22).

In dementia care, the respect of both rights is of paramount importance because the patient might not be capable to understand what data are processed, to what extent they are

[55] See Reform of EU data protection rules: http://ec.europa.eu/justice/data-protection/reform/index_en.htm

processed, and, accordingly, might not be able to give appropriate consent. Furthermore, the collected information is huge and very sensitive. To this regard, the General Data Protection Regulation expected to enter in force in 2018 aims at reinforcing the current data protection schema offering an easier access to the collected data, the right to data portability, the right to be forgotten and the right to know when the information has been hacked.[56] Issues of informed consent in elderly people, privacy *post mortem*, third uses of the collected data or *cognitive* privacy in neurotechnology applications are still under discussion.

Privacy and Security in Ambient Assisted Living Technologies

Ambient Assisted Living (AAL) or Ambient Assistive Technologies (AAT) are a family of assistive systems that incorporate pervasive and ubiquitous computing into the design of housing facilities for the elderly as well as for people with physical and cognitive disabilities. These technologies "seek to aid people, particularly the elderly, live independently for a longer time period than would otherwise be possible" (83). A large number of AAL systems have been tested effective also in the support and assistance of older adults with dementia and their informal caregivers. AATs are normally focused on the prevention and management of chronic conditions, the preservation of social interaction, the facilitated completion of ADL, the compensation of specific functional deficits (80), the delivery of medical and rehabilitative interventions, and the fulfillment of the oft-stated wish of older adults to age-in-place. In addition, AATs seek to active ageing (89), and improve the quality of life of the patients. AATs work on a distributed cloud-of-care basis allowing smart integrated technology to track, monitor, supervise, guide and support the elder's behavior in a relatively non-invasive way (90).

In 2008, a Study Report of the European Commission addressed a number of general ethical and legal issues linked to e-Health (84). In 2014, the AALIANCE research group identified a core set of specific ethical and legal issues associated with the implementation and use of AAT (*501*). In this document, researchers identified the major legal corpuses relevant for AAL and in accordance to which every AAL system should be designed, developed, produced and implemented. These corpuses include: data protection regulation (transparency, legitimate purpose and proportionality), patient safety and medical device regulations (85), consumer protection (fair treatment, products which meet acceptable standards and a right of redress if something goes wrong) (92), and the legislation regarding services (e-commerce) (93). In

56 See: http://ec.europa.eu/justice/data-protection/

addition, they identified some legislative gaps on a number of regulatory issues including (i) broadband access (addressing the question of whether the access to the Internet should become a right in the near future), (ii) data mining and the automatic decision making process (highlighting the responsibility issues after an automatic wrong decision), (iii) the integration of new technologies into AAL system (e.g. mHealth, robots, biometrics, smart homes and nanotechnologies), (iv) the accessibility of different goods and services (96) and, finally, (v) the quality of services.

To date, many data protection-related issues associated with the use of AATs remain largely unexplored, e.g. the intertwinement of the mental capacity of elderly people with dementia and their capacity to give informed consent or the third uses of the collected data (see *infra*). It also remains unclear where the line between privacy and competing interest should be drawn and by which actor (e.g. manufacturer vs user) or who is the data controller/processor, especially in the case of different service/device providers that need to share information to give a coherent response in AAL. In addition, the collection of non-personal data from the AAT could generate personally identifiable information, information about the user's patterns of behavior and, potentially, release these data to third parties without the user's consent and awareness as with Samsung Smart TVs (*502*).

Researchers have suggested some pre-requisites for promoting privacy protection and user acceptance. These include: the use of non-invasive sensors, the implementation of sustainability measures, the possibility of home-based data storage (106) and the obtainment of informed and dynamic consent. Of course, technical limitations constrain the applicability of such protection. For example, home-based platforms for data management are very expensive and require external access by the manufacturing company in case of system failure. Similarly, dynamic consent is easier to obtain in research contexts than in the context of IAT implementation. More research is needed to explore how dynamic consent could be obtained when implementing in-home technologies for ADL (*503*). In addition, from an ethical and legal perspective, there privacy-enhancing protections must be balanced to emerging rights such as the right to be forgotten (Art. 17 GDPR) and the right-not-to-know in relation to accidental findings (e.g. if the system detects any disease that could affect his/her emotional or psychological integrity). As stated previously, there is a need for "finding appropriate balances between privacy and multiple competing interests" (91).

Privacy protection comes along with security issues (91). These are related to the physical security such as preventing any breach, allowing authorized access, no delay on leaving the house in case of danger, but also the prevention of falls (107), external threats (in the event of fire or flood, the system should respond safely), electronic data security, and theft prevention technology. The prevention of other users commanding the house of the dementia patient is of paramount importance (100). The dwelling of the person should be a “fail-safe” environment; data should be always secured even though the broadband access is not yet solved although it has been recognized as a human right by United Nations (*504*). In any case, any unauthorized access should be prevented. This would go in line with the protection of the physical integrity of the person, although safeguards concerning the mental integrity should be also considered. Some authors believe that offering perfect transparency, making the user the master and fighting laziness should be taken into account (106). However, dementia patients might not have the capacity to be the master of the AAL system. Delegation issues are of crucial importance.

Privacy and Security in Service Robotics: The Case of Telepresence robots

Service robots differ from industrial robots because they are designed for non-expert usage. They perform multi-tasks in unstructured environments and their level of human-robot interaction (HRI) is very high. In dementia care, telepresence robots have been used to support doctor-patient interaction through videoconference, but also as autonomous robots providing companionship, handling objects or exchanging information (1-3). Some of them have been used along with AAL technologies (4).

These robots normally provide a two-way audio and video communication, a user interface, an integrated map, multiple cameras and sensors, and the possibility to autonomously navigate around the house (5). They differ from AAL or wearable technology because they provide the capacity of third users to sense and interact with remote environments, leading to an overall sense of extended agency in that environment (6-7). The capacity of sense, together with their mobile physical appearance raises privacy concerns both in respect for private and family life and data protection either in telepresence or autonomous mode.

Concerning the protection of data collected by the robot, although the processing of sensitive data is lawful for “health security, monitoring and alert purposes, prevention or control of communicable diseases and other serious threats to health” (8), and it is deemed necessary in dementia care, appropriate safeguards need to protect how the collection, transmission and storage of the dementia patient’s sensitive data is carried out. As FBI stated “if the device is capable of remote operation or transmission of data, it could be a target for malicious actor”. Robots lacking security capabilities provide criminals with opportunities to access the robot and steal personal data, broadcast images on the Internet, control health data collection and monitor, or remotely control the robot, which could also interfere with their physical safety (9). In fact, "robotics combines […] the promiscuity of information with the capacity to do physical harm" (10). Under the new GDPR, the data controller has the obligation to inform both the supervisory authority and the patient if the robot has been hacked or a data breach has occurred (Art. 31-32 GDPR) although it remains unclear how these notifications can be done to dementia patients, if they should be directly done to their proxy or what should be appropriate to do such a case: to get rid of the system, to change the access keys, etc.

Teleconferences between the patient and the care provider as well as with patient's relatives or friends, should remain private and confidential in any case, as eavesdropping represents an interference with the right to privacy (11), and only stored in the cases necessary for the monitoring. Access to stored information should be granted to those in charge of the patient upon signing confidentiality agreement. In teleconference mode, moreover, it should be clear in which cases the pilot (e.g. the doctor) can access the camera and establish a conversation with the patient, as in some cases elderly prefer to pilot a mobile robotic platform system rather than receiving a visit via the robot system (7). Oral contracts or agreements performed through teleconference system should be subject to the patient's capacity so as to avoid any abuse. In any case, consent should be unambiguous, clear, affirmative and explicit.

In autonomous or companionship mode, the robot will have to process a lot more quantity of information, not only to be capable to deal with pitfalls but also because the spontaneous HRI in telepresence mode will turn into a life-long relationship once the robot reaches personal environments and needs to provide company (12). The use of cloud robotics to process all that information, lighten the weight of the robot and decrease response timing will challenge data protection. First, it will create confusion on the identification of the data controller and data processor by the patient, which would imply difficulty on the allocation of responsibilities (13-14). Second, the contract between the healthcare provider and the cloud provider should meet all the requirements of the cloud computing contracts such as avoidance of unfair terms and conditions (15), the establishment of a right to switch (in accordance with the right to data portability, Art. 18 GDPR) (16) or liability in case of non-availability of the service. Third, it should be clear who would have to carry out a data protection impact assessment, a new obligation of the GDPR when a large scale of special categories of data will be processed (Art. 33.2.b) GDPR). And fourth, special attention should be drawn to the collection of co-habitants of the patient (or visitors)'s personal data.

Extensive research has investigated how to transform HRI into a Human-Robot Safe Interaction (HRSI) trying to standardize on the robot's spatial behavior in response to human presence, the robot's noise level for robots in human environment, the perception for HRI, the establishment of some generic and some high-priority commands for HRI, gestures across different cultures, etc. (17). Nurses, physiotherapists and physicians should be given a map in order to safely navigate in the patient's dwelling, as they might not be familiar with this private environment as well as a set of rules on how should this access be performed. The HRSI should be combined with all the by-design principles (privacy, transparency) but also with some code of ethics (that would include empathy, social awareness and proxemics) to make the life-long relationship not only safe but also pleasant.

Privacy and Security in Wearable Technology

Wearable systems "are designed to be permanently useful and usable in a wide range of mobile settings" (*505*). Wearables differ from other types of mobile technology (e.g. smartphones or tablets) because they are not, or only rarely, handheld and enable direct interaction between the system, the user and the environment (*505*). Wearable computing devices may be worn under, over or in clothing or may also be themselves clothes (28); and they are capable of collecting a wide range of information from the user's body (e.g. health status, habits or mood) and environment (e.g., images, temperature, location, sounds or even third parties' personal data) (49).

Wearable technology is being increasingly used in neurogeriatric care including sleep measurement and enhancement (34); assistive tool for caregivers of elders with Alzheimer's (36) or Parkinson disease (39). While the potential benefit of wearable technology in dementia care and, more generally, in healthcare is disruptive, it also raises privacy concerns (*204, 506*). Indeed, the collection of massive quantity of data may clash with the principle of data minimization enshrined in the data protection regulations. In addition, it raises several related legal issues including information security, consent, data ownership, and control. While these emerging ethical and legal issues apply also to other categories of IATs such as robots and distributed systems, the permanent usage and friction-free design of wearable devices may elevate these issues to a great order of magnitude. In particular, the high level of integration between the wearable device and the user may reduce the user's awareness of the ongoing data collection and processing (*507*). In addition, wearables can collect a larger variety of physiological and other health-related data than most other families of IAT, including sensitive data such as heart-beat rates, blood pressure, sugar levels, and podometrics. Even more remarkably, neurowearables such as consumer-grade brain computer interfaces (BCI) can record brain-waves, a form of personally identifiable data. A viable strategy to guarantee privacy and protection of data when implementing wearable technology into dementia care is to carry out a Wearable Impact Assessment (WIA) (41). This methodology could help proactively identify the precise context of implementation, the appropriate characteristics or capabilities of the device, the target user population, the potential unintended risks involved and the associated safeguards. Following the Art. 33 GDPR, we suggest to incorporate a Privacy Impact Assessment (PIA) as well as to introduce privacy-enhancing and data-protection safeguards early in the design of wearable assistive devices.

Recommendations

While different in architecture, usability, and functionality, AAL systems, telepresence robots and wearables have the common denominator of collecting and processing large volumes of data from the user with the purpose extracting valuable information on their health conditions, monitoring or assisting their activities, supervising or facilitating the completion of everyday tasks, enhancing their overall quality of life and quality of care.

Based on the previous technical, ethical and legal analysis, we argue that in the context of AAL technology for elderly adults with dementia, eight fundamental privacy-related questions must be addressed: (i) what data can be legitimately monitored or tracked (ii) in what volume and variety, (iii) what degree of intrusion into a person's privacy is legitimated by the goals of dementia care, (iv) from which subjects can the data be collected (v) where these data are stored, (vi) who has ownership over and access to those data, (vii) what are the appropriate procedures for informed consent (viii) what third uses of the collected data are legitimate.

The first three questions are strictly connected. AAL and other distributed systems usually collect behavioral, physiological and environmental data in a quantity and quality that vary depending on the specific goals of the system. For example, fall detecting systems collect primarily behavioral data with the purpose of detecting anomalies in the resident's motion to alert caregivers about fall or similar domestic accidents. In contrast, smoke detecting systems collect primarily environmental data from (i.e. CO2 levels) from the resident's domestic environment with the purpose of detecting anomalies that correlate with an increased risk of fire or suffocation. We argue that, the quality of data being collected should be coherent with the purpose explicitly stated in the system's specifications. Producers should include into the product package clear statements about what types of data and in what volume are collected by the system, as well as motivate the reason for their collection from the perspective of care. Anomalous patterns of data collection should be prevented by design and users should be informed about anomalies in the data collection process Circumstances where the system collects volumes and varieties of data that were not explicitly stated in the product package should be prevented by specific regulations.

It is important to note, however, that since for most AAL systems this *monitoring* of activity levels is a continuous process, it may be hard to determine what volume of data is coherent with the assistive goals of the system. In addition, the increasing use of big data predictive analytics may extremely benefit from the collection of large volumes of data and utilize them not only to automatically generate post-event alerts but also to predict upcoming risk situations. For this reason, we recommend that privacy and data-protection regulations in the context of assistive technologies for dementia provide sufficient elasticity for maximizing the benefits of technological progress while minimizing the risks of technology misuse. Excessive regulatory restrictiveness may harm not only current technology-assisted dementia care, but also temper the future development of technological innovations.

Issues of data volume and variety are subsumed by the problem of determining the degree of intrusion into a person's privacy that is legitimated by the goals of dementia care. A possible solution to address this problem is the appeal to a special application of the principle of proportionality. As previously mentioned, the degree of intrusiveness of a certain IAT intervention should be in proportion to their contribution to achieving the goals of good care and promoting the patient's best interest. The patient's best interest, in turn, is determined by the severity of their medical condition and their specific care needs. This application of the proportionality principle is one viable resolution of the conflict between the bioethical principles of privacy and beneficence presented in the first Chapter. As we have already seen, the principle of beneficence states that any procedure or intervention be provided with the intent of doing the best interest of the patient involved and to promote their welfare. Therefore, IATs systems can legitimately operate intrusions into the patient's private domain (e.g. domestic environment and continuous activity levels) if these partial sacrifices of the patient's privacy are in the best interest of the patient. For example, the continuous gait monitoring of a patient with mild to moderate dementia may be justified by the prevention of falls and other mobility-related accidents.

The appeal to the principle of proportionality, however, requires technology producers and manufacturers to make explicit claims about the goals and capabilities of their marketed devices. General goals of IAT systems for dementia care include (i) extending the time people can live in their preferred environment by increasing their autonomy, self-confidence and mobility; (ii) supporting the preservation of health and functional capabilities of the elderly, (iii) promoting a better and healthier lifestyle for individuals at risk; (iv) enhancing security, preventing social isolation and supporting the preservation of the multifunctional network around the individual; (v) supporting carers, families and care organizations; and (vi) increasing the efficiency and productivity of used resources in the ageing societies[57]. The degree of intrusiveness of iAT interventions should be in proportion to their contribution to achieving these goals as well as to promoting the best interest of the patient.

With regard to the subjects whose data can be legitimately collected, specific focus should be diverted to the elder with dementia. Data from third parties should only be collected if the third party explicitly consents to their collection. As we have discussed previously, in fact, most jurisdictions allow the third-party data processing under specific circumstances. Third parties should be aware that their data are being processed, for what purposes, and by whom. In addition, they need to provide explicit informed consent.

Standards for correct data storage also must be clarified. As AAL systems, telepresence robots, wearable technologies and other IATs may collect highly sensitive and personal identifiable information, safe and secure storage of that information must be guaranteed. Following the Art. 23 GDPR, we suggest enacting the following safeguards: (I) The immunity of systems to abusive third-party apps should be secured by design; (II) The access to the data should be limited and the cloud provider should not (except for exceptional circumstances) retain access; (III) Cloud storage must be either avoided or supported by cloud encryption and free support services in case the patient, their caregivers or responsible health professionals require additional information or have special needs.

Data ownership is a complicated legal issue not only in the assistive and medical context but also for commercial uses. In the corporate sector, governmental entities have already tried to claim the holder of documents (i.e. the cloud provider), is the one responsible and therefore legally obligated to turn over documents [58]. The emergence of similar scenarios in the context of

[57] AAL Europe, see:
http://www.aal-europe.eu/about/objectives/#sthash.j7SyeY8N.dpuf (last accessed 02/02/2016).

[58] See for instance the USA patriot act: https://www.fincen.gov/statutes_regs/patriot/

IATs should be prevented. Elderly adults with dementia should be able to claim ownership over their data. Wherever they can no longer exercise their ownership right due to the progression of their disease, data ownership should be extended by proxy (e.g. to the closest family caregiver). It is also important to establish clear roles between controllers and processors.

As we have seen in multiple occurrences throughout this Chapter, issues of legitimate degree of intrusion into privacy, data access, storage, ownership and the role of third parties, all presuppose the enforcement of formal procedures for the attainment of informed consent.

Informed consent can be obtained from people with dementia in three ways: (i) directly, (ii) proactively through advanced directives, (iii) or through proxy decision making. Direct consent can be obtained when the patient explicitly shows competence and cognitive capacity. Advanced directives are (usually written) externalizations of a person's decisions and wishes regarding future medical courses of action. Through these directives, patients at early stage of AD or other dementias can spell out decisions about their future choices ahead of time, i.e. before the progression of the disease makes them incapable to take autonomous and competent choices. Proxy decision making is when the decision is (partly) made by a person different that the patient (proxy) who was previously appointed by the patient or is relevant to the patient in some significant sense. Alzheimer Europe has produced several recommendations for the obtainment of informed consent from persons with dementia.

When providing information for the purpose of consent during the installation of a certain IAT, healthcare professionals and caregivers should communicate it in a manner adapted to the patient, respond to questions, use visual and other aids if necessary, and facilitate the communication of the decision by the patient. If consent is being sought for the purpose of installing and using a robot in the patient's home, it must be ensured that the user understands the basic functionality of the robot and its potential usefulness for their daily life.

A crucial requirement of consent among dementia patients is that it should be obtained at various intervals throughout the study, following an iterative model usually described as "ongoing consent". Due to the progressive and mood-changing character of the disease, patients may revoke their initial consent and must be free to withdraw from using the technology at any time. In the institutional setting, health professionals should be attentive to signs of distress linked to technology use and if necessary check with the participants whether they wish to withdraw from using the specific IAT that caused their distress. In the in-home setting, caregivers should be attentive to signs of distress linked to the use of the IAT or to its presence in the house (as in the case of environmental sensors and distributed systems).

Conclusions

In this Chapter, we have described the major privacy and security issues associated with the use of Intelligent Assistive Technologies in dementia care with special focus on three major families of assistive applications: ambient assisted living technology, telepresence robots and wearables. After presenting the philosophical and legal framework on privacy and data protection, we have analyzed in detail each of the three aforementioned technological families and their peculiarities from the perspective of informational privacy and data protection. Based on this analysis, we have produced general policy recommendations for enacting or enhancing privacy safeguards in the context of technology-assisted dementia care. Future research is needed to adapt these general recommendations to specific case scenarios of IAT use and to specific patient populations. In addition, future normative studies are required to explore potential conflicts among competing moral values. While the potential of IATs for improving dementia care is disruptive, the ethical use and social uptake of these technologies risk to be tampered if privacy protections are not integrated early in the design and development of such assistive applications.

*2.12 - Social and Assistive Robotics in Dementia Care: Ethical Recommendations for Research and Practice**

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Abstract

The increasing number of older adults being diagnosed and living with dementia poses a major challenge for global health. The integration of robotics into both formal and informal dementia care has a great potential for improving the life of patients and alleviating the burden on caregivers and the healthcare services. However, ethical, legal and social implications should be considered early in the development of assistive and social robots for dementia to prevent slow social uptake, incorrect implementation and inappropriate use. This paper delineates the ethical landscape and provides recommendations for design and use aimed at protecting users and maximizing the benefit in assisting such vulnerable population.

Keywords*: Dementia, Alzheimer's disease, robotics, ethics, informed consent, recommendations.*

The Global Burden of Dementia and Ageing

According to current projections, there will be over 130 million people with dementia worldwide: 1 in 85 world inhabitants (*508, 509*). The increasing prevalence of dementia poses a major problem for public health and the health-care services in terms of financial management

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and caregiving burden. Alzheimer's disease (AD), the most common form of dementia, is among the most expensive diseases for human societies, with a total estimated worldwide cost of US$818 billion (*161, 508*). Such significant costs arise primarily from long-term care at nursing homes and other institutions (*510*), whose burden affects not only public finances but also the elders, their informal caregivers (e.g. relatives) and the healthcare system.

The disabling condition of dementia patients progressively undermines their capability to live independently at home, interact with other members of society and perform activities of daily living (ADLs). In most countries, the primary source of care, assistance and support for dementia patients is represented by informal caregivers, mostly family members such as spouses, children and siblings. This informal caregiving service is highly time-consuming and requires great effort from caregivers in terms of physical and mental energy. The provision of caregiving services frequently comes at high socioeconomic and psychophysical costs for caregivers (*511*). Increasing evidence shows that informal caregivers of dementia patients may experience negative psychological consequences in the form of emotional and psychological stresses, mood disturbances such as anxiety and depression and other psychological conditions (*511, 512*). In spite of this multi-domain burden, informal care is, in most countries, neither accounted for nor reimbursed in the healthcare economy (*513*).

From the perspective of the patient, the burden of dementia results in a dramatically reduced quality of life (QoL), depression and other mood disturbances as well as in an increased risk of social isolation (*514, 515*).

Alzheimer's Disease and Other Dementias

Dementia is an umbrella term used to identify a syndrome "usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgment" (*516*). According to the International Classification of Diseases and Related Health Problems (ICD) of the World Health Organization, in order to be classified as dementia such condition of decline in mental ability should be severe enough to interfere with a person's daily life (*516*).

Alzheimer's disease (AD) is the most common form of dementia as it accounts for 60 to 80 percent of dementia cases worldwide (*161*). AD is a progressive neurodegenerative disorder with distinct neuropathology characterized by the presence of plaques and tangles in the brain (*517*). The prevalence of AD worldwide is rapidly increasing over time as a consequence of the demographic trend known as population ageing. The probability of developing AD, in fact, dramatically increases with age. A U.S. study found that dementia affects 5% of people aged 71 to 79, rising to 37.4% of people aged 90 and older. Among this population, AD was the cause of dementia for 46.7% of people in their 70s and for 79.5% of people in their 90s (*518*). The neurodegenerative progression of AD is described in three macro-stages — mild (early-stage), moderate (middle-stage), and severe (late-stage). Mild Alzheimer's disease (≤ 1 according to the Clinical Dementia Rating Scale) is the stage when the patient still largely retains independence in spite of frequent memory lapses. During moderate Alzheimer's disease (CDR-2), in contrast, the patient usually needs greater care to compensate for severe impairments in the short-term memory and other functions. Finally, during severe Alzheimer’s disease (CDR-3) patients require full-time care as they experience severe cognitive deficits, reduced awareness and personality change (*517, 519*).

These epidemiological and neuropathological facts are crucial to produce technology designs that better match the specific needs of people living with dementia. In particular, knowledge of the specific cognitive deficits or emotional and behavioral disturbances caused by AD and other dementias is essential to produce robotic devices that can effectively alleviate or compensate for those deficits and disturbances. In addition, knowledge of the correlation between dementia and age is crucial to take into consideration not only the specific deficits of dementia but also the general motor and learning deficits that are typical of the old age (*520*). Finally, knowledge of the progressive character of AD and other dementias is fundamental to recognize the importance of adaptive designs that can cope with the progressive intellectual and physical decline of users, as well as to identify the specific technological needs of users at each stage of the disease.

Robotics for an Ageing World: Social and Ethical Challenges

Given the current limited possibilities for pharmacological treatment, a promising approach in response to the emerging global crisis of AD and other dementias is the development and deployment of Intelligent Assistive Technologies (IATs) that compensate for the specific physical and cognitive deficits of people with dementia, and there by, also reduce caregiver burden related to long-term care and institutionalization (*2*). In fact, technologies that can help dementia patients to continue living independently at home or maintain independence in skilled facilities would provide a *triple-win effect* (*67, 73*). IATs could aid in: (I) saving significant costs to the health-care system by delaying or obviating the need for institutional long-term care (*521*), (II) reducing the burden on informal caregivers (*522*), and (III) improving the quality of life of patients by improving their autonomy, social interaction and help fulfil their wish to *age in place* (*523*). The potential of IAT for dementia care has been recognized also by the European Commission, whose Information Society Policy Link (ISPL) initiative emphasized that "[…] home-based care is much more cost-effective than care in a hospital or care home. As demand for these services increases, effective use of ICT technologies and services offers an attractive alternative to the costs and disruptions of early and unnecessary institutionalized care." (*524*).

Robotics constitutes a major component of the IAT spectrum. Research has shown extensive applicability and effectiveness of various robotherapy interventions targeted at older adults with dementia both in the in-home and the residential setting (*525-527*). In particular, four categories of robots are increasingly being implemented into dementia care: rehabilitation robots, service robots, telepresence robots and companion robots. Rehabilitation robots such as the Cyberdyne's HAL system are mainly used in physical rehabilitation and can support or assist several physical or cognitive functions of the user, especially locomotion and motor control. Service robots are primarily used to deliver direct care to patients with dementia, hence replacing or integrating the care delivered by human caregivers. For example, Fraunhofer IPA's Care-o-bot (now at its 4th generation, Care-O-bot 4), has been successfully tested to assist the specific memory deficits of older adults with dementia and assist them in the completion of a number of activities of daily living. Telepresence robots, such as Giraff and VGo, have proven effective in providing remote monitoring of adults with dementia and enabling long-distance control or interaction between patients and caregivers, often in combination with telephony and long-range remote control. Finally, companion robots such as Paro (now at its 8th generation) provide a wide spectrum of psychosocial support including the elicitation of positive (e.g. calming) emotional responses.

While robots open up the prospect of improving the quality of life of the elderly and reducing the financial, logistical and professional burden on the healthcare system, yet their distribution and uptake is still very low (*2*). One reason for that stems from a multi-level gap in the cross-section of technology and healthcare (*107*). This gap does not arise exclusively from current strategies for the implementation of robots into neuro-geriatric care but concerns three inherent dimensions of the relationship between technological products and target users: the societal, the legal and the ethical dimension.

In the following sections, we will delineate the major ethical, social and legal implications of robotics in dementia care. This analysis aims at proactively integrating ethical considerations into the design of robots for dementia care, hence maximizing the benefits of these technologies for dementia care, preventing unintended pitfalls, and favoring their acceptance and ethically appropriate use among target users. This ethical analysis does not pretend to be exhaustive but only to identify some core issues with the purpose of guiding individual use and healthcare practice. Further research is required to expand this analysis into a general framework.

The Societal Dimension and the Information Gap

At the societal level, the low distribution and uptake of robots is generally ascribed to an *information gap* in the cross-sections of technological development, healthcare and society (*107, 528*). According to Kramer, this *information gap* is a major cause of the lower-than-expected acceptance of robots and other IATs among the senior population (*107*). At present, limited information is available to designers and developers regarding the specific needs, wishes, and expectations of their target population. Reviews report that several devices are developed without or with limited involvement of people with dementia and their carers (*2*). The reason for that is threefold. First, research on the use of robots among elderly and cognitively disabled users is at a germinal stage of development and current knowledge is far from being extensive, generalizable and theoretically systematic. In addition, methodological quality of studies has been often reported to be low (*529, 530*). Second, research trials that directly involve older adults with dementia or other disabilities is time-consuming and requires extremely high standards of ethical rigor. With direct information from target users being hard to achieve, prototypes are often developed in absence of systematic knowledge about the users' needs. This risks to generate a vicious circle since unmet users' expectations are a major indicator of low societal uptake and use.

Third the implementation of robots among target users is subject to several structural limitations. In fact, patients learning to work with new devices are hindered by several factors including (i) memory, learning and orientation problems, (ii) limited understanding of verbal instructions, (iii) problems with execution of purposeful activities, (iv) poor recognition of audio-visual prompts, and (v) other cognitive or physical limitations. As a response to this triple challenge we recommend the establishment of platforms for knowledge dissemination, the creation of incentives for user-driven research and the promotion of user-centered functional designs.

Knowledge dissemination is a key concept to favor interaction and information sharing among all relevant stakeholders involved in the care and management of robots for dementia care, in particular: designers, software developers, hardware engineers, manufacturing companies, geriatricians, neurologists and other healthcare professionals, healthcare institutions, regulatory agencies, informal caregivers, and, most importantly, patients. Healthcare institutions and individual professionals should increase their awareness about available technological opportunities that may be beneficial for the patient and favor their introduction into care. To achieve this goal, the organization of cross-disciplinary workshops and other shared activities should be encouraged. In addition, the exploratory introduction into residential care (e.g. geriatric hospitals) could increase the perception of robots as standard care practice; hence favor the introduction also in the in-home setting.

User-driven research is a framework or paradigm according to which research is driven by the needs and wishes of end users (*531*). The shift to this research paradigm is crucial to favor the development of user-centered technology designs. By producing large-scale or personalized knowledge about the needs and wishes of end-users, researchers can create prototypes whose functional specifications better match these needs and wishes. User-driven research conducted to date has identified several functional requirements that are particularly needed among elders with dementia. These include (i) user-friendly, simple-to-use and intuitive interfaces, (ii) high degree of personalisability (according to the user's preferences), (iii) usefulness in daily life. More specific functional requirements can be identified by investigating the users' perceptions about their own needs in relation to available services. A large-scale interview-based study has investigated the needs of 231 community-dwelling persons with dementia and 321 caregivers and assessed them according to the Camberwell Assessment of Need in the Elderly (CANE) (*532*). Results show that the highest proportions of unmet needs reported by persons with dementia concern the support for memory problems, the availability of information about dementia, the access to care and treatment, and the compensation for isolation and psychological distress; in contrast, the highest proportion of unmet needs reported by informal carers concern issues of memory, daytime activities and company (*532, 533*). Following Niemeijer et al. and Robinson et al., we call for a rapid transition to a user-centered model of technology design and development where the specific needs of persons with dementia and of their carers are carefully identified, considered, and integrated into the robots' functionality (*533, 534*). A similarly participatory model should be implemented at the stage of technology assessment and evaluation. A good example in this direction is an exploratory study by Heerink et al. in which researchers interviewed professional caregivers of older adults with dementia to identify a list of functional requirement perceived by them as suitable for therapy and subsequently used such list to assess commercially available robotic pets (*535*).

Informed Consent

Before enrolling people with dementia as research subjects into user-driven research, researchers have an ethical and legal obligation to obtain informed consent. This obligation also partly applies to installing and utilizing a robot both in the in-home and residential setting with the purpose of interacting with an adult with dementia. The obligation to informed consent, postulated in numerous codes and declarations such as the Declaration of Helsinki (1964-2008) and the Additional Protocol on the Convention of Human Rights and Biomedicine concerning Biomedical Research (2005), is an essential mechanism for the protection of a person's wellbeing and self-determination (*536*). In the context of AD and other dementias, the problem of obtaining informed consent is exacerbated by the increased difficulty to determine whether a person has the capacity to give informed consent as a consequence of the cognitive and emotional deficits caused by the disease. Competence, in fact, is to a great extent -but not exclusively- linked to cognitive capacity.

Informed consent can be obtained from or on behalf of people with dementia in three ways: (i) directly, (ii) proactively through advanced directives, (iii) or through proxy decision making. Direct consent can be obtained when the patient explicitly shows competence and cognitive capacity, usually at the early stage of AD or in the case of mild cognitive impairment. Advanced directives are (usually written) externalizations of a person's decisions and wishes regarding future medical courses of action. Through these directives, patients at early stage of AD or other dementias can spell out decisions about their future choices ahead of time, i.e. before the progression of the disease make them incapable to make autonomous and competent choices (*537*). Proxy decision making occurs when the decision involves a person other than the patient (called proxy), usually the patient's legal representative according to the local law or a person who was previously appointed by the patient. Alzheimer Europe has produced several recommendations for the obtainment of informed consent from persons with dementia (*537*). Although designed for guiding research, such recommendations are largely applicable to the implementation and use of robots too. Alzheimer Europe's recommendations are articulated into seven main tasks: capacity and willingness assessment, provision of information, ongoing consent and withdrawal, capacity loss, third-party involvement, advanced directives, further use of data [60].

At the level of capacity assessment, it is important to know that required cognitive levels vary depending on the complexity of the decision to be made. In general, a diagnosis of dementia should be considered as reasonable grounds for doubt concerning a person's capacity to consent and to justify the assessment of their capacity; however, it should never be considered alone a sufficient justification. While a person with mild dementia might be competent for many medical decisions, the symptoms at this stage of the disease could already interfere with competency for very complex situations. For any type of more advanced dementia, physicians would need to argument actively why they evaluated a patient as competent for a given decision. Cognitive testing alone may be insufficient (*538*). In the context of enrolling people with dementia for research, researchers must ensure that potential research subjects agreed to participate freely and willingly after having been given all relevant information, having understood this information, having received satisfactory responses to questions and without undue pressure from third parties. Similar external pressures should also be prevented at the level of domestic or residential use of robots. In particular, scenarios where family members or other informal caregivers *force* a patient with capacity to consent to have a service robot in the house ─e.g. because they want to reduce their time-investment and caregiving-workload should be prevented. We suggest that the combination of advanced directives, behavioral observation and confirmation by proxy may offer a triple protection. A scenario where (i) a patient at the early stage of the disease makes advanced directives to the use of the device while still mentally competent, (ii) shows enjoyment and no observable sign of distress during the continuative use of the device after the disease progresses, (iii) a proxy confirms the advanced directives based on behavioral observation, should be considered the optimal model.

When providing information for the purpose of consent, researchers or healthcare professionals should adapt their communication to the patient, respond to questions, use visual and other aids if necessary, and facilitate the communication of the decision by the patient. If consent is being sought for the purpose of enrollment in research, it should be ensured that potential participants with dementia understand the difference between treatment and research, emphasizing the fact that the direct objective of research is not to benefit the individual

[60] Our recommendations on informed consent are largely based or further elaborated upon Alzheimer Europe's report „The Ethics of Dementia Research." 537. A. Europe, *The ethics of dementia research*. (Alzeheimer Europe, 2011).

participant. If consent is being sought for the purpose of installing and using a robot in the patient's home, it must be ensured that the user understands the basic functionality of the robot and its potential usefulness for their daily life.

A crucial requirement of research involving dementia patients is that informed consent should be obtained at various intervals throughout the study. Due to the progressive and mood-changing character of the disease, patients may revoke their initial consent and must be free to withdraw at any time. In the research setting, researchers should be attentive to signs of distress linked to participation and if necessary ask the participants if they wish to withdraw from the study. In the implementation setting, caregivers should be attentive to signs of distress linked to the use of the robot or to its presence in the house.

If a person loses capacity during the study, and did not express prior to the study a wish to continue, should be withdrawn from the study. For this reason, clauses regarding the continuation of participation as well as regarding future use of data should be early included in the informed consent process when the person is still competent. In contrast, in the case of using a robot in the in-home or institutional setting, the use can continue after the patient loses capacity if the application provides a recognizable therapeutic or assistive benefit and no signs of distress are observable.

Ideally, third parties, especially spouses or partners, should be involved in the consent process. If the third party opposes the will of a person with dementia who has the capacity to consent, their opposition is not sufficient to override the will of that person. To prevent such conflicts and to avoid risks associated with sudden loss of capacity, the practice of writing advanced directives to externalize future preferences should be encouraged. While in the context of research enrollment such directives should state explicitly whether the person with dementia would or would not like to take part in research, in the context of technology use they could contain more specific preferences about everyday life and social activities: instead of either yes-robot or no-robot choices, users should be able to externalize what features, functionalities or activities of the robot they wish to continue or interrupt.

In the research context, researchers should be encouraged to include a clause on the consent form where participants can state whether or not they agree to their data being used for possible future studies. In the in-home and institutional setting, data should be only collected from users for the purposes that have been clearly explained to the user and to which the user has consented. Any additional use of the data should require additional consent. For example, monitoring data collected by telepresence robots for the purpose of increasing safety and conveying the presence of caregivers should not be used for additional (research, marketing etc.) purposes unless (i) the person with dementia has previously and explicitly consented to this further use, (ii) the reuse of that information can provide a recognizable therapeutic or assistive benefit for the patient.

It may be observed that, from the perspective of research, the promotion of user-driven studies and the strict criteria for consent in research delineated above pose an ethical dilemma. In fact, while large-scale enrollment of patients with dementia is highly desirable to maximize the benefits of robotics for people with dementia worldwide, strict procedures for informed consent limit and strictly regulate this enrollment process among individual participants. The major ethical challenge is to resolve this dilemma by promoting user-driven research in a context of rigorous application of ethical standards for informed consent.

Privacy and Data Security

Privacy is originally described as the right to be let alone (*497*). Within the context of social robotics for dementia it is crucial to determine what specific components of the right to privacy are at stake. Niemeijer and Hertogh proposed to distinguish four types of privacy: (i) informational privacy, (ii) physical privacy, (iii) attentional privacy, (iv) and decisional privacy (*539*). Informational privacy pertains to the capacity to seclude sensitive, confidential or private information. Physical privacy pertains to the capacity to demarcate one's personal physical space. Attentional privacy pertains to the capacity to retain one's attention from unsolicited prompts such as mail or telephone calls. Finally, decisional privacy pertains to the ability to choose a particular course of action without intrusion or interference from other agents. Informational privacy is particularly relevant in the context of telepresence robots. Robots such as Giraff and VGo may create a problem for informational privacy since they can be used as a 24-hour videosurveillance and recording system. Following the EU Data Protection Directive (*540*), we recommend that the collection and usage of visual information from elderly people with dementia meets the conditions of transparency, legitimate purpose and proportionality.

Transparency implies that the patient who is controlled is aware of being monitored and has given informed consent both to the installation of the robot and to the monitoring process. In addition, it also implies that the data collector and manager (e.g. the responsible informal or formal caregiver) has stated why data are being collected and processed. This procedure may be perceived as redundant from the perspective of family members whose goal is to increase safety, interaction, or conveying a sense of personal presence. However, it serves to prevent illegitimate third parties from managing those data. Exceptions should be allowed for monitoring interventions that prevent patients from being harmed (especially patients in the moderate to severe stages of the disease), following similar regulatory standards to those regulating monitoring technology for severely ill and incompetent patients in residential care (e.g. Intensive Care Units). In addition, data collectors should be reasonably informed about the potential risks associated with the illicit access to the data by malicious agents. Legitimate purpose is when the monitoring is performed for a specific purpose that is in the best interest of the patient and to which the patient or caregiver has previously consented. Legitimate purposes for videomonitoring include increasing safety, reducing risks and facilitating communication. Illegitimate purposes, in contrast, may include unauthorized surveillance or spying. Finally, the principle of proportionality requires that the videomonitoring is not disproportionate to the real therapeutic, assistive or emotional needs of the patient. For example, a non-stop video surveillance of an otherwise independent patient with mild to moderate dementia might not be proportionate to the needs of the patient and their condition.

Further ethical and legal reflection is needed within a twofold framework. In particular, from the perspective of criminal law, there is a need for a proactive and rigorous definition of the conditions for legal responsibility and culpability in both patients and robots. In emerging scenarios where the person with dementia has lost the capacity to consent, neither the patient nor the robot can be considered fully competent agents, hence fully responsible and ultimately culpable for their actions. To face these scenarios, unequivocal standards are required. For example, in case the robot harms the user in a non-programmatic way or the user harms another agent through the robot, unequivocal standards of accountability, responsibility and liability for both the robot and the user will be needed. Interdisciplinary work at the intersection between roboethics, neuroethics, criminal law, and forensic psychology should be encouraged to produce those standards.

Safety, Beneficence, Non-Maleficence and Autonomy

Good system safety norms require that a robot used in health care or as a commercial application is safe and that its use does not cause any increased risk of harm for users. Safety should be achieved through scientific, technical, and ethical-social strategies of risk identification, risk analysis, and elimination, control, or ongoing management of risks throughout the life-cycle of the robot and its activities. In ethical language, safety largely translates into the concept of non-maleficence, i.e. the principle of avoiding (preventing and notinflicting) harm. This ethical principle is usually paired with the principle of beneficence, i.e. the principle of promoting what is in the best interest of the user (*118*). In the context of robocare, the principles of beneficence and non-maleficence require a careful assessment of the balance between therapeutic, assistive or psychosocial benefit, on the one hand, and potential risks or distress, on the other hand. The promotion of the best interest of the user would also require a careful and continuative evaluation of their positive and negative experiences, with the knowledge that the user's preferences and experiences may change over the progression of the disease and that their ability to communicate those preferences and experiences may decrease over time. In addition to safety, data security must be taken into account too. In fact, the more data the robot is capable to collect and process, the higher the risk that such data can be used for unintended purposes, including purposes that are malicious or detrimental for the user and/or third parties. Data security standards are particularly relevant for monitoring and tracking devices, as well as for devices that can access and process personally identifiable and medical information of the users.

Robotic interventions that are in the best interest of the patients are those that prevent the patient from being harmed, and protect or promote the patient physical, cognitive, emotional and social wellbeing. Preventing harm and protecting or promoting wellbeing must be the common goals of robotic applications in dementia care, in ways that are specific of and appropriate to each type of robot. For example, telepresence robots are mainly designed for preventing harm, rehabilitation robots for promoting physical and cognitive wellbeing, and social or companion robots for emotional and psychosocial wellbeing. As previously stated, under specific circumstances, the best interest of the patient may reasonably justify partial exceptions to competitive moral rights such as privacy or consent. For example, when a robotherapy intervention supports life-maintaining functions in a patient with advanced dementia, this intervention may be delivered also in absence of explicit consent from the patient or the proxy to pursue the best interest of the patient ─unless previously rejected by the patient via advanced directives or assessed as futile by the local medical team and ethics committee.

Some authors have argued that the use of robots in dementia care, especially robotic pets and other companion robots, raises the moral and psychological risk of making patients more infantile and dehumanizing care by reducing human interaction (*541, 542*). These risks could be avoided by increasing the awareness and active decisional role of patients. The patient should not be overridden but constantly included in the decision making process about the use of a new robotic application. This will not only reduce the risk of infantilization but also ─and most importantly, promote their perception of the robotic application as empowering, hence as a valuable instrument for the promotion of their autonomy and independence.

Justice, equity and fair distribution

Until now, social justice and distributive justice have not been considered as primary concerns in the introduction of robotics into healthcare. Neither attaining fairness, nor applying substantive principles in allocating robotic applications are an easy task. A one-size-fits-all policy could be inadequate because of the specific functional characteristics of each application, and the fluctuation in the costs for their provision caused by the current level of maturity of their market. Moreover, the healthcare systems of different countries follow different principles of justice and answer to dissimilar needs surging from social structures and diverse cultures in each country. *Universal access by fair opportunity* to assistive technologies should be the target in the long run, but in the early stages their fair distribution has to be prioritized.

Distributive justice is not a matter of chance or plain equality. Its principles are guidelines for providing rightfulness, fairness, and redress in institutional settings. One option for healthcare institutions and robot manufacturers to attain these principles is to curb the costs by promoting the development of low-cost robot technologies. To this purpose, the dissemination of open-source initiatives for affordable devices such as the OpenBionics (http://www.openbionics.org/) should be encouraged.

From a regulatory perspective, robots for dementia are often in a gray zone between the regulation of medical applications and that of general ICT applications. A striking example is Paro, who is classified as Class 2 medical device by the U.S. FDA regulation but not in the EU. Therefore, a principle of justice in disseminating innovation should take into account the dual nature of these robot types as well as the differences in local regulations. Emphasizing each of these aspects –respectively the medical and the commercial- has both regulatory advantages and disadvantages. A privileged focus on the medical aspects would favor the application to care robots of standard medical practices, the implementation of safeguards that are specific for medical applications, and the development of more welfarist plans for technology access and distribution. As a downside, it could slow down the increase in performance (as implied by the Moore’s law) as well as the price fall over time. In contrast, a privileged focus on the commercial aspects would accelerate the decrease in price and increase in computational power of future application. As a downside, however, it would decrease the level of safeguards; hence increase the vulnerability of future applications to technical, ethical, legal, and social risks.

When developing robotic applications for dementia it is fair *to recognize* the special needs of patients, their differences from healthy users, and the fact that they are not responsible for their health conditions. Some corrective measures could help reduce inequality and provide redress such as the promotion of experimental settings with assistive robots in state owned retirement houses, the establishment of State incentives for developing better technologies (when is the case, for example in the EU), and the promotion of user-centered research involving patients and caregivers. Patient well-being should not exclusively rely on their economic resources.

Conclusions

Robotics opens the prospects of providing a triple-win effect on the management of the global crisis posed by dementia and population ageing. Nonetheless, such potential benefits risk to be tampered if social, legal and ethical questions remain unaddressed. We took a first step into delineating the ethical, legal and social landscape of robotics for dementia care. Further interdisciplinary research is required to extensively address each specific issue and develop a systematic framework to maximize the benefits of these emerging technologies while minimizing the unintended risks. In particular, further cross-cultural empirical research involving older adults with dementia and their caregivers is required to better inform technology producers about the specific needs of this vulnerable target population. In parallel, translational research at the intersection between robotics, geriatrics, gerontology and the nursing sciences should be conducted to increase the implementation and uptake of robotic applications in dementia care. Finally, further research in bio- and neuroethics is required to promote the ethical development and responsible application of future applications.

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*2.13 - Towards New Human Rights in the Age of Neuroscience and Neurotechnology**

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Abstract

Rapid advancements in human neuroscience and neurotechnology open unprecedented possibilities for accessing, collecting, sharing and manipulating information from the human brain. Such applications raise important challenges to human rights principles that need to be addressed to prevent unintended consequences. This paper assesses the implications of emerging neurotechnology applications in the context of the human rights framework and suggests that existing human rights may not be normatively sufficient to respond to these emerging issues. After analysing the relationship between neuroscience and human rights, we identify four new rights that may become of great relevance in the coming decades: the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity.

Introduction

The quotation in the epigraph is from the play *Comus*, written by John Milton in 1634. The piece, an exhortation to virtue, follows the story a young noblewoman who has been abducted by a sorcerer called Comus. He has bounded her to an enchanted chair and tried to seduce her with arguments about the charm of bodily pleasure. Despite all his rhetorical assaults, the woman repeatedly refuses his advances and claims that, no matter what he does or says, she will continue asserting her freedom of mind, which is beyond his physical power. In the end, she is rescued by her brothers, who chase off Comus.

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The quoted sentence conveys the idea that the mind is a kind of last refuge of personal freedom and self-determination. While the body can easily be subject to domination and control by others, our mind, along with our thoughts, beliefs and convictions, are to a large extent beyond external constraint. Yet, with advances in neural engineering, brain imaging and pervasive neurotechnology, the mind might no longer be this unassailable fortress. As we will explain in this paper, emerging neurotechnologies have the potential to allow access to at least some components of mental information. While these advances can be greatly beneficial for individuals and society, they can also be misused and create unprecedented threats to the freedom of the mind and to the individual capacity to freely govern her behaviour.

In the research context, brain imaging techniques are widely used to understand the functioning of the human brain and detect the neural correlates of mental states and behaviour. Clinical applications of brain imaging as well as other neurotechnologies are significantly improving the well-being of patients suffering from neurological disorders, offering new preventive, diagnostic and therapeutic tools. Outside the clinics, pervasive commercial applications are rapidly providing new possibilities for self-quantification, cognitive enhancement, personalized communication and entertainment for normal users. Furthermore, a number of neurotechnology applications are becoming of major interest in the legal domain, especially tort law, criminal law and law enforcement.

On the other hand, these same technologies, if misused or inadequately implemented, risk creating unparalleled forms of intrusion into people's private sphere, potentially causing physical or psychological harm, or allowing undue influence on people's behaviour.

This paper makes the case that the possibilities opened up by neurotechnological developments and their application to various aspects of human life will force a reconceptualization of certain human rights, or even the creation of new rights to protect people from potential harm.

In 2013, US President Obama called attention to the potential impact of neuroscience on human rights, emphasising the need to address questions such as those

"(…) relating to privacy, personal agency, and moral responsibility for one's actions; questions about stigmatization and discrimination based on neurological measures of intelligence or other traits; and questions about the appropriate use of neuroscience in the criminal-justice system" (*543*).

This article begins by exploring the current possibilities and challenges of neurotechnology, and considers what neurotechnological trends will drive this ethical and legal reconceptualization. After carefully analyzing the relationship between neuroscience and human rights, this paper identifies four new rights that may become of relevance in the coming decades: the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity.

THE NEUROTECHNOLOGY REVOLUTION

For a long time, the boundaries of the skull have been generally considered the separation line between the observable and unobservable dimension of the living human being. In fact, although primitive forms of neurosurgery used in ancient societies, including pseudo-scientific procedures such as trepanation, could allow for the observation and even manipulation (e.g. selective removal) of brain tissue, yet the neural and mental processes run in the brain and underlying emotions, reasoning and behavior remained at length unobservable. In contrast, modern advancements in neuroscience and neurotechnology have progressively allowed for the unlocking of the human brain and provided insights into brain processes as well as their link to, respectively, mental states and observable behaviour. In 1878 Richard Canton discovered the transmission of electrical signals through an animal's brain. Forty-six years later the first human electroencephalography (EEG) was recorded. Since then, a neurotechnology explosion has occurred inside and outside the clinics. In the 1990s, sometimes referred to as the 'decade of the brain', the use of imaging techniques for neurobehavioral studies had increased dramatically (*544*). Today, as a wide and rapidly expanding spectrum of neuroimaging technologies has become clinically and commercially available, the non-invasive recording and display of patterns of brain activity (often associated with the completion of physical or cognitive tasks) has become standard practice. For example, EEG recordings are being widely used to non-invasively measure electrical activity of the brain and detect voltage fluctuations. In addition, derivatives of the EEG technique such as evoked potentials (EPs) and event-related potentials (ERP) allow to average EEG responses to the presentation and processing of stimuli, hence to read brain signalling during the performance of specific sensory, cognitive or motor processes. Another technique, functional Magnetic Resonance Technology (fMRI), allows to measure brain's electrical activity indirectly, i.e. by using hemodynamic responses (cerebral blood flow) as indirect markers. Current fMRI techniques can localize brain activity, graphically display patterns of brain activation, and determine their intensity by color-coding the strength of activation. fMRI techniques are implemented for a variety of purposes including pre-surgery risk assessment, and functional mapping of brain areas to detect abnormalities (e.g. left-right hemispherical asymmetry in language and memory regions) or to observe post-stroke or post-surgery recovery, as well as the effects of pharmacological and behavioral therapies. In addition, a number of neurological conditions including depression and Alzheimer's disease can now be diagnosed with the use of fMRI (*545*).

The capacity of neuroimaging techniques to map brain functioning has been tested effective also in gaining insights into people's intentions, views and attitudes. For example, scientists were able to infer from decoded brain activity which actions participants in their trial were intending to perform. The task in question was to decide whether to add or subtract two numbers and to covertly hold their intention for a few seconds. During that delay, it was possible for scientists to determine with 70% accuracy which of two tasks the subjects were covertly intending to perform (*546*). In another study, participants toured several virtual-reality houses, and then had their brains scanned while touring another selection. By identifying certain patterns of brain activity for each house, scientists were able to determine which houses their subjects had been to before (*547*). Brain scans do not only allow to "read" concrete experiment-related intentions and memories. They appear even able to decode more general preferences. A US study has shown that fMRI scans can be used to successfully infer the political views of the users by identifying functional differences in the brains of respectively Democrats and Republicans (*548*). Similarly, men's frequent preference for sport cars has been correlated with specific functional differences in the men's vs the women's brain (*549*).

The possibility of non-invasively identifying such mental correlates of brain functional differences is of particular interest for marketing purposes. Over a decade ago, McClure et al. (2004) used fMRI to show functional differences (increased activation in the dorsolateral prefrontal cortex, hippocampus and midbrain) in the brain of people knowingly drinking Coca Cola as opposed to the same people drinking unlabeled Coke. Their results showed that marketing strategies (e.g. the Coca Cola label) can determine different responses in the brain of consumers (*550*). These results have pioneered the establishment of a new spin-out branch of neuroscience at the intersection with marketing research called neuromarketing, which has expanded rapidly over the past decade. Today, several multinational companies including Google, Disney, CBS, and Frito-Lay use neuromarketing research services to measure consumer preferences and impressions on their advertisements or products. In addition, a number of specialized neuromarketing companies including EmSense, Neurosence, MindLab International and Nielsen, routinely apply neuroimaging techniques, mostly fMRI and EEG, but also Steady State Topography (SST) and physiological measurements (e.g. galvanic skin response) to study, analyze and predict consumer behavior. This possibility of *mining the mind* (or at least informationally rich structural aspects of the mind) can be potentially used not only to infer mental preferences, but also to prime, imprint or trigger those preferences. For example, company Neurofocus has tested subliminal techniques —for instance embedding stimuli shorter 30 milliseconds, hence under the threshold of conscious perception — with the purposes of eliciting responses (e.g. preferring item A instead of B) that people cannot consciously register (*551*). In view of these developments, authors have stressed the need to establish ethical and legal standards for neuromarketing practices (*552*).

Brain imaging techniques were originally developed and are still mostly implemented within the context of clinical medicine and neuroscience research. In recent years, however, a number of neurotechnology applications have made their way onto the market and are now integrated into a number of consumer-grade devices for healthy users with various non-clinical purposes. The umbrella term usually used to encompass all these non-invasive, scalable and potentially ubiquitous of neurotechnologies is "pervasive neurotechnology" (*474*), a notion borrowed from the most widespread notion of pervasive computing. Today, pervasive neurotechnology applications include brain-computer interfaces (BCIs) for device control or real-time neuromonitoring, neurosensor-based vehicle operator systems, cognitive training tools, electrical and magnetic brain stimulation, wearables for mental wellbeing, and virtual reality systems.

Most of these applications use EEG recordings to monitor electrical activity in the brain for a variety of purposes including neuromonitoring (real time evaluation of brain functioning), neurocognitive training (using certain frequency bands to enhance neurocognitive functions), and device control. EEG-based BCIs are being increasingly used as wearable accessories for a number of everyday activities including gaming, entertainment, and smartphone's remote control. For examples, companies Emotiv and Neurosky offer a large assortment of wireless headsets for everyday use that can be connected to compliant smartphones and personal computers (*281*). Brain-control can be used to remotely control several types of devices and engage in several activities including gaming and other forms of entertainment, marketing, self-monitoring and communicating.

The possibility of non-invasive brain control has raised the attention of the mobile communication industry. Several leading companies including Apple and Samsung are incorporating neurogadgets into the accessory assortments of their major products. For instance, iPhone accessories such as the XWave headset already allow to plug directly into compliant iPhones and read brainwaves. Meanwhile, prototypes of next-generation Samsung Galaxy Tabs and other mobile or wearable devices have being tested to be controlled by brain activity via EEG-based BCI (*553*). In the light of these trends, Yuan and colleagues predicted that neurodevices will gradually replace the keyboard, the touch screen, the mouse and the voice command device as humans' preferred ways to interact with computers (*456*).

Not only neuroimaging devices and BCIs fit into the category of pervasive neurotechnology. Several electrical brain stimulators fit into this category too. Unlike neuroimaging tools, neurostimulators are not used for recording or decoding brain activity but rather for stimulating or modulating brain activity electrically. Portable, easy-to-use, consumer based t*ranscranial direct current stimulation* (*tDCS*) devices are the most widespread form of consumer-grade neurostimulator. They are used in a number of low-cost direct-to-consumer applications aimed at optimizing brain performance on a variety of cognitive tasks, depending on the brain region being stimulated.[62] Recently, transcranial magnetic stimulation (TMS) — a magnetic method used to briefly stimulate small regions of the brain for both diagnostic and therapeutic purposes, has also evolved into portable devices, which resulted effective in the treatment of migraine (*554*). Finally, an invasive surgical technique called deep brain stimulation (DBS) involving the implantation of a neurostimulator in the ventrointermediate nucleus of the thalamus has obtained FDA approval and is now increasingly used as a treatment for essential tremor, Parkinson's disease, dystonia and obsessive–compulsive disorder.

In sum, if in the past decades neurotechnology has unlocked the human brain and made it readable under scientific lenses, the upcoming decades will see neurotechnology becoming pervasive and embedded in numerous aspects of our lives and increasingly effective in modulating the neural correlates of our psychology and behavior. While welcoming continuing progress in neurotechnology development, in this paper we argue that the ethical and legal implications of the neurotechnology explosion should be considered early and in a proactive manner. More in detail, we argue that the legal system has to be adequately prepared to deal with these new challenges that might emerge out of emerging neurotechnology, in particular in the context of human rights. As neurotechnology advances, it is critical to assess whether our current human rights framework is conceptually and normatively well-equipped to face the novel challenges arising at the brain-computer-society entanglement, hence to provide

[62] For example, the website The Brain Stimulator offers a wide assortment of affordable tDCS devices, with prices ranging between 60$ and 200$. See: https://thebrainstimulator.net/shop/

simultaneously guidance to researchers and developers while providing protection to individuals and groups.

BRAIN TECHNOLOGY AND THE LAW

Neuroscience and the law intersect on many levels and on various different issues. This is not surprising. While neuroscience studies the brain processes that underlie human behaviour, legal systems are quintessentially concerned with the regulation of human behaviour. It is therefore reasonable to claim that both disciplines are destined to be "natural partners" (*555*). The underlying idea of the new field called "neurolaw" is precisely that better knowledge of the brain will lead to better-designed laws and fairer legal procedures. Examples of potentially legally relevant applications of neurotechnology are numerous. Brain imaging techniques, for instance, might possibly contribute to more evidence-based decisions in criminal justice, from investigation and the assessment of criminal responsibility, to punishment, rehabilitation of offenders, and the evaluation of their risk of recidivism. The tools offered by neuroscience could potentially play also a role in civil law procedures, for example, in the assessment of an individual's capacity to contract, or of the severity of the plaintiff's pain in compensation claims. New and more reliable lie detection technologies based on our knowledge of the brain functioning might help to assess the reliability of witnesses. Memory erasure of recidivist violent criminals and of victims of especially traumatic offences (e.g. sexual abuse) is also mentioned as another possibility opened by our new knowledge of the brain (*555*).

A possibly game-changing use of neurotechnology in the legal field has been illustrated by Aharoni and colleagues (2013). In this study, researchers followed a group of 96 male prisoners at prison release. Using fMRI, prisoners' brains were scanned during the performance of computer tasks in which they had to make quick decisions and inhibit impulsive reactions. The researchers followed the ex-convicts for four years to see how they behaved. The study results indicate that those individuals showing low activity in a brain region associated with decision-making and action (the Anterior Cingulate Cortex, ACC) are more likely to commit crimes again within four years of release (*556*). According to the study, the risk of recidivism is *more than double* in individuals showing low activity in that region of the brain than in individuals with high activity in that region. Their results suggest a "potential neurocognitive biomarker for persistent antisocial behavior". In other words, brain scans can theoretically help determine whether certain convicted persons are at an increased risk of reoffending if released.

This prospect evokes Philip Dick's 1956 science fiction story "The Minority Report", which was adapted into a movie in 2002. The plot is about a special police unit ("Precrime Division") which is able to identify and arrest murderers before they commit their crimes. The system is believed to be flawless until an officer from that same unit is mistakenly accused of a future murder (*557*). This dystopian scenario, which could result from the new knowledge about the brain, raises important ethical and human rights questions. How much evidence is needed to prove that brain scans are likely to flag only the truly high risk offenders? Can neurotechnology-generated data, which have a probabilistic nature, be straightforwardly applied to predict the criminal behaviour of a particular individual? Can these preliminary findings, which were based on a very specific cohort, be generalized to other groups? In any case, it is clear that much more work is needed to ensure the reliability of the technique before authorising its use by courts, certainly not as a substitute for current methods for dangerousness assessment, but maybe as an additional, complementary tool.

Other brain technologies that may be relevant for the legal system are lie detectors, mental decoders, and brain printers. Lie detectors are devices capable to record and measure brain responses associated with the retrieval of memories, with the purpose of ascertaining the truth-values of statements relative to those memories. Traditional lie detectors, like the polygraph, measure some bodily markers such as blood pressure, heart rate, and muscular reactions. Despite their low reliability, they are regularly used by some government agencies to screen their employees. However, they are very rarely accepted as evidence in US courts. The new generations of lie detectors, which are EEG-based and fMRI-based, are regarded as much more reliable than the polygraph, as they detect the lie at its source: the brain. In the United States, at least two companies –*No Lie MRI* and *Cephos Corp*– are currently offering fMRI lie-detection services (*558*). A study published in 2005 by a research group linked to Cephos, claimed that fMRI-based lie detection has a reliability of around 90%. The study predicted that the procedure will be further improved and ready to be used in courts in the not too distant future (*559*). Today, recent studies have confirmed the higher reliability of fMRI-based lie detectors compared to polygraphy (*560*). In parallel, mental decoders are capable of decoding mental states and translating them into observable outputs such as text, verbal signals or graphic images. For example, Herff et al. (2015) and Mirkovic et al. (2015) have independently demonstrated the effectiveness of a decoder capable of reconstructing speech from brain waves (*561, 562*). Such devices have a great potential for beneficial clinical applicability as they could benefit several classes of neurological patients, especially those suffering from locked-in syndrome and paralysis. Such patients, who have lost their capacity to produce verbal communication, would be enabled to re-interact with the external world by producing speech solely by brain activity. Outside the clinical setting, such decoders are tested to enhance mobile communication through thought-to-text converters. Not all mental decoders are designed to enhance users' autonomy. Some devices are currently tested for monitoring brain states with the purpose of guiding the individual's behavior. For example, NASA and Jaguar are jointly developing a technology called *Mind Sense,* which will measure brainwaves to monitor the driver's concentration in the car (*563*). If brain activity indicates poor concentration, then the steering wheel or pedals could vibrate to raise the driver's awareness of the danger. This technology can contribute to reduce the number of accidents caused by drivers who are stressed or distracted. However, it also opens theoretically the possibility for third parties to use brain decoders to eavesdropping on people's states of mind.

Similar implications are raised by brain printers. These are prototypical devices that are currently tested as brain-based authentication methods. For example, researchers at Binghamton University in the state of New York have devised a way to verify a person's identity based on how their brain responds to certain words. The researchers observed the brain signals of 45 volunteers as they read a list of 75 acronyms, such as FBI and DVD, and recorded the brain's reaction to each group of letters, focusing on the part of the brain associated with reading and recognizing words. It turns out that participants' brains reacted differently to each acronym — so that a computer system was able to identify each volunteer with 94% accuracy (*564*). This technology, which could in the short term replace passwords and fingerprints as authentication tool for personal accounts, raises novel privacy and security issues.

As neurotechnology advances and opens novel opportunities monitoring and controlling cognitive function, there is uncertainty on how the law should cope with such advancements. In particular, it remains debatable whether emerging trends in neurotechnology call for a revision or even a replacement of existing legal concepts at various levels including civil law, tort law, business law and legal philosophy. While increasing attention is being devoted in the literature to emerging neurotechnology applications in the context of criminal law or to the increasing use of neuroscience evidence in courts, little focus has been directed to the implications of advancing neuroscience and neurotechnology for human right law. This neglected component of the neurolaw discourse is of particular relevance since the universal nature of the human right framework could provide a solid foundation for this emerging "jurisprudence of the mind".

Neuroscience and Human Rights

Overview

While neurotechnology has the potential to impact human rights such as privacy, freedom of thought, the right to mental integrity, the freedom from discrimination, the right to a fair trial, or the principle against self-incrimination, yet international human rights law does not make any explicit reference to neuroscience. In contrast to other biomedical developments, which have already been the subject of standard-setting efforts at the domestic and international level, neurotechnology still largely remains a *terra incognita* for human rights law. Nonetheless, the implications raised by neuroscience and neurotechnology for inherent features of human beings, urge a prompt and adaptive response from human rights law.

The adaptive ability that human rights law has shown in responding to the challenges posed by genetic technology may help to anticipate how this branch of law could evolve in the coming years in response to new issues raised by neuroscience. Since the end of the 1990s, the international community has made significant efforts to address a great variety of issues that result from the increasing access to human genetic data. In 1997, the *Universal Declaration on the Human Genome and Human Rights* (UDHGHR) was adopted to prevent that genetic information is collected and used in ways that are incompatible with respect for human rights, and to protect the human genome from improper manipulations that may harm future generations. The principles contained in this instrument were further developed in 2003 by the *International Declaration on Human Genetic Data* (IDHGD*)*, which sets out more specific rules for the collection of human biological samples and genetic data. It is interesting to note that from the interaction between genetics and human rights resulted entirely new rights, such as the "right not to know one's genetic information", which is formally recognized by the UDHGHR (Art. 5(c)) and the IDHGD (Art. 10), as well as by other international and national regulations. In addition to the recognition of new rights, "old" rights –such as the right to privacy and the right against discrimination- were specifically adapted to the novel challenges posed by genetics. This close connection between life sciences and human rights was further strengthened by the 2005 Universal Declaration on Bioethics and Human Rights, which comprehensively addresses the linkage between both fields (*565*). This latter document sets out principles that are applicable not only to genetics but to other biomedical and life sciences issues.

In this paper we claim that, similarly to the historical trajectory of the "genetic revolution", the ongoing "neuro-revolution" will reshape some of our ethical and legal notions. In particular, we argue that the growing sensitivity and availability of neurodevices will require in the coming years the emergence of new rights or at least the further development of traditional rights to specifically address the challenges posed by neuroscience and neurotechnology. This argument is in accordance with the observation of how human rights have historically emerged and developed in modern societies. Human rights, in fact, have always arisen as specific responses to recurrent threats to fundamental human interests (*566*), to human dignity (*567*), or to what is required by a "minimally good life" (*568*). As we attempt to show in this paper, the individual quest to exert control over one's own neuro-cognitive dimension as well as the emergence of potential threats to basic human goods or interests posed by the misuse or inadequate application of neurotechnological devices may require a reconceptualization of some traditional human rights or even the creation of new neuro-specific rights.

It goes beyond the scope of this article to discuss the different theories about the foundations of human rights, or to take a position in this regard. For the purposes of our investigation we chose to adopt a broad practical conception of human rights, like the one proposed by Beitz (2011, p. 109), who argues that they are "requirements whose object is to protect urgent individual interests against predictable dangers ('standard threats') to which they are vulnerable under typical circumstances of life in a modern world order composed of states" (*569*). In general terms, it can be said that the scope of human rights is to guarantee both the necessary negative and positive prerequisites for leading a minimally good life (*570*).

A common objection against the recognition of new rights is that it leads to the so-called "rights inflation", which is the objectionable tendency to label everything that is morally desirable as a "human right". The unjustified proliferation of new rights is indeed problematic because it spreads skepticism about all human rights, as if they were merely wishful thinking or purely rhetorical claims. Rights inflation is to be avoided because it dilutes the core idea of human rights and distracts from the central goal of human rights instruments, which is to protect a set of truly fundamental human interests, and not everything that would be desirable or advantageous in an ideal world.

A frequently accepted way to avoid rights inflation is to impose justificatory tests for specific human rights. For example, according to Nickel (2014), it could be required that a proposed human right should not only deal with some very important good but also respond to a common and serious threat to that good, impose burdens on the addressees that are justifiable and no larger than necessary, and be feasible in most of the world's countries (*571*). The international law scholar Philip Alston (1984) has suggested a list of criteria that a given claim must satisfy in order to qualify as a "human right" in terms of international law (*151*). In his view, the proposed new human right must “reflect a fundamentally important social value”; “be consistent, but not merely repetitive, of the existing body of international human rights law”; “be capable of achieving a very high degree of international consensus”, and “be sufficiently precise as to give rise to identifiable rights and obligations”.

For the reasons we give below, we think that the new rights advocated in this paper −the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity− fulfill these requirements and therefore do not raise the risk of rights inflation.

This proposal of neuro-specific human rights is consistent with Glen Boire’s advocacy of a “jurisprudence of the mind” that “takes account of the latest understandings of the brain” and “which situates these within our country’s tradition of embracing individual, self-determination and limited government” (Boire 2003, p10). As brain technology is rapidly reshaping the infosphere and the digital infrastructures in our societies, there is an urgent need to proactively assess whether our current ethical and legal frameworks are ready to face this emerging scenario.

It is also worth noting *in limine* that many of the issues discussed in this paper are not unique to cutting-edge neurotechnology but have precedents in more traditional interventions. For example, breaches for mental privacy emerged before the invention of neuroimaging and neuromonitoring technologies through more rudimental techniques such as interrogation and polygraph-based lie detection. These interventions, however, do not target neural processing directly but only via proxy-processes such as speech, behavior, and physiological indices (e.g. pulse and skin conductivity). In addition, the degree of accuracy and resolution of such techniques is remarkably low (*572*), hence often insufficient to support epistemologically justified inferences about mental information. Similarly, threats to mental integrity and psychological continuity were posed by non-computational interventions such as psychoactive drugs and hypnotic inductions way before the invention of neurostimulation and brain-machine interfacing. However, these techniques are often characterized by limited efficacy and reliability in purposively manipulating mental activity as well as low degrees of selectivity in targeting neural processes. Based on these considerations, we argue that advanced neurotechnology enables a degree of access into and manipulation of neural processes significantly higher than other techniques. Therefore, while we consider the ethical and legal analysis presented in this paper applicable to the entire spectrum of both computational and non-computational brain interventions, we argue that the degree of perturbation of advanced neurotechnology on the current ethical-legal framework is quantitatively higher than non-computational techniques. For this reason we situate neurotechnology as the focus of our proposed normative upgrade.

Cognitive Liberty

A first, essential step towards the creation of a neuro-oriented human rights framework has been the recent debate over the notion of cognitive liberty. According to Bublitz (2013), this complex notion, often also referred to as *mental self-determination*, comprises two fundamental and intimately related principles: (a) the right of individuals to use emerging neurotechnologies; (b) the protection of individuals from the coercive and unconsented use of such technologies. As he concisely put it, cognitive liberty is the principle that guarantees “the right to alter one’s mental states with the help of neurotools as well as to refuse to do so” (Bublitz 2013).

Proponents of cognitive liberty suggest considering it a “fundamental human right” as well as “a central legal principle guiding the regulation of neurotechnologies” (*408*). The reason of its fundamental function stems from the fact that “the right and freedom to control one’s own consciousness and electrochemical thought processes is the necessary substrate for just about every other freedom” (*406*). In fact, as Bublitz argued, “it is hard to conceive any conception of a legal subject in which the mind and mental capacities (e.g. acting from reasons, deliberation) are not among its necessary constitutive conditions” (*408*). Cognitive liberty, therefore, is necessary to all other liberties, because it is their neuro-cognitive substrate. As such, cognitive liberty resembles the notion of ‘freedom of thought’ which is usually considered the essential justification of other freedoms such as freedom of choice, freedom of speech, freedom of press, and freedom of religion. Not surprisingly, Sententia (2004) presented cognitive liberty as a *conceptual update* of freedom of thought that “takes into account the power we now have, and increasingly will have to monitor and manipulate cognitive function” (Sententia 2004). Some legal scholars such as Boire and Sententia have interpreted the right to cognitive liberty with special focus on the protection of individual freedom and self-determination from the State. For example, Sententia has claimed that “the State cannot, consistent with the First Amendment of the Constitution, forcibly manipulate the mental states, and implicitly the brain states of individual citizens”.

Given its conceptual complexity, cognitive liberty is multi-dimensional. Bublitz recognizes at least three “interrelated but not identical dimensions” (Bubliz 2013). These are: (i) the liberty to change one’s mind or to choose whether and by which means to change one’s mind; (ii) the protection of interventions into other minds to protect mental integrity, and (iii) the ethical and legal obligation to promoting cognitive liberty. These three dimensions configure cognitive liberty as a complex right which involves the prerequisites of both negative and positive liberties in Berlin's sense (*573*): the negative liberty of making choices about one's own cognitive domain in absence of governmental or non-governmental obstacles, barriers or prohibitions; the negative liberty of exercising one's own right to mental integrity in absence of constrains or violations from corporations, criminal agents or the government; and finally, the positive liberty of having the possibility of acting in such a way as to take control of one's mental life.

Being the neurocognitive substrate of all other liberties, cognitive liberty cannot be reduced to existing rights, hence is immune to the risk of rights inflation. In addition, since cognitive life, although in various forms and degrees, is inherent in all human beings, cognitive liberty is consistent with a definition of human rights as inalienable fundamentals rights "to which a person is inherently entitled simply because she or he is a human being" (*574*), regardless of their nation, location, language, religion, ethnic origin or any other status. Consequently, its integration into the human right framework would enable the protection of constitutive features of human beings that are not being entirely protected by existing rights.

For the purposes of our analysis, in this article we will focus exclusively on the negative formulation of the right to cognitive liberty, namely as the right to refuse coercive uses of neurotechnology. In addition, while we welcome the introduction of the right to cognitive liberty, we argue that this notion is not sufficient alone to cover the entire spectrum of ethical and legal implications associated with neurotechnology. Rather, the establishment of cognitive liberty as a human right should be coordinated with a simultaneous reconceptualization of existing rights or even the creation of other new neuro-specific rights. These are the right to mental privacy, the right to mental integrity and the right to psychological continuity.

The right to mental privacy

Today's infosphere is more intrusive than at any other time in history. Websites regularly use cookies to record store visitors' information such as browsing activities, preferences, personal data, visited pages, passwords, credit card numbers, etc. Big and small corporations engage in data-mining activities that capture massive amounts of data about users. Much of this information is about daily activities: what was purchased, when, where and how much was paid. E-mail accounts are stuffed with advertisements and unsolicited offers. Phone numbers and personal addresses are captured in databases and sold to corporations and government agencies.

In addition, video surveillance, facial recognition technology, spyware are opening up people's daily activities for public consumption. As Moore (2010) puts it, today "informational privacy is everywhere under siege" (*575*).

The widespread availability of neurotechnology applications will provide multiple opportunities for individuals to access and exert control over their brain-activity, hence resulting in a number of potentially beneficial activities such as self-monitoring, neuro-enhancement, and brain-controlled computer use. However, these same tools will disseminate an unprecedented volume and variety of brain information outside the clinical domain and potentially increase the availability of such information to third parties. As pervasive applications of neurotechnology are introducing brain data into the infosphere, they are thereby exposing them to the same degree of intrusiveness and vulnerability to which is exposed any other bit of information circulating in the digital ecosystem. At present, no specific legal or technical safeguard protects brain data from being subject to the same data-mining and privacy intruding measures as other types of information. In the words of Nita Farahany, "there are no legal protections from having your mind involuntarily read".[63] The reason for that stems from the fact, as Charo observes, that "technology innovates faster than the regulatory system can adapt" (*481*).

A large number of ethical, legal, and social questions arise from these neurotechnological possibilities. These include: For what purposes and under what conditions can brain information be collected and used? What components of brain information shall be legitimately disclosed and made accessible to others? Who shall be entitled to access those data (employers, insurance companies, the State)? What should be the limits to consent in this area?

Although a first attempt of response to these questions can be made by appealing to existing legal norms, we claim that specific legal notions and provisions have to be developed. The first notion involved in these debates is that of *privacy*. International human rights law formally recognises the right to privacy. The Universal Declaration of Human Rights (UDHR) states that "no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks" (Article 12). Similarly, the 1950 European Convention on Human Rights (ECHR) stipulates that "everyone has the right to respect for his private and family life, his home and correspondence" (Article 8 para 1). It is

63 Speech at Panel on "What If: Your Brain Confesses?" World Economic Forum – Annual Meeting, Davos, 20-23 January 2016. Available at: https://www.weforum.org/events/world-economic-forum-annual-meeting-2016/sessions/what-if-your-brain-confesses/

interesting to note that the right to privacy is one of the few rights that was recognised by international law as a broad, umbrella right before it was included in any state constitution (*576*).

At the European level, the right to privacy recognised by the ECHR was developed by the 1995 EU Data Protection Directive (95/46/EC), which specifically aims at protecting individuals with regard to the processing and transfer of personal data. Currently, the EU is planning to adapt the data protection rules to the challenges to privacy posed by the new digital environment. The overall goal of the upcoming Directive and Regulation is to empower individuals with more control over their personal data.[64] Also the EU Charter of Fundamental Rights, adopted in 2000, states the general right to protection of private life in Article 7 and specifies in Article 8 that "everyone has the right to the protection of personal data concerning him or her" (para 1). According to paragraph 2 of the latter provision,

"[s]uch data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified".

The first question that arises in the context of the current privacy protection standards is whether the traditional right to privacy also covers the data contained in and generated by our minds. An answer to this dilemma is not immediately available, not least because there is no consensus in the legal literature on a definition of privacy. This can be explained by the disparate content of this right, which includes not only the right to control access to personal information, but also to our bodies and to specific private places. In their seminal article, published in 1890, Samuel Warren and Louis Brandeis articulated the right to privacy as "a right to be let alone" (*497*). Their primary concern was the increasing interest of the yellow press in gossiping and revealing personal information about individuals, including pictures of private persons without their consent. This specific instance of privacy was further developed by Alan Westin and other authors into the broader notion of informational privacy, i.e. the control over information about oneself. According to Westin, privacy can be described in terms of our claim to determine for ourselves when, how, and to what extent information about us is communicated to others (*498*). Today, the "right to be let alone" delineated by Warren and Brandeis more than one century ago has clearly become relevant to areas far removed from their original concerns. The various facets of the modern understanding of privacy continue to expand as technological

[64] See: http://ec.europa.eu/justice/data-protection/reform/index_en.htm

developments continue. Neuroscience is very likely to become in the near future one of the new areas in which the right to privacy is called to play a fundamental and unexpected role.

The emergence of a right to mental privacy

Science fiction can be very helpful to anticipate the challenges that science and technology may pose in the future, as well as the possible responses to them. In a *Star Trek* novel written in 1990, Captain Kirk has been informed that a dangerous spy has surreptitiously joined one of the groups that are visiting the spaceship *Enterprise*. Kirk desperately wants to identify the intruder and to know more about him and his plans. By appealing to one of his staff members who has telepath abilities, Kirk wants to read the minds of all the visitors. However, the Captain is reminded by one of his assistants that, according to the law, "the right to mental privacy is an inalienable right of all Federation citizens and shall not be abrogated without due process of law" (*577*). Moreover, "to find one guilty individual in either of those groups means there is a large probability of invading the privacy of a number of innocent people" (Ibid., p. 150). The kind of dilemmas described in this futuristic scenario, which is set in the 23rd-century, may become a reality much earlier than expected. Developments in neuroimaging, like those mentioned above, have raised concerns about the ethics and legality of 'mind-reading'. It is true that functional brain imaging cannot really "read" thoughts, but can only highlight differences between brain activations during different cognitive tasks, and to infer from such differences certain conclusions about an individual's thoughts. However, the fact remains that, even if in an indirect manner, the new tools are increasingly able to determine with a high degree of accuracy certain brain data that belong to the private sphere and deserve to be protected from public scrutiny.

In modern societies, privacy and data protection norms cover the use and disclosure of various kinds of personal information. Since the data decoded from an individual's brain can be regarded as "personal information" −or "personally identifiable information", as it is called in the US−, there is in principle no reason why such data could not be covered by existing privacy and data protection regulations. If one has a "reasonable expectation of privacy"[65] regarding the identifying information derived from one's blood or saliva samples, surely one has a reasonable expectation of privacy regarding the data decoded from one's own mind (*578*).

65 The expression "reasonable expectation of privacy" was coined by the US Supreme Court in 1967 to distinguish legitimate police searches and seizures from unreasonable ones in the light of the Fourth Amendment that protects privacy rights.

However, the special nature of brain data, which relate very directly to one’s inner life and personhood, and the distinct way in which such data are obtained, suggest that specific safeguards will be probably needed in this domain. It should be noted that traditional privacy rules seek to safeguard “external” information about people.

The particularity of brain data is that the *information* to be protected is not easily distinguishable from the *source* itself that produced the data: the individual’s neural processing. This is what we can call the “inception problem”, which complicates the analysis of the issues at stake when traditional approaches to privacy are used. In other terms, the neurotechnological future we are approaching will require us to guarantee protection not only to the information we record and share, but also to the *source* of that information since they may be inseparable. In order to implement this we would need wider privacy and data protection rights that can be also applied at a higher and chronologically antecedent level: *our neural activity.*

An additional reason for concern about privacy in this domain is that brain signals allow to distinguish or trace an individual‘s identity and are potentially linkable to that individual. Some brain records (e.g. EEG-recorded signals) can be used as a unique biometric identifier, similarly to fingerprints or DNA. Back in 2007, Palanippan and colleagues developed a EEG based biometric framework for automatic identity verification (*579*). Since then, a huge number of unobtrusive EEG-based biometric systems have been developed for the purposes of individual recognition (*580, 581*), person authentication (*582, 583*), and person identification (*584, 585*). However, unlike other identifiable information, brainwaves can be potentially recorded without individual’s awareness, and therefore in absence of a real ability of the person to consent to the collection and use of that information. With the growing market of portable EEG-based neuroheadsets and in absence of a real possibility for obtaining informed consent for the processing of the records they generate, there is a need for the law to lay down new protective responses to the processing of brain data. The need to protect information generated below the threshold of voluntary control demands for the recognition of a new right that is specifically tailored on the characteristics of brain information and the new possibilities opened by mind-reading technologies.

In the light of the emerging neurotechnologies, it is also necessary to explore the –technical and legal– possibility of applying a filter to the flow of brain information with the purpose of distinguishing the information we consciously want to keep private from the one we want to disclose publicly. In the current information society we are constantly required to draw a distinction between private and public information: for example, when we set up the contact page on our website or when we decide with whom to share our mobile phone number. The basic psychological assumption that underlies this phenomenon is that competent adults have the psychological capacity to consciously filter the information flow and reasonably identify the bits of information that must be kept private. Privacy, in fact, is both a right and an ability. As an ability, it enables individuals or groups to seclude themselves, or information about themselves, and thereby express themselves selectively. This idea has been widely imported into the information technology sphere, where privacy is often described as the ability (or perceived ability) to control submitted personal information -especially when using the Internet (*586*). In order to exercise this ability meaningfully we need a rational medium that is capable to filter the information flow and decide what to disclose. This medium is thought, as well captured by the famous adagio in computer security "the best anti-virus software is the brain".

Based on these specific challenges, we argue that current privacy and data protection rights are insufficient to cope with the emerging neurotechnological scenarios. Consequently, we suggest the formal recognition of a right to mental privacy, which aims to protect any bit or set of brain information about an individual recorded by a neurodevice and shared across the digital ecosystem. This right would protect brainwaves not only as data but also as data generators or sources of information. In addition, it would cover not only conscious brain data but also data that are not (or are only partly) under voluntary and conscious control. Finally, it guarantees the protection of brain information in absence of an external tool for identifying and filtering that information. In short, the right to brain privacy aims to protect people against illegitimate access to their brain information and to prevent the indiscriminate leakage of brain data across the infosphere.

It is worthy of mention that violations of mental privacy can occur also in absence of direct intrusion into the victim's neural processing. For example, brain data collected for research purposes are usually stored for analysis on externally located EEG-databases and repositories. Similarly brain-data generated by consumer-grade brain-computer interfaces (BCI) are sent to a connected app and can be stored in the cloud or other data store end points. In either case, these data can be accessed also in absence of the person who generated those data and without intervening into the person's brain signaling.

Is the right to mental privacy an absolute or a relative right?

Most human rights, including privacy rights, are *relative,* in the sense that they can be limited in certain circumstances, provided that some restrictions are necessary and are a proportionate way of achieving a legitimate purpose.[66] In specifically dealing with the right to privacy, the European Convention on Human Rights states that this right admits some restrictions "for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others" (Art. 8, para 2). Only very few rights, such as the freedom of thought, freedom from slavery, torture and inhuman or degrading treatment or punishment are regarded by international human rights law as not subject to any exceptions and, therefore, as *absolute rights.* In which of both categories should the right to mental privacy be placed? Can nonconsensual intrusions into people's brain data be justified in certain circumstances or should be unconditionally banned? More concretely, does the right to mental privacy protect individuals from being compelled by courts or the state to brain-based interrogations?

Paul Root Wolpe has suggested that due to fears of government oppression, we should draw a bright line around the use of mind-reading technologies:

"The skull should be designated as a domain of absolute privacy. No one should be able to probe an individual's mind against their will. We should not permit it with a court order. We should not permit it for military or national security. We should forgo the use of the technology under coercive circumstances even though using it may serve the public good" (*587*).

Similarly, it has been argued that "nonconsensual mind reading is not something we should never engage in" (*588*). The claim is that mind-reading techniques constitute "a fundamental affront to human dignity" (Ibid). Consequently, "we must not let our civilization's privacy principles degrade so far that attempting to peer inside a person's own head against their will ever become regarded as acceptable" (Ibid).

Are these calls for an unconditional ban on compulsory mind-reading justified? Or could this procedure be acceptable in certain circumstances (for instance, when faced with a serious crime or a terrorist attack)? As mentioned above, privacy rights are not absolute, but relative.

66 "In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society" (UDHR, Article 29.2).

The collection, use and disclosure of private information is permissible when the public interest is at stake. For example, in many jurisdictions, compulsory genetic testing can be undertaken to attempt to identify criminal offenders. Considering the non-invasive and painless nature of brain-scans, there are prima facie good reasons for thinking that their nonconsensual use would be justified, with a court warrant, under special circumstances when there are reasonable grounds to believe that an individual has committed a serious crime or is involved in the planning of a serious crime.

However, this dilemma becomes more intricate when it is seen not in connection to privacy issues, but in the light of the principle of prohibiting coerced self-incrimination. This problem particularly arises when the results of brain scans are regarded not as mere *information* about individuals (such as buccal or blood-derived DNA, fingerprints, etc.), but as a *testimony* because in this latter case the self-incrimination clause would enter into play.

The ban on coerced self-incrimination is widely recognized across the democratic world as being an integral component of a fair criminal justice. This privilege is a logic consequence of the presumption of innocence, which places the burden of proof of guilt on the prosecution. In other words, people suspected of a crime do not have any obligation to assist in providing evidence against themselves. The privilege against self-incrimination is very closely related to the right to remain silent and can overlap with it. However, there is a conceptual difference between them: while the former concerns the threat of coercion in order to make an accused yield certain information, the latter concerns the drawing of adverse inferences when an accused fails to testify or to answer questions (*589*).

This privilege is enshrined in the International Covenant on Civil and Political Rights, which stipulates that "in the determination of any criminal charge against him, everyone shall be entitled (…) not to be compelled to testify against himself or to confess guilt" (Art. 14(3)(g)). A similar provision can be found in the American Convention on Human Rights and in the Rome Statute of the International Criminal Court.[67] Although the European Convention on Human Rights does not explicitly refer to the privilege against self-incrimination, the European Court of

[67] American Convention on Human Rights, art. 8(2)(g): "Every person accused of a criminal offense has the right (…) not to be compelled to be a witness against himself or to plead guilty"; Rome Statute of the International Criminal Court, art. 55(1)(a): "In respect of an investigation under this Statute, a person: (a) Shall not be compelled to incriminate himself or herself or to confess guilt". Paragraph 2(b) of the same Article 55 adds that the person suspected of having committed a crime has the right "to remain silent, without such silence being a consideration in the determination of guilt or innocence".

Human Rights (ECtHR) has repeatedly asserted that this principle is implied in the general right to a fair trial, which is guaranteed by Article 6 of the Convention.[68] In the US, the Fifth Amendment protects against "coercion [to] prove [a] charge against an accused out of his mouth". Interpreting this clause, the US Supreme Court introduced in 1966 the distinction between being compelled to provide *real or physical evidence* (which is allowed) and being forced to give self-incriminating *testimony* (which is forbidden).[69]

The ECtHR draws a more subtle distinction when it differentiates between compelling "real evidence which has an existence independent of the will of the suspect" (ex. documents acquired pursuant to a warrant, breath, blood and urine samples and bodily tissues for the purpose of DNA testing) and evidence which is "not truly independent of the will of the suspect".[70] Answers to questions are the most obvious examples of this second category because they are inconceivable without the will of the subject. However, in the case of *Funke v. France*, the ECtHR has considered that also being compelled to produce certain documents (in the case, bank statements from accounts in foreign banks, and which might serve to incriminate the individual for tax evasion), would amount to an infringement of the privilege.

Therefore, the lecture of the privilege made by the ECtHR can been understood in the sense that the key issue is not so much whether the evidence is real or oral (i.e. physical as opposed to answers to questions), but whether the evidence requires the *active co-operation* of the individual or not (*590*). In other words, "the privilege only covers assistance from the suspect which could not be substituted by employing direct force" (*591*).

If we accept this understanding of the privilege, the question then becomes whether the mere record of thoughts and memories –without any coerced oral testimony or declaration– is evidence that can be legally compelled, or whether this practice necessarily requires the "will of the suspect" and therefore constitutes a breach of the privilege against forced self-incrimination. Unfortunately, it is extremely difficult to give a clear-cut answer to this dilemma. In our opinion, the issue has to be the matter of public discussion in order to find an adequate balance between the private and public interests at stake. The dilemma is particularly arduous because, on the one hand, it could be argued that thoughts and memories are purely internal operations that *per se* cannot be forced, and consequently the non-incrimination clause would not be applicable to them. However, on the other hand, if mind-reading techniques are allowed in

68 *Funke v. France,* 256 ECtHR (ser. A) (1993); *John Murray v. United Kingdom,* 1996-I ECtHR 30.
69 US Supreme Court, *Miranda v. Arizona*, 384 U.S. 436 (1966).
70 *Saunders,* 1996-VI

criminal proceedings, there is in the long term the risk to completely water down the privilege against self-incrimination, especially if the techniques become more reliable and efficient than they are at present. People might still be formally protected against self-incriminatory oral statements, but not against the very source of such testimonies: their own thoughts. As Nita Farahany puts it, self-incrimination may occur *silently* just as aloud (*592*).

The right to mental integrity

Intrusions into people's brains cannot only result in a violation of their mental privacy, but may also have a direct impact on their neural computation and result in direct harm to them. Ienca and Haselager (2016) have introduced the notion of *malicious brain-hacking* to refer to neurocriminal activities that influence directly neural computation in the users of neurodevices in a manner that resembles how computers are hacked in computer crime (*281*). Focusing on brain-computer interface (BCI), they identify four types of malicious brain-hacking based on the various levels of the BCI cycle where the attack can occur. Three of these types, i.e. when the attack occurs at the level of measurement, decoding and feedback, may involve direct manipulation of a person's neural computation. Malicious agents may add noise or override the signal sent to the device with the purpose of diminishing or expunging the control of the user over the application, or even hijacking the victim's voluntary control. For example, a criminal actor could override the signal sent by the users and hijack the BCI-controlled device (e.g. smartphone, electronic wheelchair) without the user's permission.

In this kind of cases, the users' mental privacy and the protection of their brain data are not the only rights at risk. Rather, the physical and mental integrity of the victim are at stake too. In fact, the forced intrusion into and alteration of a person's neural processes pose an unprecedented threat to that person's mental integrity.

The right to personal physical and mental integrity is protected by the EU's Charter of fundamental rights (Article 3), stating that "everyone has the right to respect for his or her physical and mental integrity." Understandably, the Charter emphasizes the importance of this right in the fields of medicine and biology, because of the direct impact that biomedical technologies may have on people's physical and mental integrity. The provision focuses in particular on four requirements: free and informed consent, the non-commercialization of body elements, and the prohibition of eugenic practices and human reproductive cloning. No explicit reference is made to neurotechnology-related practices. This silence is understandable if we consider that the Charter was adopted in 2000, when the discussion on the ethical and legal implications of neuroscience was at a very early stage. Today however, potential applications of neurotechnology open the prospects of impacting personal integrity in a manner that is comparable to that of genetics and other biomedical practices. For this reason, the normative framework should keep up with neurotechnological advances and extend the protection of people's integrity to this new area.

We propose to fill this normative gap by calling for a reconceptualization of the right to mental integrity. In fact, while the ECHR and ECFR consider mental integrity as a right to mental-health, pendant of the right of physical integrity understood as physical health, a more complex dimension of mental integrity is elicited by neurotechnology. Mental integrity in this broader sense should not only guarantee the right of individuals with mental conditions to access mental health schemes and receive psychiatric treatment or support wherever needed. In addition to that, it should also guarantee the right of all individuals to protect their mental dimension from potential harm.

This reconceptualized right should provide a specific normative protection from potential neurotechnology-enabled interventions involving the unauthorized alteration of a person's neural computation and potentially resulting in direct harm to the victim. For an action X, to qualify as a threat to mental integrity, it has to: (i) involve the direct access to and manipulation of neural signaling (ii) be unauthorized –i.e. must occur in absence of the informed consent of the signal generator, (iii) result in physical and/or psychological harm. As neurotechnology becomes part of the digital ecosystem and neural computation rapidly enters the infosphere, the mental integrity of individuals will be increasingly endangered if specific protective measures are not implemented.

Threats to mental integrity do not limit to malicious brain-hacking and similar illicit activities. Unauthorized alterations of a person's neural computation could also emerge out of military applications of BCI technology for warfighter enhancement. Lebedev et al. have described that a neurologically controlled prosthetic could send tactile information back to the brain in nearly real time by using intracortical microstimulation (ICMS), essentially creating a "brain-machine-brain interface" (*593*). Such interventions may directly modify neurological activity and can be used to exert some degree of control over ground troop soldiers. For example, the Committee on Opportunities in Neuroscience for Future Army Applications of the National Research Council of the National Academies has investigated the use of portable technologies such as near infrared spectroscopy (NIRS) to detect deficiencies in a warfighter's neurological processes and utilizing transcranial magnetic stimulation (TMS) to suppress or enhance individual brain processes (*594*). Similarly, mental integrity rights should be included among the rights of war prisoners to prevent the use of invasive brain-washing interventions.

Brain stimulation is an additional domain where the right to mental integrity may play a role. With the growing number of portable neurostimulators available on the market or assembled do-it-yourself devices, the risk that people may misuse these devices with consequent negative impact on their neural functioning should be avoided. For example, while consumer-grade t*ranscranial direct current stimulation* (tDCS) are designed to safely function in a certain frequency band, little safeguards prevent users or third persons from manipulating the device's frequency.

The medical domain is not exempt from the possible application of the right to mental integrity. Invasive neurotechnology interventions such as deep-brain stimulation (DBS) involve the alteration of the patient's neural processing by electrode-delivered electrical impulses. While this procedure provides therapeutic benefits for otherwise treatment-resistant neurological patients, there is also the potential for neuropsychiatric adverse-effects including apathy, compulsive behavior and hallucinations (*595*). In addition, being a surgical procedure, there is a risk of infection, bleeding and rejection of the implanted neurostimulator. Therefore, although in such medical procedure informed consent is always obtained based on minimal medical ethics requirement, still there is a risk that the alteration of neural computation enabled by DBS may cause a disproportionate harm as compared to the therapeutic benefit. This high potential for adverse effects is the reason why, although having proved some effectiveness in the treatment of conditions such as obesity and anorexia nervosa, DBS is still not approved by the Food and Drug Administration (FDA) for the treatment of those conditions. In this context, mental integrity rights stand to prevent from harm, absolutely conceived, but to prevent to a disproportionate relative harm compared to the potential therapeutic benefit.

Finally, the growing field of memory engineering will likely represent a paramount challenge to the right to mental integrity. Several techniques have been developed to engineer (e.g. boost or selectively erase) memories from a person's mind. For example, Nabavi and colleagues used an optogenetics technique to erase and subsequently restore selected memories *by applying a stimulus via optical laser that selectively strengthens or weakens synaptic connections* (*596*). While they have not reached yet the level of human experimentation, these findings may hold big potential for the treatment of such diseases as Alzheimer's and post-traumatic stress disorder (PTSD). At the same time, however, the misuse of these techniques by malevolent actors may generate unprecedented opportunities for mental manipulation and brain-washing. For example, criminally motivated actors could selectively erase memories from their victims' brains to prevent being identified by them later on or simply to cause them harm. On the long term-scenario, they could be used by surveillance and security agencies with the purpose of selectively erasing dangerous, inconvenient from people's brain as portrayed in the movie *Men in Black* with the so-called *neuralyzer*. The potential motives of illicit memory alteration are various, including increasing national security or exerting control over individuals or groups.

Like the right to mental privacy, also the right to mental integrity may not be absolute. For example, it might be argued on utilitarian grounds that controlled and temporary violations of the right to mental integrity should be allowed as a form of moral enhancement for persistent violent offenders. For example, Savulescu and Persson (2008) have argued that if safe and effective biomedical moral enhancements were developed then they should be compulsory (*597*). Similarly, Ellegaard and Kragh have argued that it is not only morally permissible, but morally required to force persistent violent offenders to undergo morally enhancing treatments provided the demonstrated effectiveness of such interventions (*598*). These possible exceptions to the right to mental integrity would obviously require broad societal discussion to determine whether –and when– such compulsory manipulations of the deepest dimension of the self could be justified for the greater benefit of society.

While taking a position in the long-standing debate over moral enhancement is beyond the scope of this paper, it is important to consider that the postulation of the rights to mental privacy and mental integrity does not *ipso fact*o implies the absolute character of these new rights.

The right to psychological continuity

In addition to mental privacy and mental integrity, also people's perception of their own identity may be put at risk by inadequate uses of emerging neurotechnology. As we have seen in the first section, neural devices can be used not exclusively for monitoring brain signals but also for stimulating or modulating brain function. For example, transcranial direct current stimulation (tDCS) devices apply constant, low current delivered to the brain area of interest via electrodes on the scalp with the purpose of modulating brain function. Since it causes neuron's resting membrane potential to depolarize or hyperpolarize, this stimulation causes alterations in brain function that are potentially beneficial for patients. Transcranial magnetic stimulation (TMS) and deep brain stimulation (DBS) open the possibility of intervening into brain function even more substantially. Given the increasing therapeutic effectiveness of tDCS, TMS and DBS, and the rapid advancement of the technology, brain stimulation devices are likely to expand to wider psychiatric groups and, in the case of the first two ones, also to the general population.

However, changes in brain function caused by brain stimulation may also cause unintended alterations in mental states critical to personality, and can thereby affect an individual's personal identity (*599*). In particular, it has been observed that brain stimulation may have an impact on the psychological continuity of the person, i.e. the crucial requirement of personal identity consisting in experiencing oneself as persisting through time as the same person (*600*). Several cases have been reported in the scientific literature in which DBS has led to behavioral changes such as increased impulsivity and aggressiveness (*601, 602*) or changes in sexual behavior (*603*). A study involving patients treated with DBS showed that more than half of them articulated a feeling of strangeness and unfamiliarity with themselves after surgery ("I do not feel like myself anymore"; "I feel like a robot" or "I have not found myself again after the surgery") (*604*). More recent studies have evidenced personality changes in the direction of increased impulsivity (*605, 606*). In parallel, memory engineering technologies may impact a person's identity by selectively removing, altering, adding or replacing individual memories that are relevant to their self-recognition as persons.

Surely it is an empirical question to determine the frequency and magnitude of these psycho-behavioral changes and it is a question for criminal and tort law to assess the impact of these changes on liability and responsibility. But the question we are interested in here is whether such personality changes induced by neurostimulation or memory manipulating technology could constitute in some circumstances a violation of a basic human right. This might theoretically be the case, for instance, if the patient is legally incompetent (for instance, a child) and the personality change turns out to be psychologically disturbing for him or her. In such circumstances, if the patient's legal representatives refuse to consent to the removal of the device on the grounds that it has reduced the neurological disorder symptoms, they could be regarded as acting against the individual's right to psychological continuity.

However, threats to this right are more likely to happen outside clinical settings. For instance, in the context of intelligence and military agencies, it has been reported that over the last decades violations of human rights might have taken place in experiments involving brain electrodes, LSD, hypnosis, the creation of Manchurian candidates[71], and the implantation of false memories and creation of amnesia. Many of these experiments were conducted on unwitting civilians and in the absence of any external review, or representation for the experimental subjects, or any meaningful follow-up (*607*). The new knowledge and technologies in the field of neuroscience clearly offer new and more efficient possibilities for carrying out unconsented personality changes. For example, Pycroft et al. (2016) recently reported the concern that brain implants like DBS are vulnerable to attack by third parties who want to exert malicious control over the users' brain activity. They called this risk of modification of a person's brain activity through unauthorized use of neurodevices by third parties 'brainjacking' (*608*). Negative consequences of brainjacking include (i) information theft, which would result in a violation of the right to mental privacy; (ii) cessation of stimulation, draining implant batteries, inducing tissue damage, and impairment of motor function, which would result in violations of the right to mental integrity. However, some possible consequences of brainjacking such as alteration of impulse control, modification of emotions or affect, induction of pain, and modulation of the reward system could be achieved even in absence of any violation of mental privacy and integrity. In those circumstances of unauthorized modification of the cognitive-emotional-affective dimension a different type of human right violation seems to be at stake: the violation of the right to psychological continuity.

In short, the right to psychological continuity ultimately tends to preserve personal identity and the coherence of the individual's behavior from unconsented modification by third parties. It protects the continuity across a person's habitual thoughts, preferences, and choices by protecting the underlying neural functioning. As Paul Tiedemann points out, we understand ourselves as personal unities and as subjects and source of attitudes as long as these attitudes

[71] The expression "Manchurian candidate" refers to "a person who is (or is believed to be) brainwashed into becoming a subversive agent, especially an assassin" (Oxford Dictionary). The expression was popularized by the 1962 film *The Manchurian Candidate*, adapted from the 1959 novel of the same name by Richard Condon.

have a minimum level of coherence. This is why a serious lack of coherence makes it impossible to understand oneself (*609*).

The right to psychological continuity can be seen as a special neuro-focused instance of the right to identity. The right to identity was developed by the European Court of Human Rights (ECtHR) from the right to private life included in Article 8 of the European Convention on Human Rights."[72] As we have seen in the first section, Article 8 protects against unwanted intrusion and provides for the respect of an individual's private space. However, privacy and personal identity should be distinguished. What the right to psychological continuity aims to prevent is not the unrestricted access to brain information but the induced alteration of neural functioning.

The UDHR also addresses the right to have and develop a personality. Article 22 states: "Everyone is entitled to the realization of the rights needed for one's dignity and the free development of their personality." In addition, Article 29 states: "[e]veryone has duties to the community in which alone the free and full development of his personality is possible." According to Mănuc (2012), personality rights can be defined as those expressing the quintessence of the human person, and are intrinsic to being human (*610*). In here analysis, these rights recognize the "spirit" within an individual and have developed from the issues of privacy. It is questionable, however, if current personality rights are well-equipped to address the problem of stimulation-induced alterations in one's personality.

However, it is questionable whether current personality rights can fully account for the threats posed to psychological continuity. In fact, while this family of rights protects the translation of mental states into action, psychological continuity guarantees protection at an antecedent level: at the level of raw neural functioning. In the risk scenario presented above, misused brain stimulation does not impact the link between mental processes and action, i.e. the expression of mental states, but the mental processes themselves. To provide this more intimate level of protection, there is a need for a new right that preserves the continuity of a person's mental life from external abusive alteration or disruption.

The right to psychological continuity is closely related to the right to mental integrity, and may factually overlap with it. Both rights stand to protect people from abusive and unconsented alterations of their mental dimension. However, they differ to the extent that the right to psychological continuity also applies to emerging scenarios that do not directly involve

[72] *Goodwin v the UK* (2002) 35 ECHR 18 at 90.

neural or mental harm. In contrast, as we have seen in the previous section, the presence of harm is a necessary condition for an action to qualify as an offence to a person's mental integrity.

To appreciate this difference, it is important to consider that psychological continuity could be threatened not only by misused brain stimulation but also by less invasive, even unperceivable interventions. A good example is unconscious neural advertising via neuromarketing. As we have seen in the first section, neuromarketing companies are testing subliminal techniques such as embedding subliminal stimuli with the purpose of eliciting responses (e.g. preferring item A instead of B) that people cannot consciously register. This has raised criticism among consumer advocate organizations, such as the Center for Digital Democracy, which have warned against neuromarketing's potentially invasive technology. Jeff Chester, the executive director of the organization, has claimed that "though there has not historically been regulation on adult advertising due to adults having defense mechanisms to discern what is true and untrue", it should now be regulated "if the advertising is now purposely designed to bypass those rational defenses" (*611*). We argue that a right to psychological continuity can provide the conceptual basis be a viable solution to overcome the problems addressed by Chester.

Potential threats that could be prevented by the right to psychological continuity also include new forms of brain-washing. Hoolbrook et al. (2016) used transcranial magnetic stimulation (TMS) to neuromodulate the brain regions responsible for social prejudice and political and religious beliefs (*612*). Their results show that by temporarily turning off the posterior medial frontal cortex via TMS it was possible to make participants more positive towards criticisms to their country, than the participants whose brains were unaffected. Using the same technique, they could enhance the participants' belief in afterlife. While their experiment was designed to mapping the precise neural mechanisms of high-level attitudes and beliefs, their results show that the same technique could be used to trigger a wide spectrum of alterations of a person's attitudes and beliefs. Malicious agents, for example, could use neuromodulation to exert malevolent forms of mind control. These potentially include religious leaders and coordinators of religiously inspired terrorist groups who want to achieve effective indoctrination and recruitment of youngsters, as well as leaders of authoritarian regimes who want to enforce political compliance and prevent rebellion. More mildly, marketing companies could use these techniques to modulate customers' preferences and attitudes towards their products.

Just like the previous two rights we advocate for, it is a matter of discussion whether the right to psychological continuity should be considered absolute or relative. It could be argued that some neurotechnologically-induced personality changes could be tolerated with regard to persistent violent offenders (for instance, serial rapists, killers and pedophiles). The need to protect the public from potentially dangerous individuals who are very likely to reoffend if released would justify such measures. This would even be a good alternative for those individuals themselves, who could avoid in this way spend their whole lives in prison. However, extreme caution and broad public discussion is imperative before authorizing such intentional intrusions into people's personality.

Conclusions

The volume and variety of neurotechnology applications is rapidly increasing inside and outside the clinical and research setting. The ubiquitous distribution of cheaper, scalable and easy-to-use neuroapplications has the potential of opening unprecedented opportunities at the brain-machine interface and making neurotechnology intricately embedded in our everyday life. While this technological trend may generate immense advantage for society at large in terms of clinical benefit, prevention, self-quantification, bias-reduction, personalized technology use, marketing analysis, military dominance, national security and even judicial accuracy, yet its implications for ethics and the law remain largely unexplored. We argue that in the light of the disruptive change that neurotechnology is determining in the digital ecosystem, the normative terrain should be urgently prepared to prevent misuse or unintended negative consequences. In addition, given the fundamental character of the neurocognitive dimension, we argue that such normative response should not exclusively focus on tort law but also on foundational issues at the level of human right law.

In this context, we have suggested that emerging trends in neurotechnology are eliciting coordinate amendments to the current human right framework which will require either a reconceptualization of existing human rights or even the creation of new neuro-specific rights. In particular, we have argued that emerging collateral risks associated with the widespread use of pervasive neurotechnology such as malicious brain-hacking as well as hazardous uses of medical neurotechnology may require a reconceptualization of the right to mental integrity. In fact, although mental integrity is protected by the EU's Charter of fundamental rights (Article 3), this right is conceptualized as a right to accessing and protecting mental health and is complementary to the right physical integrity. We suggest that in response to emerging neurotechnology possibilities, the right to mental integrity should not exclusively guarantee protection from mental illness or traumatic injury but also from unauthorized intrusions into a person's mental wellbeing performed through the use of neurotechnology, especially if such intrusions result in physical or mental harm to the neurotechnology user.

In addition to such reconceptualization, we have argued that the creation of neuro-specific may be required as a coping strategy against possible misuses of neurotechnology as well as a form of protection of fundamental liberties associated with individual decision-making in the context of neurotechnology use. With this respect, we have endorsed the recognition of a negative right to cognitive liberty as a right for the protection of individuals from the coercive and unconsented use of such technologies. In addition, as a complementary solution, we have proposed the recognition of two additional neuro-specific rights: the right to mental privacy and the right to psychological continuity. The right to mental privacy is a neuro-specific privacy right which protects private or sensitive information in a person's mind from unauthorized collection, storage, use, or even deletion – in digital form or otherwise. In contrast to existing privacy rights, the right to mental privacy stands to protect information prior to any extra-cranial externalization (e.g. in verbal or printed format) as well as the generator of such information (a person's neural processing). As such, it protects a person's mental dimension as the ultimate domain of information privacy in the digital ecosystem. In coordination with that, the right to psychological continuity will protect the mental substrates of personal identity from unconscious and unconsented alteration by third parties through the use of invasive or non-invasive neurotechnology.

All these proposed neuro-focused rights are mutually linked and stand in an intimate family relationship. Being the substrate of all other freedoms, cognitive liberty in its positive sense is a prerequisite of all other neuro-focused rights. As such, it is to mental privacy, mental integrity and psychological continuity in a very similar relation as freedom of thought is to privacy, integrity and identity rights. However, in its negative sense of protection from coercive use, cognitive liberty can only partly account for unintended uses of emerging neurotechnology. In fact, illicit intrusions into a person's mental privacy may not necessarily involve coercion, as they could be performed under the threshold of a persons' conscious experience. The same goes for actions involving harm to a person's mental life or unauthorized modifications of a person's psychological continuity. Given the ability of emerging neurotechnologies to intervene into a person's neural processing also in absence of the person's awareness,

This proposal of neuro-specific human rights in response to emerging advancements in neurotechnology is consistent with and a logical continuation of the proposal of developing genetic-specific human rights in response to advancements in genetics and genomics as set out by the *International Declaration on Human Genetic Data* (IDHGD*).*

Extensive future debate is required to test the normative solidity of this proposed expansion of the human right framework to the neurotechnology dimension. In parallel, future research is required to investigate the implications of such proposed human rights on other levels of law such as international humanitarian law, criminal law, tort law, property law and consumer law. Ideally, this debate should benefit from the active and cross-disciplinary participation of legal experts, neuroscientists, technology developers, neuroethicists and regulation bodies.

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*2.14 –Preserving the Right to Cognitive Liberty**

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In a masque written by John Milton in 1634 a young woman is bounded to an enchanted chair by a debauched named *Comus*. Despite being restrained against her will, she claims: "*Thou canst not touch the freedom of my mind",* confident of her capacity to protect her mental freedom from any external manipulation. This idea of the human mind as the ultimate domain of absolute protection from external intrusion has persisted for centuries. Still in 1913, historian John Bagnell Bury wrote: "A man can never be hindered from thinking whatever he chooses so long as he conceals". Today, this presumption might no longer hold. Cutting-edge neurodevices, such as sophisticated neuroimaging and brain-computer interfaces (BCI), enable to record, decode and modulate the neural correlates of mental processes. Research shows that the combination of neuroimaging technology and artificial intelligence allows to "*read"* correlates of mental states including hidden intentions, visual experiences or even dreams with an increasing degree of accuracy and resolution.

While these advances have a great potential for research and medicine, they pose a fundamental ethical, legal and social challenge: *determining whether, or under what conditions, it is legitimate to gain access to, or to interfere with another person's neural activity*.

This question has particular social relevance since many neurotechnologies have moved away from a solely clinical setting and into the commercial domain, where they are no longer subject to the strict ethical guidelines of clinical research. Today, companies like Google and Verizon use neuroimaging technology and other neuromarketing research services to detect consumer preferences and hidden impressions on their advertisements or products.

Attempts to decode mental information via neuroimaging are also occurring in court case, sometimes in a scientifically questionable way. For example, in 2008, an Indian woman was convicted of murder and sentenced to life imprisonment on the basis of a brain scan showing, according to the judge, "experiential knowledge" about the crime. The potential of neurotechnology as a forensic tool has raised particular attention in relation to lie detection for interrogation purposes. In spite of experts' skepticism, commercial companies such as No-Lie-

[73] Current Impact Factor: 1.316 (2016)

FMRI and Government Works Inc. are marketing the use of FMRI- and EEG-based technology to ascertain truth and falsehood via brain recordings. In parallel, armed forces are testing neuromonitoring techniques to detect deficiencies in a warfighter's brain activity and utilizing brain stimulation to increase their alert and attention.

In 2015, the journal *Science* released a special issue titled "The End of Privacy", highlighting how new technological trends from big data to ubiquitous Internet connections, make "traditional notions of privacy obsolete". In a sense, neurotechnology can be seen as just another technological trend that might erode our privacy in the digital world and there is little we can do about it. However, given the intimate link between mental privacy and subjectivity we might not be so willing to accept this conclusion. In his famous 1984, George Orwell projected a future where "nothing was your own except the few cubic centimeters inside your skull." In fact, when mental information is no longer secluded, nothing is secluded, and the very notion of subjectivity –the quality of existing in someone's mind rather than the external world- becomes empty.

We are facing a societal challenge: determining what rights individuals are entitled to exercise in relation to their mental dimension. This challenge might require the reconceptualization of existing human rights and even the creation of new neurospecific human rights.

A *right to cognitive liberty*, widely discussed among neurolawyers, would entitle individuals to make free and competent decisions regarding their use of neurotechnology. A *right to mental privacy* would protect individuals against the unconsented intrusion by third parties into their brain data as well as against the unauthorized collection of those data. Breaches of privacy at the neural level could be more dangerous than conventional ones because they can bypass the level of conscious reasoning, leaving individuals without protections from having their mind involuntarily read. This risk does not apply only to participants in predatory neuromarketing studies and disproportionate uses of neurotechnology in courts, but to general individuals as well. With the growing availability of Internet-connected consumer-grade brain-computer interfaces, more and more individuals are becoming users of neurodevices.

In April 2017, Facebook unveiled a plan to create brain-computer speech-to-text interface to translate thoughts directly from brain signals to a computer screen, bypassing speech and fingertips. Similar attempts are being made by major mobile communication providers, Samsung in particular. In the future, brain control could replace the keyboard and speech recognition as a primary way to interact with computers.

With interconnected neurotools becoming potentially ubiquitous, novel possibility for misuse will arise –cybersecurity breaches included. Computer scientists have already demonstrated the feasibility of hacking attacks aimed at extracting information from BCI-users without authorization. In addition, research shows that connected medical devices are vulnerable to sabotage. Neuroscientists at Oxford University suggest that the same vulnerability affects brain implants, a phenomenon labeled "*brainjacking"*. Such possibilities of misuse might urge a reconceptualization of the *right to mental integrity.* This right, recognized by international law (Article 3 of the EU's Charter of Fundamental Rights) as a right to mental health, should not only protect from mental illness but also from illicit and harmful manipulations of people's neural activity through the misuse of neurotechnology. Finally, a *right to psychological continuity* might preserve people's personal identity and the continuity of their mental life from unconsented external alteration by third parties. Psychological continuity is an important issue in the context of national security, where mandatory personality-changing interventions might be justified in light of greater strategic goals. Brain interventions that reduce the need for sleep are already in use in the military, and it's easy to imagine interventions that make soldiers more belligerent or fearless. These possibilities have already raised attention among legislators. Back in 1999 a European Parliament committee called for a global ban of research "which seeks to apply knowledge of the chemical, electrical, (…) or other functioning of the human brain to the development of weapons which might enable any form of manipulation of human beings".

Calibrated normative approaches should guarantee the alignment of neurotechnology development and personal freedoms. At the same time, they should avoid fear-mongering, unrealistic narratives that might harm scientific progress. An open debate involving neuroscientists, legal experts, ethicists and general citizens is required to maximize the benefits of advancing neurotechnology while minimizing unintended risks.

*2.15 - Democratizing Cognitive Technology: A Proactive Approach**

*A version of this article was published in *Ethics and Information Technology*[74]

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Abstract

Cognitive technology is an umbrella term sometimes used to designate the realm of technologies that assist, augment or simulate cognitive processes or that can be used for the achievement of cognitive aims. This technological macro-domain encompasses both devices that directly interface the human brain as well as external systems that use artificial intelligence to simulate or assist (aspects of) human cognition. As they hold the promise of assisting and augmenting human cognitive capabilities both individually and collectively, cognitive technologies could produce, in the next decades, a significant effect on human cultural evolution. At the same time, due to their dual-use potential, they are vulnerable to being coopted by State and non-State actors for non-benign purposes (e.g. cyberterrorism, cyberwarfare and mass surveillance) or in manners that violate democratic values and principles. Therefore, it is the responsibility of technology governance bodies to align the future of cognitive technology with democratic principles such as individual freedom, avoidance of centralized, equality of opportunity and open development. This paper provides a preliminary description of an approach to the democratization of cognitive technologies based on six normative ethical principles: avoidance of centralized control, openness, transparency, inclusiveness, user-centeredness and convergence. This approach is designed to universalize and evenly distribute the potential benefits of cognitive technology and mitigate the risk that such emerging technological trend could be coopted by State or non-State actors in ways that are inconsistent with the principles of liberal democracy or detrimental to individuals and groups.

Keywords: *Dual-Use Information Technology in the Age of Cyberwarfare and Global Surveillance*

[74] Current Impact Factor: 1.500 (2016)

Cognitive Technology

Cognitive technology (CT), also referred to as *cognition-related technology*, is an umbrella term used to designate the realm of technologies that assist, enhance or simulate cognitive processes or that can be used by humans "for the achievement of cognitive aims" (Dascal & Dror 2005).

The notion of CT was originally coined in the context of educational psychology to describe strategies and tools that could facilitate cognitive processes such as learning and problem solving (*613*). With advances in personal computing, the notion of CT has been increasingly used to refer to "virtual environments, new computer devices and software tools" (*614*) or other *"informational artifacts"* (*615*) that can support or expand human cognition. An important step towards the establishment of CT as an area of scientific investigation was the creation in the late 1990s of a *Cognitive Technology Society* (*616*) and the subsequent organization, during the early 2000s, of various CT-focused international conferences where experts from various fields of the cognitive sciences gathered to discuss "the impacts these technologies will have on human cognitive and social capacities" (*614*)[75].

In the last decade, in parallel with advances in Artificial Intelligence (AI), the label of CT has gained momentum in computer science and in the ICT industry to describe information technologies capable of performing cognitive tasks traditionally performed by humans (*617, 618*), in particular when they are used to "assist and influence humans' mental activities" (*619*). Among other companies, IBM has put CT at the center of their business transformation in what they called the "cognitive era"[76].

CT is a macro-domain encompassing, at least, two major sub-domains:

a. Neurotechnologies: Systems or devices that interface human nervous systems to assist, enhance or monitor natural cognitive processes.
b. Artificial Intelligent Systems: Artificial systems that simulate (aspects of) intelligence and exhibit it across a wide range of processes including reasoning, planning, learning, natural language processing, perception and the ability to move and manipulate objects in the physical space.

Neurotechnologies include brain-computer interfaces (BCIs), electrical and magnetic brain stimulation, neurosensor-based vehicle operator systems, real-time neuromonitoring,

[75] In 2001, the Coventry University organized a conference called "Cognitive Technology: Instruments of Mind" which marked an important milestone in the study of CT 614. M. Beynon, C. L. Nehaniv, K. Dautenhahn, *Cognitive Technology: Instruments of Mind: 4th International Conference, CT 2001 Coventry, UK, August 6-9, 2001 Proceedings*. (Springer, 2003), vol. 2117..

[76] See IBM's best practices for cognitive technology: https://www.ibm.com/watson/advantage-reports/getting-started-cognitive-technology.html

neural prosthetics and others. These technologies are capable of establishing either invasive or non-invasive connection pathways between (human) nervous systems and computing devices for a variety of purposes. For example, medical applications of BCI technology have shown clinical effectiveness in monitoring, repairing, assisting or augmenting cognitive or sensory-motor functions in patients experiencing cognitive or sensory-motor impairments including spinal cord injury (*620*), stroke (*621*), motor neuron disease such as amyotrophic lateral sclerosis (ALS) and muscular dystrophy (*622, 623*), and, more recently, age-related cognitive decline (*624*), and dementia (*182*). In parallel, direct-to-consumer applications of electroncephalogrphy-based neuromonitoring are gaining increasing commercial interest as tools for self-monitoring, self-quantification as well as tools for physical and mental training.

Artificial intelligent systems include virtual personal assistants, question answering computer systems (such as IBM Watson), intelligent robots, self-repairing hardware and others. These systems mimic (components of) functions that humans usually associate with cognitive agents such as flexibility, automatic self-improvement through experience (as in the case of machine learning algorithms), perception of the external environment (e.g. speech recognition, facial recognition, object recognition etc.), motion and manipulation (e.g. mapping, motion planning, path planning and localization) and knowledge representation.

Both neurotechnologies and artificial intelligent systems fall into the category of CT when they are utilized with the purpose of influencing, assisting, or augmenting human cognitive capacities. However, these two subdomains tend to differ with regard to how such an influence on cognition is realized. In most cases, neurotechnologies mostly affect cognition by intervening on “internal information processing systems”, i.e. by mapping or electrically modifying its underlying neurobiology. In contrast, artificial intelligent systems mostly intervene at the level of “external processing systems” (*379*), that is they emulate (aspects of) human intelligence and provide external cognitive resources to support human cognition without any direct interface with the nervous system, a phenomenon known as *environmental enrichment* (*388*). Since the external processes enabled by artificial intelligent systems are, under some circumstances, functionally similar ─according to some researchers, even equivalent─ to internal processing, authors have argued that these technologies might be considered, under such circumstances, *extensions* of the human mind (*125, 625, 626*). For example, Clark (p.4) has argued that CTs “do far more than merely allow for the external storage and transmission of ideas” and rather “constitute […] a cascade of mindware upgrades:

cognitive upheavals in which the effective architecture of the human mind is altered and transformed" (*627*).

In recent years, these two domains have experienced a strong convergence. In fact, AI features have been increasingly embedded in most advanced neurotechnologies. For example, most current BCIs use components of artificial intelligence, especially classifiers based on machine learning (ML) algorithms, to extract, classify and decode brain signals (*56*). At the same time, several artificial intelligent systems are provided with the capacity of being controlled via direct brain-machines interfaces or are designed to mimic the functioning of the human brain. These include smartphones and wearables (*553*), semi-autonomous cars (*628*), unmanned aerial vehicles (*629*), and assistive robots (*630*). This convergence is also occurring at market level with the increasing involvement in the neurotechnology sector of major players in artificial intelligence. For example, IBM, a major producer of artificial intelligent systems and developer of the famous intelligent digital assistant *Watson*, has entered the neurotechnology market and is among the top-15 patent holders in pervasive neurotechnology (*474*). This market integration has even led to the creation of entire new research and business ventures precisely designed with the mission of accelerating the convergence of neurotechnology and artificial intelligent systems. An example of this trend is a newly launched venture called Neuralink. During the Code Conference 2016, entrepreneur Elon Musk announced a plan to accelerate the convergence between neurotechnology and artificial intelligence systems, followed by great media coverage. Although Musk himself remained cryptic about this project, he initially dubbed it "neural-lace" to emphasize the element of entwining brains and artificial systems together. In March 2017, Musk unveiled his project and launched Neuralink, a company whose stated mission is to "merge the human brain with AI" (*631*).

It is worth to point out that CT is a functional characterization; hence it is not based on the type of hardware or software but on the type of function that a certain technology executes, namely assisting, supporting or expanding human cognitive capacities. Therefore, CT is creating an increasing need for addressing the ethical and social implications of CTs regardless of their hardware/software realization, but based on how these technologies influence human cognition.

This consideration has generated more interaction and dialogue among two main research communities: the Neuroethics community ─primarily concerned with the ethics of neurotechnology (*103, 159, 632*)─ and the Computer Ethics community ─primarily concerned with the ethics of computer systems and AI (*633*). The more technologies interface, assist and, possibly, expand human cognition, there higher the need for comprehensive conceptual and normative approaches that study (the ethics of) cognition across the entire bio-digital continuum. Some early signs of convergence at the level of ethical and social assessment are already observable. For example, the 2016 Annual Meeting of the International Neuroethics Society in San Diego featured a public event on future and emerging technologies where a panel of experts discussed the ethical and social implications of both neurotechnologies and artificial intelligent systems such as care robots and intelligent digital assistants (*634*). Similarly, the 2017 IEEE TechEthics Conference in Washington D.C. (https://techethics.ieee.org/events/dc-2017) featured one keynote talk and one panel on neurotechnology.

In light of the increasing convergence between these two main sub-domains, this paper will address the ethics and governance of cognitive technologies in a unitary manner.

Ethics, Security and the Dual-Use Dilemma

Some implications of cognitive technology have sparked ethical controversy. These include issues of cognitive enhancement and augmentation (*406, 635, 636*), superhuman intelligence (*637*), agency and identity (*636, 638*), human-machine hybridization (*639*), algorithmic bias (*636, 640*) and others. More recently, the application of CTs for purposes such as military dominance, surveillance, and cybercriminality has also associated CT to the ethical problem of dual-use (*140, 641*).

Dual-use technologies are artefacts that can be coopted "for making things quite unrelated to their primary purposes" (*642*), in particular when these secondary purposes involve activities that are ethically questionable or potentially detrimental to individuals and groups such as military operations, terrorism, general criminality etc. In ethical terms, dual-use potentials inherent in technological artefacts are often presented as ethical conflicts between opposing ethical duties (*643*); for example, between the promotion of good through free technological development versus the prevention of possible collateral harm resulting from the cooptation of such technological potential for new purposes. A common example is the conflict between health promotion through effective clinical applications of a civil technology X vs. the provision of resources for the harming of innocents through military operations involving X.

Information technologies have instantiated a dual-use potential since their very first applications (*644*). During the Second World War, Alan Turing's early work on computability was coopted for military purposes, especially for the cryptanalysis of Morse-coded radio communications of the Axis powers enciphered using Enigma machines (*645*). The first contracts for packet network systems, including the development of the ARPANET, were awarded by the US Department of Defense as early as the 1960s and the first rogue program to spread through a network was created as early as in 1971[77]. Today, several subcomponents of the digital revolution –sometimes referred to as the "4th revolution" (*647*), including networks, mobile communications technologies and robotics, demonstrably raise dual-use concerns.

Reports show that cyber-attacks have been growing in frequency and size in recent years. According to the Europol's 2016 Internet Organised Crime Threat Assessment (IOCTA), cybercrime offences "remain on an upward trend and have reached very high levels" (*648*). In October 2016, a massive cyber-attack targeted one of the central nodes of Internet traffic in the US, striking Twitter, Paypal, Spotify and sites of an infrastructure company in New Hampshire. Such increase in volume, scope and material cost of cybercrime has dramatically affected public perceptions on information security. Survey data of the World Economic Forum's Global Risk Report 2016, show that cyber-attacks are perceived among the top five risks globally (*649*). Increasingly, cyber-attacks have become a critical problem not only for private businesses, but also for public entities such as democratic governments (*650*), healthcare institutions (*651*), and national security organizations (*652*). Cyberterrorist acts have increased in number, magnitude and variety causing destruction and harm to personal computers, networks and the public Internet −including large-scale disruption of government systems, hospital records, and national security programs− for personal or ideological objectives (*653*). When occurring between State actors, cyberoffences have shown the potential to influence geopolitical scenarios and strategic equilibria (*654*, *655*). A widely media-covered example is the role of cyber-attacks during the 2016 US presidential election culminated in the unprecedented hacking of a presidential candidate's email server and the following diplomatic crisis between the US and Russia (*656*). Concurrently, cyberwarfare concerns have emerged as a consequence of using CTs like artificial neural networks, gun data computers, secure cryptoprocessors, and robotics for military purposes (*657, 658*). The large-scale deployment of AI has been associated by experts with an increased risk to trigger a cyber arms race, which could ultimately escalate into conventional warfare (*641*). As Taddeo has observed, these emerging trends in cybercrime, cyberterrorism,

[77] The program was called the Creeper and spread through the early Bulletin Board networks 646. D. Ferbrache, in *A Pathology of Computer Viruses*. (Springer, 1992), pp. 5-30..

and cyberwarfare “remark on the extent to which our societies depend on ICTs” and show how information technology has changed “the very infrastructure on which our societies rely” (*659*). Following a socio-technological trend known as the Internet of Things (IoT), a large number of physical devices are becoming increasingly embedded with computing technology for a variety of purposes. Internetworked technologies embedded with electronics, software, sensors, actuators, and network connectivity are being tested or preliminary deployed by armed forces and governmental agencies (*660*).

One common feature of these diverse cybercrime and cyberwarfare trends is that they often involve the use of computing systems with the deliberate purpose or unintended consequence of eroding basic democratic principles like individual freedoms, civil liberties, rule of law and democratic elections. This has raised the question of whether democratic principles and values will survive the digital era (*661*).

This technology-mediated erosion of democratic principles is not exclusively caused by cyberterrorism and cyberwarfare. Global surveillance programs reportedly run by national security agencies and other governmental actors are also fueling controversies over the violation of civil liberties and other democratic principles. Government agencies in various countries have proven able to deploy technology infrastructures for mass surveillance, enabling the collection of digital detritus — e-mails, calls, text messages, cellphone location data and a catalog of computer viruses, from individual citizens and groups. The government of China, for example, has reportedly installed over 20 million surveillance cameras across the country over the last few years and merged state surveillance with big data analytics to curb social unrest (*662*). In 2014, the Chinese Ministry of Industry and Information Technology ordered a major mobile telephone company, to put a real name registration scheme into effect and to "regulate the dissemination of objectionable information over the network" (*663*). In Russia, the Federal Security Service is legally allowed to use a system for Internet-based search and surveillance called SORM (*System for Operative Investigative Activities*). Since 2000, FSB is no longer required to provide telecommunications and Internet companies documentation on targets of interest prior to accessing information and in 2014 SORM-usage was extended to monitoring of social networks, chats and online forums (*664*). In response to these attempts of invasive governmental control, unauthorized disclosures of national security documents –as in the famous case of Edward J. Snowden vs the United States’ National Security Agency (NSA)- have been advocated by some authors as a proportionate response to preserve personal privacy and set the limits of invasive State-based surveillance (*665*).

This paper will argue that cognitive technologies can further "jeopardize democracy" (*666*) if they are not adequately aligned with fundamental democratic values and principles. I will proceed as follows. First, I will review dual-use issues associated with CT. Second, I will argue that the preferable approach to the governance of CT in light of dual-use risk is neither strict regulation nor lassaiz-faire but rather proactive democratization. In particular, I will argue that the potential held by CT for influencing human cognition urges the development of inclusive strategies that can direct cognitive technology for the benefit of people and the whole democratic society, not just restricted groups. Based on these considerations, I will outline six possible steps towards the proactive democratization of cognitive technology in the upcoming decade.

Dual-Use Cognitive Technology

Cognitive technologies hold a promising potential for improving the life of human beings through a wide spectrum of non-hostile civil applications. For example, intelligent cognitive assistants are opening new possibilities for supporting people suffering from cognitive deficits such as older people and people with dementia (*210, 667*). Similarly, BCIs are becoming increasingly effective in enabling novel opportunities for communication in patients suffering from stroke, spinal cord injury or amyotrophic lateral sclerosis (ALS) (*620, 621, 623*).

At the same time, however, these technologies have recently shown some malleability to dual-use, especially in the context of military applications. In recent years, several global players including USA, EU, Russia, Iran, India, China and Japan have been actively working on military applications of neurotechnology, especially BCI (*668*). Tennison and Moreno (2012) have comprehensively reviewed the spectrum of neurotechnologies with applications in military and national security contexts with special focus on projects funded via the United States' Defense Advanced Research Projects Agency (DARPA). Their review identified three main categories of dual-use neurotechnology: brain-computer interfaces (BCIs), neurotechnologies for warfighter enhancement, and neurotechnological systems for deception detection and interrogation (*428*). In a similar fashion, Miranda et al. have assessed DARPA-funded BCI-applications for military purposes. Their review identifies two major avenues of ongoing research: (1) restoring neural and/or behavioral function in warfighters, and (2) enhancing training and performance in warfighters and intelligence agents (*429*). For example, the *Neurotechnology for Intelligence Analysts (NIA)* program was designed to develop BCI systems utilizing non-invasively recorded EEG signals to significantly increase the efficiency and throughput of imagery analysis (*429*). Using the same technological paradigm, national security uses of BCI include the acquisition of neural information gathered from warfighters' brains to modify their equipment accordingly and the development of a Cognitive Technology Threat Warning System (CT2WS) that convert subconscious, neurological responses to danger into consciously available information (*669*).

Current military applications of artificial intelligent systems mostly focus on non-cognitive applications such as unmanned aerial vehicles (UAVs - commonly known as a drones), unmanned ground vehicles (UGVs) such as the MIDARS, a four-wheeled robot that automatically performs random or preprogrammed patrols, and other autonomous or semi-autonomous robots such as Atlas, a bipedal humanoid robot designed for search and rescue tasks. In the near future, however, artificial intelligent systems will likely be used to augment physical and cognitive capacities of combatants. For example, by the end of 2017 the US Department of Defense is announced to launch the Tactical Assault Light Operator Suit (Talos), a military hardware that encloses soldiers within a computerized exoskeleton (*670*). In parallel, augmented reality (AR) systems are being tested with the purpose of enhancing attention, learning (*671*) and situational awareness (*672*). Particular ethical concern was raised by a special type of robotic applications, the so-called lethal autonomous weapons (LAWs). Unlike vehicles that are remote-controlled by a pilot or designed for non-combatting tasks such as reconnaissance, surveillance, and sniper detection, LAWs are designed to replace an important component of human cognition, namely decision-making.

Besides State-funded military applications, cognitive technologies have proven to hold dual-use potentials also in relation to non-State cyberterrorism and general cybercrime. Pycroft et al (2016) have illustrated the possibility of targeting attacks against users of invasive neuromodulation technologies –especially deep brain stimulation (DBS), where the attackers may take control of the user's motor function, emotional dimension or simply disrupts the device's functionality (*608*). In experimental settings, Martinovic et al. (2012) have demonstrated the actual feasibility of performing side-channel attacks against users of currently marketed BCIs to reveal private and sensitive information about the users such as their pin-codes, bank membership, months of birth, debit card numbers, home location and faces of known persons (*441*). Hacking attacks have been proven feasible also against artificial intelligent systems, especially autonomous cars. The findings presented to the 2011 *National Academies Committee on Electronic Vehicle Controls and Unintended Acceleration* demonstrated the possibility of taking control of a car's computer system without direct physical access exploiting the car's Bluetooth connection (*673*).

Finally, several cognitive technologies can be used as powerful surveillance tools for national security, judicial and military purposes due to their dual-use character. While no deception detection technology is being currently used in official security operations, several devices currently in-development either are directly DARPA-commissioned (*674*, *675*) or market their services to national security agencies including the Department of Homeland Security such as the No Lie MRI device (*676*). This evidence shows that CTs can be potentially coopted for a number of purposes that involve the possible diminishment or even violation of democratic principles and values.

In this scenario, it is important for the future of democratic societies to anticipate possible challenges associated with the governance of cognitive technology and prevent that these systems can be coopted by malevolent governmental or non-governmental actors for anti-democratic aims including the triggering of a cyber arms race, the limitation of individual liberties, disproportionate mass-surveillance, the exacerbation of intra- and intergroup differences in social dominance, or direct harm to individuals and groups. This risk is believed to be particularly cogent in light of the ongoing "shrinking" of Western democracy as a consequence of the recent rise of nationalism and authoritarian populism (*677*, *678*). In such a rapidly changing global scenario, it is vital for democratic societies to prevent that cognitive technologies can be used to accelerate the crisis of democracy or to empower actors pursuing anti-democratic goals. In contrast, coordinated and proactive approaches are required to make sure that future developments of CT will be compatible with the principles of liberal democracy or even expand those principles through the human-centered permeation of such technologies in human societies. This paper proposes a preliminary characterization of the basic principles and safeguards to democratize cognitive technology in the upcoming decades.

Democratizing Cognitive Technology

Given their high dual-use potential, cognitive technologies have raised ethical concerns and elicited several proposals for policy response. Back in 2006, delegates of a workshop organized at Arizona State University addressed the issue of sociocultural risk in relation to cognitive technology[78]. Their analysis identified in cognition-related technology a "capacity for sociocultural change" due to its potential to change human intelligence and performance capabilities, and anticipated that such potential could have destabilizing effects on individuals and groups (*679*). In the resulting white paper, experts delineated an entire spectrum of possible approaches to the governance and regulation of cognitive technologies that could prevent misuse and unintended risks. The two extremes of this spectrum were represented by the following options:

a. Lassaiz-faire approaches – which emphasize the individual freedom of technology producers and end-users as well as the alleged capacity of financial markets to filter out potentially detrimental applications
b. Strict regulatory approaches – which emphasize the need for State-led regulatory interventions (often based on essentialist views on human cognition according to which the natural cognitive boundaries should not be trespassed through technology)

Lassaiz-faire approaches are being often advocated by producers of commercial neurotechnologies with the purpose of reducing FDA oversight on novel commercial products, especially limiting the applicability of FDA regulations on mobile medical applications to neurodevices for mental wellbeing[79]. In contrast, particularly restrictive approaches were recently advocated by critics of dual-use artificial cognitive systems. The most restrictive of these approaches is the call for a collective ban or moratorium. While a collective ban is usually considered "much to extreme a response" in the context of dual-use neurotechnology (*681*), it has been advocated by a large number of experts in relation to LAW. Through the group *Campaign to Stop Killer Robots* (https://www.stopkillerrobots.org/) over 1,000 experts in artificial intelligence signed an open letter calling for a global ban on LAWs arguing that it could trigger an arms race in military artificial intelligence and robotics.

[78] The workshop and the resulting white paper adopted the label "technologies for cognitive enhancement" to describe a large variety of technological applications holding "capabilities to enhance human cognition" 679. D. Sarewitz, T. H. Karas, "17 Policy Implications of Technologies for Cognitive Enhancement," *Neurotechnology: Premises, potential, and problems* (Sandia National Laboratories, Albuquerque, New Mexico, 2012)..

[79] During the 2012 Neurotech Leaders Forum, leaders of the neurotechnology industry and venture capital professionals discussed the impact of FDA approval cycles on commercialization of neurotechnology devices and investment in neurotechnology startups. They stated that "it was very difficult for them to invest in devices that require a premarket approval path through the FDA" due to "FDA tardiness in approving new devices"680. J. Cavuoto, in *Neurotech Business Report*. (2012)..

This paper attempts to find a third way between these extreme approaches and argues that the best response to dual-use cognitive technology in a free society is a calibrated combination of technological freedom and risk-management strategies based on the principles of open development, responsible innovation and liberal democracy. I call this approach *democratization of cognitive technology*. In the following, I will describe this approach by delineating its core ethical principles and make a case for its implementation as a proactive strategy for the governance of CT and its accelerating impacts on human capabilities in a free society.

By *democratization* of a technological domain, I mean, very generally, a process of group decision-making about a certain technology characterized by the possibility of fair access to the technology by all participants and a principle of equality among the participants across various stages of the collective decision-making process[80]. Consequently, democratizing cognitive technology implies a process of decision making about CT that will guarantee a possibility of fair access to CT for all users and a principle of equality among users during various stages of decision-making (including design, development and application).

In its general definition, this *democratizing* approach has elements of analogy with both strict-regulatory and lassaiz-faire approaches. With the strict-regulatory approaches it shares the observation that (i) cognitive technology requires urgent ethical assessment and policy interventions to minimize the risks associated with its dual-use potential, and (ii) that markets alone may not be conceptually and practically equipped to provide such assessment and intervention. This observation is based on a threefold factor.

First, novelty: cognitive technology is a relatively recent field of technological development. Consequently, it is still characterized by *conceptual muddles* and *policy vacuums* (*684*) that prevent the maximization of benefits of these technologies while minimizing the risks. Many of these muddles and vacuums facilitate new opportunities for malicious exploitation generated by rapid changes in the technological or social environment, unprepared technological infrastructures, defective legal coverage, and the increase in quantity, variety and velocity of data flows (*133*).

80 This definition of *democratization* is built upon the broad definition of *democracy* developed by T. Christiano. See: 682. T. Christiano, The authority of democracy. *Journal of Political Philosophy* **12**, 266-290 (2004); 683. T. Christiano, Social choice and democracy. *The idea of democracy*, 173-195 (1993).

Second, magnitude: CTs hold the potential of influencing human cognitive capabilities, hence determining a non-negligible effect on human cultural evolution and global equilibria. As observed by Moor (2005), neurotechnologies "could be the most revolutionary of all of the technologies" (*684*) given their capacity to reconstruct, manipulate or augment cognitive processes, and impact human societies in manners that are currently difficult to predict. In the military context, B.E. Moore, lieutenant colonel of the United States Air Force, has predicted that BCI technology «has the potential to revolutionize military dominance much the same way nuclear weapons have done» (*668*). Similar predictions have been made also in relation to artificial intelligent systems (*59*). Due to its novelty, this alleged revolutionary potential of CT is still largely unexpressed. To date, for example, artificial intelligent systems are still distinguishable (from the Turing's test perspective) from human intelligence across many cognitive tasks, while current neurotechnologies enable only a small degree of access to and modification of human neural processing. However, on the long term, the dual-use potential of CTs could enable unprecedented levels of intrusion into personal privacy or modification of personal autonomy (*206*), concentration of economic power, and possibilities for offending individuals and groups (*133, 685*). As such, CTs could affect the fundamental mediators of human social interaction in the information era. Special oversight may be required to guarantee that these potentially revolutionary changes occur in accordance with the mechanisms and values of democratic societies.

The third factor is timing: given their historical novelty, cognitive technologies are still at an initial stage of market maturity and societal adoption. During this introduction phase, a technological trend shows a higher degree of malleability (*684*). Therefore, control or change is less difficult to achieve compared to when the technology has become entrenched. Assumed that CT will be a critical component of our future, human societies are now at a historic juncture in which they can make proactive decisions on the type of co-existence they want to establish with these technologies. Privileging lassaiz-faire approaches at this stage of development would defer risk-management interventions to a time when cognitive technology is extensively developed and widely used, hence refractory to modification.

At the same time, the democratizing approach shares with lassaiz-faire approaches the observation that over-regulation can (a) obliterate the benefits of cognitive technology for society at large, and, if managed by non-democratic or flawed democratic governments, (b) produce an undesirable concentration of power and control. In fact, if adequately implemented, CTs open the prospects of unparalleled improvement in the quality of life of human societies across a wide range of domains: medical, economic, infrastructural, communicational etc. For example, Russel et al. project that, thank to AI, “the eradication of disease and poverty is not unfathomable” (*637*). Therefore, over-regulatory strategies that limit technological freedom and open development could constrain technological progress and the resulting benefits for individuals and society at large. Second, top-down approaches to regulation could concentrate the power generated by CT among restricted political or economic groups, hence exacerbate existing political and economic inequalities. This risk has accompanied many breakthroughs in the history of technology. For example, during the introduction stage of the computer revolution, US authorities debated “whether a central government database for all United States citizens should be created” (*684*). The creation of such government database would have produced a very different type of World Wide Web than the current one, with services distributed top-down, more concentration of power and control, and increased intrusion into individual privacy. The resulting decision not to create the data base contributed to the current informational landscape.

In the next section, I will describe a proactive democratizing approach to cognitive technology by delineating its core ethical principles. In addition, I will list, as an ostensive description, examples of currently ongoing projects and cooperative efforts that go into the direction of democratizing cognitive technology. It is worth noting that this description should not be seen as an exhaustive characterization of the ethics of CT or as a complete solution to the problems posed by dual-use dilemmas in cognitive technology. Of course, the answer to specific ethical dilemmas rising within this technological domain (e.g. trolley dilemmas for artificial intelligent agents, the personal autonomy of BCI users or the moral desirability of artificial superintelligence) may not necessarily depend on the level of democratic openness of the domain itself. Rather, this description is aimed at providing a preliminary conceptual and normative clarification of the democratizing approach and opening a public debate on its realization.

Paths to Democratization: The Six Principles

This proposal for democratizing cognitive technology consists of the combination of six normative principles:

I. Avoidance of centralized control
II. Openness
III. Transparency
IV. Inclusiveness

V. User-centeredness
VI. Convergence

These six principles condense and accentuate recurrent normative stances in the literature on the link between computing technology and democracy (*661, 686, 687*), and set out a way forward towards for responsible and democratic development in cognitive technology. These principles can be used to guide the discussion on responsible innovation in CT at various levels of technology governance including individual researchers, funding agencies, as well as national and international regulatory bodies.

Avoidance of centralized control is the principle according to which it is morally preferable to avoid centralized control on CT to prevent risks associated with unrestricted accumulation of capital, power, and control over the technology among organized groups such as large corporations or governments. This preventive measure is designed to mitigate two critical types of technological risk. Type one risk: reduction in number of actors within the technological domain. To appreciate this type of risk, consider by analogy the transformation of the Internet over time, especially the transition from Web 1.0 to 2.0. While Web 1.0 was characterized by a coexistence of many service generators, the increase in data volumes and users typical of Web 2.0 is counterbalanced by a contraction of the number of actors, with most online traffic being driven by a limited number of powerful actors such as Google, Facebook, or YouTube. In the context of CT, the centralization of technological power among certain State or non-State actors could result in monopolistic operations or even destabilize economic, geopolitical and military dominance. In parallel, at the intrastate level, it could centralize power among restricted groups or elites hence potentially enable disproportionate control over the rest of the population and their civil liberties. I call this second scenario *type two risk* and can be conceptualized as an asymmetry between the level of governmental surveillance of individual citizens and the level of surveillance of governments by individual citizens.

Normative interventions aimed at limiting this risk of centralization may be conceptualized as cyberethical counterparts of anti-trust laws. Just like anti-trust laws are required to prevent monopolies and eliminate anti-competitive practices, proactive regulatory interventions may be required to prevent practices that restrain access to or development of CT, or cause the accumulation of power and control among restricted entities (*688*). Such safeguards should apply to all societal actors and levels (including design, coding, and physical manufacturing), and are intended to allow smaller actors such as small groups or single individuals to enter the domain of cognitive technology and take advantage of its benefits. According the principle of avoiding centralized control, decentralized development models should be privileged over centralized models. Successful examples of decentralized development are open and participatory platforms such as the free encyclopedia Wikipedia, the open-source software operating system Linux (*686*) and the use of distributed ledger technology in trading and governance (*689, 690*). An interesting attempt to implement the principle of decentralized control in the context of CT is *Nervousnet*, a large-scale distributed platform using sensor networks "to measure the world around us and to build a collective *data commons*", which is often presented as a "digital nervous system" (*686*).

Openness is the principle of promoting universal access to (components of) the design or blueprint of cognitive technologies, and the universal redistribution of that design or blueprint, through an open and collaborative process of peer production. This principle also entails that the outputs of research in cognitive technology should be free of restrictions on access and use. Openness and the avoidance of control are critical requirements to make these same capabilities that will be recorded through or infused in cognitive technology — the cognitive capabilities — available to everyone. A good example in this direction is Microsoft's effort to take those same capabilities infused in intelligent apps and made them available as a set of application programming interfaces (APIs) to every developer[81]. This attempt is a form of democratization because it enables everyone to use the same *building blocks* that Microsoft uses to build intelligent devices or to make existing applications more intelligent. Another important step towards the democratization of cognitive technology through openness is Microsoft-sponsored research company *Open AI*. Open AI is a nonprofit company dedicated to precluding malicious AI, producing benevolent and safe AI, and ensuring that "AI's benefits are as widely and evenly distributed as possible" (*691*). Examples of successful application of the openness principle have also emerged within the domain of neurotechnology, especially brain-computer interfacing. A positive example is *OpenBCI*, an open source brain-computer interface platform created by Joel Murphy and Conor Russomanno in 2013. Open BCI's mission is to "provide anyone with a computer, the tools necessary to sample the electrical activity of their brains" and "harness the power of the open source movement to accelerate ethical innovation of human-computer interface technologies."[82] Today, Open BCI already offers an assortment of open source, versatile and affordable bio-sensing systems to sample electrical brain activity

[81] For more detailed information on Microsoft's approach see Microsoft Cognitive Services' Documentation: https://www.microsoft.com/cognitive-services/en-us/documentation. Last accessed: 30 January 2017.
[82] See: http://openbci.com/

(EEG), some of which can be 3D printed. Development is open and new discoveries are made and shared through "an open forum of shared knowledge and concerted effort, by people from a variety of backgrounds." Openness of cognitive technology has been seen as a critical strategy for harnessing *collective intelligence* (*661*). In fact, a pervasive distribution of CT across all socioeconomic strata of society could empower people and enable a more informed and participative deliberation.

In a more abstract sense, openness in CT involves the principle of infusing every application that we interact with, on any device, at any point in time, with (components of) cognitive technology. This process is currently ongoing. For example, an increasing number of routinely used applications incorporate (components of) artificial intelligence. These include search engines, social media, e-commerce services, video-games, medical devices and many others. At the same time, an increasing number of applications are designed to interface human cognition through neurotechnology. For example, several mobile communication companies including Samsung and Apple are testing brain-controlled handheld devices (*553*). In this more general sense, openness is strictly linked to the avoidance of centralized control. In fact, the more cognitive capabilities are pervasively embedded and disseminated across the entire digital ecosystem, the harder it is for actors to centralize power and exert control over those systems. In the words of engineer and entrepreneur Elon Musk: "if everyone has AI powers, then there's not any one person or a small set of individuals who can have AI superpower" (*692*). Therefore, the principle of openness incentivizes the infusion of cognitive capabilities into an increasing number and variety of technologies in order to prevent their uneven accumulation among restricted applications or tools.

It is worth considering, however, that while "openness may reduce the probability of AI benefits being monopolized by a small group" (*693*) it could also cause unintended detrimental consequences. For example, Bostrom (2017) has argued that a high degree of openness could exacerbate a racing dynamic in which competitors trying to be the first to develop advanced AI may accept higher levels of existential risk in order to accelerate progress (*693*). Further research is required to assess which degree of openness would ensure the optimal balance between benefits sharing and individual, national or international security.

Transparency is the principle of enabling a general public understanding of the internal processes of cognitive technologies. This is particularly challenging for approaches such as artificial neural networks, which learn or evolve to carry out a task in absence of clear mappings to chains of inference that are easy for humans to understand. This path to democratization through transparency is critical for artificial cognitive systems. For example, the principle of transparency is at core of IBM's "Guiding Ethics Principles for the Cognitive Era", a recently released ethics framework characterizing IBM's digital transformation. According to this framework, "for cognitive systems to fulfil their world-changing potential", it is vital to ensure the trust of end-users in the systems through transparency enhancing strategies (*694*). In particular, there is a need for transparency in relation to (a) when and for what purposes AI is being applied in cognitive solutions, (b) the major sources of data and expertise "that inform the insights of cognitive solutions, as well as the methods used to train those systems and solutions"; (c) data protection and ownership. It is worth noting that the transparency principle has also educational relevance, since it allows making the necessary informational tools to learn and use cognitive technologies available for everyone, including students, workers and general citizens. Ideally, with advancing CT, such educational function will be institutionalized by the school system with the purpose of helping future citizens acquire the skills, knowledge and norms to engage successfully and securely with cognitive systems and use those skills and knowledge for achieving their life objectives.

An example of practical realization of algorithmic transparency is *Automatic Statistician*, an intelligent software capable of spotting trends and anomalies in data sets and presenting its conclusion, including a detailed explanation of its reasoning (*695*). According to the researcher who created this software, such *transparency* is "absolutely critical" not only for applications in science but also for many commercial applications (ibid). At the policy level, authors have linked the principle of transparency to public trust and proposed that "in order to create sufficient transparency and trust, leading scientific institutions should act as trustees of the data and algorithms that currently evade democratic control" (*661*). This proposal would be particularly relevant in the context of data and algorithms related to reasoning and decision-making as these could have a profound impact on individual deliberation and social cohesion.

Inclusiveness is the principle of ensuring that no group of individuals or minority is marginalized or left behind during the process of permeation of cognitive technology in our society. For example, a 2012 study co-authored by a senior FBI technologist, found that face recognition algorithms of commercial vendors consistently performed 5-10% worse on African Americans than on Caucasians (*696*). As the use of face recognition technology is expected to progress significantly in the next years, it is fundamental to ensure that no ethnic group will benefit from this technology less than other groups. The inclusiveness principle is at the core of The Algorithmic Justice League (AJL) was launched by Joy Buolamwini in November 2016.

AJL provides a free platform to detect algorithmic bias that "can result in exclusionary experiences and discriminatory practices" and create "inclusive training sets."[83]

The principle of inclusiveness does not apply exclusively to facial or physiognomic traits but to any other ethically relevant social bias that may intendedly or unintendedly emerge during CT development. These include cultural, political and language bias etc. An example of minimization of cultural and language bias is the internationalization strategy outlined by Open AI's Software Requirements Specification. As the specification states: modules should be internationalized, in the sense that they "need to conform to the local language, locales, currencies etc., according to the settings specified in the configuration file or the environment in which they are running in."[84] The principle of inclusiveness is strictly related to the transparency principle. In fact, building algorithms which explain their reasoning and decision making is the best way to guarantee that hidden biases will be understood and promptly eliminated. In addition, it is important to create larger, more inclusive and diverse data sets with which to train the algorithms. Pluralism and diversity are critical notions for implementing the principle of inclusiveness in cognitive technology.

The principle of user-centeredness advocates that emerging cognitive technologies should be designed, developed and implemented according to the users' needs and personal choices. User-centered approaches to the development of cognitive technology are necessary to guarantee that end-users (as widely as possible characterized, in accordance with the principles of openness and inclusiveness) are involved in the design, development and implementation of cognitive technologies on an equal footage. This principle has both methodological and social relevance. Methodologically, user-centered approaches have been observed to increase the capacity of cognitive technology to fulfill the needs and wishes of end-users, reduce friction in human-machine interaction, facilitate usability hence increase overall user satisfaction (*210*, *697*). User-centered approaches have been observed to increase technology uptake and social adoption among end-users (*302*). Furthermore, such approaches ensure that technology is truly designed for the benefit of users instead of making users passive buyers of novel commercial products. For example, Kübler et al. have showed that user-centered design is a viable and effective approach to evaluate the usability of BCI-controlled applications, including among vulnerable end-users severe impairment (*697*). Similar approaches have been pursued with BCIs

83 See: http://www.ajlunited.org/the-coded-gaze
84 See: http://openai.sourceforge.net/OpenAI-srs.html

based on event related potentials for brain spelling (*698*) and painting (*699*). User-centeredness is particularly important in relation to cognitive technologies developed for assisting patients with cognitive disorders. In fact, these people (e.g. older adults with dementia) are often frail and vulnerable individuals, hence entitled to outmost respect of their needs and wishes (*225*). At the level of technology implementation, the principle of user-centeredness would prescribe increased individual control over one's own cognitive processing and the adaptation of cognitive technologies to the needs, wishes and capabilities of individual users.

Finally, the principle of convergence can be described both in a narrow and in a broad sense. In the narrow sense, convergence is the principle of interoperability, intercommunication and ease of integration among all components of cognitive technology (i.e. the cognitive *tools* or *modules*): in order to reach the common goal of measuring, enhancing or emulating cognition, all cognitive tools must, at some important level, speak the same language and behave in a mutually consistent manner. It is worth noting, however, that excessive interoperability might result in increased data insecurity, hence must be carefully balanced over other ethical principles and technical safeguards. In a broader and more abstract sense, it is also the principle of converging different types of cognitive technology, especially neurotechnology, on the one hand, and artificial intelligent systems on the other hand. As described in the first section of this paper, such convergence is already occurring. For example, BCIs have been combined with artificial intelligent systems (environment-sensing, obstacle-avoidance and pathfinding capabilities) to achieve shared control and context based filtering of user commands, hence enhance the overall performance of the brain–machine combination (*700, 701*). In addition, a proposals to make this link closer and more reliable via brain-computer interaction are being pursued by various companies including Facebook, Neuralink, Kernel and Emotiv (*702*). Similar convergence-aimed solutions have been pioneered also at the microscopic level. A promising example is a minimally invasive three-dimensional interpenetration of electronics within artificial structures or biological brains (*703*). Such mesh-brain implants have already demonstrated the capacity to successfully integrate into a mouse brain and enable neuronal recordings (*704*). While convergence in the narrow sense is necessary to guarantee the successful functioning of cognitive technology, broad-sense convergence might, on the medium-to-long term, empower individuals and provide ultimate control and protection against malevolent applications of cognitive technology.

Conclusions

Cognitive technologies have the potential of accelerating technological innovation and providing significant benefit for human societies. At the same time, due to their dual-use potential, they can be potentially coopted by State and non-State actors for non-benign purposes including cybercrime, cyberterrorism, cyberwarfare and mass surveillance. In light of the recent global crisis of democracy, increased militarization of the digital infosphere, and concurrent potentiation of cognitive technologies, it is important to proactively design strategies that can mitigate emerging risks and align the future of CT with the basic principles of liberal democracy in free and open societies.

In this paper, I described a proactive approach to the democratization of CT based on six normative ethical principles: avoidance of centralized control, openness, transparency, inclusiveness, user-centeredness and convergence. This approach is designed to universalize and evenly distribute the potential benefits of CT and mitigate the risk that such emerging technological trend could be coopted by State or non-State actors in ways that are inconsistent with the principles of liberal democracy or detrimental to individuals and groups. While this paper offered a preliminary and general characterization of how to democratize cognitive technology, future research is required to expand this proposal into a comprehensive ethical, legal and political framework.

Disclosures: *The author declares no conflict of interest.*

Part 3: Limitations and Future Research

This study presents several limitations. These include both general and Module-specific limitations. General limitations apply to the entire research project design while Module-specific limitations apply to each specific study component.

From the perspective of the overall study design, the ever-evolving nature of IATs and their market is a major limiting factor. In fact, as our results show, the IAT spectrum is rapidly expanding in size and variety. This implies that, at any given time, every attempt to provide an up-to-date and comprehensive assessment of this technology spectrum is affected by limited diachronic validity. For example, given the growth rates of the IAT spectrum observed in Module 1, the total number of available IATs is expected to have increased by an additional 20% in the period between the publication of the study results and the submission of the present thesis. In addition, since this expansion is not occurring only in terms of size but also in variety, it is possible that novel types of IATs may generate new opportunities, challenges as well as ethical, legal and social implications that are not accounted for in this thesis. However, this limitation is not unique of IATs for dementia and elderly care but inherent to the study of any rapidly evolving technological trend. To minimize this problem, regular updates of the present research project in all its components will be required. These updates might involve the replication of each study component at various intervals of time and the constant monitoring of future and emerging trends in IAT. Our systematic methodology and the choice to make available the paper's metadata (see Tab. 1-4 and the appendixes) offer a good basis for future replication studies.

In addition, many features and implications recognizable in IATs for dementia and elderly care might not be exclusive to this field of application but common to IATs with different clinical purposes such as IATs for people with other neuropsychiatric illnesses (e.g. Parkinson's disease) or suffering from traumatic brain and spinal cord injury. Future research should investigate the possibilities and challenges of using IATs in these other clinical domains. Concurrently, as Chapter 2.10 of this study shows, many IATs are making their way onto the commercial market and are becoming increasingly available to end-users as commercial products outside the institutional medical setting. This will urge to investigate IAT-use in a variety of sociocultural contexts, population groups and modes of application, hence require highly flexible and adaptive approaches to technology assessment and ELSI-evaluation.

Limitations of Module 1

Additional limitations apply to each Module of this research project.

Module 1 is characterized by the additional limitation that certain IATs might have not been retrieved through the search algorithm we employed during the literature search. To minimize this risk, the query logic of our search was pilot-tested through multiple trials and adapted to the specific logic of each search engine or database. It is also possible that a certain number of IATs might have been developed without published results (for example because military classified or covered under trade secret), hence could not be retrieved through literature screening. Furthermore, it is possible that certain parameters such as the prevalence of user-centered approaches and ethical considerations were addressed by technology designers in an implicit manner, i.e. without being reported in the study protocols or reported in the absence of explicit terminology (*1*). To reduce this risk, software-guided keyword search was complemented with full-text review. Finally, various phases of the categorization process, especially classification and nomination (*705*), might have been affected by subjective biases of researchers. To minimize this risk, each phase of review was performed independently by at least two researchers, while the categorization strategy and language were critically discussed, adapted and formally approved by all researchers. These limitations are explained in detail in Chapter 2.1.

Limitations of Module 2

The generalizability of the results from Module 2 is limited by its qualitative methodology and the small sample size. In fact, while the use of qualitative interviews allowed exploring a complex topic in depth, such qualitative design prevented statistically representative and generalizable conclusions. Furthermore, the study sample may not have represented the full range of health working in dementia and elderly care in the three target countries. In addition, selection biases might have occurred at the level of the recruitment process. In fact, a brief project description was included in the invitation email (see methods section) in order to provide participants with adequate information about the study. This description could have attracted health professionals who have previously worked on or reflected about IATs. In addition, this email could have prompted participants to reflect on the topic before the interview. Despite these limitations, the obtained findings already show diverse and distinctive attitudes which add significant knowledge about how health professionals' attitudes towards IATs for elderly and dementia care. Most interviewees were working at leading European healthcare institutions and had pioneer experience in the clinical implementation of smart solutions in dementia and elderly care, hence represented a very suitable informant population in light of the study objectives. Further research is required to provide (i) generalizable and statistically representative quantitative data on health professionals' views and attitudes towards IATs, (ii) qualitative insights from different (ideally extra-European) cultural settings, and (iii) insights from different stakeholder groups such as older people with dementia or other cognitive disability, cognitively healthy seniors and technology designers.

Limitations of Module 3

Research shows that different IAT types might raise different ethical, legal and social implications (*137, 706*). Therefore, while it is important to develop a comprehensive and unifying ethical framework for the entire IAT spectrum, it is also important to address in depth type-specific issues associated with each IAT-subfamily. In this project, type-specific issues were addressed in relation to four main IAT-subfamilies: BCIs and other cognitive technologies, AALs, wearables and assistive robots. Further research is required to identify the ELSI of other IAT-subfamilies identified in Module 1. These should include: distributed systems, handheld devices, powered mobility aids, software tools and wearables. While our inductive approach to the ELSI of IATs was designed to minimize theory-induced biases, it cannot be ruled out *a priori* that implicit theoretical biases (*707*) might have affected the interpretation of results or that the framework and recommendations we delineate are underdetermined by the data (*708*). Finally, since most ELSI raised by IATs ─e.g. electrophysiological monitoring of the electromechanical underpinnings of human personality and behavior─ *affect* all human beings regardless of nationality, ethnic origin, sex, location of residence, political belief, language, or any other status, our legal analysis prioritized the perspective of international human rights law. However, further research is highly necessary to address the legal implications of IATs also at the level of national legislations as well as in the context of specific fields of jurisprudence such as health law, corporate and securities law, patent law, and personal injury law.

Part 4: General Discussion

4.1. Overview of the General Discussion

The aim of the present thesis was to provide an extensive analysis of the design, distribution, clinical applicability and ethical-legal impact of intelligent technology for dementia and elderly care. IATs are rapidly transforming the delivery of assistive services for the physically and cognitively disabled population and creating novel opportunities for technology-enhanced care. Concurrently, cognitive technologies are profoundly reshaping the dynamics and social significance of human-machine interaction. Detailed analyses of the possibilities and challenges of current intelligent technologies are highly needed to inform evidence-based approaches to their implementation and governance, thus guide informed decision-making in this emerging field. The technological novelty and heterogeneity of intelligent technology applications as well as the low level of maturity of their market generate uncertainty (*75*, *709*). If not adequately addressed, this uncertainty risks to negatively affect the successful and responsible deployment of these technologies, hence to delay or obliterate their benefits for patients, care-providers and society at large.

This thesis attempted to reduce uncertainty regarding medical uses of intelligent technology by generating new evidence about their current distribution, design, clinical applicability and ethical-legal impact in the context of dementia and elderly care. As such, this thesis configures as a comprehensive technology assessment of the intelligent technology domain, with special focus on IATs and cognitive technologies.

This section aims to summarize the main findings, strengths, and implications of the studies conducted in throughout this research project. Since these findings also have societal relevance, their implications for policy, prevention and future research will be discussed. To avoid redundancies, only the main findings and implications will be discussed in this section and presented in a broader scientific context. For a more detailed analysis of type-specific issues please refer to the discussion section of each original contribution presented in section two.

4.2. Technology Push and Current Distribution

Our study findings show that the spectrum of IATs for dementia and elderly care is rapidly expanding in size and variety. With the total number of IATs nearly doubling every five years, more and more opportunities for technology-enhanced care are being opened. As the number of new IATs grows linearly, intelligent systems are likely to become increasingly pervasive in elderly and dementia care and their distribution in both institutional and home-care settings is expected to increase accordingly. These findings indicate the presence of a *technology-push* in dementia and elderly care, namely a socio-technological trend in which "research and development in new technologies drives the development of new products"(*710*). With a total number of 539 devices, the current spectrum of IATs for dementia and elderly care is rapidly emerging as an important subfield of medical technology and digital health. In addition, the linear increase in the total number of IAT applications over time (fifteen-fold increase since 2000) indicates that IAT has a potential for exponential growth and pervasive distribution. However, to translate this potential into a clinical reality, more focus on clinical validation and implementation is needed (see Chapter 4.4).

The IAT spectrum is not expanding only in size but in variety too. Our study findings indicate that, to date, at least seven main technological types are recognizable within the IAT spectrum (in order of prevalence): distributed systems, care robots, mobility and rehabilitation aids, handheld devices, software and mobile apps, wearables and human-machine interfaces. The high prevalence of distributed systems such as AAL technologies attests a technology push towards the creation of *smart-environments* for older people and/or people with cognitive disabilities. Such smart-environments can be installed in both institutional (e.g. nursing homes and hospice care facilities) and home-care settings with the purpose of enabling technology-enhanced assisted living. This trend in aged care is consistent with a broader trend towards intelligent living and home automation recognizable also among the general healthy population (*711*). Intelligent interconnected devices are being progressively integrated into regular houses as a consequence of socio-technological trends such as domotics (*712*) and the Internet of Things (*189*) for purposes such as remote monitoring and control. According to recent estimates, the home automation market was worth US$5.77 billion in 2013, and is predicted to reach a total market value of US$12.81 billion by 2020 (*713*).

Dementia and elderly care are among the sectors of society that are most likely to benefit from such smart-home trends in light of the physical and cognitive limitations of senior citizens and their consequent increased need for assistance. This is confirmed by our finding that assisting older adults during the completion of ADLs is the most common application of IATs (n=148). The results indicate that prolonging the independent living of older adults with dementia and assisting them during routine activities is a priority in current IAT development. This is further confirmed by the finding that *independence* is the most prevalent embedded value in IAT design. The current centrality of promoting independent living in the IAT enterprise seems to meet the expectations of IAT pioneers during the initial phases of development of this technological trend. For example, in the early 2000s, authors expected that technologies capable of prolonging independent living at home or maintaining independence in healthcare facilities could exert *a triple-win effect (67, 73)*, since they could (i) delay or obviate the need for institutional care, hence reduce healthcare costs, (ii) mitigate the burden on formal and informal caregivers, and (iii) improve the quality of life of patients and promote aging in place.

While the rapid expansion of the IAT spectrum generates hopes for novel technology-assisted care solutions, it is questionable whether the significant technology push described above is balanced by comparable market pulls. Several studies show that the need for IATs is high among senior citizens, people with dementia and their carers (*714-716*). Nonetheless, adoption rates among these target populations remain reportedly low (*105, 106*). In light of this evidence, our findings identify a dynamic in which technology develops faster than end-users and medical infrastructures can adopt, with consequent sub-optimal uptake and clinical implementation of IATs in care settings.

4.3. Capabilities

Our study findings show that current IATs have wide applicability in a variety of domains of dementia and elderly care. These include (in order of frequency): assistance of patients during the completion of ADLs, remote monitoring, physical and cognitive assistance, interaction, engagement, rehabilitation, and emotional assistance. In addition, they are designed to assist, partly restore or compensate for a number of deficits caused by dementia and age-related disability. These include (in order of frequency): cognitive (especially memory) impairment, motor dysfunction, emotional and mood disturbances as well as social isolation.

While the compensation for the afore listed specific deficits is important, most IATs appeared to be designed for general-purpose support (n = 250). This fact is likely to be a consequence of the complex disabling condition caused by dementia and age-related disability which simultaneously affects various facets of a person's psycho-physical dimension. For this reason, it is possible that highly flexible and adaptive IATs that can promptly respond to multiple individual deficits and assist in a variety of care tasks, are most likely to produce better clinical outcomes compared to less flexible and adaptive ones. This possibility is corroborated by rapid advances in adaptive intelligence within the AI domain (*717*). On the long term, adaptive intelligent systems (AISs) are likely to play a predominant role within the IAT domain as they will be able to cope with "situations that vary dynamically along several key dimensions" such as "different combinations of required tasks, different configurations of available resources, contextual conditions ranging from benign to stressful, and different performance criteria" (*718*) ─all factors of variability that are typical of dementia and elderly care contexts (*719*, *720*).

The relative frequency of IATs for cognitive assistance is a predictable consequence of the cognitive impairments caused by advancing age and/or progressive dementia. There is a longstanding debate among AI experts and neuroscientists about whether artificial intelligence is isomorphic to human natural intelligence, hence can adequately simulate aspects of human cognition (*721*, *722*). The application of AI to dementia and elderly care poses the collateral question of whether rising artificial intelligence can (or will) compensate for declining human intelligence in the aging brain. While this question is empirical in character, hence experimentally testable, it also has philosophical implications. Therefore, both empirical studies and philosophical reflections need to be explored by future research to address these issues.

It is worth to point out that cognitive faculties such as memory can be amplified or extended "through improvement or augmentation of internal or external information processing systems" (*379*). Our findings indicate that all current cognition-enhancing IATs are designed to augment cognitive faculties by augmenting external information processing systems, that is through interventions that do not directly target the underlying neurobiology of the older person but rather non-invasively provide external cognitive resources to support cognition from outside the brain. The reason for that stems from the fact that technologies for the augmentation of internal information processing systems (i.e. interventions that invasively target the underlying neurobiology of the older person) involve significantly higher risks for the patient (*723*, *724*) or are outperformed by pharmacological interventions (*725*, *726*). However, in the near future it is highly possible that implantable micro-IATs might improve cognitive function intracranially. Already today, several private tech-companies such as Neuralink (*631*) and Kernel are "building advanced neural interfaces to treat disease and dysfunction"[85] by "connecting humans and computers"[86] or even "merging the human brain with AI"(*631*). In parallel, preliminary findings from research on memory restoration are showing a promising potential. For example, a device called Restorative Encoding Memory Integration Neural Device (*REMIND*) has proven capable, in animal models, to detect patterns of functional brain connectivity associated with successful

85 See Kernel's mission statement: https://kernel.co/
86 See Neuralink's statement: https://www.neuralink.com/

memory encoding and retrieval, and to significantly improve the reminiscence of an event via electrical stimulation (*432*). In the future, similar applications could reach human experimentation and ultimately become available as medical devices for people with dementia and other memory disturbances. This will pose additional sets of ethical and legal questions.

The high number of devices designed for providing physical assistance to older adults and people with dementia shows that current IATs (especially robots) have the potential to address not only declining cognition but also the physical limitations associated with age-dependent frailty and disability. This is important from a clinical perspective since physical disability and frailty have been recognized as markers of reduced quality of life among community-dwelling seniors (*727*). It is worth considering, however, that the cognitive and physical dimension are intricately connected. For example, research has shown that impaired executive function (cognitive dimension) has a direct impact on gait stability (physical dimension) (*728*). The low frequency of devices for emotional assistance attests the presence of greater theoretical and technical challenges in artificial emotional intelligence compared to other sub-fields of AI (*729*). Nonetheless, positive clinical effects associated with the use of socially assistive robots for alleviating mood disturbances in psychogeriatric care (*48, 333*), show a promising way ahead also in relation to this underrepresented subfield of IAT.

The promotion of safety also appears as an important capability of current IATs. Our findings show that several AALs, monitoring systems as well as handheld devices and related apps were designed with the purpose of increasing the safety of older adults and people with dementia and protecting them across a wide spectrum of reported risks including falls (*730, 731*), wandering (*732*) and home accidents (e.g. smoke inhalation). This capability is enabled by very diverse technological types including environmental sensors, wearable activity trackers, GPS devices, and camera-based monitoring systems.

Finally, the relative proportion of IATs for supporting engagement and social interaction has a twofold implication. First, it attests the need to address the relational dimension of older adults and people with dementia, which is reportedly affected by loneliness, increased social isolation and other constrains (*733, 734*). This is consistent with previous considerations highlighting the multi-domain complexity of dementia. Second, it suggests that IATs are not only designed to compensate for the psycho-physical deficits of older adults and people with dementia but also to preserve their social networks and inter-personal dynamics. Our review identified both IATs for human-machine interaction (e.g. companionship robots and intelligent conversational agents) and intelligent systems for facilitating human-to-human interaction such as telecommunication technologies and telepresence robots for promoting interaction between people with dementia and their family caregivers (*735, 736*). These results indicate that reported worries about the potential risk of dehumanizing care or weakening the patient-health professional relationship through technology (*145, 193, 737*) might be misplaced. IATs for human-machine and human-human interaction show that technology-enabled care is not in logical conflict with interpersonal dynamics and is not necessarily alternative to human-delivered care but complementary to it. This idea, which can be summarized under the motto "*complement-not-replace"*, is consistent with similar conclusions from previous studies (*48*) as well as across the findings of all three study Modules.

Overall, our study findings attest that IATs have a powerful potential for enhancing the delivery of care services among older people and patients with dementia in relation to a wide variety of care tasks. This is further confirmed by the generally positive attitudes of key health professionals towards their clinical deployment. However, major barriers in product design and development currently affect the clinical adoption of these technologies. This is further discussed in the next section.

4.4. Models of IAT Design: Current Stand and Emerging Challenges

4.4.1. User-centered design and Clinical Validation

Design is a critical phase of technology development and product lifecycle (*738*). In this phase, a new technology is conceived, specified in terms of requirements, analyzed, tested, simulated and progressed to (in chronological order) prototype testing, pilot release and eventually full product launch (*739*). Therefore, the design phase shapes the functionality and future impact of a new technology. Our findings indicate that, at present, most IATs (59.9%) are developed in absence of user-centered approaches to design. Since involvement of end-users in the design phase is a constitutive feature of bottom-up models of technology design (*740*), this low prevalence of user-centered approaches also testifies a dominance of top-down design models in IAT for dementia and elderly care. While bottom-up approaches are primarily concerned with the user-driven validation of a new technology in real-world scenarios, top-down approaches are primarily concerned with high-level functional requirements (*741*). These findings cast doubts on the ability of current IATs to adequately address end-users' needs. In fact, involving end-users early on in the design phase has often been observed to positively contribute to system success and increase user satisfaction (*742-744*). Additionally, the low prevalence of UC design has often been recognized as one major codeterminant of lower-than-expected adoption of IATs for dementia (*199*, *745*). Therefore, IATs developed in absence of UCD are less likely to guarantee that the needs and wishes of patients, their caregivers and health professionals are adequately elicited, properly reflected into the product specifications, and verified thoroughly by tests and adequate clinical validation.

This consideration is corroborated by the finding that about one in every two IATs (50.65%) did not receive clinical validation through clinical trials involving human subjects. This finding confirms a lack of solid and generalizable clinical validation in current IATs. Additionally, it casts doubts and uncertainty about the clinical effectiveness of those devices among end-users. Even among the subset of IATs that received clinical validation (49.35%), flaws in the validation methodology were recognizable. In fact, most validation tests (95.5% of all IAT-studies involving clinical validation) were conducted with very small sample sizes (< 20 participants). Furthermore, methodological limitations were also observed at the level of study design as randomized-controlled trials (RCTs) was reported in only 1.1% of all validation studies. This finding casts doubts about the presence of allocation biases and the balancing of prognostic factors in current validation studies. These problems are reflected in the concerns of the health professionals involved in the interview study. Virtually all stakeholders considered most current IATs inadequately validated, hence unfit for massive clinical deployment at care institutions or home-care settings. Absence of adequate clinical validation was presented as a "major barrier" to the clinical use of IATs at their institutions. While they all welcomed further investments in IAT-development, they recognized an urgent need for corroborating clinical evidence (*746*) in support of current products and facilitating their clinical implementation .

In absence of adequate validation, health professionals are not equipped with the necessary knowledge about product safety and effectiveness required to implement new IATs in the clinical setting. Participants reported issues of poor clinical evidence, difficulties in replicating laboratory experiments in real-world settings, and uncertainty about product safety and effectiveness as major obstacles towards adoption of IATs among their patient groups. These findings reveal a *signal-to-noise* problem in the IAT market (*747*), i.e. the problem of distinguishing safe, effective and adequately validated IATs (the *signal*) from ones that do not provide sufficient clinical guarantees to users and health professionals (the *noise*). This problem is exacerbated by the fact that, to date, there are no formal mechanisms in place to orient health professionals and patients across the ever-evolving IAT spectrum. Therefore, our findings indicate a need for developing mechanisms to support clinicians and primary users in the process of filtering signal from noise in the IAT market, hence distinguishing safe, clinically effective, adequately validated and socially beneficial devices from those that do not meet these requirements.

The signal-to-noise problem is not only caused by inadequate clinical validation or insufficient evidence of clinical benefit. As our interview findings indicate, product requirements and specifications play an important role too. Health professionals highlighted that many IATs they saw or tested were characterized by poor technical specifications, functional errors, and user-unfriendly interfaces. These technical limitations were often reported to result in diminished technology adoption among end users or even technology abandonment. The presence of unresolved technical limitations is likely to depend, at least in part, on the low prevalence of UCD. In fact, UCD approaches have been observed to effectively filter out technical imperfections of prototypes and improve their functionality by performing adequate testing among end-users in real-world scenarios (*302*).

The high number of IATs developed in absence of end-user involvement in the design phase urges close ethical and clinical oversight to avoid possible drawbacks including ethical conflicts, misuse, discomfort or even distress among end-users, as well as ineffective clinical application. Our findings identify a need for more coordinated efforts to involve end-users in the design and development of IATs for dementia and elderly care. The need for accelerating the transition to UC models of IAT design is corroborated by the findings of our interview study, where virtually all participants expressed preferences for UCD and called for more user-driven research in the IAT field. Concurrently, further research involving both primary (e.g. older adults and people with dementia) and secondary (e.g. formal and informal caregivers) stakeholders is needed to test end-users' satisfaction in relation to existing IATs.

While accelerating the transition to UC approaches emerges as a scientific imperative, an ongoing trend in this direction is already observable. In fact, the results of our logistic regression indicate a progressive trend towards user-centeredness in the design of IATs. If this trend remains steady over time, it is predictable that UC approaches will characterize the majority of IATs for dementia by 2019 and two thirds of them by 2022. This trend testifies an ongoing transition in technology design which does not restrict only to IATs for dementia and elderly care but has also been observed in relation to other sectors of healthcare technology including eHealth, ambient intelligence and agile software development (*748-750*). If this trend is maintained, the clinical validity and applicability of IATs are likely to improve for the benefit of end-users and healthcare services.

4.4.2. Value-sensitive and ethical design

VSD has been often recognized as a gateway to responsible technological innovation (*751, 752*). Our study findings indicate that VSD approaches in IAT for dementia and elderly care are remarkably rare as they characterize only one third of the IAT spectrum. This low prevalence casts doubts on the degree of ethical sensitivity and sustainability of current IATs for dementia and elderly care. In addition, since VSD approaches are believed to increase the benefits and reduce the harms of a technology among a stakeholder group (*92*), their low prevalence could negatively affect the outcomes of IATs among end-users.

The low prevalence of VSD raises particular concern in relation to ethical values. Our study findings reveal that ethical design ─the proactive incorporation of ethical values in IAT design─ is scarce. This fact poses a challenge for designers since ethical design, as previously discussed, is believed to prevent various forms of harm to technology users and other stakeholders including interpersonal, psychological, and social/societal harm (*93*). Deficient ethical design might undermine the ability of IATs to account for the ethical values of elderly people (including people with dementia), their caregivers as well as of health professionals involved in the delivery of care services. Consequently, it could possibly contribute ─together with the lack of user-centered design and adequate clinical validation─ to diminished user satisfaction, sub-optimal adoption, and delayed clinical implementation. This hypothesis is corroborated by the findings of our interview study, as many health professionals expressed ethical concerns in relation to the use of current IATs for dementia and elderly care.

Within the subset of IATs that do incorporate ethical values, the high prevalence of *independence* considerations confirms that a primary goal in IAT design is maximizing the capacity for independent living of older adults (*2*). This goal might be justified not only by the moral commitment to empower older adults and improve their QoL but also by financial and healthcare management motivations. This is consistent with repeated calls by gerontology experts for "maintaining and promoting functional independence in older adults" (*753*). In fact, maintaining the independent living at home of older adults and people with dementia or providing them with greater independence in skilled facilities is likely to delay the need for institutionalized long-term care, hence significantly reduce healthcare costs, and reduce the burden on formal caregivers (*67, 75*). The promotion of independence is also consistent with respecting the oft stated wish of elderly adults to *age in place* (*75, 754*), a wish that appeared widely respected and promoted by the health professionals involved in our interview study.

In contrast, the low frequency of considerations and values related to fair access, equality and distributive justice underline a major ethical-societal challenge that could negatively affect the future of IATs for dementia. Our findings reveal that the number of IATs presenting low-cost hardware and open-source software, hence designed to be affordable to end-users from various socioeconomic classes, is very low (<10%). Concurrently, the absence of considerations related to fair and universal technology access raise the concern that the adoption of IATs will be limited by socio-economic factors or could even exacerbate existing socio-economic problems. Unless immediate action is taken, there is a risk that the most vulnerable and disadvantaged population segments (e.g. elderly adults living in poverty) will be excluded from the clinical and social benefits of IATs. This could cause the creation of a technology divide that mirrors or even deepens pre-existing wealth inequalities, a phenomenon that has already been observed in various other sectors of the information society (*755*). The need to take action and prevent unfair technology access is particularly relevant in light of the fact that the greatest relative cost increases are occurring in low-income African and in East Asia regions (*279*).

Finally, the rarity of privacy and security considerations, especially of those related to informational privacy and data protection (<5%), indicates that guaranteeing privacy and security by design (*282*, *756*) is currently not a priority among IAT developers. In absence of adequate safeguards, breaches for privacy and security will emerge ─many of which already have (*757*), as Chapters 2.8-2.11 of this thesis report.

In summary, our findings indicate that although IAT innovation is proceeding fast and rapidly creating new opportunities for technology-assisted care, yet major challenges in IAT design can be observed. These include low prevalence of UCD and VSD, lack of adequate clinical validation, poor technical quality of devices and rarity of user-friendly interfaces. Additionally, the reported neglect of important ethical requirements cast doubts on the ethical sensitivity and social sustainability of current IATs for dementia and elderly care. For this reason, a comprehensive discussion of the major ethical, legal and social implications associated with IAT development and use is necessary. This will be discussed in the next section.

4.5. Ethical, Legal and Social Implications (ELSI)

4.5.1. Dual-Use and Malicious Hacking

Our findings attest that IATs for elderly care raise important ethical, legal and social implications. Among them, dual-use is critical. As our analysis indicates, IATs hold a potential for dual-use because they can demonstrably be coopted for different purposes than those originally addressed by designers, including malevolent purposes. Research shows that several IATs such as BCIs (*142, 143*), robots (*758*), exoskeletons (*759*), wearables (*760, 761*) and AALs (*762*) can be turned against their users or exploited to open breaches for privacy and data security. While the potential vulnerability to malevolent cooptation is common to any computing technology, this risk acquires particular relevance in relation to IATs for a twofold reason. First, users of IATs are usually vulnerable people who need assistance (hence the word *assistive* in the acronym) such as older adults and people with dementia or other psychophysical disability. According to the World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects, vulnerable people are the most disadvantaged sub-segments of the community (*763*). Therefore, authors have argued that they should be entitled to "utmost care, specific ancillary considerations and augmented protections" (*764*). In light of their vulnerability, users of IATs might have a limited freedom and capability to protect themselves from intended or unintended risks associated with technology use. The second reason stems from the fact that most IATs operate in close proximity or direct physical contact with end-users (*295, 320*), manipulate instruments inside, worn upon or directly interfaced with their bodies, and might even have invasive or non-invasive connections with the human nervous system (*295*). For these reasons, they raise a need for increased ethical scrutiny as they might enable a higher degree of intrusion into and manipulation of the personal (behavioral and physiological) information of users. This need for increased ethical focus is consistent with public perceptions in relation to new technology. Survey results show that 53% of people in the United States think it would be a bad thing if "most people wear implants or other devices that constantly show them information about the world around them." In contrast, just over one third (37%) think this would be "a change for the better" (*327*), hence showing a clear pattern of public concern that is proportional to the degree of access to personal information enabled by a new device.

Our descriptive and normative analysis indicates that the dual-use potential of IATs is strongly linked with their vulnerability to cyber risk, a phenomenon already observed in virtually all sectors of computing technology. In particular, the risk of malicious hacking ─exploitation of computer technology and its information processing for malevolent purposes─ is critical. A recent cybersecurity report attests that robot technologies appear "to be insecure in a variety of ways, and that insecurity could pose serious threats to the people they operate in and around" (*765*). Due to the vulnerability of their end-users, this risk is particularly significant in the context of IATs for dementia and elderly care. Of particular ethical relevance is the risk of malicious hacking associated with the subgroup of intelligent technologies that establish direct interfaces with the human nervous system such as BCIs and other neurotechnologies. The reason for that stems from the fact that these technologies enable a "direct connection pathway between the human nervous system and external computer devices" (*181*), hence an unmediated access to neural processing. As neural processes constitute the electrochemical underpinnings of human mental processes, these types of IATs "offer a powerful, alternative way to access a person's mental life" (*138*). If not secured through adequate safeguards, the malicious exploitation of or intrusion into a person's mental life could result in unprecedented ethical and legal challenges.

Our analysis provided a comprehensive technical, ethical and legal assessment of malicious hacking risks associated with neurally-controlled IATs, a phenomenon that we have labeled *malicious brain hacking* (or *neurohacking*). This assessment identified four different types of cyberattacks based on the level of the BCI cycle at which the attack might occur. For each type of attack, we described the associated ethical problems and possible illicit activities. Our analysis reveals that hacking attacks to neurally-controlled IATs can occur at four phases of the BCI cycle: input processing, measurement, decoding and output processing. Cyberattacks at the level of input processing are most likely to occur in the form of generating misleading inputs, for example via subliminal manipulation of visual stimuli. The primary application of this kind of neurohacking model is the unauthorized extraction of information from end-users. This type of attack has already been proven feasible by a number of experimental studies using commercially available non-invasive BCIs (*141*, *143*, *766*). In all these experiments, researchers were able to manipulate input processing to extract private and sensitive information from end-users without their consent. The practical feasibility of this form of cyber risk raises major implications for personal privacy and security (see next section). Cyberattacks at the level of measurement can occur in the form of noise addition or manipulation of the classification process. This type of attack might result in disruption or termination of the device functionality as well as in the risk of hijacking by malevolent third parties. The same risks apply to cyberattacks targeting the decoding phase, for example attacks aimed at overriding the signal sent to output. As our results illustrate, all these cyber activities might cause both physical and psychological harm to end-users, a risk that is exacerbated in case of vulnerable users such as older adults. Additionally, the possibility of remote hijacking raises the problem of diminished agency. In fact, as our analysis suggests, users that are victims of this kind of hack might no longer qualify as agents given the traditional definition of agency as the capacity of someone to deliberate or act on the basis of one's own desires and plans instead of being product of manipulative or distorting external forces (*767*). Finally, altering the signal's feedback at the level of output processing might generate the additional risks of uncertain personhood and moral responsibility. The reason for that stems from the fact that the output of the BCI cycle is salient to users' conscious perception. Therefore, manipulating output processing might result in manipulating a person's conscious experience and introduce an alien degree of control into that person's reasoning and decision-making. This problem is exacerbated in the context of cognitive technologies that use machine learning algorithms. In fact, in those circumstances, control might be distributed across three different agents: the end-user, the malicious hacker and the artificial intelligence. This raises the problem of determining and attributing the responsibility of actions arising from such triangular dynamics.

According to its standard definition (*643*), dual use risk does not apply exclusively to technology cooptation for (cyber)criminal purposes but also to military applications. As our analysis describes, intelligent technologies are of primary interest for military and national security agencies as these technologies might be applicable to various activities of warfare preparation and realization. Our review-based analysis reveals that a wide number of IATs with application to dementia and elderly care are currently being tested by military and national security agencies. These include EEG-based BCIs, non-invasive neurostimulation devices, autonomous robots and wearable exoskeletons. In the military, intelligent technologies originally developed for assistive purposes in the civilian sector can be used to provide assistance to physically injured or mentally disturbed veterans. In addition, they can be coopted for non-assistive purposes including the physical and cognitive enhancement of field combatants. It is notable, however, that the dual-use dynamics of IATs is not unidirectional. In fact, in parallel to the cooptation of civilian technology for military purposes, a spillover effect from the military to various civilian sectors ─especially the clinical sector─ is recognizable. Our analysis illustrates that a number of IATs currently under investigation in military research have potential applicability as assistive tools for civilians. Furthermore, advances in military funded IAT research are likely to accelerate technological progress and result in more reliable and effective clinical applications. This bidirectional dynamics, known as reverse dual-use, highlights the complex nature of dual-use challenges in intelligent technology. This complexity needs to be reflected also in ethical evaluations regarding the moral permissibility of dual-use in intelligent technology. In fact, overlooking the reverse component of dual-use in intelligent technology might result in obliterating the clinical benefits that are likely to result from the spillover of advancing military research into the civilian sector. This risk is particularly significant in light of global population aging and the increasing burden of dementia and other neurological disorders, as these trends are urging the development of innovative and scalable solutions. For this reason, we proposed an ethical stance for guiding decision-making in relation to dual-use problems in intelligent technology based on calibrated cost-benefit analyses. According to this proposal, regulatory and governance strategies should aim at maximizing the clinical benefits of IATs for the aging and cognitively disabled population, while minimizing unintended risks associated with the military proliferation of these technologies. This will require closer ethical oversight on military research and evidence-based approaches to cost-benefit assessment with particular focus on the prevention of possible human rights violations (see next two Chapters).

4.5.2. Informational Privacy and Security

As reported in the previous section, our systematic review results reveal a lack of privacy and security by design approaches in current IATs. This finding is consistent with previous evidence reporting privacy and security vulnerabilities in various intelligent technology families such as care robots (*133, 765*), wearables (*768*), BCIs (*133, 769*), and AALs (*133*). For example, cybersecurity reports evidence that virtually all wearable devices are vulnerable to location tracking, data leakage, and other privacy or security weaknesses (*768*). This problem is exacerbated by the fact that most of these devices did not have privacy policies (ibid). Therefore, the privacy and security of end-users is exposed by a twofold weakness: at the level of technology design and at the level of terms of use. As we have discussed in relation to malicious brain-hacking, the risks for privacy and security are directly proportional to the degree of intrusion into and manipulation of the personal (behavioral and physiological) information of users enabled by a certain technology. Consequently, IATs that enable direct connection pathways between the human and the machine are at greater risk because they process private and sensitive information of the user, including information that is below the user's threshold of conscious control. This risk is becoming of primary relevance because many human-machine interfaces[87] and other cognitive technologies developed for assistive purposes have made their way onto the market and into the consumer sector. Today, an increasing number of private tech companies offer assortments of direct-to-consumer human-machine interfaces (e.g. BCIs and wearable activity trackers) that can be purchased without prescription and used without medical supervision. Market analyses show that the number of commercially available consumer-grade IATs is experiencing exponential growth as these technologies are becoming increasingly pervasive (*474*). In light of unresolved privacy and security vulnerabilities, this pervasive proliferation of unsupervised IAT applications is likely to generate insecurity and novel opportunities for privacy violation, especially in relation to technologies that process neural information or other forms of privacy-sensitive computation (see Tab. 4 at p. 49). For this reason, our ethical analysis devoted particular attention to the identification and prevention of privacy and security vulnerabilities in current pervasive neurally-controlled IATs. This analysis identified structural weaknesses in privacy and security protection at a threefold level: technology design, terms of use and international regulation. Overall, these findings attest a general unpreparedness of current digital and regulatory infrastructures for the pervasive expansion of the IAT market, especially in relation to neurally-controlled technology. Furthermore, they confirm a trend identified in the first study Module, namely that the pace of technological innovation is way faster than the adaptation of social infrastructures to such innovation. In absence of prompt upgrades in ethically sensitive technical requirements, terms of service, user policies and general laws, this structural lag risks tempering the social benefits of IAT development.

4.5.3. Cognitive Liberty, Mental Privacy and Human Rights Protection

IATs that enable to record, monitor, decode and modulate electrophysiological activity (e.g. BCIs, neurally-controlled exoskeletons etc.) pose a fundamental ethical, legal and social challenge: determining whether, or under what conditions, it is legitimate to gain access to or to interfere with another person's electrophysiological ─especially neural─ mechanisms. This question is of primary relevance in the clinical setting. For example, there is controversy among researchers about the legitimate degree of interference with the neural activity of a person suffering from Parkinson's disease dementia using deep-brain stimulation (*465, 770*). Similarly, devices that enable continuous non-invasive recording and monitoring of users' electrophysiological activity ─e.g. BCIs, biosensors, physiological monitoring devices and other eHealth applications─ raise the question of determining the conditions for legitimate access to such activity by third parties. With the increasing commercial pervasiveness of IATs and their dual-use potential, these kinds of questions are also arising in extra-clinical contexts such as the consumer market and the military.

These questions need to be addressed at various levels of jurisprudence, the most fundamental of which is the level of basic human rights. In fact, IATs for electrophysiological monitoring enable an unprecedented degree of access to the electromechanical underpinnings of human personality and behavior, i.e. intimate aspects of the person that are inherent to all human beings regardless of nationality, ethnic origin, sex, location of residence, political belief, language, or any other status. Therefore, it is critical to determine whether this electromechanical dimension should be protected by rights inherent to all human beings regardless of their status. This is particularly relevant in relation to neural activity, since this type of electrophysiological processing is considered the major causal determinant of mental faculties such as memory, personhood, consciousness ─all qualities that characterize human identity (*138*).

Our ELSI analysis addressed the question of which rights users are entitled to exercise in relation to their private dimension when using activity-tracking IATs, especially those enabling neural monitoring. Based on comparative legal research and normative ethical analysis we concluded that current trends in IAT might require an evolutionary interpretation of existing human rights or even the creation of new human rights. These are*:* the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity. The *right to cognitive liberty* protects the right of competent individuals to make free and competent decisions regarding their use of IATs. In its negative connotation, it guarantees the protection of individuals from the coercive and unconsented use of such technologies by third parties such as via malicious hacking. In its positive connotation, vice versa, it protects the positive right of competent individuals to freely opt for technology adoption in absence of paternalistic constrains. The right to cognitive liberty is particularly important among cognitively healthy older adults and people in the early phases of dementia (MCI or AD in

CDR-1), since these end-user categories are usually still in possess of mental capacity. In contrast, the right to cognitive liberty might be legitimately overridden by health professionals in case of mentally incapacitated users, e.g. people with advanced dementia, if this right is in conflict with competing principles such safety or beneficence. This is the reason why the right to cognitive liberty was presented as a *relative*, not *absolute* right.

As we have seen in the previous section, the unconsented intrusion by third parties into a user's neural data ─as well as against the unauthorized collection of those data─ open breaches for privacy violation. Therefore, our analysis suggests that current privacy rights need to be expanded to protect individuals from such intrusions and unauthorized collections. Users of neuromonitoring IATs should be entitled to selectively seclude their mental dimension and determine for themselves when, how, and to what extent their neural information can be accessed by others. In other words, they should be entitled to exercise a right to mental privacy. Similarly, the *right to mental integrity,* which is already recognized by international law (Article 3 of the EU's Charter of Fundamental Rights) in relation to the promotion of mental health, should be expanded to protect also against illicit and harmful manipulations of users' mental activity such as those resulting from malicious hacking. Under the specific circumstance of malicious hacking via output manipulation, a *right to psychological continuity* might also be required to protect users' personal identity. In fact, as our technical assessment revealed, victims of this type of hack might experience diminished conscious control of their behavior and unconsented external alteration of their mental life by third parties. In non-criminal contexts, this right is also applicable to IATs in which the AI components (e.g. machine learning algorithms) can override decisions intended by the user.

This proposal is consistent with the widely acknowledged obligation to guarantee that users of new technologies are afforded fundamental rights to protect themselves in the digital infosphere (*647*). In particular, it is consistent with Floridi's proposal "to understand the right to informational privacy as a right to personal immunity from unknown, undesired or unintentional changes in one's own identity as an informational entity" (*152*). Our proposal recognizes that, in light of new advances in cognitive technology, the act of collecting, storing, sharing and manipulating personal information "amounts now to stages in cloning and breeding someone's personal identity" or "altering her or his nature as an informational entity without consent" (ibid). Our proposal should also be viewed in close continuity with repeated calls for adapting the human rights framework in response to new developments in cognitive technology, in particular neurotechnogy. For example, CCLE founder[88] Wrye Sententia argued that "in anticipation of even greater precision in understanding and manipulating higher cognitive processes, it is incumbent upon us as a society to anticipate individual rights in relation to these developments" (*406*). Along these lines, Bublitz has argued that this incumbent task should be pursued not only in the context of ethical analysis but also and foremost in relation to basic human rights (*408*). This need is urged by a twofold consideration. First, because, with the global diffusion of intelligent technology, ELSI "do not characteristically emerge" only within specific "ethical and cultural traditions" (*158*), but apply to all global users as citizens of the digital society. Second, because as Sententia as observed, "the right and freedom to control one's own consciousness and electrochemical thought processes is the necessary substrate for just about every other freedom" (*406*).

Based on these considerations, this thesis prioritized a legal analysis at the level of fundamental rights. However, as already expressed in the Limitations (Chapter 3.3), further research should explore the legal significance of cognitive and other intelligent technologies also at the level of local jurisdictions and other areas of jurisprudence.

88 Center for Cognitive Liberty & Ethics (CCLE)

Part 5: Policy Recommendations

Our findings reveal an urgent need for calibrated and coordinated regulatory strategies to keep up with the social impacts of advancing technology. These strategies should be deployed at various levels of technology governance including product design, terms of services, clinical guidelines, global health policy and international law.

At the level of product design, our analysis identified a need for accelerating the transition to UCD and VSD and promoting the incorporation of ethical values into technology design. For example, affordable hardware and open software were suggested as viable specifications that could promote the ethical principles of fairness, equality and distributive justice by intervening on technology requirements. Involving end-users in the design process through collaborative and participatory dynamics is a primary ethical obligation of IAT designers. This participative involvement should be incentivized through calibrated regulatory interventions aimed at removing all barriers that currently obstacle the successful realization of UCD and VSD in IAT. These include financial (*771*), conceptual (*772*), sociocultural (*773*) and logistic barriers (*771, 774*). IAT designers and manufacturers should be incentivized to develop new prototypes in adherence to the needs of end-users, involve them constructively into product design and seek adequate clinical validation. In particular, there is an urgent need to foster validation studies involving large population samples and clearly defined end-user groups, ideally through randomized control trials. To achieve such goal, this thesis has proposed to legally require FDA approval for more-than-minimally-invasive intelligent technologies, hence expand the FDA regulatory framework for mobile medical applications[89]. However, such calibrated regulatory intervention should be implemented in a manner that does not delay or obliterate technological progress. In fact, while quality control is highly required, this should not occur at the expenses of innovation.

After reviewing various approaches to product development, this thesis proposed a framework for ethical design in IAT, which was called the Proactive Ethical Design for Assistive & Rehabilitation Technology (PED-ART) framework. This framework is characterized by four basic normative requirements: minimizing power imbalances in the design phase, increasing compliance with ethical norms and values, accelerating translation from the designing lab to the clinics and raising awareness at the societal level. This framework was conceptualized and firstly operationalized during the 2016 edition of the Cybathlon Competition, where the author of this thesis was invited by the event organizers to address

[89]See FDA Regulation of Mobile Medical Applications: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm255978.htm

ethical considerations among the community of IAT biomedical engineers. The event was followed by a number of activities for the promotion of ethical design in IAT and biomedical engineering. These included a seminar and a workshop held in February 2017 at the Department of Engineering Sciences at Uppsala University (Sweden), where the author of this thesis was invited to introduce ethical design to graduate students in electronic engineering, biomedical engineering and industrial design. Such activities represented an opportunity to operationalize the results of this research project as to produce an impact on technology design, development and governance.

In light of the reported absence of protective mechanisms, our analysis also identified an urgent need for enhancing the privacy and security of current IAT infrastructures. We concur with Bonaci and associates (*142*), that this should be achieved though the incorporation of privacy and security-enhancing specifications in product designs. A closer collaboration between technology developers and cybersecurity experts is necessary to embedding privacy and security-enhancing safeguards into current products. These might include ─depending on the IAT type─ encryption, immunization and distributed ledger systems. Furthermore, mechanisms should be put in place by manufacturers to filter out privacy-threatening features such as unnecessary location tracking and data leakage. The principles of proportionality and legitimate purpose, which are recognized by the EU Data Protection Directive (*775*), appear to offer a useful normative basis to guide design requirements and general regulations. According to these principles, the volume and quality of data to be collected by each intelligent technology should be limited to what is necessary to achieve the objectives of to the assistive task for which that IAT was designed. A positive example of embedding privacy values in design through proportionality and legitimate purpose is the BCI Anonymizer, a patented system capable of decomposing the recorded neural signals into a collection of characteristic signal components in real time (*464*). From these components, the system can extract information that is necessary to a user's intended BCI commands, while filtering out any unnecessary and disproportionate recording (e.g. private and sensitive information). Regulators should carefully consider the possibility of developing calibrated regulatory interventions to make basic immunization mandatory in future intelligent technologies or to incentivize those companies that prioritize immunization on a voluntary basis. This would be particularly important in relation to those technologies that enable access to and manipulation of highly private and sensitive information (see Tab. 4 at p. 49).

While privacy and security by design should be the golden rule, the "fundamental open-loop characteristics" of most IATs "make inherent safety difficult to achieve" (*776*). Therefore, regulatory interventions at the level of terms of services are also required to prevent vulnerability. This is particularly relevant in light of recent evidence showing that most IATs lack privacy policies in their terms of use (*482*). Therefore, this thesis identified a need for expanding and upgrading current terms of service with the purpose of enforcing higher standards for privacy and data security protection. Accepting the terms of use of an IAT should not expose users to privacy and security risks that are disproportionate to the assistive task of the IAT. For example, we have proposed that the terms of service of privacy sensitive intelligent technologies should not allow manufacturing companies to share data with third party apps or reuse those data for further purposes in absence of explicit consent from the users. This is particularly relevant in the context of technologies capable of recording electrophysiological signatures of disease or mental states, as this information can lead not only to a loss of privacy but also to stigmatization and discrimination. Additionally, we have suggested to eliminate forms of implicit coercion currently recognizable in the terms of use of several products. For example, companies should not entitle themselves the right to reduce service benefits or disable product functionalities if IAT-users refuse the cloud storage of their data, a phenomenon that appeared widespread among consumer BCIs. Upgrading the terms of service is a particularly important task in the context of direct-to-consumer products, since these are commercially available in absence of medical oversight and without provision of adequate information about their risks and benefits.

Clinical guidelines are also needed to orient ethically responsible implementation of IATs in the clinical setting. This thesis has provided a set of guidelines for health professionals using socially assistive robotics in elderly and dementia care. These guidelines include (i) obtaining iterative informed consent during technology installation and further use as recommended by Alzheimer Europe's best practices, (ii) pursuing the principles of transparency, legitimate purpose and proportionality when implementing IATs for clinical purposes, and (iii) carefully assessing the balance between therapeutic, assistive or psychosocial benefits, on the one hand, and potential risks or distress, on the other hand. This latter point also involves a continuative evaluation of the patients' experiences, especially in light of the high variability of patients' preferences and experiences throughout aging and/or dementia progression. This proposal is not only theoretical but in the process of translating into an actionable deliverable. In fact, the recommendations presented in this thesis have been included by the Foundation for Responsible Robotics (FRR) and The Hague Institute for Global Justice into an open consultation document for the development of European standards for robots in healthcare. Furthermore, several recommendation presented in this thesis will be incorporated in a FRR white paper on the governance of healthcare robots and a related roadmap of guidelines for Human-Robot Interaction (HRI) in healthcare settings.

At the level of global health policy, this thesis identified a need for health policies that promote and facilitate the responsible uptake of IATs among end-users across various patient population groups, socioeconomic segments and world regions. These policies are required not only to prevent the technological potential of IATs from remaining underused, but also to intercept ramping inequalities in technology access and distribution. With the highest relative cost increases of dementia and elderly care occurring in developing countries (*413*) and with fair technology access not being a priority for manufacturing companies, there is a risk that the IAT revolution might result in exacerbating global inequality and digital divide.

Maximizing the benefits of IATs for individuals and society should be the guiding principle of technology governance and health policy. To achieve this aim, using technology with the aim of compensating for individual deficits should not be the sole legitimate application of IATs. In addition to that, the evidence collected in this thesis suggests that the responsible use of IATs for prevention and cognitive enhancement purposes could also have a positive impact on individual and public health. For example, it was observed that facilitating the use of AI-mediated cognitive assistants and neuromonitoring IATs among healthy older adults could provide these people with increased physical and cognitive wellbeing, prolonged working productivity, preserve their social interactions and enable early diagnosis of dementia and other cognitive disturbances. Of course, as repeatedly stated in this thesis, such benefits should be balanced over the intended and unintended risks associated with IAT use.

Finally, at the level of international law, this thesis proposed to open a public debate on the evolutionary interpretation or even cautious expansion of international human rights law to account for disruptive technological innovation in IAT. This upgrade proposal, which was received with great attention from the international press[90], would not be historically unprecedented since international human rights law has already experienced adaptive expansions in response to scientific and technological advances, e.g. in the field of genetic engineering (*407*). Echoing previous calls (*406*), this thesis argued that emerging trends in IAT

[90] Among others The Times, The Independent, and The New Scientist

such as neurotechnology, AI and autonomous robotics have a comparable if not superior disruptive potential, hence require increased oversight and inclusive approaches to policy and governance. This need is particularly relevant in light of recently demonstrated opportunities for technology misuse that can result in unprecedented forms of violation of basic rights such as privacy, integrity and personal identity. To this purpose, the present thesis has delineated a preliminary proposal for upgrading human rights in response to advancing cognitive technology. The operationalization of this proposal is currently being discussed as some relevant regulatory bodies have expressed interest in this respect. However, for this operationalization to be possible, it is necessary to involve more interdisciplinary experts in the debate. A positive step in this direction has been taken by Jamais Cascio, senior fellow at the Institute for Ethics and Emerging Technologies (IEET) and at the Institute for the Future. In commenting our proposal, Cascio has agreed that current digital infrastructures and regulations "are unsuited to this new era" and largely endorsed our bid for expanded human rights protection, observing that the new rights we propose "are already under threat". However, he has observed that a number of collateral dilemmas arise and need to be promptly addressed, especially in relation to the legal permissibility of mandatory technology interventions that might guarantee significant social benefit. Therefore, he concluded that we "need to begin discussion now, before these technologies spread" (*777*). In accordance with Cascio's conclusion, any contribution aimed at fostering this debate is welcomed by the author of this thesis.

While thoughtful regulatory approaches are highly desirable, this thesis warned against the risk of hyper-restrictive policy and governance. In particular, the many proposals for a global ban or moratorium against specific IAT types or against their dual-use (*778*, *779*) strike as a disproportionate policy solution which risks obliterating the social benefits of IATs. Building upon the experience of biosecurity frameworks developed in other areas of science and technology, we proposed a framework for risk assessment involving increased monitoring, and evidence-based evaluation. Instead of seeking restrictions to technological innovation, policy makers should focus their efforts on preventing misuse, guaranteeing fairness and aligning the future of IAT with the basic principles of international law. *Democratizing* technology is the buzzword introduced in this thesis to refer to the need for leveraging technological innovation in a socially inclusive, ethically responsible, and lawful manner. To this purpose, an approach to the democratization of IATs was delineated based on seven normative ethical principles: avoidance of centralized control, pervasiveness, openness, transparency, inclusiveness, user-centeredness and convergence. According the principle of avoiding centralized control, decentralized development models should be privileged over centralized models. Distributed computing, especially distributed ledger systems, might represent useful tools to operationalize this principle at the technical level. This should be combined with guaranteeing an open and pervasive access to intelligent technologies and their computing capabilities for every citizen. This thesis has proposed that key components of the design or blueprint of cognitive technologies should be open-sourced to promote fairness and limit digital inequality. A virtuous example of this principle is Open AI, a nonprofit enterprise dedicated to ensuring that “AI's benefits are as widely and evenly distributed as possible”[91]. In a similar fashion, IBM’s “Guiding Ethics Principles for the Cognitive Era” provide a virtuous attempt to fulfil transparency and inclusiveness. Regulators should urgently recognize the need for spotting trends and anomalies in the algorithms employed in intelligent technology and providing a transparent explanation of their reasoning, wherever possible. Failing to do so might result in morally opaque human-machine interactions that are potentially detrimental to individuals and groups. Finally, increased inclusiveness is needed to avoid implicit biases that might lead to social discrimination. While user-centered design remains crucial, the additional creation of open platforms for the detection of algorithmic bias, such as the Algorithmic Justice League[92], is encouraged. This approach was designed to universalize the potential benefits of IATs, ensure a fairer distribution and mitigate the risk that such emerging technologies could be coopted for malevolent purposes (*103, 780*).

In the near future, an increasing number of aging citizens will become users of intelligent technologies. Concurrently, these technologies will become more and more intricately intertwined in their life. Therefore, human societies have a moral obligation to make sure the benefits of intelligent technology will be fairly and evenly distributed.

91 For further information see: https://openai.com/
92 See: https://www.ajlunited.org/

Part 6: Appendixes

6.1. Appendix 1 – Systematic Review Analysis – Variables Measured in R software

- Publication year
- Study Type
- Device Type
- Cognitive or Physical function being assisted
- Activity supported/enabled
- Target population
  - Publication Year
- 2000
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
  - Study type
- Design and/or development
- Assessment and/or evaluation
- Both

▪ Device types

- Multimedia
- Smartphone
- Tablet
- Other
- Distributed System
- Monitoring System
- AAL/Smart Homes
- IoTs
- Sensor
- Cognitive Prosthetics
- Framework
- Interface
- Protocol
- Software
- Mobile App
- Web App
- Other
- Robot
- Locomotion system (is this a robot?) exoskeleton/wheelchair/
- Rehabilitation machine

▪ Goal

- Behavioral monitoring BM
- Health monitoring HM
- ADL ASSISTANCE - ADL A
- MOBILITY – MOB
- ORIENT NAVIG
- ALARM
- SOC INT
- COG SUPP
- EMOT SUPP

Function being assisted

- Memory

- Decision Making
- Consciousness
- Reasoning
- Perception
- Visual
- Tactile
- Auditory
- Olfactory
- Orientation and/or spatial navigation
- Verbal and/or Non-verbal communication
- Mood and emotional states
- Locomotion and/or motor control
- General Purpose
  - Activity supported/enabled
- Activities of Daily Living
- Hygiene and personal care
- Reading
- Fall detection
- Care and Therapy
- Health monitoring
- Environmental and/or sensing and/or monitoring
- Mood enhancement
- Social behavior
- Communication
- Verbal communication
- Telephoning
- Mobility
- Entertainment
- Music
- Art
- Device control (Human-Machine interaction)
  - Target Population
- Alzheimer's disease

- Mild Cognitive Impairment
- AD and other dementias
- Any Cognitive Impairment
- General elderly and disabled population (GEDB)

6.2. Appendix 2: Systematic Review Analysis – List of Logistic Regressions' Source Codes

In Module 1, the following logistic regressions were carried out using the R open-source programming language and software environment for statistical computing[93].

```
# == Analysis ==
# Logistic regression
library(xlsx)
library(rms)

# Read the data into memory
dataset = read.xlsx(file.choose(),1)

# Compute logistic regression using default GLM model
model1 = glm(Modelofdevelopment ~ YearofPublication, family = "binomial", data = dataset)
print(summary(model1))

# Compute logistic regression using rms' lrm function
# as it contains more statistics (e.g., pseudo-R2)
model2 = lrm(Modelofdevelopment ~ YearofPublication, data = dataset, tol = 0)
print(model2)
```

[93] For more information see R Foundation for Statistical Computing: https://cran.r-project.org/

6.3. Appendix 3: Qualitative Data Collection – Interview Guide

Title: Intelligent Assistive Technology for Dementia and Neurocognitive Decline

Study goal: The goal of this study is to examine the attitudes and values of health professionals regarding the use of Intelligent Assistive Technology in dementia care.

Interview guide questions

1) Could you briefly explain your profession and your role in dementia care?
2) What are the major limitations and problems you experience in current dementia care?

   Prompts:

- Do you perceive a lack of resources and caregiving tools?
- Did you ever experience caregiving burden?
- Do you think we could do more to enhance care?

3) What are the major factors affecting the quality of life of people with dementia?
4) What are the major components of caregiving burden for caregivers of people with dementia?
5) Have you ever used any computer technology or robotic system to facilitate the assistance of people with dementia or the delivery of care? If yes, could you please tell me more about your experience with it?
6) What is "intelligent technology" for you?

- (Assistance and hints from the interviewer if needed)

7) Based on the situation at your unit, how do you think intelligent technology could help improve dementia care and the life of people with dementia?

   Prompts:

- Physical assistance?
- Care delivery?
- Cognitive support?
- Favouring interaction?
- Quality of life? Quality of care?

8) How aware are you of current technological availabilities for dementia care?

   Prompts:

- How many IATs do you think have application to dementia care?

- For the compensation of what specific deficits?
- For the achievement of what caregiving needs?

9) Have you ever attended a course about assistive technology or had a professional exchange with IAT developers and producers?
10) Have you ever interacted (e.g. during conferences, seminars, informal meetings or as a consultant) with IAT designers and developers?
11) If you could contribute to the design of an IAT for dementia care what would you primarily focus on?

    Prompts:

- What patients' needs would focus on? What caregivers' needs?
- Would you involve patients in the research design to assess the end-users' needs?

12) If you could contribute to the development and implementation of an IAT, what would your major concern be?

    Prompts:

- Logistics issues
- Financial issues
- Ethical issues

13) At the ethical level, what is of greater concern? And why?

    Prompts:

- Privacy, Information Security, Hacking
- Human dignity and dehumanization of care
- Autonomy and independence of the patient
- Affordability, equality and justice
- Beneficence and best interest of the patient

14) What strategies, in your view, could facilitate the incorporation of patients' and caregivers' needs/views into the design of future technologies?
15) How do you imagine dementia care and, specifically, your profession in 20 years?

    Prompts:

- In the light of demographic trends
- In the light of technology development

Before I end our discussion, I would like to ask whether you have anything that you would like to add concerning your experience with people with dementia, the major care needs and your prospects for the future.

Please feel free to contact me marcello.ienca@unibas.ch or if you have questions and need to discuss the study. Here is my university business card for further inquiries.
Thank You.

6.4. Appendix 4: Qualitative Data Collection – Invitation to Participate

INVITATION TO PARTICIPATE IN IN-DEPTH INTERVIEW

Dear Sir/Madam,

My name is Marcello Ienca. I am a researcher at the Institute for Biomedical Ethics, University of Basel, Switzerland. We are currently carrying out a study on "Intelligent Assistive Technology for Elderly and Dementia Care".

This information is being given to you because I wish to invite you to participate in this study. The goal of this study is to examine the needs, attitudes and values of health professionals in Europe regarding the use of Intelligent Assistive Technology in elderly and dementia care. The study seeks to explore their views, attitudes and levels of awareness towards Intelligent Assistive Technologies (IATs) for elderly and dementia care. This knowledge is critical to understand how IATs should be designed, developed and implemented in a manner that maximizes their benefits for patients and caregivers.

To this purpose, I would like to invite you to participate in an in-depth interview (IDI) with me at a time, place or system of communication of your convenience. The IDI would last for between 20 and 30 minutes. In case you won't be able to attend a face-to-face meeting, the interview could be also performed via telephone or online (e.g. via Skype or alike). Before the IDI, I will thoroughly explain the study once again and complete the informed consent process.

Your responses will be protected through utmost confidentiality of subject data. In particular, study codes will be applied on data documents and identifiable data will be encrypted. In addition, data documents will be securely stored within locked locations and security codes will be assigned to computerized records. Confidentiality of information collected from research participants will be maintained throughout the entire study. Only the investigator(s) or individuals of the research team can identify the responses of individual subjects

Please note that your participation in this study is entirely voluntary. It is your choice to decide whether you wish to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. If you decide to participate now but change your mind later, you have the right to withdraw at any time.

I look forward to your response. I would be highly thankful if you would inform me about your decision in a week's time. Please do not hesitate to contact me should you have any questions or doubts.

Yours faithfully,

Marcello Ienca, M.Sc., M.A.

6.5. Appendix 5 - Participant Information and Informed Consent Document

Title: Intelligent Assistive Technology for Dementia and Neurocognitive Decline

Dear Participants,

My name is Marcello Ienca. I am a PhD candidate at the Institute for Biomedical Ethics, University of Basel, Switzerland. I am doing a research on the use of Intelligent Assistive Technologies (IATs) for dementia and neurocognitive decline. This research is necessary for the completion of my PhD program at the University of Basel.

Below is information about this study that will inform you on the study purpose and your rights as a research participant. Please feel free to contact me via email or phone, if anything is unclear to you.

Purpose of research

The goal of this study is to understand the needs, views, attitudes, and expectations European experts, researchers and health professionals involved in dementia and elderly care regarding the use of IATs. The study seeks to explore what values, considerations and care needs are critical to maximize the possible benefits of these technologies for patients and caregivers.

Voluntary participation

Your participation in this research is entirely voluntary. It is your choice to decide whether you wish to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. If you decide to participate now but change your mind later, you have the right to withdraw from the study at any time.

Study participants

For this study, participants will be health professionals working in dementia care or elderly care belonging to the following categories:

Doctors (MDs) with specialization in geriatrics, psychiatry, or neurology and with direct professional experience in the assistance and care of older adults with dementia or other neurocognitive disability.

Neuropsychologists, psychologists, and psychotherapists.

Specialized nurses with direct professional experience in the assistance and care of older adults with dementia or other neurocognitive disability.

Rehabilitation and occupational therapists with professional experience in the assistance and care of older adults with dementia or other neurocognitive disability.

Reason for participating

You are being requested to take part in this research because you belong to one of the three categories mentioned above and are thus qualified to participate in this research. By taking part in this research, you are contributing to the understanding of the specific care needs and considerations that are relevant to the correct design, development and implementation of IATs in dementia care. The knowledge generated by your participation in this research may be used to inform the creation and use of assistive devices that better match the care needs of people living with dementia and their carers. On the long term, this might result in improving the quality of care and the quality of life of this vulnerable patient population.

Research Procedure

This research includes a one-on-one in-depth interview (IDIs). The in-depth interview will take approximately 30 - 40 minutes). Your participation is voluntary and you have the right to withdraw from the study anytime.

Questions will regard your professional dimension and the context of elderly and dementia care. During and after the recording of the interview your anonymity will be protected.

In case you have any doubt or curiosity as well as in case you may want to ask questions yourself, you are free to ask me anytime – including during the interview. In case you are not familiar with one of the notions or concepts referred to in my interview questions, I will provide conceptual clarification.

Risk

Both the questionnaire and the interview questions will focus on your professional experience and will not directly allude to private or sensitive issues. There is a possibility that you may share some personal or confidential information unintentionally, or that you may feel uncomfortable recalling some events of your professional life in the context of dementia care. However, you are free to decline to answer any question you feel uncomfortable with. In addition, your anonymity will be strictly protected and your responses will not by identifiable by anyone except the Project Leader (MI).

Benefit

There will be no direct benefit to you, but your participation may help us find out more about how to design, develop and use IATs that better match the care needs of people living with dementia and their carers. On the long term, this might result in improving the quality of care and the quality of life of this vulnerable patient population.

Incentive/compensation

No financial compensation will be given for taking part in this study. However, interviews participants will be provided with light refreshment during the course of the discussion/interview.

Confidentiality

The entire discussion and interview will be tape-recorded upon your consent, but no one will be identified by name in the tape. Consequently, your responses will not by identifiable by anyone except the interviewer (myself). During the discussion and interview no one else but the people, who take part in the discussion and interview, will be present. You have the right to request for the destruction of your recorded interview tape if you do not want to continue in the study.

Your responses will be protected through utmost confidentiality of subject data. In particular, study codes will be applied on data documents and identifiable data will be encrypted. In addition, data documents will be securely stored within locked locations and security codes will be assigned to computerized records. Confidentiality of information collected from research participants will be maintained throughout the entire study. Only the investigator(s) or individuals of the research team can identify the responses of individual subjects. The tapes will be destroyed after the completion of my PhD program at a specified time by the Institute for Biomedical Ethics, University of Basel, Switzerland.

Project Financing: This study is funded by the Institute for Biomedical Ethics, University of Basel, Bernoullistrasse 28, CH 4056, Basel - Switzerland.

Who to Contact

If you have any questions, you can ask us now or later. If you wish to ask questions later, you may contact any of the following:

Marcello Ienca

Institute for Biomedical Ethics

Bernoullistrasse 28, CH 4056,

University of Basel, Switzerland.

Phone: +41 (0)61 267 17 85

E-mail address: marcello.ienca@unibas.ch

Prof. Dr. med. Reto W. Kressig

Supervisor

Chair of Geriatrics, University of Basel, Switzerland

University Center for Medicine of Aging, Felix Platter Hospital, Basel, Switzerland

Phone number: +41 (0)61 265 29 98

E-mail: RetoW.Kressig@fps-basel.ch

Prof. Dr. med. Bernice Simone Elger

Head of Department

Institute for Biomedical Ethics,

Bernoullistrasse 28, CH 4056,

University of Basel, Switzerland.

Phone number: +41 (0)61 267 17 78

E-Mail: b.elger@unibas.ch

Participant's consent to participate

I confirm that the researcher has done the following:

Informed me orally and in writing of the purpose and structure of the study.

Answered all my questions about participating in the research to my satisfaction.

Stated that I can keep the written participation information and my declaration of consent.

Based on the study information provided above, I state that:

I am participating in the study of my own free will.

I understand that I can withdraw my consent to take part at any time without explaining my reason for doing so, and without being put at a disadvantage of any form.

I have been given sufficient time to reach a decision.

I therefore consent to take part in this study.

Participants Last name and first name (Please print):	
Place, date	Signature of study participants

Confirmation by investigator:

I hereby confirm that I have explained the significance and implication of the study to the participant. I affirm that I will fulfil the entire obligation connected with this study in accordance with applicable law. If at any time during the study I am made aware of any aspect that could influence the participant's willingness to take part in the study, I will inform her immediately.

Place, date	Signature of investigator

6.6. Appendix 6: Qualitative Data Collection – Protocoll Snyopsis Submitted for Approval to the Ethikkommission Nordwest- und Zentralschweiz (EKNZ)

Project Leader	Marcello Ienca (M.Sc., M.A.)

Sponsor/Sponsor-Investigator	Prof. Dr. med. Bernice Elger (M.D., PhD)
Study Title:	Intelligent Assistive Technology for Dementia and Neurocognitive Disability
Short Title/Study ID:	INTEND
Protocol Version and Date:	Version 1; July 26, 2016
Study Category with Rationale	(A) Research project in which qualitative interviews and survey questionnaires are conducted with healthy subjects (health professionals working in dementia care)
Background and Rationale:	With the growing prevalence of dementia and neurocognitive disability worldwide, the massive deployment of Intelligent Assistive Technologies (IATs) represents a revolutionary solution to increase the quality of life and quality of care of people with dementia and reduce burden on caregivers. However, the translation of IAT into the clinical practice of dementia care is still reportedly low. In our study we investigate the views and attitudes of health professionals working in dementia care in order to explore their perceived care needs, predict determinants of low adoption and understand what considerations should be incorporated into IATs to maximize the benefits of these technologies among dementia patients and their caregivers.
Objective(s):	The objective of this study is investigate the views and attitudes of professional caregivers of older adults with dementia in order to explore their perceived care needs, predict determinants of low adoption and understand what clinical, logistical and ethical-social evaluations should be incorporated into IATs to maximize the benefits of these technologies for dementia patients and their caregivers.
Outcomes	On the short term, the knowledge produced by this study will contribute to the understanding of (i) what factors are currently

	delaying the adoption of IATs as part of standard clinical practice, (ii) what features should be incorporated in IAT designs in order to better match care needs, hence increase their clinical effectiveness, and (iii) what ethical-social considerations should be prioritized when using IATs in the clinical setting. On the long term, the knowledge produced by this study could favour the design and development of IATs that better match care needs and provide a greater assistive benefit for elders with dementia and their caregivers.
Study Design	Mixed method research that integrates quantitative (survey questionnaire) and qualitative (in-depth interviews) data within a sequential design. Following previous studies (*781-784*), the sampling will be purposive in nature, a form of non-probability sampling method. Respondents will be divided into the following three segments: doctors (e.g. geriatricians, neurologists, psychiatrists), nurses and occupational/rehabilitation therapists.
Inclusion/Exclusion Criteria	The project population comprises health professionals working in Switzerland as formal caregivers of elderly patients with dementia. Participants will be further divided into three sub-segments: (i) doctors (e.g. neurologists, geriatricians and psychiatrists); (ii) nurses; and (iii) rehabilitation and occupational therapists.
Measurements and Procedures:	A two-phase iterative data collection strategy will be adopted. In the first phase, a survey questionnaire will be administered both online and in printed version among 150 health professionals working in dementia care in Switzerland (50 participants for each sub-segment). Survey questions will be close-ended, and the response categories are developed in accordance with previous well-validated sources.In the second phase, in-depth qualitative interviews will be performed with 20 health professionals working in dementia care, recorded and transcribed verbatim.
Study Product/Intervention	Survey questionnaire and in-depth interviews
Number of Participants with Rationale (if no Power Analysis	The overall number of participants projected for the entire study is 150-170. 150 health professionals will be recruited for the survey questionnaire, 50 for each population sub-segment (doctors, nurses, care therapists). 20 health professionals will be recruited

conducted):	for the in-depth interviews. Sample size of each study component is calibrated based on previous study (*781-784*).
Study Duration:	1 year
Study Schedule:	Month Year of First-Participant-In: October 2016 Month Year of Last-Participant-Out: February 2017 Completion of Data Analysis: July 2017 End of the Project: October 2017
Investigator(s):	Marcello Ienca Institute for Biomedical Ethics Bernoullistrasse 28, CH 4056, University of Basel, Switzerland. Phone: +41 (0)61 267 17 85 E-mail address: marcello.ienca@unibas.ch Prof. Dr. med. Reto W. Kressig Supervisor Chair of Geriatrics, University of Basel, Switzerland University Center for Medicine of Aging, Felix Platter Hospital, Basel, Switzerland Phone number: +41 (0)61 265 29 98 E-mail: RetoW.Kressig@fps-basel.ch Prof. Dr. med. Bernice Simone Elger

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Study Centre(s):	Multi-centre Data will be collected from health professionals from 5 major centres in Basel (University Hospital, Memory Clinic, Felix Platter Hospital), Aarau (Psychiatrische Dienste Aargau AG, Memory Clinic), Luzern (Memory Clinic Zentralschweiz), Olten (Olten), Zürich (Psychiatrische Universitätsklinik, Memory Clinic Rehalp).
GCP Statement:	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.

Explanation for the Inclusion of vulnerable Subjects (if applicable): No vulnerable subjects will be involved in the study.

Recruitment Procedure: The invitation letter (in attachment) will be sent to target respondents both in printed and online form. Personal delivery in loco will be performed in case the other strategies are not applicable.

Informed consent will be obtained from all participants involved in the research project (see enclosed Informed Consent Form). Participants will be extensively informed about the research project (what data will be collected, how, by whom and for what purposes) and consent will be sought for general and further reuse of data from each participant following research ethics guidelines. No monetary compensation for participants is foreseen.

Study Procedure: A sequential data collection strategy will be adopted to perform a data collection in an iterative process. In-depth qualitative interviews will be performed with 20 health professionals working in dementia care. Interviews will be recorded and transcribed verbatim. Data analysis will be performed on both the quantitative and qualitative data. Interviews will be recorded, transcribed verbatim using the F4 software (equipped with headset and foot pedal) and analyzed assisted by MaxQDA. Transcripts will be searched for common thematic elements by using thematic analysis. The themes and subthemes will be coded as recurring motifs in the text and will be identified through a thorough reading of the transcripts. This framework will be then applied to the data, which will be organized initially into the following core themes: (i) technical/functional evaluations, (ii) psychosocial evaluations, (iii) ethical evaluations and (iv) other.

Risks/ Inconveniences, which are Study specific: The study does not involve any increased risk for the physical and psychological safety of research participants. To guarantee the privacy and security of collected data, interviews will be anonymized and data will be coded and securely archived by the Project Leader.

Coverage of Damages: Yes

Storage of Data-and Samples for Future Research Aims: No

Individual participant medical information obtained as a result of this research project is considered confidential and disclosure to third parties will not occur. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to information in the computer files.

Ethical Considerations:

The relevance of this study chiefly relies in the oft stated demand of making IATs more user-oriented, hence more capable to fulfil unmet clinical, technological and psychosocial needs in the context of dementia care (*75, 107, 167*). On the long term, this project has the potential to change the way IATs for elders with dementia are developed and implemented, and maximize their potential benefit at the individual, familial, and societal levels. At the micro-level, it will gather data on to use IATs with the purpose of improving the quality of life of older patients and thereby, promote healthy and successful aging-in-place. At the familial level, the study stands to provide information to help alleviate caregiving burden, and for the society at large, cost-reduction for public finances.

The probability and magnitude of physical or psychological harm anticipated in the research (survey questionnaires and interviews) are not greater in and of themselves than those ordinarily encountered in daily life.

Possible risks associated with this study include the risk of unauthorised data access and/or unwanted identification of project participants. Risks to project participants will be minimised by anonymizing interviewees and by utilising identification code numbers to correspond to information in the computer files.

No immediate benefit to the project participant is foreseen. However, the results of the project could benefit health professionals working in dementia care as well as dementia patients since they could lead to a better understanding of the possible uses of IAT, their adaptation to caregiving needs, hence resulting in a more effective and successful integration of IAT into dementia care and standard clinical practice. On the long term, research results could lead to increase societal uptake of IATs, reduced caregiving burden among formal and informal caregivers, and improved wellbeing of people living with dementia and neurocognitive disability.

The research project will be carried out in accordance to the research plan and with principles enunciated in the current version of the Declaration of Helsinki (DoH), the Essentials of Good Epidemiological Practice issued by Public Health Schweiz (EGEP), the Swiss Law and Swiss regulatory authority's requirements as applicable. The EKNZ and regulatory authorities will be informed about project start, termination and possible amendments to the project design. Commencement of this research project is conditional of the documented decision of the EC (and if applicable the FOPH) concerning the conduct of the project. The researchers will only begin the data collection once approval from all required authorities has been received.

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Selbstverfasste Deklaration

I declare that I have written this dissertation, *Intelligent Technologies for the Aging Brain: Opportunities and Challenges*, with only the aid specified therein and that I have not submitted it to any other university or to any other faculty of the University of Basel.

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